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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.

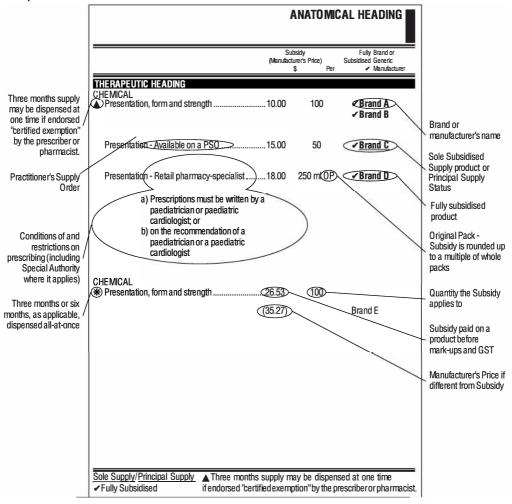
The Pharmaceuticals in this book are listed by therapeutic group, which is based on the WHO Anatomical Therapeutic Chemical (ATC) system. The listings are displayed alphabetically under each heading.

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

SECTION B: ALIMENTARY TRACT AND MET	TABOLISM			
	Subsidy (Manufacturer's Price) \$	Su Per	Fully bsidised	Brand or Generic Manufacturer
Antacids and Antiflatulents				
Antacids and Reflux Barrier Agents				
ALGINIC ACID  Sodium alginate 225 mg and magnesium alginate 87.5 mg pe sachet		30	<b>√</b> G	aviscon Infant
* Tab 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg - peppermint flavour	1.80 (14.39)	60	G	aviscon Extra Strength
Oral liq 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml		500 ml	A	cidex
Phosphate Binding Agents				
ALUMINIUM HYDROXIDE  * Tab 600 mg  CALCIUM CARBONATE  Oral liq 1,250 mg per 5 ml (500 mg elemental per 5 ml) –		100		lu-Tab
Subsidy by endorsement	47.30	500 ml 473 ml	<b>√</b> C	oxane alcium carbonate PAI <sup>829</sup>
Only when prescribed for patients unable to swallow calc inappropriate and the prescription is endorsed accordingl		ts or whe	ere calciur	n 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	✓ N ✓ <u>D</u>	odia iamide Relief
Rectal and Colonic Anti-inflammatories				
BUDESONIDE  Cap modified-release 3 mg - Special Authority see SA1886  below - Retail pharmacy	87.60	90	<b>✓</b> <u>B</u>	udesonide Te Arai

## ⇒SA1886 Special Authority for Subsidy

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

Both:

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

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

continued...

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

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

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

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

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

All of the following:

- 1 Patient has autoimmune hepatitis\*: and
- 2 Patient does not have cirrhosis; and
- 3 Any of the following:
  - 3.1 Diabetes: or
  - 3.2 Cushingoid habitus; or
  - 3.3 Osteoporosis where there is significant risk of fracture: or
  - 3.4 Severe acne following treatment with conventional corticosteroid therapy; or
  - 3.5 History of severe psychiatric problems associated with corticosteroid treatment; or
  - 3.6 History of major mental illness (such as bipolar affective disorder) where the risk of conventional corticosteroid treatment causing relapse is considered to be high; or
  - 3.7 Relapse during pregnancy (where conventional corticosteroids are considered to be contraindicated); 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)26.55	15 g OP	<ul><li>Colifoam</li></ul>
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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
OLSALAZINE				
Tab 500 mg	56.02	60	<b>✓</b>	Atnahs
				Olsalazine S29
	93.37	100	✓ [	Dipentum
Cap 250 mg	53.00	100	✓ [	Dipentum
SODIUM CROMOGLICATE Cap 100 mg	113.35	100	<b>√</b> F	Ralicrom
SULFASALAZINE  * Tab 500 mg	16.52	100	<b>√</b> 9	Salazopyrin
* Tab EC 500 mg		100		Salazopyrin EN

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

## **Antihaemorrhoidal Preparations**

FLUOCORTOLONE CAPROATE WITH FLUOCORTOLONE PIVALATE AND CINCHOCAINE				
Oint 950 mcg, with fluocortolone pivalate 920 mcg, and				
cinchocaine hydrochloride 5 mg per g13.05	30 g OP	<ul><li>Ultraproct</li></ul>		
Suppos 630 mcg, with fluocortolone pivalate 610 mcg, and				
cinchocaine hydrochloride 1 mg8.61	12	<ul><li>Ultraproct</li></ul>		
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

GLYCERYL TRINITRATE − Special Authority see SA1329 below − Retail pharmacy

★ Oint 0.2%......22.00 30 g OP

✓ Rectogesic

## **⇒SA1329** Special Authority for Subsidy

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

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

Inj 200 mcg per ml, 1 ml ampoule – Up to 10 inj available on a			
PSO	19.00	5	✓ Robinul
HYOSCINE BUTYLBROMIDE			
* Tab 10 mg	2.25	20	<ul> <li>✓ Hyoscine Butylbromide (Adiramedica)</li> </ul>
	6.35	100	✓ Buscopan
* Inj 20 mg, 1 ml – Up to 5 inj available on a PSO(Buscopan Tab 10 mg to be delisted 1 April 2025)	1.91	5	✓ <u>Spazmol</u>
MEBEVERINE HYDROCHLORIDE			
* Tab 135 mg	8.50	90	✓ Colofac

ALIMENTARY TRACT AND METABOLISM Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per Manufacturer **Antiulcerants** Antisecretory and Cytoprotective MISOPROSTOL - Wastage claimable \* Tab 200 mcg - Up to 120 tab available on a PSO ......47.73 ✓ Cytotec 120 **Helicobacter Pylori Eradication CLARITHROMYCIN** 14 Klacid a) Maximum of 28 tab per prescription b) Subsidised only if prescribed for helicobacter pylori eradication and prescription is endorsed accordingly. Note: the prescription is considered endorsed if clarithromycin is prescribed in conjunction with a proton pump inhibitor and either amoxicillin or metronidazole. **H2 Antagonists** FAMOTIDINE - Only on a prescription \* Tab 20 mg ......4.91 ✓ Famotidine 100 Hovid S29 100 ✓ Famotidine Hovid S29 Inj 10 mg per ml, 4 ml - Subsidy by endorsement ......CBS 10 ✓ Mylan S29 Subsidy by endorsement – Subsidised for patients receiving treatment as part of palliative care. **Proton Pump Inhibitors** LANSOPRAZOLE ✓ Lanzol Relief 100 Lanzol Relief to be Principal Supply on 1 February 2025 100 ✓ Lanzol Relief Lanzol Relief to be Principal Supply on 1 February 2025 **OMEPRAZOLE** For omeprazole suspension refer Standard Formulae, page 276 ✓ Omeprazole Teva 90 Omeprazole actavis 10 ✓ Omeprazole Teva 90 ✓ Omeprazole actavis 20 ✓ Omeprazole Teva 90 ✓ Omeprazole actavis

PANTOPRAZOLE	
¥ Toh EC 00 mg	4

*	Tab EC 20 mg1.9	9 9	0
*	Tab EC 40 mg2.7	4 9	0

<sup>✓</sup> Panzop Relief
✓ Panzop Relief

40

✓ Midwest

✓ <u>Dr Reddy's</u>

<u>Omeprazole</u>
✓ Ocicure \$29

5 q

5

<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 Brand or Subsidised Generic Manufacturer
Site Protective Agents			
COLLOIDAL BISMUTH SUBCITRATE  Tab 120 mgSUCRALFATE	14.51	50	✓ Gastrodenol S29
Tab 1 g	35.50 (48.28)	120	Carafate
Bile and Liver Therapy			
RIFAXIMIN – Special Authority see SA1461 below – F Tab 550 mg Xifaxan to be Principal Supply on 1 December	625.00	56	✓ Xifaxan
■ SA1461 Special Authority for Subsidy Initial application only from a gastroenterologist, hepathepatologist. Approvals valid for 6 months where the ptolerated doses of lactulose.  Renewal only from a gastroenterologist, hepatologist of the pathologist. Approvals valid without further renewal uppenefiting from treatment.	patient has hepatic encephalop or Practitioner on the recommen	athy d	lespite an adequate trial of maximum n of a gastroenterologist or
Diabetes			
Hyperglycaemic Agents			
DIAZOXIDE - Special Authority see SA1320 below -			
Cap 25 mg		100	✓ Proglicem §29
Cap 100 mg		100	✓ Proglicem \$29
Oral liq 50 mg per ml	620.00 3	0 ml C	P <b>✓ e5 Pharma</b> S29
⇒SA1320 Special Authority for Subsidy initial application from any relevant practitioner. App hypoglycaemia caused by hyperinsulinism.	rovals valid for 12 months whe	re use	d for the treatment of confirmed
Renewal from any relevant practitioner. Approvals val appropriate and the patient is benefiting from treatmen		ss noti	fied where the treatment remains
GLUCAGON HYDROCHLORIDE Inj 1 mg syringe kit – Up to 5 kit available on a PS	O32.00	1	✓ Glucagen Hypokit
Insulin - Short-acting Preparations			
INSULIN NEUTRAL			
Inj human 100 u per ml		0 ml C	✓ Humulin R
▲ Inj human 100 u per ml, 3 ml	42.66	5	<ul><li>Actrapid Penfill</li><li>Humulin R</li></ul>
Insulin - Intermediate-acting Preparation	าร		
INSULIN ASPART WITH INSULIN ASPART PROTAM			
▲ Inj 100 iu per ml, 3 ml prefilled pen	52.15	5	✓ NovoMix 30 FlexPen

	Subsidy (Manufacturer's F	Price) Subs	Fully Brand or idised Generic
	\$	Per	✓ Manufacturer
NSULIN ISOPHANE			
▲ Inj human 100 u per ml	17.68	10 ml OP	<ul><li>✓ Humulin NPH</li><li>✓ Protaphane</li></ul>
Inj human 100 u per ml, 3 ml	29.86	5	✓ Humulin NPH ✓ Protaphane Penfill
NSULIN ISOPHANE WITH INSULIN NEUTRAL			
Inj human with neutral insulin 100 u per ml	25.26	10 ml OP	✓ Humulin 30/70
,			✓ Mixtard 30
Inj human with neutral insulin 100 u per ml, 3 ml	42.66	5	✓ Humulin 30/70
			<ul><li>✓ PenMix 30</li><li>✓ PenMix 50</li></ul>
NSULIN LISPRO WITH INSULIN LISPRO PROTAMINE			
Inj lispro 25% with insulin lispro protamine 75% 100 u per ml,			
3 ml		5	✓ Humalog Mix 25
Inj lispro 50% with insulin lispro protamine 50% 100 u per ml,			ŭ
3 ml	42.66	5	<ul><li>Humalog Mix 50</li></ul>
Insulin - Long-acting Preparations			
NSULIN GLARGINE	00.00		/ Lautus
Inj 100 u per ml, 10 ml		1	✓ Lantus
Inj 100 u per ml, 3 ml		5 5	✓ Lantus
Inj 100 u per ml, 3 ml disposable pen	94.50	5	✓ Lantus SoloStar
Insulin - Rapid Acting Preparations			
NSULIN ASPART			
Inj 100 u per ml, 10 ml	30.03	1	✓ NovoRapid
Inj 100 u per ml, 3 ml		5	✓ NovoRapid Penfill
Inj 100 u per ml, 3 ml syringe	51.19	5	✓ NovoRapid FlexPen
NSULIN GLULISINE			
Inj 100 u per ml, 10 ml	27.03	1	✓ Apidra
Inj 100 u per ml, 3 ml	46.07	5	✓ Apidra
Inj 100 u per ml, 3 ml disposable pen		5	✓ Apidra SoloStar
NSULIN LISPRO			
Inj 100 u per ml, 10 ml	34.92	10 ml OP	✓ Humalog
Inj 100 u per ml, 3 ml	59.52	5	✓ Humalog
Alpha Glucosidase Inhibitors			
CARBOSE			
₭ Tab 50 mg	11 20	90	✓ Accarb
Accarb to be Principal Supply on 1 February 2025	11.20	50	- Accuin
* Tab 100 mg	17.38	90	✓ Accarb
Accarb to be Principal Supply on 1 February 2025			7.000.0
Oral Hypoglycaemic Agents			
GLIBENCLAMIDE			
<b>★</b> Tab 5 mg	7.50	100	✓ Daonil
GLICLAZIDE			
* Tab 80 mg	20.10	500	✓ Glizide
r 100 00 Hig	20.10	500	GIIZIUE

<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	1	Manufacturer
GLIPIZIDE				
* Tab 5 mg	6.86	100	1	Minidiab
METFORMIN HYDROCHLORIDE				
* Tab immediate-release 500 mg	14.74	1,000	<b>/</b>	Metformin Viatris
* Tab immediate-release 850 mg	11.28	500	•	Metformin Viatris
PIOGLITAZONE				
* Tab 15 mg	6.15	90	1	Vexazone
Vexazone to be Principal Supply on 1 December 2024			_	
* Tab 30 mg	7.25	90	/	Vexazone
Vexazone to be Principal Supply on 1 December 2024	10.00	00	,	V
* Tab 45 mg	12.00	90	•	Vexazone
Vexazone to be Principal Supply on 1 December 2024				
VILDAGLIPTIN	05.00			• •
Tab 50 mg	35.00	60	/	Galvus
VILDAGLIPTIN WITH METFORMIN HYDROCHLORIDE				
Tab 50 mg with 1,000 mg metformin hydrochloride		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 a funded SGLT-2 inhibitor or other GLP-1 agonist.

## **⇒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 SA2339 below - Retail pharmacy

- a) Maximum of 9 ini per prescription
- b)
- a) Not to be given in combination with a funded SGLT-2 inhibitor or other GLP-1 agonist.
- b) Maximum of 1 pack of 3 (6 mg per ml, 3 ml) prefilled pens will be funded per month.

## **⇒SA2339** 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.

#### **SGLT2 Inhibitors**

#### ⇒SA2068 Special Authority for Subsidy

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

Either:

- 1 Patient has previously received an initial approval for a GLP-1 agonist; or
- 2 All of the following:
  - 2.1 Patient has type 2 diabetes; and
  - 2.2 Any of the following:

(Manufacturer's Price) Subsidised Generic \$ Per ✓ Manufacturer	Subsidy	Ful	y Brand or
\$ Per ✔ Manufacturer	(Manufacturer's Price)	Subsidise	d Generic
	 \$	Per •	Manufacturer

continued...

- 2.2.1 Patient is Maori 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.

 ${\sf EMPAGLIFLOZIN}\ - {\sf Special}\ {\sf Authority}\ {\sf see}\ {\sf SA2068}\ {\sf on}\ {\sf the}\ {\sf previous}\ {\sf page}\ - \ {\sf Retail}\ {\sf pharmacy}$ 

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

*	Tab 10 mg58	3.56	30	<ul><li>Jardiance</li></ul>
*	Tab 25 mg58	3.56	30	<ul><li>Jardiance</li></ul>

EMPAGLIFLOZIN WITH METFORMIN HYDROCHLORIDE - Special Authority see SA2068 on the previous page - Retail pharmacy

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

*	Tab 5 mg with 1,000 mg metformin hydrochloride	58.56	60	<ul><li>Jardiamet</li></ul>
*	Tab 5 mg with 500 mg metformin hydrochloride	58.56	60	<ul><li>Jardiamet</li></ul>
*	Tab 12.5 mg with 1,000 mg metformin hydrochloride	58.56	60	<ul><li>Jardiamet</li></ul>
*	Tab 12.5 mg with 500 mg metformin hydrochloride	58.56	60	<ul><li>Jardiamet</li></ul>

## **Diabetes Management**

## **Ketone Testing**

BLOOD KETONE DIAGNOSTIC TEST STRIP - Subsidy by endorsement

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

The prescription must be endorsed accordingly.

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

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

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

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

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

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

✓ CareSens Dual 1 OP

## **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
  - 4) has a genetic or an acquired disorder of glucose homeostasis, excluding type 1 or type 2 diabetes and metabolic syndrome.

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

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

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

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

1 OP ✓ CareSens N ✓ CareSens N POP 20.00 ✓ CareSens N Premier

Note: Only 1 meter available per PSO

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

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

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

- 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 strips3	33.69	50 test OP	•	SensoCard
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# Insulin Syringes and Needles

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

#### INSULIN PEN NEEDLES - Maximum of 200 dev per prescription

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

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

## **Insulin Pumps**

INSULIN PUMP - Special Authority see SA1603 below - Retail pharmacy

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

(MiniMed 770G Min basal rate 0.025 U/h to be delisted 1 January 2025)

#### ⇒SA1603 Special Authority for Subsidy

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

All of the following:

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

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

All of the following:

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

Subsidy (Manufacturer's Price)		Fully Subsidised	Brand or Generic	
(Waitulatule 31 Noe)	Per	oubsidised ✓	Manufacturer	

continued...

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

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

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

continued...

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

Subsidy acturer's Price)	Ful Subsidise	,	rand or ieneric
\$ P	Per •	<b>/</b> M	lanufacturer

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.

✓ 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:
  - 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 5 sets per prescription
- b) Only on a prescription
- c) Maximum of 19 packs of cartridge sets will be funded per year.
- ★ Cartridge 300 U, t:lock x 10......86.00
  1 OP
  ✓ Tandem Cartridge

\* 8.5 mm steel needle; straight insertion; 80 cm line x 10 with

\* 6 mm steel cannula; straight insertion; 80 cm line x 10 with

\* 8 mm steel cannula; straight insertion; 80 cm line × 10 with

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

\* 8 mm steel cannula: straight insertion: 60 cm line × 10 with

10 needles......182.00

10 needles......182.00

		Subsidy (Manufacturer's Price)	Sub Per	Fully osidised	Brand or Generic Manufacturer		
INIC	SULIN PUMP INFUSION SET (STEEL CANNULA) – Special A	uthority see SA2380					
IIVC	a) Maximum of 5 set per prescription     b) Only on a prescription     c) Maximum of 19 infusion sets will be funded per year.	dunonty see SA2000	on the p	nevious į	oage – Hetali phamacy		
*		130.00	1 OP	✓ M	liniMed Sure-T MMT-864A		
*	6 mm steel needle; 80 cm tubing × 10	130.00	1 OP	<b>✓</b> M	liniMed Sure-T MMT-866A		
*	8 mm steel needle; 60 cm tubing × 10	130.00	1 OP	<b>✓</b> M	liniMed Sure-T MMT-874A		
*	8 mm steel needle; 80 cm tubing × 10	130.00	1 OP	<b>✓</b> M	liniMed Sure-T MMT-876A		
(M) (M)	(MiniMed Sure-T MMT-864A 6 mm steel needle; 60 cm tubing $\times$ 10 to be delisted 1 October 2026) (MiniMed Sure-T MMT-866A 6 mm steel needle; 80 cm tubing $\times$ 10 to be delisted 1 October 2026) (MiniMed Sure-T MMT-874A 8 mm steel needle; 60 cm tubing $\times$ 10 to be delisted 1 October 2026) (MiniMed Sure-T MMT-876A 8 mm steel needle; 80 cm tubing $\times$ 10 to be delisted 1 October 2026)						
	SULIN PUMP INFUSION SET (STEEL CANNULA, STRAIGHT ge – 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	INSERTION) - Spe	cial Auth	ority see	SA2380 on the previous		
	10 needles	136.00	1 OP	<b>√</b> m	ylife Orbit micro		
	10 needles	136.00	1 OP	<b>✓</b> m	ylife Orbit micro		
*	5.5 mm steel needle; straight insertion; 80 cm line × 10 with 10 needles	136.00	1 OP	✓ m	ylife Orbit micro		
*	8.5 mm steel needle; straight insertion; 60 cm line × 10 with 10 needles	136.00	1 OP	<b>√</b> m	ylife Orbit micro		

1 OP

1 OP

1 OP

1 OP

1 OP

✓ mylife Orbit micro

✓ TruSteel

✓ TruSteel

✓ TruSteel

✓ TruSteel

Subsidy Fully Brand or (Manufacturer's Price) Generic Subsidised Per Manufacturer INSULIN PUMP INFUSION SET (TEFLON CANNULA) - Special Authority see SA2380 on page 19 - 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-923A 6 mm teflon needle, 60 cm blue tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-923A 6 mm teflon needle, 60 cm pink tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-945A 6 mm teflon needle, 60 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-945A 6 mm teflon needle, 80 cm blue tubing to be delisted 1 October 2026) (MiniMed Mio MMT-955A 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-935A 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 Quick-Set MMT-397A 9 mm teflon needle, 60 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Quick-Set MMT-397A 9 mm teflon needle, 80 cm clear 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	SERT	ION DEVICE	E) - Special Authority see
	2380 on page 19 – 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	m			
	line x 10 with 10 needles		1 OP	✓ A	utoSoft 30
*	13 mm teflon cannula; angle insertion; insertion device; 60 cm line × 10 with 10 needles		1 OP	✓ A	utoSoft 30
IN!	SULIN PUMP INFUSION SET (TEFLON CANNULA, FLEXIBLE	INSERTION WITH	INSF	RTION DEV	ICF) - Special Authority
	e SA2380 on page 19 – Retail pharmacy	INOLITION WITH		THOIT DEV	iot) opeoidi ridirionty
	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 cm	n			
•	line × 10 with 10 needles		1 OP	✓ m	vlife Inset soft
*	6 mm teflon cannula; flexible insertion; insertion device; 60 cm	n			,
•	line with integrated inserter × 10 with 10 needles		1 OP	✓ m	ylife Inset soft
*	6 mm teflon cannula; flexible insertion; insertion device; 80 cm				,
•	line × 10 with 10 needles		1 OP	✓ m	vlife Inset soft
*	9 mm teflon cannula; flexible insertion; insertion device; 60 cm				,
•	line × 10 with 10 needles		1 OP	✓ m	ylife Inset soft
*	9 mm teflon cannula; flexible insertion; insertion device; 80 cn				,
•	line × 10 with 10 needles		1 OP	✓ m	vlife Inset soft
INI	SULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIGH		INICE		•
	e SA2380 on page 19 – Retail pharmacy	I INSLITTION WITH	IIVOL	ITTION DE	rioL) - Special Authority
500	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	<b>✓</b> Δ	utoSoft 90
*	6 mm teflon cannula; straight insertion; insertion device; 60 cr				
-,-	line × 10 with 10 needles		1 OP	<b>✓</b> Δ	utoSoft 90
*	9 mm teflon cannula; straight insertion; insertion device;			- 70	u.00011 00
-,-	110 cm line × 10 with 10 needles	182 00	1 OP	✓ A	utoSoft 90
*	9 mm teflon cannula; straight insertion; insertion device; 60 cr			- 70	u.00011 00
-,-	line × 10 with 10 needles		1 OP	<b>✓</b> Δ	utoSoft 90
INIC			. •.		
	SULIN PUMP INFUSION SET (TEFLON CANNULA, VARIABLI tail pharmacy	= INSERTION) - SP	eciai	Authority See	e SA2360 on page 19 -
ne	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		1 OP	✓ V	ariSoft
	TO HOCUICS	102.00	1 01	- V	anoon

MMT-332A

	Subsidy (Manufacturer's Price) \$	S Per	Fully Brand or Subsidised Generic Manufacturer
INSULIN PUMP RESERVOIR - Special Authorit	ty see SA2380 on page 19 – Retail ph	narmac	СУ
a) Maximum of 9 sets per prescription			
b) Only on a prescription			
<ul> <li>c) Maximum of 36 packs of resevoir sets wil</li> </ul>	ll be funded per year.		
* 10 × 1.6 ml glass reservoir for YpsoPump	50.00	1 OP	mylife YpsoPump Reservoir
* 10 × luer lock conversion cartridges 1.8 ml fo	or Paradigm pumps50.00	1 OP	✓ ADR Cartridge 1.8
* Cartridge for 7 series pump; 3.0 ml x 10	50.00	1 OP	✓ MiniMed
- , ,			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 × 10 to be delisted 1 October 2026)

#### Continuous Glucose Monitor

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

- a) Brand switch fee payable (Pharmacode 2692147) see page 273 for details
- b) Only on a prescription

Maximum of 28 dev will be funded per year.

## ⇒SA2371 Special Authority for Subsidy

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

#### Both:

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

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

CONTINUOUS GLUCOSE MONITOR (STANDALONE) - Special Authority see SA2370 on the next page - Retail pharmacy

- a) Brand switch fee payable (Pharmacode 2692139) see page 273 for details
- b) Only on a prescription
- ★ Sensor (Dexcom ONE+) Maximum of 9 dev per prescription ......81.00 1
  ✓ Dexcom ONE+
  Maximum of 40 dev will be funded per year.
- ★ Sensor (Freestyle Libre 2) Maximum of 7 dev per prescription.....92.83
  1
  ✓ Freestyle Libre 2
  Maximum of 29 dev will be funded per year.

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

## ⇒SA2370 Special Authority for Subsidy

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

Any of the following:

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

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

# **Digestives Including Enzymes**

#### PANCREATIC ENZYME

Cap pancreatin 150 mg (amylase 8,000 Ph Eur O, 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			
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 SA1739 belo	w – Retail pha	rmacy	
Cap 250 mg	33.95	100	<ul><li>Ursosan</li></ul>

#### ⇒SA1739 Special Authority for Subsidy

Initial application — (Alagille syndrome or progressive familial intrahepatic cholestasis) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

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

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

All of the following:

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

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

Both:

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

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

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

\$ Per ✔ Manufacturer
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continued...

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

#### Laxatives

## **Bulk-forming Agents**

101	Mariotin (i o i Etiowi) Hook	Only on a procomption		
*	Powder for oral soln	20.00	500 g OP	✓ Konsyl-D

# Faecal Softeners

DOCUSATE SODIUM - Only on a prescription		
* Tab 50 mg3.20	100	✓ Coloxyl
* Tab 120 mg4.98	100	✓ Coloxyl
DOCUSATE SODIUM WITH SENNOSIDES Tab 50 mg with sennosides 8 mg	200	✓ <u>Laxsol</u>
POLOXAMER – Only on a prescription		
Not funded for use in the ear.		
* Oral drops 10%4.17	30 ml OP	✓ Coloxyl

# **Opioid Receptor Antagonists - Peripheral**

ISPACHLILA (PSVI LILIM) HLISK - Only on a prescription

METHYLNALTREXONE BROMIDE - Special Authority	see SA1691 below - Retail	pharmacy	
Inj 12 mg per 0.6 ml vial	36.00	1	✓ Relistor
, .,	246.00	7	✓ Relistor

#### ⇒SA1691 Special Authority for Subsidy

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

Both:

- 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.

	Subsidy (Manufacturer's Price) \$	) Per	Fully Subsidised	Brand or Generic Manufacturer
Osmotic Laxatives				
GLYCEROL  * Suppos 2.8/4.0 g - Only on a prescription	10.39	20	✓	Lax-suppositories Glycerol
LACTULOSE – Only on a prescription  * Oral liq 10 g per 15 ml  MACROGOL 3350 WITH POTASSIUM CHLORIDE, SODIUM BIO	CARBONATE AND	500 m SODIU		<u>Laevolac</u> IDE
Powder for oral soln 13.125 g with potassium chloride 46.6 m sodium bicarbonate 178.5 mg and sodium chloride 350.7	•	30	•	<u>Molaxole</u>
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 Enema 90 mg with sodium lauryl sulphoacetate 9 mg per ml, 5 ml	, ,	iption 50	<b>✓</b>	<u>Micolette</u>
Stimulant Laxatives				
BISACODYL – Only on a prescription  * Tab 5 mg  * Suppos 10 mg  Lax-Suppositories to be Principal Supply on 1 February 2	4.14	200 10		Bisacodyl Viatris Lax-Suppositories
SENNA – Only on a prescription  * Tab, standardised	2.17 (8.21) 0.43 (2.06)	100 20		Senokot Senokot
SODIUM PICOSULFATE — Special Authority see SA2053 below Oral soln 7.5 mg per ml	7.40 3	30 ml O		Dulcolax SP Drop

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

## **⇒SA1986** Special Authority for Subsidy

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

1 The patient is aged up to 24 months at the time of initial application and has been diagnosed with infantile Pompe disease;

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

continued...

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 - Spe	cial Authority see SA2042 below – Retail pharmacy		
Tab 1,000 mg	CBS	90	<ul><li>Clinicians</li></ul>
Cap 500 mg	CBS	50	✓ Solgar
Powder	CBS	400 a	✓ Biomed

#### ⇒SA2042 Special Authority for Subsidy

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

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

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

#### **⇒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:

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

continued...

- 2.1 A cystathionine beta-synthase (CBS) deficiency; or
- 2.2 A 5,10-methylene-tetrahydrofolate reductase (MTHFR) deficiency; or
- 2.3 A disorder of intracellular cobalamin metabolism; and
- 3 An appropriate homocysteine level has not been achieved despite a sufficient trial of appropriate vitamin supplementation.

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

COENZYME Q10 - Special Authority see SA2039 below - Retail pharmacy

Cap 120 mg	CBS	30	<ul><li>Solgar</li></ul>
Cap 160 mg	CBS	60	Go Healthy

## ⇒SA2039 Special Authority for Subsidy

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

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

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

GALSULFASE - Special Authority see SA1988 below - Retail pharmacy

## ⇒SA1988 Special Authority for Subsidy

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

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

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

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

IDURSULFASE - Special Authority see SA1623 below - Retail pharmacy

#### ⇒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 Fither:
  - 2.1 Diagnosis confirmed by demonstration of iduronate 2-sulfatase deficiency in white blood cells by either enzyme

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

continued...

assav in cultured skin fibroblasts: or

- 2.2 Detection of a disease causing mutation in the iduronate 2-sulfatase gene; and
- 3 Patient is going to proceed with a haematopoietic stem cell transplant (HSCT) within the next 3 months and treatment with idursulfase would be bridging treatment to transplant; and
- 4 Patient has not required long-term invasive ventilation for respiratory failure prior to starting Enzyme Replacement Therapy (ERT); and
- 5 Idursulfase to be administered for a total of 24 weeks (equivalent to 12 weeks pre- and 12 weeks post-HSCT) at doses no greater than 0.5 mg/kg every week.

LARONIDASE – Special Authority see SA1695 below	– Retail pharmacy		
Inj 100 U per ml, 5 ml vial	1,335.16	1	✓ Aldurazyme

#### ⇒SA1695 Special Authority for Subsidy

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

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

LEVOCARNITINE - Special Authority see SA2040 below - F	letail pharmacy		
Tab 500 mg	CBŚ	30	✓ Solgar
Cap 250 mg	CBS	30	✓ Solgar
Cap 500 mg	CBS	60	✓ Balance
•		300	✓ Metabolics
Oral lig 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

## ⇒SA2040 Special Authority for Subsidy

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

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

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

RIBOFLAVIN – Special Authority see SA2041 on the next page - Tab 100 mg	, ,	100	✓ Country Life ✓ Puritan's Pride Vitamin B-2 100 mg \$29
Cap 100 mg	CBS	100	✓ Solgar

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

## **⇒SA2041** Special Authority for Subsidy

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

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

#### Both:

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

SAPROPTERIN DIHYDROCHLORIDE - Special Authority see SA1989 below - Retail pharmacy

## **⇒SA1989** Special Authority for Subsidy

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

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

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

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

## All of the following:

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

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

SODIUM BENZOATE – Special Authority see SA1599 below – Retail pharmacy

#### ⇒SA1599 Special Authority for Subsidy

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

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

SODIUM PHENYLBUTYRATE - Special Authority see SA1990 on the next page - Retail pharmacy

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

100 ml

✓ Amzoate S29

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

#### ⇒SA1990 Special Authority for Subsidy

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

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

TAURINE - Special Authority see SA2043 below - Retail pharmacy

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

## ⇒SA2043 Special Authority for Subsidy

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

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

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

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

#### ⇒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

	Subsidy (Manufacturer's F \$	Price) Subs	Fully sidised	Brand or Generic Manufacturer
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disease; or  3.5 Patient is a child and has experienced growth 6-12 month period; and	n failure with significan	nt decrease in p	ercentile	e linear growth over a
4 Taliglucerase alfa is to be administered at a dose no whole vial (200 units).	greater than 30 unit/k	kg every other v	week rou	nded to the nearest
Note: Indication marked with * is an unapproved indication Renewal only from a metabolic physician or any relevant pr Approvals valid for 3 years for applications meeting the follo All of the following:	actitioner on the recorwing criteria:	mmendation of	a metab	olic physician.
Patient has demonstrated a symptomatic improvement symptoms for which therapy was started; and	ent and has maintaine	d improvement	s in the r	main symptom or
2 Patient has demonstrated a clinically objective impro- liver and spleen size; and	vement or no deterior	ation in haemo	globin le	vels, platelet counts and
3 Radiological (MRI) signs of bone activity performed a demonstrate no deterioration shown by the MRI, con or adjusted dose; and				
Patient has not developed another medical condition ERT; and     Patient is adherent with regular treatment and taliglu		,		·
every other week rounded to the nearest whole vial (		illillistereu at a	a dose no	greater than 30 unityky
, ,	200 amio).			
Mouth and Throat	200 umoj.			
•	Zoo unito).			
Mouth and Throat  Agents Used in Mouth Ulceration  BENZYDAMINE HYDROCHLORIDE				
Mouth and Throat  Agents Used in Mouth Ulceration	19.00	500 ml	Diff	(O
Mouth and Throat  Agents Used in Mouth Ulceration  BENZYDAMINE HYDROCHLORIDE  Soln 0.15% - Higher subsidy of \$22.60 per 500 ml with Endorsement	1 9.00 (22.60)			fflam for cancer, and the
Mouth and Throat  Agents Used in Mouth Ulceration  BENZYDAMINE HYDROCHLORIDE  Soln 0.15% - Higher subsidy of \$22.60 per 500 ml with Endorsement	1 9.00 (22.60)			
Mouth and Throat  Agents Used in Mouth Ulceration  BENZYDAMINE HYDROCHLORIDE  Soln 0.15% - Higher subsidy of \$22.60 per 500 ml with Endorsement	1	as a result of tre	eatment t	
Mouth and Throat  Agents Used in Mouth Ulceration  BENZYDAMINE HYDROCHLORIDE  Soln 0.15% - Higher subsidy of \$22.60 per 500 ml with Endorsement	9.00 (22.60) no has oral mucositis a 17.20 4.55	as a result of tre	eatment t	for cancer, and the
Mouth and Throat  Agents Used in Mouth Ulceration  BENZYDAMINE HYDROCHLORIDE  Soln 0.15% - Higher subsidy of \$22.60 per 500 ml with Endorsement	9.00 (22.60) no has oral mucositis a 17.20 4.55 (7.90)	as a result of tro	eatment t	for cancer, and the
Mouth and Throat  Agents Used in Mouth Ulceration  BENZYDAMINE HYDROCHLORIDE  Soln 0.15% – Higher subsidy of \$22.60 per 500 ml with Endorsement	9.00 (22.60) to has oral mucositis a 17.20 4.55 (7.90) 1.52 (3.60)	as a result of tro	eatment f	for cancer, and the
Mouth and Throat  Agents Used in Mouth Ulceration  BENZYDAMINE HYDROCHLORIDE  Soln 0.15% - Higher subsidy of \$22.60 per 500 ml with Endorsement	9.00 (22.60) to has oral mucositis a 17.20 4.55 (7.90) 1.52 (3.60) 8.48	as a result of tro	Sto	for cancer, and the  omahesive  abase  abase
Mouth and Throat  Agents Used in Mouth Ulceration  BENZYDAMINE HYDROCHLORIDE  Soln 0.15% – Higher subsidy of \$22.60 per 500 ml with Endorsement	9.00 (22.60) to has oral mucositis a 17.20 4.55 (7.90) 1.52 (3.60)	as a result of tro	Sto	for cancer, and the  omahesive  abase

Lozenges 10 mg......5.86

Oral gel 20 mg per g......5.19

Decozol to be Principal Supply on 1 February 2025

20

40 g OP

✓ Fungilin

✓ Decozol

AMPHOTERICIN B

**MICONAZOLE** 

	(Mon	Subsidy	oo) Cubo	Fully Brand or idised Generic
	(Wall	nufacturer's Pri \$	Per Subsi	✓ Manufacturer
NYS	TATIN			
	Oral liq 100,000 u per ml	2.22	24 ml OP	✓ <u>Nilstat</u>
Vit	amins			
	amin B			
	ROXOCOBALAMIN		_	
*	nj 1 mg per ml, 1 ml ampoule – Up to 6 inj available on a PSO	2.46	3	<ul> <li>✓ Cobal-B12 ©29</li> <li>✓ Hydroxocobalamin Panpharma</li> </ul>
				✓ Vita-B12
		4.10	5	✓ Cobalin-H S29 ✓ Neo-Cytamen
		8.20	10	S29 S29 ✓ Vitarubin Depot
/\/ita	P12 Ini 1 mg por ml 1 ml ampoula to be delicted 1 July 2025)			Injection S29
•	-B12 Inj 1 mg per ml, 1 ml ampoule to be delisted 1 July 2025)			
	IDOXINE HYDROCHLORIDE			
	a) No more than 100 mg per dose b) Only on a prescription			
	Fab 25 mg - No patient co-payment payable	3.43	90	✓ Vitamin B6 25
	Гаb 50 mg		500	✓ Pyridoxine
				multichem
	MINE HYDROCHLORIDE - Only on a prescription			
	Гаb 50 mg	4.65	100	✓ Thiamine multichem
	MIN B COMPLEX	44.05	500	<b>4.</b> D. J.
*	Fab, strong, BPC	11.25	500	✓ Bplex
Vit	amin C			
6	ORBIC ACID  a) No more than 100 mg per dose			
	o) Only on a prescription Fab 100 mg	12 50	500	✓ Cvite
.,.	1 45 105 mg	12.00	000	- <u> </u>
Vit	amin D			
	ACALCIDOL			
* (	Cap 0.25 mcg	26.32	100	✓ One-Alpha
<b>*</b> (	Cap 1 mcg	97.00	100	<ul> <li>✓ One-Alpha S29 S29</li> <li>✓ One-Alpha</li> </ul>
	Oral drops 2 mcg per ml		20 ml OP	✓ One-Alpha ✓
	CITRIOL			
	Cap 0.25 mcg	7.89	100	✓ Calcitriol-AFT
* (	Cap 0.5 mcg	13.68	100	✓ Calcitriol-AFT ✓ Calcitriol-AFT S29 S29
	ECALCIFEROL			4 . W. = -
	Cap 1.25 mg (50,000 iu) – Maximum of 12 cap per prescription		12 5 ml OD	✓ <u>Vit.D3</u>
* (	Oral liq 188 mcg per ml (7,500 iu per ml)	9.00	5 ml OP	✓ Clinicians

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

	Subsidy (Manufacturer's Price	) Cuba	Fully	Brand or Generic
	(Manufacturer's Price \$	) Subsi Per	alsea •	Manufacturer
Multivitamin Preparations				
MULTIVITAMIN RENAL - Special Authority see SA1546 below -   * Cap		30	1	Clinicians Renal Vit
■ SA1546 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid the following criteria: Either:	d without further ren	ewal unless	notifi	ed for applications meeting
<ul> <li>The patient has chronic kidney disease and is receiving ei</li> <li>The patient has chronic kidney disease grade 5, defined a 15 ml/min/1.73 m² body surface area (BSA).</li> </ul>	,		,	,
MULTIVITAMINS – Special Authority see SA1036 below – Retail  * Powder		200 g OP	•	Paediatric Seravit
■ SA1036 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid inborn errors of metabolism.  Renewal from any relevant practitioner. Approvals valid without approval for multivitamins.				
VITAMINS  * Tab (BPC cap strength)		1,000	✓	<u>Mvite</u>
* Cap (fat soluble vitamins A, D, E, K) – Special Authority see SA1720 below – Retail pharmacy		60	1	Vitabdeck
■ SA1720 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid 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 s 3 Patient has severe malabsorption syndrome.		ewal unless	notifi	ed for applications meeting
Minerals				
Calcium				
CALCIUM CARBONATE  * Tab 1.25 g (500 mg elemental)  * Tab eff 1.25 g (500 mg elemental) – Subsidy by endorsemental		250 100		Calci-Tab 500 Calcium 500 mg Hexal <sup>829</sup>
Subsidy by endorsement – Only when prescribed for pactonsidered unsuitable.	ediatric patients (< 5	years) whe	re cal	cium carbonate oral liquid is
CALCIUM GLUCONATE  * Inj 10%, 10 ml ampoule	32.00	10	•	Max Health - HameIn S29
lodine				
POTASSIUM IODATE  * Tab 253 mcg (150 mcg elemental iodine)	5.99	90	•	NeuroTabs

	Subsidy (Manufacturer's Price) \$	Sul Per	Fully bsidised	Brand or Generic Manufacturer
Iron				
FERROUS FUMARATE  * Tab 200 mg (65 mg elemental)  Ferro-tab to be Principal Supply on 1 February 2025	3.49	100	✓ F	erro-tab
FERROUS FUMARATE WITH FOLIC ACID  * Tab 310 mg (100 mg elemental) with folic acid 350 mcg  Ferro-F-Tabs to be Principal Supply on 1 December 202		100	✓ F	erro-F-Tabs
FERROUS SULFATE  * 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	✓ F	<u>errograd</u> erro-Liquid erodan
IRON (AS FERRIC CARBOXYMALTOSE) – Special Authority se		Retail pha 1		erinject

#### ⇒SA2394 Special Authority for Subsidy

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

All of the following:

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

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

Both:

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

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

Both:

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

Renewal — (iron deficiency anaemia) only from an internal medicine physician, obstetrician, gynaecologist, anaesthetist or

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(Manufacturer's Price)	Subsidised	Generic	
	Por 🗸	Manufacturer	

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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.

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*	Inj 50 mg per ml, 2 ml ampoule	34.50	5	✓ Ferrosig
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Magnesium		

MAGNESIUM HYDROXIDE Suspension 8%33.60	355 ml	✓ Phillips Milk of Magnesia 529
MAGNESIUM SULPHATE		
* Inj 2 mmol per ml, 5 ml ampoule	10	✓ Martindale
* Inj 2 mmol per ml, 10 ml ampoule75.06	10	✓ Inresa S29
Zinc		

ZINC SULPHATE	
* Cap 137.4 mg (50 mg elemental)	11.00

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 ju 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	Binocrit
Inj 2,000 iu in 1 ml, syringe		6	Binocrit
Inj 3,000 iu in 0.3 ml, syringe		6	Binocrit
Inj 4,000 iu in 0.4 ml, syringe		6	Binocrit
Inj 5,000 iu in 0.5 ml, syringe		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

	(Manufacturer's Price)		lised	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	

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# **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.

Treaters Group in conjunction with the National Ha	emophilia Management grou	ıp.	
Inj 250 iu vial	612.50	1	Alprolix
Inj 500 iu vial	1,225.00	1	✓ Alprolix
Inj 1,000 iu vial	2,450.00	1	✓ Alprolix
Inj 2,000 iu vial	4,900.00	1	✓ Alprolix
Inj 3,000 iu vial	7,350.00	1	✓ Alprolix
Inj 4,000 iu vial	9,800.00	1	Alprolix
ELTROMBOPAG – Special Authority see SA1743 belo Wastage claimable	w – 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:

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

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

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

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

All of the following:

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

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

continued...

and significant mucocutaneous bleeding.

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

Both:

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

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

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

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

#### All of the following:

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

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

#### Both:

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

#### EMICIZUMAB - [Xpharm] - Special Authority see SA2272 below

3,570.00	1	✓ Hemlibra
7,138.00	1	✓ Hemlibra
12,492.00	1	✓ Hemlibra
17,846.00	1	✓ Hemlibra
	3,570.00 7,138.00	7,138.00 1 12,492.00 1

#### ⇒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

#### FACTOR EIGHT INHIBITOR BYPASSING FRACTION - [Xpharm]

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

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

#### MOROCTOCOG ALFA [RECOMBINANT FACTOR VIII] - [Xpharm]

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

Subject to criteria.			
Inj 250 iu prefilled syringe	287.50	1	Xyntha
Inj 500 iu prefilled syringe	575.00	1	Xyntha
Inj 1,000 iu prefilled syringe	1,150.00	1	Xyntha
Inj 2,000 iu prefilled syringe		1	Xyntha
Inj 3,000 iu prefilled syringe	3,450.00	1	Xyntha

#### NONACOG GAMMA, [RECOMBINANT FACTOR IX] - [Xpharm]

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

Inj 500 iu vial	435.00	1	✓ RIXUBIS
Inj 1,000 iu vial		1	✓ RIXUBIS
Inj 2,000 iu vial		1	✓ RIXUBIS
Ini 3.000 iu vial		1	✓ RIXUBIS

(RIXUBIS Inj 500 iu vial to be delisted 1 February 2025)

### OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (ADVATE) - [Xpharm]

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

Inj 250 iu vial	210.00	1	Advate
Inj 500 iu vial	420.00	1	Advate
	840.00	1	✓ Advate
	1,260.00	1	✓ Advate
Ini 2.000 iu vial	1,680.00	1	✓ Advate
• •	2,520.00	1	✓ Advate

(Advate Inj 250 iu vial to be delisted 1 February 2025)

(Advate Inj 1,500 iu vial to be delisted 1 February 2025)

### OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (KOGENATE FS) - [Xpharm]

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

Inj 250 iu vial	237.50	1	✓ Kogenate FS
Inj 500 iu vial	475.00	1	✓ Kogenate FS
Inj 1,000 iu vial	950.00	1	✓ Kogenate FS
Inj 2,000 iu vial	1,900.00	1	✓ Kogenate FS
Inj 3,000 iu vial	2,850.00	1	✓ Kogenate FS

	Subsidy		Fully	
	(Manufacturer's Price)		Subsidised	
	<u> </u>	Per		Manufacturer
RURIOCTOCOG ALFA PEGOL [RECOMBINANT FACTOR VIII]	- [Xpharm]			
For patients with haemophilia A receiving prophylaxis treatme	nt. Access to funde	d trea	atment is r	nanaged by the Haemophil
Treaters Group in conjunction with the National Haemophilia I	Management group.			
Inj 250 iu vial	300.00	1	✓	Adynovate
Inj 500 iu vial	600.00	1	✓	Adynovate
Inj 1,000 iu vial		1	✓	Adynovate
Inj 2,000 iu vial	2,400.00	1	✓	Adynovate
(Adynovate Inj 250 iu vial to be delisted 1 February 2025)				•
(Adynovate Inj 500 iu vial to be delisted 1 February 2025)				
SODIUM TETRADECYL SULPHATE				
* Inj 3% 2 ml	28 50	5		
7 III 0/0 Z III	(73.00)	Ü		Fibro-vein
TRANSVAMIO ACID	(10.00)			I IDIO VOIII
TRANEXAMIC ACID	10.45	00		Manarana Dhanna
Tab 500 mg		60		Mercury Pharma
	45.68	100	•	Cyklokapron
Vitamin K				
VILAIIIII K				
PHYTOMENADIONE				
Inj 2 mg per 0.2 ml – Up to 5 inj available on a PSO	8.00	5	/	Konakion MM
Inj 10 mg per ml, 1 ml – Up to 5 inj available on a PSO		5	/	Konakion MM
,	- "			
Antithrombotic Agents				
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# **Antiplatelet Agents**

ASPIRIN  * Tab 100 mg	12.65	990	✓ Ethics Aspirin EC
CLOPIDOGREL  * Tab 75 mg	5.07	84	✓ Arrow - Clopid
DIPYRIDAMOLE  * Tab long-acting 150 mg	13.93	60	✓ Pytazen SR
TICAGRELOR – Special Authority see SA1955 below – F  * Tab 90 mg  Ticagrelor Sandoz to be Principal Supply on 1 De	20.35	56	✓ Ticagrelor Sandoz

### ⇒SA1955 Special Authority for Subsidy

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

#### Both:

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

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

Both:

#### 1 Either:

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

continued...

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

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

All of the following:

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

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

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

Both:

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

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

Both:

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

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

All of the following:

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

Notes: indications marked with \* are unapproved indications.

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

Subsidised

Fully

Brand or

Generic

	<b></b>	Per	Manufacturer
Heparin and Antagonist Preparations			
ENOXAPARIN SODIUM - Special Authority see SA2152 below - Re	tail pharmacy		
Inj 20 mg in 0.2 ml syringe	21.90	10	✓ Clexane
Clexane to be Principal Supply on 1 February 2025			
Inj 40 mg in 0.4 ml syringe	29.74	10	✓ Clexane
Clexane to be Principal Supply on 1 February 2025			
Inj 60 mg in 0.6 ml syringe	42.47	10	✓ Clexane
Clexane to be Principal Supply on 1 February 2025			
Inj 80 mg in 0.8 ml syringe	56.62	10	✓ Clexane
Clexane to be Principal Supply on 1 February 2025			
Inj 100 mg in 1 ml syringe	70.91	10	✓ Clexane
Clexane to be Principal Supply on 1 February 2025			
Inj 120 mg in 0.8 ml syringe	88.11	10	Clexane Forte
Clexane Forte to be Principal Supply on 1 February 2025			
Inj 150 mg in 1 ml syringe	100.70	10	Clexane Forte
Clexane Forte to be Principal Supply on 1 February 2025			

Subsidy

(Manufacturer's Price)

### ⇒SA2152 Special Authority for Subsidy

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

Any of the following:

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

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

Any of the following:

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

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

All of the following:

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

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

Any of the following:

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
HEPARIN SODIUM				
Inj 1,000 iu per ml, 10 ml vial	127.44	25	✓	Pfizer S29
Inj 1,000 iu per ml, 5 ml ampoule	25.49	10	1	Wockhardt S29
	127.44	50	1	Pfizer
Inj 5,000 iu per ml, 5 ml vial	83.00	10	•	Heparin Sodium Panpharma
Inj 5,000 iu per ml, 1 ml	70.33	5	1	Hospira
Inj 25,000 iu per ml, 0.2 ml	22.42	5	1	Hospira
	42.40		1	Heparin DBL \$29
	482.20	50	•	Heparin DBL S29
HEPARINISED SALINE				
Inj 10 iu per ml, 5 ml	96.91	50	•	Pfizer
Oral Anticoagulants				
DABIGATRAN				
Cap 75 mg - No more than 2 cap per day	27.99	60	1	Pradaxa
Cap 110 mg	27.99	60		Pradaxa
Cap 150 mg	27.99	60	1	<u>Pradaxa</u>
RIVAROXABAN				
Tab 10 mg - No more than 1 tab per day	15.60	30	1	Xarelto
Tab 15 mg - Up to 14 tab available on a PSO	14.56	28	1	Xarelto
Tab 20 mg	14.56	28	1	Xarelto
WARFARIN SODIUM				
Note: Marevan and Coumadin are not interchangeable.				
* Tab 1 mg	3.46	50	✓	Coumadin
	7.50	100	•	Marevan
* Tab 2 mg	4.31	50		Coumadin
* Tab 3 mg		100		Marevan
* Tab 5 mg	5.93	50		Coumadin
	13.50	100	✓	Marevan
Blood Colony-stimulating Factors				
FILGRASTIM - Special Authority see SA1259 below - Retail p	harmacy			
Inj 300 mcg per 0.5 ml prefilled syringe	•	10	1	Nivestim

FI	LGRASTIM - Special Authority see SA1259 below - Retail pharm	nacy		
	Inj 300 mcg per 0.5 ml prefilled syringe	86.60	10	✓ Nivestim
	Nivestim to be Principal Supply on 1 December 2024			
	Inj 480 mcg per 0.5 ml prefilled syringe	133.72	10	✓ Nivestim
	Nivestim to be Principal Supply on 1 December 2024			

### ⇒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

	Subsidy (Manufacturer's Price)	•		Brand or Generic	
	\$	Per	1	Manufacturer	
continued					

- 4 Treatment of severe chronic neutropenia (ANC < 0.5 ×10<sup>9</sup>/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.

PEGFILGRASTIM - Special Authority see SA1912 below - Retail pharmacy

✓ Ziextenzo

### ⇒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 PSO34.75  * Inj 50%, 90 ml bottle – Up to 5 inj available on a PSO17.50		✓ Biomed ✓ Biomed
POTASSIUM CHLORIDE		
* Inj 75 mg per ml, 10 ml65.00	50	<ul><li>✓ Juno</li><li>✓ LumaCina</li><li>✓ Pfizer S29</li></ul>
SODIUM BICARBONATE		
Inj 8.4%, 50 ml23.52	2 1	Biomed
a) Up to 5 inj available on a PSO     b) Not in combination		
Inj 8.4%, 100 ml24.10	) 1	Biomed

- a) Up to 5 ini available on a PSO
- b) Not in combination

#### SODIUM CHLORIDE

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

Inj 0.9%, bag	- Up to 2000 ml available on a PSO	1.33	500 ml	✓ Baxter
-		1.36	1 000 ml	✓ Baxter

Only if prescribed on a prescription for renal dialysis, maternity or post-natal care in the home of the patient, or on a PSO for emergency use. (500 ml and 1.000 ml packs)

Inj 23.4% (4 mmol/ml), 20 ml ampoule	38.25	5	Biomed
For Sodium chloride oral liquid formulation refer Standa	ard Formulae, page	276	
Inj 0.9%, 5 ml ampoule - Up to 5 inj available on a PSO	4.00	20	✓ Fresenius Kabi
Inj 0.9%, 10 ml ampoule - Up to 5 inj available on a PSO	5.25	50	✓ Fresenius Kabi
Inj 0.9%, 20 ml ampoule	5.00	20	✓ Fresenius Kabi
TAL PARENTERAL NUTRITION (TPN)			

# TOT

InfusionCBS	1 OP	✓ TPN
-------------	------	-------

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

#### WATER

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

Inj 10 ml ampoule – Up to 5 inj available on a PSO Inj 20 ml ampoule – Up to 5 inj available on a PSO		✓ <u>Multichem</u> ✓ <u>Fresenius Kabi</u>
Oval Administration		

Oral Administration		
CALCIUM POLYSTYRENE SULPHONATE Powder169.85 COMPOUND ELECTROLYTES	300 g OP	✓ Calcium Resonium
Powder for oral soln — Up to 5 sach available on a PSO9.53	50	✓ <u>Electral</u>
COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE] Soln with electrolytes6.53	1,000 ml OP	✓ <u>Hydralyte -</u> <u>Lemonade</u>
PHOSPHORUS		
Tab eff 500 mg (16 mmol)82.50	100	Phosphate Phebra
POTASSIUM CHLORIDE		
* Tab eff 548 mg (14 m eq) with chloride 285 mg (8 m eq)	60	
(17.10)		Chlorvescent
* Tab long-acting 600 mg (8 mmol)	200	✓ Span-K
SODIUM BICARBONATE		
Cap 840 mg8.52	100	✓ Sodibic
		✓ Sodibic
SODIUM POLYSTYRENE SULPHONATE		
Powder84.65	454 g OP	✓ Resonium-A

Subsidy		Fully	Brand or
(Manufacturer's Price)	Su	bsidised	Generic
` <b>\$</b>	Per	_	Manufacturer

# **Alpha Adrenoceptor Blockers**

DOXAZOSIN			
* Tab 2 mg	17.35	500	<ul> <li>Doxazosin Clinect</li> </ul>
* Tab 4 mg	20.94	500	<ul> <li>Doxazosin Clinect</li> </ul>
PHENOXYBENZAMINE HYDROCHLORIDE			
* Cap 10 mg	65.00	30	✓ BNM S29
	216.67	100	✓ Dibenzyline S29
PRAZOSIN			
* Tab 1 mg	5.53	100	✓ Arrotex-Prazosin S29 S29
	9.98		✓ Minipress S29
* Tab 2 mg	7.00	100	✓ Arrotex-Prazosin
			<b>S29</b> S29
	13.29		✓ Minipress S29
* Tab 5 mg	11.70	100	✓ Arrotex-Prazosin
			<b>S29</b> S29
	22.00		✓ Minipress S29
* Cap 1 mg	15.40	100	✓ Prazosin Mylan S29
* Cap 2 mg	15.58	100	✓ Prazosin Mylan S29
* Can 5 mg		100	✓ Prazosin Mylan \$29

# Agents Affecting the Renin-Angiotensin System

### **ACE Inhibitors**

#### **CAPTOPRIL**

*	Oral liq 5 mg per ml86.00	100 ml OP	DP-Captopril
	Oral liquid restricted to children under 12 years of age		

### CILAZAPRIL - Subsidy by endorsement

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

* Tab 0.5 mg	2.69	90	✓ Zaprii
* Tab 2.5 mg	5.79	90	✓ Zapril
Tab 5 mg		90	✓ Zapril
ENALAPRIL MALEATE			
* Tab 5 mg	1.75	90	✓ Acetec
* Tab 10 mg		90	✓ Acetec
* Tab 20 mg		90	✓ Acetec
LISINOPRIL			
* Tab 5 mg	11.07	90	<ul> <li>Ethics Lisinopril</li> </ul>
•			✓ Teva Lisinopril
* Tab 10 mg	11.67	90	<ul> <li>Ethics Lisinopril</li> </ul>
			✓ Teva Lisinopril
* Tab 20 mg	14.69	90	<ul> <li>Ethics Lisinopril</li> </ul>
			Teva Lisinopril

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

	Subsidy		Fully	
	(Manufacturer's Price) \$	Per	Subsidised	I Generic Manufacturer
PERINDOPRIL				
* Tab 2 mg	1.79	30	1	Coversyl
Coversyl to be Principal Supply on 1 December		•		
* Tab 4 mg		30	1	Coversyl
Coversyl to be Principal Supply on 1 December		00		coroloy.
★ Tab 8 mg		30	1	Coversyl
Coversyl to be Principal Supply on 1 December		00	•	Coversyr
UINAPRIL				
★ Tab 5 mg	10.24	90	✓	Arrow-Quinapril 5
★ Tab 10 mg	12.51	90	1	Arrow-Quinapril 10
★ Tab 20 mg	14.83	90	1	Arrow-Quinapril 20
AMIPRIL				
	17.05	90	.1	Truzon
3		90	•	Tryzan
Tryzan to be Principal Supply on 1 February 203		00		T
Cap 2.5 mg		90	•	Tryzan
Tryzan to be Principal Supply on 1 February 20				_
Cap 5 mg		90	•	Tryzan
Tryzan to be Principal Supply on 1 February 20			_	
- Cap 10 mg		90	•	Tryzan
Tryzan to be Principal Supply on 1 February 203	25			
Angiotensin II Antagonists				
ANDESARTAN CILEXETIL				
€ Tab 4 mg	2 68	90	1	Candestar
Candestar to be Principal Supply on 1 February		00	-	ouridoota.
Tab 8 mg		90	1	Candestar
Candestar to be Principal Supply on 1 February		50	•	Variacotai
Tab 16 mg		90	1	Candestar
•		90	•	Canucsiai
Candestar to be Principal Supply on 1 February		90	./	Candestar
Tab 32 mg		90	•	Candestar
Candestar to be Principal Supply on 1 February	2025			
OSARTAN POTASSIUM				
Tab 12.5 mg	2.00	84	1	Losartan Actavis
₹ Tab 25 mg	2.29	84	✓	Losartan Actavis
Fab 50 mg	2.86	84	1	Losartan Actavis
€ Tab 100 mg	4.57	84	/	Losartan Actavis
Angiotensin II Antagonists with Diuretics				
-				
CANDESARTAN CILEXETIL WITH HYDROCHLOROTH				
Fab 16 mg with hydrochlorothiazide 12.5 mg	4.10	30	•	APO-Candesartan
. T				HCTZ 16/12.5
Tab 32 mg with hydrochlorothiazide 12.5 mg	5.25	30	•	APO-Candesartan HCTZ 32/12.5
				11012 32/12.3
OSARTAN POTASSIUM WITH HYDROCHLOROTHIA				
Fab 50 mg with hydrochlorothiazide 12.5 mg	4.00	30	•	Arrow-Losartan &
				Hydrochlorothiazi

Subsidy		Fully	Brand or	
(Manufacturer's Price)	9	Subsidised	Generic	
\$	Per	1	Manufacturer	

# **Angiotensin II Antagonists with Neprilysin Inhibitors**

SACUBITRIL WITH VALSARTAN - Special Authority see S	A2302 below – Retail p	oharmacy	
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
  - 2.3 Patient is in NYHA/WHO functional class IV; and
- 3 Either:
  - 3.1 Patient has a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%; or
  - 3.2 An ECHO is not reasonably practical, and in the opinion of the treating practitioner the patient would benefit from treatment; and
- 4 Patient is receiving concomitant optimal standard chronic heart failure treatments.

