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#### Circulation

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

#### Production

Typeset automatically from XML and T<sub>F</sub>X. XML version of the Schedule available from schedule.pharmac.govt.nz/pub/schedule

#### **Programmers**

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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.

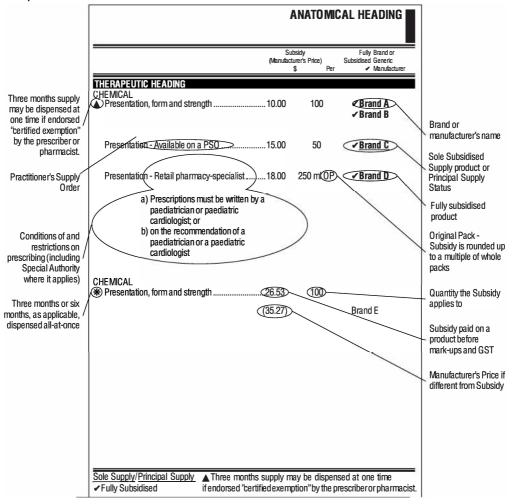
The Pharmaceuticals in this book are listed by therapeutic group, which is based on the WHO Anatomical Therapeutic Chemical (ATC) system. The listings are displayed alphabetically under each heading.

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**

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

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

millimoleunit	
Solution	Supp Tab
Trans Dermal Delivery System	TDDS

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

## **SECTION B: ALIMENTARY TRACT AND METABOLISM**

	0		E. Il.	Dunand au
	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
Antacids and Antiflatulents				
Antacids and Reflux Barrier Agents				
ALGINIC ACID  Sodium alginate 225 mg and magnesium alginate 87.5 mg posachet		30	<b>√</b> G	aviscon Infant
SODIUM ALGINATE  * Tab 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg - peppermint flavour	1.80 (17.99)	60	G	Saviscon Extra Strength
* Oral liq 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml		500 m		cidex
Phosphate Binding Agents				
ALUMINIUM HYDROXIDE  * Tab 600 mg  CALCIUM CARBONATE	12.56	100	<b>✓</b> A	ılu-Tab
Oral liq 1,250 mg per 5 ml (500 mg elemental per 5 ml) – Subsidy by endorsement		500 m 173 m		Roxane Calcium carbonate PAI S29
Only when prescribed for patients unable to swallow calc inappropriate and the prescription is endorsed according		s or v	vhere calciu	m carbonate tablets are
Antidiarrhoeals				
Agents Which Reduce Motility				
LOPERAMIDE HYDROCHLORIDE – Up to 30 cap available on a  * Tab 2 mg  * Cap 2 mg	10.75	400 400		lodia Diamide Relief
Rectal and Colonic Anti-inflammatories				
BUDESONIDE  Cap modified-release 3 mg - Special Authority see SA1886  below - Retail pharmacy		90 alid fo	_	Budesonide Te Arai

Both:

- 1 Mild to moderate ileal, ileocaecal or proximal Crohn's disease; and
- 2 Any of the following:
  - 2.1 Diabetes; or

continued...

Subsidy (Manufacturer's P	Price) S	Fully Subsidised	Brand or Generic	
\$	Per	1	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); or3.8 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 ACETATE Rectal foam 10%, CFC-Free (14 applications)57.09	15 g OP	✓ Colifoam
HYDROCORTISONE ACETATE WITH PRAMOXINE HYDROCHLORIDE		
Topical aerosol foam, 1% with pramoxine hydrochloride 1%26.55	10 g OP	✓ Proctofoam S29
MESALAZINE		
Tab 400 mg49.50	100	✓ Asacol
Tab long-acting 500 mg56.10	100	✓ Pentasa
Tab 800 mg85.50	90	✓ Asacol
		✓ Asacol S29 S29
Modified release granules, 1 g118.10	100 OP	✓ Pentasa
Enema 1 g per 100 ml41.30	7	✓ Pentasa
Suppos 500 mg22.80	20	✓ Asacol
Suppos 1 g50.96	28	✓ Pentasa
(Asacol S29 S29 Tab 800 mg to be delisted 1 July 2025)		

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Generic
OLSALAZINE				
Tab 500 mg	56.02	60	•	Atnahs
				Olsalazine S29
	93.37	100	1	Dipentum
Cap 250 mg	53.00	100	1	Dipentum
SODIUM CROMOGLICATE Cap 100 mg	113.35	100	•	Ralicrom
SULFASALAZINE				
* Tab 500 mg		100		Salazopyrin
* Tab EC 500 mg	20.54	100	•	Salazopyrin EN

## **Local preparations for Anal and Rectal Disorders**

## **Antihaemorrhoidal Preparations**

FLUOCORTOLONE CAPROATE WITH FLUOCORTOLONE PIVALATE AND CIT	NCHOCAINE	
Oint 950 mcg, with fluocortolone pivalate 920 mcg, and		
cinchocaine hydrochloride 5 mg per g13.05	30 g OP	✓ Ultraproct
Suppos 630 mcg, with fluocortolone pivalate 610 mcg, and		
cinchocaine hydrochloride 1 mg8.61	12	✓ Ultraproct
HYDROCORTISONE WITH CINCHOCAINE		
Oint 5 mg with cinchocaine hydrochloride 5 mg per g15.00	30 g OP	✓ Proctosedyl
Suppos 5 mg with cinchocaine hydrochloride 5 mg per g9.90	12	✓ Proctosedyl

## **Management of Anal Fissures**

#### ⇒SA1329 Special Authority for Subsidy

CL VCODVDDONII IM DDOMIDE

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

## **Antispasmodics and Other Agents Altering Gut Motility**

Inj 200 mcg per ml, 1 ml ampoule – Up to 10 inj available on a			
PSOPSO	19.00	5	✓ Robinul
HYOSCINE BUTYLBROMIDE			
* Tab 10 mg	2.25	20	✓ <u>Hyoscine</u>
			<u>Butylbromide</u> (Adiramedica)
* Inj 20 mg, 1 ml - Up to 5 inj available on a PSO	1.91	5	✓ Spazmol
MEBEVERINE HYDROCHLORIDE			
* Tab 135 mg	8.50	90	✓ Colofac

## **Antiulcerants**

## **Antisecretory and Cytoprotective**

Subs	sidy Fu	lly Brand or
(Manufacture	rer's Price) Subsidise	ed Generic
\$	Per •	✓ Manufacturer

## **Helicobacter Pylori Eradication**

#### CLARITHROMYCIN

Tab 500 mg − Subsidy by endorsement......14.58 14 ✓ Klacid

- a) Maximum of 28 tab per prescription
- Subsidised only if prescribed for helicobacter pylori eradication and prescription is endorsed accordingly.
   Note: the prescription is considered endorsed if clarithromycin is prescribed in conjunction with a proton pump inhibitor and either amoxicillin or metronidazole.

## **H2 Antagonists**

FΑ	MOTIDINE - Only on a prescription			
*	Tab 20 mg	4.91	100	✓ Famotidine  Hovid \$29
*	Tab 40 mg	10.32	100	✓ Famotidine Hovid (\$29)
*	Inj 10 mg per ml, 4 ml - Subsidy by endorsement	CBS	10	✓ Mylan S29
	Subsidy by endorsement – Subsidised for patients receiving tr	reatment as par	t of palliative	e care.

## **Proton Pump Inhibitors**

LANSOPRAZOLE		
* Cap 15 mg4.04	100	✓ Lanzol Relief
* Cap 30 mg	100	✓ Lanzol Relief
OMEPRAZOLE		
For omeprazole suspension refer Standard Formulae, page 276		
* Cap 10 mg	90	Omeprazole Teva
		<ul> <li>Omeprazole actavis</li> </ul>
		10
* Cap 20 mg2.02	90	✓ Omeprazole Teva
, •		<ul> <li>Omeprazole actavis</li> </ul>
		20
* Cap 40 mg3.18	90	✓ Omeprazole Teva
		<ul> <li>Omeprazole actavis</li> </ul>
		40
* Powder – Only in combination	5 g	✓ Midwest
Only in extemporaneously compounded omeprazole suspension.	ŭ	
* Inj 40 mg ampoule with diluent	5	✓ Dr Reddy's
		Omeprazole
		✓ Ocicure \$29
PANTOPRAZOLE		
	90	✓ Panzop Relief
· · · · · · · · · · · · · · · · · · ·		-
* Tab EC 40 mg2.74	90	✓ Panzop Relief
Site Protective Agents		

COLLOIDAL BISMUTH SUBCITRATE			
Tab 120 mg	14.51	50	✓ Gastrodenol  S29
SUCRALFATE			
Tab 1 g	35.50	120	
	(48.28)		Carafate

<sup>▲</sup>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

## **Bile and Liver Therapy**

56 ✓ Xifaxan

#### ⇒SA1461 Special Authority for Subsidy

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

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

#### **Diabetes**

## Hyperglycaemic Agents

DIAZOXIDE - Special Authority see SA1320 below - Retail pharmacy

Cap 25 mg110.00	100	✓ Proglicem S29
Cap 100 mg280.00	100	✓ Proglicem S29
Oral lig 50 mg per ml	30 ml OP	✓ e5 Pharma S29

## **⇒SA1320** Special Authority for Subsidy

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

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

#### **GLUCAGON HYDROCHLORIDE**

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

## Insulin - Short-acting Preparations

INSL	ШI	N	N	FΙ	ΙT	R	ΔI

$\blacksquare$	Inj human 100 u per mi, 3 mi42.66	5	<ul> <li>Actrapid Pentil</li> </ul>
			✓ Humulin R
$\blacktriangle$	Inj human 100 u per ml, 10 ml vial25.26	1 OP	✓ Actrapid

✓ Humulin R

# Insulin - Intermediate-acting Preparations

	Inj 100 iu per ml, 3 ml prefilled pen	52.15	5	✓ NovoMix 30 FlexPen
IN:	SULIN DEGLUDEC WITH INSULIN ASPART			
•	Ini degludec 70 u with inculin generat 30 u 100 u per ml 3 ml	80 00	5	✓ Byzoden

#### inj degidaco 70 a with modili aspart o

INS	SULIN ISOPHANE		
$\blacktriangle$	Inj human 100 u per ml, 3 ml29.86	5	✓ Humulin NPH
			✓ Protaphane Penfill

70/30 Penfill

	Subsidy (Manufacturer's Price) \$	Per	Fully Brand or Subsidised Generic  Manufacturer
ISULIN ISOPHANE WITH INSULIN NEUTRAL			
Inj human with neutral insulin 100 u per ml, 3 ml	42.66	5	<ul><li>✓ Humulin 30/70</li><li>✓ PenMix 30</li><li>✓ PenMix 50</li></ul>
Inj human with neutral insulin 100 u per ml, 10 ml vial	25.26	1 OP	
PenMix 50 Inj human with neutral insulin 100 u per ml, 3 ml to b Mixtard 30 Inj human with neutral insulin 100 u per ml, 10 ml via			5)
ISULIN LISPRO WITH INSULIN LISPRO PROTAMINE			
Inj lispro 25% with insulin lispro protamine 75% 100 u per m 3 ml		5	✓ Humalog Mix 25
Inj lispro 50% with insulin lispro protamine 50% 100 u per m 3 ml		5	✓ Humalog Mix 50
Insulin - Long-acting Preparations			
ISULIN GLARGINE			
Inj 100 u per ml, 10 ml		1	✓ Lantus
Inj 100 u per ml, 3 ml		5	✓ Lantus
Inj 100 u per ml, 3 ml disposable pen	94.50	5	✓ Lantus SoloStar
Insulin - Rapid Acting Preparations			
ISULIN 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
ISULIN GLULISINE Inj 100 u per ml, 10 ml	27.03	1	✓ Apidra
Inj 100 u per ml, 3 ml		5	✓ Apidra
Inj 100 u per ml, 3 ml disposable pen		5	✓ Apidra SoloStar
ISULIN LISPRO	E0 E0	_	√ Humalag
lnj 100 u per ml, 3 ml Inj 100 u per ml, 10 ml vial		5 1 OP	<ul><li>✓ Humalog</li><li>✓ Humalog</li></ul>
· ·		1 01	- Hamalog
Alpha Glucosidase Inhibitors  CARBOSE			
CARDOSE → Tab 50 mg	11 20	90	✓ Accarb
: Tab 100 mg		90	✓ Accarb
Oral Hypoglycaemic Agents			
LIBENCLAMIDE			<b>4 -</b> 11
: Tab 5 mg	7.50	100	✓ Daonil
LICLAZIDE • Tab 80 mg	20.10	500	✓ Glizide
LIPIZIDE	20.10	500	MILING
E Tab 5 mg	6.86	100	✓ Minidiab
ETFORMIN HYDROCHLORIDE		100	• Inninaias
ETFORMIN HYDROCHLORIDE ₹ Tab immediate-release 500 mg	14 74	1,000	✓ Metformin Viatris
Tab immediate-release 850 mg		500	✓ Metformin Viatris

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Generic
PIOGLITAZONE				
* Tab 15 mg	6.15	90	✓	Vexazone
* Tab 30 mg	7.25	90	✓	Vexazone
* Tab 45 mg		90	✓	Vexazone
VILDAGLIPTIN				
Tab 50 mg	35.00	60	✓	Galvus
VILDAGLIPTIN WITH METFORMIN HYDROCHLORIDE				
Tab 50 mg with 1,000 mg metformin hydrochloride	35.00	60	✓	Galvumet
Tab 50 mg with 850 mg metformin hydrochloride	35.00	60	•	Galvumet

#### **GLP-1 Agonists**

DULAGLUTIDE - Special Authority see SA2338 below - Retail pharmacy

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. ✓ Trulicity

#### ⇒SA2338 Special Authority for Subsidy

Note: Subsidy for patients with existing approvals prior to 1 May 2024. Approvals valid without further renewal unless notified. No new patients will be granted from 1 May 2024 until further notice.

LIRAGLUTIDE - Special Authority see SA2440 below - Retail pharmacy

- a) Maximum of 9 ini 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 empaqliflozin / empaqliflozin 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 prefilled pen .......383.72 ✓ Victoza

#### ⇒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

continued...

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

continued...

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 Fither
  - 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
  - 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.

ΕM	PAGLIFLOZIN – Special Authority see SA2408 above – Retail pharmacy		
*	Tab 10 mg58.56	30	<ul><li>Jardiance</li></ul>
*	Tab 25 mg	30	<ul> <li>Jardiance</li> </ul>

		(manadatator o r noo)	Our	Joialooa	adilono	
_		\$	Per	•	Manufacturer	
ΕN	IPAGLIFLOZIN WITH METFORMIN HYDROCHLORIDE -	Special Authority see S	A2408 oı	n the prev	ious page – Reta	ail
ph	armacy					
*	Tab 5 mg with 1,000 mg metformin hydrochloride	58.56	60	✓ Ja	rdiamet	
*	Tab 5 mg with 500 mg metformin hydrochloride	58.56	60	✓ Ja	rdiamet	
*	Tab 12.5 mg with 1,000 mg metformin hydrochloride	58.56	60	✓ Ja	rdiamet	
*	Tab 12.5 mg with 500 mg metformin hydrochloride	58.56	60	✓ Ja	rdiamet	

Subsidy

(Manufacturer's Price)

Fully

Subsidised

Brand or

Generic

#### **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.

## **Dual Blood Glucose and Blood Ketone Testing**

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

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

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

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

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

## **Blood Glucose Testing**

BLOOD GLUCOSE DIAGNOSTIC TEST METER - Subsidy by endorsement

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

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

- 1) type 1 diabetes; or
- 2) permanent neonatal diabetes: or
- 3) undergone a pancreatectomy; or
- 4) cystic fibrosis-related diabetes.

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

Note: Only 1 meter available per PSO

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

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

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

Test strips	50 test OP	✓ CareSens N
		✓ CareSens PRO

#### BLOOD GLUCOSE TEST STRIPS (VISUALLY IMPAIRED)

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

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

Blood glucose test strips	33.69	50 test OP	✓ SensoCard
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Subsidy	Fu	ly B	rand or
(Manufacturer's Price)	Subsidise	ed G	Generic
\$	Per	/ N	Manufacturer

### **Insulin Syringes and Needles**

Subsidy is available for disposable insulin syringes, needles, and pen needles if prescribed on the same form as the one used for the supply of insulin or 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.

IIV	ocini i chi necocco – maximum di 200 dev pei prescripti	1011		
*	29 g × 12.7 mm	10.95	100	✓ B-D Micro-Fine
*	31 g × 5 mm		100	✓ B-D Micro-Fine
*	31 g × 6 mm	9.50	100	✓ Berpu
*	31 g × 8 mm		100	✓ B-D Micro-Fine
*	32 g × 4 mm		100	✓ B-D Micro-Fine
INS	SULIN SYRINGES, DISPOSABLE WITH ATTACHED NEED	LE - Maximum of 2	200 dev per p	orescription
*	Syringe 0.3 ml with 29 g x 12.7 mm needle	13.56	100	B-D Ultra Fine
		1.36	10	
		(1.99)		B-D Ultra Fine
*	Syringe 0.3 ml with 31 g x 8 mm needle	13.56	100	✓ B-D Ultra Fine II
	, ,	1.30	10	
		(1.99)		B-D Ultra Fine II
*	Syringe 0.5 ml with 29 g x 12.7 mm needle	13.56	100	✓ B-D Ultra Fine
	, ,	1.36	10	
		(1.99)		B-D Ultra Fine
*	Syringe 0.5 ml with 31 g x 8 mm needle	13.56	100	✓ B-D Ultra Fine II
	, ,	1.36	10	
		(1.99)		B-D Ultra Fine II
*	Syringe 1 ml with 29 g x 12.7 mm needle	13.56	100	✓ B-D Ultra Fine
	, ,	1.36	10	
		(1.99)		B-D Ultra Fine
*	Syringe 1 ml with 31 g × 8 mm needle	13.56	100	✓ B-D Ultra Fine II
		1.36	10	
		(1.99)		B-D Ultra Fine II
		` '		

## **Insulin Pumps**

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

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

c) Maximum of 1 insulin pump per patient each four year period.				
Min basal rate 0.02 U/h	8,970.00			
Min boool rate 0.1 LI/b	7 652 00			

✓ mylife YpsoPump with CamAPS FX

✓ Tandem t:slim X2 with Basal-IQ

✓ Tandem t:slim
X2 with Control-IQ

#### **⇒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:

continued...

1

(Manufacturer 5 Files) Substitused General General Substitution Substitution Substitution General General Control of the Substitution		Subsidy Manufacturer's Price)	Fully Subsidise	
	Ţ,	\$		

continued...

- 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.

#### **Insulin Pump Consumables**

#### ⇒SA2380 Special Authority for Subsidy

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

INSULIN PUMP CARTRIDGE - Special Authority see SA2380 above - Retail pharmacy

- a) Maximum of 50 cart per prescription
- b) Only on a prescription
- c) Maximum of 190 cartridges will be funded per year.
- **★** Cartridge 300 u, t:lock × 10 .......86.00 10 OP **✓ Tandem Cartridge**

		(Manufacturer's Pr	rice) Sub	osidised Generic	
_		\$	Per	✓ Manufacturer	
INS	SULIN PUMP INFUSION SET (STEEL CANNULA) - Special	Authority see SA2	2380 on the p	revious page - Retail pharmac	су
	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 steel needle; 60 cm tubing × 10	130.00	1 OP	✓ MiniMed Sure-T MMT-864A	
*	6 mm steel needle; 80 cm tubing × 10	130.00	1 OP	<ul><li>MiniMed Sure-T MMT-866A</li></ul>	
*	8 mm steel needle; 60 cm tubing × 10	130.00	1 OP	✓ MiniMed Sure-T MMT-874A	
*	8 mm steel needle; 80 cm tubing × 10	130.00	1 OP	✓ MiniMed Sure-T MMT-876A	
(Mi	niMed Sure-T MMT-866A 6 mm steel needle; 80 cm tubing × niMed Sure-T MMT-874A 8 mm steel needle; 60 cm tubing × niMed Sure-T MMT-876A 8 mm steel needle; 80 cm tubing ×	10 to be delisted 10 to be delisted	1 October 20 1 October 20	26) 26)	nue
	SULIN PUMP INFUSION SET (STEEL CANNULA, STRAIGHT	INSERTION) -	Special Auth	ority see SA2380 on the previo	ous
pag	pe – Retail pharmacy a) Maximum of 5 sets per prescription				
	b) Only on a prescription				
	c) Maximum of 19 infusion sets will be funded per year.				
	5.5 mm steel cannula; straight insertion; 45 cm line × 10 with	1			
	10 needles		1 OP	✓ mylife Orbit micro	
	5.5 mm steel needle; straight insertion; 60 cm line × 10 with			•	
	10 needles	136.00	1 OP	<ul> <li>mylife Orbit micro</li> </ul>	
*	5.5 mm steel needle; straight insertion; 80 cm line $\times10$ with				
	10 needles	136.00	1 OP	mylife Orbit micro	
*	8.5 mm steel needle; straight insertion; 60 cm line × 10 with 10 needles	136.00	1 OP	✓ mylife Orbit micro	
*	8.5 mm steel needle; straight insertion; 80 cm line $\times10$ with				
	10 needles	136.00	1 OP	mylife Orbit micro	
*	6 mm steel cannula; straight insertion; 80 cm line × 10 with			4 - 4	
	10 needles	182.00	1 OP	✓ TruSteel	
*	8 mm steel cannula; straight insertion; 80 cm line × 10 with				

10 needles......182.00

\* 6 mm steel cannula; straight insertion; 60 cm line × 10 with

\* 8 mm steel cannula; straight insertion; 60 cm line x 10 with

Subsidy

Fully

Brand or

✓ TruSteel

✓ TruSteel

✓ TruSteel

1 OP

1 OP

1 OP

Subsidy Fully Brand or (Manufacturer's Price) Generic Subsidised Per Manufacturer INSULIN PUMP INFUSION SET (TEFLON CANNULA) - Special Authority see SA2380 on page 17 - 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. 1 OP ✓ MiniMed Silhouette MMT-381A ✓ MiniMed Silhouette 1 OP MMT-377Δ ✓ MiniMed Silhouette 1 OP MMT-378A 6 mm teflon needle, 110 cm tubing × 10 ......130.00 ✓ MiniMed Quick-Set 1 OP MMT-398A 6 mm teflon needle, 45 cm blue tubing × 10 ......130.00 1 OP ✓ MiniMed Mio MMT-941A 6 mm teflon needle, 45 cm pink tubing × 10......130.00 ✓ MiniMed Mio 1 OP MMT-921A 6 mm teflon needle, 60 cm blue tubing × 10 ......130.00 1 OP ✓ MiniMed Mio MMT-943A ✓ MiniMed Mio 1 OP MMT-923A 1 OP ✓ MiniMed Quick-Set MMT-399A ✓ MiniMed Mio 1 OP MMT-945A 6 mm teflon needle, 80 cm clear tubing × 10 ......130.00 ✓ MiniMed Mio 1 OP MMT-965A ✓ MiniMed Mio 1 OP MMT-925A ✓ MiniMed Quick-Set 1 OP MMT-396A ✓ MiniMed Quick-Set 1 OP MMT-397A 1 OP ✓ 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, 110 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-943A 6 mm teflon needle, 60 cm blue tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-943A 6 mm teflon needle, 60 cm pink tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-943A 6 mm teflon needle, 60 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Quick-Set MMT-399A 6 mm teflon needle, 60 cm blue tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-945A 6 mm teflon needle, 80 cm blue tubing v 10 to be delisted 1 October 2026) (MiniMed Mio MMT-945A 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-936A 9 mm teflon needle, 110 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Quick-Set MMT-396A 9 mm teflon needle, 60 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-975A 9 mm teflon needle, 80 cm clear tubing × 10 to be delisted 1 October 2026)

		Subsidy (Manufacturer's Price)	Per	Fully Subsidised	Brand or Generic Manufacturer
INS	SULIN PUMP INFUSION SET (TEFLON CANNULA, ANGLE IN	ISERTION WITH INS	SERTI	ON DEVICE	E) - Special Authority see
	2380 on page 17 – Retail pharmacy				-, -, -, -, -, -, -, -, -, -, -, -, -, -
	a) Maximum of 5 sets per prescription				
	b) Only on a prescription				
	c) Maximum of 19 infusion sets will be funded per year.				
*	13 mm teflon cannula; angle insertion; insertion device; 110 c				
	line x 10 with 10 needles		1 OP	✓ A	utoSoft 30
*	13 mm teflon cannula; angle insertion; insertion device; 60 cm line x 10 with 10 needles		1 OP	<b>✓</b> A	utoSoft 30
INS	SULIN PUMP INFUSION SET (TEFLON CANNULA, FLEXIBLE	INSERTION WITH	INSEF	RTION DEV	ICE) - Special Authority
	e SA2380 on page 17 – 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.				
*	6 mm teflon cannula; flexible insertion; insertion device; 46 cn	n			
	line × 10 with 10 needles	157.00	1 OP	✓ m	ylife Inset soft
*	6 mm teflon cannula; flexible insertion; insertion device; 60 cn	n			
	line with integrated inserter × 10 with 10 needles		1 OP	✓ m	ylife Inset soft
*	6 mm teflon cannula; flexible insertion; insertion device; 80 cn				
	line × 10 with 10 needles	157.00	1 OP	✓ m	ylife Inset soft
*	9 mm teflon cannula; flexible insertion; insertion device; 60 cm	n			
	line × 10 with 10 needles		1 OP	✓ m	ylife Inset soft
*	9 mm teflon cannula; flexible insertion; insertion device; 80 cn	n			
	line × 10 with 10 needles	157.00	1 OP	<b>✓</b> m	ylife Inset soft
INS	SULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIGH	T INSERTION WITH	INSF	RTION DEV	VICE) - Special Authority
	e SA2380 on page 17 – Retail pharmacy				, op,
	a) Maximum of 5 sets per prescription				
	b) Only on a prescription				
	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	182.00	1 OP	✓ A	utoSoft 90
*	6 mm teflon cannula; straight insertion; insertion device; 60 cr	m			
	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	182.00	1 OP	✓ A	utoSoft 90
*	9 mm teflon cannula; straight insertion; insertion device; 60 cr	m			
	line x 10 with 10 needles	182.00	1 OP	✓ A	utoSoft 90
INS	SULIN PUMP INFUSION SET (TEFLON CANNULA, VARIABLE	E INSERTION) - Sp	ecial A	Authority see	e SA2380 on page 17 -
	tail 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 cannula; variable insertion; 60 cm line × 10 with				
	10 needles	182.00	1 OP	✓ V	ariSoft

MMT-332A

		Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
INS	SULIN PUMP RESERVOIR – Special Authority see SA2380 or	page 17 – Retail ph	narma	су	
	a) Maximum of 90 cart per prescription     b) Only on a prescription     c) Maximum of 360 reservoirs will be funded per year.				
*	10 × 1.6 ml glass reservoir for YpsoPump	50.00	10 OP	o ✓ n	nylife YpsoPump Reservoir
*	10 $\times$ luer lock conversion cartridges 1.8 ml for paradigm pump Cartridge for 7 series pump; 3.0 ml $\times$ 10		10 OP 10 OP		DR Cartridge 1.8 liniMed 3.0 Reservoir

(ADR Cartridge 1.8 10 × luer lock conversion cartridges 1.8 ml for paradigm pumps to be delisted 1 October 2026) (MiniMed 3.0 Reservoir MMT-332A Cartridge for 7 series pump; 3.0 ml x 10 to be delisted 1 October 2026)

#### Continuous Glucose Monitor

CONTINUOUS GLUCOSE MONITOR (INTEROPERABLE) - Special Authority see \$A2371 below - Retail pharmacy Only on a prescription

	constitution (Donostin Co) maximum or r dor		
	per prescription990.00	1 OP	✓ Dexcom G6
	Maximum of 5 dev will be funded per year.		
*	Sensor (Dexcom G7) – Maximum of 9 dev per prescription110.00	1	✓ Dexcom G7
	Maximum of 40 dev will be funded per year.		
*	Sensor (Freestyle Libre 3 Plus) – Maximum of 6 dev per		
	prescription99.46	1	✓ Freestyle Libre
	' '		3 Plus

Maximum of 28 dev will be funded per year.

\* Sensor (9) and transmitter (Dexcom G6) - Maximum of 1 dev

#### ⇒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)

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) \$	Sub Per	Fully sidised	Brand or Generic Manufacturer
CONTINUOUS GLUCOSE MONITOR (STANDALONE) - Spec	ial Authority see SA23	70 below	– Retail	pharmacy
Only on a prescription				
* Sensor (Dexcom ONE+) – Maximum of 9 dev per prescripti Maximum of 40 dev will be funded per year.	on81.00	1	<b>✓</b> D	excom ONE+
* Sensor (Freestyle Libre 2 Plus) - Maximum of 6 dev per				
prescription	99.46	1		reestyle Libre 2 Plus
Maximum of 28 dev will be funded per year.				
* Sensor (Freestyle Libre 2) – Maximum of 7 dev per prescrip Maximum of 29 dev will be funded per year.		1	✓ F	reestyle Libre 2
(Freestyle Libre 2 Sensor (Freestyle Libre 2) to be delisted 1 Ma	y 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

PAN	NORE	ΑI		INZ	YIVIL	
	Can	nar	cre	atin	150	m

Cap pancreatin 150 mg (amylase 8,000 Ph Eur U, lipase 10,000 Ph Eur U, total protease 600 Ph Eur U)	34 93	100	✓ Creon 10000
Cap pancreatin 300 mg (amylase 18,000 Ph Eur U, lipase	04.00	100	• Olcoll 10000
25,000 Ph Eur U, total protease 1,000 Ph Eur U)	94.38	100	✓ Creon 25000
Modified release granules pancreatin 60.12 mg (amylase			
3,600 Ph Eur U, lipase 5,000 Ph Eur U, protease 200 Ph			
Eur U)	34.93	20 g OP	<ul><li>Creon Micro</li></ul>
URSODEOXYCHOLIC ACID - Special Authority see SA2448 below	– Retail pha	ırmacy	
Cap 250 mg	33.95	100	✓ <u>Ursosan</u>
Eur U)	– Retail pha	ırmacy	✓ Creon Micro ✓ <u>Ursosan</u>

#### ⇒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...

Subsidy		Fully	Brand or
(Manufacturer's Price)	) :	Subsidised	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 500 q OP ✓ Konsyl-D **Faecal Softeners** DOCUSATE SODIUM - Only on a prescription 100 Coloxyl 100 Coloxyl DOCUSATE SODIUM WITH SENNOSIDES Tab 50 mg with sennosides 8 mg......3.50 200 Laxsol POLOXAMER - Only on a prescription Not funded for use in the ear. \* Oral drops 10%......4.17 30 ml OP ✓ Coloxyl

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

## **Opioid Receptor Antagonists - Peripheral**

#### ⇒SA1691 Special Authority for Subsidy

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

Both:

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

#### Osmotic Laxatives

* Suppos 2.8/4.0 g - Only on a prescription	10.39	20	✓ <u>Lax-suppositories</u>
			<u>Glycerol</u>
LACTULOSE – Only on a prescription			
* Oral liq 10 g per 15 ml	3.61	500 ml	✓ <u>Laevolac</u>
MACROGOL 3350 WITH POTASSIUM CHLORIDE, SODIUM BIO	CARBONATE A	ND SODIUM C	CHLORIDE
Powder for oral soln 13.125 g with potassium chloride 46.6 m			
sodium bicarbonate 178.5 mg and sodium chloride 350.7	mg8.50	30	APO Health
			Macrogol S29
			✓ Molaxole
SODIUM ACID PHOSPHATE - Only on a prescription			
Enema 16% with sodium phosphate 8%	2.50	1	✓ Fleet Phosphate
			Enema
SODIUM CITRATE WITH SODIUM LAURYL SULPHOACETATE	- Only on a pre	escription	
Enema 90 mg with sodium lauryl sulphoacetate 9 mg per ml,			
5 ml	25.00	50	✓ Micolette
		30	▼ <u>IMICOIELLE</u>
		50	<u>Micolette</u>
Stimulant Laxatives	33.69	30	wilcolette
Stimulant Laxatives	33.03	30	WICOICIE
Stimulant Laxatives BISACODYL – Only on a prescription		200	✓ Bisacodyl Viatris
Stimulant Laxatives  BISACODYL – Only on a prescription  * Tab 5 mg	5.80		
Stimulant Laxatives  BISACODYL – Only on a prescription  * Tab 5 mg  * Suppos 10 mg	5.80	200	✓ Bisacodyl Viatris
Stimulant Laxatives  BISACODYL – Only on a prescription  * Tab 5 mg	5.80 4.14	200	✓ Bisacodyl Viatris
Stimulant Laxatives  BISACODYL – Only on a prescription  * Tab 5 mg  * Suppos 10 mg  SENNA – Only on a prescription	5.80 4.14	200 10	✓ Bisacodyl Viatris
Stimulant Laxatives  BISACODYL – Only on a prescription  * Tab 5 mg  * Suppos 10 mg  SENNA – Only on a prescription	5.80 4.14	200 10	✓ Bisacodyl Viatris ✓ Lax-Suppositories
Stimulant Laxatives  BISACODYL – Only on a prescription  * Tab 5 mg  * Suppos 10 mg  SENNA – Only on a prescription	5.80 4.14 2.17 (9.38)	200 10 100	✓ Bisacodyl Viatris ✓ Lax-Suppositories
Stimulant Laxatives  BISACODYL – Only on a prescription  * Tab 5 mg  * Suppos 10 mg  SENNA – Only on a prescription		200 10 100 20	✓ Bisacodyl Viatris ✓ Lax-Suppositories  Senokot

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic \$ Per ✔ Manufacturer
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#### ⇒SA2053 Special Authority for Subsidy

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

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

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

## **Metabolic Disorder Agents**

ALGLUCOSIDASE ALFA − Special Authority see SA1986 below − Retail pharmacy Inj 50 mg vial .......1,142.60 1 ✓ Myozyme

#### ⇒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	e – Retail pharmacy		
Tab 1,000 mg	CBS	90	<ul><li>Clinicians</li></ul>
Cap 500 mg	CBS	50	✓ Solgar
Powder	CBS	400 a	✓ Biomed

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

#### **⇒SA2042** Special Authority for Subsidy

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

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

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

#### **⇒SA1987** Special Authority for Subsidy

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

- 1 The patient has a confirmed diagnosis of homocystinuria; and
- 2 Any of the following:
  - 2.1 A cystathionine beta-synthase (CBS) deficiency; or
  - 2.2 A 5,10-methylene-tetrahydrofolate reductase (MTHFR) deficiency; or
  - 2.3 A disorder of intracellular cobalamin metabolism; and
- 3 An appropriate homocysteine level has not been achieved despite a sufficient trial of appropriate vitamin supplementation.

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

#### ⇒SA2039 Special Authority for Subsidy

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

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

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

#### ⇒SA1988 Special Authority for Subsidy

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

- 1 The patient has been diagnosed with mucopolysaccharidosis VI; and
- 2 Either:
  - 2.1 Diagnosis confirmed by demonstration of N-acetyl-galactosamine-4-sulfatase (arylsulfatase B) deficiency by either enzyme activity assay in leukocytes or skin fibroblasts; or
  - 2.2 Detection of two disease causing mutations and patient has a sibling who is known to have mucopolysaccharidosis VI.

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

1 The treatment remains appropriate for the patient and the patient is benefiting from treatment; and

continued...

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	ufacturer's Price)	Subsidised	Generic
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#### continued...

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

#### ⇒SA1623 Special Authority for Subsidy

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

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

#### ⇒SA1695 Special Authority for Subsidy

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

- 1 The patient has been diagnosed with Hurler Syndrome (mucopolysacchardosis I-H); and
- 2 Either:

ı

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

LEVOCARNITINE - Special Authority see SA204	0 on the next page - Retail phar	macy	
Tab 500 mg	CBS	30	✓ Solgar
Cap 250 mg	CBS	30	✓ Solgar
Cap 500 mg	CBS	60	✓ Balance
		300	✓ Metabolics
Oral liq 1 g per 10 ml	CBS	118 ml	✓ Carnitor S29
			✓ Novitium Sugar
			Free S29
Oral liq 500 mg per 10 ml	CBS	300 ml	✓ Balance

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

RIBOFLAVIN - Special Authority see SA2041 below -	Retail pharmacy		
Tab 100 mg	CBS	100	<ul><li>Country Life</li></ul>
			✓ Puritan's Pride Vitamin B-2 100 mg \$29
Cap 100 mg	CBS	100	✓ Solgar

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

continued...

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

continued...

- 4 Sapropterin to be used alone or in combination with PKU dietary management; and
- 5 Total treatment duration with sapropterin will not exceed 22 months for each pregnancy (includes time for planning and becoming pregnant) and treatment will be stopped after delivery.

SODIUM BENZOATE - Special Authority see SA1599 below - Retail pharmacy Soln 100 mg per ml ......CBS 100

100 ml ✓ Amzoate S29

#### ⇒SA1599 Special Authority for Subsidy

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

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

SODIUM PHENYLBUTYRATE - Special Authority see SA1990 below - Retail pharmacy

#### ⇒SA1990 Special Authority for Subsidy

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

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

TAURINE - Special Authority see SA2043 below - Retail pharmacy

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

#### ⇒SA2043 Special Authority for Subsidy

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

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

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

TRIENTINE – Special Authority see SA2324 below – Retail pharmacy
Cap 250 mg......2,022.00

100

Trientine Waymade

#### ⇒SA2324 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 confirmed Wilson disease; and
- 2 Treatment with D-penicillamine has been trialled and discontinued because the person has experienced intolerable side effects or has not received sufficient benefit; and
- 3 Treatment with zinc has been trailled and discontinued because the person has experienced intolerable side effects or has not received sufficient benefit, or zinc is considered clinically inappropriate as the person has symptomatic liver disease and requires copper chelation.

#### Gaucher's Disease

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

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

#### CARMELLOSE SODIUM WITH GELATIN AND PECTIN

Paste	17.20	56.7 g OP	Stomahesive
	4.55	15 g OP	
	(7.90)	ŭ	Orabase
	`1.52 <sup>´</sup>	5 g OP	
	(3.60)	·	Orabase
Powder	8.48 <sup>′</sup>	28 g OP	
	(10.95)	ŭ	Stomahesive

	Subsidy (Manufacturer's P	rice) Subs	Fully Brand or idised Generic
	\$	Per	✓ Manufacturer
RIAMCINOLONE ACETONIDE		- 05	
Paste 0.1%	5.49	5 g OP	✓ Kenalog in Orabase
Oropharyngeal Anti-infectives			
MPHOTERICIN B			
Lozenges 10 mg	5.86	20	✓ Fungilin
MICONAZOLE Oral gel 20 mg per g	5 10	40 g OP	✓ Decozol
NYSTATIN		40 g Oi	<u> </u>
Oral liq 100,000 u per ml	2.22	24 ml OP	✓ <u>Nilstat</u>
Vitamins			
Vitamin B			
HYDROXOCOBALAMIN			
★ Inj 1 mg per ml, 1 ml ampoule – Up to 6 inj available on a	PSO2.46	3	✓ Cobal-B12 ©29 ✓ Vita-B12
	3.95		<ul><li>Hydroxocobalamin Panpharma</li></ul>
	4.10	5	✓ Cobalin-H S29 ✓ Neo-Cytamen S29 S29
	8.20	10	✓ Vitarubin Depot Injection \$29
Hydroxocobalamin Panpharma to be Principal Supply Cobal-B12 S29 Inj 1 mg per ml, 1 ml ampoule to be delisted Vita-B12 Inj 1 mg per ml, 1 ml ampoule to be delisted 1 July 2 Cobalin-H S29 Inj 1 mg per ml, 1 ml ampoule to be delisted Neo-Cytamen S29 S29 Inj 1 mg per ml, 1 ml ampoule to be Vitarubin Depot Injection S29 Inj 1 mg per ml, 1 ml ampoule PYRIDOXINE HYDROCHLORIDE  a) No more than 100 mg per dose b) Only on a prescription	1 July 2025) 1025) 1 July 2025) delisted 1 July 2025		
★ Tab 25 mg – No patient co-payment payable		90	✓ Vitamin B6 25
<b>★</b> Tab 50 mg	23.45	500	✓ Pyridoxine multichem
HIAMINE HYDROCHLORIDE - Only on a prescription	1 GE	100	✓ Thiamine multichem
₭ Tab 50 mg/ /ITAMIN B COMPLEX	4.00	100	- manime munucilem
★ Tab, strong, BPC	11.25	500	✓ Bplex
Vitamin C			
ASCORBIC ACID			
a) No more than 100 mg per dose			
b) Only on a prescription  * Tab 100 mg	12 50	500	✓ Cvite
	12.00	550	<u> </u>

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

31

Vitamin D		
ALFACALCIDOL  * Cap 0.25 mcg26.32	100	✓ One-Alpha ✓ One-Alpha S29 S29
* Cap 1 mcg       87.98         * Oral drops 2 mcg per ml       60.68         (One-Alpha S29 S29 Cap 0.25 mcg to be delisted 1 July 2025)	100 20 ml OP	✓ One-Alpha ✓ One-Alpha
CALCITRIOL	100	✓ Calcitriol XL ©29 ✓ Calcitriol-AFT
<b>*</b> Cap 0.5 mcg	100	✓ Calcitriol XL S29 ✓ Calcitriol-AFT
COLECALCIFEROL  * Cap 1.25 mg (50,000 iu) – Maximum of 12 cap per prescription3.65  * Oral liq 188 mcg per ml (7,500 iu per ml)	12 5 ml OP	✓ <u>Vit.D3</u> ✓ Clinicians
Multivitamin Preparations		
MULTIVITAMIN RENAL – Special Authority see SA1546 below – Retail pharmac  * Cap	су 30	✓ Clinicians Renal Vit
■ SA1546 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid without further the following criteria: Either:  1 The patient has chronic kidney disease and is receiving either peritoneal disease.		.,
2 The patient has chronic kidney disease grade 5, defined as patient with an 15 ml/min/1.73 m² body surface area (BSA).		
MULTIVITAMINS – Special Authority see SA1036 below – Retail pharmacy  * Powder74.88	200 g OP	✓ Paediatric Seravit
■SA1036 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid without further inborn errors of metabolism.	renewal unless	notified where the patient has
Renewal from any relevant practitioner. Approvals valid without further renewal upproval for multivitamins.  VITAMINS	unless notified v	where patient has had a previous
VITAIVIIVO		

Subsidy

(Manufacturer's Price)

Fully

Subsidised

Per

Brand or

Generic

Manufacturer

VII	AIVIIVO		
*	Tab (BPC cap strength)18.50	1,000	✓ Mvite
*	Cap (fat soluble vitamins A, D, E, K) - Special Authority see		
	SA1720 below – Retail pharmacy 23.40	60	✓ Vitabdeck

## **⇒SA1720** Special Authority for Subsidy

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

Any of the following:

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

	ALIMENTAN	IINACI	ANI	DIVIETABOLISIVI
	Subsidy (Manufacturer's Price) \$	) Subsi	Fully dised	Brand or Generic Manufacturer
Minerals				
Calcium				
CALCIUM CARBONATE  * Tab 1.25 g (500 mg elemental)  * Tab eff 1.25 g (500 mg elemental) – Subsidy by endorsem	ent260.00	250 100	1	Calci-Tab 500 Calcium 500 mg Hexal <sup>S29</sup>
Subsidy by endorsement – Only when prescribed for p considered unsuitable.	aediatric patients (< 5	years) wher	e cal	cium carbonate oral liquid is
CALCIUM GLUCONATE  * Inj 10%, 10 ml ampoule	32.00	10	<b>√</b>	Max Health - Hameln 629
lodine				
POTASSIUM IODATE  * Tab 253 mcg (150 mcg elemental iodine)	5.99	90	<b>✓</b> <u>I</u>	NeuroTabs
Iron				
FERROUS FUMARATE  * Tab 200 mg (65 mg elemental)	3.49	100	<b>✓</b> <u>I</u>	Ferro-tab
FERROUS FUMARATE WITH FOLIC ACID  * Tab 310 mg (100 mg elemental) with folic acid 350 mcg FERROUS SULFATE	5.98	100	<b>✓</b> <u>I</u>	Ferro-F-Tabs
** Tab long-acting 325 mg (105 mg elemental)      ** Oral liq 30 mg (6 mg elemental) per 1 ml	9.25	30 250 ml 500 ml	<b>✓</b> i	Ferrogra <u>d</u> Ferro-Liquid Ferodan
IRON (AS FERRIC CARBOXYMALTOSE) – Special Authority Inj 50 mg per ml, 10 ml vial		Retail pharm 1		Ferinject
SA2394   Special Authority for Subsidy     Initial application — (Anaemia) from any relevant practitioner following criteria:   All of the following:		3 months for	appli	ications meeting the
2.2.1 Sarum farritin is between 20 and 50 mcg/	l·and			

- 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

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

#### 

Magnesium		
MAGNESIUM HYDROXIDE Suspension 8%33.60	355 ml	✓ Phillips Milk of Magnesia \$29
MAGNESIUM SULPHATE       ★ Inj 2 mmol per ml, 5 ml ampoule	10 10	✓ <u>Martindale</u> ✓ Inresa \$29
Zinc		
ZINC SULPHATE  * Cap 137.4 mg (50 mg elemental)11.00	100	✓ Zincaps

✓ Ferrosia

5

#### **BLOOD AND BLOOD FORMING ORGANS**

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per 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	250.00	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	Binocrit
Inj 4,000 iu in 0.4 ml, syringe		6	<ul><li>Binocrit</li></ul>
Inj 5,000 iu in 0.5 ml, syringe	125.00	6	Binocrit
Inj 6,000 iu in 0.6 ml, syringe	145.00	6	Binocrit
Inj 8,000 iu in 0.8 ml, syringe		6	Binocrit
Inj 10,000 iu in 1 ml, syringe		6	Binocrit
Inj 40,000 iu in 1 ml, syringe		1	Binocrit

#### **BLOOD AND BLOOD FORMING ORGANS**

	Subsidy (Manufacturer's Price) \$		Fully ised ✓	Brand or Generic Manufacturer
Megaloblastic				
FOLIC ACID  * Tab 0.8 mg	26.60	1,000		olic Acid multichem
* Tab 5 mg Oral liq 50 mcg per ml		100 5 ml OP	_	olic Acid Viatris omed

## **Antifibrinolytics, Haemostatics and Local Sclerosants**

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

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

reaters Group in conjunction with the National	Haemophilia Management gro	up.	
Inj 250 iu vial	612.50	1	Alprolix
Inj 500 iu vial	1,225.00	1	✓ Alprolix
Inj 1,000 iu vial	2,450.00	1	✓ Alprolix
Inj 2,000 iu vial	4,900.00	1	✓ Alprolix
Inj 3,000 iu vial	7,350.00	1	✓ Alprolix
lnj 4,000 iu vial	9,800.00	1	Alprolix
ELTROMBOPAG – Special Authority see SA1743 b Wastage claimable	pelow - Retail pharmacy		
Tab 25 mg	1,550.00	28	✓ Revolade
Tab 50 mg	3,100.00	28	Revolade

#### ⇒SA1743 Special Authority for Subsidy

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

All of the following:

Ε

- 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 eltrombopage 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

continued...

