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#### **Programmers**

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Introducing Pharmac

## **Introducing Pharmac**

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

#### Pharmac's role:

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

Pae Ora (Healthy Futures) Act 2022

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

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

## **Purpose of the Pharmaceutical Schedule**

The purpose of the Schedule is to list:

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

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

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

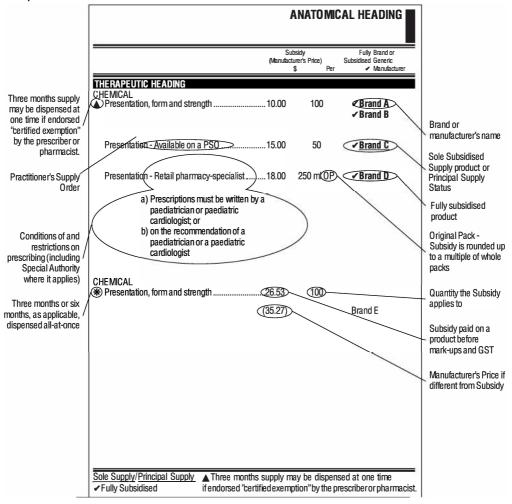
The Pharmaceuticals in this book are listed by therapeutic group, which is based on the WHO Anatomical Therapeutic Chemical (ATC) system. The listings are displayed alphabetically under each heading.

The index lists both chemical entities and product brand names.

# **Explaining pharmaceutical entries**

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

### Example



# Glossary

## **Units of Measure**

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

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

millimoleunit	
Solution	Supp Tab
Trans Dermal Delivery System	TDDS

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

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

SECTION B. ALIMENTART TRACT AND ME	IADOLISM			
	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
Antacids and Antiflatulents				
Antacids and Reflux Barrier Agents				
ALGINIC ACID Sodium alginate 225 mg and magnesium alginate 87.5 mg p sachet		30	<b>✓</b>	Gaviscon Infant
SODIUM ALGINATE  * Tab 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg - peppermint flavour	1.80 (17.99)	60		Gaviscon Extra Strength
Oral liq 500 mg with sodium bicarbonate 267 mg and calciun carbonate 160 mg per 10 ml		500 m		Acidex
Phosphate Binding Agents				
ALUMINIUM HYDROXIDE  * Tab 600 mg	12.56	100	✓.	Alu-Tab
Oral liq 1,250 mg per 5 ml (500 mg elemental per 5 ml) – Subsidy by endorsement		500 m 473 m		Roxane Calcium carbonate
Only when prescribed for patients unable to swallow calinappropriate and the prescription is endorsed according		ts or w	here calci	
Antidiarrhoeals				
Agents Which Reduce Motility				
LOPERAMIDE HYDROCHLORIDE – Up to 30 cap available on  * Tab 2 mg*  * Cap 2 mg	10.75	400 400		Nodia Diamide Relief
Rectal and Colonic Anti-inflammatories				
BUDESONIDE  Cap modified-release 3 mg - Special Authority see SA1886  below - Retail pharmacy  Budesonide Te Arai to be Principal Supply on 1 Decemb	33.38	90	1	Budesonide 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:

continued...

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

continued...

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

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

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

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

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

All of the following:

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

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

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

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

HYDROCORTISONE ACETATE		
Rectal foam 10%, CFC-Free (14 applications)57.09	15 g OP	✓ Colifoam
HYDROCORTISONE ACETATE WITH PRAMOXINE HYDROCHLORIDE	-	
Topical aerosol foam, 1% with pramoxine hydrochloride 1%26.55	10 g OP	✓ Proctofoam S29
MESALAZINE		
Tab 400 mg49.50	100	✓ Asacol
71.00	90	✓ Octasa S29
Tab long-acting 500 mg56.10	100	✓ Pentasa
Tab 800 mg85.50	90	✓ Asacol
		✓ Asacol S29 S29
Tab 1,600 mg85.50	60	✓ Asacol 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	Generic
OLSALAZINE				
Tab 500 mg	56.02	60	1	Atnahs
				Olsalazine S29
	93.37	100	1	Dipentum
Cap 250 mg	53.00	100	1	Dipentum
SODIUM CROMOGLICATE Cap 100 mg	113.35	100	✓	Ralicrom
SULFASALAZINE				
* Tab 500 mg		100		Salazopyrin
* Tab EC 500 mg	20.54	100	•	Salazopyrin EN