## **Antiarrhythmics**

For lignocaine hydrochloride refer to NERVOUS SYSTEM, Anaesthetics, Local,	page 126	
AMIODARONE HYDROCHLORIDE		
▲ Tab 100 mg	30	✓ Aratac
▲ Tab 200 mg4.49	30	✓ Aratac
Inj 50 mg per ml, 3 ml ampoule - Up to 10 inj available on a PSO9.12	6	✓ Cordarone-X
15.22	10	✓ Max Health
ATROPINE SULPHATE		
* Inj 600 mcg per ml, 1 ml ampoule - Up to 5 inj available on a		
PSO16.10	10	✓ Juno S29
		<ul><li>Martindale</li></ul>
Martindale to be Principal Supply on 1 February 2025		
DIGOXIN		
* Tab 62.5 mcg – Up to 30 tab available on a PSO	240	✓ Lanoxin PG
* Tab 250 mcg - Up to 30 tab available on a PSO16.90	240	✓ Lanoxin
* Oral liq 50 mcg per ml	60 ml	✓ Lanoxin
		<ul><li>Lanoxin Paediatric</li></ul>
		Elixir
		✓ Lanoxin S29 S29
DISOPYRAMIDE PHOSPHATE		
▲ Cap 100 mg23.87	100	Rythmodan
55.90	84	<ul><li>Rythmodan -</li></ul>
		Cheplafarm \$29

	Subsidy		Fully	
(1	Manufacturer's Price)	_	Subsidised	
	\$	Per		Manufacturer
LECAINIDE ACETATE				
▲ Tab 50 mg	19.95	60	✓	Flecainide BNM
Cap long-acting 100 mg	35.78	90	1	<u>Flecainide</u>
				Controlled
				Release Teva
Cap long-acting 200 mg	54.28	90	✓	Flecainide
				Controlled
				Release Teva
Inj 10 mg per ml, 15 ml ampoule	108.16	5	✓	Tambocor
EXILETINE HYDROCHLORIDE				
Cap 150 mg	162.00	100	1	Teva S29
Cap 250 mg		100	1	Teva S29
ROPAFENONE HYDROCHLORIDE	202.00			
	40.00	50	./	Dutmonorm
Tab 150 mg	40.90	50	•	Rytmonorm
Antihypotensives				
Antinypotensives				
IDODRINE - Special Authority see SA1474 below - Retail pharm	nacy			
Tab 2.5 mg	36.68	100	✓	MAR-Midodrine S29
ů			1	Midodrine
				Medsurge
Midodrine Medsurge to be Principal Supply on 1 February	2025			
Tab 5 mg		100	1	MAR-Midodrine S29
			_	Midodrine

Midodrine Medsurge to be Principal Supply on 1 February 2025

### **⇒SA1474** Special Authority for Subsidy

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

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

# **Beta-Adrenoceptor Blockers**

### **Beta Adrenoceptor Blockers**

ATENOLOL			
* Tab 50 mg	11.00	500	✓ Viatris
Viatris to be Principal Supply on 1 February 2025			
* Tab 100 mg	18.50	500	Atenolol Viatris
Atenolol Viatris to be Principal Supply on 1 February 20	25		
* Oral lig 25 mg per 5 ml		300 ml OP	✓ Atenolol AFT
Restricted to children under 12 years of age.			
BISOPROLOL FUMARATE			
* Tab 2.5 mg	1.36	90	✓ Ipca-Bisoprolol
* Tab 5 mg	1.91	90	✓ Ipca-Bisoprolol
* Tab 10 mg		90	✓ Ipca-Bisoprolol
CARVEDILOL			
* Tab 6.25 mg	2.24	60	✓ Carvedilol Sandoz
* Tab 12.5 mg		60	✓ Carvedilol Sandoz
* Tab 25 mg		60	✓ Carvedilol Sandoz

Medsurge

	Subsidy		Fully	
	(Manufacturer's Price)	_	Subsidised	
	\$	Per		Manufacturer
ABETALOL				
★ Tab 100 mg	14.50	100	1	Trandate
★ Tab 200 mg	27.00	100	1	Trandate
k 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	1	Myloc CR
Fab long-acting 47.5 mg		90	✓	Myloc CR
Fab long-acting 95 mg		90	✓	Myloc CR
Fab long-acting 190 mg		90	1	Myloc CR
METOPROLOL TARTRATE				
₹ Tab 50 mg	5.66	100	1	IPCA-Metoprolol
₭ Tab 100 mg		60		IPCA-Metoprolol
₹ Tab long-acting 200 mg		28		Slow-Lopresor
₭ Inj 1 mg per ml, 5 ml vial		5		Metoprolol IV Mylan
, 3,1-1				Metoprolol IV Viatris
IADOLOL				
# Tab 40 mg	19.19	100	1	Nadolol BNM
₭ Tab 80 mg		100		Nadolol BNM
PROPRANOLOL				
* Tab 10 mg	7.04	100	1	Drofate
k Tab 40 mg		100		IPCA-Propranolol
Cap long-acting 160 mg		100		Cardinol LA
★ Oral liq 4 mg per ml — Special Authority see SA1327 below —		100	•	Outumor EA
Retail pharmacy		500 m	nl 🗸	Roxane-
Total plantady		JJU 11	•	Propranolol \$29

## **⇒SA1327** Special Authority for Subsidy

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

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

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

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

## SOTALOL

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

# **Calcium Channel Blockers**

## **Dihydropyridine Calcium Channel Blockers**

AM	IL	0	DI	IΡ	ΙN	Ε

*	Tab 2.5 mg	90	✓ Vasorex
	Tab 5 mg1.21	90	✓ Vasorex
	Tab 10 mg	90	✓ Vasorex

<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	
ELODIPINE					
Plendil ER to	.5 mgbe Principal Supply on 1 February 2025	;	30	•	Plendil ER
	mgbe Principal Supply on 1 February 2025		90	•	Felo 5 ER
	0 mgo be Principal Supply on 1 February 202		90	/	Felo 10 ER
IFEDIPINE					
Tab long-acting 1	0 mg - Subsidy by endorsement	19.42	56	✓	Tensipine MR10 S29
endorsed acc	or patients who were taking nifedipine tal cordingly. Pharmacists may annotate the finifedipine tab long-acting 10 mg.				
	0 mg	17.72	100		Nyefax Retard
Tab long-acting 3	0 mg	4.78	14	•	Mylan Italy (24 hr release) \$29
		34.10	100	•	Mylan (24 hr release) \$29
★ Tab long-acting 6	0 mg	52.81	100	•	Mylan (24 hr release) \$29
Other Calcium	Channel Blockers				
ILTIAZEM HYDROC	CHLORIDE				
Cap long-acting 1	20 mg	65.35	500	✓	<b>Diltiazem CD Clinect</b>
Cap long-acting 1	80 mg	7.00	30		Cardizem CD
<ul> <li>Cap long-acting 2</li> </ul>	.40 mg	9.30	30	•	Cardizem CD
ERHEXILINE MALE					
€ Tab 100 mg		62.90	100	/	Pexsig
ERAPAMIL HYDRO					
			100		Isoptin
€ Tab 80 mg		11.74	100		Isoptin
<ul> <li>Tab long-acting 1</li> </ul>	20 mg	36.02	100		Isoptin Retard \$29
. Tabilana asilan 6	40	45.40	00		Isoptin SR
	40 mg		30	•	Isoptin SR
, , ,	2 ml ampoule – Up to 5 inj available on		5	•	Isoptin
Centrally-Actin	g Agents				
LONIDINE					
	0 mcg per day - Only on a prescription.		4		<u>Mylan</u>
	mcg per day - Only on a prescription		4		Mylan
Patch 7.5 mg, 30	0 mcg per day - Only on a prescription.	17.90	4	1	<u>Mylan</u>
LONIDINE HYDRO					
* Tab 25 mcg		29.32	112		Clonidine Teva
Catapres to I	ne Principal Supply on 1 February 2025		100		Catapres
,	nl, 1 ml ampoule	14.10 29.68	5 10		Catapres Medsurge
Catapres to b Medsurge Inj 150 ma	pe Principal Supply on 1 January 2025 og per ml, 1 ml ampoule to be delisted 1 o	January 2025)			

			<b>VASC</b>	COLAN STSTEW
	Subsidy (Manufacturer's Price \$	) Subs Per	Fully sidised	Brand or Generic Manufacturer
METHYLDOPA  * Tab 250 mg	15.10	100	✓ I	Methyldopa Viatris
Diuretics				
Loop Diuretics				
BUMETANIDE * Tab 1 mg		100		Burinex Burinex
* Inj 500 mcg per ml, 4 ml vial  FUROSEMIDE [FRUSEMIDE]		5		
Tab 40 mg — Up to 30 tab available on a PSO  IPCA-Frusemide to be Principal Supply on 1 February 1	2025	1,000		PCA-Frusemide
Tab 500 mg      Oral liq 10 mg per ml      Inj 10 mg per ml, 25 ml ampoule      Inj 10 mg per ml, 2 ml ampoule — Up to 5 inj available on a	11.20 3 60.65	50 30 ml OP 6 5	<b>√</b> [	Jrex Forte Lasix Lasix Furosemide-Baxter
Potassium Sparing Diuretics	1 002.10	, and the second		arccomine Baxtor
AMILORIDE HYDROCHLORIDE				
Oral liq 1 mg per ml  EPLERENONE – Special Authority see SA1728 below – Retail		25 ml OP	<b>√</b> E	Biomed
Tab 25 mgInspra to be Principal Supply on 1 December 2024		30		nspra
Tab 50 mgInspra to be Principal Supply on 1 December 2024	25.00	30	<b>√</b>	nspra
■ SA1728 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals va the following criteria: Both:	lid without further ren	ewal unless	notifie	ed for applications meeting
<ul><li>1 Patient has heart failure with ejection fraction less than 4</li><li>2 Either:</li></ul>	10%; and			
<ul><li>2.1 Patient is intolerant to optimal dosing of spironola</li><li>2.2 Patient has experienced a clinically significant ad</li></ul>	•	optimal dos	ing of	spironolactone.
SPIRONOLACTONE           * Tab 25 mg	3.68	100		Spiractin
* Tab 100 mg Oral liq 5 mg per ml		100 25 ml OP	_	Spiractin Biomed
Potassium Sparing Combination Diuretics				
AMILORIDE HYDROCHLORIDE WITH FUROSEMIDE  * Tab 5 mg with furosemide 40 mg	8.63	28	<b>√</b> F	Frumil
AMILORIDE HYDROCHLORIDE WITH HYDROCHLOROTHIA:  * Tab 5 mg with hydrochlorothiazide 50 mg		50	<b>✓</b> I	Moduretic

	Subsidy (Manufacturer's Price) \$	S Per	Fully Subsidised	Brand or Generic Manufacturer
Thiazide and Related Diuretics				
BENDROFLUMETHIAZIDE [BENDROFLUAZIDE]  * Tab 2.5 mg - Up to 150 tab available on a PSO	51.50	500	✓ <u>A</u>	rrow- Bendrofluazide
May be supplied on a PSO for reasons other than emerg  * Tab 5 mg		500	✓ <u>A</u>	rrow- Bendrofluazide
CHLOROTHIAZIDE Oral liq 50 mg per ml	29.21 2	5 ml OF	• <b>✓</b> B	iomed
CHLORTALIDONE [CHLORTHALIDONE]  * Tab 25 mg	6.95	50	<b>✓</b> <u>H</u>	ygroton
INDAPAMIDE	16.00	90	<b>√</b> <u>D</u>	apa-Tabs
Tab 5 mg	CBS	1 50		letolazone S29 aroxolyn S29
Vasopressin receptor antagonists				
TOLVAPTAN – Special Authority see SA2166 below – Retail pha Tab 15 mg	•	28 OP	<b>√</b> Ji	inarc

letali pnarmacy		
873.50	28 OP	<ul><li>Jinarc</li></ul>
873.50	28 OP	<ul><li>Jinarc</li></ul>
1,747.00	56 OP	<ul><li>Jinarc</li></ul>
1,747.00	56 OP	<ul><li>Jinarc</li></ul>
	56 OP	Jinarc

### **⇒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 m² 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.

	Subsidy (Manufacturer's Price) \$	Full Subsidise Per •	
Lipid-Modifying Agents			
Fibrates			
BEZAFIBRATE  * Tab 200 mg  * Tab long-acting 400 mg			´ Bezalip ´ Bezalip Retard
Other Lipid-Modifying Agents			
ACIPIMOX  * Cap 250 mg	38.19	30	<b>∕</b> Olbetam
Resins			
COLESTYRAMINE Powder for oral suspension 4 g sachet	61.50		Colestyramine - Mylan ©29 Quantalan sugar free ©29
HMG CoA Reductase Inhibitors (Statins)			
ATORVASTATIN  * Tab 10 mg  Lorstat to be Principal Supply on 1 December 2024	5.16	500	<b>C</b> Lorstat
* Tab 20 mg	8.12	500	Lorstat
* Tab 40 mg	13.79	500	Lorstat
* Tab 80 mg Lorstat to be Principal Supply on 1 December 2024	25.39	500	Lorstat
PRAVASTATIN			<b>.</b>
* Tab 40 mg			Clinect Clinect
ROSUVASTATIN - Special Authority see SA2093 below - Reta	ail pharmacy		
* Tab 5 mg			Rosuvastatin Viatris
* Tab 10 mg			Rosuvastatin Viatris
* Tab 20 mg			Rosuvastatin Viatris
* Tab 40 mg			Rosuvastatin Viatris  d without further renewal
1 Both:			
1.1 Patient is considered to be at risk of cardiovascula	ar disease: and		

- 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:

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

continued...

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

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

### Both:

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

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

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

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

Both:

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

SIMVASTATIN			
* Tab 10 mg	1.68	90	<ul><li>Simvastatin Mylan</li></ul>
Ÿ			✓ Simvastatin Viatris
* Tab 20 mg	2.54	90	✓ Simvastatin Viatris
* Tab 40 mg		90	✓ Simvastatin Mylan
Ÿ			✓ Simvastatin Viatris
* Tab 80 mg	8.81	90	✓ Simvastatin Viatris
(Simvastatin Mylan Tab 40 mg to be delisted 1 Decer			

# **Selective Cholesterol Absorption Inhibitors**

Tab 10 mg	1.76	30	<ul><li>✓ Ezemibe Viatris</li><li>✓ Ezetimibe Sandoz</li></ul>
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		30	✓ 7imvhe

E7ETIMIRE

(A)	Subsidy Manufacturer's \$	Price) Subs Per	Fully Brand or idised Generic  Manufacturer
Nitrates			
GLYCERYL TRINITRATE			
* Oral pump spray, 400 mcg per dose – Up to 250 dose available on a PSO	7.48	250 dose OP	✓ Nitrolingual Pump Spray
★ Patch 25 mg, 5 mg per day	15.73	30	✓ Nitroderm TTS
Patch 50 mg, 10 mg per day		30	✓ Nitroderm TTS
SOSORBIDE MONONITRATE			
★ Tab 20 mg		100	✓ <u>Ismo 20</u>
* Tab long-acting 40 mg		30	✓ Ismo 40 Retard
* Tab long-acting 60 mg	13.50	90	✓ <u>Duride</u>
Sympathomimetics			
DRENALINE			
Inj 1 in 1,000, 1 ml ampoule - Up to 5 inj available on a PSO		5	✓ Aspen Adrenaline
	13.27		✓ DBL Adrenaline
	25.30	10	✓ HameIn S29
Inj 1 in 10,000, 10 ml ampoule – Up to 5 inj available on a PSC	49.00	5 10	<ul><li>✓ Hospira</li><li>✓ Aspen Adrenaline</li></ul>
V			.,
Vasodilators			
HYDRALAZINE HYDROCHLORIDE			
★ Tab 25 mg - Special Authority see SA1321 below - Retail			
pharmacy	CBS	1	✓ Hydralazine
		56	✓ Onelink S29
		84	✓ AMDIPHARM S29
		100	✓ Camber S29
k Inj 20 mg ampoule	25.90	5	✓ Apresoline
<ul> <li>SA1321 Special Authority for Subsidy</li> <li>nitial application from any relevant practitioner. Approvals valid we need following criteria:</li> <li>iither:</li> <li>1 For the treatment of refractory hypertension; or</li> </ul>	vithout furthe	r renewal unless	notified for applications meetin
2 For the treatment of heart failure in combination with a nitrate	e. in patients	who are intolera	Int or have not responded to AC

# MINOXIDIL

MIN TO ALBIE			
▲ Tab 10 mg	47.04	60	✓ Minoxidil Roma S29
· ·	78.40	100	✓ Loniten
NICORANDIL			
▲ Tab 10 mg	21.73	60	✓ Max Health
▲ Tab 20 mg		60	✓ Max Health
PAPAVERINE HYDROCHLORIDE			
* Inj 12 mg per ml, 10 ml ampoule	257.12	5	✓ Hospira
PENTOXIFYLLINE [OXPENTIFYLLINE]			
Tab 400 mg	44.37	50	✓ Trental 400

inhibitors and/or angiotensin receptor blockers.

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

## **Endothelin Receptor Antagonists**

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

⇒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 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

Subsidy	Full	y Brand or	
(Manufacturer's Price)	Subsidise	d Generic	
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- 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 Either:
    - 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).

**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

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(Manufact	turer's Price) Subsi	dised	Generic
	\$ Per	•	Manufacturer

continued...

- 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.

		BOSENTAN – Special Authority see SA2254 below – Retail pharmacy
✓ Bosentan Dr	60	Tab 62.5 mg100.00
Reddy's		
		Bosentan Dr Reddy's to be Principal Supply on 1 January 2025
✓ Bosentan Dr Reddy's	60	Tab 125 mg100.00

Bosentan Dr Reddy's to be Principal Supply on 1 January 2025

#### ⇒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

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

continued...

- 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

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:

applications meeting the following criteria:

- 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 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

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

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therapeutic response to treatment according to a validated risk stratification tool\*\*: or

6.2 Patient is presenting in NYHA/WHO functional class III or IV, and in the opinion of the treating clinician would likely benefit from initial dual therapy.

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

All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH)\*; and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH has been confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
    - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
    - 4.1.4 Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm<sup>5</sup>); and
    - 4.1.5 Any of the following:
      - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †; or
      - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool\*\*; or
      - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
  - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease; or
  - 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
- 5 Both:
  - 5.1 Bosentan is to be used as part of 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 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.

Brand or

Generic

Fully

Subsidised

	\$	Per	✓ Manufacturer
Phosphodiesterase Type 5 Inhibitors			
SILDENAFIL - Special Authority see SA2255 below - Retail pharmacy			
Tab 25 mg	0.72	4	✓ Vedafil
Vedafil to be Principal Supply on 1 December 2024			
Tab 50 mg	1.45	4	✓ Vedafil
Vedafil to be Principal Supply on 1 December 2024			
Tab 100 mg	.11.22	12	✓ Vedafil
Vedafil to be Principal Supply on 1 December 2024			

Subsidy

(Manufacturer's Price)

### ⇒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
    - 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.

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

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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

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

### **Prostacyclin Analogues**

EPOPROSTENOL - Special Authority see SA2256 below - Retail pharmacy

Inj 500 mcg vial	36.61	1	✓ Veletri
Inj 1.5 mg vial	73.21	1	✓ Veletri

### ⇒SA2256 Special Authority for Subsidy

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

All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH); and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class III or IV; and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH has been confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
    - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
    - 4.1.4 A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm<sup>5</sup>); and
    - 4.1.5 Any of the following:
      - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these 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 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

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

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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
      - 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

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✓ 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:

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

continued...

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 applications meeting the following criteria:

All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH); and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH has been confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
    - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
    - 4.1.4 A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm<sup>-5</sup>); and
    - 4.1.5 Any of the following:
      - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †; or

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

continued...

- 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 Fither
    - 5.2.1 Patient has an absolute contraindication to or has experienced intolerable side effects on sildenafil; or
    - 5.2.2 Patient has an absolute or relative contraindication to or experienced intolerable side effects with a funded endothelin receptor antagonist; and
  - 5.3 Either:
    - 5.3.1 Patient has tried a PAH monotherapy for at least three months and remains in an unacceptable risk category according to a validated risk stratification tool\*\*; or
    - 5.3.2 Patient is presenting in NYHA/WHO functional class III or IV, and in the opinion of the treating clinician would benefit from initial dual therapy.

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

#### All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH); and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH has been confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
    - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
    - 4.1.4 A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm<sup>5</sup>); and
    - 4.1.5 Any of the following:
      - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †; or
      - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool\*\*; or
      - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
  - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease; or
  - 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
- 5 Both:
  - 5.1 Iloprost is to be used as PAH triple therapy; and
  - 5.2 Any of the following:
    - 5.2.1 Patient is on the lung transplant list; or

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

continued...

- 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 Manufacturer

# **Antiacne Preparations**

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 97

#### ADAPAI FNF

a) Maximum of 30 g per prescription

b) Only on a prescription Gel 0.1%	22.89	30 g OP	✓ Differin
ISOTRETINOIN - Special Authority see SA2023 below - Retail pl	harmacy	J	
Cap 5 mg	•	60	<ul><li>Oratane</li></ul>
Oratane to be Principal Supply on 1 December 2024			
Cap 10 mg	18.75	120	<ul><li>Oratane</li></ul>
Oratane to be Principal Supply on 1 December 2024			
Cap 20 mg	26.73	120	<ul><li>Oratane</li></ul>
Oratane to be Principal Supply on 1 December 2024			

#### ⇒SA2023 Special Authority for Subsidy

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

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

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

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

#### **TRFTINOIN**

Crm 0.5 mg per g - Maximum of 50 g per prescription	16.82	50 g OP	✓ ReTrieve
ReTrieve to be Principal Supply on 1 February 2025			

# **Antibacterials Topical**

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 97

	maio, page or		
HYDROGEN PEROXIDE			
* Crm 1%	8.56	10 g OP	<ul><li>Crystaderm</li></ul>
MUPIROCIN			
Oint 2%	6.60	15 g OP	
	(13.00)	_	Bactroban
a) Only on a procorintion			

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

## **DERMATOLOGICALS**

	Subsidy (Manufacturer's F \$	Price) Subs	Fully sidised	Brand or Generic Manufacturer
SODIUM FUSIDATE [FUSIDIC ACID]				
Crm 2%	1.69	5 g OP	<b>√</b> F	oban
a) Maximum of 5 g per prescription				
b) Only on a prescription				
c) Not in combination				
d) Foban to be Principal Supply on 1 February 2025 Oint 2%	1.60	5 g OP	./ 5	oban
a) Maximum of 5 g per prescription	1.09	3 y OF	• 1	ODali
b) Only on a prescription				
c) Not in combination				
d) Foban to be Principal Supply on 1 February 2025				
SULFADIAZINE SILVER				
Crm 1%	10.80	50 g OP	<b>√</b> F	lamazine
	15.44	J	<b>√</b> p	Scend \$29
a) Up to 250 g available on a PSO				
b) Not in combination				
Antifungals Topical  For systemic antifungals, refer to INFECTIONS, Antifungals, pa  AMOROLFINE  a) Only on a prescription	ge 104			
b) Not in combination				
Nail soln 5%	21.87	5 ml OP	✓ N	/lycoNail
CLOTRIMAZOLE			_	
* Crm 1%	1.10	20 g OP	✓ (	Clomazol
a) Only on a prescription		·		
b) Not in combination				
* Soln 1%	4.36	20 ml OP		
	(7.55)		C	Canesten
a) Only on a prescription				
b) Not in combination				
ECONAZOLE NITRATE				
Crm 1%		20 g OP	_	Nava med
a) Oaks an a massadation	(8.09)		F	Pevaryl
a) Only on a prescription     b) Not in combination				
Foaming soln 1%, 10 ml sachets	0.80	3		
1 oanning soll 170, 10 mil sachots	(18.64)	J	F	Pevaryl
	(10.01)			1 .

a) Only on a prescriptionb) Not in combination

		L	DERMATOLOGICALS
	Subsidy (Manufacturer's P \$	Price) Subs Per	Fully Brand or sidised Generic ✓ Manufacturer
MICONAZOLE NITRATE			
* Crm 2%	0.90	15 g OP	✓ <u>Multichem</u>
<ul><li>a) Only on a prescription</li><li>b) Not in combination</li></ul>			
* Lotn 2%	4.36 (10.03)	30 ml OP	Daktarin
a) Only on a prescription	(10.00)		Dantaiii
b) Not in combination			
* Tinct 2%	4.36	30 ml OP	
	(12.10)		Daktarin
<ul><li>a) Only on a prescription</li><li>b) Not in combination</li></ul>			
Antipruritic Preparations			
CALAMINE a) Only on a prescription b) Not in combination			
Crm, aqueous, BP	3.45	100 g	✓ healthE Calamine  Aqueous

# CROTAMITON

a) Only on a prescription

b) Not in combination
Crm 10%......3.49 20 g OP ✓ Itch-Soothe
Itch-Soothe to be Principal Supply on 1 February 2025

#### MENTHOL - Only in combination

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

Crystals	6.92	25 g	✓ MidWest
	29.60	100 g	✓ MidWest

# **Corticosteroids Topical**

For systemic corticosteroids, refer to CORTICOSTEROIDS AND RELATED AGENTS, page 87

### Corticosteroids - Plain

BE.	FAMETHASONE DIPROPIONATE		
	Crm 0.05%	15 g OP	<ul> <li>Diprosone</li> </ul>
	36.00	50 g OP	✓ Diprosone
	Oint 0.05%	15 g OP	✓ Diprosone
	36.00	50 g OP	✓ Diprosone
	Oint 0.05% in propylene glycol base4.33	30 g OP	✓ Diprosone OV
BE	FAMETHASONE VALERATE		
*	Crm 0.1%5.85	50 g OP	✓ Beta Cream
	Beta Cream to be Principal Supply on 1 February 2025	•	
*	Oint 0.1%7.90	50 g OP	✓ Beta Ointment
	Beta Ointment to be Principal Supply on 1 February 2025	ŭ	
*	Lotn 0.1%	50 ml OP	✓ Betnovate

	Subsidy		Fully	Brand or
	(Manufacturer's P	rice) Subs	sidised	Generic
	\$	Per	1	Manufacturer
LOBETASOL PROPIONATE				
€ Crm 0.05%	2.40	30 g OP	<b>✓</b>	Dermol
€ Oint 0.05%	2.33	30 g OP	1	Dermol
LOBETASONE BUTYRATE				
Crm 0.05%	5.38	30 g OP		
	(10.00)	00 g 0.		Eumovate
YDROCORTISONE	(10100)			
Crm 1% – Only on a prescription	1 70	30 g OP	1	Ethics
Citil 1/8 – Only on a prescription	20.40	500 g	-	Noumed
Powder – Only in combination		25 q		ABM
Up to 5% in a dermatological base (not proprietary Top galenicals	icai Corticosteriou	– Plain) With C	or with	out other dermatologica
YDROCORTISONE AND PARAFFIN LIQUID AND LANOLIN				
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% - Only	on			
a prescription		250 ml	1	DP Lotn HC
YDROCORTISONE BUTYRATE				
Lipocream 0.1%	4 85	100 g OP	1	Locoid Lipocream
Oint 0.1%		100 g OP		Locoid
Milky emul 0.1%		100 ml OP		Locoid Crelo
	12.00	100 1111 01		Locola Orcio
IETHYLPREDNISOLONE ACEPONATE	4.05	15 × OD		Advantan
Crm 0.1%		15 g OP	-	Advantan
Oint 0.1%	4.95	15 g OP	•	<u>Advantan</u>
IOMETASONE FUROATE				
Crm 0.1%		15 g OP		Elocon Alcohol Free
	3.50	50 g OP		Elocon Alcohol Free
Elocon Alcohol Free to be Principal Supply on 1 Februa				
Oint 0.1%		15 g OP		Elocon
	3.50	50 g OP	•	Elocon
Elocon to be Principal Supply on 1 February 2025				
Lotn 0.1%	4.99	30 ml OP	•	Elocon
Elocon to be Principal Supply on 1 February 2025				
RIAMCINOLONE ACETONIDE				
Crm 0.02%	6.49	100 g OP	1	Aristocort
Oint 0.02%	6.54	100 g OP	1	Aristocort
Corticosteroids - Combination				
	101010 1010			
ETAMETHASONE VALERATE WITH SODIUM FUSIDATE [FU	•			
Crm 0.1% with sodium fusidate (fusidic acid) 2%		15 g OP		
	(10.45)			Fucicort
a) Maximum of 15 g per prescription				
b) Only on a prescription				
YDROCORTISONE WITH MICONAZOLE - Only on a prescri	iption			
Crm 1% with miconazole nitrate 2%		15 g OP	1	Micreme H
Micreme H to be Principal Supply on 1 February 2025		<b>J</b> -		
YDROCORTISONE WITH NATAMYCIN AND NEOMYCIN - (	Only on a presering	tion		
Oint 1% with natamycin 1% and neomycin sulphate 0.5%		15 g OP	<b>/</b> 1	Pimafucort
Sinc 1/3 with natarnyonr 1/3 and neomyonr sulphate 0.5/6		15 9 01	•	i iliaidoon

		U	ENWATOLOGICALS
	Subsidy (Manufacturer's I \$	Price) Subsi Per	Fully Brand or dised Generic  Manufacturer
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCII	N AND NYSTA	TIN	
Crm 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 mcg per g - Only on a prescription		15 g OP	Viaderm KC
Barrier Creams and Emollients			
Barrier Creams			
DIMETHICONE  * Crm 5% pump bottle	4.30	500 ml OP	✓ <u>healthE</u> Dimethicone 5%
* Crm 10% pump bottle	4.52	500 ml OP	✓ healthE  Dimethicone 10%
ZINC AND CASTOR OIL  * Oint	4.25	500 g	✓ <u>Evara</u>
Emollients			
AQUEOUS CREAM Crm	1.30	100 g	✓ healthE Aqueous  Cream SLS Free
	1.65 1.73	500 g	✓ Evara ✓ GEM Aqueous Cream
(healthE Aqueous Cream SLS Free Crm to be delisted 1 March 2 (GEM Aqueous Cream Crm to be delisted 1 March 2025) CETOMACROGOL	025)		
* Crm BP  Cetomacrogol-AFT to be Principal Supply on 1 February		500 g	✓ Cetomacrogol-AFT
CETOMACROGOL WITH GLYCEROL Crm 90% with glycerol 10%	2.13 3.50	500 ml OP 1,000 ml OP	✓ <u>Evara</u> ✓ <u>Evara</u>
# Oint BP	3.13	500 g	✓ Emulsifying Ointment ADE
OIL IN WATER EMULSION  * Crm	2.04 2.10	500 g	<ul> <li>✓ Fatty Cream AFT</li> <li>✓ Fatty Emulsion</li> <li>Cream (Evara)</li> </ul>
(Fatty Cream AFT Crm to be delisted 1 April 2025)			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
PARAFFIN Oint liquid paraffin 50% with white soft paraffin 50%	4.94	500 g OP	✓ White Soft Liquid Paraffin AFT
UREA			

100 g OP

✓ healthE Urea Cream

<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

## **DERMATOLOGICALS**

	Subsidy (Manufacturer's F	Price) Subs	Fully idised	Brand or Generic Manufacturer
WOOL EAT WITH MINERAL OIL Only on a prescription	Ψ	1 01		Mariaracturer
WOOL FAT WITH MINERAL OIL — Only on a prescription				
* Lotn hydrous 3% with mineral oil	5.60	1,000 ml		
·	(14.96)			OP Lotion
	(20.53)		A	Alpha-Keri Lotion
	` 1.40 <sup>′</sup>	250 ml OP		
	(5.87)			OP Lotion
	`5.60 <sup>°</sup>	1,000 ml		
	(23.91)		Е	3K Lotion
	1.40	250 ml OP		
	(7.73)		E	BK Lotion

## **Other Dermatological Bases**

P	٩R	ΔΙ	FΙ	=11	١

White soft – Only in combination4.74	450 g	✓ EVARA White Soft
19.00	2.500 a	Paraffin  ✓ EVARA White Soft
10.00	<u> </u>	Paraffin

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

# **Minor Skin Infections**

POVIDONE IODINE			
Oint 10%	7.40	65 g OP	✓ Betadine
a) Maximum of 130 g per prescription		_	
b) Only on a prescription			
Antiseptic Solution 10%	4.99	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

# **Parasiticidal Preparations**

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DIN	ı⊏ı	ПΙ	$\sim$	ハハロ

* Lotn 4%	200 ml OP	✓ healthE  Dimethicone 4%  Lotion
IVERMECTIN - Special Authority see SA2294 below - Retail pharmacy		

- 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:

## DERMATOLOGICALS

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

continued...

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 — (Scables) 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.

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**

ACITRETIN - Special Authority see SA2024 below - Retail ph	narmacy		
Cap 10 mg	26.20	60	Novatretin
Cap 25 mg	57.37	60	✓ Novatretin

#### ⇒SA2024 Special Authority for Subsidy

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

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



Subs (Manufactur		
\$	Per	Manufacturer

continued...

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 actitetin 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

Foam spray 500 mcg with calcipotriol 50 mcg per g		60 g OP 60 g OP	<ul><li>✓ Enstilar</li><li>✓ Daivobet</li></ul>
Oint 500 mcg with calcipotriol 50 mcg per g	14.31	30 g OP	✓ Daivobet
CALCIPOTRIOL Oint 50 mcg per g	40.00	120 g OP	✓ Daivonex
COAL TAR Soln BP - Only in combination	36.25	200 ml	✓ Midwest

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

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

Soln 5% with sulphur 0.5%, menthol 0.75%, phenol 0.5% and			
allantoin crm 2.5%	6.59	75 g OP	
	(8.00)	Ü	Egopsoryl TA
	3.43	30 g OP	
	(4.35)	Ü	Egopsoryl TA
COAL TAR WITH SALICYLIC ACID AND SULPHUR			
Soln 12% with salicylic acid 2% and sulphur 4% oint	4.97	25 g OP	✓ Coco-Scalp
·	7.05	40 a OP	✓ Coco-Scaln

PIMECROLIMUS - Special Authority see SA1970 below - Retail pharmacy

- a) Maximum of 15 g per prescription
- b) Note: a maximum of 15 g per prescription and no more than one prescription per 12 weeks.

#### ⇒SA1970 Special Authority for Subsidy

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

#### Both:

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

PINE TAR WITH TROLAMINE LAURILSULFATE AND FLUORESCEIN - Only on a prescription

\* Soln 2.3% with trolamine laurilsulfate and fluorescein sodium..........5.41 500 ml / Pinetarsol

		I	DERM	ATOLOGICALS
	Subsidy (Manufacturer's P	rice) Sub	Fully sidised	Brand or Generic Manufacturer
SALICYLIC ACID				
Powder - Only in combination		250 g		lidwest
<ol> <li>Only in combination with a dermatological base or</li> <li>With or without other dermatological galenicals.</li> </ol>	r proprietary Topic	al Corticoster	oid – Pla	ain or collodion flexible
SULPHUR				
Precipitated – Only in combination		100 g		lidwest
<ol> <li>Only in combination with a dermatological base or</li> <li>With or without other dermatological galenicals.</li> </ol>	r proprietary Topic	al Corticoster	oid – Pla	ain
TACROLIMUS				
Oint 0.1% - Special Authority see SA2074 below - Retail				
pharmacy	33.00	30 g OP	<b>✓</b> <u>Z</u>	<u>ematop</u>
<ul><li>a) Maximum of 30 g per prescription</li><li>b) Note: a maximum of 30 g per prescription and no m</li></ul>	nore than one pres	scription per 1	2 weeks	3.
⇒SA2074 Special Authority for Subsidy	.о.о и.а отго ртос	20p.u.opo		•
Initial application only from a dermatologist, paediatrician or ar	ny relevant practiti	oner on the re	comme	ndation of a dermatologist,
paediatrician, . Approvals valid without further renewal unless n				
Both:				
<ul><li>1 Patient has atopic dermatitis on the face; and</li><li>2 Patient has at least one of the following contraindications</li></ul>	to tonical cartica	atoroido: pori	rificial d	Aarmatitia raaaaa
documented epidermal atrophy or documented allergy to			niiciai (	dermanns, rosacea,
Scalp Preparations				
BETAMETHASONE VALERATE				
* Scalp app 0.1%	12.95	100 ml OP	<b>✓</b> E	Beta Scalp
Beta Scalp to be Principal Supply on 1 February 2025				
CLOBETASOL PROPIONATE				
* Scalp app 0.05%	6.26	30 ml OP	✓ [	<u>Jermol</u>
HYDROCORTISONE BUTYRATE				
Scalp lotn 0.1%	6.57	100 ml OP	<b>✓</b> L	ocoid
KETOCONAZOLE	0.00	100   00		lahimala
Shampoo 2%	4.09	100 ml OP	_	<u>sebizole</u> sebizole
a) Maximum of 100 ml per prescription	4.03		- 9	COILOIG
b) Only on a prescription				
0				
Sunscreens				
SUNSCREENS, PROPRIETARY – Subsidy by endorsement				
Only if prescribed for a patient with severe photosensitivity s	accordent to a def	finad alinical a	ondition	and the prescription is

200 g OP

✓ Marine Blue Lotion

SPF 50+

endorsed accordingly.

## **DERMATOLOGICALS**

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

\$ Per ✓ Manufacturer

# **Wart Preparations**

For salicylic acid preparations refer to PSORIASIS AND ECZEMA PREPARATIONS, page 75

**PODOPHYLLOTOXIN** 

a) Maximum of 3.5 ml per prescription

b) Only on a prescription

# **Other Skin Preparations**

Anti	neop	last	ICS.

IMIQUIMOD

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

		Subsidy (Manufacturaria Brica)	^	Fully	Brand or Generic
		(Manufacturer's Price) \$	Per	ubsidised •	Manufacturer
20	ontraceptives - Non-hormonal				
Co	ondoms				
	NDOMS			_	
	49 mm - Up to 144 dev available on a PSO		144	1	Moments
6	53 mm	1.15	10	✓	Moments
		14.25	144	✓	Moments
	<ul> <li>a) Maximum of 60 dev per prescription</li> </ul>				
	b) Up to 60 dev available on a PSO				
6	53 mm, 0.05 mm thickness	1.15	10	✓	Moments
		14.25	144	1	Moments
	a) Up to 60 dev available on a PSO				
	b) Maximum of 60 dev per prescription				
÷	53 mm, chocolate, brown	1 15	10	1	Moments
	55, 51000idto, 510111	14.25	144		Moments
	a) Up to 60 dev available on a PSO	17.25	1 T T	•	
	b) Maximum of 60 dev per prescription				
<del>.</del>	53 mm, strawberry, red	1 15	10	1	Moments
•	55 mm, snawberry, red		144		Moments
	\	14.25	144	•	woments
	a) Up to 60 dev available on a PSO				
	b) Maximum of 60 dev per prescription			_	
+	56 mm		10		Moments
		14.50	144	/	Moments
	<ul> <li>a) Maximum of 60 dev per prescription</li> </ul>				
	b) Up to 60 dev available on a PSO				
÷	56 mm, 0.05 mm thickness	2.00	12	1	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	1	Gold Knight
	a) Maximum of 60 dev per prescription			-	innyin
	b) Up to 60 dev available on a PSO				
_	56 mm, 0.08 mm thickness	1 15	10	.1	Moments
+	JU IIIII, U.UO IIIII IIIICKIIESS				
	) II + 00 I	14.25	144	•	Moments
	a) Up to 60 dev available on a PSO				
	b) Maximum of 60 dev per prescription		4.6	_	
+	56 mm, 0.08 mm thickness, red		10		Moments
		14.25	144	/	Moments
	<ul> <li>a) Up to 60 dev available on a PSO</li> </ul>				
	<ul> <li>b) Maximum of 60 dev per prescription</li> </ul>				
÷	56 mm, chocolate	1.79	12		Gold Knight
		21.45	144	1	Gold Knight
	a) Up to 60 dev available on a PSO				
	b) Maximum of 60 dev per prescription				
÷	56 mm, strawberry	1.79	12	1	Gold Knight
		21.45	144		Gold Knight
	a) Up to 60 dev available on a PSO	==			· 3···
	b) Maximum of 60 dev per prescription				
<u>.</u>	60 mm	1 22	12	1	Gold Knight XL
	VV 11111111111111111111111111111111111	21.89	144		Gold Knight XL
	a) Maximum of 60 days now avacariation	21.03	174	•	adia Kiliyili AL
=	a) Maximum of 60 dev per prescription b) ⊌prந்துக்குமுத்து lable on a PSO				
	U) POPINION DIA MIRIYARWANIADIE ON A PSU	S29 Unapprove	l medicii	ne supplie	d under Section 29

Subsidy	Fully	Brand or
(Manufacturer's Price)	Subsidised	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

*	IUD 29.1 mm length × 23.2 mm width29.80	1	✓ Choice 380 7med  Nsha Silver/ copper Short
*	IUD 33.6 mm length × 29.9 mm width26.80	1	✓ TCu 380 Plus Normal
*	IUD 35.5 mm length × 19.6 mm width	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

The additional subsidy will fund Mercilon and Maryelon 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

#### ETHINYLOFSTRADIOL 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 (Manufacturer's Price)	Per	Fully Subsidised	
ETHINIVI OF OTRADIOL WITH LEVONODOF OTREI	Ψ	1 01		Mariaracturer
ETHINYLOESTRADIOL WITH LEVONORGESTREL				
* Tab 20 mcg with levonorgestrel 100 mcg and 7 inert tablets			_	
Up to 84 tab available on a PSO		84	•	Lo-Oralcon 20 ED
* Tab 30 mcg with levonorgestrel 150 mcg	6.62	63		
	(16.50)			Microgynon 30
<ul><li>a) Higher subsidy of \$15.00 per 63 tab with Special Autl</li><li>b) Up to 63 tab available on a PSO</li></ul>	nority see SA0500 on	the	previous pa	age
* Tab 30 mcg with levonorgestrel 150 mcg and 7 inert tablets	_			
Up to 84 tab available on a PSO	1.50	84	✓	Oralcon 30 ED
ETHINYLOESTRADIOL WITH NORETHISTERONE				
Tab 35 mcg with norethisterone 1 mg and 7 inert tab	12.25	84	✓	Alyacen S29
			✓	Brevinor 1/28
	16.33	112	1	Brevinor-1 28 Day
			1	Norimin-1 28 Day
<ul><li>a) Brand switch fee payable (Pharmacode 2692112) - s</li><li>b) Up to 84 tab available on a PSO</li></ul>		ls		·
Tab 35 mcg with norethisterone 500 mcg and 7 inert tab - U				
to 84 tab available on a PSO	21.99	84	✓	Norimin
(Brevinor-1 28 Day Tab 35 mcg with norethisterone 1 mg and 7 ir (Norimin-1 28 Day Tab 35 mcg with norethisterone 1 mg and 7 in				

## **Progestogen-only Contraceptives**

## ⇒SA0500 Special Authority for Alternate Subsidy

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

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

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

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

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

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

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

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

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

## LEVONORGESTREL

*	Tab 30 mcg - Up to 84 tab available on a PSO	16.50 22.00	84 112	<ul><li>✓ Microlut</li><li>✓ Microlut</li></ul>
*	Subdermal implant (2 × 75 mg rods) – Up to 3 pack available	22.00	112	<b>▼</b> IWICTOIUL
	on a PSO1	06.92	1	✓ <u>Jadelle</u>

		GENIT	O-URIN	IARY SYSTEM
	Subsidy (Manufacturer's Price) \$	Sub:	Fully sidised	Brand or Generic Manufacturer
MEDROXYPROGESTERONE ACETATE Inj 150 mg per ml, 1 ml syringe – Up to 5 inj available on a P NORETHISTERONE – Brand switch fee payable (Pharmacode 2 Tab 350 mcg – Up to 84 tab available on a PSO	2692120) - see page	1 273 for de 84	etails ✔ No	po-Provera orethinderone - CDC oriday 28
<b>Emergency Contraceptives</b>				
# Tab 1.5 mg	1.75	1		vonorgestrel BNM
<ul><li>a) Maximum of 2 tab per prescription</li><li>b) Up to 5 tab available on a PSO</li><li>c) Note: Direct Provision by a pharmacist permitted unce</li></ul>	der the provisions in	Part I of S	ection A.	
Antiandrogen Oral Contraceptives				
Prescribers may code prescriptions "contraceptive" (code "O") wh and prescription charge will be as per other contraceptives, as fol  A maximum \$5.00 prescription charge (patient co-payment)  prescription may be written for up to six months supply.  Prescriptions coded in any other way are subject to any non contraceptive period of supply. ie. Prescriptions may be writed to the contraceptive period of supply. ie. Prescriptions may be writed to the contraceptive period of supply. Tab 2 mg with ethinyloestradiol 35 mcg and 7 inert tabs — Up to 168 tab available on a PSO	lows: may apply. raceptive prescriptior tten for up to three m	n charges	that apply	y, and the
Gynaecological Anti-infectives				
ACETIC ACID WITH HYDROXYQUINOLINE AND RICINOLEIC A Jelly with glacial acetic acid 0.94%, hydroxyquinoline sulphat 0.025%, glycerol 5% and ricinoleic acid 0.75% with applications of the control of the c	е	00 g OP	Ac	i-Jel
CLOTRIMAZOLE  * Vaginal crm 1% with applicators  * Vaginal crm 2% with applicators  MICONAZOLE NITRATE	3.85 2	5 g OP 0 g OP	✓ Clo	omazol omazol
* Vaginal crm 2% with applicator		0 g OP 5 g OP	✓ Mil	creme
	5.70 7	3 y OF	V INII	<u>siai</u>
Myometrial and Vaginal Hormone Preparations ERGOMETRINE MALEATE				

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

5

15 g OP

15

✓ DBL Ergometrine

✓ Ovestin ✓ Ovestin

**OESTRIOL** 

Inj 500 mcg per ml, 1 ml ampoule - Up to 5 inj available on a

PSO.......160.00

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
OXYTOCIN – Up to 5 inj available on a PSO				
Inj 5 iu per ml, 1 ml ampoule	4.98	5	✓	Oxytocin BNM
Inj 10 iu per ml, 1 ml ampoule	5.98	5	✓	Oxytocin BNM
	11.96	10	✓	Oxytocin
				Panpharma
OXYTOCIN WITH ERGOMETRINE MALEATE - Up to 5 inj avai	lable on a PSO			
Inj 5 iu with ergometrine maleate 500 mcg per ml, 1 ml ampo		5	✓	Syntometrine

# **Pregnancy Tests - hCG Urine**

PREGNANCY TESTS - HCG URINE

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

(Smith BioMed Rapid Pregnancy Test Cassette to be delisted 1 March 2025)

## **Urinary Agents**

For urinary tract Infections refer to INFECTIONS, Antibacterials, page 116

## 5-Alpha Reductase Inhibitors

FINASTERIDE – Special Authority see SA0928 below – Retail pharmacy

★ Tab 5 mg .......4.79 100 ✓ Ricit

#### ⇒SA0928 Special Authority for Subsidy

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

#### Both:

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

# 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 Pri \$	ice) Su Per	Fully bsidised	Brand or Generic Manufacturer
Other Urinary Agents				
OXYBUTYNIN				
* Tab 5 mg	5.42	100		chemy Oxybutynin
POTASSIUM CITRATE				, ,
Oral liq 3 mmol per ml - Special Authority see SA1083 belov Retail pharmacy		200 ml OP	<b>✓</b> Bi	omed
■ SA1083 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid Both:  1 The patient has recurrent calcium oxalate urolithiasis; and		or application	ns meeting	the following criteria:
2 The patient has had more than two renal calculi in the two	years prior to the			
<b>Renewal</b> from any relevant practitioner. Approvals valid for 2 year benefitting from the treatment.	ars where the trea	itment rema	ins approp	riate and the patient is
SODIUM CITRO-TARTRATE				
* Grans eff 4 g sachets	3.50	28	✓ <u>Ur</u>	<u>al</u>
SOLIFENACIN SUCCINATE Tab 5 mg	2 05	30	✓ Sc	lifenacin Viatris
Tab 10 mg		30		lifenacin Viatris
Detection of Substances in Urine				
ORTHO-TOLIDINE				
* Compound diagnostic sticks	7.50 (8.25)	50 test OP	He	mastix
TETRABROMOPHENOL				
* Blue diagnostic strips	13.92	100 test OF	✓ AI	bustix
Obstetric Preparations				
Antiprogesterones				
MIFEPRISTONE				
Tab 200 mg - Up to 15 tab available on a PSO		1		fegyne fegyne
	180.00	3	♥ IVII	fegyne

Subsidy (Manufacturer's Price)	Subsid	-ully	Brand or Generic
(Manufacturer's Frice)	Per	√ seu	Manufacturer

# Calcium Homeostasis

CALCITONIN			
* Inj 100 iu per ml, 1 ml ampoule	121.00	5	✓ Miacalcic
CINACALCET - Special Authority see SA2170 below - Retail	pharmacy		
Tab 30 mg - Wastage claimable	25.24	28	<ul> <li>Cinacalet Devatis</li> </ul>
Cinacalet Devatis to be Principal Supply on 1 December	per 2024		
Tab 60 mg - Wastage claimable	50.47	28	<ul> <li>Cinacalet Devatis</li> </ul>
Cinacalet Devatis to be Principal Supply on 1 December	per 2024		

#### ⇒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 Fither:
  - 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 Fither:
  - 1.1 Patient has tertiary hyperparathyroidism and markedly elevated parathyroid hormone (PTH) with hypercalcaemia;
  - 1.2 Patient has symptomatic secondary hyperparathyroidism and elevated PTH; and
- 2 Patient is on renal replacement therapy: and

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

#### continued...

- 3 Any of the following:
  - 3.1 Residual parathyroid tissue has not been localised despite repeat unsuccessful parathyroid explorations; or
  - 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:

#### Either:

- 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**

Zoledronic acid Viatris to be Principal Supply on 1 December 2024

# Corticosteroids and Related Agents for Systemic Use

BE	TAMETHASONE SODIUM PHOSPHATE WITH BETAMETHASONE ACETAT	Έ	
*	Inj 3.9 mg with betamethasone acetate 3 mg per ml, 1 ml19.20	5	
	(36.96)		Celestone
			Chronodose
DE	XAMETHASONE		
*	Tab 0.5 mg - Up to 60 tab available on a PSO	30	<ul> <li>Dexmethsone</li> </ul>
	Dexmethsone to be Principal Supply on 1 February 2025		
*	Tab 4 mg - Up to 30 tab available on a PSO	30	<ul> <li>Dexmethsone</li> </ul>
	Dexmethsone to be Principal Supply on 1 February 2025		
	Oral liq 1 mg per ml52.80	25 ml OP	Biomed
DE	XAMETHASONE PHOSPHATE		
	Dexamethasone phosphate injection will not be funded for oral use.		
*	Inj 4 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO7.86	10	✓ Hameln
	Inj 4 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO 13.10	10	✓ Hameln
	JDROCORTISONE ACETATE		<del></del>
*	Tab 100 mcg11.46	100	✓ Florinef
		100	<u> </u>
	DROCORTISONE		
*	Tab 5 mg	100	✓ Douglas
	Tab 20 mg20.32	100	✓ Douglas
*	Inj 100 mg vial	1	✓ Solu-Cortef
	a) Not on a BSO		
	b) Up to 5 inj available on a PSO		
	c) Solu-Cortef to be Principal Supply on 1 December 2024		
ME	THYLPREDNISOLONE		
*	Tab 4 mg112.00	100	✓ Medrol
*	Tab 100 mg 223.10	20	✓ Medrol

	Subsidy (Manufacturer's Price \$	e) Subs	Fully sidised	Brand or Generic Manufacturer
IETHYLPREDNISOLONE (AS SODIUM SUCCINATE)				
Inj 40 mg vial	22.30	1	✓ 9	Solu-Medrol-Act- O-Vial
Inj 125 mg vial	34.10	1	✓ 9	Solu-Medrol-Act- O-Vial
Inj 500 mg vial	26.88	1	✓ 9	Solu-Medrol-Act- O-Vial
Inj 1 g vial	32.84	1	✓ 9	Solu-Medrol
ETHYLPREDNISOLONE ACETATE				
Inj 40 mg per ml, 1 ml vial	47.06	5	✓ [	Depo-Medrol
REDNISOLONE				
<ul> <li>Oral liq 5 mg per ml - Up to 30 ml available on a PSO</li> <li>a) Restricted to children under 12 years of age.</li> <li>b) Redipred to be Principal Supply on 1 December 202.</li> </ul> REDNISONE		30 ml OP	<b>✓</b> F	Redipred
Tab 1 mg	18 58	500	<b>/</b> [	Prednisone Clinect
Tab 2.5 mg		500		Prednisone Clinect
Tab 5 mg - Up to 30 tab available on a PSO		500		Prednisone Clinect
Tab 20 mg - Up to 30 tab available on a PSO		500	-	Prednisone Clinect
ETRACOSACTRIN				
Inj 250 mcg per ml, 1 ml ampoule	86.25	1	/	Synacthen
ing 250 mag per mil, i mil ampoule	00.20	'		JK Synacthen
Inj 1 mg per ml, 1 ml ampoule	690.00	1	✓ 9	Synacthen Depot Synacthene Retard \$29
RIAMCINOLONE ACETONIDE				
Inj 10 mg per ml, 1 ml ampoule		5	_	Kenacort-A 10
Inj 40 mg per ml, 1 ml ampoule	52.63	5	✓ <u>k</u>	Kenacort-A 40
Sex Hormones Non Contraceptive				
Androgen Agonists and Antagonists				
YPROTERONE ACETATE				
Tab 50 mg		50	✓ 9	Siterone
Tab 100 mg	28.03	50	✓ 9	Siterone
ESTOSTERONE				
Gel (transdermal) 16.2 mg per g	52.00	88 g OP	✓ ]	<u> Festogel</u>
ESTOSTERONE CIPIONATE				
Inj 100 mg per ml, 10 ml vial	85.00	1	✓ [	Depo-Testosterone
ESTOSTERONE ESTERS				
Inj 250 mg per ml, 1 ml	12.98	1	✓ 9	Sustanon Ampoules
ESTOSTERONE UNDECANOATE				•
Cap 40 mg - Subsidy by endorsement	36.00	100	✓ 0	Steril-Gene S29
Subsidy by endorsement – subsidised for patients who was			-	
1 November 2021 and the prescription is endorsed acco				
where there exists a record of prior dispensing of testosi				
Inj 250 mg per ml, 4 ml vial		1		Reandron 1000

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

# **Hormone Replacement Therapy - Systemic**

# **Oestrogens**

	•			
-	STRADIOL Tab 1 mg	A 12	28 OP	
~	Tab Ting	(11.10)	20 01	Estrofem
*	Tab 2 mg	, ,	28 OP	LStrotein
*	rab 2 mg		28 UP	Catuatana
	0-1/h1\ 0.000/ (750/1\)	(11.10)	00 · OD	Estrofem
	Gel (transdermal) 0.06% (750 mcg/actuation)		80 g OP	✓ Estrogel
	Patch 25 mcg per day	9.85	8	Estradiol TDP Mylan
		13.50		✓ Estraderm MX S29
		14.50		✓ Estradot
		21.35		✓ Lyllana
	a) No more than 2 patch per week			-
	b) Only on a prescription			
	Patch 50 mcg per day	10.75	8	✓ Estradiol TDP Mylan
	. a.o. ooog po. aa,		ū	✓ Estradiol Viatris
		14.50		✓ Estraderm MX S29
		14.50		
				✓ Estradiol Sandoz
		04.55		✓ Estradot
		21.55		✓ Lyllana
	<ul> <li>a) No more than 2 patch per week</li> </ul>			
	b) Only on a prescription			
	Patch 75 mcg per day	11.88	8	<ul><li>Estradiol TDP Mylan</li></ul>
				<ul><li>Estradiol Viatris</li></ul>
		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
	Tater 100 meg per day	12.33	U	✓ Estradiol Viatris
		14.50		✓ Estradiol Sandoz
		14.50		✓ Estradioi Sandoz
		15.50		✓ Estraderm MX S29
		22.77		✓ Lyllana
	<ul> <li>a) No more than 2 patch per week</li> </ul>			
	b) Only on a prescription			
OF	STRADIOL VALERATE			
	Tab 1 mg	12.36	84	✓ Progynova
	Tab 2 mg		84	✓ Progynova
	-	12.00	04	- i logyilova
	STROGENS			
*	Conjugated, equine tab 300 mcg	3.01	28	
		(19.25)		Premarin
*	Conjugated, equine tab 625 mcg	4.12	28	
		(19.25)		Premarin

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	I Generic
Progestogens				
MEDROXYPROGESTERONE ACETATE				
★ Tab 2.5 mg	6.56	30	1	Provera
	8.75	56		Provera
<b>米</b> Tab 5 mg		56		Provera
N. Tab 40	20.13	100		Provera
★ Tab 10 mg	10.28	30	•	Provera
Progestogen and Oestrogen Combined Prepara	ations			
DESTRADIOL WITH NORETHISTERONE				
* Tab 1 mg with 0.5 mg norethisterone acetate	5.40	28 OI	Р	
	(18.10)			Kliovance
* Tab 2 mg with 1 mg norethisterone acetate	5.40	28 OI	P	
	(18.10)			Kliogest
* Tab 2 mg with 1 mg norethisterone acetate (10), and 2 mg				
oestradiol tab (12) and 1 mg oestradiol tab (6)		28 OI	Р	<b>-</b> .
	(18.10)			Trisequens
Other Oestrogen Preparations				
DESTRIOL				
⊁ Tab 2 mg	7.70	30	/	Ovestin
- 140 ± 119				<u> </u>
Other Progestogen Preparations				
EVONORGESTREL				
LEVONONGESTREL  ★ Intra-uterine device 52 mg	269 50	1	1	Mirena
Intra-uterine device 13.5 mg		i		Jaydess
MEDROXYPROGESTERONE ACETATE		-		,
Tab 100 mg	133.57	100	/	Provera HD
NORETHISTERONE - Brand switch fee payable (Pharmacode				
♣ Tab 5 mg – Up to 30 tab available on a PSO		30		Primolut N
PROGESTERONE		00	•	·······································
* Cap 100 mg	14.85	30	1	Utrogestan
- Oup 100 mg	17.00	00		<u>on ogeotani</u>
Thyroid and Antithyroid Agents				
CARBIMAZOLE				

\* Tab 5 mg .......7.56

100

✓ Neo-Mercazole

	Subsidy	·	Fully	
	(Manufacturer's Price)		Subsidised	
	\$	Per	<b>✓</b>	Manufacturer
LEVOTHYROXINE				
* Tab 25 mcg	5.55	90	1	Synthroid
* Tab 50 mcg	1.71	28	1	Mercury Pharma
	5.79	90	1	Synthroid
	64.28	1,000	1	Eltroxin
* Tablet 50 mcg - Brand switch fee payable (Pharmacode				
2689251) - see page 273 for details	12.86	200	1	Eltroxin
* Tab 100 mcg	1.78	28	1	Mercury Pharma
	6.01	90	1	Synthroid
	66.78	1,000	1	Eltroxin
* Tablet 100 mcg - Brand switch fee payable (Pharmacode				
2689251) - see page 273 for details	13.36	200	1	Eltroxin
PROPYLTHIOURACIL - Special Authority see SA1199 below - F	Retail pharmacy			
Tab 50 mg	35.00	100	✓	PTU S29
⇒SA1199 Special Authority for Subsidy				

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

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

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

# **Trophic Hormones**

#### **Growth Hormones**

SOMATROPIN (OMNITROPE) – Special Authority see SA2032 b	oelow – Retail pha	armacy	
* Inj 5 mg cartridge	80.21	1	<ul><li>Omnitrope</li></ul>
			✓ Omnitrope S29 S29
Omnitrope to be Principal Supply on 1 February 2025			
* Inj 10 mg cartridge	80.21	1	✓ Omnitrope
			✓ Omnitrope S29 S29
Omnitrope to be Principal Supply on 1 February 2025			•
* Inj 15 mg cartridge	139.50	1	✓ Omnitrope
			✓ Omnitrope S29 S29
Omnitrope to be Principal Supply on 1 February 2025			•
(Omnitrope S29 S29 Inj 5 mg cartridge to be delisted 1 February	2025)		
(Omnitrope S29 S29 Inj 10 mg cartridge to be delisted 1 Februar	y 2025)		
(Omnitrope S29 S29 Inj 15 mg cartridge to be delisted 1 Februar	y 2025)		

## ⇒SA2032 Special Authority for Subsidy

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

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

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

continued...