Sub	sidy Fu	ully Brand or
(Manufactu		sed Generic
	Per 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	3,570.00	1	✓ Hemlibra
Inj 60 mg in 0.4 ml vial	•	1	✓ Hemlibra
Inj 105 mg in 0.7 ml vial	12,492.00	1	✓ Hemlibra
Inj 150 mg in 1 ml vial	17,846.00	1	✓ Hemlibra

### ⇒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:

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

	Subsidy		Fully	
	(Manufacturer's Price) \$	Per	Subsidised •	Generic Manufacturer
FACTOR EIGHT INHIBITOR BYPASSING FRACTION - [Xpr	arm]			
For patients with haemophilia. Preferred Brand of bypass	ing agent for > 14 days	oredic	ted use.	Access to funded treatmen
is managed by the Haemophilia Treaters Group in conjunc	tion with the National H	aemo	ohilia Mar	nagement Group.
Inj 500 U	1,315.00	1	1	FEIBA NF
Inj 1,000 U	2,630.00	1	✓	FEIBA NF
Inj 2,500 U	6,575.00	1	1	FEIBA NF
MOROCTOCOG ALFA [RECOMBINANT FACTOR VIII] - [Xp	harml			
For patients with haemophilia. Rare Clinical Circumstance		reco	mhinant f	actor VIII. Access to funder
treatment is managed by the Haemophilia Treaters Group				
subject to criteria.	in conjunction with the i	<b>v</b> ation	arriadine	prima management areap
Inj 250 iu prefilled syringe	287 50	1	1	Xyntha
Inj 500 iu prefilled syringe		i		Xyntha
Inj 1,000 iu prefilled syringe		1		Xyntha
Inj 1,000 iu prefilled syringe	· ·	1		Xyntha
Inj 3,000 iu prefilled syringe	· ·	1		Xyntha
	•	'	•	лупша
NONACOG GAMMA, [RECOMBINANT FACTOR IX] - [Xphai				
For patients with haemophilia. Access to funded treatmer	it is managed by the Ha	emopl	nilia Treat	ers Group in conjunction
with the National Haemophilia Management Group.				
Inj 1,000 iu vial		1	•	RIXUBIS
Inj 2,000 iu vial	1,740.00	1	•	RIXUBIS
Inj 3,000 iu vial	2,610.00	1	✓	RIXUBIS
OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (ADVATE)	- [Xpharm]			
For patients with haemophilia. Preferred Brand of short ha		r VIII.	Access to	o 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
• •	•	•	-	, iu ruio
OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (KOGENAT				
For patients with haemophilia. Rare Clinical Circumstance				
		vanon		mbilia Managanana Ant Oussus
treatment is managed by the Haemophilia Treaters Group	in conjunction with the i	1011	arriacino	philia Management Group
subject to criteria.			_	
subject to criteria. Inj 250 iu vial	237.50	1	/	Kogenate FS
subject to criteria. Inj 250 iu vialInj 500 iu vial	237.50 475.00	1	<b>√</b>	Kogenate FS Kogenate FS
subject to criteria. Inj 250 iu vialInj 500 iu vialInj 1,000 iu vial	237.50 475.00 950.00	1 1 1	<b>V V</b>	Kogenate FS Kogenate FS Kogenate FS
subject to criteria. Inj 250 iu vialInj 500 iu vialInj 1,000 iu vialInj 1,000 iu vialInj 2,000 iu vialInj 2,000 iu vialInj 2,000 iu vial.	237.50 475.00 950.00 1,900.00	1 1 1 1	<b>V V V</b>	Kogenate FS Kogenate FS Kogenate FS Kogenate FS
subject to criteria. Inj 250 iu vial Inj 500 iu vial Inj 1,000 iu vial Inj 2,000 iu vial Inj 3,000 iu vial	237.50 475.00 950.00 1,900.00 2,850.00	1 1 1	<b>V V V</b>	Kogenate FS Kogenate FS Kogenate FS
subject to criteria. Inj 250 iu vial Inj 500 iu vial Inj 1,000 iu vial Inj 2,000 iu vial Inj 3,000 iu vial	237.50 475.00 950.00 1,900.00 2,850.00	1 1 1 1	<b>V V V</b>	Kogenate FS Kogenate FS Kogenate FS Kogenate FS
subject to criteria. Inj 250 iu vial Inj 500 iu vial Inj 1,000 iu vial Inj 2,000 iu vial Inj 3,000 iu vial	237.50 475.00 950.00 1,900.00 2,850.00	1 1 1 1	\ \ \ \	Kogenate FS Kogenate FS Kogenate FS Kogenate FS Kogenate FS
subject to criteria. Inj 250 iu vialInj 500 iu vialInj 1,000 iu vialInj 1,000 iu vialInj 2,000 iu vialInj 2,000 iu vialInj 3,000 iu vial.	237.50 475.00 950.00 1,900.00 2,850.00 III] – [Xpharm] tment. Access to funder	1 1 1 1	\ \ \ \	Kogenate FS Kogenate FS Kogenate FS Kogenate FS Kogenate FS
subject to criteria. Inj 250 iu vial	237.50 475.00 950.00 1,900.00 2,850.00 III] – [Xpharm] tment. Access to funder	1 1 1 1	tment is n	Kogenate FS Kogenate FS Kogenate FS Kogenate FS Kogenate FS
subject to criteria. Inj 250 iu vial		1 1 1 1 1	tment is n	Kogenate FS Kogenate FS Kogenate FS Kogenate FS Kogenate FS Ananaged by the Haemophili
subject to criteria. Inj 250 iu vial		1 1 1 1 1 d treat	tment is n	Kogenate FS Kogenate FS Kogenate FS Kogenate FS Kogenate FS anaged by the Haemophili
subject to criteria. Inj 250 iu vial		1 1 1 1 1 d treat	tment is n	Kogenate FS Kogenate FS Kogenate FS Kogenate FS Kogenate FS Ananaged by the Haemophili
subject to criteria. Inj 250 iu vial		1 1 1 1 1 d treat	tment is n	Kogenate FS Kogenate FS Kogenate FS Kogenate FS Kogenate FS anaaged by the Haemophili Adynovate Adynovate
subject to criteria. Inj 250 iu vial		1 1 1 1 1 d treat	tment is n	Kogenate FS Kogenate FS Kogenate FS Kogenate FS Kogenate FS Ananaged by the Haemophili
subject to criteria.  Inj 250 iu vial		1 1 1 1 1 d treat 1 1	treent is n	Kogenate FS Kogenate FS Kogenate FS Kogenate FS Kogenate FS managed by the Haemophili Adynovate Adynovate Fibro-vein
subject to criteria.  Inj 250 iu vial		1 1 1 1 1 1 1 1 5	tment is n	Kogenate FS Kogenate FS Kogenate FS Kogenate FS Kogenate FS anaged by the Haemophili Adynovate Adynovate Fibro-vein Mercury Pharma
subject to criteria.  Inj 250 iu vial		1 1 1 1 1 d treat 1 1	tment is n	Kogenate FS Kogenate FS Kogenate FS Kogenate FS Kogenate FS managed by the Haemophili Adynovate Adynovate Fibro-vein

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised		
Vitamin K					
PHYTOMENADIONE Inj 2 mg per 0.2 ml – Up to 5 inj available on a PSOInj 10 mg per ml, 1 ml – Up to 5 inj available on a PSO		5 5		Konakion MM Konakion MM	

### **Antithrombotic Agents**

# **Antiplatelet Agents**

•	•			
ASPIRIN  * Tab 100 mg		12.65	990	✓ Ethics Aspirin EC
CLOPIDOGREL			000	<u> </u>
ŭ		5.07	84	✓ Arrow - Clopid
DIPYRIDAMOLE	150 mg	13 03	60	✓ Pytazen SR
0 0	pecial Authority see SA1955 below – Retail p		00	1 ytuzon on
	, , , , , , , , , , , , , , , , , , , ,	•	56	✓ <u>Ticagrelor Sandoz</u>

#### ⇒SA1955 Special Authority for Subsidy

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

#### Both:

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

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

Both:

#### 1 Fither:

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

#### 2 Either:

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

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

#### All of the following:

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

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

Renewal — (subsequent acute coronary syndrome) from any relevant practitioner. Approvals valid for 12 months for

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

continued...

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 SA215	2 below – Retail pharmacy		
Inj 20 mg in 0.2 ml syringe	21.90	10	✓ Clexane
Inj 40 mg in 0.4 ml syringe	29.74	10	✓ Clexane
Inj 60 mg in 0.6 ml syringe		10	✓ Clexane
Inj 80 mg in 0.8 ml syringe		10	✓ Clexane
Inj 100 mg in 1 ml syringe	70.91	10	✓ Clexane
Inj 120 mg in 0.8 ml syringe	88.11	10	✓ Clexane Forte
Ini 150 mg in 1 ml syringe		10	✓ Clexane Forte

⇒SA2152 Special Authority for Subsidy

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

Any of the following:

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

Initial application — (Venous thromboembolism other than in pregnancy or malignancy) from any relevant practitioner. Approvals valid for 1 month for applications meeting the following criteria:

Any of the following:

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

Initial application — (Short-term use during treatment of COVID-19 with nirmatrelvir with ritonavir) from any relevant

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

continued...

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 vial127.44	25	✓ Pfizer S29
Inj 1,000 iu per ml, 5 ml ampoule25.49	10	✓ Wockhardt S29
103.70		✓ Wockhardt PSF   S29
127.44	50	✓ Pfizer
Inj 5,000 iu per ml, 5 ml vial83.00	10	✓ <u>Heparin Sodium</u> Panpharma
Inj 5,000 iu per ml, 1 ml70.33	5	✓ Hospira
Inj 25,000 iu per ml, 0.2 ml25.78	5	✓ Hospira
482.20	50	✓ Heparin DBL S29
HEPARINISED SALINE		
Inj 10 iu per ml, 5 ml96.91	50	✓ Pfizer
Oral Anticoagulants		
DABIGATRAN		
Cap 75 mg - No more than 2 cap per day27.99	60	✓ Pradaxa
Cap 110 mg27.99	60	✓ Pradaxa
Cap 150 mg27.99	60	✓ Pradaxa
RIVAROXABAN		<del></del>
Tab 10 mg - No more than 1 tab per day15.60	30	✓ Xarelto
Tab 15 mg - Up to 14 tab available on a PSO14.56	28	✓ Xarelto
Tab 20 mg14.56	28	✓ Xarelto
WARFARIN SODIUM		
Note: Marevan and Coumadin are not interchangeable.		
* Tab 1 mg3.46	50	✓ Coumadin
7.50	100	✓ Marevan
* Tab 2 mg4.31	50	✓ Coumadin
* Tab 3 mg12.00	100	✓ Marevan
* Tab 5 mg5.93	50	✓ Coumadin
13.50	100	✓ Marevan

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

# **Blood Colony-stimulating Factors**

FILGRASTIM - Special Authority see SA1259 below - Retail pharm	acy		
Inj 300 mcg per 0.5 ml prefilled syringe	86.60	10	✓ Nivestim
Inj 480 mcg per 0.5 ml prefilled syringe	133.72	10	✓ Nivestim

#### ⇒SA1259 Special Authority for Subsidy

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

Any of the following:

- 1 Prevention of neutropenia in patients undergoing high risk chemotherapy for cancer (febrile neutropenia risk greater than or equal to 20%\*); or
- 2 Peripheral blood stem cell mobilisation in patients undergoing haematological transplantation; or
- 3 Peripheral blood stem cell mobilisation or bone marrow donation from healthy donors for transplantation; or
- 4 Treatment of severe chronic neutropenia (ANC < 0.5 ×109/L); or
- 5 Treatment of drug-induced prolonged neutropenia (ANC < 0.5 ×10<sup>9</sup>/L).

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

### **⇒SA1912** Special Authority for Subsidy

**Initial application** only from a relevant specialist, vocationally registered general practitioner or medical practitioner on the recommendation of a relevant specialist. Approvals valid without further renewal unless notified where used for prevention of neutropenia in patients undergoing high risk chemotherapy for cancer (febrile neutropenia risk greater than or equal to 5%\*). Note: \*Febrile neutropenia risk greater than or equal to 5% after taking into account other risk factors as defined by the European Organisation for Research and Treatment of Cancer (EORTC) guidelines.

# Fluids and Electrolytes

### Intravenous Administration

GLUCOSE [DEXTROSE]  * Inj 50%, 10 ml ampoule – Up to 5 inj available on a PSO  * Inj 50%, 90 ml bottle – Up to 5 inj available on a PSO  POTASSIUM CHLORIDE		5 1	✓ Biomed ✓ Biomed
* Inj 75 mg per ml, 10 ml	65.00	50	<ul><li>✓ Juno</li><li>✓ LumaCina</li><li>✓ Pfizer S29</li></ul>
SODIUM BICARBONATE			
Inj 8.4%, 50 ml	24.70	1	Biomed
a) Up to 5 inj available on a PSO b) Not in combination Inj 8.4%, 100 ml	25.31	1	✓ Biomed
a) Up to 5 inj available on a PSO     b) Not in combination			

	Subsidy		Fully	Brand or
	(Manufacturer's Price		osidised	Generic
	\$	Per		Manufacturer
SODIUM CHLORIDE				
Not funded for use as a nasal drop. Not funded for nebuliser for nebuliser use.	ruse except when u	sed in cor	junction	with an antibiotic intended
Inj 23.4% (4 mmol/ml), 20 ml ampoule	40.15	5	<b>✓</b> B	iomed
For Sodium chloride oral liquid formulation refer Standar	d Formulae, page 2	76		
Inj 0.9%, 5 ml ampoule - Up to 5 inj available on a PSO		20	<b>√</b> <u>F</u>	resenius Kabi
Inj 0.9%, 10 ml ampoule - Up to 5 inj available on a PSO		50	<b>√</b> <u>F</u>	resenius Kabi
Inj 0.9%, 20 ml ampoule		20	_	resenius Kabi
Inj 0.9%, 1,000 ml bag - Up to 2 bag available on a PSO		1	_	axter
Only if prescribed on a prescription for renal dialysis, ma for emergency use. (500 ml and 1,000 ml packs)		care in the		•
Inj 0.9%, 500 ml bag - Up to 4 bag available on a PSO		1		axter
Only if prescribed on a prescription for renal dialysis, ma for emergency use. (500 ml and 1,000 ml packs)	ternity or post-natal	care in the	e home d	of the patient, or on a PSO
TOTAL PARENTERAL NUTRITION (TPN)				
Infusion	CBS	1 OP	<b>✓</b> T	PN
WATER				
Schedule requiring a solvent or diluent; or 2) On a bulk supply order; or 3) When used in the extemporaneous compounding of ey 4) When used for the dilution of sodium chloride soln 7% to		tients only		
Inj 10 ml ampoule - Up to 5 inj available on a PSO	7.60	50	✓ N	lultichem
Inj 20 ml ampoule - Up to 5 inj available on a PSO	5.00	20	<b>✓</b> F	resenius Kabi
Oral Administration				
CALCIUM POLYSTYRENE SULPHONATE				
Powder	160.95	800 g OP	./ c	alcium Resonium
	109.00	ou y OF	• 0	aiciuiii nesoiliuiii
COMPOUND ELECTROLYTES	0.50			
Powder for oral soln — Up to 5 sach available on a PSO	9.53	50	✓ E	<u>lectral</u>
COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE]				
Soln with electrolytes	6.53	1 OP	✓ H	lydralyte -
				Lemonade
PHOSPHORUS				
Tab eff 500 mg (16 mmol)	82.50	100	<b>✓</b> P	hosphate Phebra
POTASSIUM CHLORIDE				•
* Tab eff 548 mg (14 m eq) with chloride 285 mg (8 m eq)	5,26	60		
	(17.10)		C	hlorvescent
* Tab long-acting 600 mg (8 mmol)		200		pan-K
SODIUM BICARBONATE				•
Cap 840 mg	8.52	100	_	odibic odibic

454 g OP

✓ Resonium-A

Powder ......84.65

SODIUM POLYSTYRENE SULPHONATE

	Subsidy		Fully	/ Brand or
	(Manufacturer's Price)		Subsidised	
	\$	Per		Manufacturer
Aluba Advana anton Diaglana				
Alpha-Adrenoceptor Blockers				
Alpha Adrenoceptor Blockers				
DOXAZOSIN				
* Tab 2 mg	17.35	500	1	Doxazosin Clinect
* Tab 4 mg		500	1	Doxazosin Clinect
PHENOXYBENZAMINE HYDROCHLORIDE				
* Cap 10 mg	65.00	30	_	BNM S29
A Cap to hig	216.67	100		Dibenzyline \$29
(Dibenzuline coe Con 10 mg to be delicted 1 July 2005)	210.07	100	•	Dibenzyline 329
(Dibenzyline \$29 Cap 10 mg to be delisted 1 July 2025)				
PRAZOSIN			_	
* Tab 1 mg	5.53	100	•	Arrotex-Prazosin
				S29 S29
	9.98		•	Minipress S29
* Tab 2 mg	7.00	100	•	Arrotex-Prazosin
				S29 S29
	13.29		•	Minipress S29
* Tab 5 mg	11.70	100	•	Arrotex-Prazosin
				S29 S29
	22.00		1	Minipress S29
* Cap 1 mg	15.40	100		Prazosin Mylan S29
* Cap 2 mg		100		Prazosin Mylan S29
* Cap 5 mg		100		Prazosin Mylan S29
- Cap σ mg	20.02	100	•	Trazosiii mylan
Agents Affecting the Renin-Angiotensin System	n			
ACE Inhibitors				
CAPTOPRIL				
* Oral liq 5 mg per ml	86.00 10	0 ml 0	OP 🗸	DP-Captopril
Oral liquid restricted to children under 12 years of age.		•		<u> </u>
ENALAPRIL MALEATE				
* Tab 5 mg	1 75	90	_	Acetec
* Tab 10 mg		90		Acetec
* Tab 20 mg		90	_	Acetec
LISINOPRIL				<u></u>
* Tab 5 mg	11.07	90		Ethics Lisinopril
Tab Jilly	11.07	30		Teva Lisinopril
* Tab 10 mg	11.67	90		Ethics Lisinopril
Tub 10 mg	11.07	50		Teva Lisinopril
* Tab 20 mg	14.69	90		Ethics Lisinopril
		••		Teva Lisinopril
PERINDOPRIL				
* Tab 2 mg	1 79	30	1	Coversyl
* Tab 4 ma	0.44	20	./	Covered

✓ Coversyl

✓ Coversyl

30

30

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	I Generic
QUINAPRIL				
* Tab 5 mg	10.24	90	✓	Arrow-Quinapril 5
* Tab 10 mg	12.51	90	✓	Arrow-Quinapril 10
* Tab 20 mg	14.83	90	✓	Arrow-Quinapril 20
RAMIPRIL				
* Cap 1.25 mg	17.25	90	/	Tryzan
₭ Cap 2.5 mg		90		Tryzan
<b>★</b> Cap 5 mg		90		Tryzan
<b>★</b> Cap 10 mg		90	✓	Tryzan
Angiotensin II Antagonists				
CANDESARTAN CILEXETIL				
* Tab 4 mg	2.68	90	/	Candestar
⊁ Tab 8 mg		90		Candestar
⊁ Tab 16 mg		90		Candestar
₭ Tab 32 mg		90		Candestar
OSARTAN POTASSIUM				
★ Tab 12.5 mg	2.00	84	1	Losartan Actavis
★ Tab 25 mg		84		Losartan Actavis
★ Tab 50 mg		84		Losartan Actavis
₭ Tab 100 mg		84		Losartan Actavis
•		07	•	LOSAITAII ACIAVIS
Angiotensin II Antagonists with Diuretics				
CANDESARTAN CILEXETIL WITH HYDROCHLOROTHIAZIDE				
* Tab 16 mg with hydrochlorothiazide 12.5 mg	4.10	30	✓	APO-Candesartan
0 ,				HCTZ 16/12.5
★ Tab 32 mg with hydrochlorothiazide 12.5 mg	5.25	30	1	APO-Candesartan
· · · · · · · · · · · · · · · · · · ·				HCTZ 32/12.5
OSARTAN POTASSIUM WITH HYDROCHLOROTHIAZIDE				
* Tab 50 mg with hydrochlorothiazide 12.5 mg	4.00	30	ſ	Arrow-Losartan &
rab 50 mg with hydrochilofothiazide 12.5 mg	4.00	50	•	Hydrochlorothiazide
				11yaroomoroumazide
Angiotensin II Antagonists with Neprilysin Inhi	bitors			
SACHRITRII WITH VALSARTAN - Special Authority see SA23	200 halaw Datail aha			

SACUBITRIL WITH VALSARTAN - Special Authority see SA23	302 below – Retail	pharmacy	
Tab 24.3 mg with valsartan 25.7 mg	190.00	56	✓ Entresto 24/26
Tab 48.6 mg with valsartan 51.4 mg	190.00	56	✓ Entresto 49/51
Tab 97.2 mg with valsartan 102.8 mg	190.00	56	✓ Entresto 97/103

# ⇒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

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

continued...

- 2.3 Patient is in NYHA/WHO functional class IV; and
- 3 Fither:
  - 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, Anaesthetics, Lo	cal, page 121	
AMIODARONE HYDROCHLORIDE		
▲ Tab 100 mg	19 30	✓ Aratac
▲ Tab 200 mg		✓ Aratac
Inj 50 mg per ml, 3 ml ampoule – Up to 10 inj available on a PSO9.1		✓ Cordarone-X
15.2		✓ Max Health
ATROPINE SULPHATE		
* Inj 600 mcg per ml, 1 ml ampoule – Up to 5 inj available on a		
PSO16.1	10 10	✓ Hikma S29
10.1	10 10	✓ Juno \$29
		✓ Martindale
DIOCUM		<u>waitinuale</u>
DIGOXIN	040	/ Lamavin DO
* Tab 62.5 mcg – Up to 30 tab available on a PSO		✓ <u>Lanoxin PG</u> ✓ Lanoxin
* Tab 250 mcg - Up to 30 tab available on a PSO		✓ <u>Lanoxin</u> ✓ Lanoxin
* Oracing 50 mgg per mi10.0	00 00 1111	
		✓ Lanoxin S29 S29
DISOPYRAMIDE PHOSPHATE		
▲ Cap 100 mg		✓ Rythmodan
55.9	90 84	Rythmodan -
		Cheplafarm \$29
(Rythmodan Cap 100 mg to be delisted 1 November 2025)		
FLECAINIDE ACETATE		
▲ Tab 50 mg19.9	95 60	✓ Flecainide BNM
▲ Cap long-acting 100 mg	78 90	✓ <u>Flecainide</u>
		<u>Controlled</u>
		Release Teva
▲ Cap long-acting 200 mg54.2	28 90	✓ Flecainide
		Controlled
		Release Teva
Inj 10 mg per ml, 15 ml ampoule102.7		✓ Almarytm S29
108.1	16	✓ Tambocor
		✓ Tambocor
		German S29
MEXILETINE HYDROCHLORIDE		
▲ Cap 150 mg162.0	00 100	✓ Teva S29
▲ Cap 250 mg	00 100	✓ Teva S29
PROPAFENONE HYDROCHLORIDE		
▲ Tab 150 mg40.8	90 50	✓ Rytmonorm
		,

Subsidy	Fu	ılly Bra	nd or
(Manufacturer's Price)	Subsidis	ed Ger	neric
\$	Per	✓ Mar	nufacturer

ман	aw	nn		$\mathbf{r}$	100
Anti	ПV	w	ш	P-11	V-1-
	-				

,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
MIDODRINE - Special Authority see SA1474 below - Ret	ail pharmacy		
Tab 2.5 mg	36.68	100	✓ MAR-Midodrine S29
ů			✓ Midodrine
			Medsurge
Tab 5 mg	58.88	100	✓ MAR-Midodrine S29
•			✓ Midodrine
			Medsurge

### ⇒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	11.00	500	✓ <u>Viatris</u>
* Tab 100 mg	18.50	500	✓ <u>Atenolol Viatris</u>
Oral liq 25 mg per 5 ml  Restricted to children under 12 years of age.	49.85	300 ml OP	✓ Atenolol AFT
BISOPROLOL FUMARATE			
* Tab 2.5 mg	1.36	90	✓ Ipca-Bisoprolol
* Tab 5 mg	1.91	90	✓ Ipca-Bisoprolol
* Tab 10 mg	2.71	90	✓ Ipca-Bisoprolol
CARVEDILOL			
* Tab 6.25 mg	2.24	60	✓ Carvedilol Sandoz
* Tab 12.5 mg		60	✓ Carvedilol Sandoz
* Tab 25 mg	2.95	60	✓ Carvedilol Sandoz
LABETALOL			
* Tab 100 mg	14.50	100	✓ Trandate
* Tab 200 mg	27.00	100	✓ Trandate
* Inj 5 mg per ml, 20 ml ampoule	59.06	5	
	(88.60)		Trandate
METOPROLOL SUCCINATE			
* Tab long-acting 23.75 mg	4.20	90	✓ Myloc CR
* Tab long-acting 47.5 mg	3.65	90	✓ Myloc CR
* Tab long-acting 95 mg	5.24	90	✓ Myloc CR
* Tab long-acting 190 mg	9.76	90	✓ Myloc CR
METOPROLOL TARTRATE			
* Tab 50 mg	5.66	100	✓ IPCA-Metoprolol
* Tab 100 mg	7.55	60	✓ IPCA-Metoprolol
* Tab long-acting 200 mg	23.40	28	✓ Slow-Lopresor
* Inj 1 mg per ml, 5 ml vial	26.50	5	Metoprolol IV Mylan
			Metoprolol IV Viatris

<sup>▲</sup>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
NADOLOL				
* Tab 40 mg	19.19	100	✓ N	adolol BNM
* Tab 80 mg	30.39	100	✓ N	adolol BNM
PROPRANOLOL				
* Tab 10 mg	7.04	100	<b>✓</b> D	rofate
* Tab 40 mg	8.75	100	✓ IF	PCA-Propranolol
* Cap long-acting 160 mg	18.17	100	✓ C	ardinol LA
* Oral liq 4 mg per ml - Special Authority see SA1327 below -	-			
Retail pharmacy		500 ml	✓ R	oxane-
				Propranolol S29

### ⇒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
- 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:

1 For the treatment of a child under 12 years with an haemangioma causing functional impairment (not for cosmetic reasons

2 For the treatment of a child under 12 years with cardiac arrthymias or congenital cardiac abnormalities.

#### SOTALOL

AMI ODIPINE

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

# **Calcium Channel Blockers**

# **Dihydropyridine Calcium Channel Blockers**

7.11/12/05/11 11/12			
* Tab 2.5 mg	1.45	90	✓ Vasorex
* Tab 5 mg	1.21	90	✓ Vasorex
* Tab 10 mg		90	✓ Vasorex
FELODIPINE			
* Tab long-acting 2.5 mg	2.18	30	✓ Plendil ER
* Tab long-acting 5 mg		90	✓ Felo 5 ER
* Tab long-acting 10 mg		90	✓ Felo 10 ER
NIFEDIPINE			
* Tab long-acting 10 mg - Subsidy by endorsement	19.42	56	✓ Tensipine MR10 S29
Subsidised for patients who were taking nifedip endorsed accordingly. Pharmacists may anno dispensing of nifedipine tab long-acting 10 mg.	tate the prescription as endo		
* Tab long-acting 20 mg	17.72	100	✓ Nyefax Retard
* Tab long-acting 30 mg	4.78	14	✓ Mylan Italy (24 hr release) \$29
	34.10	100	✓ Mylan (24 hr
	04.10	100	release) \$29
* Tab long-acting 60 mg	52.81	100	✓ Mylan (24 hr release) S29

	Subsidy		Fully	
	(Manufacturer's Price \$	) Per	Subsidised	Generic Manufacturer
Other Calcium Channel Blockers	<u> </u>			
ILTIAZEM HYDROCHLORIDE				
Cap long-acting 120 mg	65.35	500	/	Diltiazem CD Clinect
Cap long-acting 180 mg		30		Cardizem CD
Cap long-acting 240 mg		30	1	Cardizem CD
ERHEXILINE MALEATE				
← Tab 100 mg	62.90	100	✓	Pexsig
ERAPAMIL HYDROCHLORIDE				
€ Tab 40 mg	7.01	100	1	Isoptin
† Tab 80 mg	11.74	100	1	Isoptin
Tab long-acting 120 mg	36.02	100	1	Isoptin Retard \$29
				Isoptin SR
Tab long-acting 240 mg		30	/	Isoptin SR
Inj 2.5 mg per ml, 2 ml ampoule – Up to 5 inj available on a		_		1
PSO	25.00	5	•	Isoptin
Centrally-Acting Agents				
LONIDINE				
RECONDING Fatch 2.5 mg, 100 mcg per day − Only on a prescription	11 70	4	1	Mylan
Patch 5 mg, 200 mcg per day — Only on a prescription		4		Mylan
Patch 7.5 mg, 300 mcg per day – Only on a prescription		4		Mylan
CLONIDINE HYDROCHLORIDE				
€ Tab 25 mcg	29.32	112	1	Clonidine Teva
€ Tab 150 mcg		100		Catapres
f Inj 150 mcg per ml, 1 ml ampoule		5	_	Catapres
1ETHYLDOPA				
F Tab 250 mg	15.10	100	✓	Methyldopa Viatris
Diuretics				
Loop Diuratios				
Loop Diuretics				
UMETANIDE	16.26	100		Burinex
€ Tab 1 mg		100 5		Burinex
	1.30	J	•	DUITIEA
UROSEMIDE [FRUSEMIDE] Tab 40 mg - Up to 30 tab available on a PSO	10.00	1 000		IDCA-Erusamida
Tab 500 mg		1,000 50		IPCA-Frusemide Urex Forte
F Oral liq 10 mg per ml		30 ml C		Lasix
Inj 10 mg per ml, 25 ml ampoule	60.65	6	✓	Lasix
Inj 10 mg per ml, 2 ml ampoule - Up to 5 inj available on a l		5	•	Furosemide-Baxter
Potassium Sparing Diuretics				
MILORIDE HYDROCHLORIDE				
Tab 5	81.07	100	1	Padagis S29
1 ab 5 mg				
Tab 5 mg	171.41	28		Wockhardt S29

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

	Subsidy (Manufacturer's Price) \$		Fully Subsidised	Brand or Generic Manufacturer	
EPLERENONE – Special Authority see SA1728 below – Retail p	harmacy				
Tab 25 mg	15.84	30	✓ <u>In</u>	<u>ispra</u>	
Tab 50 mg	25.00	30	✓ <u>In</u>	nspra	

⇒SA1728 Special Authority for Subsidy

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

Both:

- 1 Patient has heart failure with ejection fraction less than 40%; and

<ul><li>2.1 Patient is intolerant to optimal dosing of spironolactone; or</li><li>2.2 Patient has experienced a clinically significant adverse effect while o</li></ul>	n optimal dos	ing of spironolactone.
SPIRONOLACTONE       3.68         * Tab 25 mg       3.68         * Tab 100 mg       10.65         Oral liq 5 mg per ml       35.70	100 100 25 ml OP	✓ <u>Spiractin</u> ✓ <u>Spiractin</u> ✓ Biomed
Potassium Sparing Combination Diuretics		
AMILORIDE HYDROCHLORIDE WITH FUROSEMIDE  * Tab 5 mg with furosemide 40 mg8.63  AMILORIDE HYDROCHLORIDE WITH HYDROCHLOROTHIAZIDE	28	✓ Frumil
* Tab 5 mg with hydrochlorothiazide 50 mg5.00	50	✓ Moduretic
Thiazide and Related Diuretics		
BENDROFLUMETHIAZIDE [BENDROFLUAZIDE]  * Tab 2.5 mg - Up to 150 tab available on a PSO51.50	500	✓ <u>Arrow-</u> Bendrofluazide
May be supplied on a PSO for reasons other than emergency.  * Tab 5 mg61.00	500	✓ <u>Arrow-</u> <u>Bendrofluazide</u>
CHLOROTHIAZIDE Oral liq 50 mg per ml30.67 CHLORTALIDONE [CHLORTHALIDONE]	25 ml OP	✓ Biomed
* Tab 25 mg	50	✓ <u>Hygroton</u>
INDAPAMIDE  * Tab 2.5 mg16.00  METOLAZONE	90	✓ <u>Dapa-Tabs</u>

(Metolazone S29 Tab 5 mg to be delisted 1 July 2025)

50

✓ Metolazone S29

✓ Zaroxolyn S29

Subsidy	Fully		Brand or	
(Manufacturer's Price)	Subsidised		Generic	
(wandatata 5 1 100)	Per	✓	Manufacturer	

# Vasopressin receptor antagonists

TOLVAPTAN - Special Authority see SA2166 below - Ret	ail pharmacy		
Tab 15 mg	873.50	28 OP	<ul><li>Jinarc</li></ul>
Tab 30 mg	873.50	28 OP	<ul><li>Jinarc</li></ul>
Tab 45 mg + 15 mg	1,747.00	56 OP	<ul><li>Jinarc</li></ul>
Tab 60 mg + 30 mg	1,747.00	56 OP	<ul><li>Jinarc</li></ul>
Tab 90 mg + 30 mg	1,747.00	56 OP	<ul><li>Jinarc</li></ul>

### ⇒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 Either:
  - 3.1 Patient's disease is rapidly progressing, with a decline in eGFR of greater than or equal to 5 mL/min/1.73 m² 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 m² 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	✓ <u>Bezalip</u> ✓ <u>Bezalip Retard</u>
Other Lipid-Modifying Agents		
ACIPIMOX	30	✓ Olbetam
Resins		
COLESTYRAMINE Powder for oral suspension 4 g sachet61.50	50	✓ Colestyramine - Mylan \$29 ✓ Quantalan sugar free \$29

	(Manufacturer's Price)	Per	Subsidised	Generic Manufacturer
HMG CoA Reductase Inhibitors (Statins)				
ATORVASTATIN				
* Tab 10 mg	0.31	30	✓ [	Lorstat
	5.16	500	✓ [	Lorstat
* Tab 20 mg	8.12	500	✓ [	<u>Lorstat</u>
* Tab 40 mg	13.79	500	✓ [	<u>Lorstat</u>
* Tab 80 mg	25.39	500	✓	<u>Lorstat</u>
PRAVASTATIN				
* Tab 20 mg	7.16	100	1	Clinect
* Tab 40 mg		100	1	Clinect
ROSUVASTATIN - Special Authority see SA2093 below - Retai	l pharmacy			
* Tab 5 mg	1.29	30	✓	Rosuvastatin Viatris
* Tab 10 mg		30	✓ [	Rosuvastatin Viatris
* Tab 20 mg	2.71	30	✓	Rosuvastatin Viatris
* Tab 40 mg	4.55	30	✓ ]	Rosuvastatin Viatris
⇒SA2093 Special Authority for Subsidy				

Subeidy

Fully

Brand or

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	
	(Manufacturer's Pric \$	e) Per	Subsidised	Generic Manufacturer
SIMVASTATIN	<u> </u>			THE HEIGHT OF
* Tab 10 mg	1 68	90	1	Simvastatin Mylan
* Tab To Hig	1.00	30		Simvastatin Viatris
* Tab 20 mg	2.54	90	_	Simvastatin Viatris
* Tab 40 mg	4.11	90	✓	Simvastatin Viatris
* Tab 80 mg	8.81	90	✓	Simvastatin Viatris
Selective Cholesterol Absorption Inhibitors				
EZETIMIBE				
* Tab 10 mg	1.76	30	✓	Ezemibe Viatris
			✓	Ezetimibe Sandoz
(Ezemibe Viatris Tab 10 mg to be delisted 1 July 2025)				
EZETIMIBE WITH SIMVASTATIN				
Tab 10 mg with simvastatin 10 mg	5.15	30	✓	Zimybe
Tab 10 mg with simvastatin 20 mg		30		Zimybe
Tab 10 mg with simvastatin 40 mg		30		Zimybe
Tab 10 mg with simvastatin 80 mg	8.15	30	•	Zimybe
Nitrates				
GLYCERYL TRINITRATE				
* Oral pump spray, 400 mcg per dose - Up to 250 dose				
available on a PSO	7.48 29	50 dose	OP 🗸	Nitrolingual Pump Spray
* Patch 25 mg, 5 mg per day	15.73	30	✓	Nitroderm TTS
* Patch 50 mg, 10 mg per day	18.62	30	✓	Nitroderm TTS
ISOSORBIDE MONONITRATE				
* Tab 20 mg	22.49	100	✓	Ismo 20
* Tab long-acting 40 mg	9.80	30	✓	Ismo 40 Retard
* Tab long-acting 60 mg	13.50	90	✓	<u>Duride</u>
Sympathomimetics				
ADRENALINE				
Inj 1 in 1,000, 1 ml ampoule – Up to 5 inj available on a P	SO 4 98	5	1	Aspen Adrenaline
ing i in 1,000, i iiii ampoule — op to 5 ing available on a i	13.27	3		DBL Adrenaline
	25.30	10		Hameln \$29
Inj 1 in 10,000, 10 ml ampoule - Up to 5 inj available on a		5	_	Hospira
, ,,,,,,,,,,,	49.00	10		Aspen Adrenaline
Vasodilators				
HYDRALAZINE HYDROCHLORIDE				
* Tab 25 mg - Special Authority see SA1321 on the next p	ane –			
Retail pharmacy		1	1	Hydralazine
. totali priarriaoj		56		Onelink S29
		84		AMDIPHARM \$29
		100		Camber \$29
* Inj 20 mg ampoule	25.90	5		Apresoline
,		ū		r

<sup>▲</sup>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

# **⇒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	7.04	60	✓ Minoxidil Roma S29
78	3.40	100	✓ Loniten
NICORANDIL			
▲ Tab 10 mg21	1.73	60	✓ Max Health
▲ Tab 20 mg	7.44	60	✓ Max Health
PAPAVERINE HYDROCHLORIDE			
* Inj 12 mg per ml, 10 ml ampoule257	7.12	5	✓ Hospira
PENTOXIFYLLINE [OXPENTIFYLLINE]			
Tab 400 mg44	1.37	50	✓ Trental 400

# **Endothelin Receptor Antagonists**

AMBRISENTAN - Special Authority see SA2253 below - Retail	pharmacy			
Tab 5 mg	200.00	30	1	<b>Ambrisentan Viatris</b>
Tab 10 mg	200.00	30	1	<b>Ambrisentan Viatris</b>

#### ⇒SA2253 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 (Manufacturer's Price)	Fully Subsidised	Brand or
 (Manufacturer's Price) \$	Per 🗸	Generic Manufacturer

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- 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 All of the following:
  - 5.1 Ambrisentan is to be used as PAH dual therapy; and
  - 5.2 Fither:
    - 5.2.1 Patient has tried a PAH monotherapy (sildenafil or bosentan) 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 tried PAH dual therapy including bosentan and has experienced intolerable side effects on bosentan; and
  - 5.3 Both:
    - 5.3.1 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; and
    - 5.3.2 Patient has an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease).

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

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**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: 2022 ECS/ERS Guidelines for the diagnosis and 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	Generic
BOSENTAN - Special Authority see SA2254 below - Retail phar	rmacy			
Tab 62.5 mg	100.00	60	1	Bosentan Dr
				Reddy's
Tab 125 mg	100.00	60	✓	Bosentan Dr
				Reddv'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 quidelines) †: 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 (Manufacturer's Price)	Subs	Fully	Brand or Generic	
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- 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 quidelines) †: 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 part of PAH triple therapy; and

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

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- 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: 2022 ECS/ERS Guidelines for the diagnosis and 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 mg	4	✓ Vedafil
Tab 50 mg1.45	4	✓ Vedafil
Tab 100 mg11.22	12	✓ Vedafil

#### ⇒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:

- 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

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

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- 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: 2022 ECS/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension PAH

# **Prostacyclin Analogues**

		EPOPROSTENOL – Special Authority see SA2256 below – Retail pharmacy
✓ Veletri	1	Inj 500 mcg vial36.61
✓ Veletri	1	Inj 1.5 mg vial73.21

#### ⇒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

<sup>\*\*\*</sup> 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.

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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) Subsidised Generic Manufacturer

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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: 2022 ECS/ERS Guidelines for the diagnosis and 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.

ILOPROST - Special Authority see SA2257 below - Retail pharmacy

✓ Vebulis

### ⇒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 quidelines) †; 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 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

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

continued...

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 quidelines) † : 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 Iloprost is to be used as PAH dual therapy with either sildenafil or an endothelin receptor antagonist; and
  - 5.2 Either:
    - 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

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turer's Price) Subsid	dised	Generic
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continued...

- 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 quidelines) †: 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: 2022 ECS/ERS Guidelines for the diagnosis and 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) Subsidised Generic \$
Per ✓ Manufacturer

# **Antiacne Preparations**

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 92

#### **ADAPALENE**

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

b) Only on a prescription			
Gel 0.1%	22.89	30 g OP	<ul><li>Differin</li></ul>
ISOTRETINOIN - Special Authority see SA2449 below - Re	etail pharmacy		
Cap 5 mg	11.26	60	<ul><li>Oratane</li></ul>
Cap 10 mg	18.75	120	✓ Oratane
Cap 20 mg		120	✓ Oratane

### ⇒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.

#### **TRETINOIN**

Crm 0.5 mg per g − Maximum of 50 g per prescription ......16.82 50 g OP ✓ ReTrieve

# **Antibacterials Topical**

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 92

HYDROGEN PEROXIDE  * Crm 1%	8.56	10 g OP	✓ Crystaderm
MUPIROCIN		Ü	•
Oint 2%	6.60	15 g OP	
	(13.00)		Bactroban

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

# **DERMATOLOGICALS**

	Subsidy (Manufacturer's F \$	rice) Subs	Fully sidised	Brand or Generic Manufacture
SODIUM FUSIDATE [FUSIDIC ACID]				
Crm 2%	1.69	5 g OP	<b>√</b> <u>F</u>	<u>oban</u>
a) Maximum of 5 g per prescription     b) Only on a prescription     c) Not in combination Oint 2%  a) Maximum of 5 g per prescription	1.69	5 g OP	<b>√</b> <u>F</u>	<u>'oban</u>
b) Only on a prescription c) Not in combination				
SULFADIAZINE SILVER				
Crm 1%	10.80 15.44	50 g OP		lamazine Ascend \$29
<ul><li>a) Up to 250 g available on a PSO</li><li>b) Not in combination</li></ul>				
(Ascend S29 Crm 1% to be delisted 1 July 2025)				
Antifungals Topical				
For systemic antifungals, refer to INFECTIONS, Antifungals,	page 100			
AMOROLFINE				
a) Only on a prescription				
b) Not in combination Nail soln 5%	21.87	5 ml OP	✓ N	lycoNail
CLOTRIMAZOLE	21.07	3 1111 01	- <u>IV</u>	iyoonan
* Crm 1%	1.10	20 g OP	<b>√</b> 0	lomazol
a) Only on a prescription	-	- 3 -	_	
b) Not in combination				
* Soln 1%	·	20 ml OP	_	\
a) Only on a proparintian	(7.55)		C	Canesten
<ul><li>a) Only on a prescription</li><li>b) Not in combination</li></ul>				
ECONAZOLE NITRATE				
Crm 1%	8.04	20 g OP	<b>✓</b> P	evaryl
<ul><li>a) Only on a prescription</li><li>b) Not in combination</li></ul>		9		,.
c) Pevaryl to be Principal Supply on 1 June 2025		-		
Foaming soln 1%, 10 ml sachets		3	-	Povorul
	(18.64)		Р	evaryl

a) Only on a prescriptionb) Not in combination

✓ healthE Calamine

Aqueous

	Subsidy (Manufacturer's P	rice) Subs	Fully sidised	Brand or Generic Manufacturer
MICONAZOLE NITRATE				
* Crm 2%	0.90	15 g OP	✓ N	<u>lultichem</u>
a) Only on a prescription				
b) Not in combination				
* Lotn 2%	4.36	30 ml OP		
	(10.03)		D	aktarin
a) Only on a prescription				
b) Not in combination				
* Tinct 2%		30 ml OP		
	(12.10)		D	aktarin
a) Only on a prescription				
b) Not in combination				
Antipruritic Preparations				
CALAMINE				

### CROTAMITON

a) Only on a prescription

a) Only on a prescriptionb) Not in combination

b) Not in combination
Crm 10%......3.49 20 g OP

20 g OP ✓ <u>Itch-Soothe</u>

100 a

# MENTHOL - Only in combination

1) Only in combination with a dermatological base or proprietary Topical Corticosteriod – Plain

2) With or without other dermatological galenicals.

# **Corticosteroids Topical**

For systemic corticosteroids, refer to CORTICOSTEROIDS AND RELATED AGENTS, page 82

### Corticosteroids - Plain

BETAMETHASONE DIPROPIONATE			
Crm 0.05%	2.96	15 g OP	Diprosone
	36.00	50 g OP	✓ Diprosone
Oint 0.05%	2.96	15 g OP	✓ Diprosone
	36.00	50 g OP	✓ Diprosone
Oint 0.05% in propylene glycol base	4.33	30 g OP	✓ Diprosone OV
BETAMETHASONE VALERATE		-	
* Crm 0.1%	5.85	50 g OP	✓ Beta Cream
* Oint 0.1%	7.90	50 g OP	✓ Beta Ointment
* Lotn 0.1%	30.00	50 ml OP	✓ Betnovate
CLOBETASOL PROPIONATE			
* Crm 0.05%	2.40	30 g OP	✓ Dermol
* Oint 0.05%	2.33	30 g OP	✓ Dermol

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

CLOBETASONE BUTYRATE Crm 0.05%	Subsidy Manufacturer's F \$5.38 (10.00)	Price) Subs Per 30 g OP	Fully idised	Brand or Generic Manufacturer
CLOBETASONE BUTYRATE Crm 0.05%	5.38	Per		Manufacturer
Crm 0.05%  HYDROCORTISONE  * Crm 1% - Only on a prescription		30 g OP		
HYDROCORTISONE  * Crm 1% - Only on a prescription		30 g OP		
* Crm 1% – Only on a prescription	(10.00)	-		
* Crm 1% – Only on a prescription			Ει	umovate
* Crm 1% – Only on a prescription				
	1.78	30 g OP	✓ Et	thics
	20.40	500 g		oumed
* Powder – Only in combination		25 g	✓ Al	
Up to 5% in a dermatological base (not proprietary Topical	l Corticosterio			
galenicals				
HYDROCORTISONE AND PARAFFIN LIQUID AND LANOLIN				
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% – Only on		250 ml	./ DI	P Lotn HC
a prescription	12.03	230 1111	<b>▼</b> <u>DI</u>	r Loui no
HYDROCORTISONE BUTYRATE				
Lipocream 0.1%		100 g OP		ocoid Lipocream
Oint 0.1%		100 g OP		ocoid
Milky emul 0.1%	12.33	100 ml OP	✓ Lo	ocoid Crelo
METHYLPREDNISOLONE ACEPONATE				
Crm 0.1%	4.95	15 g OP	✓ <u>A</u>	<u>dvantan</u>
Oint 0.1%	4.95	15 g OP	✓ <u>A</u>	<u>dvantan</u>
MOMETASONE FUROATE				
Crm 0.1%	2.25	15 g OP	✓ EI	ocon Alcohol Free
	3.50	50 g OP	✓ EI	ocon Alcohol Free
Oint 0.1%	2.25	15 g OP	✓ EI	ocon
	3.50	50 g OP	✓ EI	ocon
Lotn 0.1%	4.99	30 ml OP	✓ EI	ocon
TRIAMCINOLONE ACETONIDE				
Crm 0.02%	6.49	100 g OP	✓ Aı	ristocort
Oint 0.02%		100 g OP	_	ristocort
Corticosteroids - Combination				
BETAMETHASONE VALERATE WITH SODIUM FUSIDATE [FUSI	IDIC ACIDI			
Crm 0.1% with sodium fusidate (fusidic acid) 2%		15 g OP		
2 2 /2 (	(10.45)	. o g o .	Fu	ucicort
a) Maximum of 15 g per prescription	(10110)			
b) Only on a prescription				
HYDROCORTISONE WITH MICONAZOLE - Only on a prescription	nn .			
* Crm 1% with miconazole nitrate 2%		15 g OP	✓ M	icreme H
		·	▼ IVI	ICI CITIC II
HYDROCORTISONE WITH NATAMYCIN AND NEOMYCIN - Only	y on a prescrip			
Oint 1% with natamycin 1% and neomycin sulphate 0.5%	3.35	15 g OP	<b>✓</b> Pi	mafucort
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCIN	AND NYSTAT	ΓIN		
Crm 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg				
and gramicidin 250 mcg per g - Only on a prescription	3.49	15 g OP		
	(9.28)	="	Vi	aderm KC

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

Barrier Creams and Emollients			
Barrier Creams			
DIMETHICONE	4.00	400 · OD	/ backlibe
F Crm 5% pump bottle	4.30	460 g OP	✓ <u>healthE</u> Dimethicone 5%
₭ Crm 10% pump bottle	4.52	460 g OP	✓ healthE  Dimethicone 10%
INC AND CASTOR OIL			
k Oint	4.25	500 g	✓ Evara
Emollients			
QUEOUS CREAM			
<b>₭</b> Crm	1.65	500 g	✓ Evara
CETOMACROGOL			
k Crm BP	2.29	500 g	✓ Cetomacrogol-AFT
CETOMACROGOL WITH GLYCEROL	0.10	400 = OD	<b>/</b> F
Crm 90% with glycerol 10%	3.50	460 g OP 920 g OP	<ul> <li>✓ Evara</li> <li>✓ Evara</li> </ul>
EMULSIFYING OINTMENT	3.30	920 g OF	▼ <u>Evala</u>
* Oint BP	3 13	500 g	✓ Emulsifying
		000 g	Ointment ADE
DIL IN WATER EMULSION			
<b>₭</b> Crm	2.10	500 g	✓ Fatty Emulsion
			Cream (Evara)
PARAFFIN			•
Oint liquid paraffin 50% with white soft paraffin 50%	4.94	500 g OP	✓ White Soft Liquid
IDEA			Paraffin AFT
JREA <b>k</b> Crm 10%	1 37	100 g OP	✓ healthE Urea Cream
VOOL FAT WITH MINERAL OIL - Only on a prescription	1.07	100 g Oi	· Ilcaltile Orca Orcalii
Lotn hydrous 3% with mineral oil	5.60	1,000 ml	
	(14.96)	.,000	DP Lotion
	(20.53)		Alpha-Keri Lotion
	1.40	250 ml OP	
	(5.87)	1 000	DP Lotion
	5.60 (23.91)	1,000 ml	BK Lotion
	1.40	250 ml OP	DIT EQUOIT
	(7.73)		BK Lotion
Other Dermatological Bases			
PARAFFIN			
White soft - Only in combination	4.74	450 g	✓ EVARA White Soft Paraffin
	19.00	2,500 g	✓ EVARA White Soft
			Paraffin

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

<sup>\*</sup>Three months or six months, as applicable, dispensed all-at-once



Minor Skin Infections			
POVIDONE IODINE			
Oint 10%	7.40	65 g OP	✓ Betadine
a) Maximum of 130 g per prescription			
b) Only on a prescription			
Antiseptic Solution 10%	4.99	100 ml	✓ Riodine
Antiseptic soln 10%	3.83	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

Subsidy

(Manufacturer's Price)

Fully

Subsidised

Per

Brand or

Generic

Manufacturer

# **Parasiticidal Preparations**

D	IM	E٦	Ή	IC	ИО	١E

IVERMECTIN – Special Authority see SA2294 below – Retail pharmacy

Tab 3 mg − Up to 100 tab available on a PSO .......17.20 4 Stromectol

- PSO for institutional use only. Must be endorsed with the name of the institution for which the PSO is required and a valid Special Authority for patient of that institution.
- 2) Ivermectin available on BSO provided the BSO includes a valid Special Authority for a patient of the institution.
- For the purposes of subsidy of ivermectin, institution means age related residential care facilities, disability care facilities or prisons.