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

## **Antihaemorrhoidal Preparations**

FLUOCORTOLONE CAPROATE WITH FLUOCORTOLONE PIVALATE AND CII	NCHOCAINE	
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

## ⇒SA1329 Special Authority for Subsidy

CL VCODVDDONII IM DDOMIDE

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

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

40.00	-	/ Dateback
19.00	5	✓ Robinul
2.25	20	<ul> <li>Hyoscine</li> </ul>
		Butylbromide (Adiramedica)
1.91	5	✓ Spazmol
8.50	90	✓ Colofac
		2.25 20

## **Antiulcerants**

# **Antisecretory and Cytoprotective**

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

# **Helicobacter Pylori Eradication**

#### CLARITHROMYCIN

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

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

## **H2 Antagonists**

FΑ	MOTIDINE - Only on a prescription			
*	Tab 20 mg	4.86	100	✓ Famotidine
				Hovid S29
*	Tab 40 mg	10.27	100	✓ Famotidine Hovid
	•			MY S29
*	Inj 10 mg per ml, 4 ml - Subsidy by endorsement	CBS	10	✓ Mylan S29
	Subsidy by endorsement – Subsidised for patients receiving			ve care.

## **Proton Pump Inhibitors**

LANSOPRAZOLE		
* Cap 15 mg4.04	100	✓ Lanzol Relief
* Cap 30 mg5.43	100	✓ Lanzol Relief
OMEPRAZOLE		
For omeprazole suspension refer Standard Formulae, page 284		
* Cap 10 mg	90	✓ Omeprazole Teva
Out 10 mg	00	✓ Omeprazole actavis
		10
* Cap 20 mg2.02	90	✓ Omeprazole Teva
		<ul> <li>Omeprazole actavis</li> </ul>
		20
* Cap 40 mg3.18	90	Omeprazole Teva
		<ul> <li>Omeprazole actavis</li> </ul>
		<u>40</u>
* Powder – Only in combination42.50	5 g	✓ Midwest
Only in extemporaneously compounded omeprazole suspension.	·	
* Inj 40 mg ampoule with diluent	5	✓ Dr Reddy's
, , ,		Omeprazole
		✓ Ocicure S29
PANTOPRAZOLE		
	90	✓ Panzop Relief
=		•
* Tab EC 40 mg	90	✓ Panzop Relief
Site Protective Agents		
Site Protective Agents		

COLLOIDAL DISINIOTTI SUDCITINATE			
Tab 120 mg	14.51	50	✓ Gastrodenol S29
SUCRALFATE			
Tab 1 g	35.50	120	
•	(48.28)		Carafate

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

# **Bile and Liver Therapy**

RIFAXIMIN - Special Authority see SA1461 below - Retail pharmacy 56

Xifaxan

### ⇒SA1461 Special Authority for Subsidy

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

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

#### **Diabetes**

## Hyperglycaemic Agents

DIAZOXIDE - Special Authority see SA1320 below - Retail pharmacy

Cap 25 mg	110.00	100	✓ Proglicem S29
Cap 100 mg	280.00	100	✓ Proglicem S29
Oral liq 50 mg per ml	620.00	30 ml OP	✓ e5 Pharma S29

## ⇒SA1320 Special Authority for Subsidy

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

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

#### GLUCAGON HYDROCHLORIDE

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

# **Insulin - Short-acting Preparations**

INICI	11 11	N I/	FII:	TRAI	

$\blacktriangle$	Inj human 100 u per ml, 3 ml	42.66	5	<ul> <li>Actrapid Penfill</li> </ul>
				✓ Humulin R
•	Ini human 100 u nor ml. 10 ml vial	25.26	1 OP	✓ Actranid