- 2 All of the following:
  - 2.1 Height velocity < 25th percentile for age adjusted for bone age/pubertal status if appropriate over 6 or 12 months using the standards of Tanner and Davies (1985); and
  - 2.2 A current bone age is < 14 years (female patients) or < 16 years (male patients); and
  - 2.3 Peak growth hormone value of < 5.0 mcg per litre in response to two different growth hormone stimulation tests. In children who are 5 years or older, GH testing with sex steroid priming is required; and</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:

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.

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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/1.73m<sup>2</sup> as measured by the Schwartz method (Height(cm)/plasma creatinine (umol/l)) × 40 = corrected GFR (ml/min/1.73m<sup>2</sup>) in a child who may or may not be receiving dialysis; or
  - 6.2 The patient has received a renal transplant and has received < 5mg/ m²/day of prednisone or equivalent for at least 6 months..

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

All of the following:

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

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

All of the following:

- 1 The patient has a diagnosis of Prader-Willi syndrome that has been confirmed by genetic testing or clinical scoring criteria; and
- 2 The patient is aged six months or older; and
- 3 A current bone age is < 14 years (female patients) or < 16 years (male patients); and
- 4 Sleep studies or overnight oximetry have been performed and there is no obstructive sleep disorder requiring treatment, or

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<u> </u>	\$	Per	✓	Manufacturer

continued...

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 Fither:
  - 5.1 Both:
    - 5.1.1 The patient is aged two years or older; and
    - 5.1.2 There is no evidence of type II diabetes or uncontrolled obesity defined by BMI that has increased by greater than or equal to 0.5 standard deviations in the preceding 12 months; or
  - 5.2 The patient is aged between six months and two years and a thorough upper airway assessment is planned to be undertaken prior to treatment commencement and at six to 12 weeks following treatment initiation.

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

All of the following:

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

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

All of the following:

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

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

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

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

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

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

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

Any of the following:

1 All of the following:

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

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

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

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

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

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

# **GnRH Analogues**

000555111

GOSERELIN			
Implant 3.6 mg, syringe	66.48	1	Zoladex
Implant 10.8 mg, syringe	138.23	1	✓ Zoladex
LEUPRORELIN			

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

Inj 3.75 mg prefilled dual chamber syringe - Higher subsidy of			
\$221.60 per 1 inj with Endorsement	66.48	1	
	(221.60)		Lucrin Depot 1-month
Inj 11.25 mg prefilled dual chamber syringe - Higher subsidy			
of \$591.68 per 1 inj with Endorsement	177.50	1	
	(591.68)		Lucrin Depot 3-month

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Vasopressin Agonists				
DESMOPRESSIN Wafer 120 mcg DESMOPRESSIN ACETATE	47.00	30	✓ N	Ainirin Melt
Tab 100 mcg Tab 200 mcg  A Nasal spray 10 mcg per dose	54.45	30 30 6 ml OP	✓ N	Ainirin Ainirin Desmopressin- PH&T
Inj 4 mcg per ml, 1 ml	67.18	10	<b>✓</b> N	<i>l</i> inirin
Other Endocrine Agents				
CABERGOLINE Tab 0.5 mg - Maximum of 2 tab per prescription; can be				

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

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

Any of the following:

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

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

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

$\sim$	$\sim$	ALCC	 $\sim$ 1	TRA	TE

Tab 50 mg	29.84	10	✓ Mylan  Clomiphen  S25
METYRAPONE			
Cap 250 mg	558.00	50	✓ Metopirone

INFECTIONS - AGENTS FOR SYSTEMIC USE Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per Manufacturer **Anthelmintics** ALBENDAZOLE - Special Authority see SA1318 below - Retail pharmacy 60 ✓ Fskazole S29 **⇒SA1318** Special Authority for Subsidy Initial application only from an infectious disease specialist or clinical microbiologist. Approvals valid for 6 months where the patient has hydatids. Renewal only from an infectious disease specialist or clinical microbiologist. Approvals valid for 6 months where the treatment remains appropriate and the patient is benefitting from the treatment. MEBENDAZOLE - Only on a prescription ✓ Vermox Vermox to be Principal Supply on 1 December 2024 Oral liq 100 mg per 5 ml ......2.18 15 ml (7.83)Vermox **PRAZIQUANTEL** ✓ Biltricide **Antibacterials** a) For topical antibacterials, refer to DERMATOLOGICALS, page 69 b) For anti-infective eye preparations, refer to SENSORY ORGANS, page 268 Cephalosporins and Cephamycins

CEFACLOR MONOHYDRATE			
Cap 250 mg		100	Ranbaxy-Cefactor
Grans for oral liq 125 mg per 5 ml - Wastage claimable	3.75	100 ml	Ranbaxy-Cefaclor
CEFALEXIN			
Cap 250 mg	3.85	20	✓ Cephalexin ABM
Cap 500 mg		20	✓ Cephalexin ABM
Grans for oral liq 25 mg per ml - Wastage claimable	7.88	100 ml	Flynn
Grans for oral liq 50 mg per ml - Wastage claimable		100 ml	✓ Flynn
, ,,	11.75		✓ Cefalexin Sandoz
CEFAZOLIN - Subsidy by endorsement			
Only if prescribed for dialysis or cellulitis in accordance with a	a Health NZ Hos	pital approved	protocol and the prescription is
endorsed accordingly.		p p-p	p
Inj 500 mg vial	3.39	5	✓ Cefazolin-AFT
Inj 1 g vial		5	✓ Cefazolin-AFT
Inj 2 g vial		5	✓ Cefazolin-AFT
CEFTRIAXONE – Subsidy by endorsement			
a) Up to 10 inj available on a PSO			
b) Subsidised only if prescribed for a dialysis or cystic fibros	is natient or the	treatment of o	nonorrhoea or the treatment of
pelvic inflammatory disease, or the treatment of suspecte			
endorsed accordingly.	u		a the processpaness of a GC to
Inj 500 mg vial	0.79	1	✓ Ceftriaxone-AFT
Inj 1 g vial		5	✓ Ceftriaxone-AFT
, ,			
CEFUROXIME AXETIL — Subsidy by endorsement Only if prescribed for prophylaxis of endocarditis and the pre	corintian is anda	rood according	alv
Tab 250 mg	•	20	giy. <b>✓ Ascend-</b>
1 au 200 mg		20	
			Cefuroxime S29

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

#### **Macrolides**

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

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

## **⇒SA1683** Special Authority for Waiver of Rule

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

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

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

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

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

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

**⇒SA1857** Special Authority for Waiver of Rule

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

Either:

Subsidy	Ful	y Brand or	
(Manufacturer's Price)	Subsidise	d Generic	
\$	Per •	<ul> <li>Manufacturer</li> </ul>	

continued...

- 1 Atypical mycobacterial infection; or
- 2 Mycobacterium tuberculosis infection where there is drug-resistance or intolerance to standard pharmaceutical agents.

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

Both:

- 1 For the eradication of helicobacter pylori in a patient unable to swallow tablets; and
- 2 For use only in combination with omeprazole and amoxicillin as part of a triple therapy regimen.

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

ERYTHROMYCIN (AS LACTOBIONATE) Inj 1 g vial10.00	1	✓ Erythrocin IV
ERYTHROMYCIN ETHYL SUCCINATE		
Tab 400 mg16.95	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 liq 200 mg per 5 ml5.00	100 ml	<ul><li>E-Mycin</li></ul>
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 ml6.77	100 ml	E-Mycin
a) Up to 200 ml available on a PSO		
b) Wastage claimable		
ROXITHROMYCIN		
Tab 150 mg13.19	50	✓ Arrow-
		Roxithromycin
Tel: 000	50	. A
Tab 300 mg25.00	50	✓ <u>Arrow-</u> Roxithromycin
		noxithromycin

	Subsidy (Manufacturer's F \$	Price) Subs Per	Fully idised	Brand or Generic Manufacturer
Penicillins				
AMOXICILLIN Cap 250 mg a) Up to 30 cap available on a PSO	27.50	500	•	Miro-Amoxicillin
b) Up to 10 x the maximum PSO quantity for RFPP Cap 500 mg      a) Up to 30 cap available on a PSO	41.00	500	1	Miro-Amoxicillin
b) Up to 10 x the maximum PSO quantity for RFPP Grans for oral liq 125 mg per 5 ml	2.22	100 ml	•	Alphamox 125
Grans for oral liq 250 mg per 5 ml	2.81	100 ml	•	Alphamox 250
Inj 250 mg vial	15 97	10	1	lbiamox
Inj 500 mg vial		10		Ibiamox
Inj 1 g vial – Up to 5 inj available on a PSO		10		Ibiamox
AMOXICILLIN WITH CLAVULANIC ACID  Tab 500 mg with clavulanic acid 125 mg - Up to 30 tab  available on a PSO		10	/	Curam Duo 500/125
Grans for oral liq amoxicillin 25 mg with clavulanic acid 6.25 r		.0		<u> </u>
per mla) Up to 200 ml available on a PSO b) Wastage claimable	-	100 ml	•	Augmentin
Grans for oral liq amoxicillin 50 mg with clavulanic acid 12.5 r per ml - Up to 200 ml available on a PSO		100 ml OP		Curam Amoxiclav Devatis Forte
(Curam Grans for oral liq amoxicillin 50 mg with clavulanic acid 12	2.5 mg per ml to	be delisted 1	lune 2	025)
BENZATHINE BENZYLPENICILLIN	01			,
Inj 900 mg (1.2 million units) in 2.3 ml syringe – Up to 5 inj available on a PSO	375.97	10	1	Bicillin LA
BENZYLPENICILLIN SODIUM [PENICILLIN G] Inj 600 mg (1 million units) vial – Up to 5 inj available on a PS	SO 16.50	10	•	Sandoz
FLUCLOXACILLIN	15.70	050		Fluelevesillin AFT
Cap 250 mg - Up to 30 cap available on a PSO		250 500		Flucloxacillin-AFT Flucloxacillin-AFT
Grans for oral liq 25 mg per ml		100 ml		AFT
<ul><li>a) Up to 200 ml available on a PSO</li><li>b) Wastage claimable</li><li>c) AFT to be Principal Supply on 1 February 2025</li></ul>				
Grans for oral liq 50 mg per ml	5.89	100 ml	•	AFT
Inj 250 mg vial	42.60	10	1	Flucloxin
Inj 500 mg vial	45.63	10	1	Flucloxin
Inj 1 g vial – Up to 5 inj available on a PSO	6.00	5	1	Flucil

	Subsidy (Manufacturer's Price)		Fully		
	\$	Per	<b>√</b>	Manufacturer	
PHENOXYMETHYLPENICILLIN (PENICILLIN V)					
Cap 250 mg - Up to 30 cap available on a PSO	7.68	50	•	Cilicaine VK	
Cilicaine VK to be Principal Supply on 1 February 2025			_		
Cap 500 mg	13.72	50	/	Cilicaine VK	
a) Up to 20 cap available on a PSO					
<ul><li>b) Up to 2 x the maximum PSO quantity for RFPP</li><li>c) Cilicaine VK to be Principal Supply on 1 February 202</li></ul>	)E				
Grans for oral lig 125 mg per 5 ml		100 ml	/	AFT	
a) Up to 200 ml available on a PSO		100 1111		<u>Al 1</u>	
b) Wastage claimable					
Grans for oral liq 250 mg per 5 ml	4.24	100 ml	1	<u>AFT</u>	
a) Up to 300 ml available on a PSO					
b) Up to 2 x the maximum PSO quantity for RFPP					
c) Wastage claimable					

# **Tetracyclines**

DOXYCYCLINE			
* Tab 100 mg - Up to 30 tab available on a PSO	64.43	500	Doxine
MINOCYCLINE HYDROCHLORIDE			
* Tab 50 mg - Additional subsidy by Special Authority see			
SA1355 below – Retail pharmacy	5.79	60	
	(12.05)		Mino-tabs
* Cap 100 mg	19.32	100	
•	(52.04)		Minomycin

## **⇒SA1355** Special Authority for Manufacturers Price

**Initial application** from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has rosacea.

TETRACYCLINE - Special Authority see SA1332 below - Retail pharmacy
Tab 250 mg .......58.20 28 ✓ Accord 29

# ⇒SA1332 Special Authority for Subsidy

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

- 1 For the eradication of helicobacter pylori following unsuccessful treatment with appropriate first-line therapy; and
- 2 For use only in combination with bismuth as part of a quadruple therapy regimen.

	Subsidy (Manufacturer's Price)	Per	Fully Subsidised	
Other Antibiotics				
For topical antibiotics, refer to DERMATOLOGICALS, page 69 CIPROFLOXACIN Recommended for patients with any of the following: i) microbiologically confirmed and clinically significant pse ii) prostatitis; or iii) pyelonephritis; or iv) gonorrhoea.	eudomonas 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  Ipca-Ciprofloxacin to be Principal Supply on 1 Decembe	3.10 4.80 5.95	28 28 28	<b>✓</b>	Ipca-Ciprofloxacin Ipca-Ciprofloxacin Ipca-Ciprofloxacin Cipflox
(Cipflox Tab 750 mg to be delisted 1 December 2024)				
CLINDAMYCIN Cap hydrochloride 150 mg Dalacin C to be Principal Supply on 1 December 2024	4.94	24	•	Dalacin C
Inj 150 mg per ml, 4 ml ampoule		10	✓	<u>Hameln</u>
COLISTIN SULPHOMETHATE – Retail pharmacy-Specialist – S Only if prescribed for dialysis or cystic fibrosis patient and the Inj 150 mg	e prescription is endor65.0095.00	rsed 1 5	1	Colistin-Link  DBL Gentamicin
Only if prescribed for a dialysis or cystic fibrosis patient of endorsed accordingly.	or complicated unitary	liac	t irriection	and the prescription is
Inj 10 mg per ml, 2 ml ampoule – Subsidy by endorsement Only if prescribed for a dialysis or cystic fibrosis patient of endorsed accordingly.		5 trac		Wockhardt S29 and the prescription is
Inj 40 mg per ml, 2 ml ampoule - Subsidy by endorsement	18.38 91.90	10 50	_	Pfizer Gentamicin Noridem \$29
Only if prescribed for a dialysis or cystic fibrosis patient of endorsed accordingly.	or complicated urinary	trac	t infection	
MOXIFLOXACIN – Special Authority see SA1740 below – Retai No patient co-payment payable	l pharmacy			
Tab 400 mg	42.00	5	✓	Avelox
■ SA1740 Special Authority for Subsidy Initial application — (Tuberculosis) only from a respiratory specifor applications meeting the following criteria:  Any of the following:	ecialist or infectious di	iseas	se specialis	st. Approvals valid for 1 yea
1 Both:				
<ul><li>1.1 Active tuberculosis*; and</li><li>1.2 Any of the following:</li></ul>				
1.2.1 Documented resistance to one or more first	t-line medications; or			

INFE	CHONS - AC	aLIVI 3	or on s	OTSTEWNC USE
(Mar	Subsidy nufacturer's Price) \$	Sul Per	Fully osidised	Brand or Generic Manufacturer
continued				
<ul> <li>1.2.2 Suspected resistance to one or more first-line m area with known resistance), as part of regimen</li> <li>1.2.3 Impaired visual acuity (considered to preclude e</li> <li>1.2.4 Significant pre-existing liver disease or hepatoto</li> <li>1.2.5 Significant documented intolerance and/or side or</li> </ul>	containing other thambutol use); of xicity from tubero	second- or culosis m	line agen nedicatior	ts; or es; or
2 Mycobacterium avium-intracellulare complex not responding to 3 Patient is under five years of age and has had close contact wi Note: Indications marked with * are unapproved indications. Renewal only from a respiratory specialist or infectious disease special	th a confirmed m	nulti-drug	resistan	tuberculosis case.
remains appropriate and the patient is benefiting from treatment.	• • • • • • • • • • • • • • • • • • • •		,	
Initial application — (Mycoplasma genitalium) only from a sexual health specialist. Approvals valid for 1 month for applications rall of the following:				the recommendation of a
<ul><li>1 Has nucleic acid amplification test (NAAT) confirmed Mycoplas</li><li>2 Either:</li></ul>	ma genitalium* a	and is sy	mptomati	c; and
<ul><li>2.1 Has tried and failed to clear infection using azithromycir</li><li>2.2 Has laboratory confirmed azithromycin resistance; and</li></ul>	ı; or			
3 Treatment is only for 7 days.				
Initial application — (Penetrating eye injury) only from an ophthaln requires prophylaxis following a penetrating eye injury and treatment is Note: Indications marked with * are unapproved indications.			for 1 mo	nth where the patient
PAROMOMYCIN - Special Authority see SA1689 below - Retail pha	rmacy			
Cap 250 mg	.126.00	16	<b>✓</b> H	umatin S29
■ SA1689 Special Authority for Subsidy Initial application only from an infectious disease specialist, clinical n month for applications meeting the following criteria:  Either:	nicrobiologist or	gastroen	terologist	. Approvals valid for 1
<ol> <li>Patient has confirmed cryptosporidium infection; or</li> <li>For the eradication of Entamoeba histolyica carriage.</li> </ol>				
<b>Renewal</b> only from an infectious disease specialist, clinical microbiolo applications meeting the following criteria: Either:	gist or gastroent	erologist	. Approv	als valid for 1 month for
<ul><li>1 Patient has confirmed cryptosporidium infection; or</li><li>2 For the eradication of Entamoeba histolyica carriage.</li></ul>				
PYRIMETHAMINE – Special Authority see SA1328 below – Retail ph Tab 25 mg	•	30	<b>✓</b> D	araprim S29
Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid with the following criteria: Any of the following:		wal unles		•
1 For the treatment of toxoplasmosis in patients with HIV for a pe 2 For pregnant patients for the term of the pregnancy; or	eriod of 3 months	s; or		

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✓ Fucidin

SODIUM FUSIDATE [FUSIDIC ACID]

3 For infants with congenital toxoplasmosis until 12 months of age.

	Subsidy		Fully	Brand or
	(Manufacturer's Price)		Subsidised	Generic
	\$	Per	✓	Manufacturer
SULFADIAZINE SODIUM - Special Authority see SA1331 below	w – Retail pharmacy			
Tab 500 mg	150.70	100	<b>√</b> 9	Sulfadiazin-Heyl S29
	543.20	56	<b>✓</b> \	Wockhardt \$29
<b>⇒SA1331</b> Special Authority for Subsidy				

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

Any of the following:

- 1 For the treatment of toxoplasmosis in patients with HIV for a period of 3 months; or
- 2 For pregnant patients for the term of the pregnancy; or
- 3 For infants with congenital toxoplasmosis until 12 months of age.

# TORRAMYCIN

OBRAMYCIN			
Inj 40 mg per ml, 2 ml vial - Subsidy by endorsement	15.50	5	✓ Tobramycin (Viatris)
a) Only if prescribed for dialysis or cystic fibrosis pati-	ent and the prescrip	otion is endors	ed accordingly.
b) Tobramycin (Viatris) to be Principal Supply on 1 D	ecember 2024		
Solution for inhalation 60 mg per ml, 5 ml - Subsidy by			
endorsement	395.00	56 dose	Tobramycin BNM

a) Wastage claimable

b) Only if prescribed for a cystic fibrosis patient and the prescription is endorsed accordingly.

## TRIMETHOPRIM

*	Tab 300 mg - Up to 30 tab available on a PSO27.83	50	✓ TMP
	TMP to be Principal Supply on 1 February 2025		

#### TRIMETHOPRIM WITH SULPHAMETHOXAZOLE [CO-TRIMOXAZOLE]

Tab trimethoprim 80 mg and sulphamethoxazole 400 mg - Up	•		
to 30 tab available on a PSO	115.74	500	Trisul
Trisul to be Principal Supply on 1 February 2025			

#### VANCOMYCIN - Subsidy by endorsement

Only if prescribed for a dialysis or cystic fibrosis patient or for prophylaxis of endocarditis or for treatment of Clostridium difficile following metronidazole failure and the prescription is endorsed accordingly.

# Antifungals

- a) For topical antifungals refer to DERMATOLOGICALS, page 70
- b) For topical antifungals refer to GENITO URINARY, page 83

#### FLUCONAZOLE

LOODINAZOLL		
Cap 50 mg4.10	28	Mylan
Cap 150 mg	1	✓ Mylan
Cap 200 mg8.90	28	✓ Mylan
Powder for oral suspension 10 mg per ml - Special Authority		
see SA1359 below – Retail pharmacy129.02	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

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

continued...

meeting the following criteria:

#### Both:

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

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

#### All of the following:

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

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

#### Both:

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

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

#### All of the following:

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

#### **ITRACONAZOLE**

Cap 100 mg	15	Itrazole
Oral lig 10 mg per ml - Special Authority see SA1322 below -		
Retail pharmacy141.80	150 ml OP	✓ Kent S29
		✓ Sporanox

#### ⇒SA1322 Special Authority for Subsidy

**Initial application** only from an infectious disease specialist, clinical microbiologist, clinical immunologist or any relevant practitioner on the recommendation of a infectious disease physician, clinical microbiologist or clinical immunologist. Approvals valid for 6 months where the patient has a congenital immune deficiency.

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

CRS

✓ Rurel \$29

#### KFTOCONAZOI F

Tah 200 mg - PCT

7ab 250 mg - 7 0 1		100	✓ Strides Shasun S29 ✓ Taro S29 ✓ Teva-
			Ketoconazole \$29
NYSTATIN			
Tab 500,000 u	14.16	50	
	(17.09)		Nilstat
Cap 500,000 u	12.81	50	
	(15.47)		Nilstat
POSACONAZOLE - Special Authority see SA2383 on th	e next page – Retail ph	armacy	
Tab modified-release 100 mg		24	✓ Posaconazole Juno
Oral lig 40 mg per ml		105 ml OP	✓ Devatis

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

## **⇒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:

#### Fither:

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

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

#### Either:

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

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

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

#### Both:

- 1 The patient is at risk of invasive fungal infection; and
- 2 Fither:
  - 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:

- 1 The patient is at risk of invasive fungal infection; and
- 2 Either:

TERRINIAFINE

- 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).

* Tab 250 mg	4.48	42	✓ Apo-Terbinafine S29
	8.97	84	✓ <u>Deolate</u>
VORICONAZOLE - Special Authority see SA2384 on the next	page - Retail phar	macy	
Tab 50 mg	91.00	56	✓ Vttack
Tab 200 mg	350.00	56	✓ Vttack
Powder for oral suspension 40 mg per ml - Wastage			
claimable	1,523.22	70 ml	✓ Vfend

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

#### ⇒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 Fither:
  - 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).

**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**

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

## **⇒SA1684** Special Authority for Subsidy

**Initial application** only from an infectious disease specialist or clinical microbiologist. Approvals valid for 1 month for applications meeting the following criteria:

#### Both:

- 1 The patient has vivax or ovale malaria; and
- 2 Primaquine is to be given for a maximum of 21 days.

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

#### Both:

- 1 The patient has relapsed vivax or ovale malaria; and
- 2 Primaguine 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
	33.15		✓ Metrogyl
Tab 400 mg - Up to 15 tab available on a PSO	4.29	21	✓ Metronidamed
	5.23		✓ Metrogyl
Oral liq benzoate 200 mg per 5 ml	25.00	100 ml	✓ Flagyl-S
Suppos 500 mg	24.48	10	✓ Flagyl
(Metrogyl Tab 200 mg to be delisted 1 March 2025)			
(Metrogyl Tab 400 mg to be delisted 1 March 2025)			
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.

BEDAQUILINE - Special Authority see SA2244 below - Retail pharmacy

No patient co-payment payable

#### **⇒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.

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.

INFECTIONS - AGENTS FOR SYSTEMIC US				
	Subsidy (Manufacturer's Price) \$	S Per	Fully Subsidised	Brand or Generic Manufacturer
DAPSONE – Retail pharmacy-Specialist	•			
a) No patient co-payment payable     b) Prescriptions must be written by, or on the recommendation     dermatologist	on of, an infectious d	isease	physician,	clinical microbiologist or
Tab 25 mg	268.50	100		Dapsone
Tab 100 mg		100	✓ [	Dapsone
ETHAMBUTOL HYDROCHLORIDE - Retail pharmacy-Specialist	t			
<ul> <li>a) No patient co-payment payable</li> <li>b) Prescriptions must be written by, or on the recommendation respiratory physician</li> </ul>			_	
Tab 100 mg	85.73	100	<b>✓</b> E	MB Fatol S29
Tab 400 mg	49.34	56	✓ N	Ayambutol S29
ISONIAZID - Retail pharmacy-Specialist				
<ul> <li>a) No patient co-payment payable</li> <li>b) Prescriptions must be written by, or on the recommendation microbiologist, dermatologist or public health physician</li> </ul>	on of, an internal med	dicine p	ohysician,	paediatrician, clinical
* Tab 100 mg	23.00	100	<b>✓</b> F	PSM
	94.50		<b>√</b>	soniazid Teva S29
ISONIAZID WITH RIFAMPICIN – Retail pharmacy-Specialist     a) No patient co-payment payable     b) Prescriptions must be written by, or on the recommendation microbiologist, dermatologist or public health physician				
* Tab 100 mg with rifampicin 150 mg Rifinah to be Principal Supply on 1 February 2025	89.82	100	<b>✓</b> F	Rifinah
* Tab 150 mg with rifampicin 300 mg Rifinah to be Principal Supply on 1 February 2025	179.13	100	<b>√</b> F	Rifinah
LINEZOLID – Special Authority see SA2234 below – Retail pharr No patient co-payment payable Tab 600 mg	•	10	✓ Z	'yvox
Zyvox to be Principal Supply on 1 December 2024 Oral liq 20 mg per ml		150 ml		Lyvox
	1,075.00	100 1111		JVOX
■ SA2234   Special Authority for Subsidy Initial application — (multi-drug resistant tuberculosis) from applications meeting the following criteria: Both:		ner. A	approvals v	ralid for 18 months for
<ol> <li>The person has multi-drug resistant tuberculosis (MDR-TB 2 Ministry of Health's Tuberculosis Clinical Network has reviet the treatment regimen.</li> </ol>		ase ar	nd recomm	ends linezolid as part of
PARA-AMINO SALICYLIC ACID – Retail pharmacy-Specialist a) No patient co-payment payable				
b) Prescriptions must be written by, or on the recommendation     respiratory physician	on of, an infectious d	isease	specialist,	clinical microbiologist or
Grans for oral liq 4 g sachet	280.00	30	<b>✓</b> F	Paser S29
PROTIONAMIDE - Retail pharmacy-Specialist				
<ul> <li>a) No patient co-payment payable</li> <li>b) Prescriptions must be written by, or on the recommendation respiratory physician</li> </ul>		isease		v
Tab 250 mg	305.00	100	<b>√</b> F	Peteha S29

	INFECTIONS - AGENTS FOR SYSTEMIC USE	=			
		Subsidy (Manufacturer's Price \$		Fully lised	Brand or Generic Manufacturer
PY	RAZINAMIDE – Retail pharmacy-Specialist				
	a) No patient co-payment payable				
	<ul> <li>Prescriptions must be written by, or on the recommendation respiratory physician</li> </ul>	on of, an infectious	disease phys	sician	, clinical microbiologist or
*	Tab 500 mg	64.95	100	1	AFT-Pyrazinamide
	ABUTIN – Retail pharmacy-Specialist				
	a) No patient co-payment payable				
	b) Prescriptions must be written by, or on the recommendation gastroenterologist	on of, an infectious	disease phys	sician	, respiratory physician or
*	Cap 150 mg	353.71	30	<b>√</b>	Mycobutin
RIF	AMPICIN - Subsidy by endorsement				
	a) No patient co-payment payable				
	b) For confirmed recurrent Staphylococcus aureus infection				' '
	antimicrobial based on susceptibilities and the prescription				
	Retail pharmacy - Specialist. Specialist must be an intern paediatrician, or public health physician.	iai medicine pnysici	an, ciinicai m	iicrop	lologist, dermatologist,
*	Cap 150 mg	58.54	100	1	Rifadin_
*	Cap 300 mg		100		Rifadin
	•				Rifadin Sanofi
*	Oral liq 100 mg per 5 ml	12.60	60 ml	<b>/</b> ]	<u>Rifadin</u>
A	ntivirals				
For	eye preparations refer to Eye Preparations, Anti-Infective Pre	parations, page 268	3		
Н	epatitis B Treatment				
EN	TECAVIR				
*	Tab 0.5 mg	12.04	30	1	Entecavir (Rex)
LAI	MIVUDINE - Special Authority see SA1685 below - Retail pha	armacy			
	Tab 100 mg	12.06	28	1	<u>Zetlam</u>
	Oral liq 5 mg per ml	270.00 2	40 ml OP	1	Zeffix
	SA1685 Special Authority for Subsidy				
	ial application only from a relevant specialist or medical pract		nmendation of	of a re	elevant specialist.
	provals valid for 1 year where used for the treatment or preven newal from any relevant practitioner. Approvals valid for 2 year		ho trootmont	or n	avention of honotitic B
	NOFOVIR DISOPROXIL	ars wriere used for t	ne neament	oi pi	evention of nepatitis b.
[	Tenofovir disoproxil prescribed under endorsement for the tre	eatment of HIV is in	cluded in the	COLIN	t of up to 4 subsidised
	antiretrovirals for the purposes of Special Authority SA2139.,		Jiddod III liilo	oouii	t of up to 4 subsidised
*	Tab 245 mg (300 mg as a maleate)		30	•	Tenofovir Disoproxil <u>Viatris</u>
Н	erpesvirus Treatments				
ΔΩ	CLOVIR				
*	Tab dispersible 200 mg	1.78	25	1	Lovir
*	Tab dispersible 400 mg		56		Lovir
*	Tab dispersible 800 mg	6.46	35	<b>/</b> ]	<u>Lovir</u>

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer	
VALACICLOVIR					
Tab 500 mg	9.64	30	✓ V	/aclovir	
Vaclovir to be Principal Supply on 1 February 2025					
Tab 1,000 mg	17.78	30	✓ V	/aclovir	
Vaclovir to be Principal Supply on 1 February 2025					
VALGANCICLOVIR - Special Authority see SA1993 below - R	etail pharmacy				
Tab 450 mg	140.89	60	<b>✓</b> V	/alganciclovir Viatris	

Valganciclovir Viatris to be Principal Supply on 1 February 2025

### ⇒SA1993 Special Authority for Subsidy

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

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

#### Either:

- 1 Both:
  - 1.1 Patient has undergone a solid organ transplant and received anti-thymocyte globulin and requires valganciclovir therapy for CMV prophylaxis: and
  - 1.2 Patient is to receive a maximum of 90 days of valganciclovir prophylaxis following anti-thymocyte globulin; or
- 2 Both:
  - 2.1 Patient has received pulse methylprednisolone for acute rejection and requires further valganciclovir therapy for CMV prophylaxis; and
  - 2.2 Patient is to receive a maximum of 90 days of valganciclovir prophylaxis following pulse methylprednisolone.

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

Both:

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

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

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

All of the following:

- 1 Patient has undergone a lung transplant; and
- 2 Either:
  - 2.1 The donor was cytomegalovirus positive and the patient is cytomegalovirus negative; or
  - 2.2 The recipient is cytomegalovirus positive; and
- 3 Patient has a high risk of CMV disease.

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

#### Both:

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

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

continued...

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

Tab 90 mg with sofosbuvir 400 mg......24,363.46 28 ✓ Harvoni

### ⇒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 <a href="http://www.pharmac.govt.nz/maviret">http://www.pharmac.govt.nz/maviret</a> or:

The Coordinator, Hepatitis C Treatment Panel

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

Email: hepcpanel@pharmac.govt.nz

# **HIV Prophylaxis and Treatment**

EMTRICITABINE WITH TENOFOVIR DISOPROXIL — Subsidy by endorsement; can be waived by Special Authority see SA2138 on the next page

- 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 113 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.

*	maleate)15.45	30	✓ <u>Tenofovir Disoproxil</u> <u>Emtricitabine Viatr</u>
*	Tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a succinate)	30	✓ Teva

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

### ⇒SA2138 Special Authority for Subsidy

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

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

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

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

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

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

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

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

### **COVID-19 Treatments**

MOLNUPIRAVIR - [Xpharm] - Subsidy by endorsement

- a) No patient co-payment payable
- b) Treatment is funded only if patient meets access criteria for oral antiviral COVID-19 treatments (as on <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.

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.

### 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:

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

continued...

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

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

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

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

Both:

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

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

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

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

Both:

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

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

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

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

	Subsidy (Manufacturer's Pri \$	ce) Subsi	Fully Brand or dised Generic  Manufacturer
Non-nucleosides Reverse Transcriptase Inhibito	ors		
EFAVIRENZ – Special Authority see SA2139 on page 113 – Reta Tab 200 mg	190.15	90 30	✓ Stocrin ✓ Stocrin ✓ Efavirenz Milpharm 529
ETRAVIRINE – Special Authority see SA2139 on page 113 – Re Tab 200 mg	770.00	60	✓ Intelence
NEVIRAPINE – Special Authority see SA2139 on page 113 – Re Tab 200 mg  Nevirapine Viatris to be Principal Supply on 1 February 2	198.25	60	✓ Nevirapine Viatris
Oral suspension 10 mg per ml	203.55	240 ml OP	✓ Viramune Suspension
Nucleosides Reverse Transcriptase Inhibitors			
ABACAVIR SULPHATE – Special Authority see SA2139 on page Tab 300 mg		irmacy 60	✓ Ziagen
ABACAVIR SULPHATE WITH LAMIVUDINE — Special Authority Note: abacavir with lamivudine (combination tablets) counts anti-retroviral Special Authority. Tab 600 mg with lamivudine 300 mg	as two anti-retrov		
Tab ood mg with annivaring ood mg	20.00	00	Lamivudine Viatris
EFAVIRENZ WITH EMTRICITABINE AND TENOFOVIR DISOPF pharmacy Note: Efavirenz with emtricitabine and tenofovir disoproxil coanti-retroviral Special Authority Tab 600 mg with emtricitabine 200 mg and tenofovir disoprox 245 mg (300 mg as a maleate)	unts as three anti	•	. •
EMTRICITABINE – Special Authority see SA2139 on page 113 – Cap 200 mg		30	✓ Emtriva
LAMIVUDINE - Special Authority see SA2139 on page 113 - Re Tab 150 mg Oral liq 10 mg per ml	98.00	60 240 ml OP	✓ <u>Lamivudine Viatris</u> ✓ 3TC
ZIDOVUDINE [AZT] — Special Authority see SA2139 on page 11: Cap 100 mg Oral liq 10 mg per ml	152.25	100 200 ml OP	✓ Retrovir ✓ Retrovir
ZIDOVUDINE [AZT] WITH LAMIVUDINE – Special Authority see Note: zidovudine [AZT] with lamivudine (combination tablets) the anti-retroviral Special Authority.			-
Tab 300 mg with lamivudine 150 mg	92.40	60	<ul><li>Lamivudine/ Zidovudine Viatris</li></ul>

	Subsidy (Manufacturer's Price) \$	Subsidis Per	ully Brand or Generic  Manufacturer
Protease Inhibitors			
ATAZANAVIR SULPHATE – Special Authority see SA2139 on pa Cap 150 mg Cap 200 mg	85.00	60	<ul> <li>Atazanavir Mylan</li> <li>Atazanavir Mylan</li> <li>Atazanavir Viatris</li> </ul>
DARUNAVIR — Special Authority see SA2139 on page 113 — Ret Tab 400 mg Tab 600 mg  LOPINAVIR WITH RITONAVIR — Special Authority see SA2139 of Tab 100 mg with ritonavir 25 mg	150.00 225.00 on page 113 – Retail	60 harmacy	<ul> <li>Darunavir Viatris</li> <li>Darunavir Viatris</li> <li>Lopinavir/Ritonavir Mylan</li> </ul>
Tab 200 mg with ritonavir 50 mg		120	✓ Lopinavir/Ritonavir Mylan
Lopinavir/Ritonavir Mylan to be Principal Supply on 1 Fet RITONAVIR – Special Authority see SA2139 on page 113 – Reta Tab 100 mg	ail pharmacy	30	✓ Norvir
Strand Transfer Inhibitors			
DOLUTEGRAVIR — Special Authority see SA2139 on page 113 - Tab 50 mg  DOLUTEGRAVIR WITH LAMIVUDINE — Special Authority see S.	1,090.00		✓ Tivicay macy
Tab 50 mg with lamivudine 300 mg  RALTEGRAVIR POTASSIUM – Special Authority see SA2139 or Tab 400 mg	n page 113 – Retail p 1,090.00	harmacy 60	✓ Dovato ✓ Isentress ✓ Isentress HD
Immune Modulators			
PEGYLATED INTERFERON ALFA-2A — Special Authority see S	A2034 below – Retai	l pharmacy	

Note: Pharmac will consider funding ribavirin for the small group of patients who have a clinical need for ribavirin and meet Special Authority criteria. Please contact the Hepatitis C Coordinator at Pharmac on 0800-023-588 option 4. Inj 180 mcg prefilled syringe......748.50 ✓ Pegasys

### ⇒SA2034 Special Authority for Subsidy

Initial application — (chronic hepatitis C - genotype 1, 4, 5 or 6 infection or co-infection with HIV or genotype 2 or 3 post liver transplant) from any specialist. Approvals valid for 18 months for applications meeting the following criteria: Both:

- 1 Any of the following:
  - 1.1 Patient has chronic hepatitis C, genotype 1, 4, 5 or 6 infection; or
  - 1.2 Patient has chronic hepatitis C and is co-infected with HIV; or
  - 1.3 Patient has chronic hepatitis C genotype 2 or 3 and has received a liver transplant; and
- 2 Maximum of 48 weeks therapy.

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:

Subsidy (Manufacturer's Price)	Fully Subsidised		
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Φ	rei •	Manuacturei	

continued...

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

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

All of the following:

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

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

Both:

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

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

All of the following:

- 1 Patient has confirmed Hepatitis B infection (HBsAg positive for more than 6 months); and
- 2 Patient is Hepatitis B treatment-naive; and
- 3 ALT > 2 times Upper Limit of Normal; and
- 4 HBV DNA < 10 log10 IU/ml; and
- 5 Either:
  - 5.1 HBeAg positive; or
  - 5.2 serum HBV DNA greater than or equal to 2,000 units/ml and significant fibrosis (Metavir Stage F2 or greater or moderate fibrosis); and
- 6 Compensated liver disease; and
- 7 No continuing alcohol abuse or intravenous drug use; and
- 8 Not co-infected with HCV, HIV or HDV; and
- 9 Neither ALT nor AST > 10 times upper limit of normal; and
- 10 No history of hypersensitivity or contraindications to pegylated interferon; and
- 11 Maximum of 48 weeks therapy.

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

Any of the following:

- 1 Patient has a cutaneous T cell lymphoma\*; or
- 2 All of the following:
  - 2.1 Patient has a myeloproliferative disorder\*; and

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

continued...

- 2.2 Patient is intolerant of hydroxyurea; and
- 2.3 Treatment with an grelide and busulfan is not clinically appropriate; or
- 3 Both:
  - 3.1 Patient has a myeloproliferative disorder; and
  - 3.2 Patient is pregnant, planning pregnancy or lactating.

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

All of the following:

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and patient is benefitting from treatment; and
- 3 Either:
  - 3.1 Patient has a cutaneous T cell lymphoma\*; or
  - 3.2 Both
    - 3.2.1 Patient has a myeloproliferative disorder\*; and
    - 3.2.2 Either:
      - 3.2.2.1 Remains intolerant of hydroxyurea and treatment with anagrelide and busulfan remains clinically inappropriate; or
      - 3.2.2.2 Patient is pregnant, planning pregnancy or lactating.

Note: Indications marked with \* are unapproved indications.

**Initial application** — **(post-allogenic bone marrow transplant)** from any relevant practitioner. Approvals valid for 3 months where patient has received an allogeneic bone marrow transplant\* and has evidence of disease relapse.

**Renewal — (post-allogenic bone marrow transplant)** from any relevant practitioner. Approvals valid for 3 months where patient is responding and ongoing treatment remains appropriate.

Note: Indications marked with \* are unapproved indications.

# **Urinary Tract Infections**

FOSFOMYCIN - Special Authority see SA2406 below - Retail pharmacy

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

1 ✓ 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: 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.

	Subsidy (Manufacturer's Price)	Per	Fully Subsidised	Brand or Generic Manufacturer
METHENAMINE (HEXAMINE) HIPPURATE				
* Tab 1 g	19.95	100	<b>✓</b> <u>F</u>	<u>liprex</u>
NITROFURANTOIN				
* Tab 50 mg - Up to 30 tab available on a PSO	22.20	100	<b>✓</b> N	lifuran
* Tab 100 mg	37.50	100	<b>✓</b> N	Nifuran
* Cap modified-release 100 mg - Up to 15 cap available on a PSO		100	✓ N	//acrobid
NORFLOXACIN			_	
Tab 400 mg - Subsidy by endorsement	245.00	100	<b>✓</b>	Arrow-Norfloxacin
Only if prescribed for a patient with an uncomplicated uri with proven resistance to first line agents and the prescri	nary tract infection th			re to a first line agent or

	Subsidy		Fully Brand or	
	(Manufacturer's Price	e) Sub	sidised Generic	
	\$	Per	<ul> <li>Manufacturer</li> </ul>	
Anticholinesterases				
NEOSTIGMINE METILSULFATE				
Inj 2.5 mg per ml, 1 ml ampoule	48.25	10	✓ Max Health	
Max Health to be Principal Supply on 1 February 2025		. •		
,				
PYRIDOSTIGMINE BROMIDE			_	
▲ Tab 60 mg	50.28	100	Mestinon	
Non-Steroidal Anti-Inflammatory Drugs				
DICLOFENAC SODIUM				
* Tab EC 25 mg	2.19	50	✓ Diclofenac Sandoz	
Diclofenac Sandoz to be Principal Supply on 1 February				
		20	✓ Voltaren D	
the second are personal and are the second are the				
* Tab EC 50 mg		50	<ul> <li>Diclofenac Sandoz</li> </ul>	
Diclofenac Sandoz to be Principal Supply on 1 February				
* Tab long-acting 75 mg	19.60	100	✓ Voltaren SR	
* Inj 25 mg per ml, 3 ml ampoule – Up to 5 inj available on a P	SO 13.20	5	✓ Voltaren	
* Suppos 12.5 mg	2.04	10	✓ Voltaren	
* Suppos 25 mg	2.44	10	✓ Voltaren	
* Suppos 50 mg - Up to 10 supp available on a PSO		10	✓ Voltaren	
* Suppos 100 mg		10	✓ Voltaren	
	7.00	10	Voltaren	
IBUPROFEN				
* Tab 200 mg	21.40	1,000	✓ Relieve	
* Tab long-acting 800 mg	3.05	30	✓ Brufen SR	
• •	3.65		✓ Ibuprofen SR BNM	
* Oral liq 20 mg per ml	2.85	200 ml	✓ Ethics	
(Brufen SR Tab long-acting 800 mg to be delisted 1 April 2025)			00	
, , ,				
KETOPROFEN			_	
* Cap long-acting 200 mg	12.07	28	Oruvail SR	
MEFENAMIC ACID				
* Cap 250 mg	1.25	50		
* Cap 250 mg		50	Danatan	
	(10.82)	00	Ponstan	
	0.50	20		
	(7.50)		Ponstan	
NAPROXEN				
* Tab 250 mg	39 23	500	✓ Noflam 250	
Noflam 250 to be Principal Supply on 1 February 2025	00.20	000	· Honain 200	
,	04.45	050	✓ Noflam 500	
* Tab 500 mg	34.45	250	• Nonam 500	
Noflam 500 to be Principal Supply on 1 February 2025				
* Tab long-acting 750 mg		28	Naprosyn SR 750	
Naprosyn SR 750 to be Principal Supply on 1 February 2				
* Tab long-acting 1 g	11.50	28	Naprosyn SR 1000	
Naprosyn SR 1000 to be Principal Supply on 1 February			• •	
TENOXICAM	10.50	100	/ Tileatil	
* Tab 20 mg		100	✓ <u>Tilcotil</u>	
* Inj 20 mg vial	9.95	1	✓ AFT	

	MU	JSCI	JLOSKE	ELETAL SYSTEM
	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
NSAIDs Other				
CELECOXIB Cap 100 mg	3.45	60		Celebrex
Cap 200 mg	3.20	30	1	Celecoxib Pfizer Celebrex Celecoxib Pfizer
Topical Products for Joint and Muscular Pain				
CAPSAICIN  Crm 0.025% - Special Authority see SA1289 below - Retai		15 g O	iD 🖋	Zo-Rub Osteo S29
рнаннасу		60 g O	1	Zostrix Rugby Capsaicin Topical
Antirheumatoid Agents  HYDROXYCHLOROQUINE – Subsidy by endorsement Subsidised only if prescribed for rheumatoid arthritis, system suppression, relevant dermatological conditions (cutaneous mucosal ulceration)*, sarcoidosis (pulmonary and non-pulmonary and non-pulm	forms of lupus and lic onary)*, and the pres	chen p criptio	olanus, cut n is endor	aneous vasculitides and sed accordingly.
Pharmacists may annotate the prescription as endorsed who hydroxychloroquine. Note: Indication marked with a * is an	unapproved indication	n.		v
* Tab 200 mg LEFLUNOMIDE	8./8	100	•	Plaquenil
* Tab 10 mg * Tab 20 mg		30 30		Arava Arava
PENICILLAMINE				<u></u>
Tab 125 mg Tab 250 mg		100 100		D-Penamine D-Penamine
Drugs Affecting Bone Metabolism				
Alendronate for Osteoporosis				
ALENDRONATE SODIUM  * Tab 70 mg	3.10	4	/	Fosamax
ALENDRONATE SODIUM WITH COLECALCIFEROL  * Tab 70 mg with colecalciferol 5,600 iu	1.99	4	•	Fosamax Plus
Other Treatments				

1

✓ Prolia

DENOSUMAB – Special Authority see SA1777 on the next page – Retail pharmacy Inj 60 mg prefilled syringe.......326.00

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

### **⇒SA1777** Special Authority for Subsidy

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

#### All of the following:

- 1 The patient has severe, established osteoporosis; and
- 2 Fither:
  - 2.1 The patient is female and postmenopausal; or
  - 2.2 The patient is male or non-binary; and
- 3 Any of the following:
  - 3.1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) greater than or equal to 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -2.5) (see Note); or
  - 3.2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons; or
  - 3.3 History of two significant osteoporotic fractures demonstrated radiologically; or
  - 3.4 Documented T-Score less than or equal to -3.0 (see Note); or
  - 3.5 A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or
  - 3.6 Patient has had a Special Authority approval for alendronate (Underlying cause Osteoporosis) prior to 1 February 2019 or has had a Special Authority approval for raloxifene; and
- 4 Zoledronic acid is contraindicated because the patient's creatinine clearance is less than 35 mL/min; and
- 5 The patient has experienced at least one symptomatic new fracture after at least 12 months' continuous therapy with a funded antiresorptive agent at adequate doses (see Notes); and
- 6 The patient must not receive concomitant treatment with any other funded antiresorptive agent for this condition or teriparatide.

#### Notes:

- a) BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA).
   Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable
- b) Evidence suggests that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score less than or equal to -2.5 and, therefore, do not require BMD measurement for treatment with denosumab
- c) Osteoporotic fractures are the incident events for severe (established) osteoporosis and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less
- d) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body
- e) Antiresorptive agents and their adequate doses for the purposes of this Special Authority are defined as: risedronate sodium tab 35 mg once weekly; alendronate sodium tab 70 mg or tab 70 mg with cholecalciferol 5,600 iu once weekly; raloxifene hydrochloride tab 60 mg once daily. If an intolerance of a severity necessitating permanent treatment withdrawal develops during the use of one antiresorptive agent, an alternate antiresorptive agent must be trialled so that the patient achieves the minimum requirement of 12 months' continuous therapy

#### 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

Sub	bsidy Fu	ly Brand or
(Manufactu	urer's Price) Subsidise	d Generic
•	\$ Per	Manufacturer

### ⇒SA1779 Special Authority for Subsidy

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

Any of the following:

- 1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) greater than or equal to 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -2.5) (see Notes); or
- 2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
- 3 History of two significant osteoporotic fractures demonstrated radiologically: or
- 4 Documented T-Score less than or equal to -3.0 (see Notes); or
- 5 A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Notes); or
- 6 Patient has had a Special Authority approval for zoledronic acid (Underlying cause Osteoporosis) or has had a Special Authority approval for alendronate (Underlying cause - Osteoporosis) prior to 1 February 2019.

#### Notes:

- a) BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA).
   Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.
- b) Evidence suggests that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score less than or equal to -2.5 and, therefore, do not require BMD measurement for raloxifene funding.
- c) Osteoporotic fractures are the incident events for severe (established) osteoporosis, and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less.
- d) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

#### RISEDRONATE SODIUM

Tab 35 mg2.50	4	✓ Risedronate Sandoz
TERIPARATIDE - Special Authority see SA1139 below - Retail pharmacy		
Inj 250 mcg per ml, 2.4 ml	1	✓ Teriparatide - Teva

#### ⇒SA1139 Special Authority for Subsidy

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

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

#### Notes:

- a) The bone mineral density (BMD) measurement used to derive the T-score must be made using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable
- b) Antiresorptive agents and their adequate doses for the purposes of this Special Authority are defined as: alendronate sodium tab 70 mg or tab 70 mg with colecalciferol 5,600 iu once weekly; raloxifene hydrochloride tab 60 mg once daily; zoledronic acid 5 mg per year. If an intolerance of a severity necessitating permanent treatment withdrawal develops

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

#### continued...

during the use of one antiresorptive agent, an alternate antiresorptive agent must be trialled so that the patient achieves the minimum requirement of 12 months' continuous therapy.

- c) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.
- d) A maximum of 18 months of treatment (18 cartridges) will be subsidised.

#### ZOLEDRONIC ACID

# Hyperuricaemia and Antigout

ΑL	LO.	Рι	IRI	N	0	L

*	Tab 100 mg	17.99	1,000	✓ <u>Ipca-Allopurinol</u>
	Tab 300 mg		500	✓ Ipca-Allopurinol
BE	NZBROMARONE – Special Authority see SA1963 below – F	Retail pharmacy		
	Tab 50 mg	32.00	100	✓ Narcaricin mite S29

### ⇒SA1963 Special Authority for Subsidy

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

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

#### COLCHICINE

002002			
* Tab 500 mcg	6.00	100	✓ Colgout
FEBUXOSTAT - Special Authority see SA2054 below			<del></del>
Tab 80 mg	4.73	28	✓ Febuxostat (Teva)
Tab 120 mg	11.78	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

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

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

BA	CLOFEN			
*	Tab 10 mg	3.70	100	✓ Pacifen
	Pacifen to be Principal Supply on 1 December 2024			
	Inj 0.05 mg per ml, 1 ml ampoule - Subsidy by endorsement	11.55	1	✓ Lioresal Intrathecal
	Subsidised only for use in a programmable pump in patier			ents have been ineffective or have
	caused intolerable side effects and the prescription is end	orsed according	ıly.	
	Inj 2 mg per ml, 5 ml ampoule - Subsidy by endorsement	306.82	5	✓ Medsurge
		490.91	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.