### ⇒SA2294 Special Authority for Subsidy

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

# Either:

- 1 The person has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
- 2 Both:
  - 2.1 The person has a confirmed diagnosis of scabies or is a close contact of a scabies case; and
  - 2.2 Fither:
    - 2.2.1 The person is unable to complete topical therapy; or
    - 2.2.2 Previous treatment with topical therapy has been tried and not cleared the infestation.

**Initial application — (Other parasitic infections)** from any relevant practitioner. Approvals valid for 1 month for applications meeting 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 applications meeting the following criteria: Either:

- 1 The person has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
- 2 Both:
  - 2.1 The person has a confirmed diagnosis of scabies or is a close contact of a scabies case; and
  - 2.2 Fither:

### **DERMATOLOGICALS**

Subsidy	Fu	lly Brand or	
(Manufacturer's Price)	Subsidis	ed Generic	
\$	Per	<ul> <li>Manufacturer</li> </ul>	

continued...

- 2.2.1 The person is unable to complete topical therapy; or
- 2.2.2 Previous treatment with topical therapy has been tried and not cleared the infestation.

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

Any of the following:

- 1 filariasis: or
- 2 cutaneous larva migrans (creeping eruption); or
- 3 strongyloidiasis.

#### **PERMETHRIN**

# **Psoriasis and Eczema Preparations**

		cial Authority see SA2024 below – Retail pharmacy	ACITRETIN - Special A
✓ Novatretin	60	26.20	Cap 10 mg
✓ Novatretin	60	57.37	Cap 25 mg

### ⇒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 CAI CIPOTRIOL

DETAMETHASONE DIFFICINATE WITH CALCIFOTHIOL		
Foam spray 500 mcg with calcipotriol 50 mcg per g59.9	95 60 g OP	<ul><li>Enstilar</li></ul>
Gel 500 mcg with calcipotriol 50 mcg per g40.9	92 60 g OP	<ul> <li>Daivobet</li> </ul>
Oint 500 mcg with calcipotriol 50 mcg per g14.3	31 30 g OP	✓ Daivobet
CALCIPOTRIOL		
Oint 50 mcg per g40.0	00 120 g OP	Daivonex
COAL TAR		
Soln BP - Only in combination36.2	25 200 ml	✓ Midwest

- 1) Up to 10% only in combination with a dermatological base or proprietary Topical Corticosteriod Plain
- 2) With or without other dermatological galenicals.

	Subsidy (Manufacturaria Pr	ioo) Cub	Fully Brand or sidised Generic
	(Manufacturer's Pr	Per Sub	sidised Generic  Manufacturer
COAL TAR WITH ALLANTOIN, MENTHOL, PHENOL AND SUL	PHUR		
Soln 5% with sulphur 0.5%, menthol 0.75%, phenol 0.5% an			
allantoin crm 2.5%	6.59	75 g OP	
	(8.00)		Egopsoryl TA
	3.43	30 g OP	E 174
	(4.35)		Egopsoryl TA
COAL TAR WITH SALICYLIC ACID AND SULPHUR			
Soln 12% with salicylic acid 2% and sulphur 4% oint		25 g OP	✓ Coco-Scalp
	7.95	40 g OP	✓ Coco-Scalp
PIMECROLIMUS – Special Authority see SA1970 below – Reta	il pharmacy		
a) Maximum of 15 g per prescription		: 10	- alia
b) Note: a maximum of 15 g per prescription and no more to Cream 1%		15 g OP	eks. ✓ Elidel
	33.00	13 y OF	Elidei
■ SA1970 Special Authority for Subsidy Initial application only from a dermatologist, paediatrician, opht	halmalagist or an	rolovant pra	otitionar on the recommendation
of a dermatologist, paediatrician or ophthalmologist. Approvals			
meeting the following criteria:	valia without furthe	or renewar arm	icos notifica for applications
Both:			
1 Patient has atopic dermatitis on the eyelid; and			
2 Patient has at least one of the following contraindications			
documented epidermal atrophy, documented allergy to to	pical corticosteroi	ds, cataracts,	glaucoma, or raised intraocular
pressure.			
PINE TAR WITH TROLAMINE LAURILSULFATE AND FLUORE		a prescriptio	n
* Soln 2.3% with trolamine laurilsulfate and fluorescein sodium	n5.41	500 ml	✓ Pinetarsol
SALICYLIC ACID			
Powder – Only in combination	18.88	250 g	✓ Midwest
<ol> <li>Only in combination with a dermatological base or</li> </ol>	proprietary Topic	al Corticoster	oid – Plain or collodion flexible
<ol><li>With or without other dermatological galenicals.</li></ol>			
SULPHUR			
Precipitated - Only in combination		100 g	✓ Midwest
<ol> <li>Only in combination with a dermatological base or</li> </ol>	proprietary Topic	al Corticoster	oid – Plain
2) With or without other dermatological galenicals.			
TACROLIMUS			
Oint 0.1% - Special Authority see SA2074 below - Retail	00.00	00 00	
pharmacy	33.00	30 g OP	✓ Zematop
a) Maximum of 30 g per prescription	ara than ana	ovintion no= 4:	O waaka
b) Note: a maximum of 30 g per prescription and no m	ore man one pres	cription per 1	∠ weeks.
⇒SA2074 Special Authority for Subsidy			
Initial application only from a dermatologist, paediatrician or an	y reievant practition	oner on the re	commendation of a dermatologis

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

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

### **DERMATOLOGICALS**

✓ Locoid

100 ml OP

	Subsidy (Manufacturer's Price) \$	Sub Per	Fully sidised	Brand or Generic Manufacturer
Scalp Preparations				
BETAMETHASONE VALERATE  * Scalp app 0.1%	12.95 10	0 ml OP	✓ <u>B</u> e	eta Scalp
CLOBETASOL PROPIONATE  * Scalp app 0.05%	6.26 30	) ml OP	✓ <u>De</u>	<u>ermol</u>

 KETOCONAZOLE

 Shampoo 2%
 3.23
 100 ml OP
 ✓ Sebizole

 4.09
 ✓ Sebizole

a) Maximum of 100 ml per prescription

b) Only on a prescription

#### **Sunscreens**

SUNSCREENS. PROPRIETARY - Subsidy by endorsement

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

# **Wart Preparations**

For salicylic acid preparations refer to PSORIASIS AND ECZEMA PREPARATIONS, page 71

**PODOPHYLLOTOXIN** 

a) Maximum of 3.5 ml per prescription

b) Only on a prescription

# Other Skin Preparations

### **Antineoplastics**

FI LIOROURAC	

IMIQUIMOD

QUIMOD

Crm 5%, 250 mg sachet .......21.72 24 ✓ Perrigo

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

Subsidy		Fully	Brand or	
(Manufacturer's Price)		Subsidised	Generic	
\$	Por	_	Manufacturer	

# **Contraceptives - Non-hormonal**

## **Condoms**

COND		14.05	144	✓ Moments
	mm – Up to 144 dev available on a PSOmm		10	✓ Moments
• 55		14.25	144	✓ Moments
	a) Maximum of 60 dev per prescription	14.20	177	- momento
	b) Up to 60 dev available on a PSO			
÷ 53	mm, 0.05 mm thickness	1.15	10	✓ Moments
	, , , , , , , , , , , , , , , , , , , ,	14.25	144	✓ Moments
	a) Up to 60 dev available on a PSO			
	b) Maximum of 60 dev per prescription			
53	mm, chocolate, brown	1.15	10	✓ Moments
		14.25	144	✓ Moments
	a) Up to 60 dev available on a PSO			
	b) Maximum of 60 dev per prescription			
53	mm, strawberry, red	1.15	10	✓ Moments
		14.25	144	✓ Moments
	a) Up to 60 dev available on a PSO			
	b) Maximum of 60 dev per prescription			
56	mm		10	✓ Moments
		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		12	✓ Gold Knight
		24.10	144	Gold Knight
	a) Up to 60 dev available on a PSO			
	b) Maximum of 60 dev per prescription			
56	mm, 0.05mm thickness (bulk pack)	20.17	144	Gold Knight
	a) Maximum of 60 dev per prescription			
	b) Up to 60 dev available on a PSO			
56	mm, 0.08 mm thickness		10	✓ Moments
		14.25	144	✓ Moments
	a) Up to 60 dev available on a PSO			
	b) Maximum of 60 dev per prescription			
56	mm, 0.08 mm thickness, red		10	✓ Moments
		14.25	144	✓ Moments
	a) Up to 60 dev available on a PSO			
	b) Maximum of 60 dev per prescription	4 70	40	A Cald Madella
56	mm, chocolate		12	✓ Gold Knight
	a) Ha ta 00 day aya'labla ay a BOO	21.45	144	✓ Gold Knight
	a) Up to 60 dev available on a PSO			
EC	b) Maximum of 60 dev per prescription	1 70	10	✓ Cald Value
56	mm, strawberry	1.79 21.45	12 144	✓ Gold Knight
	a) Ha ta CO day available an a DCO	∠1.45	144	✓ Gold Knight
	a) Up to 60 dev available on a PSO			
60	b) Maximum of 60 dev per prescription mm	1 00	12	✓ Gold Knight XL
60		21.89	144	✓ Gold Knight XL ✓ Gold Knight XL
	a) Maximum of 60 day now proporting	21.09	144	- Goid Killyill AL
	a) Maximum of 60 dev per prescription			

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

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

### Contraceptive Devices

#### INTRA-UTERINE DEVICE

- a) Up to 40 dev available on a PSO
- b) Only on a PSO

*	IUD 29.1 mm length × 23.2 mm width	9.80	1 🗸	Choice 380 7med
				Nsha Silver/
				copper Short
*	IUD 33.6 mm length × 29.9 mm width2	6.80	1 🗸	TCu 380 Plus
	•			Normal
*	IUD 35.5 mm length × 19.6 mm width	3.00	1 🗸	Cu 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 to 84 tab available on a PSO......10.00 84 ✓ Mercilon 28

	Subsidy		Fully	Brand or
	(Manufacturer's Price)		Subsidised	Generic
	\$	Per	•	Manufacturer
ETHINYLOESTRADIOL WITH LEVONORGESTREL				
* Tab 20 mcg with levonorgestrel 100 mcg and 7 inert tablets	_			
Up to 84 tab available on a PSO	1.50	84	<b>✓</b> L	o-Oralcon 20 ED
* Tab 30 mcg with levonorgestrel 150 mcg	6.62	63		
	(16.50)		N	licrogynon 30
a) Higher subsidy of \$15.00 per 63 tab with Special Auti b) Up to 63 tab available on a PSO  * Tab 30 mcg with levonorgestrel 150 mcg and 7 inert tablets Up to 84 tab available on a PSO	-	the page 1		ge Oralcon 30 ED
'	1.30	04	V <u>U</u>	Maicon 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		Myacen Brevinor 1/28
Tab 35 mcg with norethisterone 500 mcg and 7 inert tab - U	lp			
to 84 tab available on a PSO	21.99	84	✓ N	lorimin

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

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

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

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

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

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

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

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

#### 

	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	✓	Norethinderone - CDC Noriday Noriday 28

### **Emergency Contraceptives**

LEVONORGESTREL

- - a) Maximum of 2 tab per prescription
  - b) Up to 5 tab available on a PSO
  - c) Note: Direct Provision by a pharmacist permitted under the provisions in Part I of Section A.

## **Antiandrogen Oral Contraceptives**

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

- 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

# **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 applicator8.43	100 g OP	
(24.87)	100 g O1	Aci-Jel
CLOTRIMAZOLE		
* Vaginal crm 1% with applicators	35 g OP	✓ Clomazol
* Vaginal crm 2% with applicators	20 g OP	✓ Clomazol
MICONAZOLE NITRATE		
* Vaginal crm 2% with applicator	40 g OP	✓ Micreme
NYSTATIN		
Vaginal crm 100,000 u per 5 g with applicator(s)5.70	75 g OP	✓ Nilstat

# **Myometrial and Vaginal Hormone Preparations**

	Inj 500 mcg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	160.00	5	✓ DBL Ergometrine
OE	STRIOL			
*	Crm 1 mg per g with applicator	6.95	15 g OP	✓ Ovestin
*	Pessaries 500 mcg	7.55	15	✓ Ovestin

FRGOMETRINE MAI FATE

✓ <u>David One Step</u>

<u>Cassette</u>

Pregnancy Test

40 test OP

	Subsidy (Manufacturer's Price)	Sub: Per	Fully sidised	Brand or Generic Manufacturer
OXYTOCIN – Up to 5 inj available on a PSO				
Inj 5 iu per ml, 1 ml ampoule	4.98	5	<b>✓</b> 0	xytocin BNM
Inj 10 iu per ml, 1 ml ampoule		5	✓ 0	xytocin BNM
	11.96	10		Dxytocin Panpharma
(Oxytocin Panpharma Inj 10 iu per ml, 1 ml ampoule to be deliste	ed 1 July 2025)			•
OXYTOCIN WITH ERGOMETRINE MALEATE – Up to 5 inj avai Inj 5 iu with ergometrine maleate 500 mcg per ml, 1 ml ampo		5	<b>√</b> <u>s</u>	yntometrine
Pregnancy Tests - hCG Urine				
BETA-HCG LOW SENSITIVITY URINE TEST KIT – Up to 15 tes Note: For use in abortion services only.	st available on a PSO	)		
Midstream	16.28 1	test OP	<b>√</b> C	heckTop

# **Urinary Agents**

b) Only on a PSO

For urinary tract Infections refer to INFECTIONS, Antibacterials, page 111

## 5-Alpha Reductase Inhibitors

PREGNANCY TESTS - HCG URINE

a) Up to 200 test available on a PSO

FINASTERIDE – Special Authority see SA0928 below – Retail pharmacy

\* Tab 5 mg .......4.79 100

#### ⇒SA0928 Special Authority for Subsidy

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

#### Roth:

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

## Alpha-1A Adrenoreceptor Blockers

TAMSULOSIN HYDROCHLORIDE - Special Authority see SA1032 below - Retail pharmacy

### ⇒SA1032 Special Authority for Subsidy

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

#### Both:

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

	Subsidy (Manufacturer's Pr \$	ice) S Per	Fully Subsidised	Brand or Generic Manufacturer
Other Urinary Agents				
XYBUTYNIN Tab 5 mg	5.42	100	<b>√</b> µ	Alchemy Oxybutynin
DTASSIUM CITRATE				
Oral liq 3 mmol per ml — Special Authority see SA1083 be Retail pharmacy		200 ml O	P 🗸 E	Biomed
•SA1083 Special Authority for Subsidy itial application from any relevant practitioner. Approvals vale th:  1 The patient has recurrent calcium oxalate urolithiasis; a 2 The patient has had more than two renal calculi in the two	nd			ng the following criteria:
enewal from any relevant practitioner. Approvals valid for 2 yenefitting from the treatment.				opriate and the patient is
DDIUM CITRO-TARTRATE	0.50	00		11
Grans eff 4 g sachets	3.50	28	<b>√</b> [	<u>Jrai</u>
DLIFENACIN SUCCINATE  Tab 5 mg	1.95	30	<b>√</b> 9	Solifenacin succinate Max Health
Solifenacin succinate Max Health to be Principal Supp Tab 10 mg		30		Solifenacin Viatris Solifenacin succinate Max
Solifenacin succinate Max Health to be Principal Supp colifenacin Viatris Tab 5 mg to be delisted 1 November 2025) colifenacin Viatris Tab 10 mg to be delisted 1 June 2025)	3.72 ly on 1 June 2025		<b>√</b> §	Health Solifenacin Viatris
Detection of Substances in Urine				
RTHO-TOLIDINE				
Compound diagnostic sticks	7.50 (8.25)	50 test O		lemastix
ETRABROMOPHENOL	. ,			
Blue diagnostic strips	13.92	100 test C	)P <b>/</b> A	Albustix
Obstetric Preparations				

Tab 200 mg - Up to 15 tab available on a PSO......83.90

180.00

✓ Mifegyne✓ Mifegyne

MIFEPRISTONE

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

# **Calcium Homeostasis**

CALCITONIN  * Inj 100 iu per ml, 1 ml ampoule121.00	5	✓ Miacalcic
CINACALCET - Special Authority see SA2170 below - Retail pharmacy		
Tab 30 mg - Wastage claimable25.24	28	✓ Cinacalet Devatis
Tab 60 mg - Wastage claimable50.47	28	✓ Cinacalet Devatis

⇒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:

Fither:

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

**Renewal — (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:
  - 3.1 Residual parathyroid tissue has not been localised despite repeat unsuccessful parathyroid explorations; or

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

continued...

- 3.2 Parathyroid tissue is surgically inaccessible; or
- 3.3 Parathyroid surgery is not feasible.

Renewal — (secondary or tertiary hyperparathyroidism) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

#### Fither:

- 1 The patient has had a kidney transplant, and following a treatment free interval of at least 12 weeks a clinically acceptable parathyroid hormone (PTH) level to support ongoing cessation of treatment has not been reached; or
- 2 The patient has not received a kidney transplant and trial of withdrawal of cinacalcet is clinically inappropriate.

#### **ZOLEDRONIC ACID**

# Corticosteroids and Related Agents for Systemic Use

BETAMETHASONE SODIUM PHOSPHATE WITH BETAMETHASONE ACETATE

* Inj 3.9 mg with betamethasone acetate 3 mg per ml, 1 ml	5	Celestone Chronodose
DEXAMETHASONE		
* Tab 0.5 mg - Up to 60 tab available on a PSO	30	✓ Dexmethsone
* Tab 4 mg - Up to 30 tab available on a PSO	30	✓ Dexmethsone
Oral liq 1 mg per ml53.86	25 ml OP	✓ Biomed
DEXAMETHASONE PHOSPHATE		
Dexamethasone phosphate injection will not be funded for oral use.		
* Inj 4 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO7.86	10	✓ <u>Hameln</u>
* Inj 4 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO13.10	10	✓ <u>Hameln</u>
FLUDROCORTISONE ACETATE		
* Tab 100 mcg11.46	100	✓ Florinef
HYDROCORTISONE		
* Tab 5 mg	100	✓ Douglas
* Tab 20 mg	100	✓ Douglas
* Inj 100 mg vial	1	✓ Solu-Cortef
a) Not on a BSO		
b) Up to 5 inj available on a PSO		
METHYLPREDNISOLONE		
* Tab 4 mg112.00	100	✓ Medrol
* Tab 100 mg223.10	20	✓ Medrol
METHYLPREDNISOLONE (AS SODIUM SUCCINATE)		
Inj 40 mg vial	1	✓ Solu-Medrol-Act-
, 13g 1	·	O-Vial
Inj 125 mg vial34.10	1	✓ Solu-Medrol-Act-
		O-Vial
lni 500 ma vial	1	✓ Solu-Medrol-Act-
Inj 500 mg vial43.01	I	O-Vial
		O-viai
Inj 1 g vial52.54	1	✓ Solu-Medrol

	Subsidy (Manufacturer's Price \$		ully Brand or sed Generic Manufacturer
METHYLPREDNISOLONE ACETATE			
Inj 40 mg per ml, 1 ml vial	47.06	5	✓ Depo-Medrol
PREDNISOLONE			•
* Oral liq 5 mg per ml – Up to 30 ml available on a PSO  Restricted to children under 12 years of age.	6.00	30 ml OP	✓ <u>Redipred</u>
PREDNISONE			
* Tab 1 mg	18.58	500	✓ Prednisone Clinect
* Tab 2.5 mg	21.04	500	✓ Prednisone Clinect
* Tab 5 mg - Up to 30 tab available on a PSO	19.30	500	✓ Prednisone Clinect
* Tab 20 mg - Up to 30 tab available on a PSO	50.51	500	✓ Prednisone Clinect
TETRACOSACTRIN			
* Inj 250 mcg per ml, 1 ml ampoule	86.25	1	✓ Synacthen
, , , ,			✓ UK Synacthen
* Inj 1 mg per ml, 1 ml ampoule	690.00	1	✓ Synacthen Depot
, , , ,			✓ Synacthene
			Retard \$29
TRIAMCINOLONE ACETONIDE			
Inj 10 mg per ml, 1 ml ampoule	21.42	5	✓ Kenacort-A 10
Inj 40 mg per ml, 1 ml ampoule	52.63	5	✓ Kenacort-A 40
Inj 40 mg per mi, 1 mi ampoule	52.00	3	Neliacolt-A 40
Sex Hormones Non Contraceptive			
Androgen Agonists and Antagonists			
CYPROTERONE ACETATE			
Tab 50 mg	17.05	50	✓ Siterone
Siterone to be Principal Supply on 1 July 2025			
Tab 100 mg	31.00	50	✓ Siterone
Siterone to be Principal Supply on 1 July 2025			
TESTOSTERONE			
Gel (transdermal) 16.2 mg per g, 88 g	52 00	60 OP	✓ Testogel
		00 01	1 Icologui
TESTOSTERONE CIPIONATE	05.00	1	/ Dama Tantantarana
Inj 100 mg per ml, 10 ml vial	03.00	ı	✓ Depo-Testosterone
TESTOSTERONE ESTERS			
Inj 250 mg per ml, 1 ml	12.98	1	✓ Sustanon Ampoules
TESTOSTERONE UNDECANOATE			
Cap 40 mg - Subsidy by endorsement	36.00	100	✓ 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 testos	ordingly. Pharmacis	ts may annota	te the prescription as endorse
lai 050 and a small Amelaid	00.00	,	( D

Inj 250 mg per ml, 4 ml vial......86.00

✓ Reandron 1000

<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

# **Hormone Replacement Therapy - Systemic**

# **Oestrogens**

OE	STRADIOL			
*	Tab 1 mg	4.12	28 OP	
		(11.10)		Estrofem
*	Tab 2 mg	4.12	28 OP	
	· ·	(11.10)		Estrofem
*	Gel (transdermal) 0.06% (750 mcg/actuation)	14.25 <sup>′</sup>	80 g OP	✓ Estrogel
	Patch 25 mcg per day		8	✓ Estradiol TDP Mylan
	5 13   7 1 1 1	13.50		✓ Estraderm MX S29
		14.50		✓ Estradot
		21.35		✓ Lyllana
	a). No mare than 0 noteb nor week	21.00		Lylialia
	a) No more than 2 patch per week			
	b) Only on a prescription	40.75		/ Faturalial TDD Malan
	Patch 50 mcg per day	10./5	8	✓ Estradiol TDP Mylan
				<ul><li>Estradiol Viatris</li></ul>
		14.50		✓ Estraderm MX S29
				<ul><li>Estradiol Sandoz</li></ul>
				✓ Estradot
		21.55		✓ Lyllana
	a) No more than 2 patch per week			
	b) Only on a prescription			
	Patch 75 mcg per day	11.88	8	<ul><li>Estradiol TDP Mylan</li></ul>
	5 13   7 1 1 1			✓ Estradiol Viatris
		14.50		✓ Estradiol Sandoz
				✓ Estradot
		22.37		✓ Lyllana
	a) No more than 2 patch per week			_,
	b) Only on a prescription			
	Patch 100 mcg per day	12.05	8	✓ Estradiol TDP Mylan
	ratori 100 mcg per day	12.90	O	✓ Estradiol Viatris
		14.50		✓ Estradiol Sandoz
		14.50		✓ Estradot
		15.50		✓ Estraderm MX S29
		22.77		<ul><li>Lyllana</li></ul>
	<ul> <li>a) No more than 2 patch per week</li> </ul>			
	b) Only on a prescription			
OE	STRADIOL VALERATE			
	Tab 1 mg	12.36	84	✓ Progynova
	Tab 2 mg		84	✓ Progynova
	STROGENS		•	
		0.04	00	
*	Conjugated, equine tab 300 mcg		28	Duamania
	Operitorial and a series tale 005 and	(19.25)	00	Premarin
*	Conjugated, equine tab 625 mcg		28	D
		(19.25)		Premarin

	0.1.11		
	Subsidy (Manufacturer's Price)	Subsi	Fully Brand or idised Generic
	\$	Per	✓ Manufacturer
Progestogens			
MEDROXYPROGESTERONE ACETATE			
* Tab 2.5 mg	6.56	30	✓ Provera
	8.75	56	✓ Provera
★ Tab 5 mg		56 100	✓ Provera
€ Tab 10 mg	20.13 10.28	100 30	<ul><li>✓ Provera</li><li>✓ Provera</li></ul>
· Tub To Tily	10.20		Tioveia
Progestogen and Oestrogen Combined Prepara	ations		
ESTRADIOL WITH NORETHISTERONE			
Fab 1 mg with 0.5 mg norethisterone acetate		28 OP	
Tab O man with 4 man manathint are a salate	(18.10)	00.00	Kliovance
Tab 2 mg with 1 mg norethisterone acetate		28 OP	Klingeet
. Tab 2 ma with 1 ma parathistorona accepts (10) and 2 ma	(18.10)		Kliogest
<ul> <li>Tab 2 mg with 1 mg norethisterone acetate (10), and 2 mg oestradiol tab (12) and 1 mg oestradiol tab (6)</li> </ul>	5.40	28 OP	
occuration tab (12) and 1 mg occuration tab (0)	(18.10)	20 01	Trisequens
	· · · · · · /		4
Other Oestrogen Preparations			
ESTRIOL			
- Tab 2 mg	7.70	30	✓ Ovestin
Other Progestogen Preparations			
EVONORGESTREL  Intra-uterine device 52 mg	260.50	1	✓ Mirena
Intra-uterine device 32 mg		1	✓ Jaydess
EDROXYPROGESTERONE ACETATE	210.00	•	- vayacoo
Tab 100 mg	133.57	100	✓ Provera HD
ORETHISTERONE		100	
ORETHISTERONE  Tab 5 mg = Up to 30 tab available on a PSO	5 40	30	✓ Primolut N
ROGESTERONE		00	- I IIIIVIULIN
Cap 100 mg	14.85	30	✓ Utrogestan
	17.00	00	- onogodan
Thyroid and Antithyroid Agents			
ARBIMAZOLE			
НВМАZOLE : Tab 5 mg	7 56	100	✓ Neo-Mercazole
-		100	- NGO-WIGI GAZOIG
EVOTHYROXINE  • Tab 25 mcg	5 55	90	✓ Synthroid
Tab 50 mcg		28	✓ Mercury Pharma
140 00 Hog	5.79	90	✓ Synthroid
	64.28	1,000	✓ Eltroxin
Tablet 50 mcg		200	✓ Eltroxin
Tab 100 mcg	1.78	28	Mercury Pharma
	6.01	90	✓ Synthroid
T 11 1 100	66.78	1,000	✓ Eltroxin
Fablet 100 mcg	13.36	200	✓ Eltroxin

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

	Subsidy (Manufacturer's Price)		Fully Subsidised	Brand or Generic		
	\$	Per	1	Manufacturer		
PROPYLTHIOURACIL - Special Authority see SA1199 below - Retail pharmacy						
Tab 50 mg	35.00	100	<b>√</b> P	TU \$29		
⇒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 be	elow – Retail pha	armacy	
*	Inj 5 mg cartridge	80.21	ĺ	<ul> <li>Omnitrope</li> </ul>
*	Inj 10 mg cartridge	80.21	1	✓ Omnitrope
*	Inj 15 mg cartridge	139.50	1	✓ Omnitrope

#### ⇒SA2032 Special Authority for Subsidy

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

Fither:

- 1 Growth hormone deficiency causing symptomatic hypoglycaemia, or with other significant growth hormone deficient sequelae (e.g. cardiomyopathy, hepatic dysfunction) and diagnosed with GH < 5 mcg/l on at least two random blood samples in the first 2 weeks of life, or from samples during established hypoglycaemia (whole blood glucose < 2 mmol/l using a laboratory device); or</p>
- 2 All of the following:
  - 2.1 Height velocity < 25th percentile for age adjusted for bone age/pubertal status if appropriate over 6 or 12 months using the standards of Tanner and Davies (1985); and</p>
  - 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:

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:

Subsidy	Fu	,	
(Manufacturer's Price)	Subsidise	ed Generic	
\$	Per	<ul> <li>Manufacturer</li> </ul>	

continued...

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:

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

	Subsidy	Fully	Brand or
(Manu	facturer's Price)	Subsidised	Generic
	\$ Pe	er 🗸	Manufacturer

continued...

6.2 The patient has received a renal transplant and has received < 5mg/ m²/day of prednisone or equivalent for at least 6 months..

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

All of the following:

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

**Initial application — (Prader-Willi syndrome)** only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months for applications meeting the following criteria: All of the following:

- 1 The patient has a diagnosis of Prader-Willi syndrome that has been confirmed by genetic testing or clinical scoring criteria; and
- 2 The patient is aged six months or older; and
- 3 A current bone age is < 14 years (female patients) or < 16 years (male patients); and
- 4 Sleep studies or overnight 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:

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

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

continued...

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

#### 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.

Subsidy	F	ully	Brand or
(Manufacturer's F	Price) Subsid	ised	Generic
<u> </u>	Per		Manufacturer

continued...

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**

G(	วร	ER	ELI	N
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Implant 3.6 mg, syringe	66.48	1	✓ Zoladex
Implant 10.8 mg, syringe	138.23	1	✓ Zoladex

#### I FUPRORFI IN

Additional subsidy by endorsement where the patient is a child or adolescent and is unable to tolerate administration of goserelin and the prescription is endorsed accordingly.

Inj 3.75 mg prefilled dual chamber syringe - Higher subsidy of
\$201.60 per 1 injurith Endersament

(221.60) Lucrin Depot 1-month

Inj 11.25 mg prefilled dual chamber syringe – Higher subsidy of \$591.68 per 1 inj with Endorsement......177.50

(591.68)

Lucrin Depot 3-month

# **Vasopressin Agonists**

DESMOPRESSIN	47.00	00	<b>/ 10:</b> 11 11 11
Wafer 120 mcg	47.00	30	Minirin Melt
DESMOPRESSIN ACETATE			
Tab 100 mcg	25.00	30	✓ Minirin
Tab 200 mcg	54.45	30	✓ Minirin
Inj 4 mcg per ml, 1 ml	67.18	10	✓ Minirin
▲ Nasal spray 10 mcg per dose, 6 ml		60 OP	✓ Desmopressin-
			PH&T

# **Other Endocrine Agents**

#### **CABERGOLINE**

		Tab 0.5 mg - Maximum of 2 tab per prescription; can be
<ul><li>Dostinex</li></ul>	2	waived by Special Authority see SA2070 below4.43
✓ Dostiney	8	17 94

#### ⇒SA2070 Special Authority for Waiver of Rule

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

Any of the following:

1 Hyperprolactinemia; or

ubsidy	Fully	Brand or
cturer's Price) S	Subsidised	Generic
 \$ Per	•	

continued...

- 2 Acromegaly\*; or
- 3 Inhibition of lactation.

Renewal — (for patients who have previously been funded under Special Authority form SA1031) from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has previously held a valid Special Authority which has expired and the treatment remains appropriate and the patient is benefiting from treatment.

Note: Indication marked with \* is an unapproved indication.

CLOMIFENE (	CITRATE
-------------	---------

Tab 50 mg	29.84	10	✓ Mylan Clomiphen \$29
METYRAPONE  Cap 250 mg	558.00	50	✓ Metopirone

	Subsidy		Fully Brand or
	(Manufacturer's Price	) Su	ibsidised Generic
	\$	Per	✓ Manufacturer
	<u> </u>		
Anthelmintics			
ALBENDAZOLE - Special Authority see SA1318 below - Retail	nharmacy		
		00	/ Falson Is @
Tab 400 mg	469.20	60	✓ Eskazole S29
⇒SA1318 Special Authority for Subsidy			
Initial application only from an infectious disease specialist or cl	inical microbiologist	. Approva	als valid for 6 months where the
patient has hydatids.	•	• • •	
Renewal only from an infectious disease specialist or clinical mic	robiologist Approv	als valid fo	or 6 months where the treatment
remains appropriate and the patient is benefitting from the treatm			
	Ont.		
MEBENDAZOLE – Only on a prescription		_	
Tab 100 mg		6	✓ <u>Vermox</u>
Oral liq 100 mg per 5 ml	2.18	15 ml	
	(7.83)		Vermox
PRAZIQUANTEL			
Tab 600 mg	68.00	8	✓ Biltricide
Tab 000 mg	00.00	O	• Difficial
Autibactoriala			
Antibacterials			
- \ Factorial antibartainle artest DEDMATOLOGICALO	.05		
a) For topical antibacterials, refer to DERMATOLOGICALS, page			
b) For anti-infective eye preparations, refer to SENSORY ORGA	NS, page 269		
Cephalosporins and Cephamycins			
Cephalosporius and Cephalitychis			
CEFACLOR MONOHYDRATE			
Cap 250 mg	05.05	100	✓ Ranbaxy-Cefaclor
'			
Grans for oral liq 125 mg per 5 ml - Wastage claimable	3./5	100 ml	✓ Ranbaxy-Cefaclor
CEFALEXIN			
Cap 250 mg	3.85	20	✓ Cephalexin ABM
Cap 500 mg		20	✓ Cephalexin ABM
Grans for oral lig 25 mg per ml – Wastage claimable		100 ml	✓ Flynn
Grans for oral liq 50 mg per ml — Wastage claimable		100 ml	✓ Flynn
Grans for oral liq 50 mg per mil Vvastage dalmable	11.75	100 1111	✓ Cefalexin Sandoz
	11.75		• CelalexIII Salluoz
CEFAZOLIN – Subsidy by endorsement			
Only if prescribed for dialysis or cellulitis in accordance with a	a Health NZ Hospita	l approve	d protocol and the prescription is
endorsed accordingly.			
Inj 500 mg vial	3.39	5	✓ Cefazolin-AFT
lnį 1 g vial	3.59	5	✓ Cefazolin-AFT
lnj 2 g vial		5	✓ Cefazolin-AFT
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 fibrosit</li> </ul>			
pelvic inflammatory disease, or the treatment of suspecte	d meningococcal dis	sease, an	d the prescription or PSO is
endorsed accordingly.			
Inj 500 mg vial	0.79	1	✓ Ceftriaxone-AFT
Inj 1 g vial		5	✓ Ceftriaxone-AFT
, •		-	<del></del>

CEFUROXIME AXETIL - Subsidy by endorsement

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

Cefuroxime \$29

✓ Ascend-

Subsi	idy Full	y Brand or
(Manufacture	er's Price) Subsidise	d Generic
\$	Per 🗸	Manufacturer

#### **Macrolides**

AZITHROMYCIN – Maximum of 5 days treatment per prescription; can be waived by Special Authority see SA1683 below A maximum of 24 months of azithromycin treatment for non-cystic fibrosis bronchiectasis will be subsidised on Special Authority.

Authority.		
Tab 250 mg8.19	30	Apo-Azithromycin
Tab 500 mg - Up to 8 tab available on a PSO2.57	2	✓ Zithromax
Grans for oral liq 200 mg per 5 ml (40 mg per ml) - Wastage		
claimable16.97	15 ml	✓ Zithromax

### ⇒SA1683 Special Authority for Waiver of Rule

Initial application — (bronchiolitis obliterans syndrome, cystic fibrosis and atypical Mycobacterium infections) only from a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria: Any of the following:

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

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

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

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

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

	0 1			, ,		,
Tab 250 mg				7.31	12	✓ Klaricid S29
-				8.53	14	✓ Klacid
Grans for oral lig 250 mg per 5 ml -	- Wast	age cl	aimable	192.00	50 ml	✓ Klacid

⇒SA1857 Special Authority for Waiver of Rule

**Initial application — (Mycobacterial infections)** only from a respiratory specialist, infectious disease specialist or paediatrician. Approvals valid for 2 years for applications meeting the following criteria:

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

continued...

Fither:

- 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.

Inj 1 g vial	10.00	1	✓ Erythrocin IV
ERYTHROMYCIN ETHYL SUCCINATE			
Tab 400 mg	35.82	100	<ul><li>E-Mycin</li></ul>
a) Up to 20 tab available on a PSO     b) Up to 2 x the maximum PSO quantity for RFPP Grans for oral lig 200 mg per 5 ml	6.53	100 ml	✓ E-Mycin
a) Up to 300 ml available on a PSO     b) Up to 2 x the maximum PSO quantity for RFPP     c) Wastage claimable			·
Grans for oral liq 400 mg per 5 ml	9.41	100 ml	✓ E-Mycin
ROXITHROMYCIN			
Tab 150 mg	13.19	50	✓ Arrow-

-	150 mg	13.19	50	✓ <u>Arrow-</u> <u>Roxithromycin</u>
Tab	300 mg	25.00	50	✓ <u>Arrow-</u> Roxithromycin

	Subsidy (Manufacturer's Price) \$	) ;	Fully Subsidised	
Penicillins				
AMOXICILLIN				
Cap 250 mg	27.50	500	1	Miro-Amoxicillin
a) Up to 30 cap available on a PSO				
b) Up to 10 x the maximum PSO quantity for RFPP	44.00			
Cap 500 mg	41.00	500	•	Miro-Amoxicillin
a) Up to 30 cap available on a PSO				
b) Up to 10 x the maximum PSO quantity for RFPP Grans for oral lig 125 mg per 5 ml	2 22	100 ml		Alphamox 125
a) Up to 200 ml available on a PSO	2.22	100 1111		Alphaniox 125
b) Wastage claimable				
Grans for oral lig 250 mg per 5 ml	2.81	100 ml	· •	Alphamox 250
a) Up to 300 ml available on a PSO				
b) Up to 10 x the maximum PSO quantity for RFPP				
c) Wastage claimable				
Inj 250 mg vial	15.97	10	1	Ibiamox
Inj 500 mg vial		10		Ibiamox
Inj 1 g vial – Up to 5 inj available on a PSO	21.64	10	•	Ibiamox
AMOXICILLIN WITH CLAVULANIC ACID				
Tab 500 mg with clavulanic acid 125 mg - Up to 30 tab				
available on a PSO		10	1	Curam Duo 500/125
Grans for oral liq amoxicillin 25 mg with clavulanic acid 6.25 r				
per ml	8.50	100 ml	· •	Augmentin
a) Up to 200 ml available on a PSO				
b) Wastage claimable				
Grans for oral liq amoxicillin 50 mg with clavulanic acid 12.5 r				•
per ml - Up to 200 ml available on a PSO		00 ml C		Curam
	5.61		•	Amoxiclav Devatis Forte
Amoxiclav Devatis Forte to be Principal Supply on 1 June	2025			roite
(Curam Grans for oral lig amoxicillin 50 mg with clavulanic acid 12		deliste	d 1 .lune :	2025)
BENZATHINE BENZYLPENICILLIN				,
Inj 900 mg (1.2 million units) in 2.3 ml syringe — Up to 5 inj				
available on a PSO	432 37	10	1	Bicillin LA
		10	•	PIVIIIII EA
BENZYLPENICILLIN SODIUM [PENICILLIN G] Inj 600 mg (1 million units) vial – Up to 5 inj available on a PS	SO 16.50	10	1	Sandoz
ing ood ing (1 inililon drills) vial – op to 3 ing available on a Fo	10.00	10	•	<u>Juliu02</u>

	Subsidy (Manufacturaria B	rioo\	Fully	
	(Manufacturer's P \$	Per	Subsidised •	Manufacturer
UCLOXACILLIN	· ·			
Cap 250 mg - Up to 30 cap available on a PSO	15 70	250	1	Flucloxacillin-AFT
Oap 230 mg - Op to 30 cap available on a 1 30	22.58	230		Staphlex
Staphlex to be Principal Supply on 1 August 2025	22.30		•	Stapillex
Cap 500 mg - Up to 30 cap available on a PSO	52 99	500	/	Flucloxacillin-AFT
oup ood mg op to oo dap available on a room	72.71	000		Staphlex
Staphlex to be Principal Supply on 1 August 2025	72.71		_	Otapinox
Grans for oral liq 25 mg per ml	4.89	100 m	·	AFT
a) Up to 200 ml available on a PSO				
b) Wastage claimable				
Grans for oral lig 50 mg per ml	5.89	100 m	·	AFT
a) Up to 200 ml available on a PSO				
b) Wastage claimable				
Inj 250 mg vial	42.60	10	1	Flucloxin
Inj 500 mg vial		10		Flucloxin
Inj 1 g vial – Up to 5 inj available on a PSO		5		Flucil
lucloxacillin-AFT Cap 250 mg to be delisted 1 August 2025)				
lucloxacillin-AFT Cap 500 mg to be delisted 1 August 2025)				
HENOXYMETHYLPENICILLIN (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	10.72	30	•	Omeanic VIX
b) Up to 2 x the maximum PSO quantity for RFPP				
Grans for oral lig 125 mg per 5 ml	3.40	100 m	_	AFT
a) Up to 200 ml available on a PSO		100 111	•	ALL
b) Wastage claimable				
Grans for oral liq 250 mg per 5 ml	4 24	100 m	· •	AFT
a) Up to 300 ml available on a PSO		100111		<u></u>
b) Up to 2 x the maximum PSO quantity for RFPP				
c) Wastage claimable				
o) Wastago stamasto				
etracyclines				
XYCYCLINE				
Tab 100 mg - Up to 30 tab available on a PSO	64.43	500	1	Doxine
NOCYCLINE HYDROCHLORIDE				
Tab 50 mg - Additional subsidy by Special Authority see				
SA1355 below – Retail pharmacy	5.79	60		
F,	(12.05)			Mino-tabs
Cap 100 mg	` ,	100		
3	(52.04)			Minomycin
SA1355 Special Authority for Manufacturers Price	. ,			•
itial application from any relevant practitioner. Approvals val	lid without further	renewal ur	nless notif	ied where the patient h
sacea.		<b></b> ui		alo padoliti
TRACYCLINE - Special Authority see SA1332 on the next p	age – Retail phar	macv		
Tab 250 mg	-	28	1	Accord S29
1 40 =00 mg		20	•	,

II	NFECTIONS - AC	GENTS	S FOR	SYSTEMIC USE
	Subsidy (Manufacturer's Price) \$	Su Per	Fully obsidised	Brand or Generic Manufacturer
■ SA1332 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid Both:	I for 3 months for app	olication	s meetin	g the following criteria:
For the eradication of helicobacter pylori following unsucce     For use only in combination with bismuth as part of a quad-			iate first	-line therapy; and
Other Antibiotics				
For topical antibiotics, refer to DERMATOLOGICALS, page 65 CIPROFLOXACIN Recommended for patients with any of the following: i) microbiologically confirmed and clinically significant pse ii) prostatitis; or iii) pyelonephritis; or iv) gonorrhoea.	udomonas infection;	or		
Tab 250 mg - Up to 5 tab available on a PSO Tab 500 mg - Up to 5 tab available on a PSO Tab 750 mg	3.10	28 28 28	✓	Ipca-Ciprofloxacin Ipca-Ciprofloxacin Ipca-Ciprofloxacin
CLINDAMYCIN Cap hydrochloride 150 mg Inj 150 mg per ml, 4 ml ampoule		24 10		<u>Dalacin C</u> Hameln
COLISTIN SULPHOMETHATE – Retail pharmacy-Specialist – S Only if prescribed for dialysis or cystic fibrosis patient and the Inj 150 mg	prescription is endor	rsed acc	1	Colistin-Link
Inj 2 million iu, 10 ml vial(Colistin-Link Inj 150 mg to be delisted 1 June 2025)  GENTAMICIN SULPHATE	216.67	10	•	Colomycin S29
Inj 40 mg per ml, 2 ml vial – Subsidy by endorsement	36.70	5	•	Cidomycin P/Free S29
Only if prescribed for a dialysis or cystic fibrosis patient or endorsed accordingly.	r complicated urinary	tract in	fection a	and the prescription is
Inj 10 mg per ml, 1 ml ampoule – Subsidy by endorsement Only if prescribed for a dialysis or cystic fibrosis patient of		5 tract in		DBL Gentamicin and the prescription is

190.00 ✓ Gentamicin Hikma S29 Only if prescribed for a dialysis or cystic fibrosis patient or complicated urinary tract infection and the prescription is

endorsed accordingly.

10 ✓ Gentamicin Amdipharm \$29

✓ Pfizer

✓ Gentamicin 91.90 50

10

Noridem \$29

✓ Wockhardt S29

Only if prescribed for a dialysis or cystic fibrosis patient or complicated urinary tract infection and the prescription is endorsed accordingly.

MOXIFLOXACIN - Special Authority see SA1740 on the next page - Retail pharmacy No patient co-payment payable

Inj 10 mg per ml, 2 ml ampoule - Subsidy by endorsement..........91.00

endorsed accordingly.

✓ Avelox 5

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

#### ⇒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:

#### Fither:

- 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 Authority see SA1328 on the next page - Retail pharmacy

	INFECTIONS -	AGENTS	FOR S	SYSTEMIC USE
	Subsidy (Manufacturer's Pr \$	rice) Sub Per	Fully sidised	Brand or Generic Manufacturer
■ SA1328 Special Authority for Subsidy Initial application from any relevant practitioner. Approv the following criteria: Any of the following:			s notified	d for applications meetin
<ul> <li>1 For the treatment of toxoplasmosis in patients with</li> <li>2 For pregnant patients for the term of the pregnanc</li> <li>3 For infants with congenital toxoplasmosis until 12 in</li> </ul>	y; or	onths; or		
SODIUM FUSIDATE [FUSIDIC ACID] Tab 250 mg	135.70	36	<b>√</b> F	ucidin
			٠,	ucium
SULFADIAZINE SODIUM – Special Authority see SA133 Tab 500 mg	•	100	<b>√</b> S	ulfadiazin-Heyl S29
	543.20	56	✓ W	ockhardt S29
the following criteria: Any of the following:  1 For the treatment of toxoplasmosis in patients with 2 For pregnant patients for the term of the pregnanc 3 For infants with congenital toxoplasmosis until 12 i	y; or	onths; or		
TOBRAMYCIN	-			
Inj 40 mg per ml, 2 ml vial - Subsidy by endorsemen	t15.50	5	✓ T	obramycin (Viatris)
Only if prescribed for dialysis or cystic fibrosis pa		is endorsed	accordin	gly.
Solution for inhalation 60 mg per ml, 5 ml - Subsidy endorsement	,	56 dose	<b>✓</b> T	obramycin BNM
<ul><li>a) Wastage claimable</li><li>b) Only if prescribed for a cystic fibrosis patient a</li></ul>	and the prescription is en	idorsed accor	dinaly	
TRIMETHOPRIM	and the procentation to on	1401004 40001	anigiy.	
* Tab 300 mg - Up to 30 tab available on a PSO	27.83	50	<b>✓</b> T	MP
TRIMETHOPRIM WITH SULPHAMETHOXAZOLE [CO-T	RIMOXAZOLE]			_
* Tab trimethoprim 80 mg and sulphamethoxazole 400	mg – Up			
to 30 tab available on a PSO		500	<b>✓</b> <u>T</u>	<u>risul</u>
* Oral liq 8 mg sulphamethoxazole 40 mg per ml – Up available on a PSO		100 ml	<b>✓</b> D	eprim

Only if prescribed for a dialysis or cystic fibrosis patient or for prophylaxis of endocarditis or for treatment of Clostridium

✓ Mylan

Deprim to be Principal Supply on 1 August 2025

difficile following metronidazole failure and the prescription is endorsed accordingly. 

VANCOMYCIN - Subsidy by endorsement

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

# **Antifungals**

- a) For topical antifungals refer to DERMATOLOGICALS, page 66
- b) For topical antifungals refer to GENITO URINARY, page 78

# FLUCONAZOLE

OCCINAZOLL			
Cap 50 mg	4.10	28	Mylan
Cap 150 mg	0.45	1	✓ Mylan
Cap 200 mg		28	✓ Mylan
Powder for oral suspension 10 mg per ml - Special Authority			
see SA1359 below - Retail pharmacy	129.02	35 ml	<ul><li>Diflucan</li></ul>
Wastage claimable			

### ⇒SA1359 Special Authority for Subsidy

**Initial application — (Systemic candidiasis)** from any relevant practitioner. Approvals valid for 6 weeks for applications meeting the following criteria:

Both:

- 1 Patient requires prophylaxis for, or treatment of systemic candidiasis; and
- 2 Patient is unable to swallow capsules.

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

All of the following:

- 1 Patient is immunocompromised; and
- 2 Patient is at moderate to high risk of invasive fungal infection; and
- 3 Patient is unable to swallow capsules.

Renewal — (Systemic candidiasis) from any relevant practitioner. Approvals valid for 6 weeks for applications meeting the following criteria:

Both:

- 1 Patient requires prophylaxis for, or treatment of systemic candidiasis; and
- 2 Patient is unable to swallow capsules.

**Renewal — (Immunocompromised)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient remains immunocompromised; and
- 2 Patient remains at moderate to high risk of invasive fungal infection; and
- 3 Patient is unable to swallow capsules.