Humulin R

# Insulin - Intermediate-acting Preparations

▲ Inj 100 iu per ml, 3 ml prefilled pen52.15	5	✓ NovoMix 30 FlexPen
INSULIN DEGLUDEC WITH INSULIN ASPART		
▲ Inj degludec 70 u with insulin aspart 30 u, 100 u per ml, 3 ml80.00	5	✓ Ryzodeg

## Inj degludec 70 u with insulin aspart 30 u, 100 u per ml, 3 ml..........80.00

IIV	BULIN ISOPHANE		
$\blacktriangle$	Inj human 100 u per ml, 3 ml29.86	5	✓ Humulin NPH
			Protaphane Penfill
$\blacktriangle$	Inj human 100 u per ml, 10 ml vial17.68	1 OP	✓ Humulin NPH

Protaphane

70/30 Penfill

	O. de ellete		F. II.	D d
	Subsidy (Manufacturer's Price)	Sub	Fully sidised	
	\$	Per	✓	Manufacturer
ISULIN ISOPHANE WITH INSULIN NEUTRAL				
Inj human with neutral insulin 100 u per ml, 3 ml	42.66	5	1	Humulin 30/70
,			1	PenMix 30
Inj human with neutral insulin 100 u per ml, 10 ml vial	25.26	1 OP	1	Humulin 30/70
NSULIN LISPRO WITH INSULIN LISPRO PROTAMINE				
Inj lispro 25% with insulin lispro protamine 75% 100 u per ml,				
3 ml	42.66	5	1	Humalog Mix 25
Inj lispro 50% with insulin lispro protamine 50% 100 u per ml,				ŭ
3 ml	42.66	5	1	Humalog Mix 50
Insulin - Long-acting Preparations				
ISULIN GLARGINE	60.00	4	./	Lambus
Inj 100 u per ml, 10 ml     Inj 100 u per ml, 3 ml		1 5		Lantus Lantus
Inj 100 u per mi, 3 mi		5 5		Lantus SoloStar
ing 100 d per fill, 5 fill disposable peri	94.50	J		Lantus SoloStai
Insulin - Rapid Acting Preparations				
ISULIN ASPART				
Inj 100 u per ml, 10 ml	30.03	1	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		1		Apidra
Inj 100 u per ml, 3 ml		5	_	Apidra
Inj 100 u per ml, 3 ml disposable pen	46.07	5	•	Apidra SoloStar
NSULIN LISPRO			_	
Inj 100 u per ml, 3 ml		5		Humalog
Inj 100 u per ml, 10 ml vial	34.92	1 OP	•	Humalog
Alpha Glucosidase Inhibitors				
CARBOSE				
€ Tab 50 mg	11.20	90	1	Accarb
€ Tab 100 mg	17.38	90	✓	<u>Accarb</u>
Oral Hypoglycaemic Agents				
LIBENCLAMIDE				
€ Tab 5 mg	7.50	100	1	Daonil
BLICLAZIDE				
₹ Tab 80 mg	20.10	500	1	<u>Glizide</u>
ILIPIZIDE				
Tab 5 mg	6.86	100	✓	<u>Minidiab</u>
IETFORMIN HYDROCHLORIDE				
← Tab immediate-release 500 mg	14.74	1,000	✓	Metformin Viatris
Tab immediate-release 850 mg		500	1	Metformin Viatris
IOGLITAZONE				
F Tab 15 mg	6.15	90	✓	Vexazone
€ Tab 30 mg	7 25	90	1	Vexazone
r 1ab 30 mg		00		Vexazone

<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
VILDAGLIPTIN  * Tab 50 mg	35.00	60	✓ Galvus
VILDAGLIPTIN WITH METFORMIN HYDROCHLORIDE  * Tab 50 mg with 1,000 mg metformin hydrochloride  * Tab 50 mg with 850 mg metformin hydrochloride		60 60	<ul><li>✓ Galvumet</li><li>✓ Galvumet</li></ul>