(Medsurge Inj 2 mg per ml, 5 ml ampoule to be delisted 1 March 2025)

DA	NI-	ГΟ	$\cap$	NIE
IJΑ	NI.	ıĸ	UЛ	חעו

Cap 25 mg112.1	3 100	✓ Dantrium ✓ Dantrium S29 S29
Cap 50 mg77.0	0 100	✓ Dantrium
ORPHENADRINE CITRATE		
Tab 100 mg23.2	5 100	✓ Norflex
Norflex to be Principal Supply on 1 February 2025		

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 mg38.24	60	✓ Symmetrel
63.73	100	✓ Symmetrel
APOMORPHINE HYDROCHLORIDE		·
▲ Inj 10 mg per ml, 2 ml ampoule	5	✓ Movapo
▲ Inj 10 mg per ml, 5 ml ampoule	5	✓ Movapo
ENTACAPONE	·	
▲ Tab 200 mg	100	✓ Comtan
Ÿ	100	Volitali
LEVODOPA WITH BENSERAZIDE	400	4.1. 5.11
* Tab dispersible 50 mg with benserazide 12.5 mg	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 mg22.85	100	✓ Madopar HBS
* Cap 200 mg with benserazide 50 mg26.25	100	Madopar 250
LEVODOPA WITH CARBIDOPA		
* Tab 100 mg with carbidopa 25 mg	100	Sinemet
Sinemet to be Principal Supply on 1 February 2025		
* Tab long-acting 200 mg with carbidopa 50 mg44.99	100	Sinemet CR
Sinemet CR to be Principal Supply on 1 February 2025		
* Tab 250 mg with carbidopa 25 mg	100	Sinemet
Sinemet to be Principal Supply on 1 February 2025		
PRAMIPEXOLE HYDROCHLORIDE		
▲ Tab 0.25 mg	100	✓ Ramipex
▲ Tab 1 mg	100	✓ Ramipex
RASAGILINE		<del></del>
* Tab 1 mg53.50	30	✓ Azilect S29
<b>Ç</b>	50	AZIIGUL
ROPINIROLE HYDROCHLORIDE	0.4	45 .
▲ Tab 0.25 mg	84	Ropin
▲ Tab 1 mg	84	✓ Ropin
▲ Tab 2 mg	84	Ropin
▲ Tab 5 mg14.50	84	✓ <u>Ropin</u>
TOLCAPONE		
▲ Tab 100 mg152.38	100	✓ Tasmar
Anticholineraics		

# **Anticholinergics**

BENZATROPINE MESYLATE			
Tab 2 mg	9.59	60	✓ Benztrop
Inj 1 mg per ml, 2 ml	95.00	5	✓ Phebra
a) Up to 10 inj available on a PSO			
b) Only on a PSO			
PROCYCLIDINE HYDROCHLORIDE			

✓ Kemadrin

100

### **NERVOUS SYSTEM**

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

# Agents for Essential Tremor, Chorea and Related Disorders

RILUZOLE - Special Authority see SA1403 below - Retail pharmacy

Wastage claimable

Tab 50 mg .......117.00 56 **✓ Rilutek** 

Rilutek to be Principal Supply on 1 February 2025

#### ⇒SA1403 Special Authority for Subsidy

**Initial application** only from a neurologist or respiratory specialist. Approvals valid for 6 months for applications meeting the following criteria:

### All of the following:

- 1 The patient has amyotrophic lateral sclerosis with disease duration of 5 years or less; and
- 2 The patient has at least 60 percent of predicted forced vital capacity within 2 months prior to the initial application; and
- 3 The patient has not undergone a tracheostomy; and
- 4 The patient has not experienced respiratory failure; and
- 5 Any of the following:
  - 5.1 The patient is ambulatory; or
  - 5.2 The patient is able to use upper limbs; or
  - 5.3 The patient is able to swallow.

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

- 1 The patient has not undergone a tracheostomy; and
- 2 The patient has not experienced respiratory failure; and
- 3 Any of the following:
  - 3.1 The patient is ambulatory; or
  - 3.2 The patient is able to use upper limbs; or
  - 3.3 The patient is able to swallow.

#### **TETRABENAZINE**

### **Anaesthetics**

### Local

#### LIDOCAINE [LIGNOCAINE]

a) Up to 150 ml available on a PSO

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

Gel 2%, 11 ml urethral syringe − Subsidy by endorsement...............59.50 10 ✓ Instillagel Lido

- a) Up to 5 each available on a PSO
- Subsidised only if prescribed for urethral, cervical or rectal administration and the prescription is endorsed accordingly.

	Subsidy		Fully	Brand or
	(Manufacturer's Pric	,	Subsidised	
	\$	Per	•	Manufacturer
IDOCAINE [LIGNOCAINE] HYDROCHLORIDE				
Oral (gel) soln 2%	44.00	200 m	✓	Mucosoothe
Inj 1%, 5 ml ampoule - Up to 25 inj available on a PSO	9.50	25	1	Lidocaine-Baxter
	17.50	50		
	(35.00)			Xylocaine
Inj 2%, 5 ml ampoule - Up to 5 inj available on a PSO	9.00	25	1	Lidocaine-Baxter
Inj 1%, 20 ml ampoule - Up to 5 inj available on a PSO	12.00	5		
	(20.00)			Xylocaine
Inj 1%, 20 ml vial - Up to 5 inj available on a PSO	6.85	5	1	Lidocaine-Baxter
Inj 2%, 20 ml vial - Up to 5 inj available on a PSO	7.15	5	1	Lidocaine-Baxter
Inj 10%, 5 ml ampoule - Subsidy by endorsement	CBS	10	1	Xylocard 500 S29
Subsidised only for people receiving palliative care servi		nalgesic		•

# **Topical Local Anaesthetics**

### ⇒SA0906 Special Authority for Subsidy

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

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

LIDOCAINE [LIGNOCAINE] - Special Authority see SA0906 above - Retail pharmacy						
Crm 4%	5.40	5 g OP	✓ LMX4			
	27.00	30 g OP	✓ LMX4			
LIDOCAINE [LIGNOCAINE] WITH PRILOCAINE	- Special Authority see SA09	06 above – Reta	il pharmacy			
Crm 2.5% with prilocaine 2.5%		30 g OP	EMLA			
Crm 2.5% with prilocaine 2.5% (5 g tubes)	45.00	5	EMLA			

# **Analgesics**

For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, page 120

# Non-opioid Analgesics

ASPIRIN  * Tab dispersible 300 mg - Up to 30 tab available on a PSO	5.65	100	✓ Ethics Aspirin
CAPSAICIN – Subsidy by endorsement Subsidised only if prescribed for post-herpetic neuralgia or diabetic paccordingly.	peripheral ne	europathy and	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 S29
NEFOPAM HYDROCHLORIDE Tab 30 mg	23.40	90	✓ Acupan

# **NERVOUS SYSTEM**

	Subsidy (Manufacturer's Price) \$	S Per	Fully ubsidised	Brand or Generic Manufacturer
PARACETAMOL				
Tab 500 mg - blister pack		1,000	<b>✓</b> <u>I</u>	Pacimol Pacimol
<ul> <li>a) Maximum of 300 tab per prescription; can be wait</li> <li>b) Up to 30 tab available on a PSO</li> <li>c)</li> </ul>	ved by endorsement			
Subsidy by endorsement for higher quantities regular daily dosing for one month or greated annotate the prescription as endorsed wher     Maximum of 100 tab per dispensing for non (for non-endorsed patients), then dispense Tab 500 mg - bottle pack — Maximum of 300 tab per	er, and the prescription is e dispensing history sup -endorsed patients. If qu	annota ports a uantities	ted accor ong-term prescrib	dingly. Pharmacists may condition. ed for more than 100 tabs
prescription; can be waived by endorsement	17.92	1,000	<b>√</b> <u>i</u>	Noumed Paracetamol
<ol> <li>Subsidy by endorsement for higher quantities is daily dosing for one month or greater, and the p prescription as endorsed where dispensing hist</li> <li>Maximum of 100 tab per dispensing for non-en- non-endorsed patients), then dispense in repeat</li> </ol>	orescription is annotated cory supports a long-term dorsed patients. If quant	accordi conditi tities pre	ngly. Pha on. escribed f	armacists may annotate the or more than 100 tabs (for
Oral liq 120 mg per 5 ml	3.98	200 ml	<b>√</b> <u>i</u>	Paracetamol (Ethics)
<ul> <li>a) Maximum of 600 ml per prescription; can be waiv</li> <li>b) Up to 200 ml available on a PSO</li> <li>c) Not in combination</li> <li>d)</li> </ul>	ed by endorsement			
1) Maximum of 200 ml per dispensing for non- non-endorsed patients), then dispense in re 2) Subsidy by endorsement for higher quantitic regular daily dosing for one month or greate Pharmacists may annotate the prescription condition.	peat dispensing not exce es is available for patient er and the prescription is	eeding 2 s with lo endorse	200 ml pe ong term o ed or ann	r dispensing. conditions who require otated accordingly.
3) Note: 200 ml presentations of paracetamol Pharmacist) under the provisions in Part I o 4) Note: Direct Provision by a pharmacist of u	f Section A			`
conjunction with immunisation of a child und	der 2 years of age with m		coccal B r	
<ul><li>a) Maximum of 600 ml per prescription; can be waiv</li><li>b) Up to 200 ml available on a PSO</li><li>c) Not in combination</li></ul>		200 1111		unoi
<ul> <li>d)         <ul> <li>Maximum of 200 ml per dispensing for non-non-endorsed patients), then dispense in re</li> </ul> </li> <li>Subsidy by endorsement for higher quantitie</li> </ul>	peat dispensing not exce	eeding 2	200 ml pe	r dispensing.

regular daily dosing for one month or greater and the prescription is endorsed or annotated accordingly. Pharmacists may annotate the prescription as endorsed where dispensing history supports a long-term

condition.

3) Note: 200 ml presentations of paracetamol oral liquid may be supplied on BSO to a Vaccinator (other than a Pharmacist) under the provisions in Part I of Section A

4) Note: Direct Provision by a pharmacist of up to 200 ml permitted under the provisions in Part I of Section A in conjunction with immunisation of a child under 2 years of age with meningococcal B multicomponent vaccine.

		Subsidy (Manufacturer's Price)	Per	Fully Subsidised	Generic
*	Suppos 250 mg	5.39	10		Gacet
	Suppos 500 mg		50	_	Gacet
0	pioid Analgesics				
CC	DEINE PHOSPHATE - Safety medicine; prescriber may dete		quen	су	
	Tab 15 mg	5.92	100		Noumed
	Tab 30 mg	6.98	100		Aspen
					Noumed
	Tab 60 mg	13.89	100	•	Noumed
DIF	IYDROCODEINE 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				
	<ul><li>c) Safety medicine; prescriber may determine dispensing free</li></ul>	Pallency			
	Inj 50 mcg per ml, 2 ml ampoule		10	1	Boucher and Muir
	Inj 50 mcg per ml, 10 ml ampoule		10		Boucher and Muir
	Patch 12.5 mcg per hour		5		Fentanyl Sandoz
	Fentanyl Sandoz to be Principal Supply on 1 December	2024	-		,
	Patch 25 mcg per hour		5	1	Fentanyl Sandoz
	Fentanyl Sandoz to be Principal Supply on 1 December				, . ,
	Patch 50 mcg per hour		5	1	Fentanyl Sandoz
	Fentanyl Sandoz to be Principal Supply on 1 December				•
	Patch 75 mcg per hour		5	✓	Fentanyl Sandoz
	Fentanyl Sandoz to be Principal Supply on 1 December	2024			•
	Patch 100 mcg per hour		5	1	Fentanyl Sandoz
	Fentanyl Sandoz to be Principal Supply on 1 December	2024			-
ME	THADONE HYDROCHLORIDE				
	a) Only on a controlled drug form				
	b) No patient co-payment payable				
	c) Safety medicine; prescriber may determine dispensing fre	eauencv			
	d) Extemporaneously compounded methadone will only be		e of th	ne cheape	st form available
	(methadone powder, not methadone tablets).				
	e) For methadone hydrochloride oral liquid refer Standard F	ormulae, page 276			
	Tab 5 mg		10	1	Methadone BNM
	Oral liq 2 mg per ml		200 n	nl 🗸	Biodone
	Biodone to be Principal Supply on 1 February 2025				
	Oral liq 5 mg per ml	7.80	200 n	nl 🗸	Biodone Forte
	Biodone Forte to be Principal Supply on 1 February 2025	5			
	Oral liq 10 mg per ml		200 n	nl 🗸	Biodone Extra Forte
	Biodone Extra Forte to be Principal Supply on 1 Februar				
	Inj 10 mg per ml, 1 ml	68.90	10	✓	AFT
MC	RPHINE HYDROCHLORIDE				
	a) Only on a controlled drug form				
	b) No patient co-payment payable				
	c) Safety medicine; prescriber may determine dispensing fre	equency			
	Oral liq 1 mg per ml		200 n	nl 🗸	RA-Morph
	Oral liq 2 mg per ml		200 n		RA-Morph
	Oral liq 5 mg per ml	28.20	200 n	nl 🗸	RA-Morph
	Oral liq 10 mg per ml	40.25	200 n	nl 🗸	RA-Morph

# **NERVOUS SYSTEM**

	Subsidy (Manufacturer's Price) \$	Per	Full Subsidise	,
MORPHINE SULPHATE				
a) Only on a controlled drug form				
<ul> <li>b) No patient co-payment payable</li> </ul>				
<ul> <li>Safety medicine; prescriber may determine dispensing fr</li> </ul>				
Tab immediate-release 10 mg	2.80	10	•	Sevredol
Tab immediate-release 20 mg	5.52	10	•	Sevredol
Cap long-acting 10 mg	3.00	10	•	m-Eslon
Cap long-acting 30 mg	4.30	10	•	m-Eslon
Cap long-acting 60 mg		10	•	m-Eslon
Cap long-acting 100 mg	10.50	10	•	m-Eslon
Oral liq 2 mg per ml	16.31	00 m	ıl 🗸	Wockhardt S29
, ,	29.80		•	Oramorph
			•	Oramorph CDC
				<b>S29</b> S29
Inj 5 mg per ml, 1 ml ampoule - Up to 5 inj available on a P	SO5.38	5	•	Medsurge
Inj 10 mg per ml, 1 ml ampoule - Up to 5 inj available on a	PSO 4.68	5	•	Medsurge
Inj 15 mg per ml, 1 ml ampoule – Up to 5 inj available on a	PSO5.53	5	•	Medsurge
Inj 30 mg per ml, 1 ml ampoule - Up to 5 inj available on a		5	•	Medsurge

	Subsidy (Manufacturer's P	rico)	Fully Subsidised	
	(Manufacturer's Pi	Per	Subsidised	Manufacturer
XYCODONE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing from	equency			
Tab controlled-release 5 mg		20	✓	<b>Oxycodone Sandoz</b>
Ç	3.77	28	✓	Oxycodone Sandoz
				S29 S29
	4.04	30	1	OxyContin S29
Oxycodone Sandoz to be Principal Supply on 1 Decemb				,
Tab immediate-release 5 mg		100	1	Oxycodone Amneal
Tab controlled-release 10 mg		20		Oxycodone Sandoz
•	3.77	28		Oxycodone Sandoz
				<b>S29</b> S29
Oxycodone Sandoz to be Principal Supply on 1 Decemb	ner 2024			
Tab immediate-release 10 mg		100	1	Oxycodone Amneal
Tab controlled-release 20 mg.		20		Oxycodone Sandoz
Oxycodone Sandoz to be Principal Supply on 1 Decemb				Oxyouania cunucz
Tab immediate-release 20 mg		100	1	Oxycodone Amneal
Tab controlled-release 40 mg	6.67	20		Oxycodone Sandoz
Oxycodone Sandoz to be Principal Supply on 1 Decemb				,
Tab controlled-release 80 mg.		20	/	Oxycodone Sandoz
Oxycodone Sandoz to be Principal Supply on 1 Decemb				,
Cap immediate-release 5 mg		20	/	OxyNorm
Cap immediate-release 20 mg		20		OxyNorm
Oral liq 1 mg per ml		250 m		Oxycodone Lucis
1 01				S29 S29
Inj 10 mg per ml, 1 ml ampoule	4 37	5	1	Hameln
Hameln to be Principal Supply on 1 December 2024		Ü	•	Tidilion1
Inj 10 mg per ml, 2 ml ampoule	8.62	5	1	Hameln
Hameln to be Principal Supply on 1 December 2024		ŭ		
Inj 50 mg per ml, 1 ml ampoule	14.90	5	1	Hameln
Hameln to be Principal Supply on 1 December 2024		-		
DxyNorm Cap immediate-release 5 mg to be delisted 1 Decemb	her 2024)			
DxyNorm Cap immediate-release 20 mg to be delisted 1 March	,			
ARACETAMOL WITH CODEINE – Safety medicine; prescribe	,	dienoneine	r frogueno	W
Tab paracetamol 500 mg with codeine phosphate 8 mg		پانادانغېوداد 1,000		Paracetamol +
rab paracetarior 500 mg with codeline phospitate o mg	27.50	1,000	•	Codeine (Relieve)
THIRINE HYPROCHII ORIDE				Oddenie (Heneve)
ETHIDINE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing fr		40	,	Name of Balletina
Tab 50 mg		10		Noumed Pethidine
Inj 50 mg per ml, 1 ml ampoule – Up to 5 inj available on a I	PSO29.88	5	•	DBL Pethidine
bit 50 man annual O mil annual a librata 5 bit annual air an air	000 00 70	-	,	Hydrochloride
Inj 50 mg per ml, 2 ml ampoule – Up to 5 inj available on a I	P5U30./2	5	•	DBL Pethidine
				Hydrochloride
RAMADOL HYDROCHLORIDE				
Tab sustained-release 100 mg		20		Tramal SR 100
Tab sustained-release 150 mg		20		Tramal SR 150
Tab sustained-release 200 mg		20		Tramal SR 200
Cap 50 mg	3.33	100	/	Arrow-Tramadol

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

# **Antidepressants**

AMITRIPTYLINE - Safety medicine; prescriber may dete	ermine dispensing frequence	су	
Tab 10 mg	2.99	100	Arrow-Amitriptyline
Tab 25 mg	1.99	100	Arrow-Amitriptyline
Tab 50 mg	3.14	100	✓ Arrow-Amitriptyline
CLOMIPRAMINE HYDROCHLORIDE - Safety medicine	; prescriber may determine	e dispensin	g frequency
Tab 10 mg	10.17	30	Clomipramine Teva
Tab 25 mg	11.99	30	Clomipramine Teva
	39.97	100	✓ Anafranil S29
Cap 10 mg	9.49	28	Clomipramine Teva
Cap 25 mg	11.19	28	✓ Clomipramine Teva

DOSULEPIN [DOTHIEPIN] HYDROCHLORIDE - Subsidy by endorsement

- a) Safety medicine; prescriber may determine dispensing frequency
- b) Subsidy by endorsement Subsidised for patients who were taking dosulepin [dothiepin] hydrochloride prior to 1 June 2019 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of dosulepin [dothiepin] hydrochloride.

Tab 75 mg	30
Cap 25 mg7.83	50

✓ Dosulepin Viatris ✓ Dosulepin

Viatris S29

IMIPRAMINE HYDROCHLORIDE - Safety medicine: prescriber may determine dispensing frequency

	carety meaning, procession may actorning a	op 0ogc	, 4
Tab 10 mg	5.48	50	✓ Tofranil
-	10.96	100	✓ Tofranil
Tab 25 mg	4.93	28	✓ Imipramine
			Crescent S29
	8.80	50	✓ Tofranil

Tofranil

NORTRIPTYLINE HYDROCHLORIDE - Safety medicine; prescriber may determine dispensing frequency

Tab 10 mg	.2.46	100	✓ Norpress
Tab 25 mg	.6.29	180	✓ Norpress

# Monoamine-Oxidase Inhibitors (MAOIs) - Non Selective

TRANYLCYPROMINE SULPHATE

★ Tab	o 10 mg	22.94	50	Parnate
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# **Monoamine-Oxidase Type A Inhibitors**

N A	$\sim$	CI.	$\sim$	D		۱۸ ۸		
IV/II			( )	ĸ	-	VΗ	11)	-

*	Tab 150 mg	23.60	60	<ul><li>Aurorix</li></ul>
	Aurorix to be Principal Supply on 1 February 2025			
*	Tab 300 mg	38.50	60	Aurorix
	Aurorix to be Principal Supply on 1 February 2025			

# **Selective Serotonin Reuptake Inhibitors**

#### CITALOPRAM HYDROBROMIDE

*	Tab 20 mg2	2.86	84	✓ Celapram
---	------------	------	----	------------

SCITALOPRAM	(Manufacturer's Price) \$	Sı	ıbsidised	Generic
SCITALOPRAM		Dav	-	
SCITALOPRAM	Ψ	Per		Manufacturer
★ Tab 10 mg		28		Ipca-Escitalopram
	1.07		•	Escitalopram (Ethics)
€ Tab 20 mg	1 49	28	/	Ipca-Escitalopram
LUOXETINE HYDROCHLORIDE			-	ipod zoonalopidiii
★ Tab dispersible 20 mg, scored – Subsidy by endorsement	2 50	28	1	Fluox
Subsidised by endorsement				
<ol> <li>When prescribed for a patient who cannot swallow accordingly; or</li> </ol>	w whole tablets or caps	ules an	d the pr	escription is endorsed
<ul><li>2) When prescribed in a daily dose that is not a mult</li></ul>	tiple of 20 mg in which	ooco th	n nrocori	intion is doomed to be
endorsed. Note: Tablets should be combined with				•
	•			v
€ Cap 20 mg	3.13	90	✓	Arrow-Fluoxetine
AROXETINE				
Fab 20 mg	4.11	90	✓	<u>Loxamine</u>
ERTRALINE				
★ Tab 50 mg	0.99	30	1	<u>Setrona</u>
★ Tab 100 mg	1.74	30	1	<u>Setrona</u>
IIRTAZAPINE Tab 30 mg	2.60	28	/	Noumed
		30		Noumed
Tab 45 mg	3.45	28	✓	Noumed
		30	✓	Noumed
'ENLAFAXINE				
← Cap 37.5 mg		84		Enlafax XR
€ Cap 75 mg		84		Enlafax XR
≰ Cap 150 mg	13.95	84	•	Enlafax XR
Antiepilepsy Drugs				
Agents for Control of Status Epilepticus				
	unaina fragulanau			
NAZEPAM – Safety medicine; prescriber may determine dispe Inj 5 mg per ml, 2 ml ampoule – Subsidy by endorsement		5	1	Hospira
a) Up to 5 inj available on a PSO		J	•	Ποοριια
b) Only on a PSO				
c) PSO must be endorsed "not for anaesthetic procedu	ures".			
		5	1	Stesolid
Rectal tubes 5 mg - Up to 5 tube available on a PSO				
Rectal tubes 5 mg - Up to 5 tube available on a PSO HENYTOIN SODIUM				
Rectal tubes 5 mg - Up to 5 tube available on a PSO  PHENYTOIN SODIUM  Inj 50 mg per ml, 2 ml ampoule - Up to 5 inj available on a		5	,	Hospira
Rectal tubes 5 mg - Up to 5 tube available on a PSO HENYTOIN SODIUM	104.58	5	✓	Hospira

		Subsidy (Manufacturer's Price \$	e) :	Fully Subsidised	I Generic
С	ontrol of Epilepsy				
CA	RBAMAZEPINE				
*	Tab 200 mg	14.53	100	1	Tegretol
	•			1	Tegretol AU
*	Tab long-acting 200 mg	16.98	100	✓	Tegretol CR
		33.96	200	1	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
CLO	DBAZAM - Safety medicine; prescriber may determine dispe	nsina frequency			
-	Tab 10 mg		50	1	Frisium
CLO	DNAZEPAM – Safety medicine; prescriber may determine dis				
OL	Oral drops 2.5 mg per ml		10 ml O	D 1	Rivotril
		7.50	10 1111 0	. •	mvoun
ΕII	HOSUXIMIDE				
	Cap 250 mg	78.89	56	•	Essential
					Ethosuximide S29
		140.88	100	•	Zarontin
	Oral liq 250 mg per 5 ml	56.35	200 ml	1	Zarontin
GΑ	BAPENTIN				
	Note: Not subsidised in combination with subsidised pregab	alin			
*	Cap 100 mg	6.45	100	1	Nupentin
*	Cap 300 mg	8.45	100	1	Nupentin
*	Cap 400 mg	10.26	100	✓	Nupentin
LAC	COSAMIDE – Special Authority see SA2267 below – Retail p	harmacv			
<b>_</b> "	Tab 50 mg		14	1	Vimpat
lacksquare	Tab 100 mg		14		Vimpat
	· · · · · · · · · · · · · · · · · · ·	200.24	56		Vimpat
$\blacktriangle$	Tab 150 mg	75.10	14		Vimpat
	ŭ	300.40	56		Vimpat
$\blacktriangle$	Tab 200 mg	400.55	56	1	Vimpat

**⇒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.

#### I AMOTRIGINE

$\blacktriangle$	Tab dispersible 2 mg	55.00	30	✓ Lamictal
	Tab dispersible 5 mg		30	✓ Lamictal
	Tab dispersible 25 mg		56	✓ Logem
	Tab dispersible 50 mg		56	✓ Logem
	Tab dispersible 100 mg		56	✓ Logem

### **NERVOUS SYSTEM**

	Subsidy		Fully	
(	Manufacturer's I \$	Price) S	Subsidised ✓	Generic Manufacturer
	ð	Per		Manufacturer
LEVETIRACETAM	<b>5.04</b>			
Tab 250 mg		60		Everet
Tab 500 mg		60		Everet
Tab 750 mg		60		Everet
Tab 1,000 mg		60		Everet
Oral liq 100 mg per ml		300 ml O		Levetiracetam-AFT
Inj 100 mg per ml, 5 ml vial	38.95	10	•	Levetiracetam-AFT
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	1	Noumed
				<u>Phenobarbitone</u>
PHENYTOIN SODIUM				
* Tab 50 mg	75.00	200	1	Dilantin Infatab
Cap 30 mg		200		Dilantin
Cap 100 mg		200	/	Dilantin
★ Oral lig 30 mg per 5 ml		500 ml	1	Dilantin Paediatric
PREGABALIN				
Note: Not subsidised in combination with subsidised gabapen	tin			
* Cap 25 mg		56	1	Pregabalin Pfizer
- Λ - Oαρ 25 mg	7.80	30		Milpharm S29
* Cap 75 mg		56		Pregabalin Pfizer
к Сар 75 mg		30		•
V Con 150	8.10	<b></b> 0		Milpharm S29
★ Cap 150 mg	4.01	56		Lyrica
K Can 200 mg	7.00	EC		Pregabalin Pfizer
★ Cap 300 mg		56	•	Pregabalin Pfizer
PRIMIDONE			_	
<b>₭</b> Tab 250 mg	37.35	100	/	Primidone Clinect
SODIUM VALPROATE				
Tab 100 mg	13.65	100	1	Epilim Crushable
Tab 200 mg EC		100	1	Epilim
Tab 500 mg EC		100		Epilim
* Oral liq 200 mg per 5 ml		300 ml	1	Epilim S/F Liquid
				Epilim Syrup
* Inj 100 mg per ml, 4 ml	41.50	1		Epilim IV
STIRIPENTOL - Special Authority see SA2268 below - Retail pha	rmacy			
Cap 250 mg	•	60	1	Diacomit
Powder for oral lig 250 mg sachet		60		Diacomit
TOWAGE FOR ORDERING 200 HING SACHIOT	500.20	00	•	Diagoniii

### ⇒SA2268 Special Authority for Subsidy

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

Both:

- 1 Patient has confirmed diagnosis of Dravet syndrome; and
- 2 Seizures have been inadequately controlled by appropriate courses of sodium valproate, clobazam and at least two of the following: topiramate, levetiracetam, ketogenic diet.

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

**Renewal** from any relevant practitioner. Approvals valid without further renewal unless notified where the patient continues to benefit from treatment as measured by reduced seizure frequency from baseline.

	Subsidy		Fully	Brand or
	Manufacturer's Price)		Subsidised	Generic
	\$	Per		Manufacturer
OPIRAMATE				
Tab 25 mg	11.07	60	1	Arrow-Topiramate
v			1	Topiramate Actavis
	26.04		1	Topamax
Tab 50 mg	18.81	60	1	Arrow-Topiramate
v			1	Topiramate Actavis
	44.26		1	Topamax
Tab 100 mg	31.99	60		Arrow-Topiramate
v			1	Topiramate Actavis
	75.25		1	Topamax
Tab 200 mg	55.19	60	1	Arrow-Topiramate
ů				Topiramate Actavis
	129.85		1	Topamax
Sprinkle cap 15 mg	20.84	60		Topamax
Sprinkle cap 25 mg		60	1	Topamax
GABATRIN - Special Authority see SA2088 below - Retail pha				•
Tab 500 mg	•	100	1	Sabril
Powder for oral soln 500 mg per sachet		60		Sabril
———		00		- CONTIN

### **⇒SA2088** Special Authority for Subsidy

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

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

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

#### Both:

- 1 The patient has demonstrated a significant and sustained improvement in seizure rate or severity and or quality of life; and
- 2 Fither
  - 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 120

### **Acute Migraine Treatment**

**RIZATRIPTAN** 

Tab orodispersible 10 mg.......4.84 30 ✓ <u>Rizamelt</u>

	Subsidy (Manufacturer's P \$	ice) Sub Per	Fully Brand or bsidised Generic Manufacturer
UMATRIPTAN	22.68	90 90	✓ <u>Sumagran</u> ✓ <u>Sumagran</u>
Inj 12 mg per ml, 0.5 ml prefilled pen – Maximum of 10 inj p prescription		2 OP	✓ <u>Clustran</u>
Prophylaxis of Migraine			
or Beta Adrenoceptor Blockers refer to CARDIOVASCULAR S'	YSTEM, page 50		
IZOTIFEN € Tab 500 mcg	23.21	100	✓ Sandomigran
Antinausea and Vertigo Agents			
or Antispasmodics refer to ALIMENTARY TRACT, page 8			
PREPITANT – Special Authority see SA0987 below – Retail p Cap 2 × 80 mg and 1 × 125 mg		3 OP	✓ Emend Tri-Pack
Emend Tri-Pack to be Principal Supply on 1 January 20  SA0987 Special Authority for Subsidy	25	here the pati	tient is undergoing highly
Emend Tri-Pack to be Principal Supply on 1 January 20  SA0987 Special Authority for Subsidy  Itial application from any relevant practitioner. Approvals val metogenic chemotherapy and/or anthracycline-based chemotherapy and from any relevant practitioner. Approvals valid for 12 remotherapy and/or anthracycline-based chemotherapy for the ETAHISTINE DIHYDROCHLORIDE	id for 12 months verapy for the treatmonths where the treatment of mali	ment of malig patient is und gnancy.	gnancy. dergoing highly emetogeni
Emend Tri-Pack to be Principal Supply on 1 January 20  SA0987 Special Authority for Subsidy  Itial application from any relevant practitioner. Approvals val metogenic chemotherapy and/or anthracycline-based chemothe enewal from any relevant practitioner. Approvals valid for 12 r nemotherapy and/or anthracycline-based chemotherapy for the ETAHISTINE DIHYDROCHLORIDE  Tab 16 mg	id for 12 months verapy for the treatmenths where the treatment of mali	ment of malig	gnancy.
Emend Tri-Pack to be Principal Supply on 1 January 20  *SA0987 Special Authority for Subsidy itial application from any relevant practitioner. Approvals val netogenic chemotherapy and/or anthracycline-based chemotherapy and/or anthracycline-based chemotherapy and/or anthracycline-based chemotherapy and/or anthracycline-based chemotherapy for the ETAHISTINE DIHYDROCHLORIDE  **Tab 16 mg** **YCLIZINE HYDROCHLORIDE**  Tab 50 mg**  Nausicalm to be Principal Supply on 1 February 2025	id for 12 months verapy for the treatmenths where the treatment of mali	ment of malig patient is und gnancy.	gnancy. dergoing highly emetogeni
Emend Tri-Pack to be Principal Supply on 1 January 20  *SA0987 Special Authority for Subsidy itial application from any relevant practitioner. Approvals val metogenic chemotherapy and/or anthracycline-based chemotherapy and/or anthracycline-based chemotherapy and/or anthracycline-based chemotherapy or the ementherapy and/or anthracycline-based chemotherapy for the ETAHISTINE DIHYDROCHLORIDE  ** Tab 16 mg  YCLIZINE HYDROCHLORIDE  Tab 50 mg  Nausicalm to be Principal Supply on 1 February 2025 YCLIZINE LACTATE  Inj 50 mg per ml, 1 ml ampoule — Up to 10 inj available on a PSO	id for 12 months verapy for the treatmenths where the treatment of mali	ment of malig patient is und gnancy.	gnancy. dergoing highly emetogeni  Serc
Emend Tri-Pack to be Principal Supply on 1 January 20  SA0987 Special Authority for Subsidy  itial application from any relevant practitioner. Approvals val metogenic chemotherapy and/or anthracycline-based chemotherapy and/or anthracycline-based chemotherapy and/or anthracycline-based chemotherapy for the ementherapy and/or anthracycline-based chemotherapy for the ETAHISTINE DIHYDROCHLORIDE  Tab 16 mg  YCLIZINE HYDROCHLORIDE  Tab 50 mg  Nausicalm to be Principal Supply on 1 February 2025  YCLIZINE LACTATE  Inj 50 mg per ml, 1 ml ampoule — Up to 10 inj available on a PSO  MPERIDONE	id for 12 months verapy for the treatmenths where the treatment of mali	ment of malig patient is und gnancy. 100	gnancy. dergoing highly emetogeni  Serc  Nausicalm  Hameln  Domperidone
Emend Tri-Pack to be Principal Supply on 1 January 20  *SA0987 Special Authority for Subsidy itial application from any relevant practitioner. Approvals val netogenic chemotherapy and/or anthracycline-based chemotherapy and/or anthracycline-based chemotherapy and/or anthracycline-based chemotherapy or the ementherapy and/or anthracycline-based chemotherapy for the ETAHISTINE DIHYDROCHLORIDE  Tab 16 mg  YCLIZINE HYDROCHLORIDE  Tab 50 mg  Nausicalm to be Principal Supply on 1 February 2025 YCLIZINE LACTATE  Inj 50 mg per ml, 1 ml ampoule — Up to 10 inj available on a PSO  DMPERIDONE  Tab 10 mg  Tab 10 mg	id for 12 months verapy for the treatmenths where the treatment of mali	ment of malic patient is und gnancy. 100 10	gnancy. dergoing highly emetogeni  Serc  Nausicalm  Hameln
Emend Tri-Pack to be Principal Supply on 1 January 20  *SA0987 Special Authority for Subsidy itial application from any relevant practitioner. Approvals val netogenic chemotherapy and/or anthracycline-based chemotherapy and/or anthracycline-based chemotherapy and/or anthracycline-based chemotherapy or the ementherapy and/or anthracycline-based chemotherapy for the ETAHISTINE DIHYDROCHLORIDE  ** Tab 16 mg  ** YCLIZINE HYDROCHLORIDE  Tab 50 mg  ** Nausicalm to be Principal Supply on 1 February 2025 YCLIZINE LACTATE  Inj 50 mg per ml, 1 ml ampoule — Up to 10 inj available on a PSO  ** SOMPERIDONE  ** Tab 10 mg  ** YOSCINE HYDROBROMIDE	id for 12 months verapy for the treatmenths where the treatment of mali	ment of malic patient is und gnancy. 100 10	gnancy. dergoing highly emetogeni  Serc  Nausicalm  Hameln  Domperidone
Emend Tri-Pack to be Principal Supply on 1 January 20  *SA0987 Special Authority for Subsidy itial application from any relevant practitioner. Approvals val netogenic chemotherapy and/or anthracycline-based chemotherapy and/or anthracycline-based chemotherapy and/or anthracycline-based chemotherapy or the ementherapy and/or anthracycline-based chemotherapy for the ETAHISTINE DIHYDROCHLORIDE  ** Tab 16 mg  ** YCLIZINE HYDROCHLORIDE  Tab 50 mg  ** Nausicalm to be Principal Supply on 1 February 2025 YCLIZINE LACTATE  Inj 50 mg per ml, 1 ml ampoule — Up to 10 inj available on a PSO  ** SOMPERIDONE  ** Tab 10 mg  ** YOSCINE HYDROBROMIDE	id for 12 months verapy for the treatments where the treatment of mali	ment of malic patient is und gnancy. 100 10 10	gnancy. dergoing highly emetogeni  Serc  Nausicalm  Hameln  Domperidone Viatris
Emend Tri-Pack to be Principal Supply on 1 January 20  SA0987 Special Authority for Subsidy  Itial application from any relevant practitioner. Approvals val metogenic chemotherapy and/or anthracycline-based chemotherapy and/or anthracycline-based chemotherapy and/or anthracycline-based chemotherapy for the ETAHISTINE DIHYDROCHLORIDE  Tab 16 mg  YCLIZINE HYDROCHLORIDE  Tab 50 mg  Nausicalm to be Principal Supply on 1 February 2025  YCLIZINE LACTATE  Inj 50 mg per ml, 1 ml ampoule — Up to 10 inj available on a PSO  OMPERIDONE  Tab 10 mg  YOSCINE HYDROBROMIDE  Inj 400 mcg per ml, 1 ml ampoule  Inj 400 mcg per ml, 1 ml ampoule	id for 12 months verapy for the treatmenths where the treatment of mali	ment of malic patient is und gnancy. 100 10 10	gnancy. dergoing highly emetogeni  Serc  Nausicalm  Hameln  Domperidone Viatris

(Scopoderm TTS Patch 1 mg per 72 hours to be delisted 1 January 2025) (Scopolamine - Mylan S29 S29 Patch 1 mg per 72 hours to be delisted 1 February 2025)

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

### ⇒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 PSO1.57	100	✓ Metoclopramide Actavis 10
* Inj 5 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO7.00	10	✓ Baxter
ONDANSETRON		
* Tab 4 mg2.27	50	✓ Periset
Tab disp 4 mg - Up to 10 tab available on a PSO0.56	10	✓ Periset ODT
* Tab 8 mg4.10	50	✓ Periset
Tab disp 8 mg - Up to 10 tab available on a PSO0.90	10	✓ Periset ODT
PROCHLORPERAZINE		
* Tab 3 mg buccal	50	
(30.00)		Buccastem
(30.00)		Max Health S29
(30.00)		Prochlorperazine
		Brown & Burk S29
* Tab 5 mg - Up to 30 tab available on a PSO25.00	250	✓ Nausafix
* Inj 12.5 mg per ml, 1 ml - Up to 5 inj available on a PSO25.81	10	✓ Stemetil

# **Antipsychotics**

### General

30	✓ Sulprix
60	✓ Sulprix
60	✓ Sulprix
30	<ul> <li>✓ Aripiprazole Sandoz</li> <li>✓ Ascend</li> <li>Aripiprazole S29</li> </ul>
30	✓ Aripiprazole Sandoz
30	<ul> <li>Aripiprazole Sandoz</li> </ul>
30	<ul> <li>Aripiprazole Sandoz</li> </ul>
30	✓ Aripiprazole Sandoz
	60 60 30 30 30 30 30

Characteristics   Characteri	<del>_</del>	Subsidy		Fully	Brand or
Chicago   Chic			)		
Tab 25 mg — Up to 30 tab available on a PSO		\$	Per		Manufacturer
Tab 25 mg — Up to 30 tab available on a PSO	CHLORPROMAZINE HYDROCHLORIDE - Safety medicine; p	rescriber may determ	ine dis	pensing fr	equency
Inj 25 mg per ml, 2 ml - Up to 5 in ja available on a PSO					
Inj 25 mg per ml, 2 ml - Up to 5 in ja available on a PSO	Tab 100 mg - Up to 30 tab available on a PSO	36.73	100	1	Largactil
Safety medicine; prescriber may determine dispensing frequency			10	1	Largactil
Safety medicine; prescriber may determine dispensing frequency	CLOZAPINE - Hospital pharmacy [HP4]				-
Tab 25 mg		uencv			
Tab 50 mg			50	1	Clopine
Tab 50 mg					•
Tab 50 mg		13.37	100	1	Clopine
Tab 100 mg					•
Tab 100 mg	Tab 50 mg	8.67	50	✓	Clopine
Tab 100 mg	•		100	✓	Clopine
Tab 200 mg	Tab 100 mg	17.33	50		
Tab 200 mg	· ·			1	Clozaril
Tab 200 mg		34.65	100	1	Clopine
Suspension 50 mg per ml.   69.30   100   Versacloz				1	Clozaril
Suspension 50 mg per ml	Tab 200 mg	34.65	50	✓	Clopine
ALOPERIDOL - Safety medicine; prescriber may determine dispensing frequency		69.30	100	✓	Clopine
Tab 500 mcg − Up to 30 tab available on a PSO	Suspension 50 mg per ml	67.62	100 m	ı 🗸	Versacloz
Tab 500 mcg − Up to 30 tab available on a PSO	HALOPERIDOL – Safety medicine: prescriber may determine	dispensing frequency			
Tab 1.5 mg − Up to 30 tab available on a PSO	Tab 500 mcg – Up to 30 tab available on a PSO	6.23	100	1	Serenace
Tab 5 mg — Up to 30 tab available on a PSO					
29.72   100					
Oral liq 2 mg per ml — Up to 200 ml available on a PSO	υτο <b>3</b> τη πετιμένη πετιμένη		100	1	Serenace
Inj 5 mg per ml, 1 ml ampoule — Up to 5 inj available on a PSO21.55 10	Oral lig 2 mg per ml - Up to 200 ml available on a PSO	23.84	100 m		
EVOMEPROMAZINE — Safety medicine; prescriber may determine dispensing frequency Tab 25 mg (33.8 mg as a maleate)			10	✓	Serenace
Tab 25 mg (33.8 mg as a maleate)			Hency		
Tab 25 mg as a maleate			•	1	Nozinan (Swiss)
Tab 100 mg (135 mg as a maleate)					
Tab 100 mg as a maleate					
EVOMEPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency Inj 25 mg per ml, 1 ml ampoule					
Inj 25 mg per ml, 1 ml ampoule       24.48       10       ✓ Wockhardt         ITHIUM CARBONATE – Safety medicine; prescriber may determine dispensing frequency       82.80       100       ✓ Priadel         Priadel to be Principal Supply on 1 February 2025       22.36       100       ✓ Douglas         DLANZAPINE – Safety medicine; prescriber may determine dispensing frequency       1.40       30       ✓ Zypine         Tab 5 mg       1.93       30       ✓ Zypine         Tab orodispersible 5 mg       2.42       28       ✓ Zypine         Tab 10 mg       1.93       30       ✓ Zypine         Tab orodispersible 10 mg       2.89       28       ✓ Zypine         TERICYAZINE – Safety medicine; prescriber may determine dispensing frequency       13.61       100       ✓ Neulactil         Tab 10 mg       48.45       100       ✓ Neulactil         DUETIAPINE – Safety medicine; prescriber may determine dispensing frequency       13.61       100       ✓ Neulactil         Tab 25 mg       2.36       90       ✓ Quetapel         Tab 100 mg       6.40       90       ✓ Quetapel         Tab 200 mg       10.97       90       ✓ Quetapel	•				
ITHIUM CARBONATE — Safety medicine; prescriber may determine dispensing frequency Tab long-acting 400 mg					
Tab long-acting 400 mg					Wockilaiut
Priadel to be Principal Supply on 1 February 2025         Cap 250 mg       22.36       100       ✓ Douglas         DLANZAPINE – Safety medicine; prescriber may determine dispensing frequency         Tab 2.5 mg       1.40       30       ✓ Zypine         Tab 5 mg       1.93       30       ✓ Zypine         Tab orodispersible 5 mg       2.42       28       ✓ Zypine         Tab 10 mg       1.93       30       ✓ Zypine         Tab orodispersible 10 mg       2.89       28       ✓ Zypine ODT         ERICYAZINE – Safety medicine; prescriber may determine dispensing frequency         Tab 2.5 mg       13.61       100       ✓ Neulactil         Tab 10 mg       48.45       100       ✓ Neulactil         RUETIAPINE – Safety medicine; prescriber may determine dispensing frequency       Tab 25 mg       2.36       90       ✓ Quetapel         Tab 100 mg       6.40       90       ✓ Quetapel         Tab 200 mg       10.97       90       ✓ Quetapel					Date del
Cap 250 mg       22.36       100       ✓ Douglas         DLANZAPINE - Safety medicine; prescriber may determine dispensing frequency       1.40       30       ✓ Zypine         Tab 2.5 mg       1.93       30       ✓ Zypine         Tab orodispersible 5 mg       2.42       28       ✓ Zypine ODT         Tab 10 mg       1.93       30       ✓ Zypine         Tab orodispersible 10 mg       2.89       28       ✓ Zypine ODT         ERICYAZINE - Safety medicine; prescriber may determine dispensing frequency       13.61       100       ✓ Neulactil         Tab 10 mg       48.45       100       ✓ Neulactil         RUETIAPINE - Safety medicine; prescriber may determine dispensing frequency       Tab 25 mg       2.36       90       ✓ Quetapel         Tab 100 mg       6.40       90       ✓ Quetapel         Tab 200 mg       10.97       90       ✓ Quetapel		82.80	100	•	Priadei
DLANZAPINE - Safety medicine; prescriber may determine dispensing frequency   Tab 2.5 mg		20.00	100	./	Douglas
Tab 2.5 mg       1.40       30       ✓ Zypine         Tab 5 mg       1.93       30       ✓ Zypine         Tab orodispersible 5 mg       2.42       28       ✓ Zypine ODT         Tab 10 mg       1.93       30       ✓ Zypine         Tab orodispersible 10 mg       2.89       28       ✓ Zypine ODT         VERICYAZINE – Safety medicine; prescriber may determine dispensing frequency       13.61       100       ✓ Neulactil         Tab 10 mg       48.45       100       ✓ Neulactil         DUETIAPINE – Safety medicine; prescriber may determine dispensing frequency       Tab 25 mg       2.36       90       ✓ Quetapel         Tab 100 mg       6.40       90       ✓ Quetapel         Tab 200 mg       10.97       90       ✓ Quetapel	, •		100	•	Douglas
Tab 5 mg       1.93       30       ✓ Zypine         Tab orodispersible 5 mg       2.42       28       ✓ Zypine ODT         Tab 10 mg       1.93       30       ✓ Zypine         Tab orodispersible 10 mg       2.89       28       ✓ Zypine ODT         PERICYAZINE – Safety medicine; prescriber may determine dispensing frequency       13.61       100       ✓ Neulactil         Tab 10 mg       48.45       100       ✓ Neulactil         QUETIAPINE – Safety medicine; prescriber may determine dispensing frequency       Augusta       Verify and the company of				_	
Tab orodispersible 5 mg       2.42       28       ✓ Zypine ODT         Tab 10 mg       1.93       30       ✓ Zypine         Tab orodispersible 10 mg       2.89       28       ✓ Zypine ODT         PERICYAZINE – Safety medicine; prescriber may determine dispensing frequency       13.61       100       ✓ Neulactil         Tab 10 mg       48.45       100       ✓ Neulactil         QUETIAPINE – Safety medicine; prescriber may determine dispensing frequency       Very Company       Very Company         Tab 25 mg       2.36       90       ✓ Quetapel         Tab 100 mg       6.40       90       ✓ Quetapel         Tab 200 mg       10.97       90       ✓ Quetapel	· ·			_	
Tab 10 mg       1.93       30       ✓ Zypine         Tab orodispersible 10 mg       2.89       28       ✓ Zypine ODT         PERICYAZINE – Safety medicine; prescriber may determine dispensing frequency       13.61       100       ✓ Neulactil         Tab 10 mg       48.45       100       ✓ Neulactil         QUETIAPINE – Safety medicine; prescriber may determine dispensing frequency       Very Company       2.36       90       ✓ Quetapel         Tab 100 mg       6.40       90       ✓ Quetapel         Tab 200 mg       10.97       90       ✓ Quetapel	· ·				
Tab orodispersible 10 mg       2.89       28       ✓ Zypine ODT         PERICYAZINE – Safety medicine; prescriber may determine dispensing frequency       13.61       100       ✓ Neulactil         Tab 10 mg       48.45       100       ✓ Neulactil         QUETIAPINE – Safety medicine; prescriber may determine dispensing frequency       2.36       90       ✓ Quetapel         Tab 25 mg       2.36       90       ✓ Quetapel         Tab 100 mg       6.40       90       ✓ Quetapel         Tab 200 mg       10.97       90       ✓ Quetapel					
PERICYAZINE − Safety medicine; prescriber may determine dispensing frequency  Tab 2.5 mg				_	
Tab 2.5 mg       13.61       100       ✓ Neulactil         Tab 10 mg       48.45       100       ✓ Neulactil         QUETIAPINE – Safety medicine; prescriber may determine dispensing frequency       2.36       90       ✓ Quetapel         Tab 25 mg       6.40       90       ✓ Quetapel         Tab 100 mg       6.40       90       ✓ Quetapel         Tab 200 mg       10.97       90       ✓ Quetapel	, ,		28	•	Zypine ODT
Tab 10 mg       48.45       100       ✓ Neulactil         QUETIAPINE – Safety medicine; prescriber may determine dispensing frequency       2.36       90       ✓ Quetapel         Tab 25 mg       6.40       90       ✓ Quetapel         Tab 100 mg       6.40       90       ✓ Quetapel         Tab 200 mg       10.97       90       ✓ Quetapel	PERICYAZINE – Safety medicine; prescriber may determine d	ispensing frequency			
QUETIAPINE - Safety medicine; prescriber may determine dispensing frequency         Tab 25 mg       2.36       90       ✓ Quetapel         Tab 100 mg       6.40       90       ✓ Quetapel         Tab 200 mg       10.97       90       ✓ Quetapel	Tab 2.5 mg	13.61			
Tab 25 mg       2.36       90       ✓ Quetapel         Tab 100 mg       6.40       90       ✓ Quetapel         Tab 200 mg       10.97       90       ✓ Quetapel	Tab 10 mg	48.45	100	✓	Neulactil
Tab 25 mg       2.36       90       ✓ Quetapel         Tab 100 mg       6.40       90       ✓ Quetapel         Tab 200 mg       10.97       90       ✓ Quetapel	QUETIAPINE - Safety medicine; prescriber may determine dis	pensing frequency			
Tab 100 mg       6.40       90       ✓ Quetapel         Tab 200 mg       10.97       90       ✓ Quetapel			90	✓	Quetapel
Tab 200 mg10.97 90 <b>✓ Quetapel</b>				_	
				_	
	· ·		90		

	Subsidy		Fully	Brand or
	(Manufacturer's Price)	_	Subsidised	Generic
	\$	Per		Manufacturer
RISPERIDONE - Safety medicine; prescriber may determine dis	pensing 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
·			✓	Risperidone (Teva)
	3.68		✓	Risperidone
				Sandoz S29
Tab 2 mg	2.72	60	✓	Risperdal
··g				Risperidone (Teva)
	5.38			Risperidone
				Sandoz S29
Tab 3 mg	4.50	60	1	Risperdal
1 ab 0 mg		00		Risperidone (Teva)
	8.57			Risperidone
				Sandoz S29
Tab 4 mg	6.25	60	✓	Risperidone (Teva)
Oral liq 1 mg per ml		30 m		Risperon
ZIPRASIDONE – Safety medicine; prescriber may determine disp				
Cap 20 mg		60	✓	Zusdone
Cap 40 mg		60	1	Zusdone
Cap 60 mg		60		Zusdone
Cap 80 mg		60		Zusdone
ZUCLOPENTHIXOL HYDROCHLORIDE - Safety medicine; pres		e dis	nensina fre	quency
Tab 10 mg		100		Clopixol
1 4 4 1 4 11 11 1 1 1 1 1 1 1 1 1 1 1 1		100	•	o.op.xo.

# **Depot Injections**

ARIPIPRAZOLE – Special Authority see SA2395 below			
Safety medicine; prescriber may determine dispensir	ig irequency		
Inj 300 mg vial	273.56	1	Abilify Maintena
, ,			Abilify Maintena
			S29 S29
Inj 400 mg vial	341.96	1	Abilify Maintena
			Abilify Maintena
			S29 S29

# **⇒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 Either:
  - 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



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

continued...

- 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 dispensing frequency

Inj 20 mg per ml, 1 ml - Up to 5 inj available on a PSO13.14	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 dispensing frequency

Inj 50 mg per ml, 1 ml - Up to 5 inj available on a PSO28.3	39 Š	✓ Haldol
Inj 100 mg per ml, 1 ml - Up to 5 inj available on a PSO55.9	90 5	✓ Haldol Concentrate
, ,		✓ Haldol

Decanoas S29

#### OLANZAPINE - Special Authority see SA2313 below - Retail pharmacy

a) Safety medicine: prescriber may determine dispensing frequency

b) Note – no new patients to be initiated on olanzapine.

Inj 210 mg vial	252.00	1	✓ Zyprexa Relprevv
Inj 300 mg vial	414.00	1	✓ Zyprexa Relprevv
Inj 405 mg vial	504.00	1	✓ Zyprexa Relprevy

### ⇒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 dispens	ing frequency		
Inj 25 mg syringe	194.25	1	✓ Invega Sustenna
Inj 50 mg syringe	271.95	1	✓ Invega Sustenna
Inj 75 mg syringe		1	✓ Invega Sustenna
Inj 100 mg syringe		1	✓ Invega Sustenna
Inj 150 mg syringe		1	✓ 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:

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

continued...

- 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	nvega Trinza
Inj 263 mg syringe	nvega Trinza
	nvega Trinza
	nvega 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.

**⇒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:

nviolution

- 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

4	inklorytics		
BU	SPIRONE HYDROCHLORIDE		
*	Tab 5 mg13.95	100	<ul> <li>Buspirone Viatris</li> </ul>
	Buspirone Viatris to be Principal Supply on 1 December 2024		
*	Tab 10 mg12.50	100	<ul><li>Buspirone Viatris</li></ul>
	Buspirone Viatris to be Principal Supply on 1 December 2024		-

### **NERVOUS SYSTEM**

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
CLONAZEPAM - Safety medicine; prescriber may determine	dispensing frequency			
Tab 500 mcg		100	✓	Paxam
Tab 2 mg	10.78	100	1	Paxam
DIAZEPAM - Safety medicine; prescriber may determine disp	ensing frequency			
Tab 2 mg		500	✓	Arrow-Diazepam
Tab 5 mg		500	✓	Arrow-Diazepam
LORAZEPAM - Safety medicine; prescriber may determine di	spensing frequency			
Tab 1 mg		250	1	Ativan
Ativan to be Principal Supply on 1 February 2025				
Tab 2.5 mg	13.13	100	1	Ativan
Ativan to be Principal Supply on 1 February 2025				

# **Multiple Sclerosis Treatments**

### ⇒SA2274 Special Authority for Subsidy

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

#### Either:

- 1 All of the following:
  - 1.1 Diagnosis of multiple sclerosis (MS) meets the McDonald 2017 diagnostic criteria for MS and has been confirmed by a neurologist; and
  - 1.2 Patient has an EDSS score between 0 6.0; and
  - 1.3 Patient has had at least one significant attack of MS in the previous 12 months or two significant attacks in the past 24 months; and
  - 1.4 All of the following:
    - 1.4.1 Each significant attack must be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the attack, but the neurologist/physician must be satisfied that the clinical features were characteristic); and
    - 1.4.2 Each significant attack is associated with characteristic new symptom(s)/sign(s) or substantially worsening of previously experienced symptoms(s)/sign(s); and
    - 1.4.3 Each significant attack has lasted at least one week and has started at least one month after the onset of a previous attack (where relevant); and
    - 1.4.4 Each significant attack can be distinguished from the effects of general fatigue; and is not associated with a fever (T> 37.5°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

		NE	RVOUS SYSTEM
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features of a recent attack that occurred within the last 2 ye 1.6.5 A sign of that new inflammatory activity is new T2 lesions of 2 Patient has an active approval for ocrelizumab and does not have primary Note: Treatment on two or more funded multiple sclerosis treatments simultaned Renewal — (Multiple Sclerosis - dimethyl fumarate, fingolimod, glatiramer a beta-1-beta, natalizumab and teriflunomide) from any relevant practitioner. A had an EDSS score of 0 to 6.0 (inclusive) with or without the use of unilateral or be the patient has walked 100 metres or more with or without aids in the last six mor Note: Treatment on two or more funded multiple sclerosis treatments simultaned	compared y progres ously is n acetate, i Approvals bilateral a nths).	sive MS. ot permitted interferon to valid for 12 aids at any to ot permitted	I. peta-1-alpha, interferon months where patient has ime in the last six months (ie
DIMETHYL FUMARATE — Special Authority see SA2274 on the previous page –  a) Wastage claimable b) Note: Treatment on two or more funded multiple sclerosis treatments sin Cap 120 mg	·	usly is not p	ermitted. Tecfidera Tecfidera
FINGOLIMOD – Special Authority see SA2274 on the previous page – Retail phase) Wastage claimable b) Note: Treatment on two or more funded multiple sclerosis treatments sin Cap 0.5 mg	•	, ,	ermitted. <b>Gilenya</b>
GLATIRAMER ACETATE – Special Authority see SA2274 on the previous page Note: Treatment on two or more funded multiple sclerosis treatments simulta Inj 40 mg prefilled syringe		is not perm	nitted. <u>Copaxone</u>
INTERFERON BETA-1-ALPHA — Special Authority see SA2274 on the previous  Note: Treatment on two or more funded multiple sclerosis treatments simults Inj 6 million iu prefilled syringe		is not perm	
INTERFERON BETA-1-BETA – Special Authority see SA2274 on the previous p Note: Treatment on two or more funded multiple sclerosis treatments simulta Inj 8 million iu per 1 ml		is not perm	
NATALIZUMAB – Special Authority see SA2274 on the previous page – Retail p Note: Treatment on two or more funded multiple sclerosis treatments simulta Inj 20 mg per ml, 15 ml vial		is not perm	nitted. <b>Tysabri</b>
TERIFLUNOMIDE – Special Authority see SA2274 on the previous page – Retain a) Wastage claimable b) Note: Treatment on two or more funded multiple sclerosis treatments sin Tab 14 mg		usly is not p	ermitted. Teriflunomide Sandoz
(Aubagio Tab 14 mg to be delisted 1 April 2025)		•	Aubagio
Multiple Sclerosis Treatments - Other			



Subsidy (Manufacturer's Price) Fully Subsidised Per

Brand or Generic Manufacturer

⇒SA2273 Special Authority for Subsidy

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

#### Either:

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

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

**Renewal** — (Multiple Sclerosis - ocrelizumab) from any relevant practitioner. Approvals valid for 12 months where patient has had an EDSS score of 0 to 6.0 (inclusive) with or without the use of unilateral or bilateral aids at any time in the last six months (ie the patient has walked 100 metres or more with or without aids in the last six months).