#### ITRACONAZOI F

Cap 100 mg6.83	15	✓ Itraconazole
		Cresent S29  ✓ Itrazole
27.32	60	✓ Itracap S29
Oral liq 10 mg per ml - Special Authority see SA1322 below -		
Retail pharmacy141.80	150 ml OP	✓ Itraconazole

#### ⇒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.

	Subsidy		Fully	Brand or
	(Manufacturer's Price	ce)	Subsidised	Generic
	\$	Per	1	Manufacturer
KETOCONAZOLE				
Tab 200 mg - PCT	CBS	30	✓	Burel S29
		100	/	Strides Shasun S29
			1	Taro \$29
				Teva-
			•	Ketoconazole \$29
				Ketoconazoie 529
NYSTATIN				
Tab 500,000 u	14.16	50		
	(17.09)			Nilstat
Cap 500,000 u	` ,	50		
σαρ σσο,σσο σ	(15.47)	•		Nilstat
POOA CONTATOLE Or refel Authority or CACCOO hely	,			THIOLOG
POSACONAZOLE – Special Authority see SA2383 below –	, ,		_	
Tab modified-release 100 mg		24	•	Posaconazole Juno
Oral liq 40 mg per ml	342.51	105 ml (	OP 🗸	Devatis
010000 0 114 11 11 1 0 1 11				

#### ⇒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:

#### Fither:

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

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

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 (Manufacturer's Price)	Sub	Fully	Brand or Generic
 <b>`</b> \$	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 mg	8.97	84	✓ Deolate
۷O	RICONAZOLE - Special Authority see SA2384 below -	Retail pharmacy		
	Tab 50 mg	71.00	56	✓ Vttack
	Vttack to be Principal Supply on 1 August 2025			
	Tab 200 mg	263.00	56	✓ Vttack
	Vttack to be Principal Supply on 1 August 2025			
	Powder for oral suspension 40 mg per ml - Wastage			
	claimable	1,523.22	70 ml	✓ Vfend

#### ⇒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

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

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 mg .......400.00 100

✓ Sanofi

Primaquine \$29

#### ⇒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	25.86	250	✓ Metronidamed
Tab 400 mg - Up to 15 tab available on a PSO	4.29	21	✓ Metronidamed
Oral liq benzoate 200 mg per 5 ml	25.00	100 ml	✓ Flagyl-S
Suppos 500 mg	24.48	10	✓ Flagyl
ORNIDAZOLE			
Tab 500 mg	36.52	10	✓ Arrow-Ornidazole

# **Antituberculotics and Antileprotics**

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

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per Manufacturer ⇒SA2244 Special Authority for Subsidy Initial application — (multi-drug resistant tuberculosis) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria: Both: 1 The person has multi-drug resistant tuberculosis (MDR-TB); and 2 Ministry of Health's Tuberculosis Clinical Network has reviewed the individual case and recommends bedaquiline as part of the treatment regimen. CLOFAZIMINE - Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or dermatologist. 100 ✓ Lamprene S29 CYCLOSERINE - Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or respiratory physician. 60 ✓ Cyclorin S29 DAPSONE - Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or dermatologist Dapsone 100 Tab 100 mg .......329.50 100 ✓ Dapsone ETHAMBUTOL HYDROCHLORIDE - Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or respiratory physician Tab 100 mg .......85.73 ✓ FMB Fatol \$29 100 Tab 400 mg .......49.34 56 ✓ Myambutol \$29 ISONIAZID - Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an internal medicine physician, paediatrician, clinical microbiologist, dermatologist or public health physician 100 ✓ Isoniazid Teva S29 ✓ Noumed Isoniazid 327.41 ISONIAZID WITH RIFAMPICIN - Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an internal medicine physician, paediatrician, clinical microbiologist, dermatologist or public health physician 100 Rifinah 100 Rifinah LINEZOLID - Special Authority see SA2234 on the next page - Retail pharmacy No patient co-payment payable

Zyvox

✓ Zyvox

10

150 ml

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per Manufacturer ⇒SA2234 Special Authority for Subsidy Initial application — (multi-drug resistant tuberculosis) from any relevant practitioner. Approvals valid for 18 months for applications meeting the following criteria: Both: 1 The person has multi-drug resistant tuberculosis (MDR-TB); and 2 Ministry of Health's Tuberculosis Clinical Network has reviewed the individual case and recommends linezolid as part of the treatment regimen. PARA-AMINO SALICYLIC ACID - Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an infectious disease specialist, clinical microbiologist or respiratory physician 30 ✓ Paser S29 PROTIONAMIDE - Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an infectious disease specialist, clinical microbiologist or respiratory physician 100 Peteha \$29 PYRAZINAMIDE - Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or respiratory physician \* Tab 500 mg .......64.95 100 ✓ AFT-Pvrazinamide RIFABUTIN - Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, respiratory physician or aastroenterologist \* Cap 150 mg......353.71 ✓ Mycobutin RIFAMPICIN - Subsidy by endorsement a) No patient co-payment payable b) For confirmed recurrent Staphylococcus aureus infection in combination with other effective anti-staphylococcal

antimicrobial based on susceptibilities and the prescription is endorsed accordingly; can be waived by endorsement -Retail pharmacy - Specialist. Specialist must be an internal medicine physician, clinical microbiologist, dermatologist, paediatrician, or public health physician.

*	Cap 150 mg	58.54	100	✓ Rifadin
	Cap 300 mg		100	✓ Rifadin
				✓ Rifadin Sanofi
*	Oral liq 100 mg per 5 ml	12.60	60 ml	✓ Rifadin

#### **Antivirals**

For eye preparations refer to Eye Preparations, Anti-Infective Preparations, page 269

# **Hepatitis B Treatment**

ENTECAVIR  * Tab 0.5 mg	12.04	30	✓ Entecavir (Rex)
LAMIVUDINE - Special Authority see SA1685 on the next page	- Retail pharma	су	
Tab 100 mg	12.06	28	✓ Zetlam
Oral liq 5 mg per ml	270.00	240 ml OP	✓ Zeffix

Subsidy	Fully	Brand or
	<u> </u>	
(Manutacturer's Price)	Subsidised	Generic
` ¢ ′	Por 🗸	Manufacturor

#### **⇒SA1685** Special Authority for Subsidy

**Initial application** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 1 year where used for the treatment or prevention of hepatitis B.

Renewal from any relevant practitioner. Approvals valid for 2 years where used for the treatment or prevention of hepatitis B. TENOFOVIR DISOPROXII

Tenofovir disoproxil prescribed under endorsement for the treatment of HIV is included in the count of up to 4 subsidised antiretrovirals for the purposes of Special Authority SA2139., page 109

*	Tab 245 mg (300 mg as a maleate)	30	✓ <u>Tenofovir Disoproxil</u> <u>Viatris</u>
*	Tab 245 mg (300 mg as a fumarate)15.00	30	✓ Ricovir S29

### **Herpesvirus Treatments**

ACICLOVIR	
-----------	--

* Tab dispersible 200 mg	1.78	25	<ul><li>Lovir</li></ul>
* Tab dispersible 400 mg	5.81	56	Lovir
* Tab dispersible 800 mg	6.46	35	✓ Lovir
VALACICLOVIR			
Tab 500 mg	9.64	30	✓ Vaclovir
Tab 1,000 mg	17.78	30	✓ Vaclovir
VALGANCICLOVIR - Special Authority see SA1993 bel	ow - Retail pharmacy		
Tab 450 mg	140.89	60	✓ Valganciclovir
			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	Fully	Brand or	
(Manufacturer's Price)	Subsidised	Generic	
\$	Per 🗸	Manufacturer	

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:

- ın:
  - 1 Patient is immunocompromised; and
- 2 Any of the following:
  - 2.1 Patient has cytomegalovirus syndrome or tissue invasive disease; or
  - 2.2 Patient has rapidly rising plasma CMV DNA in absence of disease; or
  - 2.3 Patient has cytomegalovirus retinitis.

Renewal — (Cytomegalovirus in immunocompromised patients) only from a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

- Both:
  - 1 Patient is immunocompromised; and
  - 2 Any of the following:
    - 2.1 Patient has cytomegalovirus syndrome or tissue invasive disease; or
    - 2.2 Patient has rapidly rising plasma CMV DNA in absence of disease; or
    - 2.3 Patient has cytomegalovirus retinitis.

Note: for the purpose of this Special Authority "immunocompromised" includes transplant recipients, patients with immunosuppressive diseases (e.g. HIV) or those receiving immunosuppressive treatment for other conditions.

# **Hepatitis C Treatment**

### GLECAPREVIR WITH PIBRENTASVIR - [Xpharm]

Note the supply of treatment is via Pharmac's approved direct distribution supply. Further details can be found on Pharmac's website <a href="https://pharmac.govt.nz/maviret">https://pharmac.govt.nz/maviret</a>

Tab 100 mg with pibrentasvir 40 mg .......24,750.00 84 OP ✓ Maviret

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

No patient co-payment payable

#### ⇒SA1605 Special Authority for Subsidy

Special Authority approved by the Hepatitis C Treatment Panel (HepCTP)

Notes: By application to the Hepatitis C Treatment Panel (HepCTP).

Applications will be considered by HepCTP and approved subject to confirmation of eligibility.

Application details may be obtained from Pharmac's website http://www.pharmac.govt.nz/maviret or:

The Coordinator, Hepatitis C Treatment Panel

Pharmac, PO Box 10-254, WELLINGTON Tel: (04) 460 4990,

Email: hepcpanel@pharmac.govt.nz

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic \$ Per ✔ 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 109 There is an approval process to become a named specialist to prescribe antiretroviral therapy in New Zealand. Further information is available on the Pharmac website

*	Tab 200 mg with tenofovir disoproxil 245 mg (300 mg as a maleate)	15.45	30	✓ <u>Tenofovir Disoprox</u> <u>Emtricitabine Via</u>	_
*	Tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a				
	succinate)	15.45	30	✓ Teva	
Τε	eva Tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a	succinate) to b	e delisted 1 A	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.

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

INFECTIONS - AGENTS FOR SYSTEMIC USE	<b>.</b>			
	Subsidy (Manufacturer's Price) \$	Subside Per	Fully dised	Brand or Generic Manufacturer
continued				
with an unknown or detectable viral load greater the 2.2 Patient has shared intravenous injecting equipment 2.3 Patient has had non-consensual intercourse and the prophylaxis is required; or 2.4 Patient has had condomless anal intercourse with a whose HIV status is unknown.	t with a known HIV p	ositive pers that the ris	k asse	
Initial application — (Percutaneous exposure) only from a nar has percutaneous exposure to blood known to be HIV positive. Notes: Tenofovir disoproxil prescribed under endorsement for HI Subsidies apply for a combination of up to four antiretroviral mediritonavir given as a booster (either as part of a combination produ purpose of accessing funding to antiretrovirals.  Renewal — (Second or subsequent percutaneous exposure) where the patient has percutaneous exposure to blood known to least the patient has percutaneous exposure to blood known to least the patient has percutaneous exposure to blood known to least the patient has percutaneous exposure to blood known to least the patient has percutaneous exposure to blood known to least the patient has percutaneous exposure to blood known to least the patient has percutaneous exposure to blood known to least the patient has percutaneous exposure to blood known to least the patient has percutaneous exposure to blood known to least the patient has percutaneous exposure to blood known to least the patient has percutaneous exposure to blood known to least the patient has percutaneous exposure to blood known to least the patient has percutaneous exposure to blood known to least the patient has percutaneous exposure.	V is included in the c cations. The combir ct or separately) will only from a named	count of up to nation of a public be counted	o 4 sul roteas as one	bsidised antiretrovirals. e inhibitor and low-dose e protease inhibitor for the
Non-nucleosides Reverse Transcriptase Inhibito	ors			
EFAVIRENZ – Special Authority see SA2139 on the previous page Tab 600 mg		y 30	✓ E	favirenz Milpharm (\$29)
ETRAVIRINE – Special Authority see SA2139 on the previous partiab 200 mg	770.00	60	✓ In	telence
NEVIRAPINE – Special Authority see SA2139 on the previous partiab 200 mg	198.25	60 -0 ml OP	✓ V	evirapine Viatris iramune Suspension
Nucleosides Reverse Transcriptase Inhibitors				
ABACAVIR SULPHATE – Special Authority see SA2139 on the page 1300 mg		ail pharmacy 60		iagen
ABACAVIR SULPHATE WITH LAMIVUDINE — Special Authority Note: abacavir with lamivudine (combination tablets) counts anti-retroviral Special Authority.				
Tab 600 mg with lamivudine 300 mg	29.50	30		<u>bacavir/</u> Lamivudine Viatris
EFAVIRENZ WITH EMTRICITABINE AND TENOFOVIR DISOPF Retail pharmacy Note: Efavirenz with emtricitabine and tenofovir disoproxil co anti-retroviral Special Authority Tab 600 mg with emtricitabine 200 mg and tenofovir disoprox	ounts as three anti-re	•		
245 mg (300 mg as a fumarate)	106.88 til	30 30		riovir 929) iatris
EMTRICITABINE – Special Authority see SA2139 on the previou				materia e

Cap 200 mg......307.20

Tab 150 mg .......98.00

Oral liq 10 mg per ml .......102.50

LAMIVUDINE - Special Authority see SA2139 on the previous page - Retail pharmacy

✓ Emtriva

**✓** 3TC

✓ Lamivudine Viatris

30

60

240 ml OP

	Subsidy (Manufacturer's Pri \$	ce) Subs Per	Fully Brand or idised Generic ✓ Manufacturer
ZIDOVUDINE [AZT] – Special Authority see SA2139 on page 1 Cap 100 mg Oral liq 10 mg per ml	152.25	100 200 ml OP	✓ Retrovir ✓ Retrovir
ZIDOVUDINE [AZT] WITH LAMIVUDINE — Special Authority so Note: zidovudine [AZT] with lamivudine (combination table the anti-retroviral Special Authority.			
Tab 300 mg with lamivudine 150 mg	92.40	60	✓ Lamivudine/ Zidovudine Viatris
Protease Inhibitors			
ATAZANAVIR SULPHATE - Special Authority see SA2139 on	page 109 – Retail r	harmacy	
Cap 150 mg		60	<ul><li>Atazanavir Mylan</li><li>Atazanavir Viatris</li></ul>
Cap 200 mg		60	✓ <u>Atazanavir Viatris</u>
DARUNAVIR – Special Authority see SA2139 on page 109 – R	letail pharmacy		
Tab 400 mg		60	✓ <u>Darunavir Viatris</u>
Tab 600 mg		60	✓ <u>Darunavir Viatris</u>
LOPINAVIR WITH RITONAVIR – Special Authority see SA213 Tab 100 mg with ritonavir 25 mg		tail pharmacy 60	✓ Lopinavir/Ritonavir
Tab 200 mg with ritonavir 50 mg	875.00	120	Mylan ✓ <u>Lopinavir/Ritonavir</u> Mylan
RITONAVIR - Special Authority see SA2139 on page 109 - Re	stail pharmacy		<u>iviyiaii</u>
Tab 100 mg		30	✓ Norvir
Strand Transfer Inhibitors			
DOLUTEGRAVIR - Special Authority see SA2139 on page 108 Tab 50 mg	, ,	30	✓ Tivicay
DOLUTEGRAVIR WITH LAMIVUDINE - Special Authority see	SA2139 on page 1	09 – Retail ph	narmacy
Tab 50 mg with lamivudine 300 mg		30	✓ Dovato
RALTEGRAVIR POTASSIUM – Special Authority see SA2139	on page 109 - Reta	ail pharmacy	
Tab 400 mg		60	✓ Isentress
Tab 600 mg	1,090.00	60	✓ Isentress HD
Immune Modulators			
PEGYLATED INTERFERON ALFA-2A – Special Authority see Note: Pharmac will consider funding ribavirin for the small Special Authority criteria. Please contact the Hepatitis C C Inj 180 mcg prefilled syringe	group of patients wl oordinator at Pharm	no have a clin	ical need for ribavirin and meet

**⇒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:

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

continued...

- 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
- - 3.1 Patient has responder relapsed; or
  - 3.2 Patient was a partial responder; and
- 4 Patient is to be treated in combination with boceprevir; and
- 5 Maximum of 48 weeks therapy.

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

All of the following:

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

Initial application — (chronic hepatitis C - genotype 2 or 3 infection without co-infection with HIV) from any specialist. Approvals valid for 12 months for applications meeting the following criteria: Both:

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

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

All of the following:

- 1 Patient has confirmed Hepatitis B infection (HBsAg positive for more than 6 months); and
- 2 Patient is Hepatitis B treatment-naive; and
- 3 ALT > 2 times Upper Limit of Normal; and
- 4 HBV DNA < 10 log10 IU/ml; and
- 5 Either:
  - 5.1 HBeAg positive; or
  - 5.2 serum HBV DNA greater than or equal to 2,000 units/ml and significant fibrosis (Metavir Stage F2 or greater or moderate fibrosis); and
- 6 Compensated liver disease; and
- 7 No continuing alcohol abuse or intravenous drug use; and
- 8 Not co-infected with HCV, HIV or HDV; and
- 9 Neither ALT nor AST > 10 times upper limit of normal; and
- 10 No history of hypersensitivity or contraindications to pegylated interferon; and

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

continued...

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 Fither
  - 3.1 Patient has a cutaneous T cell lymphoma\*: or
  - 3.2 Both:
    - 3.2.1 Patient has a myeloproliferative disorder\*; and
    - 3.2.2 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**

FOSFOMYCIN - Special Authority see SA2406 below - Retail pharmacy

Powder for oral solution, 3 g sachet ......18.70

✓ 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:
  - 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:

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

continued...

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 g19.95	100	✓ <u>Hiprex</u>
NITROFURANTOIN	100	Allfornan
* Tab 50 mg – Up to 30 tab available on a PSO	100 100	<ul><li>✓ Nifuran</li><li>✓ Nifuran</li></ul>
* Cap modified-release 100 mg - Up to 15 cap available on a PSO81.20	100	✓ <u>Macrobid</u>
NORFLOXACIN Tab 400 mg - Subsidy by endorsement245.00	100	✓ Arrow-Norfloxacin

Only if prescribed for a patient with an uncomplicated urinary tract infection that is unresponsive to a first line agent or with proven resistance to first line agents and the prescription is endorsed accordingly.

	Subsidy		Fully	Brand or
	(Manufacturer's Price)		Subsidised	Generic
	\$	Per		Manufacturer
Anticholinesterases				
NEOSTIGMINE METILSULFATE				
Inj 2.5 mg per ml, 1 ml ampoule	48 25	10	1	Max Health
		10	•	max riculti
PYRIDOSTIGMINE BROMIDE	50.00	400	,	
Tab 60 mg	50.28	100	•	Mestinon
Non-Steroidal Anti-Inflammatory Drugs				
DICLOFENAC SODIUM				
★ Tab EC 25 mg	2.19	50	1	Diclofenac Sandoz
★ Tab 50 mg dispersible		20		Voltaren D
★ Tab EC 50 mg		50		Diclofenac Sandoz
₹ Tab long-acting 75 mg		100		Voltaren SR
Voltaren SR to be Principal Supply on 1 August 2025	10.00	100	•	Voltai eli 311
Inj 25 mg per ml, 3 ml ampoule – Up to 5 inj available on a P	SO 12.20	5	1	Voltaren
		10		Voltaren
Suppos 12.5 mg				
Suppos 25 mg		10		Voltaren
Suppos 50 mg - Up to 10 supp available on a PSO		10		Voltaren
Suppos 100 mg	7.00	10	•	Voltaren
BUPROFEN				
Fab 200 mg	21.40	1,000	✓	Relieve
Fab long-acting 800 mg	3.65	30	1	Ibuprofen SR BNM
Oral liq 20 mg per ml	2.85	200 m	·	Ethics
ETOPROFEN				
	10.07	28	./	Oruvail SR
Cap long-acting 200 mg	12.07	20	•	Oruvali Sh
EFENAMIC ACID				
Cap 250 mg	1.25	50		
	(10.82)			Ponstan
	0.50	20		
	(7.50)			Ponstan
APROXEN	` ,			
Tab 250 mg	30.23	500	1	Noflam 250
· ·		250		Noflam 500
Tab long acting 750 mg				
Tab long-acting 750 mg		28		Naprosyn SR 750
Tab long-acting 1 g	11.50	28	•	Naprosyn SR 1000
ENOXICAM				
Tab 20 mg	18.50	100	✓	Tilcotil
· Inj 20 mg vial	9.95	1	✓	AFT
NSAIDs Other				
ELECOXIB			_	
Cap 100 mg	3.45	60		Celebrex
				Celecoxib Pfizer
Cap 200 mg	3.20	30		Celebrex
				Celecoxib Pfizer

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

# **Topical Products for Joint and Muscular Pain**

**CAPSAICIN** 

(Rugby Capsaicin Topical Cream S29 Crm 0.025% to be delisted 1 July 2025)

#### **⇒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**

HYE	DROXYCHLOROQUINE SULPHATE - Brand switch fee payable (Pharmacod	de 2704676) - :	see page 274 for details
*	Tab 200 mg7.80	100	✓ <u>lpca-</u> <u>Hydroxychloroquine</u>
LEF	FLUNOMIDE		
*	Tab 10 mg6.00	30	✓ Arava
*	Tab 20 mg	30	✓ Arava
PEN	NICILLAMINE		
	Tab 125 mg	100	✓ D-Penamine
	Tab 250 mg110.12	100	✓ D-Penamine

# **Drugs Affecting Bone Metabolism**

# Alendronate for Osteoporosis

ALENDRONATE SODIUM			
* Tab 70 mg3	.10	4	✓ Fosamax
•			
ALENDRONATE SODIUM WITH COLECALCIFEROL			
* Tab 70 mg with colecalciferol 5,600 iu	.99	4	✓ Fosamax Plus

# **Other Treatments**

DENOSUMAB - Special Authority see SA2441 below - Retail pharmacy

Note: Denosumab inj 60 mg per 1 ml pre-filled syringe is Medsafe approved for use in osteoporosis. Denosumab inj 120 mg per 1.7 ml vial is Medsafe approved for use in hypercalcaemia of malignancy.

Inj 120 mg per 1.7 ml vial	500.00	1	✓ Xgeva
Inj 60 mg per 1 ml prefilled syringe	250.00	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

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

#### continued...

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

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

#### PAMIDRONATE DISODIUM

Inj 3 mg per ml, 10 ml vial	32.49	1	✓ Pamisol		
Inj 6 mg per ml, 10 ml vial	88.11	1	✓ Pamisol		
Inj 9 mg per ml, 10 ml vial	94.34	1	✓ Pamisol		
RALOXIFENE HYDROCHLORIDE – Special Authority see SA1779 below – Retail pharmacy					
* Tab 60 mg	53.76	28	<ul><li>Evista</li></ul>		

## ⇒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.

	Subsidy		Fully	Brand or
(N	Manufacturer's Price \$	e) S Per	Subsidised 🗸	Generic Manufacturer
continued	-			
<ul> <li>b) Evidence suggests that patients aged 75 years and over who demonstrated radiologically are very likely to have a T-Score measurement for raloxifene funding.</li> <li>c) Osteoporotic fractures are the incident events for severe (est definitions of osteoporosis and fragility fracture. The WHO of -2.5 with one or more associated fragility fractures. Fragility forces that would not ordinarily cause fracture (minimal traunfall from a standing height or less.</li> <li>d) A vertebral fracture is defined as a 20% or greater reduction relative to the posterior height of that body, or a 20% or greated body above or below the affected vertebral body.</li> </ul>	eless than or equitablished) osteoplefines severe (esfractures are fractures). The WHO him height of the a	al to -2 orosis, a stablishe ctures th as quan	5 and, there and can be ed) osteopo at occur as tified this a	defined using the WHO brosis as a T-score below a result of mechanical s forces equivalent to a con of a vertebral body
RISEDRONATE SODIUM Tab 35 mg	2.50	4	<b>√</b> R	lisedronate Sandoz
TERIPARATIDE – Special Authority see SA1139 below – Retail ph Inj 250 mcg per ml, 2.4 ml	armacy	1	_	eriparatide - Teva
The patient has a documented T-score less than or equal to     The patient has had two or more fractures due to minimal tra     The patient has experienced at least one symptomatic new funded antiresorptive agent at adequate doses (see Notes).  Notes:	iuma; and		nonths' con	itinuous therapy with a
<ul> <li>a) The bone mineral density (BMD) measurement used to deriv absorptiometry (DXA). Quantitative ultrasound and quantitative)</li> <li>b) Antiresorptive agents and their adequate doses for the purportion sodium tab 70 mg or tab 70 mg with colecalciferol 5,600 iu or zoledronic acid 5 mg per year. If an intolerance of a severity during the use of one antiresorptive agent, an alternate antire the minimum requirement of 12 months' continuous therapy.</li> <li>c) A vertebral fracture is defined as a 20% or greater reduction relative to the posterior height of that body, or a 20% or greated body above or below the affected vertebral body.</li> <li>d) A maximum of 18 months of treatment (18 cartridges) will be</li> </ul>	ve computed ton oses of this Speci nce weekly; raloo r necessitating pe esorptive agent n in height of the a ter reduction in a	nography al Autho kifene hy ermanen nust be t nterior o	y (QCT) are ority are dei orrochloride t treatment trialled so the	e not acceptable fined as: alendronate e tab 60 mg once daily; withdrawal develops hat the patient achieves on of a vertebral body
ZOLEDRONIC ACID Inj 0.05 mg per ml, 100 ml, bag	22.53	1	<b>√</b> <u>Z</u>	oledronic Acid Viatris
Hyperuricaemia and Antigout				
ALLOPURINOL  * Tab 100 mg  * Tab 300 mg		1,000 500		oca-Allopurinol oca-Allopurinol

BENZBROMARONE - Special Authority see SA1963 on the next page - Retail pharmacy

Tab 50 mg .......32.00

✓ Narcaricin mite \$29

100

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

# ⇒SA1963 Special Authority for Subsidy

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

- 1 The treatment remains appropriate and the patient is benefitting from the treatment; and
- 2 There is no evidence of liver toxicity and patient is continuing to receive regular (at least every three months) liver function tests

#### COLCHICINE

* Tab 500 mcg6.00	100	✓ Colgout
FEBUXOSTAT - Special Authority see SA2054 below - Retail pharmacy		
Tab 80 mg4.73	28	✓ Febuxostat (Teva)
Tab 120 mg11.78	28	✓ 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**

#### Muscle Relaxants

### **BACLOFEN**

-	2,1020. 2.1				
÷	* Tab 10 mg3.70	100	✓ Pacifen		
	Inj 0.05 mg per ml, 1 ml ampoule - Subsidy by endorsement11.55	1	<ul><li>Lioresal Intrathecal</li></ul>		
	Subsidised only for use in a programmable pump in patients where oral ant	ispastic ag	ents have been ineffective or have		
	caused intolerable side effects and the prescription is endorsed accordingly.				
	Ini 2 mg per ml. 5 ml ampoule – Subsidy by endorsement	10	✓ Sintetica Baclofen		

Subsidised only for use in a programmable pump in patients where oral antispastic agents have been ineffective or have caused intolerable side effects and the prescription is endorsed accordingly.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Generic
DANTROLENE				
Cap 25 mg	145.77	100	1	Dantrium S29 S29
Cap 50 mg	77.00	100	1	Dantrium
ORPHENADRINE CITRATE				
Tab 100 mg	23.25	100	✓	Norflex

Subsidy (Manufacturer's Price)

Fully Subsidised Per

Brand or Generic Manufacturer

# **Agents for Parkinsonism and Related Disorders**

# **Dopamine Agonists and Related Agents**

AMANTADINE HYDROCHLORIDE			
▲ Cap 100 mg	38.24	60	✓ Symmetrel
	63.73	100	✓ Symmetrel
APOMORPHINE HYDROCHLORIDE			
▲ Inj 10 mg per ml, 2 ml ampoule	59.50	5	✓ Movapo
▲ Inj 10 mg per ml, 5 ml ampoule	121.84	5	✓ Movapo
ENTACAPONE			•
▲ Tab 200 mg	13.73	100	✓ Entacapone Viatris
=	18.04		✓ Comtan
Entacapone Viatris to be Principal Supply on 1 July 2025			•
(Comtan Tab 200 mg to be delisted 1 July 2025)			
LEVODOPA WITH BENSERAZIDE			
* Tab dispersible 50 mg with benserazide 12.5 mg	13.25	100	✓ Madopar Rapid
* Cap 50 mg with benserazide 12.5 mg		100	✓ Madopar 62.5
* Cap 100 mg with benserazide 25 mg		100	✓ Madopar 125
* Cap long-acting 100 mg with benserazide 25 mg		100	✓ Madopar HBS
* Cap 200 mg with benserazide 50 mg	26.25	100	✓ Madopar 250
LEVODOPA WITH CARBIDOPA			·
* Tab 100 mg with carbidopa 25 mg	26.49	100	✓ Sinemet
* Tab long-acting 200 mg with carbidopa 50 mg		100	✓ Sinemet CR
* Tab 250 mg with carbidopa 25 mg		100	✓ Sinemet
LEVODOPA WITH CARBIDOPA AND ENTACAPONE			
* Tab 50 mg with carbidopa 12.5 mg and entacapone 200 mg	27.01	100	✓ Stalevo
Stalevo to be Principal Supply on 1 July 2025			
* Tab 100 mg with carbidopa 25 mg and entacapone 200 mg	34.18	100	✓ Stalevo
Stalevo to be Principal Supply on 1 July 2025			
* Tab 150 mg with carbidopa 37.5 mg and entacapone 200 mg	44.96	100	✓ Stalevo
Stalevo to be Principal Supply on 1 July 2025			
* Tab 200 mg with carbidopa 50 mg and entacapone 200 mg	51.23	100	✓ Stalevo
Stalevo to be Principal Supply on 1 July 2025			
PRAMIPEXOLE HYDROCHLORIDE			
▲ Tab 0.25 mg		100	✓ Ramipex
▲ Tab 1 mg	18.66	100	✓ Ramipex
RASAGILINE			
* Tab 1 mg	53.50	30	✓ Azilect 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	152.38	100	✓ Tasmar
·			

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
Anticholinergics				
BENZATROPINE MESYLATE Tab 2 mg		60 5		Benztrop Phebra
PROCYCLIDINE HYDROCHLORIDE Tab 5 mg	7.40	100	•	Kemadrin
Agents for Essential Tremor, Chorea and Relate	d Disorders			
RILUZOLE - Special Authority see SA1403 below - Retail pharm Wastage claimable Tab 50 mg		56	•	Rilutek
Initial application only from a neurologist or respiratory specialist following criteria:  All of the following:  1 The patient has amyotrophic lateral sclerosis with disease 2 The patient has at least 60 percent of predicted forced vita 3 The patient has not undergone a tracheostomy; and 4 The patient has not experienced respiratory failure; and 5 Any of the following:  5.1 The patient is ambulatory; or 5.2 The patient is able to use upper limbs; or 5.3 The patient is able to swallow.  Renewal from any relevant practitioner. Approvals valid for 18 m All of the following:  1 The patient has not undergone a tracheostomy; and 2 The patient has not experienced respiratory failure; and	duration of 5 years o	or less onths	s; and prior to th	e initial application; and
3 Any of the following: 3.1 The patient is ambulatory; or 3.2 The patient is able to use upper limbs; or 3.3 The patient is able to swallow.  TETRABENAZINE Tab 25 mg	106.59	112	<b>√</b>	<u>Motetis</u>
Anaesthetics				
Local				
LIDOCAINE [LIGNOCAINE]  Gel 2%, tube — Subsidy by endorsement	dministration and the	10	cription is	Instillagel Lido

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

accordingly.

00	Per 200 ml 25 50		Generic Manufacturer lucosoothe idocaine-Baxter
00	25		
00	25		
		<b>√</b> L	idocaine-Baxter
. ^	50		
50	00		
00)		Х	ylocaine
50 <sup>°</sup>	25	✓ L	idocaine-Baxter
00	5		
00)		Х	ylocaine
50 <sup>°</sup>	5	✓ L	idocaine-Baxter
00	5	✓ L	idocaine-Baxter
	10	✓ X	ylocard 500 S29
	50 00 S	00 5 S 10	00 5 <b>~</b> L

# **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 s	see SA0906 above – Retail pl	harmacy	
Crm 4%	5.40	5 g OP	✓ LMX4
	27.00	30 g OP	✓ LMX4
LIDOCAINE [LIGNOCAINE] WITH PRILOCAINE	- Special Authority see SA0	906 above – Ret	ail pharmacy
Crm 2.5% with prilocaine 2.5%	45.00	30 g OP	✓ EMLA
Crm 2.5% with prilocaine 2.5% (5 g tubes)	45.00	5	EMLA

# **Analgesics**

For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, page 115

# **Non-opioid Analgesics**

ASPIRIN  * Tab dispersible 300 mg - Up to 30 tab available on a F	PSO5.65	100	✓ Ethics Aspirin
CAPSAICIN - Subsidy by endorsement			
Subsidised only if prescribed for post-herpetic neuralgia accordingly.	a or diabetic peripnera	i neuropatny a	ina the prescription is endorsed
Crm 0.075%	11.95	45 g OP	✓ Zo-Rub HP S29 ✓ Zostrix HP
	15.14	57 g OP	✓ Rugby Capsaicin Topical Cream \$29
(Rugby Capsaicin Topical Cream S29 Crm 0.075% to be of	lelisted 1 July 2025)		
NEFOPAM HYDROCHLORIDE			
Tah 30 mg	23.40	an	✓ Acupan

		Subsidy Fully Brand or
		(Manufacturer's Price) Subsidised Generic
_		\$ Per ✓ Manufacturer
PAF	RACETAMOL	40.75 4.000 / Besimel
	Tab 500 mg - blister pack	· · · · · · · · · · · · · · · · · · ·
	<ul><li>a) Maximum of 300 tab per prescription; can be</li><li>b) Up to 30 tab available on a PSO</li></ul>	e waived by endorsement
	c)	
	1) Subsidy by endorsement for higher que regular daily dosing for one month or annotate the prescription as endorsed 2) Maximum of 100 tab per dispensing for (for non-endorsed patients), then dispendent of the pack — Maximum of 300 tab per prescription; can be waived by endorsement	
		d the prescription is annotated accordingly. Pharmacists may annotate the
		ng history supports a long-term condition.  on-endorsed patients. If quantities prescribed for more than 100 tabs (for repeat dispensings not exceeding 100 tab per dispensing.
	Oral liq 120 mg per 5 ml	
	a) Maximum of 600 ml per prescription; can be     b) Up to 200 ml available on a PSO     c) Not in combination     d)	
	<ol> <li>Maximum of 200 ml per dispensing for non-endorsed patients), then dispense</li> <li>Subsidy by endorsement for higher qu regular daily dosing for one month or of Pharmacists may annotate the prescri condition.</li> </ol>	r non-endorsed patients. If quantities prescribed exceed 200 ml (for e in repeat dispensing not exceeding 200 ml per dispensing.  Iantities is available for patients with long term conditions who require greater and the prescription is endorsed or annotated accordingly. ption as endorsed where dispensing history supports a long-term tamol oral liquid may be supplied on BSO to a Vaccinator (other than a
	Pharmacist) under the provisions in Pa	, , ,,
	4) Note: Direct Provision by a pharmacis	st of up to 200 ml permitted under the provisions in Part I of Section A in Id under 2 years of age with meningococcal B multicomponent vaccine
	b) Up to 200 ml available on a PSO c) Not in combination	
	d)	
	non-endorsed patients), then dispense 2) Subsidy by endorsement for higher queregular daily dosing for one month or control of the control of	r non-endorsed patients. If quantities prescribed exceed 200 ml (for e in repeat dispensing not exceeding 200 ml per dispensing.  Iantities is available for patients with long term conditions who require greater and the prescription is endorsed or annotated accordingly. ption as endorsed where dispensing history supports a long-term
	Pharmacist) under the provisions in Pa 4) Note: Direct Provision by a pharmacis	st of up to 200 ml permitted under the provisions in Part I of Section A in
*	Conjunction with immunisation of a chi Suppos 125 mg	ld under 2 years of age with meningococcal B multicomponent vaccine4.29 10 ✓ Gacet

				IVL	11V0033131EW
		Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	I Generic
*	Suppos 250 mg		10 50		Gacet Gacet
C	pioid Analgesics				
CC	DEINE PHOSPHATE - Safety medicine; prescriber may dete	ermine dispensina fre	auen	CV	
	Tab 15 mg		100		Noumed
	Tab 30 mg	6.98	100	✓	Noumed
	Tab 60 mg	13.89	100	1	Noumed
DIF	HYDROCODEINE TARTRATE				
	Tab long-acting 60 mg	8.60	60	✓	DHC Continus
FF	NTANYL				
. –	a) Only on a controlled drug form				
	b) No patient co-payment payable				
	c) Safety medicine; prescriber may determine dispensing fre	equency			
	Inj 50 mcg per ml, 2 ml ampoule		10	✓	<b>Boucher and Muir</b>
	Inj 50 mcg per ml, 10 ml ampoule	9.41	10	1	<b>Boucher and Muir</b>
	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
(E	Patch 100 mcg per hourentanyl Sandoz Patch 12.5 mcg per hour to be delisted 1 Nove		5	•	Fentanyl Sandoz
•	,	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		10		Methadone BNM
	Oral lig 2 mg per ml		10 200 m		Biodone
	Oral liq 5 mg per ml		200 m		Biodone Forte
	Oral lig 10 mg per ml		200 m		Biodone Extra Forte
	Inj 10 mg per ml, 1 ml		10		AFT
MC	ORPHINE HYDROCHLORIDE				
IVIC	a) Only on a controlled drug form				
	b) No patient co-payment payable				
	c) Safety medicine; prescriber may determine dispensing fre	eauencv			
	Oral lig 1 mg per ml	' '	200 m	nl 🗸	RA-Morph
	Oral liq 2 mg per ml		200 m		RA-Morph
	Out lin F man man mi		000		DA Mariah

✓ RA-Morph

✓ RA-Morph

200 ml

200 ml

Oral liq 10 mg per ml .......40.25

MORPHINE SULPHATE			•	Manufacturer
MONFHINE SULFHATE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing fre	, ,			
Tab immediate-release 10 mg		10		Sevredol
Tab immediate-release 20 mg		10		Sevredol - Falan
Cap long-acting 10 mg		10 10		<u>m-Esion</u> m-Esion
Cap long-acting 30 mg Cap long-acting 60 mg		10		m-Esion
Cap long-acting 60 mg		10	-	m-Esion
Oral lig 2 mg per ml		100 m	-	Wockhardt S29
Oral liq 2 mg per mi	29.80	100 111		Oramorph
	23.00			Oramorph CDC
			,	S29 S29
Inj 5 mg per ml, 1 ml ampoule - Up to 5 inj available on a PS	SO 5.20	5	./ 1	Medsurge
Inj 10 mg per ml, 1 ml ampoule – Up to 5 inj available on a F	30 30	5 5	-	Medsurge Medsurge
Inj 15 mg per ml, 1 ml ampoule – Up to 5 inj available on a F	2504.00 250 5.53	5	-	Medsurge Medsurge
Inj 30 mg per ml, 1 ml ampoule – Up to 5 inj available on a F		5	-	Medsurge Medsurge
DXYCODONE HYDROCHLORIDE	00	J		<del>licusui gc</del>
a) Only on a controlled drug form     b) No potient on poyment poychia				
<ul><li>b) No patient co-payment payable</li><li>c) Safety medicine; prescriber may determine dispensing fre</li></ul>	oguopov			
Tab controlled-release 5 mg		20	1	Oxycodone Sandoz
Tab controlled-release 5 mg	3.77	28	-	Oxycodone Sandoz
	0.77	20	• ,	S29 S29
	4.04	30		OxyContin S29
Tab immediate-release 5 mg		100		Oxycodone Amneal
Tab controlled-release 10 mg		20		Oxycodone Sandoz
Tab controlled-release to mg	3.77	28	-	Oxycodone Sandoz
	0.77	20	,	S29 S29
Tab immediate-release 10 mg	18 77	100	1	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 lig 1 mg per ml		250 m	-	Oxycodone Lucis
Inj 10 mg per ml, 1 ml ampoule	4.37	5	✓	Hameln
Inj 10 mg per ml, 2 ml ampoule	8.62	5	✓ [	Hameln_
Inj 50 mg per ml, 1 ml ampoule	14.90	5	✓ [	<u>Hameln</u>
Oxycodone Sandoz S29 S29 Tab controlled-release 5 mg to be	e delisted 1 July 2025	)		
OxyContin S29 Tab controlled-release 5 mg to be delisted 1 Ju	ıly 2025)			
Oxycodone Sandoz S29 S29 Tab controlled-release 10 mg to l	• ,	5)		
PARACETAMOL WITH CODEINE - Safety medicine; prescriber	•	,	ı franılanov	,
<ul><li>Tab paracetamol 500 mg with codeine phosphate 8 mg</li></ul>		1,000		Paracetamol +
		.,500	- !	Codeine (Relieve)

	Subsidy		Fully Brand or
	(Manufacturer's Price) \$	Per	Subsidised Generic  Manufacturer
PETHIDINE HYDROCHLORIDE			
a) Only on a controlled drug form			
b) No patient co-payment payable			
c) Safety medicine; prescriber may determine dispensing fre	equency		
Tab 50 mg		10	<ul> <li>Noumed Pethidine</li> </ul>
Inj 50 mg per ml, 1 ml ampoule – Up to 5 inj available on a F	'SO29.88	5	✓ DBL Pethidine
		_	Hydrochloride
Inj 50 mg per ml, 2 ml ampoule – Up to 5 inj available on a F	SO30.72	5	✓ DBL Pethidine
TRAMARON LIVERDOCKI ORIDE			Hydrochloride
TRAMADOL HYDROCHLORIDE	1.05	20	Tramal CD 100
Tab sustained-release 100 mg  Tab sustained-release 150 mg		20 20	<ul> <li>✓ <u>Tramal SR 100</u></li> <li>✓ Tramal SR 150</li> </ul>
Tab sustained-release 130 mg		20	✓ Tramal SR 200
Cap 50 mg		100	✓ Arrow-Tramadol
Sup 55 mg			
Antidepressants			
Cyclic and Related Agents			
AMITRIPTYLINE - Safety medicine; prescriber may determine d	ispensing frequency		
Tab 10 mg	2.99	100	
Tab 25 mg		100	
Tab 50 mg		100	Arrow-Amitriptyline
CLOMIPRAMINE HYDROCHLORIDE - Safety medicine; prescri	,		
Tab 10 mg		30	✓ Clomipramine Teva
Tab 25 mg		30	✓ Clomipramine Teva
	16.99	50	<ul> <li>✓ APO Clomipramine</li> <li>✓ Anafranil S29</li> </ul>
APO Clomipramine to be Principal Supply on 1 July 202	39.97 5	100	Anairanii 529
Cap 10 mg		28	✓ Clomipramine Teva
Cap 25 mg		28	✓ Clomipramine Teva
(Clomipramine Teva Tab 10 mg to be delisted 1 July 2025)			·
(Clomipramine Teva Tab 25 mg to be delisted 1 July 2025)			
(Anafranil S29 Tab 25 mg to be delisted 1 July 2025)			
(Clomipramine Teva Cap 10 mg to be delisted 1 July 2025)			
(Clomipramine Teva Cap 25 mg to be delisted 1 July 2025)			
DOSULEPIN [DOTHIEPIN] HYDROCHLORIDE - Subsidy by en			
<ul> <li>a) Safety medicine; prescriber may determine dispensing free</li> </ul>			
b) Subsidy by endorsement – Subsidised for patients who w			
2019 and the prescription is endorsed accordingly. Phart exists a record of prior dispensing of dosulepin [dothiepin		e ine	prescription as endorsed where there
Tab 75 mg	. ,	30	✓ Dosulepin Viatris
Cap 25 mg		50	✓ Dosulepin
			Viatris \$29
IMIPRAMINE HYDROCHLORIDE - Safety medicine; prescriber	may determine dispe	ensing	g frequency
Tab 10 mg	5.48	50	✓ Tofranil
	10.96	100	
Tab 25 mg	4.93	28	✓ Imipramine
	0.00	E0	Crescent \$29
	8.80	50	✓ Tofranil

<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)	Per	Subsidised	
NORTRIPTYLINE HYDROCHLORIDE - Safety medicine; pr	escriber may determine o	lispe	nsing fregi	iency
Tab 10 mg		100		Norpress
Tab 25 mg	6.29	180	✓	Norpress
Monoamine-Oxidase Inhibitors (MAOIs) - No	n Selective			
TRANYLCYPROMINE SULPHATE				
* Tab 10 mg	22.94	50	✓	Parnate
Monoamine-Oxidase Type A Inhibitors				
MOCLOBEMIDE				
* Tab 150 mg	23.60	60	✓	Aurorix
* Tab 300 mg	38.50	60	✓	Aurorix
Selective Serotonin Reuptake Inhibitors				
CITALOPRAM HYDROBROMIDE				
* Tab 20 mg	2.86	84	✓	Celapram
ESCITALOPRAM				-
* Tab 10 mg	0.79	28	1	Ipca-Escitalopram
1 ab 10 mg	1.07	20		Escitalopram
	1.07		•	(Ethics)
* Tab 20 mg	1.49	28	1	Ipca-Escitalopram
· · · · · · · · · · · · · · · · · · ·	1.70	20	•	ipca-Lacitaiopiaiii
FLUOXETINE HYDROCHLORIDE  * Tab dispersible 20 mg, scored – Subsidy by endorseme Subsidised by endorsement	nt2.50	28	•	Fluox
When prescribed for a patient who cannot swa accordingly; or	low whole tablets or caps	ules	and the p	escription is endorsed
<ul><li>2) When prescribed in a daily dose that is not a m</li></ul>	ultiple of 20 mg in which	case	the presci	iption is deemed to be
endorsed. Note: Tablets should be combined	with capsules to facilitate	incre	emental 10	) mg doses.
* Cap 20 mg	3.13	90	/	Arrow-Fluoxetine
PAROXETINE				
	4.11	90	1	Loxamine
* Tab 20 mg	4.11	90	•	<u>Loxamine</u>
* Tab 20 mg SERTRALINE				
* Tab 20 mg SERTRALINE * Tab 50 mg	0.99	30	•	Setrona
* Tab 20 mg  SERTRALINE  * Tab 50 mg  * Tab 100 mg	0.99		•	
* Tab 20 mg SERTRALINE * Tab 50 mg	0.99	30	•	Setrona
* Tab 20 mg  SERTRALINE  * Tab 50 mg  * Tab 100 mg  Other Antidepressants	0.99	30	•	Setrona
* Tab 20 mg  SERTRALINE  * Tab 50 mg  * Tab 100 mg  Other Antidepressants	0.99	30	,	Setrona Setrona
* Tab 20 mg  SERTRALINE  * Tab 50 mg  * Tab 100 mg  Other Antidepressants  MIRTAZAPINE		30 30	,	Setrona Setrona
* Tab 20 mg		30 30 30	,	Setrona Setrona
* Tab 20 mg		30 30 30		Setrona Setrona
* Tab 20 mg		30 30 30 30	<i>'</i> ,	Setrona Setrona Noumed Noumed Enlafax XR
* Tab 20 mg  SERTRALINE  * Tab 50 mg  * Tab 100 mg  Other Antidepressants  MIRTAZAPINE    Tab 30 mg    Tab 45 mg  VENLAFAXINE  * Cap 37.5 mg		30 30 30 30 30		Setrona Setrona Noumed Noumed
MIRTAZAPINE Tab 30 mg Tab 45 mg VENLAFAXINE * Cap 37.5 mg		30 30 30 30 84 28	\( \sqrt{\chi} \)	Setrona Setrona  Noumed Noumed Enlafax XR Enlafax XR

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

# **Antiepilepsy Drugs**

Agents for 0	Control of	Status	Epilepticus
--------------	------------	--------	-------------

DIAZEPAM – Safety medicine; prescriber may determine dispensing frequency		
Inj 5 mg per ml, 2 ml ampoule - Subsidy by endorsement27.92	5	Hospira
a) Up to 5 inj available on a PSO		
b) Only on a PSO		
c) PSO must be endorsed "not for anaesthetic procedures".		
Rectal tubes 5 mg - Up to 5 tube available on a PSO54.58	5	✓ Stesolid
PHENYTOIN SODIUM		
* Inj 50 mg per ml, 2 ml ampoule - Up to 5 inj available on a		
PSO	5	✓ Hospira
* Inj 50 mg per ml, 5 ml ampoule - Up to 5 inj available on a		
PSO	5	✓ Hospira
. 33	•	. roopii u

# **Control of Epilepsy**

* Tab 200 mg	14.53	100	✓ Tegretol
			✓ Tegretol AU
* Tab long-acting 200 mg	16.98	100	✓ Tegretol CR
	33.96	200	✓ Tegretol CR
* Tab 400 mg	34.58	100	✓ Tegretol
* Tab long-acting 400 mg	39.17	100	✓ Tegretol CR
* Oral liq 20 mg per ml	26.37	250 ml	✓ Tegretol
CLOBAZAM - Safety medicine; prescriber may determine dis	pensing frequency		
Tab 10 mg	9.12	50	✓ Frisium
CLONAZEPAM - Safety medicine; prescriber may determine	dispensing frequer	icy	
Oral drops 2.5 mg per ml		10 ml OP	✓ Rivotril
ETHOSUXIMIDE			
Cap 250 mg	78.89	56	✓ Essential
			Ethosuximide S29
	140.88	100	✓ Zarontin
Oral liq 250 mg per 5 ml		100 200 ml	<ul><li>✓ Zarontin</li><li>✓ Zarontin</li></ul>
Oral liq 250 mg per 5 ml			
,	56.35		
GABAPENTIN	56.35		
GABAPENTIN  Note: Not subsidised in combination with subsidised preg	56.35 abalin 6.45	200 ml	✓ Zarontin
GABAPENTIN  Note: Not subsidised in combination with subsidised preg  * Cap 100 mg	abalin6.458.45	200 ml	✓ Zarontin ✓ Nupentin
GABAPENTIN Note: Not subsidised in combination with subsidised preg  * Cap 100 mg  Cap 300 mg  Cap 400 mg		200 ml 100 100 100	✓ Zarontin ✓ <u>Nupentin</u> ✓ <u>Nupentin</u>
GABAPENTIN Note: Not subsidised in combination with subsidised preg  * Cap 100 mg  * Cap 300 mg  * Cap 400 mg  LACOSAMIDE – Special Authority see SA2267 on the next page		200 ml 100 100 100	✓ Zarontin ✓ <u>Nupentin</u> ✓ <u>Nupentin</u>
GABAPENTIN Note: Not subsidised in combination with subsidised preg  # Cap 100 mg  Cap 300 mg  * Cap 400 mg  LACOSAMIDE – Special Authority see SA2267 on the next pa		200 ml  100 100 100 acy	✓ Zarontin  ✓ Nupentin ✓ Nupentin ✓ Nupentin
GABAPENTIN Note: Not subsidised in combination with subsidised preg  * Cap 100 mg  * Cap 300 mg  * Cap 400 mg  LACOSAMIDE – Special Authority see SA2267 on the next page		200 ml  100 100 100 acy 14	✓ Zarontin  ✓ Nupentin ✓ Nupentin ✓ Nupentin ✓ Vimpat
GABAPENTIN Note: Not subsidised in combination with subsidised preg  # Cap 100 mg  Cap 300 mg  * Cap 400 mg  LACOSAMIDE – Special Authority see SA2267 on the next pa	abalin	200 ml  100 100 100 acy 14 14	✓ Zarontin  ✓ Nupentin ✓ Nupentin ✓ Nupentin ✓ Vimpat ✓ Vimpat
GABAPENTIN Note: Not subsidised in combination with subsidised preg  # Cap 100 mg	abalin	200 ml  100 100 100 acy 14 14 56	✓ Zarontin  ✓ Nupentin ✓ Nupentin ✓ Nupentin ✓ Vimpat ✓ Vimpat ✓ Vimpat ✓ Vimpat

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

# **⇒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.

LAMOTRIGINE			
▲ Tab dispersible 2 mg	55.00	30	✓ Lamictal
▲ Tab dispersible 5 mg	50.00	30	✓ Lamictal
* Tab dispersible 25 mg	4.20	56	✓ Logem
* Tab dispersible 50 mg		56	✓ Logem
* Tab dispersible 100 mg	6.75	56	✓ Logem
LEVETIRACETAM			
Tab 250 mg	5.84	60	✓ Everet
Tab 500 mg	10.51	60	✓ Everet
Tab 750 mg	16.71	60	✓ Everet
Tab 1,000 mg	21.82	60	✓ Everet
Oral liq 100 mg per ml	44.78	300 ml OP	✓ Levetiracetam-AFT
Inj 100 mg per ml, 5 ml vial	38.95	10	<ul><li>Levetiracetam-AFT</li></ul>
PHENOBARBITONE			
For phenobarbitone oral liquid refer Standard Formulae,	page 276		
Tab 15 mg	248.50	500	✓ Noumed
			<u>Phenobarbitone</u>
Tab 30 mg	398.50	500	✓ Noumed
•			Phenobarbitone
PHENYTOIN SODIUM			
* Tab 50 mg	75.00	200	✓ Dilantin Infatab
Cap 30 mg		200	✓ Dilantin
Cap 100 mg	37.00	200	✓ Dilantin
* Oral liq 30 mg per 5 ml	22.03	500 ml	✓ Dilantin Paediatric
PREGABALIN			
Note: Not subsidised in combination with subsidised ga	bapentin		
* Cap 25 mg	•	56	✓ Pregabalin Pfizer
3	7.80		✓ Milpharm S29
* Cap 75 mg		56	✓ Pregabalin Pfizer
·	8.10		✓ Milpharm \$29
* Cap 150 mg		56	✓ Lyrica
The Coup 100 mg		00	✓ Pregabalin Pfizer
* Cap 300 mg	7.38	56	✓ Pregabalin Pfizer
PRIMIDONE			
* Tab 250 mg	37 35	100	✓ Primidone Clinect
* 1 au 200 mg		100	· Fillingone Chilect

Subsidy		Fully	Brand or
(Manufacturer's Price	e) Su	bsidised	Generic
\$	Per	/	Manufacturer
13.65	100	✓ E	pilim Crushable
27.44	100	✓ E	pilim
52.24	100	✓ E	pilim
20.48	300 ml	✓ E	pilim S/F Liquid
		✓ E	pilim Syrup
41.50	1	<b>√</b> E	pilim IV
- Retail pharmacy			
509.29	60	✓ D	iacomit
509.29	60	✓ D	iacomit
	(Manufacturer's Price \$	(Manufacturer's Price) Su Per Su Per Su Su Per Su Su Per Su Su Per Su	(Manufacturer's Price) Subsidised Per ✓ 13.65 100 ✓ E27.44 100 ✓ E52.24 100 ✓ E20.48 300 ml ✓ E41.50 1 ✓ E - Retail pharmacy509.29 60 ✓ D

### ⇒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.

## **TOPIRAMATE**

▲ Tab 25 mg	11.07	60	<ul><li>Arrow-Topiramate</li></ul>
			✓ Topiramate Actavis
	26.04		✓ Topamax
▲ Tab 50 mg	18.81	60	✓ Arrow-Topiramate
· ·			✓ Topiramate Actavis
	44.26		✓ Topamax
▲ Tab 100 mg	31.99	60	✓ Arrow-Topiramate
•			✓ Topiramate Actavis
	75.25		✓ Topamax
▲ Tab 200 mg	55.19	60	✓ Arrow-Topiramate
			✓ Topiramate Actavis
	129.85		✓ Topamax
▲ Sprinkle cap 15 mg	20.84	60	✓ Topamax
▲ Sprinkle cap 25 mg		60	✓ Topamax
VIGABATRIN - Special Authority see SA2088 below - Retai	pharmacy		
▲ Tab 500 mg		100	✓ Sabril
▲ Powder for oral soln 500 mg per sachet		60	✓ 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:



continued...