## **GLP-1 Agonists**

DULAGLUTIDE - Special Authority see SA2509 below - Retail pharmacy

## **⇒SA2509** Special Authority for Subsidy

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

All of the following:

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

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

- a) Pre-existing cardiovascular disease or risk equivalent defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.
- b) Diabetic kidney disease defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m2 in the presence of diabetes, without alternative cause identified.
- c) Funded GLP-1a treatment is not to be given in combination with funded (empagliflozin /empagliflozin with metformin hydrochloride) unless receiving funded (empagliflozin or empagliflozin in combination with metformin hydrochloride) for the treatment of heart failure.

LIRAGLUTIDE - Special Authority see SA2510 on the next page - Retail pharmacy

- a) Maximum of 9 inj per prescription
- b)
- a) Note: Not to be given in combination with another funded GLP-1 agonist or empagliflozin / empagliflozin with metformin hydrochloride unless receiving empagliflozin / empagliflozin with metformin hydrochloride for the treatment of heart failure.
- b) Maximum of 1 pack of 3 (6 mg per ml, 3 ml) prefilled pens will be funded per month.

Subs	,	Fully	Brand or
(Manufactur		lised	Generic
\$	Per	1	Manufacturer

### ⇒SA2510 Special Authority for Subsidy

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

All of the following:

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

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

- a) Pre-existing cardiovascular disease or risk equivalent defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.
- b) Diabetic kidney disease defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m2 in the presence of diabetes, without alternative cause identified.
- c) Funded GLP-1a treatment is not to be given in combination with funded (empagliflozin /empagliflozin with metformin hydrochloride) unless receiving funded (empagliflozin or empagliflozin in combination with metformin hydrochloride) for the treatment of heart failure.

#### SGI T2 Inhibitors

#### ⇒SA2408 Special Authority for Subsidy

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

All of the following:

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

Initial application — (Type 2 Diabetes) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

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

continued...

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

continued...

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

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

- a) Pre-existing cardiovascular disease or risk equivalent defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.
- b) Diabetic kidney disease defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m2 in the presence of diabetes, without alternative cause.
- c) Funded [empagliflozin / empagliflozin with metformin hydrochloride] treatment is not to be given in combination with a funded GLP-1 unless receiving (empagliflozin / empagliflozin with metformin hydrochloride] for the treatment of heart failure.

EMPAGLIFLOZIN - Special Authority see SA2408 on the previous page - Retail pharmacy

*	Tab 10 mg58.56	30	Jardiance
*	Tab 25 mg58.56	30	<ul><li>Jardiance</li></ul>

EMPAGLIFLOZIN WITH METFORMIN HYDROCHLORIDE - Special Authority see SA2408 on the previous page - Retail pharmacy

*	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	✓ Jardiamet
*	Tab 12.5 mg with 1,000 mg metformin hydrochloride	58.56	60	✓ Jardiamet
*	Tab 12.5 mg with 500 mg metformin hydrochloride	58 56	60	✓ .lardiamet

## **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
  - cvstic fibrosis-related diabetes: or
  - 5) metabolic disease or epilepsy under the care of a paediatrician, neurologist or metabolic specialist.

The prescription must be endorsed accordingly.

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

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

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

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

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

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

## **Blood Glucose Testing**

BLOOD GLUCOSE DIAGNOSTIC TEST METER - Subsidy by endorsement

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

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

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

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

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

rips.......10.00 1 OP ✓ 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	Generic
\$	Per	•	Manufacturer

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

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

- 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 strips10.56	50 test OP	<ul><li>CareSens N</li></ul>
		✓ 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.