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

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

All of the following:

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

### **NERVOUS SYSTEM**

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

- a) Restricted to patients aged 18 years or under.
- b) Vigisom to be Principal Supply on 1 December 2024

#### ⇒SA1666 Special Authority for Subsidy

**Initial application** only from a psychiatrist, paediatrician, neurologist, respiratory specialist or medical practitioner on the recommendation of a psychiatrist, paediatrician, neurologist or respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has been diagnosed with persistent and distressing insomnia secondary to a neurodevelopmental disorder (including, but not limited to, autism spectrum disorder or attention deficit hyperactivity disorder)\*; and
- 2 Behavioural and environmental approaches have been tried and were unsuccessful, or are inappropriate; and
- 3 Funded modified-release melatonin is to be given at doses no greater than 10 mg per day; and
- 4 Patient is aged 18 years or under\*.

**Renewal** only from a psychiatrist, paediatrician, neurologist, respiratory specialist or medical practitioner on the recommendation of a psychiatrist, paediatrician, neurologist or respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient is aged 18 years or under\*; and
- 2 Patient has demonstrated clinically meaningful benefit from funded modified-release melatonin (clinician determined); and
- 3 Patient has had a trial of funded modified-release melatonin discontinuation within the past 12 months and has had a recurrence of persistent and distressing insomnia; and
- 4 Funded modified-release melatonin is to be given at doses no greater than 10 mg per day.

Note: Indications marked with \* are unapproved indications.

MIDAZOLAM – Safety medicine; prescriber may determine disper Inj 1 mg per ml, 5 ml ampoule		10	✓ Midazolam-Baxter
Inj 1 mg per ml, 5 ml plastic ampoule – Up to 10 inj available on a PSO	29.90	10	✓ Pfizer
On a PSO for status epilepticus use only. PSO must be e	endorsed for stati	us epilepticu	us use only.
Inj 5 mg per ml, 1 ml plastic ampoule - Up to 10 inj available			
on a PSO	22.50	10	✓ Midazolam-Pfizer
On a PSO for status epilepticus use only. PSO must be e	endorsed for stati	us epilepticu	us use only.
Inj 5 mg per ml, 3 ml ampoule	4.75	5	✓ Midazolam-Baxter
Inj 5 mg per ml, 3 ml plastic ampoule - Up to 5 inj available of	on		
a PSO		5	✓ Pfizer
On a PSO for status epilepticus use only. PSO must be e	endorsed for state	us epilepticu	us use only.
PHENOBARBITONE SODIUM - Special Authority see SA1386 or	n the next page -	- Retail phai	rmacy
Inj 200 mg per ml, 1 ml ampoule	113.37	10	✓ Max Health S29



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

### ⇒SA1386 Special Authority for Subsidy

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

#### Both:

- 1 For the treatment of terminal agitation that is unresponsive to other agents; and
- 2 The applicant is part of a multidisciplinary team working in palliative care.

TEMAZEPAM - Safety medicine;	prescriber may	determine	dispensing frequency
Toh 10 mg			1 40

25 Normison Tab 10 mg ......1.40

ZOPICLONE - Safety medicine: prescriber may determine dispensing frequency 

500 ✓ Zopiclone Actavis Zopiclone Actavis to be Principal Supply on 1 February 2025

### Spinal Muscular Atrophy

NUSINERSEN - PCT only - Special Authority see SA2174 below Spinraza Inj 12 mg per 5 ml vial ......120,000.00

#### ⇒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 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 nusinersen; and
- 3 Nusinersen not to be administered in combination other SMA disease modifying treatments or gene therapy.

#### RISDIPLAM - [Xpharm] - Special Authority see SA2203 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 Evrvsdi

#### ⇒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

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic \$ Per ✔ Manufacturer
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- 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 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	✓ APO-Atomoxetine
Cap 80 mg	65.20	28	✓ APO-Atomoxetine
Cap 100 mg	65.71	28	✓ APO-Atomoxetine
DEXAMFETAMINE SULFATE – Special Authority see SA1149 be a) Only on a controlled drug form b) Safety medicine; prescriber may determine dispensing free		ırmacy	
Tab 5 mg	, ,	100	✓ Noumed
·			Dexamfetamine

#### ⇒SA1149 Special Authority for Subsidy

Initial application — (ADHD in patients 5 or over) only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

All of the following:

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

Initial application — (ADHD in patients under 5) only from a paediatrician or psychiatrist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 ADHD (Attention Deficit and Hyperactivity Disorder) patients under 5 years of age; and
- 2 Diagnosed according to DSM-IV or ICD 10 criteria.

**Initial application** — (Narcolepsy) only from a neurologist or respiratory specialist. Approvals valid for 24 months where the patient suffers from narcolepsy.

Renewal — (ADHD in patients 5 or over) only from a paediatrician, psychiatrist or medical practitioner on the recommendation



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

of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 Fither:
  - 2.1 Applicant is a paediatrician or psychiatrist; or
  - 2.2 Applicant is a medical practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing.

**Renewal — (ADHD in patients under 5)** only from a paediatrician or psychiatrist. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.

**Renewal** — (Narcolepsy) only from a neurologist or respiratory specialist. Approvals valid for 24 months where the treatment remains appropriate and the patient is benefiting from treatment.

METHYLPHENIDATE HYDROCHLORIDE - Special Authority see SA1964 below - Retail pharmacy

- a) Only on a controlled drug form
- b) Safety medicine; prescriber may determine dispensing frequency ✓ Rubifen Tab immediate-release 5 mg.......3.20 30 ✓ Ritalin 30 ✓ Rubifen Tab extended-release 18 mg......7.75 ✓ Methylphenidate ER 30 - Teva 30 ✓ Rubifen 30 ✓ Rubifen SR ✓ Methylphenidate ER 30 - Teva ✓ Methylphenidate ER - Teva Tab extended-release 54 mg.......22.25 ✓ Methylphenidate ER 30 - Teva

### ⇒SA1964 Special Authority for Subsidy

Initial application — (ADHD in patients 5 or over) only from a paediatrician, psychiatrist, medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

All of the following:

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

Initial application — (ADHD in patients under 5) only from a paediatrician or psychiatrist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 ADHD (Attention Deficit and Hyperactivity Disorder) patients under 5 years of age; and
- 2 Diagnosed according to DSM-IV or ICD 10 criteria.

**Initial application** — (Narcolepsy\*) only from a neurologist or respiratory specialist. Approvals valid for 24 months where the patient suffers from narcolepsy.

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

Renewal — (ADHD in patients 5 or over) only from a paediatrician, psychiatrist, medical practitioner on the recommendation of

#### **NERVOUS SYSTEM**

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

continued...

a paediatrician or psychiatrist (in writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 Either:
  - 2.1 Applicant is a paediatrician or psychiatrist; or
  - 2.2 Applicant is a medical practitioner or nurse practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing.

Renewal — (ADHD in patients under 5) only from a paediatrician or psychiatrist. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.

Renewal — (Narcolepsy\*) only from a neurologist or respiratory specialist. Approvals valid for 24 months where the treatment remains appropriate and the patient is benefiting from treatment.

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

METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE - Special Authority see SA2305 below - Retail pharmacy

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

Tab extended-release 18 mg	58.96	30	Concerta
Tab extended-release 27 mg	65.44	30	<ul><li>Concerta</li></ul>
Tab extended-release 36 mg		30	✓ Concerta
Tab extended-release 54 mg		30	✓ Concerta
Cap modified-release 10 mg	15.60	30	Ritalin LA
Cap modified-release 20 mg	20.40	30	Ritalin LA
Cap modified-release 30 mg		30	Ritalin LA
Cap modified-release 40 mg		30	Ritalin LA



Subsidy (Manufacturer's Price)	Sub	Fully	Brand or Generic
 <b>`</b> \$	Per	✓	Manufacturer

#### ⇒SA2305 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 for 24 months for applications meeting the following criteria:

All of the following:

- 1 ADHD (Attention Deficit and Hyperactivity Disorder); and
- 2 Diagnosed according to DSM-IV or ICD 10 criteria; and
- 3 Either
  - 3.1 Applicant is a paediatrician or psychiatrist; or
  - 3.2 Applicant is a medical practitioner or nurse practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing; and
- 4 Either:
  - 4.1 Patient is taking a currently subsidised formulation of methylphenidate hydrochloride (immediate-release or sustained-release) which has not been effective due to significant administration and/or difficulties with adherence; or
  - 4.2 There is significant concern regarding the risk of diversion or abuse of immediate-release methylphenidate hydrochloride.

Renewal — (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 for 24 months for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 Fither:
  - 2.1 Applicant is a paediatrician or psychiatrist; or
  - 2.2 Applicant is a medical practitioner or nurse practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing.

60

✓ Modavigil

Tab 100 mg ......29.13

MODAFINIL – Special Authority see SA1999 below – Retail pharmacy

#### ⇒SA1999 Special Authority for Subsidy

**Initial application** only from a neurologist or respiratory specialist. Approvals valid for 24 months for applications meeting the following criteria:

All of the following:

- 1 The patient has a diagnosis of narcolepsy and has excessive daytime sleepiness associated with narcolepsy occurring almost daily for three months or more; and
- 2 Either:
  - 2.1 The patient has a multiple sleep latency test with a mean sleep latency of less than or equal to 10 minutes and 2 or more sleep onset rapid eye movement periods; or
  - 2.2 The patient has at least one of: cataplexy, sleep paralysis or hypnagogic hallucinations; and
- 3 Either:
  - 3.1 An effective dose of a subsidised formulation of methylphenidate or dexamfetamine has been trialled and discontinued because of intolerable side effects; or
  - 3.2 Methylphenidate and dexamfetamine are contraindicated.

**Renewal** only from a neurologist or respiratory specialist. Approvals valid for 24 months where the treatment remains appropriate and the patient is benefiting from treatment.

# Treatments for Dementia DONEPEZIL HYDROCHLORIDE

*	Tab 5 mg	84	✓ Ipca-Donepezil
	Tab 10 mg5.50	84	✓ Ipca-Donepezil

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
RIVASTIGMINE - Special Authority see SA1488 below - Retail	oharmacy			
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
(Exelon Patch 5 Patch 4.6 mg per 24 hour to be delisted 1 March	90.00		1	Exelon Patch 10

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

✓ Buprenorphine Naloxone BNM

Tab sublingual 8 mg with naloxone 2 mg ......34.00

✓ Buprenorphine Naloxone BNM

28

#### ⇒SA1203 Special Authority for Subsidy

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

All of the following:

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

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

All of the following:

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

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

All of the following:

- 1 Patient is opioid dependent; and
- 2 Patient has previously trialled but failed detoxification with buprenorphine with naloxone with relapse back to opioid use



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

continued...

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 mg1	15.00	30	✓ <u>Zyban</u>
DISULFIRAM			
Tab 200 mg23	36.40	100	✓ Antabuse
NALTREXONE HYDROCHLORIDE - Special Authority see SA1408 bel	low – Retail ph	armacy	
Tab 50 mg	77.77	28	✓ Naltrexone AOP S29
3	33.33	30	✓ Naltraccord
10	02.60		✓ Naltrexone Max
			Health S29
13	38.88	50	✓ Revia S29

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

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

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

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

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

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

#### NICOTINE

- a) Nicotine will not be funded in amounts less than 4 weeks of treatment.
- b) Note: Direct Provision by a pharmacist permitted under the provisions in Part I of Section A. Patch 7 mg - Up to 28 patch available on a PSO ......19.62 ✓ Habitrol 28 Patch 14 mg - Up to 28 patch available on a PSO ......21.57 28 ✓ Habitrol Patch 14 mg for direct distribution only - [Xpharm]......12.49 7 ✓ Habitrol Patch 21 mg - Up to 28 patch available on a PSO ......24.72 28 ✓ Habitrol Patch 21 mg for direct distribution only - [Xpharm]......13.19 7 ✓ Habitrol Lozenge 1 mg - Up to 216 loz available on a PSO......22.53 216 ✓ Habitrol Lozenge 1 mg for direct distribution only - [Xpharm] ......12.89 36 ✓ Habitrol Lozenge 2 mg - Up to 216 loz available on a PSO......24.68 216 ✓ Habitrol Lozenge 2 mg for direct distribution only - [Xpharm] .......13.25 36 ✓ Habitrol Gum 2 mg (Fruit) - Up to 204 piece available on a PSO ......23.02 204 ✓ Habitrol ✓ Habitrol 96 Gum 2 mg (Mint) - Up to 204 piece available on a PSO......23.02 204 ✓ Habitrol Gum 2 mg (Mint) for direct distribution only - [Xpharm]......17.57 ✓ Habitrol 96 Gum 4 mg (Fruit) - Up to 204 piece available on a PSO ......25.98 204 ✓ Habitrol Gum 4 mg (Fruit) for direct distribution only - [Xpharm]...........23.87 ✓ Habitrol 96 Gum 4 mg (Mint) - Up to 204 piece available on a PSO......25.98 204 ✓ Habitrol Gum 4 mg (Mint) for direct distribution only - [Xpharm].....23.87 ✓ Habitrol

VARENICLINE TARTRATE - Special Authority see SA1845 on the next page - Retail pharmacy

- a) A maximum of 12 weeks' varenicline will be subsidised on each Special Authority approval, including the starter pack
- b) Varenicline will not be funded in amounts less than 4 weeks of treatment.
- c) The 6-month time period in which a patient can receive a funded 12-week course of varenicline tartrate starts from the date the Special Authority is approved.

Tab 0.5 mg × 11 and 1 mg × 4216.67	53 OP	✓ Varenicline Pfizer
Tab 1 mg17.62	56	✓ Varenicline Pfizer

#### ⇒SA1845 Special Authority for Subsidy

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

- 1 Short-term therapy as an aid to achieving abstinence in a patient who has indicated that they are ready to cease smoking; and
- 2 The patient is part of, or is about to enrol in, a comprehensive support and counselling smoking cessation programme, which includes prescriber or nurse monitoring; and
- 3 Either:
  - 3.1 The patient has tried but failed to quit smoking after at least two separate trials of nicotine replacement therapy, at least one of which included the patient receiving comprehensive advice on the optimal use of nicotine replacement therapy; or
  - 3.2 The patient has tried but failed to 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

### **NERVOUS SYSTEM**

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\$	Per	Manufacturer

#### continued...

- 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
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### **Chemotherapeutic Agents**

#### Alkylating Agents

BENDAMUSTINE HYDROCHLORIDE - PCT only -	- Specialist - Special Authority	see SA2398	3 below
Inj 25 mg vial	50.05	1	✓ Bendamustine Sandoz
	77.00		✓ Ribomustin
Inj 100 mg vial	200.20	1	✓ Bendamustine Sandoz
	308.00		✓ Ribomustin
Inj 1 mg for ECP	3.23	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)	Subsi	idised	Generic	
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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.

PURIL EAN DOT Potail pharmacy Charielist

BUSULFAN – PCT – Retail pharmacy-Specialist Tab 2 mg	89 25	100	✓ Myleran
CARBOPLATIN – PCT only – Specialist		100	- mylcrun
Inj 10 mg per ml, 45 ml vial	25.72	1	✓ Carboplatin Accord
ing to mg per mi, 45 mi viai	32.59	1	✓ DBL Carboplatin
			•
	45.20		✓ Carboplatin Ebewe
	48.50		✓ Carbaccord
Inj 1 mg for ECP		1 mg	✓ Baxter
(Carboplatin Ebewe Inj 10 mg per ml, 45 ml vial to be delisted	1 December 2024	()	
CARMUSTINE - PCT only - Specialist			
Inj 100 mg vial	710.00	1	✓ BiCNU
, 3			✓ BiCNU S29 S29
			✓ Novadoz S29
Inj 100 mg for ECP	710.00	100 mg OP	✓ Baxter
CHLORAMBUCIL - PCT - Retail pharmacy-Specialist			
Tab 2 mg	29.06	25	✓ Leukeran FC
CISPLATIN - PCT only - Specialist			
Inj 1 mg per ml, 50 ml vial	15.00	1	✓ Cisplatin Ebewe
Inj 1 mg per ml, 100 ml vial		1	✓ Cisplatin Accord
,	21.00	•	✓ Cisplatin Ebewe
	29.66		✓ DBL Cisplatin
Ini 1 mg for ECD		1 ma	✓ Baxter
Inj 1 mg for ECP		1 mg	▼ Daxiei

	Subsidy		Fully	
	(Manufacturer's Price) \$	Per	Subsidised	d Generic Manufacturer
2VOLORUGORIJAMIRE	Ψ	1 61		Wallulacturei
CYCLOPHOSPHAMIDE	145.00	ΕO	./	Cycleney
Tab 50 mg – PCT – Retail pharmacy-Specialist	145.00	50	•	Cyclonex
Cyclonex to be Principal Supply on 1 December 2024	47.46	4	./	Endoxan
Inj 1 g vial - PCT - Retail pharmacy-Specialist	47.46	1 6		Cytoxan
Endoxan to be Principal Supply on 1 February 2025	127.00	0	•	Суюхан
Inj 2 g vial – PCT only – Specialist	05.06	1	_	Endoxan
Endoxan to be Principal Supply on 1 February 2025	95.00	'	•	LIIUUXAII
Inj 1 mg for ECP – PCT only – Specialist	0.05	1 ma	_	Baxter
	0.03	1 mg	•	Daxiei
FOSFAMIDE – PCT only – Specialist				
lnj 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 10 mg	132.59	20	•	CeeNU
Cap 40 mg	399.15	20	•	CeeNU
	880.00		•	Medac S29
CeeNU Cap 10 mg to be delisted 1 January 2025) CeeNU Cap 40 mg to be delisted 1 January 2025) MELPHALAN				
	40.70	25	./	Alkeran
Tab 2 mg - PCT - Retail pharmacy-Specialist				
Inj 50 mg - PCT only - Specialist	48.25	1		Megval \$29
	07.00			Melpha
	67.80		•	Alkeran
DXALIPLATIN - PCT only - Specialist				
Inj 100 mg vial	25.01	1	•	Oxaliplatin Actavis 100
	110.00		•	Oxaliplatin Ebewe
Inj 5 mg per ml, 20 ml vial	33.35	1		<b>Alchemy Oxaliplatin</b>
	46.32			Oxaliplatin Accord
Inj 1 mg for ECP	0.35	1 mg	•	Baxter
THIOTEPA - PCT only - Specialist				
Inj 15 mg vial	CBS	1	1	Bedford S29
		•	_	Max Health S29
				THIO-TEPA \$29
	200 00			
In: 400 mm	398.00	_		Tepadina
Inj 100 mg vial		1		Max Health S29
	1,800.00		•	Tepadina
Antimetabolites				
AZACITIDINE - PCT only - Specialist - Special Authority see S	SA2141 on the next pa	age		
Inj 100 mg vial		1	/	Azacitidine Dr
, , , , , , , , , , , , , , , , , , , ,	<del></del>	•		Reddy's
				Baxter

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

#### **⇒SA2141** Special Authority for Subsidy

**Initial application** only from a haematologist or medical practitioner on the recommendation of a haematologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 The patient has International Prognostic Scoring System (IPSS) intermediate-2 or high risk myelodysplastic syndrome: or
  - 1.2 The patient has chronic myelomonocytic leukaemia (10%-29% marrow blasts without myeloproliferative disorder); or
  - 1.3 The patient has acute myeloid leukaemia with 20-30% blasts and multi-lineage dysplasia, according to World Health Organisation Classification (WHO); and
- 2 The patient has performance status (WHO/ECOG) grade 0-2; and
- 3 The patient has an estimated life expectancy of at least 3 months.

**Renewal** only from a haematologist or medical practitioner on the recommendation of a haematologist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

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

	Subsidy	,	Fully	
(	Manufacturer's Price \$	e) Per	Subsidised	
CALCIUM FOLINATE	<u> </u>			
Tab 15 mg - PCT - Retail pharmacy-Specialist	135.33	10	/	DBL Leucovorin
Tab to mg To Thomas pharmacy opposition	100.00		-	Calcium
Inj 3 mg per ml, 1 ml - PCT - Retail pharmacy-Specialist	17.10	5	/	Hospira
Inj 10 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specialist		1		Calcium Folinate
				Sandoz
			1	Calcium Folinate
				Sandoz S29 S29
	36.48	5	1	Eurofolic S29
Inj 50 mg - PCT - Retail pharmacy-Specialist	72.80	10	1	Leucovorin
				Pharmacia \$29
Inj 10 mg per ml, 10 ml vial - PCT only - Specialist	9.49	1	/	Calcium Folinate
ing to the post time, to this time.		•		Sandoz
	47.45	5	/	Eurofolic \$29
Inj 100 mg - PCT only - Specialist		1		Calcium Folinate
, 3				Ebewe
	94.90	10	1	Leucovorin
				Pharmacia \$29
Inj 300 mg - PCT only - Specialist	21.55	1	•	Leucovorin DBL S29
	22.51		_	Calcium Folinate
	22.01		_	Ebewe
Inj 10 mg per ml, 35 ml vial - PCT only - Specialist	25 14	1	/	Calcium Folinate
ing to mg por mi, so mi that it or only opposition		•	_	Sandoz
			/	Calcium Folinate
				Sandoz S29 S29
Inj 1 g - PCT only - Specialist	67 51	1	_	Calcium Folinate
iiij i g = i O i Oiliy = Specialist	07.51	'	•	Ebewe
Inj 10 mg per ml, 100 ml vial - PCT only - Specialist	72.00	1	_	Calcium Folinate
ing to mg per mi, too mi viai in on only openiaist	72.00	'	•	Sandoz
			/	Eurofolic \$29
Inj 1 mg for ECP - PCT only - Specialist	0.06	1 mg	_	Baxter
CAPECITABINE - Retail pharmacy-Specialist		9		
Tab 150 mg	0.90	60	_	Capecitabine Viatris
Tab 500 mg		120		Capecitabine Viatris
•		120	•	Oapecitabilie Viatrio
CLADRIBINE – PCT only – Specialist	740.00		,	I Italiano
Inj 2 mg per ml, 5 ml		1		Litak S29
Inj 1 mg per ml, 10 ml		1 0 mg (		Leustatin Baxter
	/49.90 I	o mg (	J⊦ <b>∀</b>	Daxiei
CYTARABINE	470.00	_	,	D#
Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specialist	14/2.00	5	•	Pfizer
Inj 100 mg per ml, 20 ml vial – PCT – Retail	40.00		,	Outsout law DDI
pharmacy-Specialist	48.80	1		Cytarabine DBL Pfizer
Ini 1 mg for ECD DCT only Chapitalist	0.20	10 m	_	Pfizer S29 S29
Inj 1 mg for ECP - PCT only - Specialist		10 mg	,	Baxter Baxter
Inj 100 mg intrathecal syringe for ECP - PCT only - Specialist	194.40 1	00 mg	UP •	Daxler

	Subsidy		Fully	Brand or
	(Manufacturer's Pri		idised	Generic
	\$	Per	<b>✓</b>	Manufacturer
FLUDARABINE PHOSPHATE				
Tab 10 mg - PCT - Retail pharmacy-Specialist	412.00	20	1	Fludara Oral
Inj 50 mg vial - PCT only - Specialist	126.80	1	✓	Fludarabine
				Sagent S29
	634.00	5	1	Fludarabine Ebewe
Inj 50 mg for ECP - PCT only - Specialist	126.80	50 mg OP	1	Baxter
FLUOROURACIL		Ü		
Inj 50 mg per ml, 20 ml vial – PCT only – Specialist	10.51	1	1	Fluorouracil Accord
Inj 50 mg per ml, 50 ml vial – PCT only – Specialist		1	1	Fluorouracil Accord
Inj 50 mg per ml, 100 ml vial - PCT only - Specialist	19.36	1	1	Fluorouracil Accord
Inj 1 mg for ECP - PCT only - Specialist		100 mg	<b>✓</b>	Baxter
GEMCITABINE HYDROCHLORIDE - PCT only - Specialist				
Inj 43.3 mg per ml (equivalent to 38 mg per ml gemcitabine)	١.			
26.3 ml vial		1	1	DBL Gemcitabine
Inj 1 g		1	1	Gemcitabine Ebewe
Inj 1 mg for ECP		1 mg	1	Baxter
IRINOTECAN HYDROCHLORIDE - PCT only - Specialist		ŭ		
Inj 20 mg per ml, 5 ml vial	52.57	1	1	Accord
, =09 po, 0	71.44	•	<b>✓</b>	rinotecan Actavis
				100
	100.00		1	rinotecan-Rex
Inj 1 mg for ECP	0.54	1 mg	1	Baxter
MERCAPTOPURINE		ŭ		
Tab 50 mg - PCT - Retail pharmacy-Specialist	25.90	25	1	Puri-nethol
Oral suspension 20 mg per ml — Retail pharmacy-Specialis			-	
Special Authority see SA1725 below		100 ml OP	1	Allmercap

### **⇒SA1725** Special Authority for Subsidy

Initial application only from a paediatric haematologist or paediatric oncologist. Approvals valid for 12 months where the patient requires a total dose of less than one full 50 mg tablet per day.

**Renewal** only from a paediatric haematologist or paediatric oncologist. Approvals valid for 12 months where patient still requires a total dose of less than one full 50 mg tablet per day.

	sidy	Fully	
	ırer's Price)	Subsidised Per 🗸	
	рг	EI •	Ivianulacturei
ETHOTREXATE	20 6		T
Tab 2.5 mg - PCT - Retail pharmacy-Specialist	30 8	0	Trexate
Trexate to be Principal Supply on 1 December 2024	10 0		Tueste
Tab 10 mg - PCT - Retail pharmacy-Specialist26.4	10 8	0	Trexate
Trexate to be Principal Supply on 1 December 2024	\r	- ,	Mathatususta DDI
Inj 2.5 mg per ml, 2 ml - PCT - Retail pharmacy-Specialist56.0	05	_	Methotrexate DBL
		•	Methotrexate DBL
			S29 S29
Inj 7.5 mg prefilled syringe29.	17	1	Methotrexate
			Sandoz
Methotrexate Sandoz to be Principal Supply on 1 February 2025			
Inj 10 mg prefilled syringe19.0	09	1 🗸	Methotrexate
			Sandoz
Methotrexate Sandoz to be Principal Supply on 1 February 2025			
Inj 15 mg prefilled syringe24.5	53	1 🗸	Methotrexate
			Sandoz
Methotrexate Sandoz to be Principal Supply on 1 February 2025			
F Inj 20 mg prefilled syringe	64	1 🗸	Methotrexate
, 31			Sandoz
Methotrexate Sandoz to be Principal Supply on 1 February 2025			
Inj 25 mg prefilled syringe	72	1 🗸	Methotrexate
	_	•	Sandoz
Methotrexate Sandoz to be Principal Supply on 1 February 2025			
Inj 30 mg prefilled syringe	00	1 🗸	Methotrexate
ing oo ing promiod synings			Sandoz
Methotrexate Sandoz to be Principal Supply on 1 February 2025			Junuoz
Inj 25 mg per ml, 2 ml vial – PCT – Retail pharmacy-Specialist30.0	00	5	Methotrexate DBL
inj 25 mg per mi, 2 mi viar – 1 01 – Netali priamacy-opecialist	,	•	Onco-Vial
Inj 25 mg per ml, 20 ml vial – PCT – Retail pharmacy-Specialist45.0	nn	1	DBL Methotrexate
inj 25 mg per mi, 20 mi viar – 1 01 – Netali pharmacy-opecialist45.0	00	. •	Onco-Vial
Ini 100 mg per ml. 10 ml – PCT – Retail pharmacy-Specialist25.0	20	1	Methotrexate Ebewe
, , , . , . , . , . ,	JU	. •	Menionexale Ebewe
Finj 100 mg per ml, 50 ml vial – PCT – Retail	20	. ,	Mathatuaret - Flee
pharmacy-Specialist		_	Methotrexate Ebewe
Inj 1 mg for ECP – PCT only – Specialist	טט 1 . 20 -	3	Baxter
Finj 5 mg intrathecal syringe for ECP - PCT only - Specialist4.7	13 5 m	g OP 🗸	Baxter
EMETREXED - PCT only - Specialist			
Inj 100 mg vial8.9	99	1 🗸	Pemetrexed-AFT
60.8		✓	Juno Pemetrexed
Inj 500 mg vial29.9	99	1 🗸	Pemetrexed-AFT
217.7		✓	Juno Pemetrexed
Inj 1 mg for ECP0.	11 1	mg 🗸	Baxter
HIOGUANINE - PCT - Retail pharmacy-Specialist			
Tab 40 mg	31 2	5	Lanvis
	-	-	
Other Cytotoxic Agents			
MSACRINE – PCT only – Specialist			
• •	20		Amaidine 200
Inj 50 mg per ml, 1.5 ml ampoule			Amsidine S29
4,736.0		_	Amsidine S29
Inj 75 mg1,250.0	20	5	AmsaLyo S29

<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 F	Price) Subs Per	sidised Generic  Manufacturer
		Per	Manufacturer
NAGRELIDE HYDROCHLORIDE – PCT – Retail pharmacy-			4
Cap 0.5 mg	1,175.87	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 OP	✓ Baxter
LEOMYCIN SULPHATE - PCT only - Specialist			
Inj 15,000 iu, vial	185.16	1	<ul> <li>DBL Bleomycin</li> </ul>
			Sulfate
Inj 1,000 iu for ECP	14.32	1,000 iu	✓ Baxter
ORTEZOMIB - PCT only - Specialist - Special Authority see	SA2355 below		
Inj 3.5 mg vial	74.93	1	✓ DBL Bortezomib
Inj 1 mg for ECP		1 mg	✓ Baxter
Special Authority for Subsidy		3	
itial application — (plasma cell dyscrasia) from any releva	ant practitioner A	nnrovale valid	without further renewal unle
otified where the patient has plasma cell dyscrasia, not includi			
	ing waidenstronn	macrogiobalina	cinia, requiring treatment.
ACARBAZINE – PCT only – Specialist Inj 200 mg vial	70 11	1	✓ DBL Dacarbazine
Inj 200 mg for ECP		200 mg OP	✓ Baxter
	12.11	200 Hig OF	▼ Daxlei
ACTINOMYCIN [ACTINOMYCIN D] - PCT only - Specialist			
Inj 0.5 mg vial		1	✓ Cosmegen
Inj 0.5 mg for ECP	255.00	0.5 mg OP	✓ Baxter
AUNORUBICIN - PCT only - Specialist			
Inj 2 mg per ml, 10 ml	171.93	1	✓ Pfizer
Inj 20 mg for ECP	171.93	20 mg OP	✓ Baxter
OCETAXEL - PCT only - Specialist			
Inj 20 mg	48.75	1	✓ Docetaxel Sandoz
Inj 10 mg per ml, 8 ml vial		1	✓ DBL Docetaxel
Inj 20 mg per ml, 4 ml vial	26.95	1	✓ Docetaxel
,			Accord \$29
Inj 80 mg	195.00	1	✓ Docetaxel Sandoz
Inj 1 mg for ECP		1 mg	✓ Baxter
OXORUBICIN 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
11 2 111g per 1111, 20 1111 via	17.00	'	✓ Arrow-Doxorubicin
Inj 2 mg per ml, 50 ml vial		1	✓ Doxorubicin Ebewe
Inj 2 mg per ml, 100 ml vial		i	✓ Arrow-Doxorubicin
inj 2 mg por mi, 100 mi viar	69.99	•	✓ Doxorubicin Ebewe
Inj 1 mg for ECP		1 mg	✓ Baxter
		9	
PIRUBICIN HYDROCHLORIDE – PCT only – Specialist	05.00	4	✓ Epirubicin Ebewe
Inj 2 mg per ml, 5 ml vial		1	
Inj 2 mg per ml, 25 ml vial Inj 2 mg per ml, 100 ml vial		1 1	<ul><li>✓ Epirubicin Ebewe</li><li>✓ Epirubicin Ebewe</li></ul>
IIII & IIIU DEI IIII. 100 IIII VIAI		-	✓ Epirubicin Ebewe ✓ Baxter
		1 mg	- Daxiei
Inj 1 mg for ECP			
Inj 1 mg for ECP TOPOSIDE			
Inj 1 mg for ECP TOPOSIDE Cap 50 mg – PCT – Retail pharmacy-Specialist	340.73	20	✓ Vepesid
Inj 1 mg for ECP TOPOSIDE Cap 50 mg - PCT - Retail pharmacy-Specialist Cap 100 mg - PCT - Retail pharmacy-Specialist	340.73 340.73	10	✓ Vepesid
Inj 1 mg for ECP TOPOSIDE Cap 50 mg – PCT – Retail pharmacy-Specialist	340.73 340.73 alist7.90		

	Subsidy (Manufacturer's Price)	) Si	Fully ubsidised	Brand or Generic	
	\$	Per	1	Manufacturer	
ETOPOSIDE PHOSPHATE - PCT only - Specialist					
Inj 100 mg (of etoposide base)	40.00	1	<b>√</b> E	topophos	
Inj 1 mg (of etoposide base) for ECP	0.47	1 mg	<b>✓</b> E	Baxter	
HYDROXYUREA [HYDROXYCARBAMIDE] - PCT - Retail phar	macy-Specialist				
Cap 500 mg	20.72	100	✓ [	<u>Devatis</u>	
IBRUTINIB - Special Authority see SA2168 below - Retail pharm	nacy				
Tab 140 mg	3,217.00	30	✓ li	mbruvica	
Tab 420 mg	9,652.00	30	✓ li	mbruvica	

#### ⇒SA2168 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 Patient has chronic lymphocytic leukaemia (CLL) requiring therapy; and
- 2 Patient 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 patient has 17p deletion or TP53 mutation; and
    - 4.1.2 Patient has experienced intolerable side effects with venetoclax monotherapy; or
  - 4.2 All of the following:
    - 4.2.1 Patient has received at least one prior immunochemotherapy for CLL; and
    - 4.2.2 Patient's CLL has relapsed within 36 months of previous treatment; and
    - 4.2.3 Patient has experienced intolerable side effects with venetoclax in combination with rituximab regimen; or
  - 4.3 Patient's CLL is refractory to or has relapsed within 36 months of a venetoclax regimen.

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

#### Both:

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

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 (REVLIMID) - Retail pharmacy-Specialist - Special Authority see SA2047 on the next page Wastage claimable

Cap 5 mg	5,122.76	28	✓ Revlimid
Cap 10 mg		28	✓ Revlimid
Cap 15 mg	7,239.18	28	✓ Revlimid
Can 25 mg	7 627 00	21	✓ Revlimid

(Revlimid Cap 5 mg to be delisted 1 February 2025)

(Revlimid Cap 10 mg to be delisted 1 February 2025)

(Revlimid Cap 15 mg to be delisted 1 February 2025)

(Revlimid Cap 25 mg to be delisted 1 February 2025)

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

#### ⇒SA2047 Special Authority for Subsidy

Initial application — (Relapsed/refractory disease) only from a haematologist or any relevant practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Patient has relapsed or refractory multiple myeloma with progressive disease; and
- 2 Patient has not previously been treated with lenalidomide; and
- 3 Either
  - 3.1 Lenalidomide to be used as third line\* treatment for multiple myeloma; or
  - 3.2 Both:
    - 3.2.1 Lenalidomide to be used as second line treatment for multiple myeloma; and
    - 3.2.2 The patient has experienced severe (grade 3 or higher), dose limiting, peripheral neuropathy with either bortezomib or thalidomide that precludes further treatment with either of these treatments; and
- 4 Lenalidomide to be administered at a maximum dose of 25 mg/day in combination with dexamethasone.

**Initial application** — (Maintenance following first-line autologous stem cell transplant (SCT)) only from a haematologist or any relevant practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

#### All of the following:

- 1 Patient has newly diagnosed symptomatic multiple myeloma and has undergone first-line treatment that included an autologous stem cell transplantation; and
- 2 Patient has at least a stable disease response in the first 100 days after transplantation; and
- 3 Lenalidomide maintenance is to be commenced within 6 months of transplantation; and
- 4 Lenalidomide to be administered at a maximum dose of 15 mg/day.

Renewal — (Relapsed/refractory disease) only from a haematologist or any relevant practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

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

Renewal — (Maintenance following first line autologous SCT) only from a haematologist or any relevant practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria: Both:

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

Note: Indication marked with \* is an unapproved indication. A line of treatment is considered to comprise either: a) a known therapeutic chemotherapy regimen and supportive treatments or b) a transplant induction chemotherapy regimen, stem cell transplantation and supportive treatments. Prescriptions must be written by a registered prescriber in the lenalidomide risk management programme operated by the supplier.

	Subsidy (Manufacturer's Price)		Fully Subsidised	Brand or Generic	
	\$	Per		Manufacturer	
LENALIDOMIDE (VIATRIS) – Special Authority see SA2353 bel Brand switch fee payable (Pharmacode 2689286) - see page	, ,				
Cap 5 mg		21	<b>√</b> L	enalidomide. Viatris	
Lenalidomide Viatris to be Principal Supply on 1 Februar	v 2025				
Cap 10 mg	•	21	<b>√</b> L	enalidomide. Viatris	
Lenalidomide Viatris to be Principal Supply on 1 Februar	v 2025				
Cap 15 mg	•	21	<b>√</b> L	enalidomide. Viatris	
Lenalidomide Viatris to be Principal Supply on 1 Februar	v 2025				
Cap 25 mg	•	21	<b>√</b> L	enalidomide. Viatris	

Lenalidomide Viatris to be Principal Supply on 1 February 2025

#### ⇒SA2353 Special Authority for Subsidy

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

#### Both:

- 1 Patient has plasma cell dyscrasia, not including Waldenström macroglobulinaemia, requiring treatment; and
- 2 Patient is not refractory to prior lenalidomide use.

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

#### Both:

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

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

#### Both:

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

#### MESNA

Tab 400 mg - PCT - Retail pharmacy-Specialist314.00	50	✓ Uromitexan
Tab 600 mg - PCT - Retail pharmacy-Specialist448.50	50	✓ Uromitexan
Inj 100 mg per ml, 4 ml ampoule - PCT only - Specialist177.45	15	✓ Uromitexan
Inj 100 mg per ml, 10 ml ampoule - PCT only - Specialist	15	✓ Uromitexan
Inj 1 mg for ECP - PCT only - Specialist2.96	100 mg	✓ Baxter
MITOMYCIN C - PCT only - Specialist		
Inj 5 mg vial526.00	1	✓ Mitomycin
		(Sagent) S29
577.50		✓ Mitomycin
		(Fresenius
		Kabi) S29
641.70		✓ Accord S29
Inj 20 mg vial	1	✓ Omegapharm \$29
•		✓ Teva
Inj 1 mg for ECP269.85	1 mg	✓ Baxter
MITOZANTRONE - PCT only - Specialist		
Inj 2 mg per ml, 10 ml vial97.50	1	Mitozantrone Ebewe
Inj 1 mg for ECP5.51	1 mg	✓ Baxter

<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
NIRAPARIB – Special Authority see SA2325 below – Retail phar	rmacy			
Wastage claimable				
Tab 100 mg	13,393.50	84	•	Zejula
Cap 100 mg	8,929.84	56	✓ ;	Zejula
•	13,393.50	84	✓ :	Zejula

#### ⇒SA2325 Special Authority for Subsidy

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

- 1 Patient has advanced high-grade serous\* epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
- 2 Patient has received at least one line\*\* of treatment with platinum-based chemotherapy; and
- 3 Patient has experienced a partial or complete response to the preceding treatment with platinum-based chemotherapy; and
- 4 Patient has not previously received funded treatment with a PARP inhibitor; and
- 5 Either:
  - 5.1 Treatment will be commenced within 12 weeks of the patient's last dose of the preceding platinum-based regimen;
  - 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
- 3 Treatment not to be administered in combination with other chemotherapy; and
- 4 Either:
  - 4.1 Treatment with niraparib to cease after a total duration of 36 months from commencement; or
  - 4.2 Treatment with niraparib is being used in the second-line or later maintenance setting.

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

\*\*A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments

OLAPARIB - Retail pharmacy-Specialist - Special Author	ority see SA2163 below		
Tab 100 mg	3,701.00	56	<ul><li>Lynparza</li></ul>
Tab 150 mg	3,701.00	56	✓ Lynparza

#### ⇒SA2163 Special Authority for Subsidy

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

All of the following:

- 1 Patient has a high-grade serous\* epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
- 2 There is documentation confirming pathogenic germline BRCA1 or BRCA2 gene mutation; and
- 3 Either:
  - 3.1 All of the following:
    - 3.1.1 Patient has newly diagnosed, advanced disease; and
    - 3.1.2 Patient has received one line\*\* of previous treatment with platinum-based chemotherapy; and
    - 3.1.3 Patient's disease must have experienced a partial or complete response to the first-line platinum-based regimen; or
  - 3.2 All of the following:
    - 3.2.1 Patient has received at least two lines\*\* of previous treatment with platinum-based chemotherapy; and

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

continued...

- 3.2.2 Patient has platinum sensitive disease defined as disease progression occurring at least 6 months after the last dose of the penultimate line\*\* of platinum-based chemotherapy; and
- 3.2.3 Patient's disease must have experienced a partial or complete response to treatment with the immediately preceding platinum-based regimen; and
- 3.2.4 Patient has not previously received funded olaparib treatment; and
- 4 Treatment will be commenced within 12 weeks of the patient's last dose of the immediately preceding platinum-based regimen; and
- 5 Treatment to be administered as maintenance treatment; and
- 6 Treatment not to be administered in combination with other chemotherapy.

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

All of the following:

- 1 Treatment remains clinically appropriate and patient is benefitting from treatment; and
- 2 Either:
  - 2.1 No evidence of progressive disease; or
  - 2.2 Evidence of residual (not progressive) disease and the patient would continue to benefit from treatment in the clinician's opinion; and
- 3 Treatment to be administered as maintenance treatment; and
- 4 Treatment not to be administered in combination with other chemotherapy; and
- 5 Either:
  - 5.1 Both:
    - 5.1.1 Patient has received one line\*\* of previous treatment with platinum-based chemotherapy; and
    - 5.1.2 Documentation confirming that the patient has been informed and acknowledges that the funded treatment period of olaparib will not be continued beyond 2 years if the patient experiences a complete response to treatment and there is no radiological evidence of disease at 2 years; or
  - 5.2 Patient has received at least two lines\*\* of previous treatment with platinum-based chemotherapy.

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

PACLITAXEL – PCT only – Specialist			
Inj 30 mg	47.30	5	✓ Paclitaxel Ebewe
Inj 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 se	ee SA1979 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:

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

continued...

Both:

- 1 The patient has newly diagnosed acute lymphoblastic leukaemia; and
- 2 Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol.

Initial application — (Lymphoma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months where the patient has lymphoma requiring L-asparaginase containing protocols (e.g. SMILE).

Renewal — (Acute lymphoblastic leukaemia) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The patient has relapsed acute lymphoblastic leukaemia; and
- 2 Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol.

	•		
PENTOSTATIN [DEOXYCOFORMYCIN] - PCT only -	Specialist		
Inj 10 mg	CBS	1	✓ Nipent S29
POMALIDOMIDE - Special Authority see SA2354 belo	w – Retail pharmacy		
Brand switch fee payable (Pharmacode 2689278) -	see page 273 for details		
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

### ⇒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.

PROCARBAZINE HYDROCHLORIDE – PCT – Retail pharmacy-	Specialist		
Cap 50 mg	980.00	50	✓ Natulan S29
TEMOZOLOMIDE - Special Authority see SA2275 on the next pa	ige – Retail phar	macy	
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

Brand or

Generic

Manufacturer

Subsidy Fully (Manufacturer's Price) Subsidised Per

### ⇒SA2275 Special Authority for Subsidy

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

Initial application — (neuroendocrine tumours) only from a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 Patient has been diagnosed with metastatic or unresectable well-differentiated neuroendocrine tumour\*; and
- 2 Temozolomide is to be given in combination with capecitabine; and
- 3 Temozolomide is to be used in 28 day treatment cycles for a maximum of 5 days treatment per cycle at a maximum dose of 200 mg/m<sup>2</sup> per day; and
- 4 Temozolomide to be discontinued at disease progression.

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

Both:

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

Initial application — (ewing's sarcoma) only from a relevant specialist. Approvals valid for 9 months where the patient has relapsed/refractory Ewing's sarcoma.

Renewal — (ewing's sarcoma) only from a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

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

Note: Indication marked with a \* is an unapproved indication. Temozolomide is not subsidised for the treatment of relapsed high grade glioma.

THALIDOMIDE - Retail pharmacy-Specialist - Spe	ecial Authority see SA2356 below		
Cap 50 mg	378.00	28	Thalomid
Cap 100 mg	756.00	28	Thalomid

#### ⇒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	✓ Vesanoid
VENETOCLAX - Retail pharmacy-Specialist - Special Aut	hority see SA1868 on t	he next page	
Tab 14 $\times$ 10 mg, 7 $\times$ 50 mg, 21 $\times$ 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

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

#### ⇒SA1868 Special Authority for Subsidy

Initial application — (relapsed/refractory chronic lymphocytic leukaemia) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 7 months for applications meeting the following criteria:

#### All of the following:

- 1 Patient has chronic lymphocytic leukaemia requiring treatment; and
- 2 Patient has received at least one prior therapy for chronic lymphocytic leukaemia; and
- 3 Patient has not previously received funded venetoclax; and
- 4 The patient's disease has relapsed within 36 months of previous treatment; and
- 5 Venetoclax to be used in combination with six 28-day cycles of rituximab commencing after the 5-week dose titration schedule with venetoclax; and
- 6 Patient has an ECOG performance status of 0-2.

Renewal — (relapsed/refractory chronic lymphocytic leukaemia) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Treatment remains clinically appropriate and the patient is benefitting from and tolerating treatment; and
- 2 Venetoclax is to be discontinued after a maximum of 24 months of treatment following the titration schedule unless earlier discontinuation is required due to disease progression or unacceptable toxicity.

Initial application — (previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation\*) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

#### All of the following:

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

Renewal — (previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation\*) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where the treatment remains clinically appropriate and the patient is benefitting from and tolerating treatment.

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

#### VINBLASTINE SUI PHATE

Inj 1 mg per ml, 10 ml vial - PCT - Retail pharmacy-Specialist270.37	5	✓ Hospira
Inj 1 mg for ECP - PCT only - Specialist	1 mg	✓ Baxter
VINCRISTINE SULPHATE		
Inj 1 mg per ml, 1 ml vial  - PCT - Retail pharmacy-Specialist74.52	5	<ul><li>DBL Vincristine Sulfate</li></ul>
Inj 1 mg per ml, 2 ml vial  – PCT – Retail pharmacy-Specialist 102.73	5	✓ DBL Vincristine Sulfate
Inj 1 mg for ECP - PCT only - Specialist12.60	1 mg	✓ Baxter
VINORELBINE		
Cap 20 mg30.00	1	✓ Vinorelbine Te Arai
Cap 30 mg40.00	1	✓ Vinorelbine Te Arai
Cap 80 mg60.00	1	✓ Vinorelbine Te Arai
Inj 10 mg per ml, 1 ml vial - PCT only - Specialist42.00	1	✓ Vinorelbine Ebewe
Inj 10 mg per ml, 5 ml vial - PCT only - Specialist168.00	1	✓ Navelbine S29 S29
210.00		✓ Vinorelbine Ebewe
Inj 1 mg for ECP - PCT only - Specialist	1 mg	✓ Baxter

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

### Protein-tyrosine Kinase Inhibitors

ALECTINIB - Retail pharmacy-Specialist - Special Authority see SA1870 below

Wastage claimable

#### ⇒SA1870 Special Authority for Subsidy

Initial application only from a medical oncologist or medical practitioner on the recommendation of a relevant specialist.

#### All of the following:

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

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

Both:

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

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

Tab 20 mg	132.88	60	Dasatinib-Teva
<b>S</b>	3,774.06		✓ Sprycel
Tab 50 mg	304.13	60	✓ Dasatinib-Teva
-	6,214.20		✓ Sprycel
Tab 70 mg	415.75	60	✓ Dasatinib-Teva
	7,692.58		✓ Sprycel

(Sprycel Tab 20 mg to be delisted 1 March 2025) (Sprycel Tab 50 mg to be delisted 1 March 2025)

(Sprycel Tab 70 mg to be delisted 1 March 2025)

#### ⇒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:

#### 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	OTINIR	- Retail pharmacy	-Specialist -	Special Authority see	SA2115 on the next page

		F3-	
Tab 100 mg	280.84	30	Alchemy
Tab 150 mg	484.24	30	✓ Alchemy

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

#### ⇒SA2115 Special Authority for Subsidy

**Initial application** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has locally advanced or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
- 2 There is documentation confirming that the disease expresses activating mutations of EGFR tyrosine kinase; and
- 3 Either:
  - 3.1 Patient is treatment naive; or
  - 3.2 Both:
    - 3.2.1 The patient has discontinued gefitinib due to intolerance; and
    - 3.2.2 The cancer did not progress while on gefitinib; and
- 4 Erlotinib is to be given for a maximum of 3 months.

**Renewal** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

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

All of the following:

- 1 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and
- 2 Erlotinib to be discontinued at progression; and
- 3 The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector.

GEFITINIB – Retail pharmacy-Specialist – Special Authority see SA2116 below
Tab 250 mg .......918.00 30 ✓ Iressa

#### **⇒SA2116** Special Authority for Subsidy

**Initial application** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has locally advanced, or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
- 2 Either:
  - 2.1 Patient is treatment naive; or
  - 2.2 Both:
    - 2.2.1 The patient has discontinued erlotinib due to intolerance; and
    - 2.2.2 The cancer did not progress whilst on erlotinib; and
  - 3 There is documentation confirming that disease expresses activating mutations of EGFR tyrosine kinase; and
  - 4 Gefitinib is to be given for a maximum of 3 months.

**Renewal** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

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

All of the following:

- 1 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and
- 2 Gefitinib to be discontinued at progression; and
- 3 The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector.

IMATINIB MESILATE			
* Cap 100 mg	44.93	60	✓ <u>Imatinib-Rex</u>
* Cap 400 mg	69.76	30	✓ Imatinib-Rex
MIDOSTAURIN - PCT only - Special Authority se	e SA2342 on the next page		
Cap 25 mg	10,981.00	56	Rydapt

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

#### **⇒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		
Cap 150 mg4,68	0.00 12	20 🗸 Tasigna
Cap 200 mg6,53	2.00 12	20 <b>✓ Tasigna</b>

#### ⇒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;
- 3 Maximum nilotinib dose of 800 mg/day; and
- 4 Subsidised for use as monotherapy only.

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

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

- 1 Lack of treatment failure while on nilotinib as defined by Leukaemia Net Guidelines: and
- 2 Nilotinib treatment remains appropriate and the patient is benefiting from treatment; and
- 3 Maximum nilotinib dose of 800 mg/day; and
- 4 Subsidised for use as monotherapy only.

#### PALBOCICLIB - Special Authority see SA2345 below - Retail pharmacy

wasiaye daimable	
Tab 75 mg4,000.00 21	✓ Ibrance
Tab 100 mg4,000.00 21	✓ Ibrance
·	✓ 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:

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

continued...

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

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

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

#### PAZOPANIB - Special Authority see SA1190 below - Retail pharmacy

Tab 200 mg	1,334.70	30	✓ Votrient
Tab 400 mg	2,669.40	30	✓ Votrient

#### ⇒SA1190 Special Authority for Subsidy

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

All of the following:

- 1 The patient has metastatic renal cell carcinoma; and
- 2 Any of the following:
  - 2.1 The patient is treatment naive; or
  - 2.2 The patient has only received prior cytokine treatment; or
  - 2.3 Both:
    - 2.3.1 The patient has discontinued sunitinib within 3 months of starting treatment due to intolerance; and
    - 2.3.2 The cancer did not progress whilst on sunitinib; and
- 3 The patient has good performance status (WHO/ECOG grade 0-2); and
- 4 The disease is of predominant clear cell histology; and

The patient has intermediate or poor prognosis defined as:

- 5 Any of the following:
  - 5.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or
  - 5.2 Haemoglobin level < lower limit of normal; or
  - 5.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or
  - 5.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or
  - 5.5 Karnofsky performance score of less than or equal to 70; or
  - 5.6 2 or more sites of organ metastasis; and
- 6 Pazopanib to be used for a maximum of 3 months.

**Renewal** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

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

Notes: Pazopanib treatment should be stopped if disease progresses.

Poor prognosis patients are defined as having at least 3 of criteria 5.1-5.6. Intermediate prognosis patients are defined as having 1 or 2 of criteria 5.1-5.6.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
RIBOCICLIB – Special Authority see SA2343 below – Retail pha Wastage claimable	ırmacy			
Tab 200 mg	1,883.00	21	✓	Kisqali
•	3,767.00	42	✓	Kisqali
	5,650.00	63	✓	Kisqali

#### ⇒SA2343 Special Authority for Subsidy

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

- 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 cialifiable			
Tab 5 mg	2,500.00	56	Jakavi
Tab 10mg	· ·	56	Jakavi
Tab 15 mg	5,000.00	56	Jakavi
Tab 20 mg	5,000.00	56	Jakavi

#### ⇒SA1890 Special Authority for Subsidy

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

- 1 The patient has primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis: and
- 2 Either:
  - 2.1 A classification of risk of intermediate-2 or high-risk myelofibrosis according to either the International Prognostic

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

continued...

Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or the Age-Adjusted DIPSS; or

- 2.2 Both:
  - 2.2.1 A classification of risk of intermediate-1 myelofibrosis according to either the International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or the Age-Adjusted DIPSS; and
  - 2.2.2 Patient has severe disease-related symptoms that are resistant, refractory or intolerant to available therapy;
- 3 A maximum dose of 20 mg twice daily is to be given.

**Renewal** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 A maximum dose of 20 mg twice daily is to be given.

SUNITINIB - Special Authority see SA2117 below -	Retail pharmacy		
Cap 12.5 mg	208.38	28	<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>

#### **⇒SA2117** Special Authority for Subsidy

Initial application — (RCC) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 The patient has metastatic renal cell carcinoma; and
- 2 Any of the following:
  - 2.1 The patient is treatment naive; or
  - 2.2 The patient has only received prior cytokine treatment; or
  - 2.3 The patient has only received prior treatment with an investigational agent within the confines of a bona fide clinical trial which has Ethics Committee approval: or
  - 2.4 Both:
    - 2.4.1 The patient has discontinued pazopanib within 3 months of starting treatment due to intolerance; and
    - 2.4.2 The cancer did not progress whilst on pazopanib; and
- 3 The patient has good performance status (WHO/ECOG grade 0-2); and
- 4 The disease is of predominant clear cell histology; and
  - The patient has intermediate or poor prognosis defined as:
- 5 Any of the following:
  - 5.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or
  - 5.2 Haemoglobin level < lower limit of normal; or
  - 5.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or
  - 5.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or
  - 5.5 Karnofsky performance score of less than or equal to 70; or
  - 5.6 2 or more sites of organ metastasis; and
- 6 Sunitinib to be used for a maximum of 2 cycles.

Initial application — (GIST) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 The patient has unresectable or metastatic malignant gastrointestinal stromal tumour (GIST); and
- 2 Either:

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

continued...

- 2.1 The patient's disease has progressed following treatment with imatinib; or
- 2.2 The patient has documented treatment-limiting intolerance, or toxicity to, imatinib.

**Renewal — (RCC)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

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

Notes: Sunitinib treatment should be stopped if disease progresses.

Poor prognosis patients are defined as having at least 3 of criteria 5.1-5.6. Intermediate prognosis patients are defined as having 1 or 2 of criteria 5.1-5.6

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

Both:

The patient has responded to treatment or has stable disease as determined by Choi's modified CT response evaluation criteria as follows:

- 1 Any of the following:
  - 1.1 The patient has had a complete response (disappearance of all lesions and no new lesions); or
  - 1.2 The patient has had a partial response (a decrease in size of 10% or more or decrease in tumour density in Hounsfield Units (HU) of 15% or more on CT and no new lesions and no obvious progression of non measurable disease); or
  - 1.3 The patient has stable disease (does not meet criteria the two above) and does not have progressive disease and no symptomatic deterioration attributed to tumour progression; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

Note: It is recommended that response to treatment be assessed using Choi's modified CT response evaluation criteria (J Clin Oncol, 2007, 25:1753-1759). Progressive disease is defined as either: an increase in tumour size of 10% or more and not meeting criteria of partial response (PR) by tumour density (HU) on CT; or: new lesions, or new intratumoral nodules, or increase in the size of the existing intratumoral nodules.

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

All of the following:

- 1 The patient has unresectable or metastatic malignant gastrointestinal stromal (GIST); and
- 2 The patient is clinically 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 91

ABIRATERONE ACETATE - Retail pharmacy-Specialist - Special Authority see \$A2118 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

Subsidy	F	ully	Brand or
(Manufacturer's Price)	Subsidis	sed	Generic
	Per	1	Manufacturer

continued...

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

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

All of the following:

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

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

All of the following:

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

## BICALUTAMIDE

rab 50 mg	4.18	28	Bicalutamide \$29
			✓ Binarex
FLUTAMIDE			
Tab 250 mg10	7.55	90	✓ Prostacur S29
11!	9.50	100	✓ Flutamin
FULVESTRANT - Retail pharmacy-Specialist - Special Authority see SA	1895 below		
Inj 50 mg per ml, 5 ml prefilled syringe1,06	8.00	2	✓ Faslodex

#### **⇒SA1895** Special Authority for Subsidy

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

All of the following:

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

continued...

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

continued...