- 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 115

### **Acute Migraine Treatment**

Tab orodispersible 10 mg4	1.84	30	Rizamelt
SUMATRIPTAN			
Tab 50 mg14	.41	90	Sumagran
Tab 100 mg22	2.68	90	Sumagran
Inj 12 mg per ml, 0.5 ml prefilled pen - Maximum of 10 inj per			-
prescription29	9.80 2	OP ✓	Clustran

# **Prophylaxis of Migraine**

For Beta Adrenoceptor Blockers refer to CARDIOVASCULAR SYSTEM, page 47

PIZOTIFFN

**★** Tab 500 mcg......23.21 100 **✓ Sandomigran** 

# **Antinausea and Vertigo Agents**

For Antispasmodics refer to ALIMENTARY TRACT, page 8

APREPITANT - Special Authority see SA0987 below - Retail pharmacy

#### ⇒SA0987 Special Authority for Subsidy

**Initial application** from any relevant practitioner. Approvals valid for 12 months where the patient is undergoing highly emetogenic chemotherapy and/or anthracycline-based chemotherapy for the treatment of malignancy.

**Renewal** from any relevant practitioner. Approvals valid for 12 months where the patient is undergoing highly emetogenic chemotherapy and/or anthracycline-based chemotherapy for the treatment of malignancy.

BETAHISTINE DIHYDROCHLORIDE

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
CYCLIZINE HYDROCHLORIDE Tab 50 mg	0.66	10	✓	<u>Nausicalm</u>
Inj 50 mg per ml, 1 ml ampoule – Up to 10 inj available on a	16.36	10	✓	<u>Hameln</u>
DOMPERIDONE  * Tab 10 mg	4.00	100	✓	<u>Domperidone</u> Viatris
HYOSCINE HYDROBROMIDE				
* Inj 400 mcg per ml, 1 ml ampoule	93.00	10	✓	Martindale S29
below – Retail pharmacy	88.50	10	•	Scopolamine Transdermal System 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.

METOCLOPRAMIDE HYDROCHLORIDE			
* Tab 10 mg - Up to 30 tab available on a PSO	1.57	100	✓ Metoclopramide Actavis 10
* Inj 5 mg per ml, 2 ml ampoule - Up to 5 inj available on a PSC	7.00	10	✓ Baxter
ONDANSETRON			
* Tab 4 mg	2.27	50	✓ Periset
Tab disp 4 mg - Up to 10 tab available on a PSO	0.56	10	✓ Periset ODT
* Tab 8 mg	4.10	50	✓ Periset
Tab disp 8 mg - Up to 10 tab available on a PSO	0.90	10	✓ Periset ODT
PROCHLORPERAZINE			
* Tab 3 mg buccal	5.97	50	
	(30.00)		Buccastem
	(30.00)		Max Health \$29
	(30.00)		Prochlorperazine
	, ,		Brown & Burk S29
	(30.00)		Prochlorperazine Max Health
* 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
(Buccastem Tab 3 mg buccal to be delisted 1 July 2025)			
(Max Health \$29 Tab 3 mg buccal to be delisted 1 July 2025)			
( 10 and 1			

(Prochlorperazine Brown & Burk S29 Tab 3 mg buccal to be delisted 1 July 2025)

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

Subsidy (Manufacturer's Price)

Fully Subsidised Per

Brand or Generic Manufacturer

# **Antipsychotics**

# General

AMISULPRIDE - Safety medicine; prescriber may determine dis			
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 di	snensina frequer	ncv	<del></del>
Tab 5 mg		30	✓ Aripiprazole Sandoz
1 ab 5 mg	10.50	00	✓ Ampiprazole dandoz
			Aripiprazole S29
Tab 10 mg	10.50	30	✓ Aripiprazole Sandoz
ŭ			
Tab 15 mg		30	✓ Aripiprazole Sandoz
Tab 20 mg		30	✓ Aripiprazole Sandoz
Tab 30 mg	10.50	30	<ul> <li>Aripiprazole Sandoz</li> </ul>
(Ascend Aripiprazole S29 Tab 5 mg to be delisted 1 July 2025)			
CHLORPROMAZINE HYDROCHLORIDE - Safety medicine; pre	scriber may dete	ermine dispen	sing frequency
Tab 25 mg - Up to 30 tab available on a PSO		100	✓ Largactil
Tab 100 mg - Up to 30 tab available on a PSO		100	✓ Largactil
Inj 25 mg per ml, 2 ml – Up to 5 inj available on a PSO		10	✓ Largactil
		10	Largaotti
CLOZAPINE – Hospital pharmacy [HP4]			
Safety medicine; prescriber may determine dispensing frequency	•		
Tab 25 mg	6.69	50	✓ Clopine
			✓ Clozaril
	13.37	100	Clopine
			<ul><li>Clozaril</li></ul>
Tab 50 mg	8.67	50	<ul><li>Clopine</li></ul>
	17.33	100	✓ Clopine
Tab 100 mg	17.33	50	✓ Clopine
-			✓ Clozaril
	34.65	100	✓ Clopine
			✓ Clozaril
Tab 200 mg	34.65	50	✓ Clopine
ŭ	69.30	100	✓ Clopine
Suspension 50 mg per ml	147.30	100 ml	✓ Versacloz
HALOPERIDOL – Safety medicine; prescriber may determine dis		1011	
Tab 500 mcg — Up to 30 tab available on a PSO		100	✓ Serenace
Tab 1.5 mg – Up to 30 tab available on a PSO		100	✓ Serenace
Tab 5 mg - Up to 30 tab available on a PSO		50	✓ Serenace
0 11 0 11 1 200 1 11 11 200	29.72	100	✓ Serenace
Oral liq 2 mg per ml — Up to 200 ml available on a PSO		100 ml	✓ Serenace
Inj 5 mg per ml, 1 ml ampoule – Up to 5 inj available on a PS	O21.55	10	✓ Serenace
LEVOMEPROMAZINE - Safety medicine; prescriber may detern	nine dispensing f	requency	
Tab 25 mg (33.8 mg as a maleate)		100	✓ Nozinan (Swiss)
Tab 25 mg as a maleate		100	✓ Nozinan `
Tab 100 mg (135 mg as a maleate)		100	✓ Nozinan (Swiss)
Tab 100 mg as a maleate		100	✓ Nozinan
		100	· · · · · · · · · · · · · · · · · · · ·

	Subsidy		Fully	
	(Manufacturer's Price)	Subs Per	idised •	I Generic Manufacturer
	\$			
$ LEVOMEPROMAZINE\ HYDROCHLORIDE\ -\ Safety\ medicine;\ \mu \  \   \   \   \   \   \   \ $	orescriber may detern	nine disper	nsing	frequency
Inj 25 mg per ml, 1 ml ampoule	24.48	10	1	Nozinan S29 S29
			1	Wockhardt
(Nozinan S29 S29 Inj 25 mg per ml, 1 ml ampoule to be delisted	d 1 July 2025)			
LITHIUM CARBONATE - Safety medicine; prescriber may dete	• '	Hency		
Tab long-acting 400 mg	, ,	100	1	Priadel
Cap 250 mg		100		Douglas
		100	٠	Douglas
OLANZAPINE – Safety medicine; prescriber may determine disp		00	,	
Tab 2.5 mg		30		Zypine
Tab 5 mg		30		Zypine
Tab orodispersible 5 mg		28	_	Zypine ODT
Tab 10 mg		30	_	Zypine
Tab orodispersible 10 mg	2.89	28	•	Zypine ODT
PERICYAZINE - Safety medicine; prescriber may determine dis	spensing frequency			
Tab 2.5 mg	13.61	100	1	Neulactil
Tab 10 mg	48.45	100	1	Neulactil
QUETIAPINE - Safety medicine; prescriber may determine disp	ensing frequency			
Tab 25 mg	0 1 7	30	1	Quetiapine
- 22 = 5 · · · g				Viatris S29
	2.36	90	./	Quetapel
	13.11	500		Quetaper Quetiapine
	13.11	500	•	•
T 1 400	0.40	00	,	Viatris S29
Tab 100 mg		90		Quetapel
Tab 200 mg		90		Quetapel
Tab 300 mg	15.83	90	•	Quetapel
RISPERIDONE - Safety medicine; prescriber may determine dis	spensing frequency			
Tab 0.5 mg	0.72	20		Risperdal
	2.17	60	/	Risperidone (Teva)
	4.01		/	Risperidone
				Sandoz S29
Tab 1 mg	2.44	60	1	Risperdal
y				Risperidone (Teva)
	3.68			Risperidone
				Sandoz S29
Tab 2 mg	2 72	60	1	Risperdal
Tab 2 mg		00		Risperidone (Teva)
	5.38			Risperidone
	3.30		•	•
T. I. O.	4.50	00	,	Sandoz S29
Tab 3 mg	4.50	60		Risperdal
	0.55			Risperidone (Teva)
	8.57		•	Risperidone
				Sandoz S29
Tab 4 mg	6.25	60		Risperdal
				Risperidone (Teva)
Oral liq 1 mg per ml	10.29	30 ml	/	Risperon

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Generic
ZIPRASIDONE - Safety medicine; prescriber may determine of	dispensing frequency			
Cap 20 mg	17.90	60	✓	Zusdone
Cap 40 mg	27.41	60	✓	Zusdone
Cap 60 mg	38.39	60	✓	Zusdone
Cap 80 mg	46.55	60	1	Zusdone
ZUCLOPENTHIXOL HYDROCHLORIDE - Safety medicine; p	rescriber may determin	e disp	ensing fre	equency
Tab 10 mg	•	100	•	Clopixol
Depot Injections				
ARIPIPRAZOLE – Special Authority see SA2395 below – Reta	ail pharmacy			

# **⇒SA2395** Special Authority for Subsidy

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

#### Fither:

- 1 Fither:
  - 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 dis	pensing frequ	iency
Inj 20 mg per ml, 1 ml - Up to 5 inj available on a PSO	5	✓ Fluanxol
Inj 20 mg per ml, 2 ml - Up to 5 inj available on a PSO20.90	5	✓ Fluanxol
Inj 100 mg per ml, 1 ml - Up to 5 inj available on a PSO40.87	5	✓ Fluanxol
HALOPERIDOL DECANOATE - Safety medicine; prescriber may determine disp	ensing freque	ency
Inj 50 mg per ml, 1 ml - Up to 5 inj available on a PSO28.39	5	✓ Haldol
Inj 100 mg per ml, 1 ml - Up to 5 inj available on a PSO55.90	5	Haldol Concentrate
		✓ Haldol
		Decanoas S29

	Subsidy		Fully	Brand or
	(Manufacturer's Price)	Sı	ıbsidised	Generic
	\$	Per	•	Manufacturer
OLANZAPINE - Special Authority see SA2313 below - Retail p	harmacy			
a) Safety medicine; prescriber may determine dispensing f	requency			
b) Note – no new patients to be initiated on olanzapine.				
Inj 210 mg vial	252.00	1	✓ Zy	prexa Relprevv
Inj 300 mg vial	414.00	1	✓ Zy	prexa Relprevv
Inj 405 mg vial	504.00	1	✓ Zy	prexa Relprevv

### ⇒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 below - Retail pharmacy

Safety medicine; prescriber may determine dispensing frequency	
Inj 25 mg syringe194.25	✓ Invega Sustenna
Inj 50 mg syringe271.95	✓ Invega Sustenna
Inj 75 mg syringe357.42 1	✓ Invega Sustenna
Inj 100 mg syringe	✓ Invega Sustenna
Inj 150 mg syringe435.12	✓ Invega Sustenna

# ⇒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 aripiprazole 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 Authority see SA2167 below - Retail pharmacy

Inj 175 mg syringe815.85	1 •	✓ Invega Trinza
Inj 263 mg syringe	1 •	✓ Invega Trinza
Inj 350 mg syringe	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 on the next page - Retail pharmacy

Safety medicine; prescriber may determine dispensing	frequency		
Inj 25 mg vial	135.98	1	Risperdal Consta
Inj 37.5 mg vial	178.71	1	✓ Risperdal Consta
Inj 50 mg vial	217.56	1	✓ Risperdal Consta
, ,			•



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

# **⇒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 aripiprazole 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.......19.80 5 Clopixol

# Anxiolytics

BUSPIRONE HYDROCHLORIDE			
* Tab 5 mg	13.95	100	<ul><li>Buspirone Viatris</li></ul>
* Tab 10 mg	12.50	100	Buspirone Viatris
CLONAZEPAM - Safety medicine; prescriber may determi	ne dispensing frequency	,	
Tab 500 mcg	5.64	100	✓ Paxam
Tab 2 mg	10.78	100	✓ Paxam
DIAZEPAM - Safety medicine; prescriber may determine d	ispensing frequency		
Tab 2 mg	95.00	500	✓ Arrow-Diazepam
Tab 5 mg	115.00	500	✓ Arrow-Diazepam
LORAZEPAM - Safety medicine; prescriber may determine	e dispensing frequency		
Tab 1 mg	10.20	250	✓ Ativan
Tab 2.5 mg	13.13	100	✓ Ativan

# **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

		NER	VOUS SYSTEM
Subsidy (Manufacturer's Price) \$		Fully	Brand or Generic Manufacturer
continued			
not necessarily have been seen by them during the attack, but the that the clinical features were characteristic); and  1.4.2 Each significant attack is associated with characteristic new symptor of previously experienced symptoms(s)/sign(s); and  1.4.3 Each significant attack has lasted at least one week and has started previous attack (where relevant); and  1.4.4 Each significant attack can be distinguished from the effects of gen fever (T > 37.5°C); and  1.4.5 Either:	om(s)/sig	n(s) o	r substantially worsening month after the onset of a
1.4.5.1 Each significant attack is severe enough to change either the	EDSS (	or at le	ast 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 seizures/spasms, trigeminal neuralgia, Lhermitte's symptom)	f multiple ; and	e scler	
<ul><li>1.5 Evidence of new inflammatory activity on an MRI scan within the past 24 n</li><li>1.6 Any of the following:</li></ul>	nonths; a	and	
1.6.1 A sign of that new inflammatory activity on MRI scanning (in criteric enhancing lesion; or	n 5 imm	ediate	ly above) is a gadolinium
<ul> <li>1.6.2 A sign of that new inflammatory activity is a lesion showing diffusion</li> <li>1.6.3 A sign of that new inflammatory is a T2 lesion with associated local</li> <li>1.6.4 A sign of that new inflammatory activity is a prominent T2 lesion that features of a recent attack that occurred within the last 2 years; or</li> <li>1.6.5 A sign of that new inflammatory activity is new T2 lesions compared</li> </ul>	swelling at clearly	; or is res	ponsible for the clinical
2 Patient has an active approval for ocrelizumab and does not have primary progres	ssive MS	<b>S</b> .	
Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is r Renewal — (Multiple Sclerosis - dimethyl fumarate, fingolimod, glatiramer acetate, beta-1-beta, natalizumab and teriflunomide) from any relevant practitioner. Approvals had an EDSS score of 0 to 6.0 (inclusive) with or without the use of unilateral or bilateral 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 r	interferes s valid for aids at a	on bet or 12 m iny tim	onths where patient has
DIMETHYL FUMARATE - Special Authority see SA2274 on the previous page - Retail	oharmac	y	
3	ously is n 4 6	✓ T	mitted. ecfidera ecfidera
FINGOLIMOD – Special Authority see SA2274 on the previous page – Retail pharmacy a) Wastage claimable b) Note: Treatment on two or more funded multiple sclerosis treatments simultaneous		ot peri	
GLATIRAMER ACETATE – Special Authority see SA2274 on the previous page – Retail Note: Treatment on two or more funded multiple sclerosis treatments simultaneously Inj 40 mg prefilled syringe		ermitt	ed. Copaxone
INTERFERON BETA-1-ALPHA – Special Authority see SA2274 on the previous page –  Note: Treatment on two or more funded multiple sclerosis treatments simultaneously			

INTERFERON BETA-1-BETA – Special Authority see SA2274 on the previous page – Retail pharmacy Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

139

✓ Avonex
✓ Avonex Pen

✓ Betaferon

4

4

15

(Avonex Pen Injection 6 million iu per 0.5 ml pen injector to be delisted 1 September 2025)

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



Subsidy (Manufacturer's Price)

Fully Subsidised Brand or Generic Manufacturer

NATALIZUMAB - Special Authority see SA2274 on page 138 - Retail pharmacy

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

✓ Tvsabri

TERIFLUNOMIDE - Special Authority see SA2274 on page 138 - Retail pharmacy

- a) Brand switch fee payable (Pharmacode 2701847) see page 274 for details
- b) Wastage claimable
- c) Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

✓ Teriflunomide

Sandoz

# Multiple Sclerosis Treatments - Other

OCRELIZUMAB - Special Authority see SA2273 below - Retail pharmacy

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

✓ Ocrevus

## ⇒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

## **NERVOUS SYSTEM**

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

continued...

- 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
- 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).

# **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.

### **NERVOUS SYSTEM**

	Subsidy (Manufacturer's Price)	Per	Fully Subsidised	Generic
MIDAZOLAM – Safety medicine; prescriber may determine dispe Inj 1 mg per ml, 5 ml ampoule	7.80	10	•	Midazolam-Baxter
on a PSO	29.90	10 epilep		Pfizer only.
Inj 5 mg per ml, 1 ml plastic ampoule – Up to 10 inj available on a PSO  On a PSO for status epilepticus use only. PSO must be Inj 5 mg per ml, 3 ml ampoule	22.50 endorsed for status e	10 epilep 5	oticus use	Midazolam-Pfizer only. Midazolam-Baxter
Inj 5 mg per ml, 3 ml plastic ampoule — Up to 5 inj available a PSO On a PSO for status epilepticus use only. PSO must be	22.50 endorsed for status e			Pfizer only.
PHENOBARBITONE SODIUM – Special Authority see SA1386 b		acy 10	•	Max Health S29
■ SA1386   Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid the following criteria: Both:  1 For the treatment of terminal agitation that is unresponsive	to other agents; and		ınless notif	ied for applications meeting
The applicant is part of a multidisciplinary team working in  TEMAZEPAM – Safety medicine; prescriber may determine dispertite to 10 mg	ensing frequency	25	•	Normison
ZOPICLONE – Safety medicine; prescriber may determine dispertab 7.5 mg		500	1	Zopiclone Actavis

# **Spinal Muscular Atrophy**

#### ⇒SA2174 Special Authority for Subsidy

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

All of the following:

- 1 Patient has genetic documentation of homozygous SMN1 gene deletion, homozygous SMN1 point mutation, or compound heterozygous mutation; and
- 2 Patient is 18 years of age or under; and
- 3 Either:
  - 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 nusinersen; and
- 3 Nusinersen not to be administered in combination other SMA disease modifying treatments or gene therapy.

### NERVOUS SYSTEM

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

RISDIPLAM - [Xpharm] - Special Authority see \$A2203 below

Note: the supply of risdiplam is via Pharmac's approved direct distribution supply. Further details can be found on Pharmac's website https://pharmac.govt.nz/risdiplam

Powder for oral soln 750 mcg per ml, 60 mg per bottle......14,100.00 80 ml OP ✓ Evrysdi

#### ⇒SA2203 Special Authority for Subsidy

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

#### All of the following:

- 1 Patient has genetic documentation of homozygous SMN1 gene deletion, homozygous SMN1 point mutation, or compound heterozygous mutation; and
- 2 Patient is 18 years of age or under; and
- 3 Fither:
  - 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	43.02	28	✓ APO-Atomoxetine
Cap 18 mg	45.57	28	✓ APO-Atomoxetine
Cap 25 mg	44.30	28	✓ APO-Atomoxetine
Cap 40 mg	46.21	28	✓ APO-Atomoxetine
Cap 60 mg	51.31	28	<b>✓</b> APO-Atomoxetine
Cap 80 mg	65.20	28	<b>✓</b> APO-Atomoxetine
Cap 100 mg	65.71	28	✓ APO-Atomoxetine
DEXAMFETAMINE SULFATE – Special Authority see SA2410 below – a) Only on a controlled drug form b) Safety medicine; prescriber may determine dispensing frequence	·	acy	
Tab 5 mg	29.80	100	Noumed Dexamfetamine

#### ⇒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 Fither:
  - 3.1 Applicant is a paediatrician or psychiatrist; or



Subsidy	/ Ful	y Brand or
(Manufacturer	s Price) Subsidise	d Generic
\$	Per •	Manufacturer

continued...

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.

LISDEXAMFETAMINE DIMESILATE - Special Authority see SA2415 below - Retail pharmacy

- a) Only on a controlled drug form
- b) Safety medicine; prescriber may determine dispensing frequency

Cap 30 mg - No more than 1 cap per day	60.00	30	✓ Vyvanse
Cap 50 mg	60.00	30	✓ Vyvanse
Cap 70 mg	60.00	30	✓ Vyvanse

### ⇒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:

Either:

- 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
    - 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.

Brand or

Fully

	Gubbiay		i uny	Diana oi
	(Manufacturer's Price)		Subsidised	Generic
	\$	Per		Manufacturer
METHYLPHENIDATE HYDROCHLORIDE - Special Authority	see SA2411 below – R	etail	pharmacy	
a) Only on a controlled drug form				
b) Safety medicine; prescriber may determine dispensing f	requency			
Tab immediate-release 5 mg	3.20	30	1	Rubifen
Tab immediate-release 10 mg	3.00	30	1	Rubifen
	4.00		✓	Ritalin
Tab extended-release 18 mg	7.75	30	1	Methylphenidate ER
				- Teva
Tab immediate-release 20 mg	7.85	30	✓	Rubifen
Tab sustained-release 20 mg	10.95	30	✓	Rubifen SR
Tab extended-release 27 mg		30	✓	Methylphenidate ER
•				- Teva
Tab extended-release 36 mg	15.50	30	1	Methylphenidate ER
ů				- Teva
Tab extended-release 54 mg	22 25	30	1	Methylphenidate ER
Tab Oxforded Fordage of Frig		50	•	- Teva

Subsidy

#### ⇒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
- b) Safety medicine: prescriber may determine dispensing frequency

Tab extended-release 18 mg	58.96	30	Concerta
Tab extended-release 27 mg	65.44	30	<ul><li>Concerta</li></ul>
Tab extended-release 36 mg	71.93	30	Concerta
Tab extended-release 54 mg		30	<ul><li>Concerta</li></ul>
Cap modified-release 10 mg		30	Ritalin LA
Cap modified-release 20 mg		30	✓ Ritalin LA
Cap modified-release 30 mg		30	✓ Ritalin LA
Cap modified-release 40 mg		30	✓ Ritalin LA



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

Fither:

- 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 Fither:
    - 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 274 for details

Tab 100 mg .......14.27

30

✓ Modafinil Max Health

### **⇒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

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

continued...

- 1.3.2 Methylphenidate and dexamfetamine are contraindicated; or
- 2 Both:
  - 2.1 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	✓ Ipca-Donepezil
* Tab 10 mg	5.50	84	✓ Ipca-Donepezil
RIVASTIGMINE - Special Authority see SA1488 below	- Retail pharmacy		
Patch 4.6 mg per 24 hour	49.40	30	✓ Rivastigmine Patch BNM 5
	90.00		✓ Exelon Patch 5
Patch 9.5 mg per 24 hour	49.40	30	✓ Rivastigmine Patch BNM 10
	90.00		✓ Exelon Patch 10

(Exelon Patch 5 Patch 4.6 mg per 24 hour to be delisted 1 June 2025) (Exelon Patch 10 Patch 9.5 mg per 24 hour to be delisted 1 June 2025)

#### ⇒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

- a) No patient co-payment payable
- b) Safety medicine: prescriber may determine dispensing frequency

Tab sublingual 2 mg with naloxone 0.5 mg	11.76	28	✓ <u>Buprenorphine</u> Naloxone BNM
Tab sublingual 8 mg with naloxone 2 mg	34.00	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



Subsid (Manufacturer		ully Brand or sed Generic	
\$	Per	✓ Manufactur	er

continued...

- 2 Patient is currently engaged with an opioid treatment service approved by the Ministry of Health; and
- 3 Applicant works in an opioid treatment service approved by the Ministry of Health..

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

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

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

BUPROPION HYDROCHLORIDE Tab modified-release 150 mg15.00	30	✓ <u>Zyban</u>
DISULFIRAM		
Tab 200 mg236.40	100	✓ Antabuse
NALTREXONE HYDROCHLORIDE - Special Authority see SA1408 on the r	next page – Retail pl	harmacy
Tab 50 mg77.77	28	✓ Naltrexone AOP S29
83.33	30	✓ Naltraccord
102.60	)	✓ Naltrexone Max Health \$29
138.88	3 50	✓ Revia S29
(Revia S29 Tab 50 mg to be delisted 1 July 2025)		

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

### **⇒SA1408** Special Authority for Subsidy

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

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

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

- 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 Provisions in Provisions in Provision by a pharmacist permitted under the provisions in Provision by a pharmacist permitted under the provisions in Provision by a pharmacist permitted under the provisions in Provision by a pharmacist permitted under the provision by a pharmacist permitted under the provision by a pharmacist permitted under the provisions in Provision by a pharmacist permitted under the	art I of Sect	ion A.
Patch 7 mg - Up to 28 patch available on a PSO19.62	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 PSO24.72	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	Habitrol
Gum 2 mg (Fruit) for direct distribution only - [Xpharm]17.57	96	Habitrol
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>

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	16.67	53 OP	Champix
Tab 1 mg	17.62	56	✓ Champix

#### ⇒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,

### **NERVOUS SYSTEM**

Subsidy (Manufacturer's Price)	Fu Subsidis	ılly	Brand or Generic
 \$	Per	<b>✓</b>	Manufacturer

continued...

which includes prescriber or nurse monitoring; and

- 3 Fither
  - 3.1 The patient has tried but failed to quit smoking after at least two separate trials of nicotine replacement therapy, at least one of which included the patient receiving comprehensive advice on the optimal use of nicotine replacement therapy; or
  - 3.2 The patient has tried but failed to guit smoking using bupropion or nortriptyline; and
- 4 The patient has not had a Special Authority for varenicline approved in the last 6 months; and
- 5 Varenicline is not to be used in combination with other pharmacological smoking cessation treatments and the patient has agreed to this; and
- 6 The patient is not pregnant; and
- 7 The patient will not be prescribed more than 12 weeks' funded varenicline (see note).

Renewal from any relevant practitioner. Approvals valid for 5 months for applications meeting the following criteria: All of the following:

- 1 Short-term therapy as an aid to achieving abstinence in a patient who has indicated that they are ready to cease smoking; and
- 2 The patient is part of, or is about to enrol in, a comprehensive support and counselling smoking cessation programme, which includes prescriber or nurse monitoring; and
- 3 It has been 6 months since the patient's previous Special Authority was approved; and
- 4 Varenicline is not to be used in combination with other pharmacological smoking cessation treatments and the patient has agreed to this; and
- 5 The patient is not pregnant; and
- 6 The patient will not be prescribed more than 12 weeks' funded varenicline (see note).

The patient must not have had an approval in the past 6 months.

Notes: a maximum of 12 weeks' varenicline will be subsidised on each Special Authority approval.

This includes the 4-week 'starter' pack.

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

# **Chemotherapeutic Agents**

### Alkylating Agents

BENDAMUSTINE HYDROCHLORIDE - PCT only - Specialis	st - Special Authority	/ see SA2398	B below
Inj 25 mg vial	50.05	1	<ul><li>Bendamustine Sandoz</li></ul>
	77.00		✓ Ribomustin
Inj 100 mg vial	200.20	1	✓ Bendamustine Sandoz
	308.00		✓ Ribomustin
Inj 1 mg for ECP	2.11	1 mg	✓ Baxter

### ⇒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/m² 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

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.

BUSINE FAN - PCT - Botail pharmacy-Specialist

Tab 2 mg	89.25	100	✓ Myleran
CARBOPLATIN – PCT only – Specialist			,
Inj 10 mg per ml, 45 ml vial	25.73	1	✓ Carboplatin Accord ✓ DBL Carboplatin S29 S29
	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	710.00	1	✓ BiCNU
, ,			✓ BiCNU S29 S29
			✓ Novadoz S29
Inj 100 mg for ECP	710.00	100 mg OP	✓ Baxter
(BiCNU S29 S29 Inj 100 mg vial to be delisted 1 July 2025)		3 ·	
(Novadoz S29 Inj 100 mg vial to be delisted 1 July 2025)			
, , ,			
CHLORAMBUCIL – PCT – Retail pharmacy-Specialist Tab 2 mg	20.06	25	✓ Leukeran FC
-	29.00	23	Leukeraniio
CISPLATIN – PCT only – Specialist	0.45		40: 1:: 4
Inj 1 mg per ml, 50 ml vial		1	✓ Cisplatin Accord
	15.00		Cisplatin Ebewe
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		DBL Cisplatin
Inj 1 mg for ECP	0.19	1 mg	✓ Baxter

	Subsidy		Fully	
(1)	Manufacturer's Price) \$	Per	Subsidised	
	Ψ	rei		Manuacturer
CYCLOPHOSPHAMIDE	445.00		,	0
Tab 50 mg - PCT - Retail pharmacy-Specialist		50		Cyclonex
Inj 1 g vial – PCT – Retail pharmacy-Specialist		1		Endoxan
Inj 2 g vial - PCT only - Specialist	127.80	6 1		Cytoxan
Inj 1 mg for ECP - PCT only - Specialist		•	_	Endoxan Baxter
, ,	0.05	1 mg	•	Daxiei
FOSFAMIDE - PCT only - Specialist				
Inj 1 g		1		Holoxan
Inj 2 g		_1	_	Holoxan
Inj 1 mg for ECP	0.10	1 mg	•	Baxter
OMUSTINE - PCT - Retail pharmacy-Specialist				
Cap 40 mg	880.00	20	✓	Medac \$29
1ELPHALAN				
Tab 2 mg - PCT - Retail pharmacy-Specialist	40.70	25	1	Alkeran
Inj 50 mg - PCT only - Specialist		1	1	Megval S29
inj do mg i o i omy opecialist	40.20	'		Melpha
	67.80			Alkeran
Megval \$29 Inj 50 mg to be delisted 1 July 2025)	07.00			7 intorum
XALIPLATIN – PCT only – Specialist	05.04		,	Overlie Letter A et evile
Inj 100 mg vial	25.01	1		Oxaliplatin Actavis 100
	110.00			Oxaliplatin Ebewe
Inj 5 mg per ml, 20 ml vial		1		Alchemy Oxaliplatin
	46.32			Oxaliplatin Accord
Inj 1 mg for ECP	0.35	1 mg	/	Baxter
HIOTEPA - PCT only - Specialist				
Inj 15 mg vial	CBS	1	1	Bedford S29
. •			1	Max Health S29
				THIO-TEPA S29
	398.00			Tepadina
Inj 100 mg vial		1		Max Health S29
ing 100 mg viai	1,800.00	'		Tepadina
	1,000.00		•	Торишти
Antimetabolites				
ZACITIDINE - PCT only - Specialist - Special Authority see SA2	479 below			
Inj 100 mg vial		1	•	Azacitidine Dr Reddy's
Inj 1 mg for ECP	0.54	1 mg	ſ	Baxter
IIIJ I IIIY IVI LOF	0.04	i iiig	•	Davici

### ⇒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.

	Subsidy		Fully	Brand or
	(Manufacturer's Price	)	Subsidised	I Generic
	\$	Per		Manufacturer
CALCIUM FOLINATE			_	
Tab 15 mg - PCT - Retail pharmacy-Specialist	135.33	10	•	DBL Leucovorin Calcium
Inj 3 mg per ml, 1 ml - PCT - Retail pharmacy-Specialist		5		Hospira
Inj 10 mg per ml, 5 ml vial – PCT – Retail pharmacy-Special	ist7.28	1	•	Calcium Folinate Sandoz
			•	Calcium Folinate Sandoz S29 S29
	112.20	5	✓	Eurofolic S29
Inj 50 mg - PCT - Retail pharmacy-Specialist	72.80	10	✓	Leucovorin
				Pharmacia S29
Inj 10 mg per ml, 10 ml vial - PCT only - Specialist	9.49	1	•	Calcium Folinate Sandoz
	163.35	5	1	Eurofolic S29
Inj 100 mg - PCT only - Specialist	7.33	1	•	Calcium Folinate Ebewe
	94.90	10	•	Leucovorin Pharmacia S29
Inj 300 mg - PCT only - Specialist	21.55	1	•	Leucovorin DBL §29
	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 829
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	•	Calcium Folinate Sandoz
	139.48		1	Eurofolic S29
Inj 1 mg for ECP - PCT only - Specialist	0.14	1 mg	•	Baxter
(Calcium Folinate Sandoz Inj 10 mg per ml, 5 ml vial to be deliste (Calcium Folinate Sandoz S29 S29 Inj 10 mg per ml, 5 ml vial to (Calcium Folinate Sandoz Inj 10 mg per ml, 10 ml vial to be delist	be delisted 1 Nove	mber 2	2025)	
(Calcium Folinate Ebewe Inj 100 mg to be delisted 1 November 2 (Calcium Folinate Ebewe Inj 300 mg to be delisted 1 November 2	2025)			
(Calcium Folinate Sandoz Inj 10 mg per ml, 35 ml vial to be delist		,		
(Calcium Folinate Sandoz S29 S29 Inj 10 mg per ml, 35 ml vial to (Calcium Folinate Ebewe Inj 1 g to be delisted 1 November 2025)	)		2025)	
(Calcium Folinate Sandoz Inj 10 mg per ml, 100 ml vial to be delis	sieu i November 20	123)		
CAPECITABINE – Retail pharmacy-Specialist	0.00	00		Canaditahira Vistria
Tab 150 mg Tab 500 mg		60 120		Capecitabine Viatris Capecitabine Viatris
5		120	•	Superitability Viatilis
CLADRIBINE – PCT only – Specialist Inj 1 mg per ml, 10 ml	749 96	1	1	Leustatin
Inj 10 mg for ECP		0 mg (		Baxter

	Subsidy		Fully	Brand or
	(Manufacturer's F		idised	Generic
	\$	Per		Manufacturer
CYTARABINE				
Inj 20 mg per ml, 5 ml vial - PCT - Retail pharmacy-Specia	list472.00	5	<b>✓</b> F	Pfizer
Inj 100 mg per ml, 20 ml vial – PCT – Retail				
pharmacy-Specialist	48.80	1	1	Cytarabine DBL
F				Pfizer
			<b>√</b> F	Pfizer S29 S29
Inj 1 mg for ECP - PCT only - Specialist	0.29	10 mg	_	Baxter
Inj 100 mg intrathecal syringe for ECP - PCT only - Specia		100 mg OP		Baxter
FLUDARABINE PHOSPHATE			-	
Tab 10 mg - PCT - Retail pharmacy-Specialist	412.00	20	./ [	Fludara Oral
Inj 50 mg vial – PCT only – Specialist		20 1	_	Fludara Orai Fludarabine
III 50 IIIg viai – POT OIIIy – Specialist	120.00	1	• r	Sagent S29
	634.00	5	<b>.</b> / [	Fludarabine Ebewe
Inj 50 mg for ECP - PCT only - Specialist		50 mg OP	_	Baxter
	120.00	30 mg Oi	٠.	Jaktei
FLUOROURACIL	10.51			
Inj 50 mg per ml, 20 ml vial – PCT only – Specialist		1	_	luorouracil Accord
Inj 50 mg per ml, 50 ml vial – PCT only – Specialist		1	_	luorouracil Accord
Inj 50 mg per ml, 100 ml vial – PCT only – Specialist		1		Fluorouracil Accord
Inj 1 mg for ECP - PCT only - Specialist	0.41	100 mg	• [	Baxter
GEMCITABINE HYDROCHLORIDE – PCT only – Specialist				
Inj 43.3 mg per ml (equivalent to 38 mg per ml gemcitabine).				
26.3 ml vial		1	_	DBL Gemcitabine
Inj 1 g		1	-	Gemcitabine Ebewe
Inj 1 mg for ECP	0.02	1 mg	<b>✓</b> E	Baxter
IRINOTECAN HYDROCHLORIDE - PCT only - Specialist				
Inj 20 mg per ml, 5 ml vial	52.57	1	1	Accord
	71.44		<b>✓</b> I	rinotecan Actavis
				100
	100.00		<b>✓</b> I	rinotecan-Rex
Inj 1 mg for ECP	0.54	1 mg	<b>✓</b> E	Baxter
MERCAPTOPURINE				
Tab 50 mg - PCT - Retail pharmacy-Specialist	25.90	25	<b>✓</b> F	Puri-nethol
Oral suspension 20 mg per ml - Retail pharmacy-Specialist			_	
Special Authority see SA1725 below		100 ml OP	1	Allmercap
, , , , , , , , , , , , , , , , , , , ,				(aluprine 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 (Manufacturer's Price \$	e) Per	Fully Subsidised	
IETHOTREXATE				
Tab 2.5 mg - PCT - Retail pharmacy-Specialist	7.80	90	✓	Trexate
Tab 10 mg - PCT - Retail pharmacy-Specialist		90	_	Trexate
Inj 2.5 mg per ml, 2 ml - PCT - Retail pharmacy-Specialist		5		Methotrexate DBL
Inj 7.5 mg prefilled syringe	29.17	1	_	Methotrexate
, - 3, , 3-				Sandoz
Inj 10 mg prefilled syringe	19.09	1	/	Methotrexate
m, romg promod symgen				Sandoz
Inj 15 mg prefilled syringe	24 53	1	1	Methotrexate
ing to mg promod dyringo		•	-	Sandoz
F Inj 20 mg prefilled syringe	16.64	1	1	Methotrexate
ing 20 mg premied synnige	10.04	'	•	Sandoz
Inj 25 mg prefilled syringe	20.72	1	1	Methotrexate
inj 25 mg premied symige	20.72	'	•	Sandoz
finj 30 mg prefilled syringe	EE 00	1		
r Inj 30 mg premied synnge	55.00	ļ	•	Methotrexate
Ini OF manner and O molysial - DOT - Datail alternation - Occasions	+ 20.00	_		Sandoz Mathatravata DBI
Inj 25 mg per ml, 2 ml vial - PCT - Retail pharmacy-Specialis	it30.00	5	•	Methotrexate DBL
				Onco-Vial
Inj 25 mg per ml, 20 ml vial – PCT – Retail pharmacy-Special	ıst45.00	1	•	DBL Methotrexate
			_	Onco-Vial
Inj 100 mg per ml, 10 ml - PCT - Retail pharmacy-Specialist	25.00	1	/	Methotrexate Ebewe
Inj 100 mg per ml, 50 ml vial - PCT - Retail				
pharmacy-Specialist		1		Methotrexate Ebewe
Inj 1 mg for ECP - PCT only - Specialist		1 mg		Baxter
Inj 5 mg intrathecal syringe for ECP - PCT only - Specialist	4.73	5 mg O	P 🗸	Baxter
EMETREXED - PCT only - Specialist				
Inj 100 mg vial	8.99	1	✓	Pemetrexed-AFT
	60.89		✓	Juno Pemetrexed
Inj 500 mg vial	29.99	1	✓	Pemetrexed-AFT
	217.77		✓	Juno Pemetrexed
Inj 1 mg for ECP	0.11	1 mg	✓	Baxter
HIOGUANINE - PCT - Retail pharmacy-Specialist		_		
Tab 40 mg	126.31	25	1	Lanvis
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	./	Agrylin
Cap 0.5 mg	1,1/3.8/	100	•	Agrylin
RSENIC TRIOXIDE - PCT only - Specialist			_	
Inj 1 mg per ml, 10 ml vial		10		Phenasen
Inj 10 mg for ECP	481.70	10 mg (	)P 🗸	Baxter
LEOMYCIN SULPHATE - PCT only - Specialist				
Inj 15,000 iu, vial	185.16	1	1	DBL Bleomycin Sulfate
Inj 1,000 iu for ECP	1/1 22	1,000 i		Baxter
IIII LANN III IUL EVE	14.J∠	1.000 l	u 🔻	Daxici

	Subsidy		Fully	Brand or
	(Manufacturer's F	Price) Subsi		
	\$	Per	•	Manufacturer
BORTEZOMIB - PCT only - Specialist - Special Authority see	SA2355 below			
Inj 3.5 mg vial		1	1	DBL Bortezomib
Inj 1 mg for ECP	22.26	1 mg	1	Baxter
⇒SA2355 Special Authority for Subsidy				
Initial application — (plasma cell dyscrasia) from any relevar	nt practitioner. A	pprovals valid w	/ithou	ut further renewal unless
notified where the patient has plasma cell dyscrasia, not includin	g Waldenström r	nacroglobulinae	mia,	requiring treatment.
DACARBAZINE - PCT only - Specialist				
Inj 200 mg vial	72.11	1	1	DBL Dacarbazine
Inj 200 mg for ECP	72.11	200 mg OP	1	Baxter
DACTINOMYCIN [ACTINOMYCIN D] - PCT only - Specialist		_		
Inj 0.5 mg vial	255.00	1	1	Cosmegen
Inj 0.5 mg for ECP		0.5 mg OP		Baxter
DAUNORUBICIN - PCT only - Specialist		ŭ		
Inj 2 mg per ml, 10 ml	171.93	1	1	Pfizer
Inj 20 mg for ECP		20 mg OP		Baxter
DOCETAXEL - PCT only - Specialist		3 -		
Inj 20 mg	48 75	1	/	Docetaxel Sandoz
Inj 10 mg per ml, 8 ml vial		i		DBL Docetaxel
Inj 20 mg per ml, 4 ml vial		1		Docetaxel
., F,		•		Accord S29
Inj 80 mg	195.00	1	/	Docetaxel Sandoz
Inj 1 mg for ECP		1 mg	_	Baxter
DOXORUBICIN HYDROCHLORIDE - PCT only - Specialist		9		
Inj 2 mg per ml, 5 ml vial	10.00	1	/	Doxorubicin Ebewe
Inj 2 mg per ml, 25 ml vial		1		Doxorubicin Ebewe
, =, = 0	17.00	•		Arrow-Doxorubicin
Inj 2 mg per ml, 50 ml vial	23.00	1	1	Doxorubicin Ebewe
Inj 2 mg per ml, 100 ml vial	65.00	1	1	Arrow-Doxorubicin
	69.99		1	Doxorubicin Ebewe
Inj 1 mg for ECP	0.35	1 mg	1	Baxter
EPIRUBICIN HYDROCHLORIDE - PCT only - Specialist				
Inj 2 mg per ml, 5 ml vial	25.00	1	1	Epirubicin Ebewe
Inj 2 mg per ml, 25 ml vial		1		Epirubicin Ebewe
Inj 2 mg per ml, 100 ml vial		1		Epirubicin Ebewe
Inj 1 mg for ECP	0.50	1 mg	/	Baxter
ETOPOSIDE				
Cap 50 mg - PCT - Retail pharmacy-Specialist		20		Vepesid
Cap 100 mg - PCT - Retail pharmacy-Specialist		10		Vepesid
Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specia		1		Rex Medical
Inj 1 mg for ECP - PCT only - Specialist	0.09	1 mg	•	Baxter
ETOPOSIDE PHOSPHATE – PCT only – Specialist				
Inj 100 mg (of etoposide base)		. 1		Etopophos
Inj 1 mg (of etoposide base) for ECP		1 mg	•	Baxter
HYDROXYUREA [HYDROXYCARBAMIDE] - PCT - Retail pha	rmacy-Specialist			
Cap 500 mg	20.72	100	/	<u>Devatis</u>
IBRUTINIB - Special Authority see SA2480 on the next page -	Retail pharmacy			
Tab 140 mg		30		Imbruvica
Tab 420 mg	9,652.00	30	1	Imbruvica

<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

### ⇒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	109.74	1	Zavedos
Inj 10 mg vial - PCT only - Specialist	233.64	1	✓ Zavedos
Inj 1 mg for ECP - PCT only - Specialist	25.77	1 mg	✓ Baxter
LENALIDOMIDE (VIATRIS) - Special Authority see SA23	53 below – Retail pharm	acy	
Cap 5 mg	76.92	21	✓ <u>Lenalidomide</u> <u>Viatris</u>
Cap 10 mg	50.30	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	✓ <u>Lenalidomide</u> Viatris

#### ⇒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 5g cytogenetic abnormality; and
- 2 Patient has transfusion-dependent anaemia.

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

Subsid	dy Full	y Brand or
(Manufacturer	r's Price) Subsidise	d Generic
\$	Per 🗸	<ul> <li>Manufacturer</li> </ul>

continued...

the following criteria:

#### Both:

- 1 Patient has not needed a transfusion in the last 4 months; and
- 2 No evidence of disease progression.

### **MESNA**

MESINA			
Tab 400 mg - PCT - Retail pharmacy-Specialist	314.00	50	<ul><li>Uromitexan</li></ul>
Tab 600 mg - PCT - Retail pharmacy-Specialist	448.50	50	<ul><li>Uromitexan</li></ul>
Inj 100 mg per ml, 4 ml ampoule - PCT only - Specialist	177.45	15	✓ Uromitexan
Inj 100 mg per ml, 10 ml ampoule - PCT only - Specialist.	407.40	15	✓ Uromitexan
Inj 1 mg for ECP – PCT only – Specialist		100 mg	✓ Baxter
MITOMYCIN C - PCT only - Specialist			- Junio
, ,	F47.0F		/ Assert
Inj 5 mg vial	517.65	1	✓ Accord S29
			✓ Mitomycin
			(Fresenius
			Kabi) S29
	526.00		✓ Mitomycin
			(Sagent) S29
Inj 20 mg vial	1.250.00	1	✓ Omegapharm S29
,	,		✓ Teva
Inj 1 mg for ECP	269.85	1 mg	✓ Baxter
MITOZANTRONE - PCT only - Specialist		•	
Inj 2 mg per ml, 10 ml vial	97.50	1	✓ Mitozantrone Ebewe
Inj 1 mg for ECP		1 mg	✓ Baxter
, -		9	
NIRAPARIB – Special Authority see SA2325 below – Retail ph	armacy		
Wastage claimable			4
Tab 100 mg		84	✓ Zejula
Cap 100 mg	8,929.84	56	✓ Zejula
OACOOF On a stall Assittantian Control to			

#### ⇒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
- 2 Treatment to be administered as maintenance treatment; and

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

continued...

- 3 Treatment not to be administered in combination with other chemotherapy; and
- - 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 Authorit	ty see SA2163 below		
Tab 100 mg	3,701.00	56	<ul><li>Lynparza</li></ul>
Tab 150 mg	3,701.00	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 Fither:
  - 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 Fither:
  - 2.1 No evidence of progressive disease; or
  - 2.2 Evidence of residual (not progressive) disease and the patient would continue to benefit from treatment in the clinician's opinion: and
- 3 Treatment to be administered as maintenance treatment; and
- 4 Treatment not to be administered in combination with other chemotherapy; and
- 5 Either:
  - 5.1 Both:
    - 5.1.1 Patient has received one line\*\* of previous treatment with platinum-based chemotherapy; and

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

continued...

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

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

PACLITAXEL - PCT only - Specialist			
Inj 30 mg	47.30	5	✓ Paclitaxel Ebewe
Inj 6 mg per ml, 16.7 ml vial		1	✓ Anzatax
•	24.00		✓ Paclitaxel Ebewe
	91.67		✓ Paclitaxel Actavis
Inj 150 mg	26.69	1	✓ Paclitaxel Ebewe
	137.50		✓ Anzatax
			✓ Paclitaxel Actavis
Inj 6 mg per ml, 50 ml vial	37.89	1	✓ Anzatax
•	44.00		✓ Paclitaxel Ebewe
	275.00		✓ Paclitaxel Actavis
Inj 1 mg for ECP	0.17	1 mg	✓ Baxter
PEGASPARGASE - PCT only - Special Authority see SA1	979 below		
Inj 750 iu per ml, 5 ml vial		1	<ul><li>Oncaspar LYO</li></ul>

⇒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.

Inj 10 mg	CBS	1	✓ Nipent S29
POMALIDOMIDE - Special Authority see SA2354 on the nex	t page – Retail pharn	nacy	
Cap 1 mg	47.45	14	✓ Pomolide
	71.18	21	✓ Pomolide
Cap 2 mg	94.90	14	✓ Pomolide
	142.35	21	✓ Pomolide
Cap 3 mg	142.35	14	✓ Pomolide
	213.53	21	✓ Pomolide
Cap 4 mg	189.81	14	✓ Pomolide
	284.71	21	✓ Pomolide

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

RECORDED TIME HYDROCH ORDER POT Retail pharmacy Specialist

Cap 50 mg	' '	50	✓ Natulan S29
TEMOZOLOMIDE - Special Authority see SA2275 below - Ret	ail pharmacy		
Cap 5 mg	9.13	5	✓ Temaccord
•			✓ Temozolomide-
			Taro S29
Cap 20 mg	16.38	5	✓ Temaccord
	18.30		✓ Apo-Temozolomide
Cap 100 mg	35.98	5	✓ Temaccord
	40.20		✓ Apo-Temozolomide
Cap 140 mg	50.12	5	✓ Temaccord
Cap 250 mg	86.34	5	✓ Temaccord

### ⇒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/m² 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) \$	Per	Fully Subsidised	Brand or Generic Manufacturer	
THALIDOMIDE – Retail pharmacy-Specialist – Special Authority	378.00	28	=	halomid	
Cap 100 mg	756.00	28	<b>✓</b> 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 s	see SA2481 belo	W	
Tab 14 × 10 mg, 7 × 50 mg, 21 × 100 mg	1,771.86	42 OP	✓ Venclexta
Tab 10 mg		2 OP	✓ Venclexta
Tab 50 mg	239.44	7 OP	✓ Venclexta
Tab 100 mg - Wastage claimable	8,209.41	120	✓ Venclexta

#### ⇒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 Pr	rice)	Fully Subsidised	Brand or Generic	
\$	Per	✓	Manufacturer	

continued...

Fither:

- 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

Inj 1 mg per ml, 10 ml vial – PCT – Retail pharmacy-Specialist2	70.37	5	′ Hospira
Inj 1 mg for ECP - PCT only - Specialist	.6.00	1 mg 🗸	Baxter
VINCRISTINE SULPHATE			
Inj 1 mg per ml, 1 ml vial - PCT - Retail pharmacy-Specialist	74.52	5	DBL Vincristine Sulfate
Inj 1 mg per ml, 2 ml vial - PCT - Retail pharmacy-Specialist1	02.73	5	DBL Vincristine Sulfate
Inj 1 mg for ECP - PCT only - Specialist	12.60	1 mg 🗸	Baxter
VINORELBINE			
Cap 20 mg	30.00	1	Vinorelbine Te Arai
Cap 30 mg	40.00	1	Vinorelbine Te Arai
Cap 80 mg		1	Vinorelbine Te Arai
Inj 10 mg per ml, 1 ml vial - PCT only - Specialist	42.00	1	Vinorelbine Ebewe
Inj 10 mg per ml, 5 ml vial - PCT only - Specialist1	68.00	1	Navelbine S29 S29
2	10.00	•	Vinorelbine Ebewe
Inj 1 mg for ECP - PCT only - Specialist	.3.80	1 mg 🗸	Baxter

## Protein-tyrosine Kinase Inhibitors

### ⇒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	Fully Subsidised	Generic	
AXITINIB – Special Authority see SA2458 below – Retail pharma Wastage claimable	асу				
Tab 1 mg	536.40	28		Inlyta	
Tab 5 mg	2,682.00	28	1	Inlyta	

### SA2458 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

- 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	Xalkori
Cap 250 mg		60	✓ Xalkori

### ⇒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..

#### DASATINIB - Special Authority see SA2385 below - Retail pharmacy

- a) Brand switch fee payable (Pharmacode 2700441) see page 274 for details
- b) Wastage claimable

Tab 20 mg132.88	60	✓ Dasatinib-Teva
Tab 50 mg	60	✓ Dasatinib-Teva
Tab 70 mg415.75	60	✓ Dasatinib-Teva

### ⇒SA2385 Special Authority for Subsidy

Initial application only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

#### Any of the following:

- 1 The patient has a diagnosis of chronic myeloid leukaemia (CML) in blast crisis or accelerated phase; or
- 2 The patient has a diagnosis of Philadelphia chromosome-positive acute lymphoid leukaemia (Ph+ ALL); or
- 3 Both:
  - 3.1 The patient has a diagnosis of CML in chronic phase; and
  - 3.2 Any of the following:
    - 3.2.1 Patient has documented treatment failure\* with imatinib; or
    - 3.2.2 Patient has experienced treatment-limiting toxicity with imatinib precluding further treatment with imatinib; or
    - 3.2.3 Patient has high-risk chronic-phase CML defined by the Sokal or EURO scoring system.

**Renewal** only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

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

continued...

Both:

- 1 Lack of treatment failure while on dasatinib\*: and
- 2 Dasatinib treatment remains appropriate and the patient is benefiting from treatment.

Note: \*treatment failure for CML as defined by Leukaemia Net Guidelines.

FRI OTINIB - Retail pharmacy-Specialist - Special Authority see SA2422 below

Tab 100 mg		30	✓ Alchemy
Tab 150 mg	484.24	30	✓ Alchemy

### ⇒SA2422 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

- 1 Patient has locally advanced or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
- 2 There is documentation confirming that the disease expresses activating mutations of EGFR; and
- 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 below

Tab 250 mg ......918.00 30 ✓ Iressa

## ⇒SA2423 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

- 1 Patient has locally advanced, or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
- 2 Any of the following:
  - 2.1 Patient is treatment naive: or
  - 2.2 Patient has received prior treatment in the adjuvant setting and/or while awaiting EGFR results; or
  - 2.3 Both:
    - 2.3.1 The patient has discontinued osimertinib or erlotinib due to intolerance; and
    - 2.3.2 The cancer did not progress whilst on osimertinib or erlotinib; and
- 3 There is documentation confirming that disease expresses activating mutations of EGFR.

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

		-		
IN/IA	TIN	IR.	MESII	

* Cap 100 mg * Cap 400 mg		60 30	✓ <u>Imatinib-Rex</u> ✓ <u>Imatinib-Rex</u>
LENVATINIB – Special Authority see SA2442 below Wastage claimable	/ - Retail pharmacy		
Cap 4 mg	3,407.40	30	<ul><li>Lenvima</li></ul>
Cap 10 mg	3,407.40	30	<ul><li>Lenvima</li></ul>

### ⇒SA2442 Special Authority for Subsidy

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

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

continued...

Either:

- 1 Patient is currently on treatment with lenvatinib and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 The patient has locally advanced or metastatic differentiated thyroid cancer; and
  - 2.2 Fither
    - 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:

- 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

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

continued...

- 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

Wastage claimable

## ⇒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:

- 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
 9,310.00
 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:

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

continued...

- 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
  - 223 Roth
    - 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 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

wasiaye dalmable			
Tab 75 mg	4,000.00	21	Ibrance
Tab 100 mg	4,000.00	21	✓ Ibrance
Tab 125 mg	·	21	✓ Ibrance

#### ⇒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:

Mostogo eleimeble

- 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

bsidy	Fully	Brand or
turer's Price) Subsid	dised	Generic
 \$ Per	✓	

continued...

- 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 below – R	letail pharmacy		
Brand switch fee payable (Pharmacode 2704692) - s	see page 274 for details		
Tab 200 mg	172.88	30	✓ Pazopanib Teva
Tab 400 mg	464.00	30	✓ Pazopanib Teva

#### ⇒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 Fither:
    - 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 SA2343 on the next page - Retail pharmacy Wastage claimable

Tab 200 mg	21	✓ Kisqali
3,767.00	42	✓ Kisqali
5,650.00	63	✓ Kisqali

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

### ⇒SA2343 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 Any of the following:
    - 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; or
    - 1.4.3 Both:
      - 1.4.3.1 Patient commenced treatment with ribociclib in combination with an endocrine partner prior to 1 July 2024; and
      - 1.4.3.2 There is no evidence of progressive 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
- 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 ciaimable			
Tab 5 mg	2,500.00	56	Jakavi
Tab 10mg	5,000.00	56	Jakavi
Tab 15 mg	5,000.00	56	Jakavi
Tab 20 mg	·	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

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

continued...

DIPSS: and

- 2.2.2 Patient has severe disease-related symptoms that are resistant, refractory or intolerant to available therapy;
- 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 - R	etail pharmacy		
Cap 12.5 mg	208.38	28	<ul> <li>Sunitinib Pfizer</li> </ul>
Cap 25 mg	416.77	28	<ul> <li>Sunitinib Pfizer</li> </ul>
Cap 50 mg	694.62	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
- 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

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

continued...

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.

# **Endocrine Therapy**

For GnRH ANALOGUES - refer to HORMONE PREPARATIONS, Trophic Hormones, page 86

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 Fither:
  - 4.1 All of the following:
    - 4.1.1 Patient is symptomatic; and
    - 4.1.2 Patient has disease progression (rising serum PSA) after second line anti-androgen therapy; and
    - 4.1.3 Patient has ECOG performance score of 0-1; and
    - 4.1.4 Patient has not had prior treatment with taxane chemotherapy; or
  - 4.2 All of the following:
    - 4.2.1 Patient's disease has progressed following prior chemotherapy containing a taxane; and
    - 4.2.2 Patient has ECOG performance score of 0-2; and
    - 4.2.3 Patient has not had prior treatment with abiraterone.

Renewal — (abiraterone acetate) only from a medical oncologist, radiation oncologist, urologist or medical practitioner on the recommendation of a medical oncologist, radiation oncologist or urologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Significant decrease in serum PSA from baseline; and
- 2 No evidence of clinical disease progression; and
- 3 No initiation of taxane chemotherapy with abiraterone; and
- 4 The treatment remains appropriate and the patient is benefiting from treatment.

Renewal — (pandemic circumstances) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and
- 2 Abiraterone acetate to be discontinued at progression; and
- 3 No initiation of taxane chemotherapy with abiraterone; and
- 4 The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector.

#### **BICALUTAMIDE**

	Subsidy (Manufacturer's Price)	Per	Fully Subsidised	Generic
FLUTAMIDE				
Tab 250 mg	107.55	90	✓	Prostacur S29
	119.50	100	1	Flutamin
FULVESTRANT - Retail pharmacy-Specialist - Special Authority	see SA1895 below			
Inj 50 mg per ml, 5 ml prefilled syringe	1,068.00	2	1	Faslodex
⇒SA1895 Special Authority for Subsidy				

1895 Special Authority for Subsidy

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

- 1 Patient has oestrogen-receptor positive locally advanced or metastatic breast cancer; and
- 2 Patient has disease progression following prior treatment with an aromatase inhibitor or tamoxifen for their locally advanced or metastatic disease: and
- 3 Treatment to be given at a dose of 500 mg monthly following loading doses; and
- 4 Treatment to be discontinued at disease progression.

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

All of the following:

- 1 Treatment remains appropriate and patient is benefitting from treatment; and
- 2 Treatment to be given at a dose of 500 mg monthly; and
- 3 There is no evidence of disease progression.

#### OCTRECTIDE

Inj 50 mcg per ml, 1 ml vial	27.58	5	✓ Omega S29
Inj 100 mcg per ml, 1 ml vial	48.50	5	✓ Omega S29
Inj 500 mcg per ml, 1 ml vial		5	✓ Omega S29
Inj 50 mcg per ml, 1 ml ampoule		5	✓ Max Health
			✓ Octreotide GH S29
Inj 100 mcg per ml, 1 ml ampoule	32.71	5	✓ Max Health
			✓ Octreotide GH S29
			✓ Sun Pharma S29
Inj 500 mcg per ml, 1 ml ampoule	113.10	5	✓ Max Health
			✓ Octreotide GH S29
			✓ Sun Pharma S29
TAMOXIFEN CITRATE			
* Tab 10 mg	15.00	60	✓ Tamoxifen Sandoz
* Tab 20 mg		60	✓ Tamoxifen Sandoz
· · · · · · · · · · · · · · · ·		- •	

## 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

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continued...

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
- 4 For pre-operative control of hypoglycaemia and for maintenance therapy; or
- 5 Both:
  - 5.1 Carcinoid syndrome (diagnosed by tissue pathology and/or urinary 5HIAA analysis); and
  - 5.2 Disabling symptoms not controlled by maximal medical therapy.

Note: The use of a long-acting somatostatin analogue in patients with fistulae, oesophageal varices, miscellaneous diarrhoea and hypotension will not be funded under Special Authority

**Renewal — (Other Indications)** from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

	Subsidy (Manufacturer's Price)	Subs Per	Fully sidised	Brand or Generic Manufacturer
LANREOTIDE – Special Authority see SA2445 on page 174 – R Inj 60 mg per 0.5 ml, 0.5 ml syringe Mytolac to be Principal Supply on 1 August 2025		1	✓ N	lytolac
Inj 90 mg per 0.5 ml, 0.5 ml syringe Inj 120 mg per 0.5 ml, 0.5 ml syringe Mytolac to be Principal Supply on 1 August 2025		1	_	fytolac fytolac
OCTREOTIDE LONG-ACTING — Special Authority see SA2445 Inj depot 10 mg prefilled syringe Inj depot 20 mg prefilled syringe Inj depot 30 mg prefilled syringe	438.40 583.70	pharmacy 1 1 1	✓ <u>S</u>	andostatin LAR andostatin LAR andostatin LAR
Aromatase Inhibitors				
ANASTROZOLE  * Tab 1 mg  EXEMESTANE	4.39	30	✓ <u>A</u>	natrole
* Tab 25 mg	9.86	30	<b>✓</b> <u>P</u>	fizer Exemestane
* Tab 2.5 mg	4.36 4.67	28 30		accord S29 etrole

## **Immunosuppressants**

## Cytotoxic Immunosuppressants

AZATHIOPRINE		
* Tab 25 mg	60	<ul><li>Azamun</li></ul>
* Tab 50 mg8.10	100	✓ Azamun
MYCOPHENOLATE MOFETIL		
Tab 500 mg35.90	50	<ul><li>Cellcept</li></ul>
Cap 250 mg35.90	100	✓ Cellcept
Powder for oral liq 1 g per 5 ml - Subsidy by endorsement187.25	5 165 ml OP	✓ Cellcept

Mycophenolate powder for oral liquid is subsidised only for patients unable to swallow tablets and capsules, and when the prescription is endorsed accordingly.

### **Fusion Proteins**

ETANERCEPT - Special Authority see SA2399 below - Reta	il pharmacy		
Inj 25 mg	690.00	4	<ul><li>Enbrel</li></ul>
Inj 25 mg autoinjector	690.00	4	<ul><li>Enbrel</li></ul>
Inj 50 mg autoinjector	1,050.00	4	<ul><li>Enbrel</li></ul>
Inj 50 mg prefilled syringe		4	<ul><li>Enbrel</li></ul>

### ⇒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:

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

continued...

- 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 druos (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 Fither:
  - 1.1 Applicant is a rheumatologist; or
  - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 The patient has a sustained improvement in inflammatory markers and functional status.

**Initial application — (ankylosing spondylitis)** only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Fither:

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for adalimumab for ankylosing spondylitis; and
  - 1.2 Fither
    - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
    - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for ankylosing spondylitis; or
- 2 All of the following:
  - 2.1 Patient has a confirmed diagnosis of ankylosing spondylitis present for more than six months; and
  - 2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
  - 2.3 Patient has bilateral sacroiliitis demonstrated by plain radiographs, CT or MRI scan; and
  - 2.4 Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and
  - 2.5 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:

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

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

continued...

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:

Either:

### 1 Both:

- 1.1 The patient has had an initial Special Authority approval for adalimumab for oligoarticular course juvenile idiopathic arthritis (JIA): and
- 1.2 Either:
  - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
  - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for oligoarticular course JIA; or
- 2 All of the following:
  - 2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
  - 2.2 Patient has had oligoarticular course JIA for 6 months duration or longer; and
  - 2.3 Any of the following:
    - 2.3.1 At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
    - 2.3.2 Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose); or
    - 2.3.3 High disease activity (cJADAS10 score greater than 4) after a 6-month trial of methotrexate.

Renewal — (oligoarticular course juvenile idiopathic arthritis) only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

# Both:

- 1 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2 Either:
  - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
  - 2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Initial application — (psoriatic arthritis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

#### Either:

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for adalimumab or secukinumab for psoriatic arthritis; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from adalimumab or secukinumab; or
      - 1.2.2 The patient has received insufficient benefit from adalimumab or secukinumab to meet the renewal criteria for adalimumab or secukinumab for psoriatic arthritis; or
- 2 All of the following:
  - 2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and
  - 2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and

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

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- 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 Fither:
  - 1.1 Applicant is a rheumatologist; or
  - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 Either:
  - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  - 2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior etanercept treatment in the opinion of the treating physician; and
- 3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

**Initial application — (pyoderma gangrenosum)** only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has pyoderma gangrenosum\*; and
- 2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate) and not received an adequate response; and
- 3 A maximum of 8 doses.

Note: Indications marked with \* are unapproved indications.

**Renewal — (pyoderma gangrenosum)** only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

#### All of the following:

- 1 Patient has shown clinical improvement; and
- 2 Patient continues to require treatment; and
- 3 A maximum of 8 doses.

**Initial application** — (Arthritis - rheumatoid ) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

#### Either:

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for adalimumab for rheumatoid arthritis; and
  - 1.2 Either.
    - 1.2.1 The patient has experienced intolerable side effects; or

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(Manufacturer's Price)	Subsidise	ed Generic	
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- 1.2.2 The patient has received insufficient benefit to meet the renewal criteria for rheumatoid arthritis; or
- 2 All of the following:
  - 2.1 Patient has had rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
  - 2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
  - 2.3 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
  - 2.4 Patient has tried and not responded to at least three months of methotrexate in combination with sulfasalazine and hydroxychloroguine sulphate (at maximum tolerated doses unless contraindicated); and
  - 2.5 Fither:
    - 2.5.1 Patient has tried and not responded to at least three months of methotrexate in combination with the maximum tolerated dose of ciclosporin; or
    - 2.5.2 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with methotrexate; and
  - 2.6 Fither:
    - 2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
    - 2.6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip.

**Renewal — (Arthritis - rheumatoid)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2 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:
  - 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

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

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- 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 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:

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

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#### 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 - Spe	ecialist		
Inj 50 mg per ml, 5 ml	4,439.17	5	✓ ATGAM
BACILLUS CALMETTE-GUERIN (BCG) VACCINE - PCT of	nly – Specialist		
Subsidised only for bladder cancer.			
Inj 2-8 × 100 million CFU	149.37	1	✓ OncoTICE
Inj 40 mg per ml, vial	182.45	3	✓ SII-Onco-BCG \$29

# Monoclonal Antibodies

ADALIMUMAB (AMGEVITA) - Special Authority see SA240	0 on the next page - Ret	ail phar	macy
Inj 20 mg per 0.4 ml prefilled syringe	190.00	1	✓ Amgevita
Inj 40 mg per 0.8 ml prefilled pen	375.00	2	✓ Amgevita
Inj 40 mg per 0.8 ml prefilled syringe	375.00	2	✓ Amgevita

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(Manufact	turer's Price) Subsidi	sed Generic	
	\$ Per	<ul> <li>Manufac</li> </ul>	turer

# ⇒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 Fither:
  - 2.1 The patient has severe ocular, neurological, and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s); or
  - 2.2 The patient has severe gastrointestinal, rheumatological, and/or mucocutaneous symptoms and has not responded adequately to two or more treatments appropriate for the particular symptom(s).

Note: Indications marked with \* are unapproved indications.

Initial application — (Hidradenitis suppurativa) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has hidradenitis suppurativa Hurley Stage 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 Fither:
    - 1.2.1 Patient has experienced intolerable side effects: or
    - 1.2.2 Patient has received insufficient benefit to meet the renewal criteria for 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 lesions have been present for at least 6 months from the time of initial diagnosis; or
    - 2.1.2 Patient has severe chronic plague psoriasis of the face, or palm of a hand or sole of a foot, where the plague or plagues 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

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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 Fither:
    - 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 plague 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:

- 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;
  - 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.

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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.

Initial application — (Ocular inflammation - chronic) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Fither:

- 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

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- 2.2.2 Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or
- 2.2.3 Patient is under 8 years and treatment with steroids or methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or disease requires control to prevent irreversible vision loss prior to achieving a therapeutic dose of methotrexate.

Renewal — (Ocular inflammation - chronic) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 The patient has had a good clinical response following 12 weeks' initial treatment; or
- 2 Following each 2 year treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or</p>
- 3 Following each 2 year treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.

Initial application — (Ocular inflammation - severe) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 Patient has had an initial Special Authority approval for infliximab for severe ocular inflammation; or
- 2 Both:
  - 2.1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and
  - 2.2 Any of the following:
    - 2.2.1 Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms; or
    - 2.2.2 Patient developed new inflammatory symptoms while receiving high dose steroids; or
    - 2.2.3 Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms.

Renewal — (Ocular inflammation - severe) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 The patient has had a good clinical response following 3 initial doses: or
- 2 Following each 2 year treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
- 3 Following each 2 year treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.

Initial application — (ankylosing spondylitis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Both:
  - 1.1 Patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; and
  - 12 Fither
    - 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

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- 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:

#### Fither:

- 1 Following initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
- 2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Initial application — (Arthritis - polyarticular course juvenile idiopathic) only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 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

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- 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:

#### Fither:

- 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
    - 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

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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 hydroxychloroguine sulphate at maximum tolerated doses (unless contraindicated); and
  - 2.5 Fither:
    - 2.5.1 Patient has tried and not responded to at least three months of methotrexate in combination with the maximum tolerated dose of ciclosporin; or
    - 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:

### Either:

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

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- 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 Fither:
  - 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:

Fither:

- 1 Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response in the opinion of the treating physician.

Initial application — (inflammatory bowel arthritis – axial) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
- 2 Patient has axial inflammatory pain for six months or more; and

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- 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 \$A2157 below - Retail pharmacy

Inj 20 mg per 0.2 ml prefilled syrin	e595.50	2	<ul><li>Humira</li></ul>
Inj 40 mg per 0.4 ml prefilled pen	595.50	2	✓ HumiraPen
Ini 40 mg per 0.4 ml prefilled syrin	e595.50	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:

All of the following:

- 1 Fither:
  - 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

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- 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 Fither:
  - 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 Fither:
  - 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

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- 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
- 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

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- 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:
  - 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:

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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</p>
- 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
  - 1.3 Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old; and</p>
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**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:

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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
- 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 Fither:
  - 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 - 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:

continued...

- 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:

- or the followin
- 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 — (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

⇒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
- 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

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- 4 There is no centre-involving sub-retinal fibrosis or foveal atrophy; and
- 5 After each consecutive 12 months treatment with (2nd line anti-VEGF agent), patient has retrialled with at least one injection of bevacizumab and had no response.

BENRALIZUMAB - Special Authority see SA2151 below - Retail pharmacy Inj 30 mg per ml, 1 ml prefilled pen .......3,539.00 ✓ Fasenra

⇒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 eq. vocal cord dysfunction, central airway obstruction, bronchiolitis etc. have been excluded: and
- 4 Patient has a blood eosinophil count of greater than 0.5 x 10^9 cells/L in the last 12 months; and
- 5 Patient must be adherent to optimised asthma therapy including inhaled corticosteroids (equivalent to at least 1000 mcg per day of fluticasone propionate) plus long-acting beta-2 agonist, or budesonide/formoterol as part of the anti-inflammatory reliever therapy plus maintenance regimen, unless contraindicated or not tolerated; and
- 6 Fither:
  - 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 Fither:
  - 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
- - 2.1 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 SA24	53 on the next page		
Inj 25 mg per ml, 4 ml vial	69.00	1	✓ Vegzelma
Inj 25 mg per ml, 16 ml vial	276.00	1	✓ Vegzelma
Ini 1 mg for ECP	0.71	1 ma	✓ Baxter

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⇒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:

#### Fither:

- 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
  - 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.

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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.

⇒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

✓ Adcetris

- 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:

- 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.

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

### ⇒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
- 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.

# **⇒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 m² 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).

**⇒SA2402** 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:

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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
  - 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 Fither
  - 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

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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:

- 1 Patient has acute, fulminant ulcerative colitis; and
- 2 Treatment with intravenous or high dose oral corticosteroids has not been successful.

Initial application — (ankylosing spondylitis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis; and
- 2 Either:
  - 2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
  - 2.2 Following 12 weeks of adalimumab and/or etanercept treatment, the patient did not meet the renewal criteria for adalimumab and/or etanercept for ankylosing spondylitis.

Renewal — (ankylosing spondylitis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Following 12 weeks of infliximab treatment, BASDAI has improved by 4 or more points from pre-infliximab baseline on a 10 point scale, or by 50%, whichever is less; and
- 2 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and
- 3 Infliximab to be administered at doses no greater than 5 mg/kg every 6-8 weeks.

**Initial application — (chronic ocular inflammation)** from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Fither:

- 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,</p>

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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.</p>

Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if infliximab is withdrawn.

Initial application — (fistulising Crohn's disease) 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 Fither:
  - 1.1 The number of open draining fistulae have decreased from baseline by at least 50%; or
  - 1.2 There has been a marked reduction in drainage of all fistula(e) from baseline (in the case of adult patients, as demonstrated by a reduction in the Fistula Assessment score), together with less induration and patient reported pain; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

Initial application — (neurosarcoidosis) only from a neurologist or Practitioner on the recommendation of a neurologist. Approvals valid for 18 months for applications meeting the following criteria:

All of the following:

- 1 Patient has been diagnosed with neurosarcoiosis by a multidisciplinary team; and
- 2 Patient has CNS involvement; and
- 3 Patient has steroid-refractory disease; and
- 4 Fither:
  - 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:

Fither:

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- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis: and
  - 1.2 Fither:
    - 1.2.1 Patient has experienced intolerable side effects from adalimumab, etanercept or secukinumab; or
    - 1.2.2 Patient has received insufficient benefit from adalimumab, etanercept or secukinumab to meet the renewal criteria for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis: or
- 2 All of the following:
  - 2.1 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

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value: or

- 1.3 Both:
  - 1.3.1 Patient had severe chronic localised genital or flexural plague psoriasis at the start of treatment; and
  - 1.3.2 Fither:
    - 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 Fither:
  - 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:

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All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
- 2 Either:
  - 2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
  - 2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept; and
- 3 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance.

**Renewal — (rheumatoid arthritis)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2 Either:
  - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  - 2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 3 Infliximab to be administered at doses no greater than 3 mg/kg every 8 weeks.

**Initial application — (severe Behcet's disease)** from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The patient has severe Behcet's disease which is significantly impacting the patient's quality of life (see Notes); and
- 2 Either:
  - 2.1 The patient has severe ocular, neurological and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s) (see Notes); or
  - 2.2 The patient has severe gastrointestinal, rheumatologic and/or mucocutaneous symptoms and has not responded adequately to two or more treatment appropriate for the particular symptom(s) (see Notes); and
- 3 The patient is experiencing significant loss of quality of life.

Notes: Behcet's disease diagnosed according to the International Study Group for Behcet's Disease. Lancet 1990;335(8697):1078-80. Quality of life measured using an appropriate quality of life scale such as that published in Gilworth et al J Rheumatol. 2004;31:931-7.

Treatments appropriate for the particular symptoms are those that are considered standard conventional treatments for these symptoms, for example intravenous/oral steroids and other immunosuppressants for ocular symptoms; azathioprine, steroids, thalidomide, interferon alpha and ciclosporin for mucocutaneous symptoms; and colchicine, steroids and methotrexate for rheumatological symptoms.

Renewal — (severe Behcet's disease) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has had a good clinical response to initial treatment with measurably improved quality of life; and
- 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

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used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

**Initial application — (severe ocular inflammation)** from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Fither:

- 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</p>
- 3 Following each 12 month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.</p>

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 Fither:
  - 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

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- 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 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 pvoderma gangrenosum\*; and
- 2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate) and not received an adequate response; and
- 3 A maximum of 8 doses.

Note: 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

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- 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:

#### Fither:

- 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.

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Inj 1 mg for ECP	14,457.00	1 mg	•

1 ✓ Besponsa 1 mg ✓ Baxter

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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 Fither:
  - 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 below - Retail pharmacy

# ⇒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

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excluded: and

- 4 Patient has a blood eosinophil count of greater than 0.5 x 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 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 Fither:
  - 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 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	ority see SA2155 on the	next page	
Inj 25 mg per ml, 40 ml vial	5,910.00	1	<ul><li>Gazyva</li></ul>
Inj 1 mg for ECP	6.21	1 mg	✓ Baxter

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

# ⇒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</p>
- 4 Patient has adequate neutrophil and platelet counts\* unless the cytopenias are a consequence of marrow infiltration by CLL; and
- 5 Patient has good performance status; and
- 6 Obinutuzumab to be administered at a maximum cumulative dose of 8,000 mg and in combination with chlorambucil for a maximum of 6 cycles.

Notes: Chronic lymphocytic leukaemia includes small lymphocytic lymphoma. Comorbidity refers only to illness/impairment other than CLL induced illness/impairment in the patient. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with obinutuzumab is expected to improve symptoms and improve ECOG score to < 2.

\* Neutrophil greater than or equal to  $1.5 \times 10^9$ /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.

### ⇒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

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- 3 Past or current evidence of atopy, documented by skin prick testing or RAST; and
- 4 Total serum human immunoglobulin E (IgE) between 76 IU/mL and 1300 IU/ml at baseline; and
- 5 Proven adherence with optimal inhaled therapy including high dose inhaled corticosteroid (budesonide 1,600 mcg per day or fluticasone propionate 1,000 mcg per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 mcg bd or eformoterol 12 mcg bd) for at least 12 months, unless contraindicated or not tolerated; and
- 6 Fither:
  - 6.1 Patient has received courses of systemic corticosteroids equivalent to at least 28 days treatment in the past 12 months, unless contraindicated or not tolerated; or
  - 6.2 Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral steroids; and
- 7 Patient has an Asthma Control Test (ACT) score of 10 or less; and
- 8 Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 26 weeks after the first dose to assess response to treatment.

**Initial application — (severe chronic spontaneous urticaria)** only from a clinical immunologist or dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient must be aged 12 years or older; and
- 2 Fither:
  - 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:
  - 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.

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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

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# SA2419 Special Authority for Subsidy

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

- 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
  - - 2.2.1 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. Any of the following:
          - 2.2.2.2.2.1 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);
      - 3.2.2.2 Child has unoperated or surgically palliated complex congenital heart disease; or
      - 3.2.2.3 Child has severe pulmonary hypertension (see Note C); or
      - 3.2.2.4 Child has moderate or severe left ventricular (LV) failure (see Note D); or
  - 3.3 Child has severe combined immune deficiency, confirmed by an immunologist, but has not received a stem cell transplant: or

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3.4 Child has inborn errors of immunity (see Note E) that increase susceptibility to life-threatening viral respiratory infections, confirmed by an immunologist.

#### Notes:

- a) Ventilatory/respiratory support includes those on home oxygen, CPAP/VPAP and those with tracheostomies in situ managed at home
- b) Child requires/will require heart failure medication, and/or child has significant pulmonary hypertension, and/or infant will require surgical palliation/definitive repair within the next 3 months
- c) Mean pulmonary artery pressure more than 25 mmHg
- d) LV Ejection Fraction less than 40%
- e) Inborn errors of immunity include, but are not limited to, IFNAR deficiencies

# PERTUZUMAB - PCT only - Specialist - Special Authority see SA2276 below

Inj 30 mg per ml, 14 ml vial	3,927.00	1	/	Perjeta
Inj 420 mg for ECP	3,927.00	420 mg OP	1	Baxter

### ⇒SA2276 Special Authority for Subsidy

**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 Fither:
  - 2.1 Patient is chemotherapy treatment naïve; or
  - 2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
- 3 The patient has good performance status (ECOG grade 0-1); and
- 4 Pertuzumab to be administered in combination with trastuzumab; and
- 5 Pertuzumab maximum first dose of 840 mg, followed by maximum of 420 mg every 3 weeks; and
- 6 Pertuzumab to be discontinued at disease progression.

Renewal — (metastatic breast cancer) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

#### Fither:

- 1 Both:
  - 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 pertuzumab and trastuzumab; or
- 2 All of the following:
  - 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 - Special Authority see SA1976 on the next page

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Inj 500 mg per 50	ml vial	2,688.30	1	1	Mabthera
Inj 1 mg for ECP		5.64	1 mg	✓	Baxter (Mabthera)

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### ⇒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 Fither:

- 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 Fither:

- 2.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
- 2.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
- 3 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Subsidy		Fully	Brand or	
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Renewal — (rheumatoid arthritis - re-treatment in 'partial responders' to rituximab) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 At 4 months following the initial course of rituximab infusions the patient had between a 30% and 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  - 1.2 At 4 months following the second course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  - 1.3 At 4 months following the third and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and
- 3 Either:
  - 3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
  - 3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
- 4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Renewal — (rheumatoid arthritis - re-treatment in 'responders' to rituximab) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

- 1 Either:
  - 1.1 At 4 months following the initial course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  - 1.2 At 4 months following the second and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and
- 3 Fither:
  - 3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
  - 3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
- 4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

#### RITUXIMAB (RIXIMYO) - PCT only - Specialist - Special Authority see SA2233 below

Inj 100 mg per 10 ml vial	275.33	2	✓ Riximyo
Inj 500 mg per 50 ml vial	688.20	1	✓ Riximyo
Inj 1 mg for ECP	1.38	1 mg	✓ Baxter (Riximyo)

#### ⇒SA2233 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:

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- 3.1 Induction therapy with daily oral or pulse intravenous cyclophosphamide has failed to achieve significant improvement of disease after at least 3 months; or
- 3.2 Patient has previously had a cumulative dose of cyclophosphamide > 15 g or a further repeat 3 month induction course of cyclophosphamide would result in a cumulative dose > 15 g; or
- 3.3 Cyclophosphamide and methotrexate are contraindicated; or
- 3.4 Patient is a female of child-bearing potential; or
- 3.5 Patient has a previous history of haemorrhagic cystitis, urological malignancy or haematological malignancy.

Note: Indications marked with \* are unapproved indications.

Renewal — (ANCA associated vasculitis) from any relevant practitioner. Approvals valid for 8 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient has been diagnosed with ANCA associated vasculitis\*; and
- 2 Patient has previously responded to treatment with rituximab but is now experiencing an acute flare of vasculitis; and
- 3 The total rituximab dose would not exceed the equivalent of 375 mg/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 within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; and
- 3 The patient has good performance status; and
- 4 Either:
  - 4.1 The patient does not have chromosome 17p deletion CLL; or
  - 4.2 Rituximab treatment is to be used in combination with funded venetoclax for relapsed/refractory chronic lymphocytic leukaemia; and
- 5 Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles; and
- 6 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration), bendamustine or venetoclax.

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

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Renewal — (Chronic lymphocytic leukaemia) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Either:
  - 1.1 The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; or
  - 1.2 All of the following:
    - 1.2.1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL;
    - 1.2.2 The patient has had an interval of 36 months or more since commencement of initial rituximab treatment; and
    - 1.2.3 The patient does not have chromosome 17p deletion CLL; and
    - 1.2.4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustine; and
- 2 Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles.

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

Initial application — (Neuromyelitis Optica Spectrum Disorder(NMOSD)) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m2 administered weekly for four weeks; and
- 2 Either:
  - 2.1 The patient has experienced a severe episode or attack of NMOSD (rapidly progressing symptoms and clinical investigations supportive of a severe attack of NMOSD); or
  - 2.2 All of the following:
    - 2.2.1 The patient has experienced a breakthrough attack of NMOSD; and
    - 2.2.2 The patient is receiving treatment with mycophenolate; and
    - 2.2.3 The patients is receiving treatment with corticosteroids.

Renewal — (Neuromyelitis Optica Spectrum Disorder) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria: All of the following:

- 1 One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m2 administered weekly for four weeks; and
- 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:

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- 1 The patient has had a rituximab treatment-free interval of 12 months or more; and
- 2 The patient has B-cell post-transplant lymphoproliferative disorder\*; and
- 3 To be used for no more than 6 treatment cycles.

Note: Indications marked with \* are unapproved indications.

Initial application — (Severe Refractory Myasthenia Gravis) only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 2 years for applications meeting the following criteria: Both:

- 1 One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart; and
- 2 Fither:
  - 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:

3 Fither:

- 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
- 3.1 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:

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

Note: Indications marked with \* are unapproved indications.

Initial application — (Steroid resistant nephrotic syndrome (SRNS)) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 8 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient is a child with SRNS\* where treatment with steroids and ciclosporin for at least 3 months have been ineffective;
- 2 Treatment with tacrolimus for at least 3 months has been ineffective; and
- 3 Genetic causes of nephrotic syndrome have been excluded; and
- 4 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

Renewal — (Steroid resistant nephrotic syndrome (SRNS)) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 8 weeks for applications meeting the following criteria:

All of the following:

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

Note: Indications marked with \* are unapproved indications.

Initial application — (aggressive CD20 positive NHL) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Fither:

- 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:

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- 1 Patient has mild congenital haemophilia complicated by inhibitors; or
- 2 Patient has severe congenital haemophilia complicated by inhibitors and has failed immune tolerance therapy; or
- 3 Patient has acquired haemophilia.

Renewal — (haemophilia with inhibitors) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient was previously treated with rituximab for haemophilia with inhibitors; and
- 2 An initial response lasting at least 12 months was demonstrated; and
- 3 Patient now requires repeat treatment.

Initial application — (immune thrombocytopenic purpura (ITP)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria: All of the following:

- 1 Fither:
  - 1.1 Patient has immune thrombocytopenic purpura\* with a platelet count of less than or equal to 20,000 platelets per
  - 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:

Fither:

- 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;
  - 2.2 To be used for a maximum of 6 treatment cycles.

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Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. \*Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.

Renewal — (indolent, low-grade lymphomas or hairy cell leukaemia\*) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had a rituximab treatment-free interval of 12 months or more; and
- 2 The patient has indolent, low-grade NHL or hairy cell leukaemia\* with relapsed disease following prior chemotherapy; and
- 3 To be used for no more than 6 treatment cycles.

Note: 'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. \*Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.

Initial application — (pure red cell aplasia (PRCA)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 weeks where patient has autoimmune pure red cell aplasia\* associated with a demonstrable B-cell lymphoproliferative disorder.

Note: Indications marked with \* are unapproved indications.

Renewal — (pure red cell aplasia (PRCA)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 weeks where patient was previously treated with rituximab for pure red cell aplasia\* associated with a demonstrable B-cell lymphoproliferative disorder and demonstrated an initial response lasting at least 12 months.

Note: Indications marked with \* are unapproved indications.

Initial application — (severe cold haemagglutinin disease (CHAD)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria: All of the following:

- 1 Patient has cold haemagglutinin disease\*; and
- 2 Patient has severe disease which is characterized by symptomatic anaemia, transfusion dependence or disabling circulatory symptoms; and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

Renewal — (severe cold haemagglutinin disease (CHAD)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria: 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 Fither:
  - 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.

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Renewal — (thrombotic thrombocytopenic purpura (TTP)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient was previously treated with rituximab for thrombotic thrombocytopenic purpura\*; and
- 2 An initial response lasting at least 12 months was demonstrated; and
- 3 Patient now requires repeat treatment; and
- 4 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks

Note: Indications marked with \* are unapproved indications.

**Initial application** — **(treatment refractory systemic lupus erythematosus (SLE))** only from a rheumatologist, nephrologist or Practitioner on the recommendation of a rheumatologist or nephrologist. Approvals valid for 7 months for applications meeting the following criteria:

All of the following:

- 1 The patient has severe, immediately life- or organ-threatening SLE\*; and
- 2 The disease has proved refractory to treatment with steroids at a dose of at least 1 mg/kg; and
- 3 The disease has relapsed following prior treatment for at least 6 months with maximal tolerated doses of azathioprine, mycophenolate mofetil and high dose cyclophosphamide, or cyclophosphamide is contraindicated; and
- 4 Maximum of four 1000 mg infusions of rituximab.

Note: Indications marked with \* are unapproved indications.

Renewal — (treatment refractory systemic lupus erythematosus (SLE)) only from a rheumatologist, nephrologist or Practitioner on the recommendation of a rheumatologist or nephrologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient's SLE\* achieved at least a partial response to the previous round of prior rituximab treatment; and
- 2 The disease has subsequently relapsed; and
- 3 Maximum of two 1000 mg infusions of rituximab.

Note: Indications marked with \* are unapproved indications.

Initial application — (warm autoimmune haemolytic anaemia (warm AIHA)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 8 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient has warm autoimmune haemolytic anaemia\*; and
- 2 One of the following treatments has been ineffective: steroids (including if patient requires ongoing steroids at doses equivalent to > 5 mg prednisone daily), cytotoxic agents (e.g. cyclophosphamide monotherapy or in combination), intravenous immunoglobulin; and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks.

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: Fither:

- 1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m² weekly for 4 weeks) is now planned; or
- 2 All of the following:
  - 2.1 Patient was previously treated with rituximab for 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.

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

All of the following:

- 1 Patient has confirmed antisynthetase syndrome; and
- 2 Patient has severe, immediately life or organ threatening disease, including interstitial lung disease; and
- 3 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 x 1,000mg infusions of rituximab given two weeks apart.

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

All of the following:

- 1 Patient has refractory graft versus host disease following transplant; and
- 2 Treatment with at least 3 immunosuppressants (oral steroids, ciclosporin, tacrolimus, mycophenolate, sirolimus) has not be effective at controlling active disease; and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks.

Initial application — (severe chronic inflammatory demyelinating polyneuropathy) only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Patient has severe chronic inflammatory demyelinating polyneuropathy (CIPD); and
- 2 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.

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Initial application — (anti-NMDA receptor autoimmune encephalitis) only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has severe anti-NMDA receptor autoimmune encephalitis: and
- 2 Fither
  - 2.1 Both:
    - 2.1.1 Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease; and
    - 2.1.2 At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease; or
  - 2.2 Rapid treatment is required due to life threatening complications; and
- 3 One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart.

Renewal — (anti-NMDA receptor autoimmune encephalitis) only from a neurologist or medical practitioner on the recommendation of a neurologist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in neurological function; and
- 2 The patient has not received rituximab in the previous 6 months; and
- 3 The patient has experienced a relapse and now requires further treatment; and
- 4 One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart.

Initial application — (CD20+ low grade or follicular B-cell NHL) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

Fither:

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- 1 Both:
  - 1.1 The patient has CD20+ low grade or follicular B-cell NHL with relapsed disease following prior chemotherapy; and
  - 1.2 To be used for a maximum of 6 treatment cycles; or
- 2 Both:
  - 2.1 The patient has CD20+ low grade or follicular B-cell NHL requiring first-line systemic chemotherapy; and
  - 2.2 To be used for a maximum of 6 treatment cycles.

Renewal — (CD20+ low grade or follicular B-cell NHL) from any relevant practitioner. Approvals valid for 24 months for applications meeting the following criteria:

- Both:
  - 1 Rituximab is to be used for maintenance in CD20+ low grade or follicular B-cell NHL following induction with first-line systemic chemotherapy; and
  - 2 Patient is intended to receive rituximab maintenance therapy for 2 years at a dose of 375 mg/m2 every 8 weeks (maximum of 12 cycles).

**Initial application** — (Membranous nephropathy) only from a nephrologist or any relevant practitioner on the recommendation of a nephrologist. Approvals valid for 6 weeks for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 Patient has biopsy-proven primary/idiopathic membranous nephropathy\*; or
  - 1.2 Patient has PLA2 antibodies with no evidence of secondary cause, and an eGFR of > 60ml/min/1.73m2; and
- 2 Patient remains at high risk of progression to end-stage kidney disease despite more than 3 months of treatment with conservative measures (see Note); and

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3 The total rituximab dose would not exceed the equivalent of 375mg/m2 of body surface area per week for a total of 4 weeks.

Renewal — (Membranous nephropathy) only from a nephrologist or any relevant practitioner on the recommendation of a nephrologist. Approvals valid for 6 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient was previously treated with rituximab for membranous nephropathy\*; and
- 2 Either:
  - 2.1 Treatment with rituximab was previously successful, but the condition has relapsed, and the patient now requires repeat treatment: or
  - 2.2 Patient achieved partial response to treatment and requires repeat treatment (see Note); and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks.

#### Notes:

- a) Indications marked with \* are unapproved indications.
- b) High risk of progression to end-stage kidney disease defined as > 5g/day proteinuria.
- c) Conservative measures include renin-angiotensin system blockade, blood-pressure management, dietary sodium and protein restriction, treatment of dyslipidaemia, and anticoagulation agents unless contraindicated or the patient has experienced intolerable side effects.
- d) Partial response defined as a reduction of proteinuria of at least 50% from baseline, and between 0.3 grams and 3.5 grams per 24 hours.

Initial application — (B-cell acute lymphoblastic leukaemia/lymphoma\*) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 Patient has newly diagnosed B-cell acute lymphoblastic leukaemia/lymphoma\*; and
- 2 Treatment must be in combination with an intensive chemotherapy protocol with curative intent; and
- 3 The total rituximab dose would not exceed the equivalent of 375 mg/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

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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 — (pemiphiqus\*) 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 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
- - 2.1 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 SA2482 below - Retail pharmacy

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## ⇒SA2482 Special Authority for Subsidy

Initial application — (severe chronic plaque psoriasis – second-line biologic) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab or etanercept, or has trialled infliximab in a Health NZ Hospital, for severe chronic plaque psoriasis; and
- 2 Fither:
  - 2.1 The patient has experienced intolerable side effects from adalimumab, etanercept or infliximab; or
  - 2.2 The patient has received insufficient benefit from adalimumab, etanercept or infliximab; and
- 3 A Psoriasis Area and Severity Index (PASI) assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and

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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:
  - 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, 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 Either:
  - 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 plague 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:

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- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis; and
- 2 Fithe
  - 2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
  - 2.2 Following 12 weeks of adalimumab and/or etanercept treatment, the patient did not meet the renewal criteria for adalimumab and/or etanercept for ankylosing spondylitis.