**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.

#### OCTREOTIDE

Inj 100 mcg per ml, 1 ml vial	48.50	5	✓ Omega S29
Inj 50 mcg per ml, 1 ml ampoule	27.58	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
OCTREOTIDE LONG-ACTING - Special Authority see SA2119 be	elow – Retail pharn	пасу	
Inj depot 10 mg prefilled syringe	438.40	1	Sandostatin LAR
	439.97		✓ Octreotide Depot Teva
Sandostatin LAR to be Principal Supply on 1 December 20	024		
Inj depot 20 mg prefilled syringe	583.70	1	Sandostatin LAR
	647.03		✓ Octreotide Depot Teva
Sandostatin LAR to be Principal Supply on 1 December 20	024		
Inj depot 30 mg prefilled syringe	670.80	1	Sandostatin LAR
	718.55		✓ Octreotide Depot Teva

#### Sandostatin LAR to be Principal Supply on 1 December 2024

(Octreotide Depot Teva Inj depot 10 mg prefilled syringe to be delisted 1 December 2024) (Octreotide Depot Teva Inj depot 20 mg prefilled syringe to be delisted 1 December 2024) (Octreotide Depot Teva Inj depot 30 mg prefilled syringe to be delisted 1 December 2024)

#### ⇒SA2119 Special Authority for Subsidy

Initial application — (Malignant Bowel Obstruction) from any relevant practitioner. Approvals valid for 2 months for applications meeting the following criteria:

#### All of the following:

- 1 The patient has nausea\* and vomiting\* due to malignant bowel obstruction\*; and
- 2 Treatment with antiemetics, rehydration, antimuscarinic agents, corticosteroids and analgesics for at least 48 hours has failed; and
- 3 Octreotide to be given at a maximum dose 1500 mcg daily for up to 4 weeks.

Note: Indications marked with \* are unapproved indications.

Renewal — (Malignant Bowel Obstruction) from any relevant practitioner. Approvals valid for 3 months where the treatment remains appropriate and the patient is benefiting from treatment.

Initial application — (Acromegaly) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

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

continued...

- 1 The patient has acromegaly; and
- 2 Any of the following:
  - 2.1 Treatment with surgery, radiotherapy and a dopamine agonist has failed; or
  - 2.2 Treatment with octreotide is for an interim period while awaiting the effects of radiotherapy and a dopamine agonist has failed; or
  - 2.3 The patient is unwilling, or unable, to undergo surgery and/or radiotherapy.

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

Both:

- 1 IGF1 levels have decreased since starting octreotide; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

Note: In patients with Acromegaly octreotide treatment should be discontinued if IGF1 levels have not decreased after 3 months treatment. In patients treated with radiotherapy octreotide treatment should be withdrawn every 2 years, for 1 month, for assessment of remission. Octreotide treatment should be stopped where there is biochemical evidence of remission (normal IGF1 levels) following octreotide treatment withdrawal for at least 4 weeks

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

All of the following:

- 1 Patient has acromegaly; and
- 2 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and
- 3 The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector.

Initial application — (Other Indications) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 VIPomas and Glucagonomas for patients who are seriously ill in order to improve their clinical state prior to definitive surgery; or
- 2 Both:
  - 2.1 Gastrinoma: and
  - 2.2 Either:
    - 2.2.1 Patient has failed surgery; or
    - 2.2.2 Patient in metastatic disease after H2 antagonists (or proton pump inhibitors) have failed; or
- 3 Both:
  - 3.1 Insulinomas; and
  - 3.2 Surgery is contraindicated or has failed; or
- 4 For pre-operative control of hypoglycaemia and for maintenance therapy; or
- 5 Both:
  - 5.1 Carcinoid syndrome (diagnosed by tissue pathology and/or urinary 5HIAA analysis); and
  - 5.2 Disabling symptoms not controlled by maximal medical therapy.

Note: The use of octreotide in patients with fistulae, oesophageal varices, miscellaneous diarrhoea and hypotension will not be funded as a Special Authority item

Renewal — (Other Indications) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment. Initial application — (pre-operative acromegaly) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has acromegaly; and
- 2 Patient has a large pituitary tumour, greater than 10 mm at its widest; and

	Subsidy (Manufacturer's Price) \$	S Per	Fully ubsidised	Brand or Generic Manufacturer
continued				
3 Patient is scheduled to undergo pituitary surgery in the ne	ext six months.			
TAMOXIFEN CITRATE  * Tab 10 mg  * Tab 20 mg		60 60		amoxifen Sandoz amoxifen Sandoz
Aromatase Inhibitors				
ANASTROZOLE				
* Tab 1 mg	4.39	30	✓ <u>A</u> ı	<u>natrole</u>
EXEMESTANE				
* Tab 25 mg	9.86	30	✓ <u>Pf</u>	fizer Exemestane
LETROZOLE				
* Tab 2.5 mg Letrole to be Principal Supply on 1 December 2024	4.67	30	✓ Le	etrole
Immunocupproceante				

# **Immunosuppressants**

# **Cytotoxic Immunosuppressants**

AZATHIOPRINE			
* Tab 25 mg	7.36	60	Azamun
* Tab 50 mg		100	✓ Azamun
MYCOPHENOLATE MOFETIL			
Tab 500 mg	35.90	50	<ul><li>Cellcept</li></ul>
Cap 250 mg	35.90	100	<ul> <li>Cellcept</li> </ul>
Powder for oral liq 1 g per 5 ml - Subsidy by endorsement	87.25	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 beld	ow – Retail pharmacy		
Inj 25 mg	690.00	4	Enbrel
Inj 25 mg autoinjector	690.00	4	Enbrel
Inj 50 mg autoinjector		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:
    - 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:

Subsidy	0.1	Fully	Brand or	
(Manufacturer's Price) \$	Per	sidised •	Generic Manufacturer	

continued...

- 1.2.1 The patient has experienced intolerable side effects from adalimumab and/or tocilizumab; or
- 1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or tocilizumab such that they do not meet the renewal criteria for AOSD: or
- 2 All of the following:
  - 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and
  - 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal anti-inflammatory drugs (NSAIDs) and methotrexate; and
  - 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

Renewal — (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

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

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

Either:

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for adalimumab for ankylosing spondylitis; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
    - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for ankylosing spondylitis; or
- 2 All of the following:
  - 2.1 Patient has a confirmed diagnosis of ankylosing spondylitis present for more than six months: and
  - 2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
  - 2.3 Patient has bilateral sacroiliitis demonstrated by plain radiographs, CT or MRI scan; and
  - 2.4 Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and
  - 2.5 Fither:
    - 2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following Bath Ankylosing Spondylitis Metrology Index (BASMI) measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or
    - 2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender (see Notes); and
  - 2.6 A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 6 on a 0-10 scale.

Notes: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure must be no more than 1 month old at the time of initial application.

Average normal chest expansion corrected for age and gender:

18-24 years - Male: 7.0 cm; Female: 5.5 cm 25-34 years - Male: 7.5 cm; Female: 5.5 cm 35-44 years - Male: 6.5 cm; Female: 4.5 cm 45-54 years - Male: 6.0 cm; Female: 5.0 cm

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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 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 Following 12 weeks' initial treatment and for subsequent renewals, treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less; and
- 3 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and
- 4 Etanercept to be administered at doses no greater than 50 mg every 7 days.

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

Fither:

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for adalimumab for polyarticular course juvenile idiopathic arthritis (JIA); and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
    - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for polyarticular course JIA; or
- 2 All of the following:
  - 2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
  - 2.2 Patient has had polyarticular course JIA for 6 months duration or longer; and
  - 2.3 Any of the following:
    - 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 Fither:
  - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
  - 2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Initial application — (oligoarticular course juvenile idiopathic arthritis) only from a named specialist or rheumatologist.

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Approvals valid for 6 months for applications meeting the following criteria:

#### Either:

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

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

# Both:

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

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

#### Either:

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

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- 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints; or
- 2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 2.5 Any of the following:
  - 2.5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
  - 2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or
  - 2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

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

All of the following:

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

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

All of the following:

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

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

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

Either:

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for adalimumab for rheumatoid arthritis; and
  - 1.2 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 rheumatoid arthritis; or
- 2 All of the following:

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

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

All of the following:

- 1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2 Either:
  - 2.1 Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  - 2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

**Initial application** — (severe chronic plaque psoriasis) only from a dermatologist 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 plague psoriasis; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
    - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe chronic plaque psoriasis; or
- 2 All of the following:
  - 2.1 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

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- 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 plague psoriasis at the start of treatment; and
    - 112 Fither
      - 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 plague psoriasis at the start of treatment; and
    - 1.3.2 Either:
      - 1.3.2.1 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or
      - 1.3.2.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing etanercept; and
- 2 Etanercept to be administered at doses no greater than 50 mg every 7 days.

Note: A treatment course is defined as a minimum of 12 weeks of etanercept treatment

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

All of the following:

1 Patient has undifferentiated peripheral spondyloarthritis\* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and

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

### **Monoclonal Antibodies**

ADALIMUMAB (AMGEVITA) – Special Authority see SA24	00 below – Retail pharma	СУ	
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

#### ⇒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:

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- 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: Fither:

- 1 Both:
  - 1.1 Patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and
  - 1.2 Either:
    - 1.2.1 Patient has experienced intolerable side effects; or
    - 1.2.2 Patient has received insufficient benefit to meet the renewal criteria for etanercept for severe chronic plaque psoriasis: or
- 2 All of the following:
  - 2.1 Any of the following:
    - 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a PASI score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
    - 2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; or
    - 2.1.3 Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10; and
  - 2.2 Patient has tried, but had an inadequate response to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
  - 2.3 A PASI assessment or DLQI assessment has been completed for at least the most recent prior treatment course but no longer than 1 month following cessation of each prior treatment course and is no more than 1 month old at the time of application.

**Renewal — (Plaque psoriasis - severe chronic)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

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Any of the following:

- 1 Both:
  - 1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced a 75% or more reduction in PASI score, or is sustained at this level, when compared with the pre-treatment baseline value: or
    - 1.2.2 The patient has a DLQI improvement of 5 or more, when compared with the pre-treatment baseline value; or
- 2 Both:
  - 2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
  - 2.2 Either:
    - 2.2.1 The patient has experienced reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
    - 2.2.2 The patient has experienced reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre treatment baseline value; or
- 3 Both:
  - 3.1 Patient had severe chronic localised genital or flexural 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; or
  - 2.4 Patient has an ileostomy or colostomy and has intestinal inflammation; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids.

Renewal — (Crohn's disease - adults) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

1 CDAI score has reduced by 100 points from the CDAI score, or HBI score has reduced by 3 points, from when the patient was initiated on adalimumab; or

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- 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:

Either:

- 1 The patient has had an initial Special Authority approval for infliximab for chronic ocular inflammation; or
- 2 Both:
  - 2.1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and
  - 2.2 Any of the following:
    - 2.2.1 Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective; or
    - 2.2.2 Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or
    - 2.2.3 Patient is under 8 years and treatment with steroids or methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or disease requires control to prevent irreversible vision loss prior to achieving a therapeutic dose of methotrexate.

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

Any of the following:

- 1 The patient has had a good clinical response following 12 weeks' initial treatment; or
- 2 Following each 2 year treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema): or</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</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 — (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
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects; or
    - 1.2.2 The patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis; or
- 2 All of the following:
  - 2.1 Patient has a confirmed diagnosis of ankylosing spondylitis for more than six months; and
  - 2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
  - 2.3 Patient has bilateral sacroiliitis demonstrated by radiology imaging; and
  - 2.4 Patient has not responded adequately to treatment with two or more NSAIDs, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and
  - 2.5 Either:
    - 2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following BASMI measures: a modified Schober's test of less than or equal to 4 cm and lumbar side

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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 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 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 Fither:
    - 2.3.1 At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
    - 2.3.2 Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose).

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

#### Either:

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

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 Fither:
    - 1.2.1 Patient has experienced intolerable side effects; or
    - 1.2.2 Patient has received insufficient benefit to meet the renewal criteria for polyarticular course JIA; or
- 2 All of the following:
  - 2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
  - 2.2 Patient has had polyarticular course JIA for 6 months duration or longer; and
  - 2.3 Any of the following:

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- 2.3.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
- 2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or
- 2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

Renewal — (Arthritis - polyarticular course juvenile idiopathic) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

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

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

Either:

- 1 Both:
  - 1.1 Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects; or
    - 1.2.2 The patient has received insufficient benefit from to meet the renewal criteria for psoriatic arthritis; or
- 2 All of the following:
  - 2.1 Patient has had active psoriatic arthritis for six months duration or longer; and
  - 2.2 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
  - 2.3 Patient has tried and not responded to at least three months of sulfasalazine or leflunomide at maximum tolerated doses (unless contraindicated): and
  - 2.4 Either:
    - 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
    - 2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
  - 2.5 Any of the following:
    - 2.5.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
    - 2.5.2 Patient has an ESR greater than 25 mm per hour; or
    - 2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

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

Either:

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

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

Fither:

1 Both:

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- 1.1 The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis; and
- 1.2 Fither:
  - 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 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:

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 Either:
  - 1.2.1 Patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
  - 1.2.2 Patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab; or
- 2 All of the following:
  - 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria; and
  - 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, NSAIDs and methotrexate: and
  - 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

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

All of the following:

1 Patient has active ulcerative colitis; and

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- 2 Either:
  - 2.1 Patient's SCCAI score is greater than or equal to 4; or
  - 2.2 Patient's PUCAI score is greater than or equal to 20; and
  - 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from prior therapy with immunomodulators and systemic corticosteroids; and
  - 4 Surgery (or further surgery) is considered to be clinically inappropriate.

Renewal — (ulcerative colitis) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 The SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on biologic therapy; or
- 2 The PUCAI score has reduced by 10 points or more from the PUCAI score when the patient was initiation on biologic therapy.

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

All of the following:

- 1 Patient has undifferentiated peripheral spondyloarthritis\* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 2 Patient has tried and not responded to at least three months of each of methotrexate, sulfasalazine and leflunomide, at maximum tolerated doses (unless contraindicated); and
- 3 Any of the following:
  - 3.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application: or
  - 3.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; or
  - 3.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Note: Indications marked with \* are unapproved indications

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

Either:

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

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

All of the following:

- 1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
- 2 Patient has axial inflammatory pain for six months or more; and
- 3 Patient is unable to take NSAIDs; and
- 4 Patient has unequivocal sacroillitis 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

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has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less.

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

All of the following:

- 1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
- 2 Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular; and
- 3 Patient has tried and not experienced a response to at least three months of methotrexate, or azathioprine at a maximum tolerated dose (unless contraindicated); and
- 4 Patient has tried and not experienced a response to at least three months of sulfasalazine at a maximum tolerated dose (unless contraindicated); and
- 5 Any of the following:
  - 5.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
  - 5.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; or
  - 5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

**Renewal — (inflammatory bowel arthritis – peripheral)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

#### Either:

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

ADALIMUMAB (HUMIRA - ALTERNATIVE BRAND) - Special Authority see SA2157 below - Retail pharmacy

Inj 20 mg per 0.2 ml prefilled syringe	1,599.96	2	<ul><li>Humira</li></ul>
Inj 40 mg per 0.4 ml prefilled pen	1,599.96	2	<ul><li>HumiraPen</li></ul>
Inj 40 mg per 0.4 ml prefilled syringe	1,599.96	2	<ul><li>Humira</li></ul>

### ⇒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
- 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.

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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 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 14 days.

Renewal — (Psoriasis - severe chronic plaque) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria: Both:

- 1 Either:
  - 1.1 Both:
    - 1.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
    - 1.1.2 Either:
      - 1.1.2.1 Following each prior adalimumab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-adalimumab treatment baseline value; or
      - 1.1.2.2 Following each prior adalimumab treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value; or
  - 1.2 Both:
    - 1.2.1 Patient had severe chronic plague 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

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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
  - 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:

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- 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:

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

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- 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:

All of the following

- 1 Either:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita); and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and

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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:

- 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

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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 Fither
  - 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 Fither:
  - 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:

- 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 — (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.

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

# ⇒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
- 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.

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### ⇒SA2151 Special Authority for Subsidy

Initial application — (Severe eosinophilic asthma) only from a respiratory physician or clinical immunologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient must be aged 12 years or older; and
- 2 Patient must have a diagnosis of severe eosinophilic asthma documented by a respiratory physician or clinical immunologist; and
- 3 Conditions that mimic asthma eg. vocal cord dysfunction, central airway obstruction, bronchiolitis etc. have been excluded; and
- 4 Patient has a blood eosinophil count of greater than 0.5 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 anti-inflammatory reliever therapy plus maintenance regimen, unless contraindicated or not tolerated; and
- 6 Either:
  - 6.1 Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral corticosteroids; or
  - 6.2 Patient has received continuous oral corticosteroids of at least the equivalent of 10 mg per day over the previous 3 months: and
- 7 Treatment is not to be used in combination with subsidised mepolizumab; and
- 8 Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment; and
- 9 Either:
  - 9.1 Patient has not previously received an anti-IL5 biological therapy for their severe eosinophilic asthma; or
  - 9.2 Both:
    - 9.2.1 Patient was refractory or intolerant to previous anti-IL5 biological therapy; and
    - 9.2.2 Patient was not eligible to continue treatment with previous anti-IL5 biological therapy and discontinued within 12 months of commencing treatment.

Renewal — (Severe eosinophilic asthma) only from a respiratory physician or clinical immunologist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and
- 2 Either:
  - 2.1 Exacerbations have been reduced from baseline by 50% as a result of treatment with benralizumab; or
  - 2.2 Reduction in continuous oral corticosteroid use by 50% or by 10 mg/day while maintaining or improving asthma control.

BRENTUXIMAB VEDOTIN - PCT only - Special Authority see SA2289 below Inj 50 mg vial .......5.275.18

1 ✓ Adcetris

#### ⇒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

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- 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.

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

# **⇒SA2096** Special Authority for Subsidy

Initial application — (Treatment of profoundly immunocompromised patients) from any relevant practitioner. Approvals valid for 2 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient has confirmed (or probable) COVID-19; and
- 2 The patient is in the community with mild to moderate disease severity\*; and
- 3 Patient is profoundly immunocompromised\*\* and is at risk of not having mounted an adequate response to vaccination against COVID-19 or is unvaccinated; and
- 4 Patient's symptoms started within the last 10 days; and
- 5 Patient is not receiving high flow oxygen or assisted/mechanical ventilation; and
- 6 Casirivimab and imdevimab is to be administered at a maximum dose of no greater than 2.400 mg.

Notes: \* Mild to moderate disease severity as described on the Ministry of Health Website

\*\* Examples include B-cell depletive illnesses or patients receiving treatment that is B-Cell depleting.

CETUXIMAB - PCT only - Specialist - Special Authority see SA2401 on the next page

Inj 5 mg per ml, 20 ml vial	364.00	1	Erbitux
Inj 5 mg per ml, 100 ml vial	1,820.00	1	Erbitux
Inj 1 mg for ECP	3.82	1 mg	<ul><li>Baxter</li></ul>

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#### ⇒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;
  - 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.

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 plague 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.

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 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 single maintenance and reliever therapy 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 benralizumab; and
- 8 Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment; and
- 9 Either:
  - 9.1 Patient has not previously received an anti-IL5 biological therapy for their severe eosinophilic asthma; or
  - 9.2 Both:
    - 9.2.1 Patient was refractory or intolerant to previous anti-IL5 biological therapy; and
    - 9.2.2 Patient was not eligible to continue treatment with previous anti-IL5 biological therapy and discontinued within 12 months of commencing treatment.

Renewal — (Severe eosinophilic asthma) only from a respiratory physician or clinical immunologist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and
- 2 Fither:

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- 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 Authority see \$A2155 below ✓ Gazvva Inj 1 mg for ECP ......6.21 Baxter 1 mg

⇒SA2155 Special Authority for Subsidy

Initial application — (chronic lymphocytic leukaemia) only from a haematologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has progressive Binet stage A, B or C CD20+ chronic lymphocytic leukaemia requiring treatment; and
- 2 The patient is obinutuzumab treatment naive; and
- 3 The patient is not eligible for full dose FCR due to comorbidities with a score > 6 on the Cumulative Illness Rating Scale (CIRS) or reduced renal function (creatinine clearance < 70mL/min); and
- 4 Patient has adequate neutrophil and platelet counts\* unless the cytopenias are a consequence of marrow infiltration by CLL: and
- 5 Patient has good performance status; and
- 6 Obinutuzumab to be administered at a maximum cumulative dose of 8,000 mg and in combination with chlorambucil for a maximum of 6 cycles.

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

\* Neutrophil greater than or equal to  $1.5 \times 10^9$ /L and platelets greater than or equal to  $75 \times 10^9$ /L.

Initial application — (follicular / marginal zone lymphoma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 Patient has follicular lymphoma; or
  - 1.2 Patient has marginal zone lymphoma; and
- 2 Patient is refractory to or has relapsed within 12 months of a rituximab containing combined chemo-immunotherapy regimen\*; and

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- 3 Patient has an ECOG performance status of 0-2; and
- 4 Patient has been previously treated with no more than four chemotherapy regimens; and
- 5 Obinutuzumab to be administered at a maximum dose of 1000 mg for a maximum of 6 cycles in combination with chemotherapy\*.

Note: \* includes unapproved indications

Renewal — (follicular / marginal zone lymphoma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 24 months for applications meeting the following criteria: All of the following:

- 1 Patient has no evidence of disease progression following obinutuzumab induction therapy; and
- 2 Obinutuzumab to be administered at a maximum of 1000 mg every 2 months for a maximum of 2 years; and
- 3 Obinutuzumab to be discontinued at disease progression.

OMALIZUMAB - Special Authority see SA1744 below - Retail p	harmacy		
Inj 150 mg prefilled syringe	450.00	1	✓ Xolair
			Xolair AU
Inj 150 mg vial	450.00	1	✓ Xolair

### ⇒SA1744 Special Authority for Subsidy

Initial application — (severe asthma) only from a respiratory specialist or clinical immunologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

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

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

All of the following:

- 1 Patient must be aged 12 years or older; and
- 2 Either:
  - 2.1 Both:
    - 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

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at least 6 weeks: or

- 3.2 Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and at least 3 courses of systemic corticosteroids (> 20 mg prednisone per day for at least 5 days) in the previous 6 months; or
- 3.3 Patient has developed significant adverse effects whilst on corticosteroids or ciclosporin; and
- 4 Either:
  - 4.1 Treatment to be stopped if inadequate response\* following 4 doses; or
  - 4.2 Complete response\* to 6 doses of omalizumab.

**Renewal** — (severe asthma) only from a clinical immunologist or respiratory specialist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and
- 2 A reduction in the maintenance oral corticosteroid dose or number of exacerbations of at least 50% from baseline.

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

Either:

- 1 Patient has previously adequately responded\* to 6 doses of omalizumab; or
- 2 Both:
  - 2.1 Patient has previously had a complete response\* to 6 doses of omalizumab; and
  - 2.2 Patient has relapsed after cessation of omalizumab therapy.

Note: \*Inadequate response defined as less than 50% reduction in baseline UAS7 and DLQI score, or an increase in Urticaria Control Test (UCT) score of less than 4 from baseline. Patient is to be reassessed for response after 4 doses of omalizumab. Complete response is defined as UAS7 less than or equal to 6 and DLQI less than or equal to 5; or UCT of 16. Relapse of chronic urticaria on stopping prednisone/ciclosporin does not justify the funding of omalizumab.

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	<ul><li>Baxter</li></ul>

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

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

Either:

- 1 Both:
  - 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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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 below

Inj 100 mg per 10 ml vial1,0	75.50	2	Mabthera
Inj 500 mg per 50 ml vial2,6	88.30	1 🗸	Mabthera
Inj 1 mg for ECP	5.64 1	ng 🗸	Baxter (Mabthera)

#### ⇒SA1976 Special Authority for Subsidy

Initial application — (rheumatoid arthritis - TNF inhibitors contraindicated) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Treatment with a Tumour Necrosis Factor alpha inhibitor is contraindicated; and
- 2 Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
- 3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
- 4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses); and
- 5 Any of the following:
  - 5.1 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of ciclosporin; or
  - 5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or
  - 5.3 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate; and

#### 6 Fither:

- 6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or
- 6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and

#### 7 Either:

- 7.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
- 7.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months; and

#### 8 Either:

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

Initial application — (rheumatoid arthritis - prior TNF inhibitor use) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

1 Both:

continued...

- 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.

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 on the next page

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

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

#### ⇒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:
  - 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:

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- 4.1 The patient does not have chromosome 17p deletion CLL; or
- 4.2 Rituximab treatment is to be used in combination with funded venetoclax for relapsed/refractory chronic lymphocytic leukaemia; and
- 5 Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles; and
- 6 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration), bendamustine or venetoclax.

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

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

Roth:

#### 1 Either:

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

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

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

# Both:

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

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

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

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

Initial application — (Post-transplant) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The patient has B-cell post-transplant lymphoproliferative disorder\*; and
- 2 To be used for a maximum of 8 treatment cycles.

Note: Indications marked with \* are unapproved indications.

Renewal — (Post-transplant) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following

All of the following:

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

Note: Indications marked with \* are unapproved indications.

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

- 1 One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart; and
- - 2.1 Treatment with corticosteroids and at least one other immunosuppressant for at least a period of 12 months has been ineffective: or
  - 2.2 Both:
    - 2.2.1 Treatment with at least one other immunosuppressant for a period of at least 12 months; and
    - 2.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.

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

All of the following:

- 1 One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart; and
- 2 An initial response lasting at least 12 months was demonstrated; and
- 3 Either:
  - 3.1 The patient has relapsed despite treatment with corticosteroids and at least one other immunosuppressant for a period of at least 12 months; or
  - 3.2 Both:
    - 3.2.1 The patient's myasthenia gravis has relapsed despite treatment with at least one immunosuppressant for a period of at least 12 months; and
    - 3.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.

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

All of the following:

1 Patient is a child with SDNS\* or FRNS\*: and

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- 2 Treatment with steroids for at least a period of 3 months has been ineffective or associated with evidence of steroid toxicity; and
- 3 Treatment with ciclosporin for at least a period of 3 months has been ineffective and/or discontinued due to unacceptable side effects; and
- 4 Treatment with mycophenolate for at least a period of 3 months with no reduction in disease relapses; and
- 5 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

Note: Indications marked with \* are unapproved indications.

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

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

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

Note: Indications marked with \* are unapproved indications.

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

Either:

- 1 All of the following:
  - 1.1 The patient has treatment naive aggressive CD20 positive NHL; and
  - 1.2 To be used with a multi-agent chemotherapy regimen given with curative intent; and
  - 1.3 To be used for a maximum of 8 treatment cycles; or
- 2 Both:
  - 2.1 The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy; and
  - 2.2 To be used for a maximum of 6 treatment cycles.

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Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia

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

All of the following:

- 1 The patient has had a rituximab treatment-free interval of 12 months or more; and
- 2 The patient has relapsed refractory/aggressive CD20 positive NHL; and
- 3 To be used with a multi-agent chemotherapy regimen given with curative intent; and
- 4 To be used for a maximum of 4 treatment cycles.

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia

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

Any of the following:

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

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

All of the following:

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

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

- 1 Either:
  - 1.1 Patient has immune thrombocytopenic purpura\* with a platelet count of less than or equal to 20,000 platelets per microlitre: or
  - 1.2 Patient has immune thrombocytopenic purpura\* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding; and
- 2 Any of the following:
  - 2.1 Treatment with steroids and splenectomy have been ineffective; or
  - 2.2 Treatment with steroids has been ineffective and splenectomy is an absolute contraindication; or
  - 2.3 Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy); and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

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

Either:

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

Note: Indications marked with \* are unapproved indications.

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Initial application — (indolent, low-grade lymphomas or hairy cell leukaemia\*) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

- Either:
  - 1 Both:
    - 1.1 The patient has indolent low grade NHL or hairy cell leukaemia\* with relapsed disease following prior chemotherapy; and
    - 1.2 To be used for a maximum of 6 treatment cycles; or
  - 2 Both:
    - 2.1 The patient has indolent, low grade lymphoma or hairy cell leukaemia\* requiring first-line systemic chemotherapy; and
    - 2.2 To be used for a maximum of 6 treatment cycles.

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

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

All of the following:

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

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

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

Note: Indications marked with \* are unapproved indications.

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

Note: Indications marked with \* are unapproved indications.

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

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

Note: Indications marked with \* are unapproved indications.

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

Fither:

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

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2.3 Patient now requires repeat treatment.

Note: Indications marked with \* are unapproved indications.

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

Both:

- 1 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks; and
- 2 Either:
  - 2.1 Patient has thrombotic thrombocytopenic purpura\* and has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange; or
  - 2.2 Patient has acute idiopathic thrombotic thrombocytopenic purpura\* with neurological or cardiovascular pathology.

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

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Note: Indications marked with \* are unapproved indications.

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

- 1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m² weekly for 4 weeks) is now planned; or
- 2 All of the following:
  - 2.1 Patient was previously treated with rituximab for warm autoimmune haemolytic anaemia\*; and
  - 2.2 An initial response lasting at least 12 months was demonstrated; and
  - 2.3 Patient now requires repeat treatment.

Note: Indications marked with \* are unapproved indications.

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

All of the following:

- 1 Patient has confirmed antisynthetase syndrome; and
- 2 Patient has severe, immediately life or organ threatening disease, including interstitial lung disease; and
- 3 Fither
  - 3.1 Treatment with at least 3 immunosuppressants (oral steroids, cyclophosphamide, methotrexate, mycophenolate, ciclosporin, azathioprine) has not be effective at controlling active disease; or
  - 3.2 Rapid treatment is required due to life threatening complications; and
- 4 Maximum of four 1,000mg infusions of rituximab.

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

All of the following:

- 1 Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in inflammatory markers, muscle strength and pulmonary function; and
- 2 The patient has not received rituximab in the previous 6 months; and
- 3 Maximum of two cycles of 2 x 1,000mg infusions of rituximab given two weeks apart.

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

All of the following:

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

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

- 1 Patient has severe chronic inflammatory demyelinating polyneuropathy (CIPD); and
- 2 Fither:
  - 2.1 Both:
    - 2.1.1 Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease; and
    - 2.1.2 At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease; or
  - 2.2 Rapid treatment is required due to life threatening complications; and

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

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

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

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

All of the following:

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

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

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

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

Fither:

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

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

Both:

1 Rituximab is to be used for maintenance in CD20+ low grade or follicular B-cell NHL following induction with first-line systemic chemotherapy; and

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2 Patient is intended to receive rituximab maintenance therapy for 2 years at a dose of 375 mg/m2 every 8 weeks (maximum of 12 cycles).

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

All of the following:

- 1 Either:
  - 1.1 Patient has biopsy-proven primary/idiopathic membranous nephropathy\*; or
  - 1.2 Patient has PLA2 antibodies with no evidence of secondary cause, and an eGFR of > 60ml/min/1.73m2; and
- 2 Patient remains at high risk of progression to end-stage kidney disease despite more than 3 months of treatment with conservative measures (see Note); and
- 3 The total rituximab dose would not exceed the equivalent of 375mg/m2 of body surface area per week for a total of 4 weeks.

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

All of the following:

- 1 Patient was previously treated with rituximab for membranous nephropathy\*; and
- 2 Either:
  - 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:

Fither:

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- 1 All of the following:
  - 1.1 Patient has severe rapidly progressive pemphigus; and
  - 1.2 Is used in combination with systemic corticosteroids (20 mg/day); and
  - 1.3 Any of the following:
    - 1.3.1 Skin involvement is at least 5% body surface area; or
    - 1.3.2 Significant mucosal involvement (10 or more mucosal erosions) or diffuse gingivitis or confluent large erosions; or
    - 1.3.3 Involvement of two or more mucosal sites: or
- 2 Both:
  - 2.1 Patient has pemphigus; and
  - 2.2 Patient has not experienced adequate clinical benefit from systemic corticosteroids (20 mg/day) in combination with a steroid sparing agent, unless contraindicated.

Note: Indications marked with \* are unapproved indications.

Renewal — (pemiphigus\*) only from a dermatologist or relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has experienced adequate clinical benefit from rituximab treatment, with improvement in symptoms and healing of skin ulceration and reduction in corticosteroid requirement; and
- 2 Patient has not received rituximab in the previous 6 months.

Note: Indications marked with \* are unapproved indications.

Initial application — (immunoglobulin G4-related disease (IgG4-RD\*)) from any relevant practitioner. Approvals valid for 6 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient has confirmed diagnosis of IgG4-RD\*; and
- 2 Either:
  - 2.1 Treatment with corticosteroids and/or disease modifying anti-rheumatic drugs for at least 3 months has been ineffective in lowering corticosteroid dose below 5 mg per day (prednisone equivalent) without relapse; or
  - 2.2 Treatment with corticosteroids and/or disease modifying anti-rheumatic drugs is contraindicated or associated with evidence of toxicity or intolerance; and
- 3 Total rituximab dose used should not exceed a maximum of two 1000 mg infusions of rituximab given two weeks apart.

Note: Indications marked with \* are unapproved indications.

Renewal — (immunoglobulin G4-related disease (IgG4-RD\*)) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 Treatment with rituximab for IgG4-RD\* was previously successful and patient's disease has demonstrated sustained response, but the condition has relapsed; or
  - 1.2 Patient is receiving maintenance treatment for IgG4-RD\*; and
- 2 Rituximab re-treatment not to be given within 6 months of previous course of treatment; and
- 3 Maximum of two 1000 mg infusions of rituximab given two weeks apart.

Note: Indications marked with \* are unapproved indications.

SECUKINUMAB – Special Authority see SA2403 on the next	page – Retail pharma	Cy	
Inj 150 mg per ml, 1 ml prefilled syringe	799.50	1	✓ Cosentyx
	1,599.00	2	✓ Cosentyx

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⇒SA2403 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
- 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

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DLQI prior to commencing secukinumab; or

- 1.2 Both:
  - 1.2.1 Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment; and
  - 1.2.2 Fither:
    - 1.2.2.1 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or
    - 1.2.2.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing secukinumab; and
- 2 Secukinumab to be administered at a maximum dose of 300 mg monthly.

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

Both:

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

**Renewal — (ankylosing spondylitis – second-line biologic)** only from a rheumatologist or medical practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Following 12 weeks initial treatment of secukinumab treatment, BASDAI has improved by 4 or more points from pre-secukinumab baseline on a 10 point scale, or by 50%, whichever is less; and
- 2 Physician considers that the patient has benefitted from treatment and that continued treatment is appropriate; and
- 3 Secukinumab to be administered at doses no greater than 150 mg monthly.

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

#### Either:

- 1 Both:
  - 1.1 Patient has had an initial Special Authority approval for adalimumab, etanercept or infliximab for psoriatic arthritis; and
  - 1.2 Either:
    - 1.2.1 Patient has experienced intolerable side effects from adalimumab, etanercept or infliximab; or
    - 1.2.2 Patient has received insufficient benefit from adalimumab, etanercept or infliximab to meet the renewal criteria for adalimumab, etanercept or infliximab for psoriatic arthritis; or
- 2 All of the following:
  - 2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and
  - 2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
  - 2.3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and
  - 2.4 Either:
    - 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints;
      or
    - 2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
  - 2.5 Any of the following:

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- 2.5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
- 2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or
- 2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

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

Both:

- 1 Either:
  - 1.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  - 1.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior secukinumab treatment in the opinion of the treating physician; and
- 2 Secukinumab to be administered at doses no greater than 300 mg monthly.

#### SILTUXIMAB - Special Authority see SA1596 below - Retail pharmacy

Note: Siltuximab is to be administered at doses no greater than 11 mg/kg every 3 weeks.

Inj 100 mg vial	770.57	1	Sylvant
Inj 400 mg vial	3,082.33	1	✓ Sylvant

#### ⇒SA1596 Special Authority for Subsidy

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

All of the following:

- 1 Patient has severe HHV-8 negative idiopathic multicentric Castleman's Disease; and
- 2 Treatment with an adequate trial of corticosteroids has proven ineffective; and
- 3 Siltuximab is to be administered at doses no greater than 11 mg/kg every 3 weeks.

**Renewal** only from a haematologist or rheumatologist. Approvals valid for 12 months where the treatment remains appropriate and the patient has sustained improvement in inflammatory markers and functional status.

TIXAGEVIMAB WITH CILGAVIMAB - [Xpharm] - Subsidy by endorsement

- a) No patient co-payment payable
- b) Treatment is funded only if patient meets access criteria for tixagevimab with cilgavimab (as per https://pharmac.govt.nz/Evusheld) and has been endorsed accordingly by the prescriber. The supply of treatment is via Pharmac's approved distribution process. Refer to the Pharmac website for more information about this and stock availability.

Inj 100 mg per mi, 1.5 mi viai with cligavimab 100 mg per ml,1.5 ml viai	0.00	1	✓ Evusheld
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	1,100.00	1	✓ Actemra
Ini 1 mg for FCP	2.85	1 ma	✓ 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:

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- 1.1 The patient has developed grade 3 or 4 cytokine release syndrome associated with the administration of blinatumomab for the treatment of acute lymphoblastic leukaemia; and
- 1.2 Tocilizumab is to be administered at doses no greater than 8 mg/kg IV for a maximum of 3 doses (if less than 30kg, maximum of 12 mg/kg); or
- 2 All of the following:
  - 2.1 The patient is enrolled in the Malaghan Institute of Medical Research ENABLE trial programme; and
  - 2.2 The patient has developed CRS or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) following CAR T-cell therapy for the treatment of relapsed or refractory B-cell non-Hodgkin lymphoma; and
  - 2.3 Tocilizumab is to be administered according to the consensus guidelines for CRS or ICANS for CAR T-cell therapy at doses no greater than 8 mg/kg IV for a maximum of 3 doses.

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

Both:

- 1 Patient was being treated with tocilizumab prior to 1 February 2019; and
- 2 Any of the following:
  - 2.1 rheumatoid arthritis: or
  - 2.2 systemic juvenile idiopathic arthritis; or
  - 2.3 adult-onset Still's disease; or
  - 2.4 polyarticular juvenile idiopathic arthritis; or
  - 2.5 idiopathic multicentric Castleman's disease.

Initial application — (Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept)) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
- 2 Fither:
  - 2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
  - 2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis: and
- 3 Either:
  - 3.1 The patient is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor; or
  - 3.2 Both:
    - 3.2.1 The patient has been started on rituximab for rheumatoid arthritis in a 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

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acturer's Price)	Subsidised	Generic
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- 4.1 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of ciclosporin alone or in combination with another agent; or
- 4.2 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of leflunomide alone or in combination with another agent; and

#### 5 Either:

- 5.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints;
- 5.2 Patient has persistent symptoms of poorly controlled and active disease in at least four active joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and

#### 6 Either:

- 6.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
- 6.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Initial application — (systemic juvenile idiopathic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient diagnosed with systemic juvenile idiopathic arthritis; and
- 2 Patient has tried and not responded to a reasonable trial of all of the following, either alone or in combination: oral or parenteral methotrexate; non-steroidal anti-inflammatory drugs (NSAIDs); and systemic corticosteroids.

Initial application — (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria: Either:

#### 1 Both:

- 1.1 Either:
  - 1.1.1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for adult-onset Still's disease (AOSD); or
  - 1.1.2 The patient has been started on tocilizumab for AOSD in a Health NZ Hospital; and
- 1.2 Either:
  - 1.2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
  - 1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for AOSD; or

#### 2 All of the following:

- 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and
- 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal antiinflammatory drugs (NSAIDs) and methotrexate; and
- 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

Initial application — (polyarticular juvenile idiopathic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria: Either:

#### 1 Both:

- 1.1 The patient has had an initial Special Authority approval for both etanercept and adalimumab for polyarticular course juvenile idiopathic arthritis (JIA); and
- 1.2 The patient has experienced intolerable side effects, or has received insufficient benefit from, both etanercept and adalimumab; or

#### 2 All of the following:

2.1 Treatment with a tumour necrosis factor alpha inhibitor is contraindicated; and

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- 2.2 Patient has had polyarticular course JIA for 6 months duration or longer; and
- 2.3 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance: and
- 2.4 Any of the following:
  - 2.4.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
  - 2.4.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or
  - 2.4.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

Initial application — (idiopathic multicentric Castleman's disease) only from a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has severe HHV-8 negative idiopathic multicentric Castleman's disease; and
- 2 Treatment with an adequate trial of corticosteroids has proven ineffective; and
- 3 Tocilizumab to be administered at doses no greater than 8 mg/kg IV every 3-4 weeks.

Initial application — (moderate to severe COVID-19) from any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient has confirmed (or probable) COVID-19; and
- 2 Oxygen saturation of < 92% on room air, or requiring supplemental oxygen; and
- 3 Patient is receiving adjunct systemic corticosteroids, or systemic corticosteroids are contraindicated; and
- 4 Tocilizumab is to be administered at doses no greater than 8mg/kg IV for a maximum of one dose; and
- 5 Tocilizumab is not to be administered in combination with barcitinib.

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

- 1 Following 6 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician.

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

- 1 Following up to 6 months' initial treatment, the patient has achieved at least an American College of Rheumatology paediatric 30% improvement criteria (ACR Pedi 30) response from baseline; or
- 2 On subsequent reapplications, the patient demonstrates at least a continuing ACR Pedi 30 response from baseline.

Renewal — (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months where the patient has a sustained improvement in inflammatory markers and functional status. Renewal — (polyarticular juvenile idiopathic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria: Both:

- 1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2 Fither:
  - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or

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\$	Per	✓	Manufacturer

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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 SA2293 below

Inj 150 mg vial	100.00	1	✓ Herzuma
Inj 440 mg vial	293.35	1	✓ Herzuma
Inj 1 mg for ECP	0.70	1 mg	✓ Baxter

### ⇒SA2293 Special Authority for Subsidy

**Initial application** — (early breast cancer) from any relevant practitioner. Approvals valid for 15 months for applications meeting the following criteria:

#### Both:

- 1 The patient has early breast cancer expressing HER-2 IHC 3+ or ISH + (including FISH or other current technology); and
- 2 Maximum cumulative dose of 106 mg/kg (12 months' treatment).

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

#### Either:

- 1 All of the following:
  - 1.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
  - 1.2 The patient received prior adjuvant trastuzumab treatment for early breast cancer; and
  - 1.3 Any of the following:
    - 1.3.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
    - 1.3.2 The patient discontinued lapatinib within 3 months due to intolerable side effects and the cancer did not progress whilst on lapatinib; or
    - 1.3.3 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
  - 1.4 Either:
    - 1.4.1 Trastuzumab will not be given in combination with pertuzumab; or
    - 1.4.2 All of the following:
      - 1.4.2.1 Trastuzumab to be administered in combination with pertuzumab; and
      - 1.4.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
      - 1.4.2.3 The patient has good performance status (ECOG grade 0-1); and
  - 1.5 Trastuzumab to be discontinued at disease progression; or
- 2 All of the following:
  - 2.1 Patient has previously discontinued treatment with trastuzumab in the metastatic setting for reasons other than severe toxicity or disease progression; and
  - 2.2 Patient has signs of disease progression; and
  - 2.3 Disease has not progressed during previous treatment with trastuzumab.

Note: \* For patients with relapsed HER-2 positive disease who have previously received adjuvant trastuzumab for early breast cancer

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

All of the following:

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- 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
  - 1.3 Trastuzumab to be discontinued at disease progression; or
- 2 All of the following:
  - 2.1 Patient has previously discontinued treatment with trastuzumab for reasons other than severe toxicity or disease progression; and
  - 2.2 Patient has signs of disease progression; and
  - 2.3 Disease has not progressed during previous treatment with trastuzumab.

Initial application — (gastric, gastro-oesophageal junction and oesophageal cancer) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The patient has locally advanced or metastatic gastric, gastro-oesophageal junction or oesophageal cancer expressing HER-2 IHC 2+ FISH+ or IHC3+ (or other current technology); and
- 2 Patient has an ECOG score of 0-2.

Renewal — (gastric, gastro-oesophageal junction and oesophageal cancer) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
- 2 Trastuzumab to be discontinued at disease progression.

TRASTUZUMAB EMTANSINE - PCT only - Specialist - Special Authority see SA2144 below

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

**⇒SA2144** Special Authority for Subsidy

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

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All of the following:

- 1 Patient has early breast cancer expressing HER2 IHC3+ or ISH+; and
- 2 Documentation of pathological invasive residual disease in the breast and/or auxiliary lymph nodes following completion of surgery; and
- 3 Patient has completed systemic neoadjuvant therapy with trastuzumab and chemotherapy prior to surgery; and
- 4 Disease has not progressed during neoadjuvant therapy; and
- 5 Patient has left ventricular ejection fraction of 45% or greater; and
- 6 Adjuvant treatment with trastuzumab emtansine to be commenced within 12 weeks of surgery; and
- 7 Trastuzumab emtansine to be discontinued at disease progression; and
- 8 Total adjuvant treatment duration must not exceed 42 weeks (14 cycles).

Initial application — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 Patient has previously received trastuzumab and chemotherapy, separately or in combination; and
- 3 Either:
  - 3.1 The patient has received prior therapy for metastatic disease\*; or
  - 3.2 The patient developed disease recurrence during, or within six months of completing adjuvant therapy\*; and
- 4 Patient has a good performance status (ECOG 0-1); and
- 5 Either:
  - 5.1 Patient does not have symptomatic brain metastases; or
  - 5.2 Patient has brain metastases and has received prior local CNS therapy; and
- 6 Patient has not received prior funded trastuzumab emtansine treatment; and
- 7 Treatment to be discontinued at disease progression.

Renewal — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab emtansine; and
- 2 Treatment to be discontinued at disease progression.

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

USTEKINUMAB - Special Authority see SA2182 below - Retail pharmacy

Inj 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
- 2 Both:
  - 2.1 Patient has active Crohn's disease: and
  - 2.2 Either:
    - 2.2.1 Patient has had an initial approval for prior biologic therapy for Crohn's disease and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or
    - 2.2.2 Both:
      - 2.2.2.1 Patient meets the initiation criteria for prior biologic therapies for Crohn's disease; and

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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 Fither:
    - 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:

Either:

- 1 Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment; or
- 2 Both:
  - 2.1 Patient has active ulcerative colitis: and
  - 2.2 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.

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

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

Both:

- 1 Fither:
  - 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 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

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- 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.

## Programmed Cell Death-1 (PD-1) Inhibitors

ATEZOLIZUMAB – PCT only – Specialist – Special Auth	ority see SA2264 on the n	ext page	
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

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

### ⇒SA2264 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:
- 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).

#### DURVALUMAB - PCT only - Specialist - Special Authority see SA2164 below Inj 50 mg per ml, 10 ml vial.......4,700.00 1

✓ Imfinzi ✓ Imfinzi 1 ma ✓ Baxter

## ⇒SA2164 Special Authority for Subsidy

Initial application — (Non-small cell lung cancer) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 3 months for applications meeting the following criteria: All of the following:

- 1 Patient has histologically or cytologically documented stage III, 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;
- 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 Fither:

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- 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 medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 The treatment remains clinically appropriate and the patient is benefitting from treatment; and
- 2 Either:
  - 2.1 Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks; or
  - 2.2 Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks; and
- 3 Treatment with durvalumab to cease upon signs of disease progression; and
- 4 Total continuous treatment duration must not exceed 12 months.

NIVOLUMAB – PCT only – Specialist – Special Authority see SA2405 below	NIVOLUMAB	<ul> <li>PCT only – Specialist</li> </ul>	- Special Authorit	v see SA2405 belov
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Inj 10 mg per ml, 4 ml vial	1,051.98	1	<ul><li>Opdivo</li></ul>
Inj 10 mg per ml, 10 ml vial	2,629.96	1	✓ Opdivo
Inj 1 mg for ECP	27.62	1 mg	✓ Baxter

## ⇒SA2405 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:

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:
  - 2.1 Patient has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression; and
  - 2.2 Patient has signs of disease progression; and
  - 2.3 Disease has not progressed during previous treatment with nivolumab.

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(Manufacti	urer's Price) Subsidi	sed Gener	ric
	\$ Per	✓ Manuf	facturer

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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) 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:

Fither:

- 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 Patient has metastatic renal-cell carcinoma; and
  - 2.2 The disease is of predominant clear-cell histology; and
  - 2.3 Patient has an ECOG performance score of 0-2; and
  - 2.4 Patient has documented disease progression following one or two previous regimens of antiangiogenic therapy; and
  - 2.5 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) 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 Nivolumab is to be used as monotherapy at a maximum dose of 240 mg every 2 weeks (or equivalent) and discontinued at disease progression.

		– PCT only – Specialist – Special Authority see SA2386 below	PEMBRULIZUMAB - PUT
✓ Keytruda	1	4 ml vial4,680.00	Inj 25 mg per ml, 4 ml v
✓ Baxter	1 mg	47.74	Inj 1 mg for ECP

⇒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:

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

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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:
  - 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

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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 Fither:
  - 6.1 There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 50% as determined by a validated test unless not possible to ascertain; or
  - 6.2 Both:
    - 6.2.1 There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 1% as determined by a validated test unless not possible to ascertain; and
    - 6.2.2 Chemotherapy is determined to be not in the best interest of the patient based on clinician assessment; and
- 7 Patient has an ECOG 0-2; and
- 8 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks; and
- 9 Baseline measurement of overall tumour burden is documented clinically and radiologically.

Renewal — (non-small cell lung cancer first line monotherapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 Patient's disease has had a complete response to treatment; or
  - 1.2 Patient's disease has had a partial response to treatment; or
  - 1.3 Patient has stable disease; and
- 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

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- 7 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks;
- 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: Fither:

- 1 Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Either:
    - 2.1.1 Patient has recurrent or de novo unresectable, inoperable locally advanced triple-negative breast cancer (that does not express ER, PR or HER2 IHC3+ or ISH+ [including FISH or other technology]); or
    - 2.1.2 Patient has recurrent or de novo metastatic triple-negative breast cancer (that does not express ER, PR or HER2 IHC3+ or ISH+ [including FISH or other technology]); and
  - 2.2 Patient is treated with palliative intent; and
  - 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

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(Manufacturer's Price)	Subsidised	Generic
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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:

Fither:

- 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 Fither:
    - 2.5.1 Pembrolizumab to be used in combination with platinum-based chemotherapy; or
    - 2.5.2 Pembrolizumab to be used as monotherapy; and
  - 2.6 Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks.

Renewal — (head and neck squamous cell carcinoma) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 Patient's disease has had a complete response to treatment; or
  - 1.2 Patient's disease has had a partial response to treatment: or
  - 1.3 Patient has stable disease; and
- 2 No evidence of disease progression; and
- 3 Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 4 Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Initial application — (MSI-H/dMMR advanced colorectal cancer) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

Fither:

- 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:

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- 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:

Fither:

- 1 Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Patient has inoperable locally advanced (T4) or metastatic urothelial carcinoma; and
  - 2.2 Patient has an ECOG performance score of 0-2; and
  - 2.3 Patient has documented disease progression following treatment with chemotherapy; and
  - 2.4 Pembrolizumab to be used as monotherapy at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks.

Renewal — (Urothelial carcinoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 Patient's disease has had a complete response to treatment; or
  - 1.2 Patient's disease has had a partial response to treatment; or
  - 1.3 Patient has stable disease; and
- 2 No evidence of disease progression; and
- 3 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 4 Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Initial application — (relapsed/refractory Hodgkin lymphoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: Either:

- 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).

Fully

Brand or

Subsidy

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Other Immunosuppressants				
CICLOSPORIN				
Cap 25 mg	44.63	50	✓ N	leoral
Cap 50 mg	88.91	50	✓ N	leoral
Cap 100 mg		50	✓ N	leoral
Oral liq 100 mg per ml		50 ml OP	✓ N	leoral
EVEROLIMUS – Special Authority see SA2008 below – Retail ph Wastage claimable	armacy			
Tab 10 mg	6,512.29	30	<b>✓</b> A	Afinitor
Tab 5 mg	•	30	✓ A	Afinitor
SA2008 Special Authority for Subsidy				

#### | ⇒SA2008 | Special Authority for Subsidy

Initial application only from a neurologist or oncologist. Approvals valid for 3 months for applications meeting the following criteria:

#### Roth:

- 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.

# SIROLIMUS - Special Authority see SA2270 below - Retail pharmacy

Tab 1 mg	749.99	100	Rapamune
Tab 2 mg	1,499.99	100	✓ Rapamune
Oral liq 1 mg per ml	449.99	60 ml OP	Rapamune

#### ⇒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).

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Renewal — (severe non-malignant lymphovascular malformations\*) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 Patient's disease has had either a complete response or a partial response to treatment, or patient has stable disease according to RECIST version 1.1 (see Note); or
  - 1.2 Patient's disease has stabilised or responded clinically and disease response to treatment has been clearly documents in patient notes; and
- 2 No evidence of progressive disease: and
- 3 The treatment remains clinically appropriate and the patient is benefitting from the treatment.

Notes: Baseline assessment and disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer et al. Eur J Cancer 2009;45:228-47)

Indications marked with \* are unapproved indications

Initial application — (renal angiomyolipoma(s) associated with tuberous sclerosis complex\*) only from a nephrologist or urologist. Approvals valid for 6 months for applications meeting the following criteria: Both:

- 1 Patient has tuberous sclerosis complex\*; and
- 2 Evidence of renal angiomyolipoma(s) measuring 3 cm or greater and that have shown interval growth.

Renewal — (renal angiomyolipoma(s) associated with tuberous sclerosis complex\*) from any relevant practitioner.

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

- 1 Documented evidence of renal angiomyolipoma reduction or stability by magnetic resonance imaging (MRI) or ultrasound;
- 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.

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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 SA2271 below - Retail pharmacy

Cap 0.5 mg	100	✓ Tacrolimus Sandoz
Cap 0.75 mg	100	✓ Tacrolimus Sandoz
Cap 1 mg	100	✓ Tacrolimus Sandoz
Cap 5 mg248.20	50	✓ Tacrolimus Sandoz

#### ⇒SA2271 Special Authority for Subsidy

Initial application — (organ transplant) only from a relevant specialist. Approvals valid without further renewal unless notified where the patient is an organ transplant recipient.

Note: Subsidy applies for either primary or rescue therapy.

Initial application — (non-transplant indications\*) only from a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 Patient requires long-term systemic immunosuppression; and
- 2 Fither:
  - 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

#### ⇒SA2079 Special Authority for Subsidy

Initial application — (Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept)) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
- 2 Either:
  - 2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
  - 2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis; and
- 3 Either:
  - 3.1 The patient is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor; or
  - 3.2 Both:
    - 3.2.1 The patient has been started on rituximab for rheumatoid arthritis in a Health NZ Hospital; and
    - 3.2.2 Either:
      - 3.2.2.1 The patient has experienced intolerable side effects from rituximab; or
      - 3.2.2.2 At four months following the initial course of rituximab the patient has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis.

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

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Either:

- 1 Following 6 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician.