Renewal — (ankylosing spondylitis – second-line biologic) only from a rheumatologist or medical practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Following 12 weeks initial treatment of secukinumab treatment, BASDAI has improved by 4 or more points from pre-secukinumab baseline on a 10 point scale, or by 50%, whichever is less; and
- 2 Physician considers that the patient has benefitted from treatment and that continued treatment is appropriate; and
- 3 Secukinumab to be administered at doses no greater than 300 mg monthly.

Initial application — (psoriatic arthritis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Fither:

- 1 Both:
  - 1.1 Patient has had an initial Special Authority approval for adalimumab, etanercept or infliximab for psoriatic arthritis; and
  - 1.2 Fither:
    - 1.2.1 Patient has experienced intolerable side effects from adalimumab, etanercept or infliximab; or
    - 1.2.2 Patient has received insufficient benefit from adalimumab, etanercept or infliximab to meet the renewal criteria for adalimumab, etanercept or infliximab for psoriatic arthritis; or
- 2 All of the following:
  - 2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and
  - 2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
  - 2.3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and
  - 2.4 Either:
    - 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints;
    - 2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
  - 2.5 Any of the following:
    - 2.5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
    - 2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or
    - 2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Renewal — (psoriatic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Fither
  - 1.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  - 1.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior secukinumab treatment in the opinion of the treating physician; and

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2 Secukinumab to be administered at doses no greater than 300 mg monthly.

#### SILTUXIMAB - Special Authority see SA1596 below - Retail pharmacy

Note: Siltuximab is to be administered at doses no greater than 11 mg/kg every 3 weeks.

Inj 100 mg vial	770.57	1	Sylvant
Inj 400 mg vial	3,082.33	1	✓ Sylvant

## ⇒SA1596 Special Authority for Subsidy

**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 SA2404 below

Inj 20 mg per ml, 4 ml vial	220.00	1	✓ Actemra
Inj 20 mg per ml, 10 ml vial	550.00	1	✓ Actemra
Inj 20 mg per ml, 20 ml vial		1	✓ Actemra
Inj 1 mg for ECP	,	1 mg	✓ Baxter

#### ⇒SA2404 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:

Fither:

## 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

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the following criteria:

All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
- 2 Fither:
  - 2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
  - 2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis; and
- 3 Fither:
  - 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 Fither:
  - 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 Fither:
  - 5.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints;
  - 5.2 Patient has persistent symptoms of poorly controlled and active disease in at least four active joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 6 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:

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- 1 Both:
  - 1.1 Either:
    - 1.1.1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for adult-onset Still's disease (AOSD); or
    - 1.1.2 The patient has been started on tocilizumab for AOSD in a Health NZ Hospital; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
    - 1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for AOSD; or
- 2 All of the following:
  - 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and
  - 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal antiinflammatory drugs (NSAIDs) and methotrexate; and
  - 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

Initial application — (polyarticular juvenile idiopathic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria: Either:

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for both etanercept and adalimumab for polyarticular course juvenile idiopathic arthritis (JIA); and
  - 1.2 The patient has experienced intolerable side effects, or has received insufficient benefit from, both etanercept and adalimumab; or
- 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

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- 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:

Fither:

- 1 Following 6 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician.

Renewal — (systemic juvenile idiopathic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Following up to 6 months' initial treatment, the patient has achieved at least an American College of Rheumatology paediatric 30% improvement criteria (ACR Pedi 30) response from baseline; or
- 2 On subsequent reapplications, the patient demonstrates at least a continuing ACR Pedi 30 response from baseline.

Renewal — (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months where the patient has a sustained improvement in inflammatory markers and functional status.

Renewal — (polyarticular juvenile idiopathic arthritis) only from a rheumatologist or Practitioner on the recommendation of a

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.

TRASTUZUMAB (HERZUMA) - PCT only - Special Authority see \$A2293 below

✓ Herzuma	1	100.00	 	 Inj 150 mg vial
✓ Herzuma	1	293.35	 	 Inj 440 mg vial
✓ Baxter	1 ma	0.70	 	 Ini 1 ma for ECP

## ⇒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:

- 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

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(Manufacturer's Price)		Subsidised	Generic	
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- 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 Fither:

- 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
- 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

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- 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 FCOG 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 - Special Authority see \$A2420 below 1

✓ Enhertu Inj 1 mg for ECP.......27.05 ✓ Baxter 1 ma

# ⇒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: Fither:

- 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
  - 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: 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 - Specialist - Special Authority see SA2424 on the next page

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

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

# ⇒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 neoadiuvant 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 Fither:
  - 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 below - Retail pharmacy

Ini 90 mg per ml, 1 ml pre-filled syringe........................4,162.00 1 ✓ Stelara

#### ⇒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

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(Manufacturer's Price)	Subsidised	Generic
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- 2 Both:
  - 2.1 Patient has active Crohn's disease: and
  - 22 Fither:
    - 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.

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

Fither:

- 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:

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- 2.1 Patient has active ulcerative colitis; and
- 2.2 Fither:
  - 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 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

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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:

- 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.

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# Programmed Cell Death-1 (PD-1) Inhibitors

ATEZOLIZUMAB - PCT only - Specialist - Special Author	ority see SA2443 below		
Inj 60 mg per ml, 20 ml vial	9,503.00	1	<ul><li>Tecentriq</li></ul>
Inj 1 mg for ECP	8.08	1 mg	✓ Baxter

#### ⇒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
  - 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

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- 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 Authorit	ty see SA2425 below		
Inj 50 mg per ml, 10 ml vial	4,700.00	1	Imfinzi
Inj 50 mg per ml, 2.4 ml vial	1,128.00	1	Imfinzi
Ini 1 mg for ECP	9.59	1 ma	✓ Baxter

## ⇒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 Fither:
  - 1.1 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 Fither:
  - 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 se	e SA2461 below			
Inj 5 mg per ml, 10 ml vial	5,000.00	1	✓ Yervoy	
Inj 5 mg per ml, 40 ml vial	20,000.00	1	✓ Yervoy	
Inj 1 mg for ECP	106.00	1 mg	✓ Baxter	

## ⇒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:

Fither:

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- 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..

		nly – Specialist – Special Authority see SA2454 below	NIVOLUMAB - PCT only - Spe
<ul><li>Opdivo</li></ul>	1	ml vial	Inj 10 mg per ml, 4 ml vial
✓ Opdivo	1	0 ml vial2,629.96	Inj 10 mg per ml, 10 ml vial
✓ Baxter	1 ma	27 22	Ini 1 mg for FCP

## ⇒SA2454 Special Authority for Subsidy

Initial application only from a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

- 1 Patient has metastatic or unresectable melanoma (excluding uveal) stage III or IV: and
- 2 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
- 3 The patient has ECOG performance score of 0-2; and
- 4 Either:
  - 4.1 Patient has not received funded pembrolizumab; or
  - 4.2 Both:
    - 4.2.1 Patient has received an initial Special Authority approval for pembrolizumab and has discontinued pembrolizumab within 12 weeks of starting treatment due to intolerance; and
    - 4.2.2 The cancer did not progress while the patient was on pembrolizumab; and
- 5 Documentation confirming that the patient has been informed and acknowledges that funded treatment with nivolumab will not be continued if their disease progresses.

Renewal — (less than 24 months on treatment) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 All of the following:
  - 1.1 Any of the following:
    - 1.1.1 Patient's disease has had a complete response to treatment; or
    - 1.1.2 Patient's disease has had a partial response to treatment; or
    - 1.1.3 Patient 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; and
  - 1.3 The treatment remains clinically appropriate and the patient is benefitting from the treatment; or
- 2 All of the following:
  - 2.1 Patient has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease

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progression; and

- 2.2 Patient has signs of disease progression; and
- 2.3 Disease has not progressed during previous treatment with nivolumab.

Renewal — (more than 24 months on treatment) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 Patient has been on treatment for more than 24 months; and
- 2 Fither:
  - 2.1 All of the following:
    - 2.1.1 Any of the following:
      - 2.1.1.1 Patient's disease has had a complete response to treatment; or
      - 2.1.1.2 Patient's disease has had a partial response to treatment; or
      - 2.1.1.3 Patient 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; and
    - 2.1.3 The treatment remains clinically appropriate and the patient is benefitting from the treatment; or
  - 2.2 All of the following:
    - 2.2.1 Patient has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression; and
    - 2.2.2 Patient 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
  - 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

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- 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 SA2386 below

Inj 25 mg per ml, 4 ml vial	4,680.00	1	Keytruda
Inj 1 mg for ECP	47.74	1 mg	✓ Baxter

### ⇒SA2386 Special Authority for Subsidy

Initial application — (unresectable or metastatic melanoma) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has metastatic or unresectable melanoma (excluding uveal) stage III or IV: and
- 2 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
- 3 The patient has ECOG performance score of 0-2; and
- 4 Either:
  - 4.1 Patient has not received funded nivolumab; or
  - 4.2 Both:
    - 4.2.1 Patient has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance; and
    - 4.2.2 The cancer did not progress while the patient was on nivolumab; and
- 5 Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses.

Renewal — (unresectable or metastatic melanoma, less than 24 months on treatment) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

#### Fither:

- 1 All of the following:
  - 1.1 Any of the following:
    - 1.1.1 Patient's disease has had a complete response to treatment; or
    - 1.1.2 Patient's disease has had a partial response to treatment; or
    - 1.1.3 Patient 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; and
  - 1.3 The treatment remains clinically appropriate and the patient is benefitting from the treatment; or
- 2 All of the following:

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- 2.1 Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression; and
- 2.2 Patient has signs of disease progression; and
- 2.3 Disease has not progressed during previous treatment with pembrolizumab.

Renewal — (unresectable or metastatic melanoma, more than 24 months on treatment) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 Patient has been on treatment for more than 24 months; and
- 2 Either:
  - 2.1 All of the following:
    - 2.1.1 Any of the following:
      - 2.1.1.1 Patient's disease has had a complete response to treatment; or
      - 2.1.1.2 Patient's disease has had a partial response to treatment; or
      - 2.1.1.3 Patient 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; and
    - 2.1.3 The treatment remains clinically appropriate and the patient is benefitting from the treatment; or
  - 2.2 All of the following:
    - 2.2.1 Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression; and
    - 2.2.2 Patient 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:

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- 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 — (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

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(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
- 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

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- 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 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 Either:
    - 2.1.1 Patient has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer: or
    - 2.1.2 Patient has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) unresectable colorectal cancer; and
  - 2.2 Patient is treated with palliative intent; and
  - 2.3 Patient has not previously received funded treatment with pembrolizumab; and
  - 2.4 Patient 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).

Subsidy		Fully	Brand or	
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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:

- 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 Both:
      - 2.1.1.1 Patient has relapsed/refractory Hodgkin lymphoma after two or more lines of chemotherapy; and
      - 2.1.1.2 Patient is ineligible for autologous stem cell transplant; or
    - 2.1.2 Patient has relapsed/refractory Hodgkin lymphoma and has previously undergone an autologous stem cell transplant; and
  - 2.2 Patient has not previously received funded pembrolizumab; 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	44.63	50	Neoral
Cap 50 mg	88.91	50	Neoral
Cap 100 mg	177.81	50	✓ Neoral
Oral liq 100 mg per ml	198.13	50 ml OP	✓ Neoral
EVEROLIMUS - Special Authority see SA2414 below - Retail ph	armacy		
Wastage claimable			
Tab 10 mg	6,512.29	30	✓ Afinitor
Tab 5 mg	4,555.76	30	✓ Afinitor

#### **⇒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:

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- 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 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 see SA	2270 below – Retail pharmacy
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Tab 1 mg		100	✓ Rapamune
Tab 2 mg		100	✓ Rapamune
Oral lig 1 mg per ml	· · · · · · · · · · · · · · · · · · ·	60 ml OP	✓ Rapamune

#### ⇒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

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- 2 No evidence of progressive disease; and
- 3 The treatment remains clinically appropriate and the patient is benefitting from the treatment.

Notes: Baseline assessment and disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer et al. Eur J Cancer 2009;45:228-47)

Indications marked with \* are unapproved indications

Initial application — (renal angiomyolipoma(s) associated with tuberous sclerosis complex\*) only from a nephrologist or urologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has tuberous sclerosis complex\*; and
- 2 Evidence of renal angiomyolipoma(s) measuring 3 cm or greater and that have shown interval growth.

 $\textbf{Renewal} - \textbf{(renal angiomyolipoma(s) associated with tuberous sclerosis complex*)} \ \ \text{from any relevant practitioner}.$ 

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 Fither:
  - 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 next page - Retail pharmacy

Cap 0.5 mg	49.60	100	✓ Tacrolimus Sandoz
Cap 0.75 mg	99.30	100	✓ Tacrolimus Sandoz
Cap 1 mg		100	✓ Tacrolimus Sandoz
Cap 5 mg		50	✓ Tacrolimus Sandoz

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

### ⇒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:

#### Fither:

- 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 pharmacy

Tab modified-release 15 mg	1,271.00	28	✓ Rinvoq
Tab modified-release 30 mg	2,033.00	28	✓ Rinvoq
Tab modified-release 45 mg	3,049.00	28	✓ Rinvoq

### ⇒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
- 1 The individu
  - 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
  - 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;
  - 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:

#### Fither:

- 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
  - - 2.2.1 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

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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 Fither:
    - 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:

Fither:

#### \_....

- 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:

#### Fither:

- 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.

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# **Antiallergy Preparations**

# Allergic Emergencies

ADRENALINE - Special Authority see SA2185 below - Retail pharmacy

- a) Maximum of 2 ini per prescription
- Additional prescriptions limited to replacement of up to two devices prior to expiry, or replacement of used device for treatment of anaphylaxis.

Inj 0.15 mg per 0.3 ml auto-injector	90.00	1 OP	✓ Epipen Jr
Inj 0.3 mg per 0.3 ml auto-injector	90.00	1 OP	<ul><li>Epipen</li></ul>

### ⇒SA2185 Special Authority for Subsidy

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

Both:

- 1 Either:
  - 1.1 Patient has experienced an anaphylactic reaction which has resulted in presentation to a hospital or emergency department; or
  - 1.2 Patient has been assessed to be at significant risk of anaphylaxis by a relevant practitioner; and
- 2 Patient is not to be prescribed more than two devices in initial prescription.

# **⇒SA1558** Special Authority for Subsidy

**Initial application** only from a clinical immunologist or relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Supply for anticipated emergency treatment of laryngeal/oro-pharyngeal or severe abdominal attacks of acute hereditary angioedema (HAE) for patients with confirmed diagnosis of C1-esterase inhibitor deficiency; and
- 2 The patient has undergone product training and has agreed upon an action plan for self-administration.

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

# Allergy Desensitisation

# ⇒SA1367 Special Authority for Subsidy

Initial application only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 RAST or skin test positive; and
- 2 Patient has had severe generalised reaction to the sensitising agent.

**Renewal** only from a relevant specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

BEE VENOM ALLERGY TREATMENT - Special Authority see SA1367 above - Retail pharmacy Initiation kit - 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 S29 Maintenance kit - 6 vials 120 mcg freeze dried venom, with 1 OP ✓ Venomil S29 Treatment kit - 1 vial 550 mcg freeze dried venom, 1 diluent 1 OP ✓ Albev Treatment kit - 1 vial 550 mcg freeze dried venom, with diluent ..... 305.00 1 OP ✓ Hymenoptera S29

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ASP VENOM ALLERGY TREATMENT - Special Authority see	2 SA1267 on the pro		Doto	
Treatment kit (Paper wasp venom) - 1 vial 550 mcg freeze	a SA1307 off the pre	vious paye	- nela	ш рпаппасу
dried polistes venom, 1 diluent 9 ml, 3 diluent 1.8 ml	382 23	1 OP	✓ A	Albey
Treatment kit (Paper wasp venom) - 1 vial 550 mcg freeze		1 01	٠,	шьсу
dried venom, with diluent	305.00	1 OP	<b>✓</b> H	lymenoptera S29
Treatment kit (Paper wasp venom) - 6 vials 120 mcg freeze		. 0.		-ymonopiora
dried venom, with diluent	305.00	1 OP	✓ V	enomil \$29
Treatment kit (Yellow Jacket venom) - 1 vial 550 mcg freeze			-	
dried venom, with diluent		1 OP	<b>✓</b> H	lymenoptera \$29
Treatment kit (Yellow jacket venom) - 1 vial 550 mcg freeze			-	.,
dried vespula venom, 1 diluent 9 ml, 3 diluent 1.8 ml	431.24	1 OP	<b>✓</b> Δ	Albev
Treatment kit (Yellow jacket venom) - 6 vials 120 mcg freeze			-	
dried venom, with diluent		1 OP	<b>√</b> V	enomil \$29
Antihistamines				
ETIRIZINE HYDROCHLORIDE				
	1 71	100	✓ Z	lieta
Oral lig 1 mg per ml		200 ml	_	listaclear
		200 1111	• 1	iistacicai
EXTROCHLORPHENIRAMINE MALEATE	0.00	40		
Tab 2 mg		40		Polaramine
	(8.40) 1.01	20	г	rolaramme
	(5.99)	20		Polaramine
Oral lig 2 mg per 5 ml	` '	100 ml		Olaraninie
	(10.29)	100 1111	Р	Polaramine
CYCEENIA DINIE LIVEDOCLII ODIDE	(10.23)			olaramino
EXOFENADINE HYDROCHLORIDE	4.24	20		
Tab 60 mg		20	т.	elfast
Tab 120 mg	(8.23)	30		enasi exaclear
1ab 120 mg	14.22	30	• -	Exacical
	(26.44)		т	elfast
Fexaclear to be Principal Supply on 1 July 2025	(20.44)			Cilast
Tab 180 mg	4.10	30	<b>√</b> F	exaclear
Fexaclear to be Principal Supply on 1 July 2025				
elfast Tab 120 mg to be delisted 1 July 2025)				
DRATADINE				
Tab 10 mg	1.78	100	<b>√</b> I	.orafix
Oral lig 1 mg per ml		100 ml	_	laylor syrup
ROMETHAZINE HYDROCHLORIDE			•	· , ·, ·
Tab 10 mg	1 20	50	./ A	Allersoothe
Tab 25 mg		50 50	_	Allersoothe
Oral liq 1 mg per 1 ml		100 ml	_	Allersoothe
Ordering it may por it illi	10.47	100 1111		henergan Elixir
	10.71		- 1	HONOI GUIL EILAII

(Phenergan Elixir Oral liq 1 mg per 1 ml to be delisted 1 July 2025)

	\$	Per	✓ Manufacturer
Inhaled Corticosteroids			
BECLOMETHASONE DIPROPIONATE			
Aerosol inhaler, 50 mcg per dose		200 dose OP	✓ Qvar
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose OP	✓ Beclazone 50
Aerosol inhaler, 100 mcg per dose		200 dose OP	✓ Qvar
Aerosol inhaler, 100 mcg per dose CFC-free		200 dose OP	✓ Beclazone 100
Aerosol inhaler, 250 mcg per dose CFC-free	22.67	200 dose OP	✓ Beclazone 250
BUDESONIDE			
Powder for inhalation, 100 mcg per dose	17.00	200 dose OP	✓ Pulmicort
		200 0000 0.	Turbuhaler
Powder for inhalation, 200 mcg per dose	19.00	200 dose OP	✓ Pulmicort
1 Owder for initialation, 200 mag per dose	10.00	200 0030 01	Turbuhaler
Daviday fay inhalatian 400 may nay daga	00.00	000 daaa OD	
Powder for inhalation, 400 mcg per dose	32.00	200 dose OP	✓ Pulmicort
			Turbuhaler
FLUTICASONE			
Aerosol inhaler, 50 mcg per dose	7.19	120 dose OP	✓ Flixotide
Powder for inhalation, 50 mcg per dose	8.61	60 dose OP	<ul> <li>Flixotide Accuhaler</li> </ul>
Powder for inhalation, 100 mcg per dose	7.81	60 dose OP	Flixotide Accuhaler
Aerosol inhaler, 125 mcg per dose	13.60	120 dose OP	✓ Flixotide
Aerosol inhaler, 250 mcg per dose	24.62	120 dose OP	✓ Flixotide
Powder for inhalation, 250 mcg per dose	11.93	60 dose OP	✓ Flixotide Accuhaler
. 01			
Inhaled Long-acting Beta-adrenoceptor Agonis	ts		
EFORMOTEROL FUMARATE DIHYDRATE			
Powder for inhalation 4.5 mcg per dose, breath activated			
(equivalent to eformoterol fumarate 6 mcg metered dose	a) 10.32	60 dose OP	
(equivalent to cionnotoror famarate o mog motoroa acoc	(16.90)	00 0000 01	Oxis Turbuhaler
INDAGATEROL	(10.00)		Oxio Tarbariaioi
INDACATEROL	04.00	00 des 00	( Out one Dunce had
Powder for inhalation 150 mcg		30 dose OP	✓ Onbrez Breezhaler
Powder for inhalation 300 mcg	61.00	30 dose OP	<ul> <li>Onbrez Breezhaler</li> </ul>
SALMETEROL			
Aerosol inhaler CFC-free, 25 mcg per dose	26.25	120 dose OP	✓ Serevent
B 1 ( ) 1 1 2 50		00   00	

Subsidy

(Manufacturer's Price)

Fully

Subsidised

Brand or

Generic

✓ Serevent Accuhaler

Powder for inhalation, 50 mcg per dose, breath activated ......26.25

60 dose OP

Subsidy		Fully	Brand or	
(Manufacturer's Price)	Sub	sidised	Generic	
•	Dor	./	Manufacturor	

Inhaled Corticosteroids with Long-Acting Beta-Adrenoceptor Agonists
---

д - от постольно пом - от д - от то то от р	to. Algomoto	
BUDESONIDE WITH EFORMOTEROL		
Powder for inhalation 160 mcg with 4.5 mcg eformoterol		
fumarate per dose (equivalent to 200 mcg budesonide with		
6 mcg eformoterol fumarate metered dose)41.50	120 dose OP	DuoResp Spiromax
Powder for inhalation 320 mcg with 9 mcg eformoterol fumarate		
per dose (equivalent to 400 mcg budesonide with 12 mcg		
eformoterol fumarate metered dose) – No more than 2	400 de - 0D	( D D O l
dose per day82.50	120 dose OP	✓ DuoResp Spiromax
Aerosol inhaler 100 mcg with eformoterol fumarate 6 mcg	120 dose OP 120 dose OP	✓ Vannair
Powder for inhalation 100 mcg with eformoterol fumarate 6 mcg33.74	120 dose OP	✓ Symbicort Turbuhaler 100/6
Agracal inhalar 200 mag with aformatoral fumarata 6 mag	120 dose OP	✓ Vannair
Aerosol inhaler 200 mcg with eformoterol fumarate 6 mcg21.40 Powder for inhalation 200 mcg with eformoterol fumarate 6 mcg33.74	120 dose OP	✓ Symbicort
Fowder for initial attorn 200 flicg with elothloteror furnial ate 6 flicg55.74	120 00se OF	Turbuhaler 200/6
Powder for inhalation 400 mcg with eformoterol fumarate		Turbunaler 200/0
12 mcg — No more than 2 dose per day33.74	60 dose OP	✓ Symbicort
12 mg - No more than 2 dose per day	oo dose Oi	Turbuhaler 400/12
FLUTICACONE FUDOATE WITH WILLANTEDOL		Tarbanaier 400/12
FLUTICASONE FUROATE WITH VILANTEROL  Powder for inhelation 100 mag with vilanteral 25 mag.  44.09	30 dose OP	✓ Breo Ellipta
Powder for inhalation 100 mcg with vilanterol 25 mcg44.08	30 dose OF	▼ Breo Empla
FLUTICASONE WITH SALMETEROL	400 1 00	40
Aerosol inhaler 50 mcg with salmeterol 25 mcg	120 dose OP	✓ Seretide
Aerosol inhaler 125 mcg with salmeterol 25 mcg	120 dose OP	✓ Seretide
Powder for inhalation 100 mcg with salmeterol 50 mcg – No	co doss OD	Caratida Assubalar
more than 2 dose per day	60 dose OP	<ul> <li>Seretide Accuhaler</li> </ul>
Powder for inhalation 250 mcg with salmeterol 50 mcg – No	60 dose OP	✓ Seretide Accuhaler
more than 2 dose per day44.08	60 dose OF	• Serelide Accumaler
Beta-Adrenoceptor Agonists		
SALBUTAMOL		
Oral liq 400 mcg per ml50.00	150 ml	✓ Ventolin
Infusion 1 mg per ml, 5 ml130.00	10	✓ Ventolin
Inj 500 mcg per ml, 1 ml - Up to 5 inj available on a PSO130.00	5	✓ Ventolin
Inhaled Beta-Adrenoceptor Agonists		
• •		
SALBUTAMOL 050 ( ) 1 1 1 1000		
Aerosol inhaler, 100 mcg per dose CFC free – Up to 1000	000 daaa OD	✓ CalAin
dose available on a PSO4.18	200 dose OP	✓ SalAir Ventolin
(6.80)		ventolin
Nebuliser soln, 1 mg per ml, 2.5 ml ampoule – Up to 30 neb	20	✓ Asthalin
available on a PSO	20	▼ ASIIIIIIII
available on a PSO9.43	20	✓ Asthalin
	20	- ASUIAIIII
TERBUTALINE SULPHATE		
Powder for inhalation, 200 mcg per dose (equivalent to	400 1 0=	4. n
250 mcg metered dose), breath activated22.20	120 dose OP	Bricanyl Turbuhaler

<sup>▲</sup>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	

# **Anticholinergic Agents**

#### **IPRATROPIUM BROMIDE**

		Aerosol inhaler, 20 mcg per dose CFC-free - Up to 400 dose
✓ Atrovent	200 dose OP	available on a PSO16.20
		Nebuliser soln, 250 mcg per ml, 2 ml ampoule - Up to 40 neb
<ul><li>Univent</li></ul>	20	available on a PSO11.73

# Inhaled Beta-Adrenoceptor Agonists with Anticholinergic Agents

#### SALBUTAMOL WITH IPRATROPIUM BROMIDE

Aerosol inhaler, 100 mcg with ipratropium bromide, 20 mcg per dose CFC-free	12.19	200 dose OP	✓ Duolin HFA
Nebuliser soln, 2.5 mg with ipratropium bromide 0.5 mg per vial, 2.5 ml ampoule – Up to 20 neb available on a PSO	11.04	20	✓ Duolin

# **Long-Acting Muscarinic Antagonists**

#### GLYCOPYRRONIUM - Subsidy by endorsement

- a) Inhaled glycopyrronium treatment will not be subsidised if patient is also receiving treatment with subsidised tiotropium or umeclidinium.
- b) Glycopyrronium powder for inhalation 50 mcg per dose is subsidised only for patients who have been diagnosed as having COPD using spirometry if spirometry is possible, and the prescription is endorsed accordingly.

#### TIOTROPIUM BROMIDE - Subsidy by endorsement

- a) Tiotropium treatment will not be subsidised if patient is also receiving treatment with subsidised inhaled glycopyrronium or umeclidinium.
- b) Tiotropium bromide is subsidised only for patients who have been diagnosed as having COPD using spirometry if spirometry is possible, and the prescription is endorsed accordingly. Patients who had tiotropium dispensed before 1 October 2018 with a valid Special Authority are deemed endorsed.

### UMECLIDINIUM - Subsidy by endorsement

- a) Umeclidinium will not be subsidised if patient is also receiving treatment with subsidised inhaled glycopyrronium or tiotropium bromide.
- b) Umeclidinium powder for inhalation 62.5 mcg per dose is subsidised only for patients who have been diagnosed as having COPD using spirometry if spirometry is possible, and the prescription is endorsed accordingly.

# Long-Acting Muscarinic Antagonists with Long-Acting Beta-Adrenoceptor Agonists

Combination long acting muscarinic antagonist and long acting beta-2 agonist will not be subsidised if patient is also receiving treatment with a combination inhaled corticosteroid and long acting beta-2 agonist.

# **⇒SA1584** Special Authority for Subsidy

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

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

Subsidy (Manufacturer		Fully idised	Brand or Generic	
\$	Per	✓	Manufacturer	

continued...

- 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).

# Inhaled Corticosteroid with Long-Acting Muscarinic Antagonist and Beta Agonist

BUDESONIDE WITH GLYCOPYRRONIUM AND EFORMOTEROL – Special Authority see SA2421 below – Retail pharmacy Aerosol inhaler budesonide 160 mcg with glycopyrronium

7.2 mcg and formoterol 5 mcg per dose......79.15 120 dose OP ✓ Breztri Aerosphere

# ⇒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 Pa

- 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  $0.3 \times 10^{\circ}9$  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 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

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

continued...

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  $0.3 \times 10^9$  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 below - Retail pharmacy

Note: Nintedanib not subsidised in combination with subsidised pirfenidone.

Cap 100 mg	2,554.00	60 OP	<ul><li>Ofev</li></ul>
Cap 150 mg	3,870.00	60 OP	Ofev

#### ⇒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 on the next page

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

# ⇒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:

nintedanib).

- 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

**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.

	Leukot	riene I	Recep	tor An	tagonists
--	--------	---------	-------	--------	-----------

MC	NTELUKAST			
*	Tab 4 mg	3.10	28	✓ Montelukast Viatris
*	Tab 5 mg	3.10	28	✓ Montelukast Viatris
*	Tab 10 mg	2.90	28	✓ Montelukast Viatris

# Methylxanthines

AMINOPHYLLINE		
* Inj 25 mg per ml, 10 ml ampoule - Up to 5 inj available on a		
PSO180.00	5	✓ DBL Aminophylline
THEOPHYLLINE		

*	Tab long-acting 250 mg	25.65	100	✓ Nuelin-SR
*	Oral lig 80 mg per 15 ml	18.49	500 ml	✓ Nuelin

# Mucolytics

DORNASE ALFA - Special Authority see SA1978 below - Re	etail pharmacy		
Nebuliser soln, 2.5 mg per 2.5 ml ampoule	250.00	6	✓ Pulmozyme

#### ⇒SA1978 Special Authority for Subsidy

Initial application — (cystic fibrosis) only from a respiratory physician or paediatrician. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 Patient has a confirmed diagnosis of cystic fibrosis; and

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

#### continued...

- 2 Patient has previously undergone a trial with, or is currently being treated with, hypertonic saline; and
- 3 Any of the following:
  - 3.1 Patient has required one or more hospital inpatient respiratory admissions in the previous 12 month period; or
  - 3.2 Patient has had 3 exacerbations due to CF, requiring oral or intravenous (IV) antibiotics in the previous 12 month period; or
  - 3.3 Patient has had 1 exacerbation due to CF, requiring oral or IV antibiotics in the previous 12 month period and a Brasfield score of < 22/25; or</p>
  - 3.4 Patient has a diagnosis of allergic bronchopulmonary aspergillosis (ABPA).

**Renewal** — **(cystic fibrosis)** only from a respiratory physician or paediatrician. Approvals valid without further renewal unless notified where the treatment remains appropriate and the patient continues to benefit from treatment.

ELEXACAFTOR WITH TEZACAFTOR, IVACAFTOR AND IVACAFTOR - PCT only - Special Authority see \$A2456 below

		or 25 mg, ivacaftor 37.5 mg	Tab elexacaftor 50 mg with tezacaftor 25
4 OP <b>✓ Trikafta</b>	84 OP	27,647.39	(56) and ivacaftor 75 mg (28)
		ftor 50 mg, ivacaftor 75 mg	Tab elexacaftor 100 mg with tezacaftor 50
4 OP ✓ Trikafta	84 OP	27,647.39	(56) and ivacaftor 150 mg (28)

### ⇒SA2456 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 been diagnosed with cystic fibrosis; and
- 2 Patient is 6 years of age or older; and
- 3 Either:
  - 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 https://nctr-crs.fda.gov/fdalabel/services/spl/set-ids/f354423a-85c2-41c3-a9db-0f3aee135d8d/spl-doc

IVACAFTOR - PCT only - Specialist - Special Authority	see SA2017 below		
Tab 150 mg	29,386.00	56	✓ Kalydeco
Oral granules 50 mg, sachet	29,386.00	56	✓ Kalydeco
Oral granules 75 mg, sachet	29,386.00	56	✓ Kalydeco

#### ⇒SA2017 Special Authority for Subsidy

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

All of the following:

- 1 Patient has been diagnosed with cystic fibrosis; and
- 2 Fither:

	RESPIRA	TORY SYSTE	EM AI	ND ALLERGIES
	Subsidy (Manufacturer's \$	Price) Subs Per	Fully sidised	Brand or Generic Manufacturer
continued				
Patient must have G551D mutation in the cystic least 1 allele; or     Patient must have other gating (class III) mutation.	n (G1244E, G134			
and S549R) in the CFTR gene on at least 1 allel  3 Patients must have a sweat chloride value of at least 60 sweat collection system; and	•	titative pilocarpir	ne ionto	phoresis or by Macrodu
Treatment with ivacaftor must be given concomitantly w Patient must not have an acute upper or lower respirato (including antibiotics) for pulmonary disease in the last 4 The dose of ivacaftor will not exceed one tablet or one s Applicant has experience and expertise in the managen	ry infection, pulm I weeks prior to c achet twice daily	onary exacerbat ommencing trea ; and	ion, or	changes in therapy
SODIUM CHLORIDE  Not funded for use as a nasal drop.  Soln 7%	25.73	90 ml OP	<b>√</b> E	Biomed
Nasal Preparations				
Allergy Prophylactics				
BUDESONIDE  Metered aqueous nasal spray, 50 mcg per dose  Metered aqueous nasal spray, 100 mcg per dose		200 dose OP 200 dose OP	_	iteroClear iteroClear
FLUTICASONE PROPIONATE  Metered aqueous nasal spray, 50 mcg per dose	2.57	120 dose OP	<b>√</b> F	lixonase Hayfever & Allergy
PRATROPIUM BROMIDE				
Aqueous nasal spray, 0.03%	5.23	15 ml OP	<b>7</b> (	Inivent
Respiratory Devices				
MASK FOR SPACER DEVICE a) Up to 50 dev available on a PSO b) Only on a PSO				
c) Only for children aged six years and under Small	2.70	1	<b>√</b> e	-chamber Mask
PEAK FLOW METER a) Up to 25 dev available on a PSO b) Only on a PSO				
Low range	9.54	1	✓ N	lini-Wright AFS Low Range
Normal range	9.54	1	✓ N	lini-Wright Standard
SPACER DEVICE				
a) Up to 50 dev available on a PSO				
b) Only on a PSO 220 ml (single patient)	3.65	1	<b>√</b> e	-chamber Turbo
510 ml (single patient)		1		-chamber I a

✓ e-chamber La

Grande

✓ Volumatic

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

# **Respiratory Stimulants**

**CAFFEINE CITRATE** 

Oral liq 20 mg per ml (10 mg base per ml)......16.91 25 ml OP **✔ Biomed** 

Soframycin

			SENS	SORY ORGANS
	Subsidy		Fully	Brand or
	(Manufacturer's Pri	ce) Sı Per	ubsidised	Generic Manufacturer
	Ψ	rei		Manuacturer
Ear Preparations				
FLUMETASONE PIVALATE				
Ear drops 0.02% with clioquinol 1%	4.46	7.5 ml OP	<b>√</b> L	ocacorten-Viaform ED's
			<b>√</b> L	ocorten-Vioform
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYC Ear drops 1 mg with nystatin 100,000 u, neomycin sulphate	N AND NYSTATII	N		
2.5 mg and gramicidin 250 mcg per g	5.16	7.5 ml OP	✓ K	(enacomb
Ear/Eye Preparations				
DEXAMETHASONE WITH FRAMYCETIN AND GRAMICIDIN				
Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and				
gramicidin 50 mcg per ml	4.50	8 ml OP		
	(9.27)			Otodex S29
	(9.27)		S	Sofradex
(Otodex S29) Ear/Eye drops 500 mcg with framycetin sulphate 5 2025)	mg and gramicidi	in 50 mcg p	er ml to b	e delisted 1 November
FRAMYCETIN SULPHATE				
Ear/Eye drops 0.5%	4.13	8 ml OP		

(8.65)

# **Eye Preparations**

Eye preparations are only funded for use in the eye, unless explicitly stated otherwise.

Anti-Infective Preparations		
ACICLOVIR * Eye oint 3%	4.5 g OP	✓ ViruPOS
CHLORAMPHENICOL	9	
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 in	ndications.	
CIPROFLOXACIN		
Eye drops 0.3% – Subsidy by endorsement10.85		
When prescribed for the treatment of bacterial keratitis or severe bacter		
for the second line treatment of chronic suppurative otitis media (CSON Note: Indication marked with a * is an unapproved indication.	n)"; and the pres	scription is endorsed accordingly.
SODIUM FUSIDATE [FUSIDIC ACID]		
Eye drops 1%	5 g OP	✓ Fucithalmic
		✓ Fucithalmic S29 S29
TOBRAMYCIN		
Eye oint 0.3%10.45	3.5 g OP	✓ Tobrex
Eye drops 0.3%11.48	5 ml OP	✓ Tobrex



	Subsidy		Fully	Brand or	
(M	fanufacturer's Price)	Subsi	dised	Generic	
	\$	Per	1	Manufacturer	

# **Corticosteroids and Other Anti-Inflammatory Preparations**

DE	XAMETHASONE			
*	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 below			
	- Retail pharmacy1,44	4.50	1	<ul><li>Ozurdex</li></ul>

#### ⇒SA1680 Special Authority for Subsidy

Initial application — (Diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has diabetic macular oedema with pseudophakic lens: and
- 2 Patient has reduced visual acuity of between 6/9 6/48 with functional awareness of reduction in vision; and
- 3 Fither
  - 3.1 Patient's disease has progressed despite 3 injections with bevacizumab; or
  - 3.2 Patient is unsuitable or contraindicated to treatment with anti-VEGF agents; and
- 4 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

Renewal — (Diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Patient's vision is stable or has improved (prescriber determined); and
- 2 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

Initial application — (Women of child bearing age with diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has diabetic macular oedema; and
- 2 Patient has reduced visual acuity of between 6/9 6/48 with functional awareness of reduction in vision; and
- 3 Patient is of child bearing potential and has not yet completed a family; and
- 4 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

Renewal — (Women of child bearing age with diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient's vision is stable or has improved (prescriber determined); and
- 2 Patient is of child bearing potential and has not yet completed a family; and
- 3 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

#### DEXAMETHASONE WITH NEOMYCIN SULPHATE AND POLYMYXIN B SULPHATE

* Eye oint 0.1% with neomycin sulphate 0.35% and polymyxin b		
sulphate 6,000 u per g5.39	3.5 g OP	✓ Maxitrol
* Eye drops 0.1% with neomycin sulphate 0.35% and polymyxin		
b sulphate 6,000 u per ml4.50	5 ml OP	✓ Maxitrol
DICLOFENAC SODIUM		
Eye drops 0.1%, single dose	10 dose	✓ Diclofenac Devatis
5.54	30 dose	<ul> <li>Diclofenac Devatis</li> </ul>
DILL D. H. I. D. I. I. I. I. C. D. I. I. I. C. D. D. I. I. I. C. D. D. I. I. I. C. D.		

Diclofenac Devatis to be Principal Supply on 1 July 2025

			_
	Subsidy (Manufacturer's P	Price) Subs	Fully Brand or idised Generic
	\$	Per	✓ Manufacturer
FLUOROMETHOLONE			
* Eye drops 0.1%	3.09	5 ml OP	✓ FML
	5.20		✓ Flucon
LEVOCABASTINE			
Eye drops 0.5 mg per ml	8.71	4 ml OP	
	(10.34)		Livostin
LODOXAMIDE			
Eye drops 0.1%	8.71	10 ml OP	✓ Lomide
NEPAFENAC			
Eye drops 0.3%	8.80	3 ml OP	✓ Ilevro
(Ilevro Eye drops 0.3% to be delisted 1 July 2025)			
PREDNISOLONE ACETATE			
Eye drops 1%	6.92	10 ml OP	✓ Prednisolone-AFT
	7.00	5 ml OP	✓ Pred Forte
PREDNISOLONE SODIUM PHOSPHATE - Special Authority se	e SA1715 below	/ – Retail pharn	nacy
Eye drops 0.5%, single dose (preservative free)		20 dose	✓ Minims  Prednisolone

# ⇒SA1715 Special Authority for Subsidy

**Initial application** only from an ophthalmologist or optometrist. Approvals valid for 6 months for applications meeting the following criteria:

#### Both:

1 Patient has severe inflammation; and

SODIUM CROMOGLICATE

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.

Eye drops 2%	10 ml OP	✓ <u>Allerfix</u>
Glaucoma Preparations - Beta Blockers		
# Eye drops 0.25%	5 ml OP 5 ml OP	✓ Betoptic S ✓ Betoptic
* Eye drops 0.25%	5 ml OP 5 ml OP	✓ <u>Arrow-Timolol</u> ✓ <u>Arrow-Timolol</u>
Glaucoma Preparations - Carbonic Anhydrase Inhibitors		
ACETAZOLAMIDE  * Tab 250 mg	100	<ul><li>✓ Medsurge</li><li>✓ Diamox</li></ul>
(Diamox Tab 250 mg to be delisted 1 September 2025)  BRINZOLAMIDE  * Eye drops 1%	5 ml OP	✓ Azopt
DORZOLAMIDE WITH TIMOLOL  * Eye drops 2% with timolol 0.5%	5 ml OP	✓ <u>Dortimopt</u>

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

	Subsidy (Manufacturer's I	Price) Subs	Fully Brand or sidised Generic	
	\$	Per	✓ Manufacture	r
Glaucoma Preparations - Prostaglandin Analog	jues			
BIMATOPROST				
* Eye drops 0.03%	5.15	3 ml OP	✓ <u>Lumigan</u>	
LATANOPROST  * Eye drops 0.005%	2.08	2.5 ml OP	✓ Teva	
TRAVOPROST				
* Eye drops 0.004%	6.80	2.5 ml OP	✓ Travatan	
Glaucoma Preparations - Other				
BRIMONIDINE TARTRATE				
* Eye drops 0.2%	5.16	5 ml OP	✓ Arrow-Brimon	<u>nidine</u>
BRIMONIDINE TARTRATE WITH TIMOLOL MALEATE  * Eye drops 0.2% with timolol maleate 0.5%	7.13	5 ml OP	✓ Combigan	
LATANOPROST WITH TIMOLOL		· · · · · ·	<u></u>	
* Eye drops 0.005% with timolol 0.5%	4.95	2.5 ml OP	✓ Arrow - Lattin	<u>n</u>
PILOCARPINE HYDROCHLORIDE			4	
* Eye drops 1%*  Eye drops 2%		15 ml OP 15 ml OP	✓ Isopto Carpin ✓ Isopto Carpin	
* Eye drops 2%*  * Eye drops 4%		15 ml OP	✓ Isopto Carpin	
Subsidised for oral use pursuant to the Standard Formu		10 1111 01	ioopio ouipiii	
PILOCARPINE NITRATE				
* Eye drops 2% single dose – Special Authority see SA0895	05.00	00 -1	/ Minima Dila	
below − Retail pharmacy  SA0895 Special Authority for Subsidy	35.90	20 dose	✓ Minims Piloca	arpine
Initial application from any relevant practitioner. Approvals vali Either:	d for 2 years for	applications me	eeting the following o	riteria:
1 Patient has to use an unpreserved solution due to an alle	rgy to the preser	vative; or		
2 Patient wears soft contact lenses. Note: Minims for a general practice are considered to be "tools or a general practice are considered to be a general practice are considere	of trade" and are	not approved a	s special authority it	ems
Renewal from any relevant practitioner. Approvals valid for 2 yes benefiting from treatment.				
Mydriatics and Cycloplegics				
ATROPINE SULPHATE				
* Eye drops 1%	18.27	15 ml OP	✓ Atropt	
CYCLOPENTOLATE HYDROCHLORIDE	05.40	45 ml OD	4 Ovelamil	
* Eye drops 1% TROPICAMIDE	25.16	15 ml OP	Cyclogyl	
* Eye drops 0.5%	20.52	15 ml OP	✓ Mydriacyl	
* Eye drops 1%		15 ml OP	✓ Mydriacyl	
Preparations for Tear Deficiency				
For acetylcysteine eye drops refer Standard Formulae, page 276	3			

✓ Methopt

15 ml OP

**HYPROMELLOSE** 

	(		Fully idised	Brand or Generic
	\$	Per	<b>✓</b>	Manufacturer
HYPROMELLOSE WITH DEXTRAN  ★ Eye drops 0.3% with dextran 0.1%	2.30	15 ml OP	<b>✓</b> P	oly-Tears

# **Preservative Free Ocular Lubricants**

# ⇒SA2431 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 Confirmed diagnosis by slit lamp or Schirmer test of severe secretory dry eye; and
- 2 Either:
  - 2.1 Patient is using eye drops more than four times daily on a regular basis; or
  - 2.2 Patient has had a confirmed allergic reaction to preservative in eye drop.

CARBOMER – Special Authority see SA2431 above – Retail Ophthalmic gel 0.3%, 0.5 g		30	✓ Poly-Gel
(Poly-Gel Ophthalmic gel 0.3%, 0.5 g to be delisted 1 July 202			•
POLYETHYLENE GLYCOL 400 AND PROPYLENE GLYCOL	Special Authority se	ee SA2431	above - Retail pharmacy
Eye drops 0.4% and propylene glycol 0.3%, 0.8 ml	10.78	30	Systane Unit Dose
SODIUM HYALURONATE [HYALURONIC ACID] - Special A	authority see SA2431 a	bove – Ret	ail pharmacy
Eye drops 1 mg per ml	13.58	10 ml OP	✓ Hylo-Fresh
Hylo-Fresh has a 6 month expiry after opening. The	Pharmacy Procedures	Manual res	striction allowing one bottle pe
month is not relevant and therefore only the prescribe	ed dosage to the neare	st OP may	be claimed.

Other Eye Preparations		
NAPHAZOLINE HYDROCHLORIDE  * Eye drops 0.1%5.65	15 ml OP	✓ <u>Albalon</u>
OLOPATADINE Eye drops 0.1%2.17	5 ml OP	✓ Olopatadine Teva
PARAFFIN LIQUID WITH WOOL FAT  * Eye oint 3% with wool fat 3%	3.5 g OP	✓ Poly-Visc
RETINOL PALMITATE Eye oint 138 mcg per g3.80	5 g OP	✓ VitA-POS



	Subsidy (Manufacturer's Price) \$	Subs Per	Fully Brand or sidised Generic Manufacturer
/arious			
HARMACY SERVICES  Brand switch fee	4.50	1 fee	<ul> <li>✓ BSF Dasatinib-Teva</li> <li>✓ BSF Ipca- Hydroxychloroquin</li> </ul>
			<ul> <li>✓ BSF Modafinil Max Health</li> <li>✓ BSF Pazopanib Teva</li> </ul>
a) May only be claimed once per patient.			✓ BSF Teriflunomide Sandoz
b) The Pharmacode for BSF Dasatinib-Teva is 2700 c) The Pharmacode for BSF Dasatinib-Teva is 2700 c) The Pharmacode for BSF Ipca-Hydroxychloroquii e) The Pharmacode for BSF Modafinil Max Health is f) The Pharmacode for BSF Pazopanib Teva is 270 Immunisation administration fee - flu	is 2701847 - see also pane is 2704676 - see also pane is 2704684 - see also pane is 2704684 - see also page 1704684 - see also page 170468 - see also page 1704684 - see also page 1704684 - see also	age 140 page 116 ge 146	<ul> <li>✓ Immunisation - Flu</li> <li>✓ Immunisation Other</li> <li>✓ Immunisation Flu</li> <li>and Shingles</li> </ul>
SF Dasatinib-Teva Brand switch fee to be delisted 1 June 2 SF Ipca-Hydroxychloroquine Brand switch fee to be deliste SF Modafinil Max Health Brand switch fee to be delisted 1 SF Pazopanib Teva Brand switch fee to be delisted 1 Augu SF Teriflunomide Sandoz Brand switch fee to be delisted 1	d 1 Åugust 2025) September 2025) ist 2025)		
Agents Used in the Treatment of Poisonings			
ntidotes			
ETYLCYSTEINE 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	✓ Hikma  Acetylcysteine   §29
lartindale Pharma Inj 200 mg per ml, 10 ml ampoule to be o	delisted 1 November 202	?5)	

# **Removal and Elimination**

b) Only on a PSO

a) Up to 10 inj available on a PSO

VI.	IMI	יטר	UΑ	ᆫ

a) Up to 250 ml available on a PSO

b) Only on a PSO

5

✓ <u>DBL Naloxone</u> Hydrochloride

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
DEFERASIROX – Special Authority see SA1492 below – Retail p Wastage claimable	pharmacy			
Tab 125 mg dispersible	276.00	28	✓	Exjade
Tab 250 mg dispersible	552.00	28	✓	Exjade
Tab 500 mg dispersible	1,105.00	28	✓	Exjade

# ⇒SA1492 Special Authority for Subsidy

**Initial application** only from a haematologist. Approvals valid for 2 years for applications meeting the following criteria: All of the following:

- 1 The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia; and
- 2 Deferasirox is to be given at a daily dose not exceeding 40 mg/kg/day; and
- 3 Any of the following:
  - 3.1 Treatment with maximum tolerated doses of deferiprone monotherapy or deferiprone and desferrioxamine combination therapy have proven ineffective as measured by serum ferritin levels, liver or cardiac MRI T2\*; or
  - 3.2 Treatment with deferiprone has resulted in severe persistent vomiting or diarrhoea; or
  - 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: Fither:

- 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.

#### 

#### ⇒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	151.01	10	✓ Deferoxamine Pfizer
* Inj 500 mg vial	131.31	10	S29 S29
	332.88		✓ DBL Desferrioxamine Mesylate for Inj BP
SODIUM CALCIUM EDETATE			
* Inj 200 mg per ml, 5 ml	53.31	6	
	(156.71)		Calcium Disodium Versenate



# **Standard Formulae**

Otaliaala i Olillalac			
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
, ,	·	Glycerol BP	4 ml
CODEINE LINCTUS (3 mg per 5 ml)		Water	to 40 ml
Codeine phosphate	60 mg		
Glycerol	40 ml	PILOCARPINE ORAL LIQUID	
Preservative	qs	Pilocarpine 4% eye drops	qs
Water	to 100 ml	Preservative	qs
CODEINE LINOTHO (45 5)		Water	to 500 ml
CODEINE LINCTUS (15 mg per 5 ml)	000	(Preservative should be used if quantity supplied is	for more
Codeine phosphate	300 mg	than 5 days.)	
Glycerol	40 ml	SALIVA SUBSTITUTE FORMULA	
Preservative	qs		F ~
Water	to 100 ml	Methylcellulose Preservative	5 g
FOLINIC MOUTHWASH		Water	qs to 500 ml
Calcium folinate 15 mg tab	1 tab		
Preservative	qs	(Preservative should be used if quantity supplied is than 5 days. Maximum 500 ml per prescription.)	ior more
Water	to 500 ml	man 5 days. Maximum 500 mi per prescription.)	
(Preservative should be used if quantity supplied is		SODIUM CHLORIDE ORAL LIQUID	
than 5 days. Maximum 500 ml per prescription.)	ioi illoic	Sodium chloride inj 23.4%, 20 ml	qs
than 5 days. Maximum 500 mi per prescription.		Water	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)	
(Use 1 ml of the 10% solution per 100 ml of oral liqu	id mixture)	Vancomycin 500 mg injection	5 vials
OMEDDA ZOLE OLIODENIOLONI		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	ım difficile
Sodium bicarbonate powder BP	8.4 g	following metronidazole failure)	
Water	to 100 ml		
PHENOBARBITONE ORAL LIQUID			
Phenobarbitone Sodium	1 g		
Glycerol BP	70 ml		

to 100 ml

Water

# EXTEMPORANEOUSLY COMPOUNDED PREPARATIONS AND GALENICALS

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

Per Manufacturer

# **Extemporaneously Compounded Preparations and Galenicals**

CODEINE PHOSPHATE – Safety medicine; prescriber may determin	e dispensina f	requency	
Powder – Only in combination		25 g	
	(90.09)		Douglas
Only in extemporaneously compounded codeine linctus.			
COLLODION FLEXIBLE			
Note: This product is no longer being manufactured by the suppli determined.	er and will be	delisted from 1	ine Schedule at a date to be
Collodion flexible	19.30	100 ml	✓ PSM
COMPOUND HYDROXYBENZOATE – Only in combination	10.00	100 1111	
Only in extemporaneously compounded oral mixtures.			
Soln	30.00	100 ml	✓ Midwest
GLYCERIN WITH SODIUM SACCHARIN - Only in combination			
Only in combination with Ora-Plus or when used in the vancomyc	in oral Iquuid S	Standard Form	nulae.
Suspension	30.95	473 ml	✓ Ora-Sweet SF
GLYCERIN WITH SUCROSE - Only in combination			
Only in combination with Ora-Plus or when used in the vancomyc	in oral Iquuid S		
Suspension	30.95	473 ml	✓ Ora-Sweet
GLYCEROL			•
* Liquid – Only in combination		500 ml	✓ healthE Glycerol BP
Only in extemporaneously compounded oral liquid preparatio	ns.		
METHYL HYDROXYBENZOATE	0.00	05	/ Mishanat
Powder	8.98	25 g	✓ Midwest
METHYLCELLULOSE Powder	26.05	100 ~	✓ MidWoot
Suspension – Only in combination		100 g 473 ml	<ul><li>✓ MidWest</li><li>✓ Ora-Plus</li></ul>
METHYLCELLULOSE WITH GLYCERIN AND SODIUM SACCHARIN			· Old-I lub
Suspension		473 ml	✓ Ora-Blend SF
METHYLCELLULOSE WITH GLYCERIN AND SUCROSE - Only in a		4701111	ora bicina or
Suspension		473 ml	✓ Ora-Blend
PHENOBARBITONE SODIUM			0.0 2.0
Powder – Only in combination	52.50	10 g	✓ MidWest
	325.00	100 g	✓ MidWest
Only in children up to 12 years		-	
PROPYLENE GLYCOL			
Only in extemporaneously compounded methyl hydroxybenzoate			_
Liq	11.25	500 ml	✓ Midwest
SODIUM BICARBONATE			
Powder BP – Only in combination		500 g	✓ Midwest
Only in extemporaneously compounded omeprazole and lans	soprazoie susp	ension.	
SYRUP (PHARMACEUTICAL GRADE) – Only in combination			
Only in extemporaneously compounded oral liquid preparations.  Liq	14 95	500 ml	✓ Midwest
•	لق.⊷ا	JUU IIII	- WIIWWEST
WATER Tap – Only in combination	0.00	1 ml	✓ Tap water
rap Only in combination	0.00	1 1111	- Iup water

Subsidy (Manufacturer's Price)

Fully 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]

400 a OP ✓ Polycal Powder .......6.72

# 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 Pri	ce)	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.

#### 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

continued...

✓ fully subsidised 279



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 pro	evious page – Hospit	al pharmacy [HP3]

Emulsion (neutral)		
38.44	500 ml OP	✓ Calogen
Emulsion (strawberry)15.38	200 ml OP	✓ Calogen
Oil	500 ml OP	✓ MCT oil (Nutricia)
MCT Emulsion, 250 ml143.65	4 OP	✓ Liquigen

### **Protein**

# ⇒SA1524 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 protein losing enteropathy; or
- 2 high protein needs; or
- 3 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula. **Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

PROTEIN SUPPLEMENT - Special Authority see SA1524	4 above – Hospital pharmacy [HP3]
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Powder	8.95	227 g OP	✓ Resource Beneprotein
	13.82	225 a OP	✓ Protifar

Subsidy (Manufacturer's Price) \$

Subsidised Per

Fully

Brand or Generic 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 S.	A1095 above – I	Hospital phare	macy [HP3]
Liquid, 500 ml bottle	4.65	1 OP	✓ Glucerna Select
DIABETIC ORAL FEED 1KCAL/ML - Special Authority see SA109	95 above – Hosp	ital pharmacy	y [HP3]
Liquid (strawberry), 200 ml bottle	2.25	1 OP	✓ Diasip
Liquid (vanilla), 200 ml bottle	2.10	1 OP	✓ Nutren Diabetes
	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.

✓ fully subsidised 281

Subsidy (Manufacturer's Price)

Fully Subsidised Brand or Generic Manufacturer

# Paediatric Products For Children Awaiting Liver Transplant

#### ⇒SA1098 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient is a child (up to 18 years) who requires a liver transplant.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

#### Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL FEED 1KCAL/ML - Special Authority see SA1098 above - Hospital pharmacy (HP3)

400 g OP ✓ Heparon Junior 

# Paediatric Products For Children With Chronic Renal Failure

# **⇒SA1099** Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 vears where the patient is a child (up to 18 years) with acute or chronic kidney disease.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

### Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL FEED 1KCAL/ML - Special Authority see SA1099 above - Hospital pharmacy [HP3] Powder .......64.26 400 a OP ✓ Kindergen

#### Paediatric Products

# ⇒SA1379 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

#### Both:

- 1 Child is aged one to ten years; and
- 2 Any of the following:
  - 2.1 the child is being fed via a tube or a tube is to be inserted for the purposes of feeding; or
  - 2.2 any condition causing malabsorption; or
  - 2.3 faltering growth in an infant/child; or
  - 2.4 increased nutritional requirements; or
  - 2.5 the child is being transitioned from TPN or tube feeding to oral feeding.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for

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

continued...

applications meeting the following criteria:

#### Roth:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

PAEDIATRIC ENTERAL FEED 1.5KCAL/ML - Special Authority see S Liquid, 500 ml bottle		the previous pa 1 OP	ge – Hospital pharmacy [HP3]  ✓ Nutrini Energy RTH
PAEDIATRIC ENTERAL FEED 1KCAL/ML - Special Authority see SA Liquid, 500 ml bottle		e previous page 1 OP	<ul> <li>Hospital pharmacy [HP3]</li> <li>Pediasure RTH</li> <li>Nutrini RTH</li> </ul>
PAEDIATRIC ENTERAL FEED WITH FIBRE 1.5KCAL/ML - Special Apharmacy [HP3]	Authority se	e SA1379 on th	ne previous page – Hospital
Liquid, 500 ml bottle	7.14	1 OP	<ul><li>Nutrini Energy Multi Fibre</li></ul>
PAEDIATRIC ORAL FEED 1.5KCAL/ML - Special Authority see SA13	379 on the	orevious page -	- Hospital pharmacy [HP3]
Liquid (strawberry), 200 ml bottle		1 OP	✓ Fortini
Liquid (vanilla), 200 ml bottle		1 OP	✓ Fortini
Liquid (vanilla), 500 ml bottle	8.67	1 OP	✓ Pediasure Plus
PAEDIATRIC ORAL FEED 1KCAL/ML - Special Authority see SA137	9 on the pro	evious page – H	lospital pharmacy [HP3]
Liquid (chocolate), 200 ml bottle		1 OP	✓ Pediasure
Liquid (strawberry), 200 ml bottle		1 OP	✓ Pediasure
Liquid (vanilla), 200 ml bottle	1.33	1 OP	✓ Pediasure
Liquid (vanilla), 250 ml can		1 OP	✓ Pediasure
PAEDIATRIC ORAL FEED WITH FIBRE 1.5KCAL/ML - Special Authopharmacy [HP3]	ority see SA	A1379 on the pr	evious page – Hospital
Liquid (chocolate), 200 ml bottle	1.90	1 OP	✓ Fortini Multi Fibre
Liquid (strawberry), 200 ml bottle	1.90	1 OP	✓ Fortini Multi Fibre
Liquid (unflavoured), 200 ml bottle		1 OP	✓ Fortini Multi Fibre
Liquid (vanilla), 200 ml bottle	1.90	1 OP	✓ Fortini Multi Fibre
PEPTIDE-BASED ORAL FEED - Special Authority see SA1379 on th	e previous	page – Hospital	pharmacy [HP3]
Powder		400 g OP	✓ Peptamen Junior

#### **Renal Products**

### ⇒SA1101 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient has acute or chronic kidney disease.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

### Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

RENAL ORAL FEED 1.8 KCAL/ML - Special Authority see SA1101 above	/e – Hospita	l pharmacy	[HP	3]
Liquid, 220 ml carton	3.31	1 OP	1	Nepro HP
				(strawberry)
			1	Nepro HP (vanilla)

✓ fully subsidised

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	(Manufacturer's Price)	Subsid	dised	Generic
	\$	Per	•	Manufacturer
RENAL ORAL FEED 2 KCAL/ML - Special Authority see SA110	1 on the previous page	ge – Hospita	al phar	macy [HP3]
Liquid, 200 ml bottle	13.24	4 OP	✓ N	ovaSource Renal
Liquid (apricot) 125 ml	13.72	4 OP	✓ R	enilon 7.5
Liquid (caramel) 125 ml	13.72	4 OP	✓ R	enilon 7.5

Subsidy

Fully

Brand or

### **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			
Liquid, 1,000 ml bottle	22.39	1 OP	✓ Vital
ORAL ELEMENTAL FEED 0.8KCAL/ML - Special Authority	see SA1377 above –	Hospital pha	macy [HP3]
Liquid (grapefruit), 250 ml carton	179.46	18 OP	✓ Elemental 028 Extra
Liquid (pineapple & orange), 250 ml carton	179.46	18 OP	✓ Elemental 028 Extra
Liquid (summer fruits), 250 ml carton	179.46	18 OP	✓ Elemental 028 Extra
ORAL ELEMENTAL FEED 1KCAL/ML - Special Authority se	e SA1377 above – Ho	ospital pharm	acy [HP3]
Powder (unflavoured), 80 g sachet	4.50	1 OP	✓ Vivonex TEN
SEMI-ELEMENTAL ENTERAL FEED 1KCAL/ML - Special A	authority see SA1377	above – Hos	pital pharmacy [HP3]
Liquid, 500 ml bottle	7.47	1 OP	<ul><li>Nutrison Advanced</li></ul>
			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:

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

continued...

- 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]

# 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.

continued...

✓ fully subsidised 285



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

continued...

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

All of the following:

1 Any of the following:

Patient is Malnourished

- 1.1 Patient has a body mass index (BMI) of less than 18.5 kg/m<sup>2</sup>; or
- 1.2 Patient has unintentional weight loss greater than 10% within the last 3-6 months; or
- 1.3 Patient has a BMI of less than 20 kg/m² and unintentional weight loss greater than 5% within the last 3-6 months; and
- 2 Any of the following:

Patient has not responded to first-line dietary measures over a 4 week period by:

- 2.1 Increasing their food intake frequency (eg snacks between meals); or
- 2.2 Using high-energy foods (e.g. milkshakes, full fat milk, butter, cream, cheese, sugar etc); or
- 2.3 Using over the counter supplements (e.g. Complan); and
- 3 A nutrition goal has been set (e.g. to reach a specific weight or BMI).

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

- 1 A nutrition goal has been set (eg reach a specific weight or BMI); and
- 2 Any of the following:

Patient is Malnourished

- 2.1 Patient has a body mass index (BMI) of less than 18.5 kg/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
    - 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

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

#### continued...

- 4 Tempomandibular surgery or glossectomy; or
- 5 Both:
  - 5.1 Pregnant: and
  - 5.2 Any of the following:
    - 5.2.1 Patient is in early pregnancy (< 13 weeks) and has severe clinical hyperemesis gravidarum requiring admission to hospital and is unlikely to meet her nutritional requirements due to continuing hyperemesis gravidarum; or
    - 5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or
    - 5.2.3 Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met.

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

### Any of the following:

- 1 Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube refer to specific medical condition criteria); or
- 2 Cystic Fibrosis; or
- 3 Liver disease: or
- 4 Chronic Renal failure: or
- 5 Inflammatory bowel disease; or
- 6 Chronic obstructive pulmonary disease with hypercapnia; or
- 7 Short bowel syndrome: or
- 8 Bowel fistula: or
- 9 Severe chronic neurological conditions: or
- 10 Epidermolysis bullosa; or
- 11 AIDS (CD4 count < 200 cells/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 SA185	9 on page 285 – Ho	spital pharma	acy [HP3]
Liquid, 1,000 ml bottle	8.68	1 OP	✓ Ensure Plus HN RTH
	9.00		✓ Nutrison Energy
Liquid, 250 ml can	2.17	1 OP	✓ Ensure Plus HN
ENTERAL FEED 1KCAL/ML - Special Authority see SA1859	on page 285 – Hosp	oital pharmac	y [HP3]
Liquid, 1,000 ml bottle	6.56	1 OP	✓ Osmolite RTH
•	6.90		✓ Nutrison RTH

✓ fully subsidised 287

	Subsidy (Manufacturer's F \$	Price) Sub	Fully sidised	Brand or Generic Manufacturer
ENTERAL FEED WITH FIBRE 0.83 KCAL/ML - Special Authority Liquid, 1,000 ml bottle		n page 285 – I 1 OP		il pharmacy [HP3] Nutrison 800 Complete Multi Fibre
ENTERAL FEED WITH FIBRE 1 KCAL/ML - Special Authority se Liquid, 1,000 ml bottle		age 285 – Hos 1 OP	' 🗸,	narmacy [HP3] Jevity RTH Nutrison Multi Fibre
ENTERAL FEED WITH FIBRE 1.2KCAL/ML - Special Authority s Liquid, 1,000 ml bottle		page 285 – Ho 1 OP		oharmacy [HP3] Jevity Plus RTH
ENTERAL FEED WITH FIBRE 1.5KCAL/ML - Special Authority s Liquid, 1,000 ml bottle		page 285 – Ho 1 OP	✓,	oharmacy [HP3] Jevity HiCal RTH Nutrison Energy Multi Fibre
ORAL FEED (POWDER) - Special Authority see SA1859 on page	e 285 – Hospita	al pharmacy [H	P31	
Powder (chocolate)		840 g OP		Sustagen Hospital Formula
	26.00	850 g OP	✓	Ensure
Powder (vanilla)	14.00	840 g OP	•	Sustagen Hospital Formula Active
	26.00	850 g OP	✓	Ensure
Additional subsidy by endorsement is available for patients be epidermolysis bullosa, or as exclusive enteral nutrition in child disease, or for patients with COPD and hypercapnia, defined a endorsed accordingly.  Liquid (banana), 200 ml bottle – Higher subsidy of up to \$1.76	ren under the a as CO2 value e	ige of 18 years	for the	treatment of Crohn's
per 1 btl with Endorsement		1 OP		
·	(1.56) (1.76)	101		Ensure Plus Fortisip
Liquid (chocolate), 200 ml bottle - Higher subsidy of up to				
\$1.76 per 1 btl with Endorsement		1 OP		
	(1.56) (1.76)			Ensure Plus Fortisip
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 p				
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		1 OP		
	(1.56)			Ensure Plus
	(1.76)			Fortisip
Liquid (vanilla), 237 ml can - Higher subsidy of \$1.65 per				
1 can with Endorsement		1 OP		
	(1.65)		ļ	Ensure Plus

	Subsidy	I	Fully	Brand or
	(Manufacturer's Price)	Subsid	lised	Generic
	\$	Per	1	Manufacturer
ORAL FEED WITH FIBRE 1.5 KCAL/ML - Special Authority see	, ,			,
Additional subsidy by endorsement is available for patients b	eing bolus fed througl	h a feeding	tube, o	or who have severe
epidermolysis bullosa. The prescription must be endorsed a	ccordingly.			

Liquid (chocolate), 200 ml bottle - Higher subsidy of \$1.76 per			
1 btl with Endorsement	0.72	1 OP	
	(1.76)		Fortisip Multi Fibre
Liquid (strawberry), 200 ml bottle - Higher subsidy of \$1.76 per			
1 btl with Endorsement	0.72	1 OP	
	(1.76)		Fortisip Multi Fibre
Liquid (vanilla), 200 ml bottle - Higher subsidy of \$1.76 per			
1 btl with Endorsement	0.72	1 OP	
	(1.76)		Fortisip Multi Fibre

## **High Calorie Products**

### ⇒SA1195 Special Authority for Subsidy

**Initial application** — **(Cystic fibrosis)** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

All of the following:

- 1 Cystic fibrosis; and
- 2 other lower calorie products have been tried; and
- 3 patient has substantially increased metabolic requirements.

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 (Manufacturer's Price) \$	S Per	Fully ubsidised	Brand or Generic Manufacturer
ENTERAL FEED 2 KCAL/ML - Special Authority see SA1195 c Liquid, 1,000 ml bottle		- Hospit 1 OP		icy [HP3] Ensure Two Cal HN RTH
Liquid, 500 ml bottle	6.82	1 OP	<b>✓</b> N	lutrison Concentrated
ORAL FEED 2 KCAL/ML – Special Authority see SA1195 on th Additional subsidy by endorsement is available for patients epidermolysis bullosa. The prescription must be endorsed a Liquid (vanilla), 200 ml bottle – Higher subsidy of \$2.34 per 1 btl with Endorsement	being bolus fed throug accordingly.		ding tube,	•

# **Food Thickeners**

#### ⇒SA1106 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient has motor neurone disease with swallowing disorder.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

FOOD THICKENER - Spe	cial Authority see SA1106 above – Hospital pharmacy	[HP3]	
Powder	8.29	300 g OP	✓ Nutilis
	24.00	380 g OP	✓ Aptamil Feed
			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 SA1	1729 above – Hospital	pharmacy [HP3]	
Powder	2.81	1,000 g OP	
	(5.15)	•	Healtheries Simple
			Baking Mix

	Subsidy		ılly Brand or
	(Manufacturer's Pri		
	\$	Per	✓ Manufacturer
LUTEN FREE BREAD MIX - Special Authority see SA1729 o	n the previous pag	e – Hospital phai	rmacy [HP3]
Powder	3.93	1,000 g OP	,. ,
	(7.32)	, 0	NZB Low Gluten
	, ,		Bread Mix
	3.51		
	(10.87)		Horleys Bread Mix
LITEN EDEC ELOUD Special Authority can SA1720 on the	, ,	Jospital pharmas	,
LUTEN FREE FLOUR - Special Authority see SA1729 on the Powder		2,000 g OP	y [i if o]
ruwuei	(18.10)	2,000 y OF	Harlove Flour
	( /		Horleys Flour
LUTEN FREE PASTA - Special Authority see SA1729 on the			y [HP3]
Buckwheat Spirals		250 g OP	
	(3.11)		Orgran
Corn and Vegetable Shells	2.00	250 g OP	
	(2.92)		Orgran
Corn and Vegetable Spirals	2.00	250 g OP	
	(2.92)		Orgran
Rice and Corn Lasagne Sheets	1.60	200 g OP	
	(3.82)		Orgran
Rice and Corn Macaroni	2.00	250 g OP	
	(2.92)	-	Orgran
Rice and Corn Penne	2.00	250 g OP	•
	(2.92)	ū	Orgran
Rice and Maize Pasta Spirals	2.00	250 g OP	•
·	(2.92)	ū	Orgran
Rice and Millet Spirals	` '	250 g OP	•
•	(3.11)	ŭ	Orgran
Rice and corn spaghetti noodles	` '	375 g OP	ŭ
	(2.92)	J	Orgran
Vegetable and Rice Spirals		250 g OP	· ·
		- 3 -	Oraran
·	(2.92)		Olulali
Italian long style spaghetti	(2.92) 2.00	220 g OP	Orgran

(Orgran Buckwheat Spirals to be delisted 1 July 2025)

(Orgran Corn and Vegetable Shells to be delisted 1 July 2025)

(Orgran Corn and Vegetable Spirals to be delisted 1 July 2025)

(Orgran Rice and Corn Lasagne Sheets to be delisted 1 July 2025)

(Orgran Rice and Corn Macaroni to be delisted 1 July 2025)

(Orgran Rice and Corn Penne to be delisted 1 July 2025)

(Orgran Rice and Maize Pasta Spirals to be delisted 1 July 2025)

(Orgran Rice and Millet Spirals to be delisted 1 July 2025)

(Orgran Rice and corn spaghetti noodles to be delisted 1 July 2025)

(Orgran Vegetable and Rice Spirals to be delisted 1 July 2025)

(Orgran Italian long style spaghetti to be delisted 1 July 2025)

# **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.

Subsidy	Fully	Brand or	
(Manufacturer's Price)	Subsidised	Generic	
` <u>^</u>	Dox /	Manufacturer	

# **Supplements For Homocystinuria**

AMINOACID FORMULA WITHOUT METHIONINE – Special Authority see SA2357 on the previous page – Hospital pharmacy [HP3]

Powder (neutral), 36 g sachets	750.30	30	HCU Anamix Junior
Powder, 12.5 g sachets	349.65	30	✓ HCU Explore 5
Powder, 25 g sachets	1,048.95	30	✓ HCU Express 15
Powder (neutral), can		500 g OP	✓ XMET Maxamum
Powder (unflavoured), can	260.00	400 g OP	✓ HCU Anamix Infant
Liquid (juicy berries), 125 ml bottle	1,684.80	30	✓ HCU Lophlex LQ
Liquid (orange), 125 ml bottle		36	✓ HCU Anamix Junior
, , ,			10

# Supplements For MSUD and short chain enoyl coA hydratase deficiency

AMINOACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE - Special Authority see SA2357 on the previous page - Hospital pharmacy [HP3]

Powder (neutral) 36 g sachets	750.00	30	<ul><li>MSUD Anamix Junior</li></ul>
Powder, 12.5 g sachets	349.65	30	✓ MSUD Explore 5
Powder, 25 g sachets		30	✓ MSUD Express 15
Powder (neutral), can		500 g OP	✓ MSUD Maxamum
Powder (orange), can	454.71	500 g OP	MSUD Maxamum
Powder (unflavoured), can	260.00	400 g OP	<ul><li>MSUD Anamix Infant</li></ul>
Liquid (orange) 125 ml bottles	941.40	36	<ul><li>MSUD Anamix Junior LQ</li></ul>
Liquid (juicy berries) 125 ml pouches	1,684.80	30	✓ MSUD Lophlex LQ 20

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

# **Supplements For PKU**

•••			
INOACID FORMULA WITHOUT PHENYLALANINE			, , .
Tabs		75 OP	✓ Phlexy 10
Powder (Lemon), 34 g sachets		30	✓ PKU Express 20
Powder (Neutral), 12.5 g sachets	220.88	30	✓ PKU Explore 5
Powder (Neutral), 34 g sachets		30	✓ PKU Express 20
Powder (Orange), 25 g sachets	441.75	30	✓ PKU Explore 10
Powder (Orange), 34 g sachets	883.50	30	✓ PKU Express 20
Powder (Raspberry), 25 g sachets	441.75	30	✓ PKU Explore 10
Powder (Tropical), 34 g sachets		30	✓ PKU Express 20
Powder (berry) 28 g sachets	936.00	30	✓ PKU Lophlex Powder
Powder (chocolate) 36 g sachet	393.00	30	<ul> <li>PKU Anamix Junior Chocolate</li> </ul>
Powder (neutral) 28 g sachets	936.00	30	✓ PKU Lophlex Powder
Powder (neutral) 36 g sachets	393.00	30	✓ PKU Anamix Junior
Powder (orange) 28 g sachets	936.00	30	✓ PKU Lophlex Powder
Powder (orange) 36 g sachet	393.00	30	<ul><li>PKU Anamix Junior Orange</li></ul>
Powder (unflavoured) 12.5 g sachets	234.00	30	✓ PKU First Spoon
Powder (vanilla) 36 g sachet	393.00	30	<ul><li>PKU Anamix Junior Vanilla</li></ul>
Infant formula	174.72	400 g OP	✓ PKU Anamix Infant
Powder (neutral), 4 × 400 g can	715.16	1,600 g OP	✓ Pku Start
Powder (orange)		500 g OP	✓ XP Maxamum
Powder (unflavoured)	320.00	500 g OP	✓ XP Maxamum
Liquid (berry), 125 ml bottle		1 ŎP	✓ PKU Anamix Junior LQ
Liquid (orange), 125 ml bottle	13.10	1 OP	✓ PKU Anamix Junior LQ
Liquid (forest berries), 250 ml carton	540.00	18 OP	✓ Easiphen Liquid
Liquid (juicy tropical) 125 ml		30 OP	✓ PKU Lophlex LQ 20
Oral semi-solid (berries) 109 g		36 OP	✓ PKU Lophlex Sensation 20
Liquid (juicy berries) 62.5 ml	939.00	60 OP	✓ PKU Lophlex LQ 10
1 . 0 . , =====			
Liquid (juicy berries) 125 ml	936.00	30 OP	✓ PKU Lophlex LQ 20

	Subsidy (Manufacturer's Price)	Cub	Fully Brand or sidised Generic
	(Manufacturer's Price)	Per	✓ Manufacturer
GLYCOMACROPEPTIDE AND AMINO ACID CONTAINS SOM	E DUENIVI AI ANIINE	Special	
page 291 – Hospital pharmacy [HP3]	E FIIENTLALANINE	– Speciai	Authority See SA2557 Off
Powder (Banana) 35 g sachets	030.00	30	✓ PKU
1 Owder (Dariana) 55 g sacriets	930.00	30	sphere20 Banana
Powder (Berry), 20 g sachets	440.00	60	✓ PKU Restore
Fowder (Derry), 20 g sacriets	449.20	00	Powder
Powder (Chocolate) 32 g sachets	000 56	30	✓ PKU Build
Fowder (Chocolate) 32 y sacriets	090.00	30	20 Chocolate
Powder (Chocolate) 35 g sachets	020.00	30	✓ PKU
Powder (Chocolate) 35 g sacriets	930.00	30	
			sphere20 Chocolate
Powder (Lemon) 35 g sachets	930.00	30	✓ PKU
. 01.00. (20.10.1, 00 g 00.01.00.11.11.11.11.11.11.11.11.11.11.1			sphere20 Lemon
Powder (Lemonade) 33.4 g sachets	936.00	30	✓ PKU GMPro Ultra
Towast (Estitoridas) 55.4 g sastistis		00	Lemonade
Powder (Neutral), 15 g sachets	449.28	30	✓ PKU Build 10
Powder (Orange), 20 g sachets		60	✓ PKU Restore
1 Owder (Orange), 20 g sacries		00	Powder
Powder (Raspberry Lemonade) 31 g sachets	808 56	30	✓ PKU Build
Towaer (Haspberry Lemonade) of g sacriets	090.00	30	20 Raspberry
			Lemonade
Powder (Smooth) 31 g sachets	909 56	30	✓ PKU Build
Fowder (Sillootti) 31 g sacriets	090.00	30	20 Smooth
Powder (Vanilla) 33 g sachets	909 56	30	✓ PKU Build 20 Vanilla
Powder (varilla) 33 g sachets		30	✓ Glytactin Bettermilk
Powder (inflation, 40 g sacriets		30	✓ PKU GMPro Mix-In
Powder (vanilla) 33.4 g sachets		30	✓ PKU GMPro Ultra
1 owder (variila) oo.4 g sacricis		00	Vanilla
Powder (Red Berry) 35 g sachets	930.00	30	✓ PKU sphere20 Red
Toward (flea berry) 00 g sacricis		00	Berry
Powder (Vanilla) 35 g sachets	030.00	30	✓ PKU
Fowder (Varilla) 55 y Sacriets	930.00	30	sphere20 Vanilla
Liquid (neutral), 250 ml carton	200.00	18	✓ PKU GMPro LQ
		30 OP	
Liquid (original), 250 ml carton	004.40	30 OF	✓ PKU Glytactin RTD  15
Liquid (Coffee Mecha) OFO ml cortan	604.45	00 OD	
Liquid (Coffee Mocha), 250 ml carton	004.40	30 OP	✓ PKU Glytactin RTD  15 Lite
Liquid (chanalata), QEO ml cortan	604.45	00 OD	
Liquid (chocolate), 250 ml carton		30 OP	✓ PKU Glytactin RTD  15
Liquid (capilla) OFO rel carter	CO4 45	00.00	15
Liquid (vanilla), 250 ml carton	084.45	30 OP	✓ PKU Glytactin RTD
			15 Lite

# Foods

LOW PROTEIN BAKING MIX — Special Authority see SA2357 on page 291 — Hospital pharmacy [HP3]
Powder ......8.55 500 g OP ✓ Loprofin Mix

	Subsidy		Fully	/ Brand or
	(Manufacturer's Price			
	\$	Per	_	Manufacturer
LOW PROTEIN PASTA - Special Authority see SA2357 on page	291 - Hospital pl	harmacy [HP3]		
Animal shapes	12.39	500 g OP	1	Loprofin
Lasagne	6.19	250 g OP	1	Loprofin
Low protein rice pasta	12.39	500 g OP	1	Loprofin
Macaroni	6.19	250 g OP	1	Loprofin
Penne	12.39	500 g OP	1	Loprofin
Spaghetti	12.39	500 g OP	1	Loprofin
Spirals		500 g OP		Loprofin
Supplements for Tyrosinaemia				
AMINOACID FORMULA WITHOUT PHENYLALANINE AND TYF	OSINE - Special	Authority see	SA	2357 on page 291 – Hospita
pharmacy [HP3]				
Powder (Neutral), 12.5 g sachets	349.65	30	1	TYR Explore 5
Powder (neutral) 36 g sachets	471.00	30	1	TYR Anamix Junior
Powder, can		400 g OP	1	TYR Anamix Infant
Liquid (juicy berries) 125 ml pouches		30		TYR Lophlex LQ 20
Liquid (orange) 125 ml bottle		36		TYR Anamix Junior
qa-a (o-ago)		•		LQ
GLYCOMACROPEPTIDE AND AMINO ACID CONTAINS SOME SA2357 on page 291 – Hospital pharmacy [HP3]	TYROSINE AND	PHENYLALAN	IINI	<del></del>
	1 200 60	20	./	TVD Caboro 20
Powder (Red Berry), 35 g sachets		30		TYR Sphere 20
Powder (Vanilla), 35 g sachets	1,398.60	30	•	TYR Sphere 20
Supplements for Organic Acidaemias				
AMINOACID FORMULA WITHOUT ISOLEUCINE, METHIONINE	THREONINE AN	ID VALINE -	Sne	cial Authority see SA2357
on page 291 – Hospital pharmacy [HP3]	.,	ID VALITE	Opc	olal rialionly see on 2007
Powder, can	260.00	400 g OP	/	MMA/PA Anamix
i owder, dari	200.00	400 g Oi	•	Infant
AMINOACID FORMULA WITHOUT METHIONINE, THREONINE	AND VALINE – S	Special Authori	ty s	ee SA2357 on page 291 –
Hospital pharmacy [HP3]				
Powder (neutral), 18 g sachets	750.30	30	/	MMA/PA Anamix
				Junior
Powder, 12.5 g sachets	349.65	30	1	MMA/PA Explore 5
Powder, 25 g sachets		30	1	MMA/PA Express 15
Supplements for Glutaric Aciduria type 1				
Supplements for Glutaric Aciduna type i				
AMINOACID FORMULA WITHOUT LYSINE - Special Authority	see SA2357 on na	age 291 – Hos	oital	I pharmacy [HP3]
Powder (neutral), 18 g sachets		30		GA1 Anamix Junior
Powder, 12.5 g sachets		30		GA Explore 5
Powder, can		400 g OP		GA1 Anamix Infant
1 Owder, carr	200.00	400 g Oi		WAT AHAIHIX IIIIAHU
Supplements for Glycogen Storage Disease				
., , , , ,				
HIGH AMYLOPECTIN CORN-STARCH - Special Authority see	SA2357 on page 2	291 – Hospital		
Powder, 60 g sachets	241.62	30	1	Glycosade
Oingle deserving solds				
Single dose amino acids				
ARGININE - Special Authority see SA2357 on page 291 - Hosp	ital pharmacy (HP	31		
Powder, 4 g sachets		30	1	Arginine2000
. 55., . g 0001010		00	-	3

	Subsidy (Manufacturer's Price \$	) Per	Fully Subsidised	
CITRULLINE - Special Authority see SA2357 on page 291 - Powder, 4 g sachets	211.45	30	1	Citrulline1000
ISOLEUCINE – Special Authority see SA2357 on page 291 – Powder, 4 g sachets	141.05	P3] 30	•	Isoleucine50
LEUCINE – Special Authority see SA2357 on page 291 – Hos Powder, 4 g sachets		30	•	Leucine100
PHENYLALANINE – Special Authority see SA2357 on page 2 Powder, 4 g sachets		y [HP3 30	-	Phenylalanine50
TYROSINE – Special Authority see SA2357 on page 291 – H Powder, 4 g sachets	ospital pharmacy [HP3			Tyrosine1000
VALINE – Special Authority see SA2357 on page 291 – Hosp Powder, 4 g sachets	, ,, ,	30	•	Valine50
Other Fat Modified Products				
ELEMENTAL FEED WITH HIGH MEDIUM CHAIN TRIGLYCE	RIDES - Special Auth	ority se	ee SA2357	on page 291 – Hospital
pharmacy [HP3] Powder (neutral), 100 g sachets	47.01	10	1	Emsogen
Carbohydrate and Fat with added vitamins an	nd minerals			
PROTEIN FREE SUPPLEMENT CONTAINING CARBOHYDF Authority see SA2357 on page 291 – Hospital pharmacy [HP3	]			·
Powder (neutral), can	49.29 4	100 g C		Energivit
Essential Amino Acids				
ESSENTIAL AMINOACID FORMULA – Special Authority see Powder (neutral), can		- Hosp 200 g C		acy [HP3] Essential Amino Acid Mix
Infant Formulae				
For Williams Syndrome				
Initial application only from a dietitian, relevant specialist or vyear where the patient is an infant suffering from Williams Syn Renewal only from a dietitian, relevant specialist, vocationally recommendation of a dietitian, relevant specialist or vocational applications meeting the following criteria:  Both:  1 The treatment remains appropriate and the patient is be	drome and associated registered general prad lly registered general p	hypero ctitione ractitio	alcaemia. r or gener	al practitioner on the
General Practitioners must include the name of the die practitioner and date contacted.	•		cationally	registered general

LOW CALCIUM INFANT FORMULA - Special Authority see SA1110 above - Hospital pharmacy [HP3]

400 g OP

✓ Locasol

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

# **Gastrointestinal and Other Malabsorptive Problems**

AMINO ACID FORMULA - Special Authority see SA2092 below - Hospital phar	macy [HP3]	
Powder43.60	400 g OP	<ul><li>✓ Alfamino</li><li>✓ Alfamino Junior</li></ul>
Powder (unflavoured)55.61	400 g OP	<ul><li>✓ Neocate Gold</li><li>✓ Neocate Junior</li><li>Unflavoured</li></ul>
65.72		✓ Neocate SYNEO ✓ Elecare ✓ Elecare LCP
Powder (vanilla)55.61	400 g OP	✓ Neocate Junior Vanilla
65.72		✓ Elecare

### ⇒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) Subsidised Generic \$ Per ✔ Manufacturer

continued...

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...

(Man	Subsidy ufacturer's Price)			Brand or Generic
·	\$	Per	•	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 pharmacy [HP3]

Liquid 1 kcal/ml, 500 ml bottle12.44	1 OP	✓ Nutrini Peptisorb
Liquid 1.5 kcal/ml, 500 ml bottle18.66	1 OP	✓ Nutrini Peptisorb
		Energy

### ⇒SA1953 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has impaired gastrointestinal function and either cannot tolerate polymeric feeds, or polymeric feeds are unsuitable; and
- 2 Any of the following:
  - 2.1 Severe malabsorption; or
  - 2.2 Short bowel syndrome; or
  - 2.3 Intractable diarrhoea; or
  - 2.4 Biliary atresia; or
  - 2.5 Cholestatic liver diseases causing malabsorption; or
  - 2.6 Cystic fibrosis; or
  - 2.7 Proven fat malabsorption; or
  - 2.8 Severe intestinal motility disorders causing significant malabsorption; or
  - 2.9 Intestinal failure: or
  - 2.10 Both:
    - 2.10.1 The patient is currently receiving funded amino acid formula; and
    - 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 - Spec	cial Authority see SA1557 on the	e next page	<ul><li>Hospital pharmacy [HP3]</li></ul>
Powder	18.10	450 g OP	✓ Pepti-Junior
	36.20	900 g OP	✓ Allerpro Syneo 1
		-	✓ Allerpro Syneo 2

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

#### ⇒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.

continued...

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

continued...

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 se	e SA1197 abo	ve – Hospital p	harmacy [HP3]
Powder (unflavoured)	36.92	300 g OP	✓ KetoCal 4:1
			✓ Ketocal 3:1
Powder (vanilla)	36.92	300 g OP •	✓ KetoCal 4:1

### SECTION I: NATIONAL IMMUNISATION SCHEDULE

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

# **Vaccinations**

#### BACILLUS CALMETTE-GUERIN VACCINE - [Xpharm]

For infants at increased risk of tuberculosis. Increased risk is defined as:

- 1) living in a house or family with a person with current or past history of TB; or
- having one or more household members or carers who within the last 5 years lived in a country with a rate of TB > or equal to 40 per 100,000 for 6 months or longer; or
- 3) during their first 5 years will be living 3 months or longer in a country with a rate of TB > or equal to 40 per 100,000 Note a list of countries with high rates of TB are available at www.health.govt.nz/tuberculosis (search for downloads) or www.bcgatlas.org/index.php.

lnj	Myc	ob	act	eri	ium	bc	ovis	BCC	3 (B	acillus	Ca	lm	ette-	Gue	rin),

Danish strain 1331, live attenuated, vial with diluent......0.00 10 

■ BCG Vaccine AJV

# COVID-19 VACCINE - [Xpharm]

Inj 3 mcg bretovameran per 0.3 ml, 0.48 ml vial; infant vaccine,

Up to three doses for previously unvaccinated children aged 6 months - 4 years at high risk of severe illness.

# Inj 10 mcg bretovameran per 0.3 ml, 0.48 ml vial; paediatric

#### Either:

- 1) One dose for previously unvaccinated children aged 5-11 years old; or
- 2) Up to three doses for immunocompromised children aged 5-11 years old.

### Inj 30 mcg bretovameran per 0.3 ml, 0.48 ml vial; adult vaccine,

(JN.1)

#### Any of the following:

- 1) One dose for previously unvaccinated people aged 12-15 years old; or
- 2) Up to three doses for immunocompromised people aged 12-15 years old; or
- 3) Up to two doses for previously unvaccinated people 16-29 years old; or
- 4) Up to four doses for people aged 16-29 at high risk of severe illness; or
- 5) One dose for previously unvaccinated people aged 30 and older; or
- 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)	Subsidised		Generic
 \$	Per	•	

#### 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.

pertussis toxoid, 8 mcg pertussis filamentous		
haemagglutinin and 2.5 mcg pertactin in 0.5 ml prefilled		
syringe	10	✓ Boostrix

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

#### 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

10 ✓ Infanrix IPV

#### 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

10

✓ Infanrix-hexa

✓ Havrix Junior

			IVATIONAL INMONISATION SCILEDOLL				
			Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer	
HAEMO	DPHIL	US INFLUENZAE TYPE B VACCINE					
a)	Only	on a prescription					
b)	No p	atient co-payment payable					
c)							
	A)	One dose for people meeting any of the following:					
		<ol> <li>For primary vaccination in children; or</li> <li>An additional dose (as appropriate) is funded</li> </ol>	for (re-)immunication f	or no	onla noet ha	aematonoietic etem cell	
		transplantation, or chemotherapy; functional a					
		transplant, pre or post cochlear implants, rena					
		3) For use in testing for primary immunodeficience	cy diseases, on the red	comm	endation of	an internal medicine	
		physician or paediatrician.					
	B)	Contractors will be entitled to claim payment from the					
		vaccine to people eligible under the above criteria p for subsidised immunisation, and they may only do				` ,	
		in the Pharmaceutical Schedule.	so in respect of the rid	a <del>c</del> ilio <sub>l</sub>	Jillus IIIIue	nzae type b vaccine listeu	
	C)	Contractors may only claim for populations within the	ne criteria that are cove	ered b	y their cont	ract, which may be a	
	,	sub-set of the population described in paragraph A			•	,	
Inj	10 m	cg vial with diluent syringe	0.00	1	✓ A	ct-HIB	
HEPAT	ITIS A	A VACCINE - [Xpharm]					
Fu	nded	for patients meeting any of the following criteria:					
		o vaccinations for use in transplant patients; or					
	,	o vaccinations for use in children with chronic liver d					
3	3) On	e dose of vaccine for close contacts of known hepat	itis A cases.				
Inj	1440	ELISA units in 1 ml syringe	0.00	1	<b>✓</b> <u>H</u>	avrix 1440	

Inj 720 ELISA units in 0.5 ml syringe.......0.00

	Subsidy		Fully	Brand or	
	(Manufacturer's Price)	Sı	bsidised	Generic	
	\$	Per	<b>✓</b>	Manufacturer	
HEPATITIS B RECOMBINANT VACCINE - [Xpharm]					

✓ Engerix-B

Funded for patients meeting any of the following criteria:

- 1) for household or sexual contacts of known acute hepatitis B patients or hepatitis B carriers; or
- 2) for children born to mothers who are hepatitis B surface antigen (HBsAq) positive; or
- 3) for children up to and under the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination or require a primary course of vaccination; or
- 4) for HIV positive patients: or
- 5) for hepatitis C positive patients; or
- 6) for patients following non-consensual sexual intercourse; or
- 7) for patients prior to planned immunosuppression for greater than 28 days; or
- 8) for patients following immunosuppression; or
- 9) for solid organ transplant patients; or
- 10) for post-haematopoietic stem cell transplant (HSCT) patients; or
- 11) following needle stick injury.

Inj 20 mcg per 1 ml prefilled syringe......0.00 ✓ Engerix-B

Funded for patients meeting any of the following criteria:

- 1) for household or sexual contacts of known acute hepatitis B patients or hepatitis B carriers; or
- 2) for children born to mothers who are hepatitis B surface antigen (HBsAg) positive; or
- 3) for children up to and under the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination or require a primary course of vaccination; or
- 4) for HIV positive patients; or
- 5) for hepatitis C positive patients; or
- 6) for patients following non-consensual sexual intercourse; or
- 7) for patients prior to planned immunosuppression for greater than 28 days; or
- 8) for patients following immunosuppression; or
- 9) for solid organ transplant patients; or
- 10) for post-haematopoietic stem cell transplant (HSCT) patients; or
- 11) following needle stick injury; or
- 12) for dialysis patients; or
- 13) for liver or kidney transplant patients.

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

nj 270 mcg in 0.5 ml syringe	0.00	10	Gardasil 9
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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)	120.00	10		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
    - i) 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.

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

### 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	0.00	10	Priorix

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

#### MENINGOCOCCAL (GROUPS A. C. Y AND W-135) CONJUGATE VACCINE

Inj 10 mcg of each meningococcal polysaccharide conjugated to a total of approximately 55 mcg of tetanus toxoid carrier 

✓ MenQuadfi

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

- A) Any of the following:
  - 1) Up to three doses and a booster every five years for patients pre- and post splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre or post solid organ transplant; or
  - 2) One dose for close contacts of meningococcal cases of any group; or
  - 3) One dose for person who has previously had meningococcal disease of any group; or
  - 4) A maximum of two doses for bone marrow transplant patients; or
  - 5) A maximum of two doses for person pre- and post-immunosuppression\*: or
- B) Both:
  - 1) Person is aged between 13 and 25 years, inclusive; and
  - 2) Either:
    - 1) One dose for individuals who are entering within the next three months, or in their first year of living in boarding school hostels, tertiary education halls of residence, military barracks, Youth Justice residences, or prisons; or
    - 2) One dose for individuals who turn 13 years of age while living in boarding school hostels.
- C) Contractors will be entitled to claim payment from the Funder for the supply of Meningococcal A, C, Y and W-135 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 A, C, Y and W-135 vaccine listed in the Pharmaceutical Schedule.
- D) 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-B above.

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

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

Ini 5 mcg of each meningococcal polysaccharide conjugated to a total of approximately 44 mcg of tetanus toxoid carrier

✓ Nimenrix

- A) Both:
  - 1) The child is under 12 months of age; and
  - 2) Any of the following:
    - 1) A maximum of three doses (dependant on age at first dose) for patients pre- and post- splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre- or post- solid organ transplant; or
    - 2) A maximum of three doses (dependant on age at first dose) for close contacts of meningococcal cases
    - 3) A maximum of three doses (dependant on age at first dose) for child who has previously had meningococcal disease of any group; or
    - 4) A maximum of three doses (dependant on age at first dose) for bone marrow transplant patients; or
    - 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.

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

#### 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.

Subsidy	Fully	Brand or
(Manufacturer's Price)	Subsidised	Generic
\$	Per 🗸	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
    - h) receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
    - i) 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
    - 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	10	✓ Prevenar 13
	1	✓ Prevenar 13

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
PNEUMOCOCCAL (PPV23) POLYSACCHARIDE V Any of the following:	ACCINE - [Xpharm]		
1) Up to three doses (as appropriate) for pati chemotherapy; pre- or post-splenectomy of complement deficiency (acquired or inheritation). 2) All of the following:	or with functional asplenia, pre- or p	ost-solid organ t	ransplant, renal dialysis,
<ul> <li>a) Patient is a child under 18 years for (</li> <li>b) Treatment is for a maximum of two d</li> <li>c) Any of the following:</li> </ul>			
immune response; or ii) with primary immune deficienci iii) with HIV infection; or iv) with renal failure, or nephrotic s	•	·	
vi) with cochlear implants or intrac vii) with cerebrospinal fluid leaks; c viii) receiving corticosteroid therapy prednisone of 2 mg/kg per day 20 mg or greater; or	or		
ix) with chronic pulmonary disease x) pre term infants, born before 28 xi) with cardiac disease, with cyan xii) with diabetes; or xiii) with Down syndrome; or xiv) who are pre-or post-splenector	osis or failure; or	h-dose corticost	eroid therapy); or
For use in testing for primary immunodefic paediatrician	• • • • • • • • • • • • • • • • • • • •	ation of an inter	nal medicine physician or
Inj 575 mcg in 0.5 ml prefilled syringe (25 mcg c 23 pneumococcal serotype)		1 <b>✓</b> <u>F</u>	Pneumovax 23
POLIOMYELITIS VACCINE – [Xpharm] Up to three doses for patients meeting either of 1) For partially vaccinated or previously unva 2) For revaccination following immunosuppre	ccinated individuals; or		
Note: Please refer to the Immunisation Handbo Inj 80D antigen units in 0.5 ml syringe			es. <b>POL</b>

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

#### **ROTAVIBUS OBAL 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 tube	0.00	10	✓ Rotarix
Oral susp live attenuated human rotavirus 1,000,000 CCID50 per dose, squeezable tube (PVC free)	0.00	10	✓ Rotarix
Oral susp live attenuated human rotavirus 1,000,000 CCID50 per dose, prefilled oral applicator	.0.00	10	✓ Rotarix

Subsidy F acturer's Price) Subsidi	,	and or eneric
 \$ Per	✓ Ma	anufacturer

### 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
    - 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
    - d) 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

# MATIONAL IMMUNICATION COUEDING

	NATIONAL	IIVIIVIUNISATI	ON SCHEDULE
	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic 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:			
1) 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	✓ Shingrix
		10	✓ Shingrix

# **Diagnostic Agents**

TUBERCULIN PPD [MANTOUX] TEST - [Xpharm]			
Inj 5 TU per 0.1 ml, 1 ml vial	0.00	1	✓ Tubersol

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