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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	Epipen

### ⇒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 - 5 yials 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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WASP VENOM ALLERGY TREATMENT - Special Authority see	•	previous par	ne – Ret	
Treatment kit (Paper wasp venom) - 1 vial 550 mcg freeze	o o	providuo pa	,	an priaminal
dried polistes venom, 1 diluent 9 ml, 3 diluent 1.8 ml	382.23	1 OP	✓	Albey
Treatment kit (Paper wasp venom) - 1 vial 550 mcg freeze				•
dried venom, with diluent	305.00	1 OP	✓	Hymenoptera S29
Treatment kit (Paper wasp venom) - 6 vials 120 mcg freeze			_	
dried venom, with diluent	305.00	1 OP	/	Venomil S29
Treatment kit (Yellow Jacket venom) - 1 vial 550 mcg freeze	005.00	1 OD		Uluman antana 222
dried venom, with diluent	305.00	1 OP	•	Hymenoptera S29
Treatment kit (Yellow jacket venom) - 1 vial 550 mcg freeze dried vespula venom, 1 diluent 9 ml, 3 diluent 1.8 ml	121 21	1 OP	J	Albey
Treatment kit (Yellow jacket venom) - 6 vials 120 mcg freeze		TOP	•	Albey
dried venom, with diluent		1 OP	1	Venomil \$29
diod volioni, with didorit		1 01		venoniii —
Antihistamines				
CETIRIZINE HYDROCHLORIDE				
* Tab 10 mg	1 71	100	/	Zista
* Oral lig 1 mg per ml		200 ml		Histaclear
DEXTROCHLORPHENIRAMINE MALEATE		200		
* Tab 2 mg	2 02	40		
- 140 E 119	(8.40)			Polaramine
	1.01	20		
	(5.99)			Polaramine
* Oral liq 2 mg per 5 ml	1.77	100 ml		
	(10.29)			Polaramine
FEXOFENADINE HYDROCHLORIDE				
* Tab 60 mg		20		
Nr. Tal. 400	(8.23)	40		Telfast
* Tab 120 mg		10		Telfast
	(8.23) 14.22	30		Tellast
	(26.44)	50		Telfast
ORATADINE	(20.11)			Tonaot
* Tab 10 mg	1 78	100	1	Lorafix
* Oral liq 1 mg per ml		100 ml		Haylor syrup
PROMETHAZINE HYDROCHLORIDE				.,,.,
* Tab 10 mg	1.39	50	1	Allersoothe
* Tab 25 mg		50		Allersoothe
* Oral liq 1 mg per 1 ml	3.39	100 ml	✓	Allersoothe
Inj 25 mg per ml, 2 ml ampoule – Up to 5 inj available on a F	PSO21.09	5	1	Hospira
Inhaled Corticosteroids				
BECLOMETHASONE DIPROPIONATE	44.04			•
Aerosol inhaler, 50 mcg per dose		200 dose O	_	Qvar
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose O 200 dose O		Beclazone 50 Qvar
Aerosol inhaler, 100 mcg per dose CFC-free		200 dose O 200 dose O		Gvar Beclazone 100
Aerosol inhaler, 700 mg per dose CFC-free		200 dose O 200 dose O		Beclazone 250
		_ , , , , , , , , , , , , , , , , , , ,		

	Subsidy (Manufacturer's		c	Fully	
	(Manuacturer S	riice)	Per		
BUDESONIDE					
Powder for inhalation, 100 mcg per dose	17.00	200	dose (	DP 🗸	Pulmicort
Toward for initialization, 100 mag per doce		200	4000	, ,	Turbuhaler
Powder for inhalation, 200 mcg per dose	19.00	200	dose (	DP 🗸	Pulmicort
1 owder for initialization, 200 mag per document		200	4000	, ,	Turbuhaler
Powder for inhalation, 400 mcg per dose	32.00	200	dose (	DP 🗸	Pulmicort
Toward for initialization, 400 mag per doce	02.00	200	4000	, ,	Turbuhaler
FLUTICASONE					Turburialor
Aerosol inhaler, 50 mcg per dose	7 10	120	dose (	np 🗸	Flixotide
Powder for inhalation, 50 mcg per dose			lose C		Flixotide Accuhaler
Powder for inhalation, 100 mcg per dose			lose C		Flixotide Accuhaler
Aerosol inhaler, 125 mcg per dose			dose (		Flixotide Accumaler
Aerosol inhaler, 250 mcg per dose			dose (		Flixotide
			lose C		Flixotide Accuhaler
Powder for inhalation, 250 mcg per dose	11.93	60 0	iose C	P ▼	Filxolide Accunaler
Inhaled Long-acting Beta-adrenoceptor Agonist	s				
innaiou zong domig zona daronoooptor rigomot					
EFORMOTEROL FUMARATE DIHYDRATE					
Powder for inhalation 4.5 mcg per dose, breath activated					
(equivalent to eformoterol fumarate 6 mcg metered dose	) 10.32	60 c	lose C	P	
	(16.90)				Oxis Turbuhaler
NDACATEROL					
Powder for inhalation 150 mcg	61.00	30.0	lose C	P 🗸	Onbrez Breezhaler
Powder for inhalation 300 mcg			lose C		Onbrez Breezhaler
· ·		00 0	1000 0	,, -	Olibicz Biccznaici
SALMETEROL 050 (see 05 manuscriptor)	00.05	400		<b>3</b> D <b>4</b>	
Aerosol inhaler CFC-free, 25 mcg per dose			dose (		Serevent
Powder for inhalation, 50 mcg per dose, breath activated	26.25	60 0	lose C	)P 🗸	Serevent Accuhaler
Inhaled Corticosteroids with Long-Acting Beta-	Adrenocep	tor A	gonis	sts	
BUDESONIDE WITH EFORMOTEROL					
Powder for inhalation 160 mcg with 4.5 mcg eformoterol					
fumarate per dose (equivalent to 200 mcg budesonide w	ith				
6 mcg eformoterol fumarate metered dose)		120	dose (	np 🗸	DuoResp Spiromax
		120	uose (	) •	Duonesp Spirolliax
Powder for inhalation 320 mcg with 9 mcg eformoterol fumars					
per dose (equivalent to 400 mcg budesonide with 12 mcg	9				
eformoterol fumarate metered dose) – No more than 2	00.50	100	(	OD .	Dua Daam Culinaman
dose per day			dose (		DuoResp Spiromax
Aerosol inhaler 100 mcg with eformoterol fumarate 6 mcg			dose (		Vannair
Powder for inhalation 100 mcg with eformoterol fumarate 6 m	icg33.74	120	dose (	JP 🗸	Symbicort Tools to 100/0
					Turbuhaler 100/6
Aerosol inhaler 200 mcg with eformoterol fumarate 6 mcg			dose (		Vannair
Powder for inhalation 200 mcg with eformoterol fumarate 6 m	ncg 33.74	120	dose (	OP 🗸	Symbicort
					Turbuhaler 200/6
Powder for inhalation 400 mcg with eformoterol fumarate					_
12 mcg - No more than 2 dose per day	33.74	60 c	lose C	)P 🗸	Symbicort
					Turbuhaler 400/12
FLUTICASONE FUROATE WITH VILANTEROL					
Powder for inhalation 100 mcg with vilanterol 25 mcg	44.08	30 c	lose C	P 🗸	Breo Ellipta
ů · · ·					•

	Subsidy (Manufacturer's \$	Price) Subs	Fully Brand or idised Generic ✓ Manufacturer
LUTICASONE WITH SALMETEROL  Aerosol inhaler 50 mcg with salmeterol 25 mcg  Aerosol inhaler 125 mcg with salmeterol 25 mcg  Powder for inhalation 100 mcg with salmeterol 50 mcg		120 dose OP 120 dose OP	✓ Seretide ✓ Seretide
more than 2 dose per day Powder for inhalation 250 mcg with salmeterol 50 mcg – No		60 dose OP	✓ Seretide Accuhaler
more than 2 dose per day  Beta-Adrenoceptor Agonists	44.08	60 dose OP	✓ Seretide Accuhaler
ALBUTAMOL Oral liq 400 mcg per ml Infusion 1 mg per ml, 5 ml Inj 500 mcg per ml, 1 ml – Up to 5 inj available on a PSO	130.00	150 ml 10 5	✓ Ventolin ✓ Ventolin ✓ Ventolin
Inhaled Beta-Adrenoceptor Agonists			
ALBUTAMOL  Aerosol inhaler, 100 mcg per dose CFC free – Up to 1000 dose available on a PSO	3.80 (6.80)	200 dose OP	✓ SalAir Ventolin
Nebuliser soln, 1 mg per ml, 2.5 ml ampoule – Up to 30 neb available on a PSO	8.96	20	✓ Asthalin ✓ PMS- Salbutamol S29
			✓ Teva-Salbutamol Sterinebs P.F. S29
			✓ Ventolin Nebules \$29
Nebuliser soln, 2 mg per ml, 2.5 ml ampoule — Up to 30 neb available on a PSO	9.43	20	✓ Asthalin ✓ PMS- Salbutamol S29
	14.15	30	✓ Salbutamol Cipla S29
ERBUTALINE SULPHATE Powder for inhalation, 200 mcg per dose (equivalent to			
250 mcg metered dose), breath activated	22.20	120 dose OP	<ul> <li>Bricanyl Turbuhaler</li> </ul>

	RESPIRAT	TORY SYSTE	EM AND ALLERGIES
	Subsidy (Manufacturer's	Price) Subsi Per	Fully Brand or dised Generic  Manufacturer
Anticholinergic Agents			
PRATROPIUM BROMIDE  Aerosol inhaler, 20 mcg per dose CFC-free – Up to 400 dos available on a PSO	16.20	200 dose OP	✓ Atrovent
Nebuliser soln, 250 mcg per ml, 2 ml ampoule – Up to 40 no available on a PSO		10 20	✓ Pharmascience \$29 ✓ Ipratropium IVAX \$29
	28.20		✓ Univent ✓ Accord S29
Inhaled Beta-Adrenoceptor Agonists with Antic	holinergic A	Agents	
SALBUTAMOL WITH IPRATROPIUM BROMIDE  Aerosol inhaler, 100 mcg with ipratropium bromide, 20 mcg place of the comment of the com	12.19	200 dose OP	✓ Duolin HFA
vial, 2.5 ml ampoule – Up to 20 neb available on a PSC	33.12	20 60	✓ Duolin ✓ Duolin Cipla S29 ✓ Duolin Respules S29
Long-Acting Muscarinic Antagonists			
CALYCOPYRRONIUM — Subsidy by endorsement     a) Inhaled glycopyrronium treatment will not be subsidised i umeclidinium.     b) Glycopyrronium powder for inhalation 50 mcg per dose is having COPD using spirometry if spirometry is possible, Powder for inhalation 50 mcg per dose	s subsidised only and the prescrip 61.00	y for patients who tion is endorsed 30 dose OP	o have been diagnosed as accordingly.  Seebri Breezhaler
<ul> <li>a) Tiotropium treatment will not be subsidised if patient is al umeclidinium.</li> <li>b) Tiotropium bromide is subsidised only for patients who has spirometry is possible, and the prescription is endorsed a 1 October 2018 with a valid Special Authority are deemer Powder for inhalation, 18 mcg per dose</li></ul>	ave been diagno accordingly. Pat d endorsed. 50.37	osed as having C	COPD using spirometry if
JMECLIDINIUM – Subsidy by endorsement			

COPD using spirometry if spirometry is possible, and the prescription is endorsed accordingly.

a) Umeclidinium will not be subsidised if patient is also receiving treatment with subsidised inhaled glycopyrronium or

b) Umeclidinium powder for inhalation 62.5 mcg per dose is subsidised only for patients who have been diagnosed as having

30 dose OP

✓ Incruse Ellipta

tiotropium bromide.

Subsidy (Manufacturer's Price) \$ Per

Fully Subsidised Brand or Generic Manufacturer

### Long-Acting Muscarinic Antagonists with Long-Acting Beta-Adrenoceptor Agonists

Combination long acting muscarinic antagonist and long acting beta-2 agonist will not be subsidised if patient is also receiving treatment with a combination inhaled corticosteroid and long acting beta-2 agonist.

#### ⇒SA1584 Special Authority for Subsidy

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

- 1 Patient has been stabilised on a long acting muscarinic antagonist; and
- 2 The prescriber considers that the patient would receive additional benefit from switching to a combination product.

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

- 1 Patient is compliant with the medication: and
- 2 Patient has experienced improved COPD symptom control (prescriber determined).

GLYCOPYRRONIUM WITH INDACATEROL - Special Authority see SA1584 above - Retail pharmacy

Powder for Inhalation 50 mcg with indacaterol 110 mcg......81.00 30 dose OP 🗸 Ultibro Breezhaler

TIOTROPIUM BROMIDE WITH OLODATEROL - Special Authority see SA1584 above - Retail pharmacy

Soln for inhalation 2.5 mcg with olodaterol 2.5 mcg ......81.00 60 dose OP Spiolto Respimat

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

### Inhaled Corticosteroid with Long-Acting Muscarinic Antagonist and Beta Agonist

FLUTICASONE FUROATE WITH UMECLIDINIUM AND VILANTEROL – Special Authority see SA2326 below – Retail pharmacy Powder for inhalation fluticasone furoate 100 mcg with

umeclidinium 62.5 mcg and vilanterol 25 mcg......104.24 30 dose OP ✓ Trelegy Ellipta

#### ⇒SA2326 Special Authority for Subsidy

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

Both:

- 1 Patient has a diagnosis of COPD confirmed by spirometry or spirometry has been attempted and technically acceptable results are not possible; and
- 2 Fither:
  - 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.

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

# **Antifibrotics**

NINTEDANIB - Special Authority see SA2012 below - Retail pharmacy

Note: Nintedanib not subsidised in combination with subsidised pirfenidone.

### ⇒SA2012 Special Authority for Subsidy

Initial application — (idiopathic pulmonary fibrosis) only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

#### All of the following:

- 1 Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist; and
- 2 Forced vital capacity is between 50% and 90% predicted; and
- 3 Nintedanib is to be discontinued at disease progression (See Note); and
- 4 Nintedanib is not to be used in combination with subsidised pirfenidone; and
- 5 Any of the following:
  - 5.1 The patient has not previously received treatment with pirfenidone; or
  - 5.2 Patient has previously received pirfenidone, but discontinued pirfenidone within 12 weeks due to intolerance; or
  - 5.3 Patient has previously received pirfenidone, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with pirfenidone).

Renewal — (idiopathic pulmonary fibrosis) only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

#### All of the following:

- 1 Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and
- 2 Nintedanib is not to be used in combination with subsidised pirfenidone; and
- 3 Nintedanib is to be discontinued at disease progression (See Note).

Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

PIRFENIDONE - Retail pharmacy-Specialist - Special Authority see SA2013 below

Note: Pirfenidone is not subsidised in combination with subsidised nintedanib.

Tab 801 mg	3,645.00	90 OP	<ul><li>Esbriet</li></ul>
Tab 267 mg	1,215.00	90	<ul><li>Esbriet</li></ul>

#### ⇒SA2013 Special Authority for Subsidy

Initial application — (idiopathic pulmonary fibrosis) only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

#### All of the following:

- 1 Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist; and
- 2 Forced vital capacity is between 50% and 90% predicted; and
- 3 Pirfenidone is to be discontinued at disease progression (See Note); and
- 4 Pirfenidone is not to be used in combination with subsidised nintedanib; and
- 5 Any of the following:
  - 5.1 The patient has not previously received treatment with nintedanib; or
  - 5.2 Patient has previously received nintedanib, but discontinued nintedanib within 12 weeks due to intolerance; or
  - 5.3 Patient has previously received nintedanib, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with nintedanib).

**Renewal — (idiopathic pulmonary fibrosis)** only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

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

continued...

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.

# **Leukotriene Receptor Antagonists**

MC	NTELUKAST		
*	Tab 4 mg	28	✓ Montelukast Viatris
*	Tab 5 mg3.10	28	✓ Montelukast Viatris
*	Tab 10 mg2.90	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
TH	EOPHYLLINE		
*	Tab long-acting 250 mg24.90	100	✓ Nuelin-SR
*	Oral lig 80 mg per 15 ml	500 ml	✓ Nuelin

### **Mucolytics**

DORNASE ALFA - Special Authority see SA1978 below - Reta	ail 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
- 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 SA2196 on the next page

Tab elexacattor 50 mg with tezacattor 25 mg, ivacattor 3	7.5 mg		
(56) and ivacaftor 75 mg (28)	27,647.39	84 OP	Trikafta
Tab elexacaftor 100 mg with tezacaftor 50 mg, ivacaftor	75 mg		
(56) and ivacaftor 150 mg (28)	27,647.39	84 OP	Trikafta

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

#### ⇒SA2196 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 <a href="https://www.accessdata.fda.gov/drugsatfda\_docs/label/2021/212273s004lbl.pdf">https://www.accessdata.fda.gov/drugsatfda\_docs/label/2021/212273s004lbl.pdf</a>

# IVACAFTOR – PCT only – Specialist – Special Authority see SA2017 below

Tab 150 mg	29,386.00	56	✓ Kalydeco
Oral granules 50 mg, sachet	29,386.00	56	✓ Kalydeco
Oral granules 75 mg, sachet	29,386.00	56	✓ Kalydeco

#### ⇒SA2017 Special Authority for Subsidy

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

#### All of the following:

- 1 Patient has been diagnosed with cystic fibrosis; and
- 2 Either:
  - 2.1 Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; or
  - 2.2 Patient must have other gating (class III) mutation (G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N and S549R) in the CFTR gene on at least 1 allele; and
- 3 Patients must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis or by Macroduct sweat collection system; and
- 4 Treatment with ivacaftor must be given concomitantly with standard therapy for this condition; and
- 5 Patient must not have an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing treatment with ivacaftor; and
- 6 The dose of ivacaftor will not exceed one tablet or one sachet twice daily; and
- 7 Applicant has experience and expertise in the management of cystic fibrosis.

#### SODIUM CHI ORIDE

Not funded for use as a nasal drop.			
Soln 7%	24.50	90 ml OP	Biomed

	(Manufacturer's	Price) Subsi	dised Generic ✓ Manufacturer
Nasal Preparations			
Allergy Prophylactics			
BUDESONIDE  Metered aqueous nasal spray, 50 mcg per dose  SteroClear to be Principal Supply on 1 February 2025	2.59	200 dose OP	✓ SteroClear
Metered aqueous nasal spray, 100 mcg per dose SteroClear to be Principal Supply on 1 February 2025	2.89	200 dose OP	✓ SteroClear
FLUTICASONE PROPIONATE  Metered aqueous nasal spray, 50 mcg per dose	1.98	120 dose OP	✓ Flixonase Hayfever  & Allergy
IPRATROPIUM BROMIDE Aqueous nasal spray, 0.03%	5.23	15 ml OP	✓ Univent
Respiratory Devices			
MASK FOR SPACER DEVICE  a) Up to 50 dev available on a PSO b) Only on a PSO			
c) Only for children aged six years and under Small	2.70	1	✓ e-chamber Mask
PEAK FLOW METER  a) Up to 25 dev available on a PSO b) Only on a PSO			
Low range	9.54	1	<ul><li>Mini-Wright AFS Low Range</li></ul>
Normal range	9.54	1	✓ Mini-Wright Standard
SPACER DEVICE  a) Up to 50 dev available on a PSO b) Only on a PSO			
220 ml (single patient)		1 1	<ul><li>✓ e-chamber Turbo</li><li>✓ e-chamber La</li><li>Grande</li></ul>
800 ml	6.50	1	✓ Volumatic
Respiratory Stimulants			
CAFFEINE CITRATE Oral liq 20 mg per ml (10 mg base per ml)	16.10	25 ml OP	✓ Biomed

Subsidy

Fully

Brand or

	Subsidy (Manufacturer's Pric \$	ce) Subs Per	Fully Brand or sidised Generic ✓ Manufacturer
Ear Preparations			
FLUMETASONE PIVALATE			
Ear drops 0.02% with clioquinol 1%	4.46	7.5 ml OP	✓ Locacorten-Viaform ED's
			✓ Locorten-Vioform
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCI	N AND NYSTATIN	١	
Ear drops 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 mcg per g	5.16	7.5 ml OP	✓ Kenacomb
Ear/Eye Preparations			
DEXAMETHASONE WITH FRAMYCETIN AND GRAMICIDIN			
Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and			
gramicidin 50 mcg per ml		8 ml OP	Otto dou con
	(9.27) (9.27)		Otodex S29 Sofradex
FRAMYCETIN SULPHATE	(0.27)		Conducx
Ear/Eye drops 0.5%	4.13	8 ml OP	
, ,	(8.65)		Soframycin
Eye Preparations			
Eye preparations are only funded for use in the eye, unless explicit	citly stated otherwis	se.	
Anti-Infective Preparations			
ACICLOVIR			
* Eye oint 3%	15.89	4.5 g OP	✓ ViruPOS
ViruPOS to be Principal Supply on 1 February 2025 CHLORAMPHENICOL			
Eye oint 1%	1 09	5 g OP	✓ Devatis
Eye drops 0.5%		10 ml OP	✓ Chlorsig
Funded for use in the ear*. Indications marked with * are	e unapproved indic	cations.	
CIPROFLOXACIN			
Eye drops 0.3% – Subsidy by endorsement	r severe bacterial of media (CSOM)*;		
SODIUM FUSIDATE [FUSIDIC ACID]			•

5 g OP

3.5 g OP

5 ml OP

✓ Fucithalmic

✓ Tobrex

✓ Tobrex

**TOBRAMYCIN** 



Subsi	sidy Ful	y Brand or
(Manufacture	er's Price) Subsidise	d Generic
<b>\$</b>	Per	Manufacturer

## **Corticosteroids and Other Anti-Inflammatory Preparations**

DEXAMETHASONE  * Eye oint 0.1%  * Eye drops 0.1%	3.5 g OP 5 ml OP	✓ Maxidex ✓ Maxidex
Ocular implant 700 mcg – Special Authority see SA1680 below  – Retail pharmacy	1	✓ Ozurdex

#### ⇒SA1680 Special Authority for Subsidy

Initial application — (Diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has diabetic macular oedema with pseudophakic lens; and
- 2 Patient has reduced visual acuity of between 6/9 6/48 with functional awareness of reduction in vision; and
- 3 Fither
  - 3.1 Patient's disease has progressed despite 3 injections with bevacizumab; or
  - 3.2 Patient is unsuitable or contraindicated to treatment with anti-VEGF agents; and
- 4 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

Renewal — (Diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Patient's vision is stable or has improved (prescriber determined); and
- 2 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

**Initial application — (Women of child bearing age with diabetic macular oedema)** only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has diabetic macular oedema; and
- 2 Patient has reduced visual acuity of between 6/9 6/48 with functional awareness of reduction in vision; and
- 3 Patient is of child bearing potential and has not yet completed a family; and
- 4 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

Renewal — (Women of child bearing age with diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient's vision is stable or has improved (prescriber determined); and
- 2 Patient is of child bearing potential and has not yet completed a family; and
- 3 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

#### DEXAMETHASONE WITH NEOMYCIN SULPHATE AND POLYMYXIN B SULPHATE

* Eye oint 0.1% with neomycin sulphate 0.35% and polymyxin b sulphate 6,000 u per g	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%	5 ml OP	✓ Voltaren Ophtha
FLUOROMETHOLONE <b>*</b> Eye drops 0.1%	5 ml OP	✓ FML ✓ Flucon

	Subsidy		Fully	Brand or
	(Manufacturer's Pr	ice) Sub	sidised	Generic
	\$	Per	✓	Manufacturer
LEVOCABASTINE				
Eye drops 0.5 mg per ml	8.71	4 ml OP		
	(10.34)		L	ivostin
LODOXAMIDE				
Eye drops 0.1%	8.71	10 ml OP	<b>√</b> L	omide
NEPAFENAC				
Eye drops 0.3%	8.80	3 ml OP	<b>✓</b>	evro
PREDNISOLONE ACETATE				
Eye drops 1%	6.92	10 ml OP	<b>✓</b> P	rednisolone-AFT
,	7.00	5 ml OP	<b>✓</b> P	red Forte
PREDNISOLONE SODIUM PHOSPHATE - Special Authority	see SA1715 below	- Retail phan	macy	
Eye drops 0.5%, single dose (preservative free)		20 dose	•-	linims Prednisolone

#### **⇒SA1715** Special Authority for Subsidy

Initial application only from an ophthalmologist or optometrist. Approvals valid for 6 months for applications meeting the following criteria:

#### Both:

- 1 Patient has severe inflammation; and
- 2 Patient has a confirmed allergic reaction to preservative in eye drops.

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

#### SODIUM CROMOGLICATE

Eye drops 2%	2.62 10	) ml OP	<u>Allerfix</u>
Eye drops 2%2	2.62 IU	) MI OP	Allertix

Glaucoma Preparations - Beta Blockers		
# Eye drops 0.25%	5 ml OP 5 ml OP	<ul><li>✓ Betoptic S</li><li>✓ Betoptic</li></ul>
TIMOLOL  * Eye drops 0.25%	5 ml OP 5 ml OP	✓ Arrow-Timolol ✓ Arrow-Timolol
Glaucoma Preparations - Carbonic Anhydrase Inhibitors		
ACETAZOLAMIDE  * Tab 250 mg17.03	100	✓ Diamox
BRINZOLAMIDE		
* Eye drops 1%	5 ml OP	✓ Azopt

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

	\$	Per	✓ Manufacturer
Glaucoma Preparations - Prostaglandin Analog	jues		
BIMATOPROST  * Eye drops 0.03%	5.15 5.95	3 ml OP	✓ Lumigan ✓ Bimatoprost Multichem
Lumigan to be Principal Supply on 1 January 2025 (Bimatoprost Multichem Eye drops 0.03% to be delisted 1 Janual LATANOPROST	ry 2025)		
* Eye drops 0.005% TRAVOPROST	2.08	2.5 ml OP	✓ Teva
* Eye drops 0.004%	6.80	2.5 ml OP	✓ Travatan
Glaucoma Preparations - Other			
BRIMONIDINE TARTRATE  * Eye drops 0.2%BRIMONIDINE TARTRATE WITH TIMOLOL MALEATE	5.16	5 ml OP	✓ Arrow-Brimonidine
★ Eye drops 0.2% with timolol maleate 0.5% Combigan to be Principal Supply on 1 December 2024	7.13	5 ml OP	✓ Combigan
LATANOPROST WITH TIMOLOL  * Eye drops 0.005% with timolol 0.5%	4.95	2.5 ml OP	✓ <u>Arrow - Lattim</u>
PILOCARPINE HYDROCHLORIDE  * Eye drops 1%	4.26	15 ml OP	✓ Isopto Carpine
* Eye drops 2%	5.35	15 ml OP	✓ Isopto Carpine
* Eye drops 4% Subsidised for oral use pursuant to the Standard Formu		15 ml OP	✓ Isopto Carpine
PILOCARPINE NITRATE			
* Eye drops 2% single dose – Special Authority see SA0895 below – Retail pharmacy	35.90	20 dose	✓ Minims Pilocarpine
<b>▶SA0895</b> Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valie Either:	d for 2 years for	applications me	eeting the following criteria:
<ol> <li>Patient has to use an unpreserved solution due to an alle</li> <li>Patient wears soft contact lenses.</li> </ol>	rgy to the preser	vative; or	
Note: Minims for a general practice are considered to be "tools or 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	0.70	45   OD	4 Occale and

Subsidy

(Manufacturer's Price)

Fully

Subsidised

Brand or

Generic

15 ml OP

20 dose

✓ Cyclogyl

✓ Minims

Cyclopentolate

prescription......84.85

\* Eye drops 1%, single dose (preservative free) - Only on a

	Subsidy (Manufacturer's Pr	,	Fully	Brand or Generic
TROPICAMIDE	\$	Per		Manufacturer
* Eye drops 0.5%*  Eye drops 1%		15 ml OP 15 ml OP		lydriacyl lydriacyl
Preparations for Tear Deficiency				
For acetylcysteine eye drops refer Standard Formulae, page 276	·			
# Eye drops 0.5%	19.50	15 ml OP	✓ N	lethopt
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**

#### ⇒SA2134 Special Authority for Subsidy

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

- 1 Confirmed diagnosis by slit lamp or Schirmer test of severe secretory dry eye; and
- 2 Either:
  - 2.1 Patient is using eye drops more than four times daily on a regular basis; or
  - 2.2 Patient has had a confirmed allergic reaction to preservative in eye drop.

**Renewal** from any relevant practitioner. Approvals valid for 24 months where the patient continues to require lubricating eye drops and has benefited from treatment.

and the same and t			
CARBOMER – Special Authority see SA2134 above – Retail pharm: Ophthalmic gel 0.3%, 0.5 g(Poly-Gel Ophthalmic gel 0.3%, 0.5 g to be delisted 1 July 2025)	•	30	✓ Poly-Gel
, , , , , , , , , , , , , , , , , , , ,			
POLYETHYLENE GLYCOL 400 AND PROPYLENE GLYCOL - Spe	ecial Authorit	y see SA2134 a	above – Retail pharmacy
Eye drops 0.4% and propylene glycol 0.3%, 0.8 ml	10.78	30	<ul> <li>Systane Unit Dose</li> </ul>
SODIUM HYALURONATE [HYALURONIC ACID] — Special Authorit Eye drops 1 mg per ml	,		, ,
<ul><li>a) Hylo-Fresh has a 6 month expiry after opening. The Phamonth is not relevant and therefore only the prescribed c</li><li>b) Hylo-Fresh to be Principal Supply on 1 December 2024</li></ul>			

# **Other Eye Preparations**

NAPHAZOLINE HYDROCHLORIDE		
* Eye drops 0.1%	15 ml OP	Naphcon Forte
5.65		✓ Albalon
Albalon to be Principal Supply on 1 January 2025		
(Naphcon Forte Eye drops 0.1% to be delisted 1 January 2025)		
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 Fully Brand or (Manufacturer's Price) Subsidised Generic Per Manufacturer Various PHARMACY SERVICES \* Brand switch fee ...... 1 fee ✓ BSF Alvacen ✓ BSF Continuous alucose monitor (interope ✓ BSF Continuous alucose monitor (standalo ✓ BSF Eltroxin ✓ BSF Lenalidomide (Viatris) ✓ BSF Norethinderone - CDC ✓ BSF Pomolide a) May only be claimed once per patient. b) The Pharmacode for BSF Eltroxin is 2689251 - see also page 91 c) The Pharmacode for BSF Pomolide is 2689278 - see also page 169 d) The Pharmacode for BSF Lenalidomide (Viatris) is 2689286 - see also page 166 e) The Pharmacode for BSF Alyacen is 2692112 - see also page 82 f) The Pharmacode for BSF Norethinderone - CDC is 2692120 - see also page 83 g) The Pharmacode for BSF Continuous glucose monitor (standalo is 2692139 - see also page 23 h) The Pharmacode for BSF Continuous glucose monitor (interope is 2692147 - see also page 23 ✓ Immunisation Administration 1 fee ✓ Immunisation Co-administration (BSF Alyacen Brand switch fee to be delisted 1 January 2025) (BSF Continuous glucose monitor (interope Brand switch fee to be delisted 1 January 2025) (BSF Continuous glucose monitor (standalo Brand switch fee to be delisted 1 January 2025) (BSF Eltroxin Brand switch fee to be delisted 1 December 2024) (BSF Lenalidomide (Viatris) Brand switch fee to be delisted 1 December 2024) (BSF Norethinderone - CDC Brand switch fee to be delisted 1 January 2025) (BSF Pomolide Brand switch fee to be delisted 1 December 2024)

# **Agents Used in the Treatment of Poisonings**

#### **Antidotes**

**ACETYLCYSTEINE** 

Inj 200 mg per ml, 10 ml ampoule	42.99 52.88	10	<ul><li>✓ DBL Acetylcysteine</li><li>✓ Martindale Pharma</li></ul>
(Martindale Pharma Inj 200 mg per ml, 10 ml ampoule to be delisted	1 April 2025)		
NALOXONE HYDROCHLORIDE			
a) Up to 10 inj available on a PSO     b) Only on a PSO			
* Inj 400 mcg per ml, 1 ml ampoule	13.29	5	✓ DBL Naloxone Hydrochloride
(Hameln Ini 400 mcg per ml. 1 ml ampoule to be delisted 1 April 202	35.26 5)	10	✓ HameIn

				VARIOUS
	Subsidy (Manufacturer's Pric \$	e) S Per	Fully Subsidised	d Generic
Removal and Elimination				
CHARCOAL  * Oral liq 50 g per 250 ml	43.50 2	250 ml O	₽ ✔	Carbosorb-X
DEFERASIROX – Special Authority see SA1492 below – Retai Wastage claimable Tab 125 mg dispersible Tab 250 mg dispersible	276.00	28 28		Exjade Exjade
Tab 500 mg dispersible  SA1492 Special Authority for Subsidy	1,105.00	28	•	Exjade
Initial application only from a haematologist. Approvals valid find the following:	or 2 years for applica	ations me	eeting the	e following criteria:
<ol> <li>The patient has been diagnosed with chronic iron overlor 2 Deferasirox is to be given at a daily dose not exceeding 4 3 Any of the following:         <ol> <li>3.1 Treatment with maximum tolerated doses of defer combination therapy have proven ineffective as m</li> <li>3.2 Treatment with deferiprone has resulted in severe 3.3 Treatment with deferiprone has resulted in arthriti 3.4 Treatment with deferiprone is contraindicated due count (ANC) of &lt; 0.5 cells per μL) or recurrent epi 0.5 - 1.0 cells per μL).</li> </ol> </li> <li>Renewal only from a haematologist. Approvals valid for 2 years Either:         <ol> <li>For the first renewal following 2 years of therapy, the treating provement in all three parameters namely serum ferritical per subsequent renewals, the treatment has been toleral.</li> </ol> </li> </ol>	riprone monotherapy leasured by serum for persistent vomiting s; or e to a history of agrarisodes (greater than s for applications meatment has been tole in, cardiac MRI T2* a	or defereritin lever or diarrhenulocytos 2 episode eting the erated and diversity or deference of the control of the erated and diversity or deference or deferen	iprone all els, liver oea; or sis (defini les) of m following d has res MRI T2*	nd desferrioxamine or cardiac MRI T2*; or ed as an absolute neutrophil oderate neutropenia (ANC g criteria: sulted in clinical levels; or
in all three parameters namely serum ferritin, cardiac MF  DEFERIPRONE – Special Authority see SA1480 below – Retai		T2* levels	š.	'
Tab 500 mg Oral liq 100 mg per 1 ml	533.17	100 250 ml O		Ferriprox Ferriprox
Initial application only from a haematologist. Approvals valid v following criteria:  Either:  1 The patient has been diagnosed with chronic iron overload 2. The patient has been diagnosed with chronic iron overload 2.	ad due to congenital	inherited	l anaemi	
DESFERRIOXAMINE MESILATE  * Inj 500 mg vial	151.31	10	•	DBL Desferrioxamine Mesylate for Inj BP

✓ Deferoxamine Pfizer S29 \$29

# **VARIOUS**

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
SODIUM CALCIUM EDETATE				
* Inj 200 mg per ml, 5 ml	53.31	6		
	(156.71)		(	Calcium Disodium Versenate

# **Standard Formulae**

ACETYLCYSTEINE EYE DROPS Acetylcysteine inj 200 mg per ml, 10 ml Suitable eye drop base	qs qs	PHENOBARBITONE ORAL LIQUID Phenobarbitone Sodium Glycerol BP Water	1 g 70 ml to 100 ml
CODEINE LINCTUS (3 mg per 5 ml) Codeine phosphate	60 mg	PHENOBARBITONE SODIUM PAEDIATRIC ORAL	LIQUID (10
Glycerol	40 ml	mg per ml)	,
Preservative	qs	Phenobarbitone Sodium	400 mg
Water	to 100 ml	Glycerol BP	4 ml
CODEINE LINCTUS (15 mg per 5 ml)		Water	to 40 ml
Codeine phosphate	300 mg	PILOCARPINE ORAL LIQUID	
Glycerol	40 ml	Pilocarpine 4% eye drops	qs
Preservative	qs	Preservative	qs
Water	to 100 ml	Water	to 500 ml
		(Preservative should be used if quantity supplied is	for more
FOLINIC MOUTHWASH	4 4 4 4	than 5 days.)	
Calcium folinate 15 mg tab	1 tab	CALIVA CUDCTITUTE FORMULA	
Preservative Water	qs to 500 ml	SALIVA SUBSTITUTE FORMULA	F ~
(Preservative should be used if quantity supplied is		Methylcellulose Preservative	5 g
than 5 days. Maximum 500 ml per prescription.)	ioi illole	Water	qs to 500 ml
than 5 days. Maximum 300 mi per prescription.		(Preservative should be used if quantity supplied is	
METHADONE MIXTURE		than 5 days. Maximum 500 ml per prescription.)	ioi illoic
Methadone powder	qs	man o dayo. Maximum ooo mi por procenpuon.	
Glycerol	qs	SODIUM CHLORIDE ORAL LIQUID	
Water	to 100 ml	Sodium chloride inj 23.4%, 20 ml	qs
METHYL HYDROXYBENZOATE 10% SOLUTION		Water	qs
Methyl hydroxybenzoate	10 g	(Only funded if prescribed for treatment of hyponatr	aemia)
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		Vancomycin 500 mg injection	5 vials
	aid illixtulo)	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		

### 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 determine	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 suppl	er and will be	delisted from	the Schedule at a date to be
determined. Collodion flexible	10 30	100 ml	✓ PSM
COMPOUND HYDROXYBENZOATE – Only in combination	10.00	100 1111	· I OM
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 vancomyo	in oral Iguuid S	Standard Form	nulae.
Suspension		473 ml	✓ Ora-Sweet SF
GLYCERIN WITH SUCROSE - Only in combination			
Only in combination with Ora-Plus or when used in the vancomyo	in oral Iquuid S	Standard Forn	nulae.
Suspension	30.95	473 ml	✓ Ora-Sweet
GLYCEROL			
* Liquid – Only in combination		500 ml	✓ healthE Glycerol BP
Only in extemporaneously compounded oral liquid preparation	ns.		
METHYL HYDROXYBENZOATE			
Powder	8.98	25 g	✓ Midwest
METHYLCELLULOSE	00.05	400	/ MI-MV 4
Powder Suspension – Only in combination		100 g 473 ml	<ul><li>✓ MidWest</li><li>✓ Ora-Plus</li></ul>
			V Ola-Flus
METHYLCELLULOSE WITH GLYCERIN AND SODIUM SACCHARIN Suspension		mbination 473 ml	✓ Ora-Blend SF
·		4/3 1111	V Ola-biellu 3F
METHYLCELLULOSE WITH GLYCERIN AND SUCROSE – Only in Suspension		473 ml	✓ Ora-Blend
PHENOBARBITONE SODIUM	00.30	4/3 1111	V Ola-Dieliu
Powder – Only in combination	52 50	10 g	✓ MidWest
1 Gwdoi Gilly in Goribination	325.00	100 g	✓ MidWest
Only in children up to 12 years		3	
PROPYLENE GLYCOL			
Only in extemporaneously compounded methyl hydroxybenzoate	10% solution.		
Liq	11.25	500 ml	✓ Midwest
SODIUM BICARBONATE			
Powder BP – Only in combination		500 g	✓ Midwest
Only in extemporaneously compounded omeprazole and lans	soprazole susp	ension.	
SYRUP (PHARMACEUTICAL GRADE) – Only in combination			
Only in extemporaneously compounded oral liquid preparations.	14.05	E00 ml	√ Midweet
Liq	14.95	500 ml	✓ Midwest
WATER	0.00	1 ml	√ Top woter
Tap - Only in combination	0.00	1 ml	✓ Tap water

Subsidy (Manufacturer's Price) \$

Subsidised Per

Fully

Brand or Generic Manufacturer

# **Nutrient Modules**

### Carbohydrate

#### ⇒SA1930 Special Authority for Subsidy

Initial application — (Cystic fibrosis or kidney disease) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Fither:

- 1 cystic fibrosis; or
- 2 chronic kidney disease.

Initial application — (Indications other than cystic fibrosis or renal failure) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria: Any of the following:

- 1 cancer in children: or
- 2 cancers affecting alimentary tract where there are malabsorption problems in patients over the age of 20 years; or
- 3 faltering growth in an infant/child; or
- 4 bronchopulmonary dysplasia; or
- 5 premature and post premature infant; or
- 6 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula. Initial application — (Inborn errors of metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified where the patient has inborn errors of metabolism. Renewal — (Cystic fibrosis or renal failure) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis or renal failure) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

CARBOHYDRATE SUPPLEMENT - Special Authority see SA1930 above - Hospital pharmacy [HP3]

# Carbohydrate And Fat

### ⇒SA1376 Special Authority for Subsidy

Initial application — (Cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

continued...

✓ fully subsidised 279



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

continued...

- 1 Infant or child aged four years or under; and
- 2 cystic fibrosis.

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 infant or child aged four years or under; and
- 2 Any of the following:
  - 2.1 cancer in children; or
  - 2.2 faltering growth; or
  - 2.3 bronchopulmonary dysplasia; or
  - 2.4 premature and post premature infants.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

#### 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

Subsid	dy Fi	ılly Brand or	
(Manufacture	r's Price) Subsidis	ed Generic	
\$	Per	<ul> <li>Manufacturer</li> </ul>	

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 previous page - Hospital pharmacy [HP3]

Emulsion (neutral)	15.38	200 ml OP	✓ Calogen
	38.44	500 ml OP	✓ Calogen
Emulsion (strawberry)	15.38	200 ml OP	✓ Calogen
Oil	37.50	500 ml OP	✓ MCT oil (Nutricia)
MCT Emulsion, 250 ml	143.65	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 abov	∕e – Hospital pha	rmacy [HP3]	
Powder	8.95	227 g OP	✓ Resource
		J	Beneprotein
	13.82	225 g OP	✓ Protifar

✓ fully subsidised 281

Subsidy (Manufacturer's Price) Fully Subsidised er 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	SA1095 above -	- Hospital pharm	acy [HP3]
Liquid	4.65	500 ml OP	✓ Glucerna Select
DIABETIC ORAL FEED 1KCAL/ML - Special Authority see SA1	095 above – Ho	spital pharmacy	[HP3]
Liquid (strawberry)	2.25	200 ml OP	✓ Diasip
Liquid (vanilla)	2.10	200 ml 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.

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

Brand or Generic Manufacturer

## **Paediatric Products For Children Awaiting Liver Transplant**

#### ⇒SA1098 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient is a child (up to 18 years) who requires a liver transplant.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

#### Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL FEED 1KCAL/ML - Special Authority see SA1098 above - Hospital pharmacy [HP3]

### Paediatric Products For Children With Chronic Renal Failure

# ⇒SA1099 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient is a child (up to 18 years) with acute or chronic kidney disease.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

#### Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL FEED 1KCAL/ML - Special Authority see SA1099 above - Hospital pharmacy [HP3]

### **Paediatric Products**

### ⇒SA1379 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

#### Both:

- 1 Child is aged one to ten years; and
- 2 Any of the following:
  - 2.1 the child is being fed via a tube or a tube is to be inserted for the purposes of feeding; or
  - 2.2 any condition causing malabsorption; or
  - 2.3 faltering growth in an infant/child; or
  - 2.4 increased nutritional requirements; or
  - 2.5 the child is being transitioned from TPN or tube feeding to oral feeding.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for

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✓ fully subsidised 283

SPECIAL FOODS				
	Subsidy (Manufacturer's Price)	) Subs	Fully sidised	Brand or Generic Manufacturer
continued applications meeting the following criteria: Both:  1 The treatment remains appropriate and the patient is ben 2 General Practitioners must include the name of the dietiti practitioner and date contacted.	•		nally re	egistered general
PAEDIATRIC ENTERAL FEED 1.5KCAL/ML - Special Authority Liquid		previous p 00 ml OP	<b>V</b> F	lospital pharmacy [HP3] rebini Energy Iutrini Energy RTH
PAEDIATRIC ENTERAL FEED 1KCAL/ML - Special Authority s Liquid	· ·	revious pag 00 ml OP	je – Ho ✓ P ✓ N	= -
PAEDIATRIC ENTERAL FEED WITH FIBRE 1.5KCAL/ML $-$ Sp pharmacy [HP3]	•			
Liquid	7.00 50	00 ml OP	<b>✓</b> F	rebini Energy Fibre

PAEDIATRIC ENTERAL FEED WITH FIBRE 1KCAL/ML	- Special Authority see SA1379 on the previous page - Hospital
pharmacy [HP3]	

7.14

Liquid7.00	500 ml OP	Frebini Original
PAEDIATRIC ORAL FEED 1.5KCAL/ML - Special Authority see SA1379 on the	he previous page -	- Hospital pharmacy [HP3]

Liquid (strawberry	)1.90	200 ml OP	Fortini	
Liquid (vanilla)	1.90	200 ml OP	Fortini	

, , ,	8.67	500 ml OP	✓ Pediasure Plus
DAEDIATRIO ODAL EEED 41/OAL/AAL	On a stall Audio with a second A4070 and the second		Lie and the Louis and the Children

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Liquid (chocolate)	1.33	200 ml OP	✓ Pediasure
Liquid (strawberry)	1.33	200 ml OP	✓ Pediasure
Liquid (vanilla)	1.33	200 ml OP	✓ Pediasure
	1.66	250 ml OP	✓ Pediasure

PAEDIATRIC ORAL FEED WITH FIBRE 1.5KCAL/ML - Special Authority see SA1379 on the previous page - Hospital pharmacy [HP3]

Liquid (unflavoured)	1.90	200 ml OP	✓ Fortini Multi Fibre
Liquid (chocolate)	1.90	200 ml OP	✓ Fortini Multi Fibre
Liquid (strawberry)	1.90	200 ml OP	✓ Fortini Multi Fibre
Liquid (vanilla)	1.90	200 ml OP	✓ Fortini Multi Fibre

PEPTIDE-BASED ORAL FEED - Special Authority see SA1379 on the previous page - Hospital pharmacy [HP3]

### **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

continued...

✓ Nutrini Energy Multi Fibre

Subsidy (Manufacturer's Price)	Full Subsidise		
\$	Per •	Manufacturer	

#### continued...

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 SA	1101 on the previo	us page – Hosp	pital pharmacy [HP3]
Liquid	3.31	220 ml OP	•
			(strawberry)
			✓ Nepro HP (vanilla)
RENAL ORAL FEED 2 KCAL/ML - Special Authority see SA11	01 on the previous	s page – Hospit	al pharmacy [HP3]
Liquid, 200 ml bottle	13.24	4 OP	✓ NovaSource Renal
Liquid (apricot) 125 ml	13.72	4 OP	✓ Renilon 7.5
Liquid (caramel) 125 ml		4 OP	✓ Renilon 7.5

### Specialised And Elemental Products

#### ⇒SA1377 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

#### Any of the following:

- 1 malabsorption: or
- 2 short bowel syndrome; or
- 3 enterocutaneous fistulas: or
- 4 eosinophilic oesophagitis; or
- 5 inflammatory bowel disease: or
- 6 patients with multiple food allergies requiring enteral feeding.

Notes: Each of these products is highly specialised and would be prescribed only by an expert for a specific disorder. The alternative is hospitalisation.

Elemental 028 Extra is more expensive than other products listed in this section and should only be used where the alternatives have been tried first and/or are unsuitable.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

#### Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL SEMI-ELEMENTAL FEED 1.5KCAL/ML - S	pecial Authority see	e SA1377 above	- Hospital pharmacy [HP3]
Liquid	22.39	1,000 ml OP	✓ Vital
ORAL ELEMENTAL FEED 0.8KCAL/ML - Special Authority se	ee SA1377 above -	- Hospital pharn	nacy [HP3]
Liquid (grapefruit), 250 ml carton	179.46	18 OP	✓ Elemental 028 Extra
Liquid (pineapple & orange), 250 ml carton	179.46	18 OP	<ul> <li>Elemental 028 Extra</li> </ul>
Liquid (summer fruits), 250 ml carton	179.46	18 OP	✓ Elemental 028 Extra
ORAL ELEMENTAL FEED 1KCAL/ML - Special Authority see	SA1377 above – I	Hospital pharma	cy [HP3]
Powder (unflavoured)	4.50	80 g OP	✓ Vivonex TEN

285 ✓ fully subsidised

	Subsidy (Manufacturer's Prio \$	ce) Subs Per	Fully idised	Brand or Generic Manufacturer
SEMI-ELEMENTAL ENTERAL FEED 1KCAL/ML - Special Autl [HP3] Liquid	•	on the previou	✓ N	Hospital pharmacy utrison Advanced Peptisorb urvimed OPD

### Paediatric Products For Children With Low Energy Requirements

#### ⇒SA1196 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 Child aged one to eight years; and
- 2 The child has a low energy requirement but normal protein and micronutrient requirements.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

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.

## 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:

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

continued...

- 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.

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

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✓ fully subsidised 287

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

continued...

- 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
- 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

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

### continued...

- 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.

9 Severe chronic neurological conditions.			
	.17	250 ml OP ,000 ml OP	[HP3]  ✓ Ensure Plus HN  ✓ Ensure Plus HN  RTH  ✓ Nutrison Energy
9	.60		✓ Fresubin HP Energy
6	.24	250 ml OP ,000 ml OP	P3]  ✓ Isosource Standard  ✓ Fresubin Original  ✓ Osmolite RTH  ✓ Nutrison RTH
ENTERAL FEED WITH FIBRE 0.83 KCAL/ML – Special Authority see SA Liquid			pital pharmacy [HP3]  Nutrison 800 Complete Multi Fibre
ENTERAL FEED WITH FIBRE 1 KCAL/ML - Special Authority see SA188 Liquid		,000 ml OP .	al pharmacy [HP3]  ✓ Jevity RTH  ✓ Fresubin Original  Fibre
7	'.21		✓ Nutrison Multi Fibre
ENTERAL FEED WITH FIBRE 1.2KCAL/ML - Special Authority see SA18 Liquid			tal pharmacy [HP3]  ✓ Jevity Plus RTH
ENTERAL FEED WITH FIBRE 1.5KCAL/ML – Special Authority see SA18 Liquid8		,000 ml OP	tal pharmacy [HP3]  ✓ Jevity HiCal RTH  ✓ Nutrison Energy  Multi Fibre
9	.80		✓ Fresubin HP Energy Fibre
ENTERAL FEED WITH PROTEIN 1.2KCAL/ML — Special Authority see S Liquid9			ospital pharmacy [HP3]  ✓ Fresubin Intensive
ORAL FEED (POWDER) - Special Authority see SA1859 on page 285 -	Hospital p	harmacy [HP3]	
Powder (chocolate)14	.00	840 g OP	✓ Sustagen Hospital Formula
26	5.00	850 g OP	✓ Ensure
Powder (vanilla)14	.00	840 g OP	✓ Sustagen Hospital Formula Active
26	5.00	850 g OP	✓ Ensure

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

ORAL FEED 1.5KCAL/ML - Special Authority see SA1859 on page 285 - Hospital pharmacy [HP3]

Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, who have severe epidermolysis bullosa, or as exclusive enteral nutrition in children under the age of 18 years for the treatment of Crohn's disease, or for patients with COPD and hypercapnia, defined as CO2 value exceeding 55mmHg. The prescription must be endorsed accordingly.

Liquid (banana) - Higher subsidy of up to \$1.76 per 200 ml with Endorsement	0.72	200 ml OP	
	(1.56) (1.76)		Ensure Plus Fortisip
Liquid (chocolate) – Higher subsidy of up to \$1.76 per 200 ml with Endorsement	0.72	200 ml OP	
with Endoisement	(1.56) (1.76)	200 IIII OF	Ensure Plus Fortisip
Liquid (fruit of the forest) — Higher subsidy of \$1.56 per 200 ml with Endorsement		200 ml OP	
Liquid (strawberry) – Higher subsidy of \$1.76 per 200 ml with	(1.56)		Ensure Plus
Endorsement	0.72 (1.76)	200 ml OP	Fortisip
Liquid (vanilla) – Higher subsidy of up to \$1.76 per 200 ml with	. ,		·
Endorsement	(1.65)	237 ml OP	Ensure Plus
	0.72 (1.56) (1.76)	200 ml OP	Ensure Plus Fortisip

ORAL FEED WITH FIBRE 1.5 KCAL/ML - Special Authority see SA1859 on page 285 - Hospital pharmacy [HP3]

Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, or who have severe epidermolysis bullosa. The prescription must be endorsed accordingly.

Liquid (chocolate) - Higher subsidy of \$1.76 per 200 ml with			
Endorsement	0.72	200 ml OP	
	(1.76)		Fortisip Multi Fibre
Liquid (strawberry) - Higher subsidy of \$1.76 per 200 ml with			
Endorsement	0.72	200 ml OP	
	(1.76)		Fortisip Multi Fibre
Liquid (vanilla) - Higher subsidy of \$1.76 per 200 ml with			
Endorsement	0.72	200 ml 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.

continued...

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

continued...

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 any condition causing malabsorption; or
  - 1.2 faltering growth in an infant/child; or
  - 1.3 increased nutritional requirements; or
  - 1.4 fluid restricted: and
- 2 other lower calorie products have been tried; and
- 3 patient has substantially increased metabolic requirements or is fluid restricted.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL FEED 2 KCAL/ML - Special Authority see	SA1195 on the previous pa	age – Hospital p	harmacy [HP3]
Liquid	6.50	500 ml OP	✓ Fresubin 2kcal HP
·	6.82		✓ Nutrison
			Concentrated
	13.64	1,000 ml OP	✓ Ensure Two Cal HN
			RTH

ORAL FEED 2 KCAL/ML — Special Authority see SA1195 on the previous page — Hospital pharmacy [HP3]
Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, or who have severe epidermolysis bullosa. The prescription must be endorsed accordingly.

### **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:

continued...

# SPECIAL FOODS

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

continued...

- 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.

### **Gluten Free Foods**

The funding of gluten free foods is no longer being actively managed by Pharmac from 1 April 2011. This means that we are no longer considering the listing of new products, or making subsidy, or other changes to the existing listings. As a result we anticipate that the range of funded items will reduce over time. Management of Coeliac disease with a gluten free diet is necessary for good outcomes. A range of gluten free options are available through retail outlets.

### ⇒SA1729 Special Authority for Subsidy

Initial application — (all patients) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria: Either:

- 1 Gluten enteropathy has been diagnosed by biopsy; or
- 2 Patient suffers from dermatitis herpetiformis.

Initial application — (paediatric patients diagnosed by ESPGHAN criteria) only from a paediatric gastroenterologist. Approvals valid without further renewal unless notified where the paediatric patient fulfils ESPGHAN criteria for biopsy free diagnosis of coeliac disease.

GLUTEN FREE BAKING MIX - Special Authority see SA1729 above - Hospital pharmacy [HP3]

riospitai priarriacy [rii oj	
2.81 1,000 g OP	
(5.15)	Healtheries Simple Baking Mix
- Hospital pharmacy [HP3]	
3.93 1,000 g OP	
(7.32)	NZB Low Gluten
	Bread Mix
3.51	
(10.87)	Horleys Bread Mix
5.62 2,000 g OP	
(18.10)	Horleys Flour
	(5.15)  - Hospital pharmacy [HP3]3.93 1,000 g OP (7.32)  3.51 (10.87) spital pharmacy [HP3]5.62 2,000 g OP

	Subsidy		Fully	Brand or
	(Manufacturer's Pri \$	ce) Sub Per	sidised •	Generic Manufacturer
GLUTEN FREE PASTA - Special Authority see SA1729 on the	previous page – H	lospital pharr	nacy [HI	P3]
Buckwheat Spirals	2.00	250 g OP		
	(3.11)		C	)rgran
Corn and Vegetable Shells	2.00	250 g OP		
	(2.92)		C	)rgran
Corn and Vegetable Spirals	2.00	250 g OP		
	(2.92)		C	)rgran
Rice and Corn Lasagne Sheets	1.60	200 g OP		
	(3.82)		C	)rgran
Rice and Corn Macaroni	2.00	250 g OP		
	(2.92)		C	)rgran
Rice and Corn Penne	2.00	250 g OP		
	(2.92)		C	)rgran
Rice and Maize Pasta Spirals	2.00	250 g OP		
	(2.92)		C	)rgran
Rice and Millet Spirals	2.00	250 g OP		
	(3.11)		C	)rgran
Rice and corn spaghetti noodles	2.00	375 g OP		
	(2.92)		C	)rgran
Vegetable and Rice Spirals	2.00	250 g OP		
	(2.92)		C	)rgran
Italian long style spaghetti	2.00	220 g OP		
	(3.11)		C	)rgran

# **Foods And Supplements For Inherited Metabolic Disease**

# ⇒SA2357 Special Authority for Subsidy

**Initial application** from any relevant practitioner. Approvals valid without further renewal unless notified where patient requires dietary management of inherited metabolic disorders.

# **Supplements For Homocystinuria**

AMINOACID FORMULA WITHOUT METHIONINE	- Special Authority see SA2357	above -	- 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	480.42	500 g O	P <b>XMET Maxamum</b>
Powder (unflavoured), can	260.00	400 g O	P   HCU Anamix Infant
Liquid (juicy berries), 125 ml bottle	1,684.80	30	✓ HCU Lophlex LQ
Liquid (orange), 125 ml bottle	941.40	36	<ul> <li>HCU Anamix Junior</li> </ul>
			LQ

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

# Supplements For MSUD and short chain enoyl coA hydratase deficiency

AMINOACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE – Special Authority see \$A2357 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 sachets1	,048.95	30 •	MSUD Express 15
Powder (neutral), can		00 g OP •	✓ MSUD Maxamum
Powder (orange), can	.454.71 5	00 g OP •	✓ MSUD Maxamum
Powder (unflavoured), can	.260.00 4	00 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 pouches1	,684.80	30	MSUD Lophlex LQ

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

AMINOACID FORMULA WITHOUT PHENYLALANINE − Special Authority see SA2357 on page 292 − Hospital pharmacy [HP Tabs	ANAINIO A OID EODNAI II A MAITH IOUT DUENNI AN ANIINE	On a stall A sale sails a sail	040057	
Powder (Lemon), 34 g sachets.         883.50         30         ✓ PKU Express 20           Powder (Neutral), 12.5 g sachets.         220.88         30         ✓ PKU Explore 5           Powder (Neutral), 34 g sachets.         883.50         30         ✓ PKU Express 20           Powder (Orange), 25 g sachets.         441.75         30         ✓ PKU Express 20           Powder (Orange), 34 g sachets.         883.50         30         ✓ PKU Express 20           Powder (Raspberry), 25 g sachets.         441.75         30         ✓ PKU Express 20           Powder (Tropical), 34 g sachets.         883.50         30         ✓ PKU Express 20           Powder (berry) 28 g sachets.         936.00         30         ✓ PKU Lophlex Powder           Powder (chocolate) 36 g sachet.         393.00         30         ✓ PKU Anamix Junior Chocolate           Powder (neutral) 28 g sachets.         936.00         30         ✓ PKU Anamix Junior Powder (orange) 28 g sachets.           Powder (orange) 28 g sachets.         393.00         30         ✓ PKU Anamix Junior Orange           Powder (unflavoured) 12.5 g sachets.         393.00         30         ✓ PKU Anamix Junior Orange				
Powder (Neutral), 12.5 g sachets         220.88         30         ✓ PKU Explore 5           Powder (Neutral), 34 g sachets         883.50         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 Express 20           Powder (Tropical), 34 g sachets         883.50         30         ✓ PKU Express 20           Powder (berry) 28 g sachets         936.00         30         ✓ PKU Lophlex Powder           Powder (chocolate) 36 g sachet         393.00         30         ✓ PKU Anamix Junior Chocolate           Powder (neutral) 28 g sachets         936.00         30         ✓ PKU Lophlex Powder           Powder (orange) 28 g sachets         936.00         30         ✓ PKU Anamix Junior Powder           Powder (orange) 36 g sachets         936.00         30         ✓ PKU Anamix Junior Orange           Powder (unflavoured) 12.5 g sachets         234.00         30         ✓ PKU First Spoon				•
Powder (Neutral), 34 g sachets         883.50         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 Express 20           Powder (Tropical), 34 g sachets         883.50         30         ✓ PKU Express 20           Powder (berry) 28 g sachets         936.00         30         ✓ PKU Lophlex Powder           Powder (chocolate) 36 g sachet         393.00         30         ✓ PKU Anamix Junior Chocolate           Powder (neutral) 28 g sachets         936.00         30         ✓ PKU Lophlex Powder           Powder (neutral) 36 g sachets         393.00         30         ✓ PKU Anamix Junior           Powder (orange) 28 g sachets         936.00         30         ✓ PKU Anamix Junior           Powder (orange) 36 g sachet         393.00         30         ✓ PKU Anamix Junior           Orange         Powder (unflavoured) 12.5 g sachets         234.00         30         ✓ PKU First Spoon	, ,, ,			
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.       883.50       30       ✓ PKU Express 20         Powder (berry) 28 g sachets.       936.00       30       ✓ PKU Lophlex Powder         Powder (chocolate) 36 g sachets.       936.00       30       ✓ PKU Anamix Junior Chocolate         Powder (neutral) 28 g sachets.       936.00       30       ✓ PKU Lophlex Powder         Powder (neutral) 36 g sachets.       936.00       30       ✓ PKU Anamix Junior         Powder (orange) 28 g sachets.       936.00       30       ✓ PKU Lophlex Powder         Powder (orange) 36 g sachets.       936.00       30       ✓ PKU Anamix Junior Orange         Powder (unflavoured) 12.5 g sachets.       234.00       30       ✓ PKU First Spoon				
Powder (Orange), 34 g sachets.         883.50         30         ✓ PKU Express 20           Powder (Raspberry), 25 g sachets.         441.75         30         ✓ PKU Express 20           Powder (Tropical), 34 g sachets.         883.50         30         ✓ PKU Express 20           Powder (berry) 28 g sachets.         936.00         30         ✓ PKU Lophlex Powder           Powder (chocolate) 36 g sachet.         393.00         30         ✓ PKU Anamix Junior Chocolate           Powder (neutral) 28 g sachets.         936.00         30         ✓ PKU Lophlex Powder           Powder (neutral) 36 g sachets.         393.00         30         ✓ PKU Anamix Junior           Powder (orange) 28 g sachets.         936.00         30         ✓ PKU Lophlex Powder           Powder (orange) 36 g sachet.         393.00         30         ✓ PKU Anamix Junior Orange           Powder (unflavoured) 12.5 g sachets.         234.00         30         ✓ PKU First Spoon	, ,			•
Powder (Raspberry), 25 g sachets         441.75         30         ✓ PKU Explore 10           Powder (Tropical), 34 g sachets         883.50         30         ✓ PKU Express 20           Powder (berry) 28 g sachets         936.00         30         ✓ PKU Lophlex Powder           Powder (chocolate) 36 g sachet         393.00         30         ✓ PKU Anamix Junior Chocolate           Powder (neutral) 28 g sachets         936.00         30         ✓ PKU Lophlex Powder           Powder (neutral) 36 g sachets         393.00         30         ✓ PKU Anamix Junior           Powder (orange) 28 g sachets         936.00         30         ✓ PKU Lophlex Powder           Powder (orange) 36 g sachet         393.00         30         ✓ PKU Anamix Junior Orange           Powder (unflavoured) 12.5 g sachets         234.00         30         ✓ PKU First Spoon				
Powder (Tropical), 34 g sachets         883.50         30         ✓ PKU Express 20           Powder (berry) 28 g sachets         936.00         30         ✓ PKU Lophlex Powder           Powder (chocolate) 36 g sachet         393.00         30         ✓ PKU Anamix Junior Chocolate           Powder (neutral) 28 g sachets         936.00         30         ✓ PKU Lophlex Powder           Powder (neutral) 36 g sachets         393.00         30         ✓ PKU Anamix Junior           Powder (orange) 28 g sachets         936.00         30         ✓ PKU Lophlex Powder           Powder (orange) 36 g sachet         393.00         30         ✓ PKU Anamix Junior Orange           Powder (unflavoured) 12.5 g sachets         234.00         30         ✓ PKU First Spoon				•
Powder (berry) 28 g sachets       936.00       30       ✓ PKU Lophlex Powder         Powder (chocolate) 36 g sachet       393.00       30       ✓ PKU Anamix Junior Chocolate         Powder (neutral) 28 g sachets       936.00       30       ✓ PKU Lophlex Powder         Powder (neutral) 36 g sachets       393.00       30       ✓ PKU Anamix Junior         Powder (orange) 28 g sachets       936.00       30       ✓ PKU Lophlex Powder         Powder (orange) 36 g sachet       393.00       30       ✓ PKU Anamix Junior Orange         Powder (unflavoured) 12.5 g sachets       234.00       30       ✓ PKU First Spoon				
Powder Powder (chocolate) 36 g sachet				•
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         ✓ PKU Anamix Junior Orange           Powder (unflavoured) 12.5 g sachets         .234.00         30         ✓ PKU First Spoon	Powder (berry) 28 g sacriets	936.00	30	•
Powder         Powder (neutral) 36 g sachets	Powder (chocolate) 36 g sachet	393.00	30	
Powder (orange) 28 g sachets	Powder (neutral) 28 g sachets	936.00	30	•
Powder         Powder           Powder (orange) 36 g sachet         393.00         30         ✓ PKU Anamix Junior Orange           Powder (unflavoured) 12.5 g sachets         234.00         30         ✓ PKU First Spoon	Powder (neutral) 36 g sachets	393.00	30	
Powder (unflavoured) 12.5 g sachets234.00 30 ✓ PKU First Spoon	Powder (orange) 28 g sachets	936.00	30	
Powder (unflavoured) 12.5 g sachets234.00 30 ✓ PKU First Spoon	Powder (orange) 36 g sachet	393.00	30	
	Powder (unflavoured) 12.5 g sachets	234.00	30	•
Vanilla				✓ PKU Anamix Junior
Infant formula	Infant formula	174.72	400 a OP	✓ PKU Anamix Infant
Powder (orange)				
Powder (unflavoured)	( 0 /		•	✓ XP Maxamum
Liquid (berry)	,		•	✓ PKU Anamix Junior
Liquid (orange)	Liquid (orange)	13.10	125 ml OP	
Liquid (unflavoured)	Liquid (unflavoured)	13.10	125 ml OP	
Liquid (forest berries), 250 ml carton540.00 18 OP ✓ Easiphen Liquid	Liquid (forest berries), 250 ml carton	540.00	18 OP	✓ Easiphen Liquid
Liquid (juicy tropical) 125 ml936.00 30 OP <b>✓ PKU Lophlex LQ 20</b>				
Oral semi-solid (berries) 109 g				
Sensation 20	, ,	,		•
Powder (neutral), 400 g can715.16 4 OP ✓ PKU Start	Powder (neutral), 400 g can	715.16	4 OP	✓ PKU Start
Liquid (juicy berries) 62.5 ml			-	
Liquid (juicy citrus) 62.5 ml				✓ PKU Lophlex LQ 10
Liquid (juicy orange) 62.5 ml				
Liquid (juicy berries) 125 ml936.00 30 OP ✓ PKU Lophlex LQ 20				
Liquid (juicy orange) 125 ml				•

(PKU Anamix Junior LQ Liquid (unflavoured) to be delisted 1 January 2025) (PKU Lophlex LQ 10 Liquid (juicy citrus) 62.5 ml to be delisted 1 January 2025) (PKU Lophlex LQ 10 Liquid (juicy orange) 62.5 ml to be delisted 1 January 2025)

	Subsidy (Manufacturer's Price) \$	Per	Fully Brand or Subsidised Generic Manufacturer	
GLYCOMACROPEPTIDE AND AMINO ACID CONTAINS SOM	IE PHENYLALANINE	– Spe		
page 292 – Hospital pharmacy [HP3]		Opo		
Powder (Banana) 35 g sachets	930.00	30	✓ PKU	
· · · · ( · · · · · · · · · · · · · · ·			sphere20 Banana	
Powder (Berry), 20 g sachets	449.28	60	✓ PKU Restore	
( ),,			Powder	
Powder (Chocolate) 32 g sachets	898.56	30	✓ PKU Build	
3 (* , 3			20 Chocolate	
Powder (Chocolate) 35 g sachets	930.00	30	✓ PKU	
3 (			sphere20 Chocolate	е
			•	
Powder (Lemon) 35 g sachets	930.00	30	✓ PKU	
			sphere20 Lemon	
Powder (Lemonade) 33.4 g sachets	936.00	30	PKU GMPro Ultra	
			Lemonade	
Powder (Neutral), 15 g sachets		30	PKU Build 10	
Powder (Orange), 20 g sachets	449.28	60	PKU Restore	
			Powder	
Powder (Raspberry Lemonade) 31 g sachets	898.56	30	PKU Build	
			20 Raspberry	
			Lemonade	
Powder (Smooth) 31 g sachets	898.56	30	PKU Build	
			20 Smooth	
Powder (Vanilla) 33 g sachets		30	PKU Build 20 Vanilla	
Powder (neutral), 40 g sachets		30	Glytactin Bettermilk	
Powder (unflavoured) 12.5 g sachets		30	✓ PKU GMPro Mix-In	
Powder (vanilla) 33.4 g sachets	936.00	30	✓ PKU GMPro Ultra	
			Vanilla	
Powder (Red Berry) 35 g sachets	930.00	30	✓ PKU sphere20 Red	
			Berry	
Powder (Vanilla) 35 g sachets	930.00	30	✓ PKU	
			sphere20 Vanilla	
Liquid (neutral), 250 ml carton		18	PKU GMPro LQ	
Liquid (original), 250 ml carton	684.45	30 OP	PKU Glytactin RTD	
			15	
Liquid (Coffee Mocha), 250 ml carton	684.45	30 OP	PKU Glytactin RTD	
			15 Lite	
Liquid (chocolate), 250 ml carton	684.45	30 OP	✓ PKU Glytactin RTD	
			15	
Liquid (vanilla), 250 ml carton	684.45	30 OP	PKU Glytactin RTD	
			15 Lite	

# Foods

LOW PROTEIN BAKING MIX — Special Authority see SA2357 on page 292 — Hospital pharmacy [HP3]
Powder .......8.55 500 g OP ✓ Loprofin Mix

	Subsidy		Fully	Brand or
	(Manufacturer's Pri			Generic
	\$	Per		Manufacturer
LOW PROTEIN PASTA - Special Authority see SA2357 on pag		,	• -	
Animal shapes		500 g OP		Loprofin
Lasagne		250 g OP		Loprofin
Low protein rice pasta		500 g OP		Loprofin
Macaroni		250 g OP		Loprofin
Penne		500 g OP		Loprofin
Spaghetti Spirals		500 g OP 500 g OP		Loprofin Loprofin
Supplements for Tyrosinaemia		000 g 01		_op.o
Supplements for Tyrosinaenna				
AMINOACID FORMULA WITHOUT PHENYLALANINE AND TYI pharmacy [HP3]	ROSINE - Special	Authority see	SA2	357 on page 292 – Hospita
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	1,684.80	30	1	TYR Lophlex LQ 20
Liquid (orange) 125 ml bottle		36	/	TYR Anamix Junior LQ
GLYCOMACROPEPTIDE AND AMINO ACID CONTAINS SOME	TYROSINE AND	PHENYLALA	NINE	- Special Authority see
SA2357 on page 292 – Hospital pharmacy [HP3]	4 000 00			TVD 0 1 00
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, METHIONINI	E. THREONINE AN	ND VALINE -	Spec	cial Authority see SA2357
on page 292 – Hospital pharmacy [HP3]	_,		-	
Powder, can	260.00	400 g OP	1	MMA/PA Anamix
		9		Infant
AMINOACID FORMULA WITHOUT METHIONINE, THREONINE	AND VALINE _ 9	Special Authori	ity ec	ο SA2357 on nage 202 —
Hospital pharmacy [HP3]	AND VALINE -	Special Author	ity Sc	66 3A2337 OH page 232 -
Powder (neutral), 18 g sachets	750.30	30	/	MMA/PA Anamix
r owder (neutral), to g eached		00	•	Junior
Powder, 12.5 g sachets	340.65	30	_	MMA/PA Explore 5
Powder, 12.5 g sachets		30		MMA/PA Express 15
1 Owder, 25 g Sacriets	1,040.93	30	_	WINIA/FA Expless 13
Supplements for Glutaric Aciduria type 1				
AMINOACID FORMULA WITHOUT LYSINE - Special Authority	see SA2357 on pa	age 292 – Hos	pital	pharmacy [HP3]
Powder (neutral), 18 g sachets		30		GA1 Anamix Junior
Powder, 12.5 g sachets		30	1	GA Explore 5
Powder, can		400 g OP		GA1 Anamix Infant
Supplements for Glycogen Storage Disease				
HIGH AMYLOPECTIN CORN-STARCH – Special Authority see Powder, 60 g sachets		292 – Hospital 30		macy [HP3] <b>Glycosade</b>
Single dose amino acids				-
onigic 4036 animo acius				
ARGININE - Special Authority see SA2357 on page 292 - Hosp		-	_	
Powder, 4 g sachets	211.45	30		Arginine2000

(1)	Subsidy Manufacturer's Price) \$	Sut Per	Fully osidised	Brand or Generic Manufacturer
CITRULLINE – Special Authority see SA2357 on page 292 – Hosp Powder, 4 g sachets		30	/	Citrulline1000
SOLEUCINE - Special Authority see SA2357 on page 292 - Hosp Powder, 4 g sachets	141.05	3] 30	/	Isoleucine50
LEUCINE – Special Authority see SA2357 on page 292 – Hospital Powder, 4 g sachets		30	/	Leucine100
PHENYLALANINE – Special Authority see SA2357 on page 292 – Powder, 4 g sachets	Hospital pharmacy	/ [HP3] 30	/	Phenylalanine50
TYROSINE – Special Authority see SA2357 on page 292 – Hospita Powder, 4 g sachets		30	/	Tyrosine1000
VALINE - Special Authority see SA2357 on page 292 - Hospital pl Powder, 4 g sachets		30	/	Valine50
Other Fat Modified Products				
ELEMENTAL FEED WITH HIGH MEDIUM CHAIN TRIGLYCERIDE	S - Special Autho	rity see	SA2357	on page 292 – Hospital
pharmacy [HP3] Powder (neutral), 100 g sachets	47.01	10	✓	Emsogen
Carbohydrate and Fat with added vitamins and m	inerals			
PROTEIN FREE SUPPLEMENT CONTAINING CARBOHYDRATE	, FAT WITH ADDE	D VITAN	IINS AN	ND MINERALS - Special
Authority see SA2357 on page 292 – Hospital pharmacy [HP3] Powder (neutral), can	49.29 40	00 g OP	•	Energivit
Essential Amino Acids				
ESSENTIAL AMINOACID FORMULA - Special Authority see SA23 Powder (neutral), can		Hospital 00 g OP		acy [HP3] Essential Amino Acid Mix
Infant Formulae				
For Williams Syndrome				
■ SA1110 Special Authority for Subsidy Initial application only from a dietitian, relevant specialist or vocati year where the patient is an infant suffering from Williams Syndrom Renewal only from a dietitian, relevant specialist, vocationally regis recommendation of a dietitian, relevant specialist or vocationally reg applications meeting the following criteria: Both:	e and associated h tered general prac	ypercalc titioner o	aemia. r genera	al practitioner on the
The treatment remains appropriate and the patient is benefit     General Practitioners must include the name of the dietitian,     practitioners and data contrated.			ionally	registered general

LOW CALCIUM INFANT FORMULA - Special Authority see SA1110 above - Hospital pharmacy [HP3]

400 g OP

Powder .......46.18

practitioner and date contacted.

	Subsidy	Fu	illy	Brand or
(Ma	nufacturer's Price)	Subsidis	ed	Generic
	\$	Per	✓	Manufacturer

### **Gastrointestinal and Other Malabsorptive Problems**

AMINO ACID FORMULA - Special Authority see SA20	92 below – Hospital pharmad	y [HP3]	
Powder	43.60	400 g OP	<ul><li>✓ Alfamino</li><li>✓ Alfamino Junior</li></ul>
Powder (unflavoured)	55.61	400 g OP	✓ Neocate Gold ✓ Neocate Junior Unflavoured
	65.72		<ul><li>✓ Neocate SYNEO</li><li>✓ Elecare</li><li>✓ Elecare LCP</li></ul>
Powder (vanilla)	55.61	100 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 IoE mediated allerov.

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...

Subsidy		Fully	Brand or	
(Manufacturer's Pri	ce)	Subsidised	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.

### ⇒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	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

PAEDIATRIC ORAL/ENTERAL FEED 1 KCAL/ML - Special Authority see SA1698 below - Hospital pharmacy [HP3] Liquid.......2.80 125 ml OP ✓ Infatrini

#### ⇒SA1698 Special Authority for Subsidy

**Initial application** only from a paediatrician, dietitian or general practitioner on the recommendation of a paediatrician or dietitian. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient is fluid restricted or volume intolerant and has been diagnosed with faltering growth; and
- 2 Patient is under the care of a paediatrician or dietitian who has recommended treatment with a high energy infant formula; and
- 3 Patient is under 18 months of age or weighs less than 8 kg.

continued...

Su	ubsidy	Fully	Brand or
(Manufac	turer's Price) Subsid	lised	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 see SA1197 above - Retail pharmacy

Powder (unflavoured)	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 BACILLUS CALMETTE-GUERIN VACCINE - [Xpharm] For infants at increased risk of tuberculosis. Increased risk is defined as: 1) living in a house or family with a person with current or past history of TB; or 2) having one or more household members or carers who within the last 5 years lived in a country with a rate of TB > or egual to 40 per 100,000 for 6 months or longer; or 3) during their first 5 years will be living 3 months or longer in a country with a rate of TB > or equal to 40 per 100,000 Note a list of countries with high rates of TB are available at www.health.govt.nz/tuberculosis (search for downloads) or www.bcgatlas.org/index.php. Inj Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331, live attenuated, vial with diluent......0.00 10 ✓ BCG Vaccine AJV BCG Vaccine AJV to be Principal Supply on 1 December 2024 COVID-19 VACCINE - [Xpharm] Inj 10 mcg raxtozinameran per 0.3 ml, 0.48 ml vial; paediatric vaccine, light blue cap .......0.00 10 ✓ Comirnaty Omicron (XBB.1.5) 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.

10 ✓ Comirnaty Omicron maroon cap.......0.00 (XBB.1.5) Up to three doses for previously unvaccinated children aged 6 months - 4 years at high risk of severe illness.

Inj 30 mcg raxtozinameran per 0.3 ml, 0.48 ml vial; adult ✓ Comirnaty Omicron 10 (XBB.1.5)

#### Any of the following:

**Vaccinations** 

Fither:

1) One dose for previously unvaccinated people aged 12-15 years old; or

Inj 3 mcg raxtozinameran per 0.2 ml, 0.4 ml vial; infant vaccine,

- 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.

Inj 30 mcg raxtozinameran per 0.3 ml, 2.25 ml vial; adult 10 ✓ Comirnaty Omicron vaccine, dark grey cap.......0.00 (XBB.1.5)

#### 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 🗸	Manufacturer

#### DIPHTHERIA. TETANUS AND PERTUSSIS VACCINE

- a) Only on a prescription
- b) No patient co-payment payable
- c)
- A) Funded for any of the following criteria:
  - 1) A single dose for pregnant women in the second or third trimester of each pregnancy; or
  - 2) A single dose for parents or primary caregivers of infants admitted to a Neonatal Intensive Care Unit or Specialist Care Baby Unit for more than 3 days, who had not been exposed to maternal vaccination at least 14 days prior to birth: or
  - 3) A course of up to four doses is funded for children from age 7 up to the age of 18 years inclusive to complete full primary immunisation; or
  - 4) An additional four doses (as appropriate) are funded for (re-)immunisation for patients post haematopoietic stem cell transplantation or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens; or
  - 5) A single dose for vaccination of patients aged from 65 years old; or
  - 6) A single dose for vaccination of patients aged from 45 years old who have not had 4 previous tetanus doses; or
  - 7) For vaccination of previously unimmunised or partially immunised patients; or
  - 8) For revaccination following immunosuppression; or
  - 9) For boosting of patients with tetanus-prone wounds.

Notes: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

- B) Contractors will be entitled to claim payment from the Funder for the supply of diphtheria, tetanus and pertussis vaccine to patients eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the diphtheria, tetanus and pertussis vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be
  a sub-set of the population described in paragraphs 1 9 above.

inj 2 io dipritriena toxolo with 20 io tetanus toxolo, 8 mcg			
pertussis toxoid, 8 mcg pertussis filamentous			
haemagglutinin and 2.5 mcg pertactin in 0.5 ml prefilled			
syringe	0.00	10	✓ Boostrix
Boostrix to be Principal Supply on 1 December 2024			

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

poliomyelitis virus in 0.5ml syringe .......0.00

10 ✓ Infanrix IPV

Infanrix IPV to be Principal Supply on 1 December 2024

#### DIPHTHERIA. TETANUS. PERTUSSIS. POLIO. HEPATITIS B AND HAEMOPHILUS INFLUENZAE TYPE B VACCINE

- a) Only on a prescription
- b) No patient co-payment payable
- c)
- A) Funded for children meeting any of the following criteria
  - 1) Up to four doses for children under the age of 10 years for primary immunisation; or
    - An additional four doses (as appropriate) for (re-)immunisation of children under the age of 18 years post haematopoietic stem cell transplantation; or
    - 3) An additional four doses (as appropriate) for (re-)immunisation of children under the age of 10 years who are post chemotherapy; pre or post splenectomy; undergoing renal dialysis and other severely immunosuppressive regimens; or
    - 4) Up to five doses for children under the age of 10 years receiving solid organ transplantation.
- B) Contractors will be entitled to claim payment from the Funder for the supply of Diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type b vaccine to people eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type b vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

Note: A course of up-to four vaccines is funded for catch up programmes for children (up to and under the age of 10 years) to complete full primary immunisation. Please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.

Inj 30IU diphtheria with 40IU tetanus and 25mcg pertussis		
toxoids, 25mcg pertussis filamentous haemagglutinin,		
8mcg pertactin, 80D-AgU polio virus, 10mcg hepatitis B		
antigen, 10mcg H. influenzae type b with tetanus toxoid		
20-40mcg in 0.5ml syringe0.00	10	✓ Infanrix-hexa
Infanrix-hexa to be Principal Supply on 1 December 2024		

✓ Havrix 1440

✓ Havrix Junior

	Subsidy (Manufacturer's Price) \$	Subs Per	Fully sidised	Brand or Generic Manufacturer
HAEMOPHILUS INFLUENZAE TYPE B VACCINE				
a) Only on a prescription				
b) No patient co-payment payable				
c)				
<ul> <li>A) One dose for people meeting any of the following</li> </ul>	<b>j</b> :			
<ol> <li>For primary vaccination in children; or</li> </ol>				
2) An additional dose (as appropriate) is fund				
transplantation, or chemotherapy; functiona				
transplant, pre or post cochlear implants, re	•	•		
<ol> <li>For use in testing for primary immunodefici physician or paediatrician.</li> </ol>	ency diseases, on the re	commend	iation o	r an internal medicine
B) Contractors will be entitled to claim payment from	n the Funder for the sun	alv of Hap	monhili	ie influenzae tyne h
vaccine to people eligible under the above criteri		,		<b>71</b>
for subsidised immunisation, and they may only	•			'
in the Pharmaceutical Schedule.	ac co in recpect of the fi	aomopilio	JO 111114C	onzao typo b vacomo notoa
C) Contractors may only claim for populations within	n the criteria that are cov	ered by th	neir con	tract, which may be a
sub-set of the population described in paragraph		,		•
Haemophilus Influenzae type B polysaccharide 10 mcg				
conjugated to tetanus toxoid as carrier protein 20-40	mcg;			
prefilled syringe plus vial 0.5 ml		1		liberix
Inj 10 mcg vial with diluent syringe	0.00	1	<b>✓</b> A	Act-HIB
Act-HIB to be Principal Supply on 1 December 2024				
(Hiberix Haemophilus Influenzae type B polysaccharide 10 mg	0 , 0	toxoid as	carrier	protein 20-40 mcg;
prefilled syringe plus vial 0.5 ml to be delisted 1 December 20	24)			
HEPATITIS A VACCINE – [Xpharm]				
Funded for patients meeting any of the following criteria:				
<ol> <li>Two vaccinations for use in transplant patients; or</li> </ol>				
2) Two vaccinations for use in children with chronic live	,			
<ol><li>One dose of vaccine for close contacts of known he</li></ol>	patitis A cases.			

Havrix 1440 to be Principal Supply on 1 December 2024

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

	Subsidy		Fully	Brand or
	(Manufacturer's Price)	5	Subsidised	Generic
	\$	Per	1	Manufacturer
HEPATITIS B RECOMBINANT VACCINE -	- [Xpharm]			
Inj 10 mcg per 0.5 ml prefilled syringe	0.00	1	<b>√</b> E	ngerix-B
<ul> <li>a) Funded for patients meeting any</li> </ul>	of the following criteria:			
<ol> <li>for household or sexual co</li> </ol>	ntacts of known acute hepatitis B patients	or hep	atitis B car	riers; or
<ol><li>for children born to mother</li></ol>	s who are hepatitis B surface antigen (HBs	sAg) p	ositive; or	
	er the age of 18 years inclusive who are co			
serology and require addit	ional vaccination or require a primary cours	se of v	accination;	or
<ol><li>for HIV positive patients; o</li></ol>	r			
<ol><li>for hepatitis C positive pat</li></ol>	ents; or			
<li>for patients following non-</li>	consensual sexual intercourse; or			
<ol><li>for patients prior to planne</li></ol>	d immunosuppression for greater than 28 of	days; d	or	
<ol><li>for patients following immu</li></ol>	unosuppression; or			
9) for solid organ transplant r	vationts: or			

- for solid organ transplant patients; or
   for post hapmatopoints stem coll transplant
- 10) for post-haematopoietic stem cell transplant (HSCT) patients; or
- 11) following needle stick injury.
- b) Engerix-B to be Principal Supply on 1 December 2024
- - a) 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
    - 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.
  - b) Engerix-B to be Principal Supply on 1 December 2024

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.

Inj 270 mcg in 0.5 ml syringe	0.00	10	Gardasil 9
Gardasil 9 to be Principal Supply on 1 December 2024			

	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		fluvac Tetra (2024 formulation)

Subsidy		Fully	Brand or	
(Manufacturer's Price)	S	ubsidised	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	e)	Subsidised	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 ml0.00	10	✓ Priorix
Priorix to be Principal Supply on 1 December 2024		

	NATIONAL	IMMUN	ISATI	ON SCHEDULE
	Subsidy (Manufacturer's Price) \$	Subs Per	Fully sidised	Brand or Generic Manufacturer
MENINGOCOCCAL (GROUPS A, C, Y AND W-135) CONJUG	ATE VACCINE			
Inj 10 mcg of each meningococcal polysaccharide conjuga	ited			
to a total of approximately 55 mcg of tetanus toxoid ca	ırrier			
per 0.5 ml vial	0.00	1	✓ M	enQuadfi
<ul> <li>a) Only on a prescription</li> </ul>				
b) No patient co-payment payable				
c)				
A) Any of the following:	f			
<ol> <li>Up to three doses and a booster every with functional or anatomic asplenia, HI solid organ transplant; or</li> </ol>				
2) One dose for close contacts of meningo	occoral cases of any are	un: or		
One dose for close contacts of mening (     The ming of the close for person who has previously a contact of the ming of the close for close contacts of mening of the close for person who has previously a close for person who has person who has person who has person who has person who have been person who has person who have been person where the person who have been person where the person who have been person where the person w			anv aroi	ın: or
A maximum of two doses for bone marr			any groc	.p, oi
5) A maximum of two doses for person pre			or	
B) Both:		,		
1) Person is aged between 13 and 25 yea	rs, inclusive; and			
2) Either:				
1) One dose for individuals who are	entering within the next	three mor	nths, or i	in their first year of living
in boarding school hostels, tertiary	education halls of resid	dence, mi	litary ba	rracks, Youth Justice
residences, or prisons; or				
<ol><li>One dose for individuals who turn</li></ol>				
C) Contractors will be entitled to claim payment				
W-135 vaccine to patients eligible under the				
(Health NZ) for subsidised immunisation, and		respect of	it the Me	eningococcal A, C, Y and
W-135 vaccine listed in the Pharmaceutical S		that ara a	avarad h	ou thair agetraat which
<ul> <li>D) Contractors may only claim for patient popula may be a sub-set of the population described</li> </ul>			overed i	by their contract, which
Note: children under seven years of age require to			r doca t	hree veers after the
primary series and then five yearly.	vo doses o weeks apair	, a boosie	i uose i	illee years after the
*Immunosuppression due to steroid or other immu	nosunnressive therany i	nust he fo	or a nerio	nd of greater than
28 days.	noodprooone morapy i	naot bo to	n a pon	od of groater than
d) MenQuadfi to be Principal Supply on 1 December	2024			
Inj 5 mcg of each meningococcal polysaccharide conjugate				
a total of approximately 44 mcg of tetanus toxoid carri				
per 0.5 ml vial – [Xpharm]		1	✓ N	imenrix

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

#### A) Both:

- 1) The child is under 12 months of age; and
- 2) Any of the following:
  - 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
  - A maximum of three doses (dependant on age at first dose) for close contacts of meningococcal cases of any group; or
  - 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
  - A maximum of three doses (dependant on age at first dose) for child pre- and post-immunosuppression\*.

Note: infants from 6 weeks to less than 6 months of age require a 2+1 schedule, infants from 6 months to less than 12 months of age require a 1+1 schedule. Refer to the Immunisation Handbook for recommended booster schedules with meningococcal ACWY vaccine.

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

#### MENINGOCOCCAL B MULTICOMPONENT VACCINE

- a) Only on a prescription
- b) No patient co-payment payable
- c) Any of the following:
  - A) Three doses for children up to 12 months of age (inclusive) for primary immunisation; or
  - B) Up to three doses (dependent on age at first dose) for a catch-up programme for children from 13 months to 59 months of age (inclusive) for primary immunisation, from 1 March 2023 to 31 August 2025; or
  - C) Both:
    - 1) Person is one year of age or over; and
    - 2) Any of the following:
      - i) up to two doses and a booster every five years for patients pre- and post-splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre- or post-solid organ transplant; or
      - ii) up to two doses for close contacts of meningococcal cases of any group; or
      - iii) up to two doses for person who has previously had meningococcal disease of any group; or
      - iv) up to two doses for bone marrow transplant patients; or
      - v) up to two doses for person pre- and post-immunosuppression\*; or
  - D) Both:
    - 1) Person is aged between 13 and 25 years (inclusive); and
    - 2) Either:
      - Two doses for individuals who are entering within the next three months, or in their first year of living in boarding school hostels, tertiary education halls of residence, military barracks, Youth Justice residences or prisons; or
      - ii) Two doses for individuals who turn 13 years of age while living in boarding school hostels.
  - E) Contractors will be entitled to claim payment from the Funder for the supply of Meningococcal B multicomponent vaccine to patients eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Meningococcal B multicomponent vaccine listed in the Pharmaceutical Schedule.
  - F) Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraphs A-D above.

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

Inj 175 mcg per 0.5 ml prefilled syringe0.00	1	✓ Bexsero
	10	✓ Beysero

Subsidy (Manufacturer's Price) \$	Fu Subsidise Per	,	
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### MENINGOCOCCAL C CONJUGATE VACCINE - [Xpharm]

Both:

- 1) The child is under 12 months of age; and
- 2) Any of the following:
  - 1) Up to three doses for patients pre- and post splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre or post solid organ transplant; or
  - 2) Two doses for close contacts of meningococcal cases of any group; or
  - 3) Two doses for child who has previously had meningococcal disease of any group; or
  - 4) A maximum of two doses for bone marrow transplant patients; or
  - 5) A maximum of two doses for child pre- and post-immunosuppression\*.

Note: children under 12 months of age require two doses 8 weeks apart. 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.

Inj 10 mcg in 0.5 ml syringe	0.00	1	✓ Neisvac-C
(Neisvac-C Ini 10 mca in 0.5 ml syringe to be delisted 1 December	2024)		

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

### PNEUMOCOCCAL (PCV13) CONJUGATE VACCINE

- a) Only on a prescription
- b) No patient co-payment payable
- c)
- A) Any of the following:
  - 1) A course of three doses for previously unvaccinated children up to the age of 59 months inclusive; or
  - Two doses are funded for high risk individuals (over the age of 12 months and under 18 years) who have previously received two doses of the primary course of PCV10: or
  - 3) Up to an additional four doses (as appropriate) are funded for the (re)immunisation of high risk children aged under 5 years with any of the following:
    - a) on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or
    - b) primary immune deficiencies; or
    - c) HIV infection: or
    - d) renal failure, or nephrotic syndrome; or
    - e) who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
    - f) cochlear implants or intracranial shunts; or
    - g) cerebrospinal fluid leaks; or
    - n) 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,

Prevenar 13 to be Principal Supply on 1 December 2024

	NATIONAL I	IMMUNISATI	ON SCHEDULE
	Subsidy (Manufacturer's Price)	Fully Subsidised Per	Brand or Generic Manufacturer
PNEUMOCOCCAL (PPV23) POLYSACCHARIDE VACCINE — Either:	[Xpharm]		
1) Up to three doses (as appropriate) for patients with HI' chemotherapy; pre- or post-splenectomy or with function complement deficiency (acquired or inherited), cochleated. 2) All of the following:	onal asplenia, pre- or p	oost-solid organ t	ransplant, renal dialysis,
<ul><li>a) Patient is a child under 18 years for (re-)immunis</li><li>b) Treatment is for a maximum of two doses; and</li><li>c) Any of the following:</li></ul>	ation; and		
<ul> <li>i) on immunosuppressive therapy or radiation immune response; or</li> <li>ii) with primary immune deficiencies; or</li> <li>iii) with HIV infection; or</li> <li>iv) with renal failure, or nephrotic syndrome; or</li> <li>v) who are immune-suppressed following organization.</li> </ul>	r	·	
or vi) with cochlear implants or intracranial shunts vii) with cerebrospinal fluid leaks; or viii) receiving corticosteroid therapy for more the prednisone of 2 mg/kg per day or greater, or 20 mg or greater; or ix) with chronic pulmonary disease (including a x) pre term infants, born before 28 weeks ges xi) with cardiac disease, with cyanosis or failur xii) with diabetes; or xiii) with Down syndrome; or xiv) who are pre-or post-splenectomy, or with fu	an two weeks, and who or children who weigh r asthma treated with hig tation; or re; or	more than 10 kg o	on a total daily dosage of
Inj 575 mcg in 0.5 ml prefilled syringe (25 mcg of each 23 pneumococcal serotype)	024 g:	1  ✓ P	neumovax 23

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch-up programmes.

Inj 80D antigen units in 0.5 ml syringe......0.00

✓ IPOL

IPOL to be Principal Supply on 1 December 2024

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

#### **BOTAVIBUS 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 tube0.00	10	Rotarix
Oral susp live attenuated human rotavirus		
1,000,000 CCID50 per dose, prefilled oral applicator0.00	10	✓ Rotarix
Rotarix to be Principal Supply on 1 December 2024		

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

#### VARICELLA VACCINE [CHICKENPOX VACCINE]

- a) Only on a prescription
- b) No patient co-payment payable
- c)
- A) Either:
  - 1) Maximum of one dose for primary vaccination for either:
    - a) Any infant born on or after 1 April 2016; or
    - 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

20 dayo			
Inj 1350 PFU prefilled syringe	0.00	10	✓ Varivax
Inj 2000 PFU prefilled syringe plus vial	0.00	10	Varilrix

Varilrix to be Principal Supply on 1 December 2024

(Varivax Inj 1350 PFU prefilled syringe to be delisted 1 December 2024)

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

a sub-set of the population described in paragraph A above.		
Inj 50 mcg per 0.5 ml vial plus vial0.00	1	✓ Shingrix
	10	✓ Shinarix

# **Diagnostic Agents**

TUBERCULIN PPD [MANTOUX] TEST - [Xpharm]			
Inj 5 TU per 0.1 ml, 1 ml vial	0.00	1	<ul><li>Tubersol</li></ul>
Tubersol to be Principal Supply on 1 December 2024			

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MiniMed Mio MMT-941A		Morphine sulphate		Natulan	
MiniMed Mio MMT-943A		Motetis		Nausafix	
		Mouth and Throat		Nausicalm	
MiniMed Mio MMT-945A					
MiniMed Mio MMT-965A		Movapo		Navelbine S29	
MiniMed Mio MMT-975A	21	Moxifloxacin	102	Nefopam hydrochloride	128

Neisvac-C	315	Noumed Dexamfetamine	149	Octreotide long-acting	18
Neo-Cytamen S29	33	Noumed Paracetamol	129	Oestradiol	8
Neo-Mercazole	90	Noumed Pethidine	132	Oestradiol valerate	8
Neocate Gold		Noumed Phenobarbitone	136	Oestradiol with norethisterone	90
Neocate Junior Unflavoured	299	Novadoz	158	Oestriol	
Neocate Junior Vanilla	299	NovaSource Renal	285	Genito-Urinary	8
Neocate SYNEO	299	Novatretin	7 <u>5</u>	Hormone	9
Neoral	255	Novitium Sugar Free	29	Oestrogens	
Neostigmine metilsulfate	120	NovoMix 30 FlexPen	10	Ofev	26
Nepafenac	271	NovoRapid	11	Oil in water emulsion	
Nepro HP (strawberry)		NovoRapid FlexPen	11	Olanzapine14	40, 14
Nepro HP (vanilla)	285	NovoRapid Penfill		Olaparib	
Neulactil	140	NovoSeven RT	39	Olbetam	5
NeuroTabs	34	Nozinan	140	Olopatadine	27
Nevirapine	115	Nozinan (Swiss)		Olopatadine Teva	27
Nevirapine Viatris	115	Nucala	218	Olsalazine	
Nicorandil	57	Nuelin		Omalizumab	22
Nicotine	155	Nuelin-SR		Omeprazole	
Nifedipine	52	Nupentin	135	Omeprazole actavis 10	
Nifuran	119	Nusinersen	148	Omeprazole actavis 20	
Nilotinib	175	Nutilis	292	Omeprazole actavis 40	
Nilstat		Nutren Diabetes	282	Omeprazole Teva	
Alimentary	33	Nutrient Modules	279	Omnitrope	9
Genito-Urinary	83	Nutrini Energy Multi Fibre	284	Omnitrope S29	
Infection	105	Nutrini Energy RTH		Onbrez Breezhaler	
Nimenrix	313	Nutrini Low Energy Multi Fibre	286	Oncaspar LYO	169
Nintedanib	265	Nutrini Peptisorb	301	OncoTICE	190
Nipent	170	Nutrini Peptisorb Energy	301	Ondansetron	
Niraparib	168	Nutrini RTH	284	One-Alpha	3
Nirmatrelvir with ritonavir	113	Nutrison 800 Complete Multi		One-Alpha S29	3
Nitrates	57	Fibre	289	Opdivo	
Nitroderm TTS	57	Nutrison Advanced Peptisorb	286	Ora-Blend	27
Nitrofurantoin	119	Nutrison Concentrated	291	Ora-Blend SF	27
Nitrolingual Pump Spray	57	Nutrison Energy	289	Ora-Plus	27
Nivestim	44	Nutrison Energy Multi Fibre	289	Ora-Sweet	27
Nivolumab	248	Nutrison Multi Fibre	289	Ora-Sweet SF	
Nodia	6	Nutrison RTH	289	Orabase	
Noflam 250	120	Nyefax Retard	5 <u>2</u>	Oral and Enteral Feeds	
Noflam 500	120	Nystatin		Oralcon 30 ED	
Non-Steroidal Anti-Inflammatory	y	Alimentary		Oramorph	
Drugs		Genito-Urinary	83	Oramorph CDC S29	
Nonacog gamma, [Recombinan		Infection		Oratane	
Factor IX]		NZB Low Gluten Bread Mix	292	Orgran	
Norethinderone - CDC	83	-0-		Ornidazole	10
Norethisterone		Obinutuzumab		Orphenadrine citrate	12
Genito-Urinary		Obstetric Preparations	85	Ortho-tolidine	8
Hormone	90	Ocicure		Oruvail SR	120
Norflex	125	Ocrelizumab	145	Osmolite RTH	28
Norfloxacin		Ocrevus		Other Endocrine Agents	
Noriday 28	83	Octocog alfa [Recombinant factor		Other Oestrogen Preparations	90
Norimin		VIII] (Advate)		Other Progestogen	
Norimin-1 28 Day		Octocog alfa [Recombinant factors		Preparations	90
Normison		VIII] (Kogenate FS)		Other Skin Preparations	7
Norpress		Octreotide		Otodex	269
Nortriptyline hydrochloride		Octreotide Depot Teva		Ovestin	
Norvir	116	Octreotide GH	181	Genito-Urinary	8

Hormone	90	Pediasure Plus	284	Pine tar with trolamine laurilsulfate	
Oxaliplatin	159	Pediasure RTH	284	and fluorescein	76
Oxaliplatin Accord	159	Pegaspargase	169	Pinetarsol	76
Oxaliplatin Actavis 100	159	Pegasys	116	Pioglitazone	12
Oxaliplatin Ebewe	159	Pegfilgrastim	45	Pirfenidone	265
Oxis Turbuhaler		Pegylated interferon alfa-2a		Pizotifen	138
Oxpentifylline		Pembrolizumab		PKU Anamix Infant	295
Oxybutynin		Pemetrexed		PKU Anamix Junior	295
Oxycodone Amneal		Pemetrexed-AFT		PKU Anamix Junior Chocolate	
Oxycodone hydrochloride		Penicillamine		PKU Anamix Junior LQ	
Oxycodone Lucis S29		Penicillin G		PKU Anamix Junior Orange	
Oxycodone Sandoz		PenMix 30		PKU Anamix Junior Vanilla	
Oxycodone Sandoz S29		PenMix 50		PKU Build 10	
OxyContin		Pentasa		PKU Build 20 Chocolate	
OxyNorm		Pentostatin [Deoxycoformycin].		PKU Build 20 Raspberry	200
Oxytocin		Pentoxifylline [Oxpentifylline]		Lemonade	206
Oxytocin BNM		Peptamen Junior		PKU Build 20 Smooth	
				PKU Build 20 Vanilla	
Oxytocin Panpharma	04	Pepti-Junior Perhexiline maleate			
Oxytocin with ergometrine	0.4			PKU Explore 10	
maleate		Pericyazine		PKU Explore 5	
Ozurdex	270	Perindopril		PKU Express 20	
· · · · · · · · · · · · · · · · · · ·	405	Periset		PKU First Spoon	
Pacifen		Periset ODT		PKU Glytactin RTD 15	
Pacimol		Perjeta		PKU Glytactin RTD 15 Lite	
Paclitaxel		Permethrin		PKU GMPro LQ	
Paclitaxel Actavis		Perrigo		PKU GMPro Mix-In	
Paclitaxel Ebewe		Pertuzumab		PKU GMPro Ultra Lemonade	
Paediatric Seravit		Peteha		PKU GMPro Ultra Vanilla	
Palbociclib		Pethidine hydrochloride		PKU Lophlex LQ 10	
Paliperidone	142	Pevaryl		PKU Lophlex LQ 20	
Paliperidone palmitate	143	Pexsig	52	PKU Lophlex Powder	
Pamidronate disodium	122	Pfizer Exemestane	183	PKU Lophlex Sensation 20	295
Pamisol	122	Pfizer S29	161	PKU Restore Powder	296
Pamol	129	Pharmacy Services	274	PKU sphere20 Banana	296
Pancreatic enzyme	24	Pharmascience	263	PKU sphere20 Chocolate	296
Pantoprazole	9	Pheburane	30	PKU sphere20 Lemon	296
Panzop Relief		Phenasen	164	PKU sphere20 Red Berry	296
Papaverine hydrochloride	57	Phenobarbitone	136	PKU sphere20 Vanilla	296
Para-amino salicylic acid		Phenobarbitone sodium		PKU Start	
Paracetamol		Extemporaneous	278	Plaquenil	121
Paracetamol (Ethics)	129	Nervous	147	Plendil ER	52
Paracetamol + Codeine		Phenoxybenzamine		PMS-Salbutamol	262
(Relieve)	132	hydrochloride	47	Pneumococcal (PCV13) conjugate	
Paracetamol with codeine		Phenoxymethylpenicillin (Penici		vaccine	
Paraffin		V)		Pneumococcal (PPV23)	
Paraffin liquid with wool fat		Phenylalanine50		polysaccharide vaccine	317
Parasiticidal Preparations		Phenytoin sodium		Pneumovax 23	
Parnate		Phillips Milk of Magnesia		Podophyllotoxin	
Paromomycin		Phlexy 10		Polaramine	
Paroxetine		Phosphate Phebra		Poliomyelitis vaccine	
Paser		Phosphorus		Poloxamer	
Paxam		Phytomenadione		Poly-Gel	
Paxlovid					
		Pilocarpine hydrochloride		Poly-Tears	
Pazopanib		Pilocarpine nitrate		Poly-Visc	
Peak flow meter		Pimafucort		Polycal	2/9
Pediasure	284	Pimecrolimus	/b	Polyethylene glycol 400 and	

propylene glycol		Protifar	281	Ribomustin	
Pomalidomide		Protionamide		Ricit	
Pomolide		Provera		Rifabutin	
Ponstan		Provera HD	90	Rifadin	
Posaconazole		Psoriasis and Eczema		Rifadin Sanofi	
Posaconazole Juno		Preparations	75	Rifampicin	
Potassium chloride	45–46	PTU	91	Rifaximin	10
Potassium citrate	85	Pulmicort Turbuhaler	261	Rifinah	10
Potassium iodate	34	Pulmozyme	266	Rilutek	
Povidone iodine	74	Puri-nethol	162	Riluzole	12
Pradaxa		Puritan's Pride Vitamin		RINVOQ	25
Pramipexole hydrochloride	126	B-2 100 mg	29	Riodine	74
Pravastatin	55	Pyrazinamide	110	Risdiplam	14
Praziquantel	97	Pyridostigmine bromide		Risedronate Sandoz	
Prazosin	47	Pyridoxine hydrochloride	33	Risedronate sodium	12
Prazosin Mylan	47	Pyridoxine multichem	33	Risperdal	
Pred Forte	271	Pyrimethamine		Risperdal Consta	14
Prednisolone	88	Pytazen SR		Risperidone14	
Prednisolone acetate		- Q -		Risperidone (Teva)	
Prednisolone sodium		Quantalan sugar free	55	Risperidone Sandoz	14
phosphate	271	Quetapel		Risperon	
Prednisolone-AFT		Quetiapine		Ritalin	
Prednisone		Quinapril		Ritalin LA	
Prednisone Clinect		Qvar		Ritonavir	
Pregabalin		-R-		Rituximab (Mabthera)	
Pregabalin Pfizer		RA-Morph	130	Rituximab (Riximyo)	
Pregnancy Tests - hCG Urine .	84	Ralicrom		Rivaroxaban	
Premarin		Raloxifene hydrochloride		Rivastigmine	
Prevenar 13		Raltegravir potassium		Rivastigmine Patch BNM 10	
Priadel		Ramipex		Rivastigmine Patch BNM 5	
Primaquine		Ramipril		Rivotril	
Primidone		Ranbaxy-Cefaclor		Riximyo	
Primidone Clinect		Rapamune	255	RIXUBIS	
Primolut N		Rasagiline		Rizamelt	
Priorix				Rizatriptan	
Probenecid		Reandron 1000			
		Recombinant factor IX		Robinul	
Probenecid-AFT		Recombinant factor VIIa		Ronapreve	
Procarbazine hydrochloride		Recombinant factor VIII		Ropin	121
Prochlorperazine	139	Rectogesic		Ropinirole hydrochloride	121
Prochlorperazine Brown &	400	Redipred		Rosuvastatin	5
Burk		Relieve		Rosuvastatin Viatris	5
Proctofoam		Relistor		Rotarix	
Proctosedyl		Remicade		Rotavirus oral vaccine	
Procyclidine hydrochloride		Renilon 7.5		Roxane-Propranolol	
Progesterone		Resonium-A		Roxithromycin	
Proglicem		Resource Beneprotein		Rubifen	
Progynova		Respiratory Devices		Rubifen SR	150
Prolia		Respiratory Stimulants		Rugby Capsaicin Topical Cream	
Promethazine hydrochloride		Retinol palmitate		Musculoskeletal	
Propafenone hydrochloride		ReTrieve		Nervous	
Propranolol	51	Retrovir		Rurioctocog alfa pegol [Recombina	
Propylene glycol		Revia		factor VIII]	
Propylthiouracil		Revlimid	165	Ruxolitinib	17
Prostacur		Revolade		Rydapt	174
Protaphane		Ribociclib	177	Rythmodan	49
Protaphane Penfill	11	Riboflavin	29	Rythmodan - Cheplafarm	

Rytmonorm	50	Sodibic	46	Stiripentol	
- S -		Sodium acid phosphate	26	Stocrin	
Sabril	137	Sodium alginate	6	Stomahesive	3
Sacubitril with valsartan	49	Sodium benzoate	30	Strides Shasun	10
SalAir	262	Sodium bicarbonate		Stromectol	7
Salazopyrin	8	Blood	45–46	Sucralfate	1
Salazopyrin EN		Extemporaneous		Sulfadiazin-Heyl	
Salbutamol		Sodium calcium edetate		Sulfadiazine Silver	
Salbutamol Cipla		Sodium chloride		Sulfadiazine sodium	
Salbutamol with ipratropium	202	Blood	45	Sulfasalazine	
bromide	262	Respiratory		Sulphur	
Salicylic acid		Sodium citrate with sodium laury		Sulprix	
,					
Salmeterol		sulphoacetate		Sumagran	
Sandomigran		Sodium citro-tartrate	85	Sumatriptan	
Sandostatin LAR		Sodium cromoglicate		Sunitinib	
Sanofi Primaquine		Alimentary		Sunitinib Pfizer	
Sapropterin dihydrochloride		Sensory	271	Sunscreens	
Scalp Preparations		Sodium Fusidate [fusidic acid]		Sunscreens, proprietary	7
Scopoderm TTS		Dermatological	70	Survimed OPD	
Scopolamine - Mylan	138	Infection	103	Sustagen Hospital Formula	28
Scopolamine - Mylan S29		Sensory		Sustagen Hospital Formula	
Sebizole	77	Sodium hyaluronate [Hyaluronic		Active	28
Secukinumab	234	acid]	273	Sustanon Ampoules	8
Sedatives and Hypnotics	147	Sodium phenylbutyrate	30	Sylvant	23
Seebri Breezhaler		Sodium picosulfate		Symbicort Turbuhaler 100/6	26
Senna	26	Sodium polystyrene sulphonate	46	Symbicort Turbuhaler 200/6	
Senokot	26	Sodium tetradecyl sulphate		Symbicort Turbuhaler 400/12	
SensoCard	15	Sodium valproate		Symmetrel	
Serc		Sofradex		Sympathomimetics	
Serenace		Soframycin		Synacthen	
Seretide		Solgar2		Synacthen Depot	8
Seretide Accuhaler		Solifenacin succinate		Synacthene Retard	8
Serevent		Solifenacin Viatris		Synthroid	
Serevent Accuhaler		Solu-Cortef		Syntometrine	
Sertraline		Solu-Medrol			
Setrona		Solu-Medrol-Act-O-Vial		Syrup (pharmaceutical grade) Systane Unit Dose	
Sevredol				- T -	21
	131	Somatropin (Omnitrope)		= = = = = = = = = = = = = = = = = = =	
Sex Hormones Non	00	Sotalol		Tacrolimus	7
Contraceptive		Spacer device		Dermatological	
Shingles vaccine		Span-K		Oncology	
Shingrix		Spazmol		Tacrolimus Sandoz	
SII-Onco-BCG		Spinal Muscular Atrophy		Taliglucerase alfa	
Sildenafil		Spinraza		Tambocor	
Siltuximab		Spiolto Respimat		Tamoxifen citrate	
Simvastatin		Spiractin	53	Tamoxifen Sandoz	
Simvastatin Mylan	56	Spiriva	263	Tamsulosin hydrochloride	8
Simvastatin Viatris	56	Spiriva Respimat	263	Tamsulosin-Rex	
Sinemet	126	Spironolactone	53	Tandem Cartridge	1
Sinemet CR	126	Sporanox	105	Tandem t:slim X2 with Basal-IQ	1
Sintetica Baclofen Intrathecal	125	Sprycel	173	Tandem t:slim X2 with	
Sirolimus	255	Stelara	243	Control-IQ	1
Sirturo	108	Stemetil	139	Tap water	27
Siterone	88	Steril-Gene	88	Taro	
Slow-Lopresor		SteroClear		Tasigna	
Smith BioMed Rapid Pregnancy	-	Stesolid		Tasmar	
Test	84	Stimulants/ADHD Treatments		Taurine	

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TCu 380 Plus Normal		Tobramycin	404	Trulicity	1
Tecentriq		Infection		TruSteel	
Tecfidera		Sensory		Tryzan	
Tegretol		Tobramycin (Viatris)		Tuberculin PPD [Mantoux] test.	
Tegretol AU		Tobramycin BNM		Tubersol	
Tegretol CR		Tobrex	269	Two Cal HN	29
Telfast	260	Tocilizumab	237	TYR Anamix Infant	
Temaccord	170	Tofranil	133	TYR Anamix Junior	29
Temazepam	148	Tolcapone	126	TYR Anamix Junior LQ	29
Temozolomide	170	Tolvaptan	54	TYR Explore 5	29
Temozolomide-Taro	170	Topamax		TYR Lophlex LQ 20	29
Tenofovir disoproxil		Topical Products for Joint an		TYR Sphere 20	
Tenofovir Disoproxil Emtricitabine	9	Muscular Pain		Tyrosine1000	29
Viatr		Topiramate	137	Tysabri	14
Tenofovir Disoproxil Viatris		Topiramate Actavis		- U -	
Tenoxicam		Total parenteral nutrition (TP		UK Synacthen	8
Tensipine MR10		TPN		Ultibro Breezhaler	
Tepadina		Tramadol hydrochloride		Ultraproct	
		•		Umeclidinium	
Terbinafine		Tramal SR 100			
Terbutaline sulphate		Tramal SR 150		Umeclidinium with vilanterol	
Teriflunomide		Tramal SR 200		Univent	
Teriflunomide Sandoz		Trandate		Upadacitinib	
Teriparatide		Tranexamic acid		Ural	
Teriparatide - Teva	123	Tranylcypromine sulphate		Urea	
Testogel	88	Trastuzumab (Herzuma)		Urex Forte	
Testosterone		Trastuzumab emtansine		Urinary Agents	
Testosterone cipionate	88	Travatan	272	Urinary Tract Infections	
Testosterone esters	88	Travoprost	272	UroFos	
Testosterone undecanoate	88	Treatments for Dementia	152	Uromitexan	16
Tetrabenazine	127	Treatments for Substance		Ursodeoxycholic acid	2
Tetrabromophenol	85	Dependence	153	Ursosan	2
Tetracosactrin	88	Trelegy Ellipta	264	Ustekinumab	24
Tetracycline	101	Trental 400		Utrogestan	9
Teva Lisinopril		Tretinoin		- V -	
Teva-Ketoconazole		Dermatological	69	Vaccinations	304
Teva-Salbutamol Sterinebs		Oncology		Vaclovir	
P.F.	262	Trexate		Valaciclovir	
Thalidomide		Triamcinolone acetonide		Valganciclovir	
Thalomid		Alimentary	30	Valganciclovir Viatris	
		Dermatological		Valine50	
Theophylline		Hormone		Vancomycin	
Thiamine hydrochloride				Vannoir	10·
Thiamine multichem		Triamcinolone acetonide with		Vannair	
THIO-TEPA		gramicidin, neomycin and		Varenicline Pfizer	
Thioguanine		Dermatological		Varenicline tartrate	15
Thiotepa		Sensory		Varicella vaccine [Chickenpox	
Thyroid and Antithyroid Agents		Trientine		vaccine]	
Ticagrelor		Trientine Waymade		Varicella zoster vaccine [Shingle	
Ticagrelor Sandoz		Trikafta	266	vaccine]	320
Tilcotil	120	Trimethoprim	104	Varilrix	
Timolol		Trimethoprim with		Various	
Tiotropium bromide	263	sulphamethoxazole		VariSoft	
Tiotropium bromide with		[Co-trimoxazole]	104	Varivax	319
olodaterol	264	Trisequens		Vasodilators	
Tivicay		Trisul		Vasopressin Agonists	
Tixagevimab with cilgavimab		Trophic Hormones		Vasorex	
TMP		Tropicamide		Vebulis	
	-				_

Vedafil	63	Extemporaneous	278	Zytiga	179
Vedolizumab	245	White Soft Liquid Paraffin AFT		Zyvox	
Veletri	64	Wool fat with mineral oil	74	·	
Venclexta	171	- X -			
Venetoclax	171	Xaluprine	162		
Venlafaxine	134	Xarelto			
Venomil2	59-260	Xifaxan	10		
VENOX		XMET Maxamum	293		
Ventolin	262	Xolair	220		
Ventolin Nebules	262	Xolair AU	220		
Vepesid	164	XP Maxamum	295		
Verapamil hydrochloride		Xylocaine	128		
Vermox		Xylocaine 2% Jelly	127		
Versacloz	140	Xylocard 500			
Vesanoid	171	Xyntha			
Vexazone	12	- Z -			
Vfend	106	Zapril	47		
Viaderm KC	73	Zarontin	135		
Victoza	12	Zaroxolyn			
Vigabatrin		Zavedos			
Vigisom	147	Zeffix			
Vildagliptin		Zejula	168		
Vildagliptin with metformin		Zematop			
hydrochloride	12	Zetlam			
Vimpat		Ziagen			
Vinblastine sulphate		Zidovudine [AZT]			
Vincristine sulphate		Zidovudine [AZT] with			
Vinorelbine		lamivudine	115		
Vinorelbine Ebewe		Ziextenzo			
Vinorelbine Te Arai		Zimybe			
Viramune Suspension		Zinc and castor oil			
ViruPOS		Zinc sulphate			
Vit.D3		Zincaps			
Vita-B12		Ziprasidone			
VitA-POS		Zista			
Vitabdeck		Zithromax			
Vital		Zo-Rub HP			
Vitamin B complex		Zo-Rub Osteo			
Vitamin B6 25		Zoladex			
Vitamins		Zoledronic acid			
Vitarubin Depot Injection		Hormone	87		
Vivonex TEN		Musculoskeletal			
Voltaren		Zoledronic acid Viatris			
Voltaren D		Hormone	87		
Voltaren Ophtha		Musculoskeletal			
Voltaren SR		Zopiclone			
Volumatic		Zopiclone Actavis			
Voriconazole		Zostrix			
Votrient		Zostrix HP			
Vttack		Zuclopenthixol decanoate			
- W -		Zuclopenthixol hydrochloride			
Warfarin sodium	44	Zusdone			
Wart Preparations		Zyban			
Wasp venom allergy treatment		Zypine			
Water		Zypine ODT			
Blood	46	Zyprexa Relprevv			
		-, p. ona . to:p. ov v			