## 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 mm	10.95	100	✓ B-D Micro-Fine
	31 g × 5 mm		100	✓ B-D Micro-Fine
	31 g × 6 mm		100	✓ Berpu
	31 g × 8 mm		100	✓ B-D Micro-Fine
	32 a × 4 mm	10.95	100	✓ R-D Micro-Fine

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

## **Insulin Pumps**

INSULIN PUMP WITH ALGORITHM - Special Authority see \$A2367 below - Retail pharmacy

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

  Min basal rate 0.02 U/h .......8,970.00

  Min basal rate 0.1 U/h .......7,653.00
- ✓ mylife YpsoPump
  with CamAPS FX
- ✓ Tandem t:slim
  X2 with Basal-IQ
- ✓ Tandem t:slim
  X2 with Control-IQ

## ⇒SA2367 Special Authority for Subsidy

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

All of the following:

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

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

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

## **Insulin Pump Consumables**

#### ⇒SA2380 Special Authority for Subsidy

Initial application — (type 1 diabetes) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

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

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

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

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

INSULIN PUMP INFUSION SET (STEEL CANNULA) - Special Authority see SA2380 above - Retail pharmacy

- a) Maximum of 5 set per prescription
- b) Only on a prescription
- c) Maximum of 19 infusion sets will be funded per year.

*	6 mm steel needle; 60 cm tubing x 10130.00	1 OP	✓ MiniMed Sure-T MMT-864A
*	6 mm steel needle; 80 cm tubing × 10130.00	1 OP	✓ MiniMed Sure-T MMT-866A
*	8 mm steel needle; 60 cm tubing × 10130.00	1 OP	✓ MiniMed Sure-T MMT-874A
*	8 mm steel needle; 80 cm tubing × 10130.00	1 OP	<ul><li>MiniMed Sure-T MMT-876A</li></ul>

(MiniMed Sure-T MMT-864A 6 mm steel needle; 60 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Sure-T MMT-866A 6 mm steel needle; 80 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Sure-T MMT-874A 8 mm steel needle; 60 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Sure-T MMT-876A 8 mm steel needle; 80 cm tubing × 10 to be delisted 1 October 2026)

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

INSULIN PUMP INFUSION SET (STEEL CANNULA, STRAIGHT INSERTION) - Special Authority see SA2380 on the previous page - Retail pharmacy

- a) Maximum of 5 sets per prescription
- b) Only on a prescription

	2) 3, 3 a p. 333p			
	c) Maximum of 19 infusion sets will be funded per year.			
*	5.5 mm steel cannula; straight insertion; 45 cm line x 10 with 10 needles	136.00	1 OP	✓ mylife Orbit micro
*	5.5 mm steel needle; straight insertion; 60 cm line × 10 with 10 needles	136.00	1 OP	✓ mylife Orbit micro
*	5.5 mm steel needle; straight insertion; 80 cm line x 10 with 10 needles	136.00	1 OP	✓ mylife Orbit micro
*	8.5 mm steel needle; straight insertion; 60 cm line × 10 with 10 needles	136.00	1 OP	✓ mylife Orbit micro
*	8.5 mm steel needle; straight insertion; 80 cm line x 10 with 10 needles	136.00	1 OP	✓ mylife Orbit micro
*	6 mm steel cannula; straight insertion; 80 cm line × 10 with 10 needles	182.00	1 OP	✓ TruSteel
*	8 mm steel cannula; straight insertion; 80 cm line × 10 with 10 needles	182.00	1 OP	✓ TruSteel
*	6 mm steel cannula; straight insertion; 60 cm line × 10 with 10 needles	182.00	1 OP	✓ TruSteel
*	8 mm steel cannula; straight insertion; 60 cm line x 10 with 10 needles	182.00	1 OP	✓ TruSteel

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

INSULIN PUMP INFUSION SET (TEFLON CANNULA) - Special Authority see SA2380 on page 18 - Retail pharmacy

- a) Maximum of 5 set per prescription
- b) Only on a prescription

	c) Maximum of 19 infusion sets will be funded per year.		
*	13 mm teflon needle, 60 cm tubing × 10	1 OP	✓ MiniMed Silhouette  MMT-381A
*	17 mm teflon needle, 110 cm tubing × 10130.00	1 OP	<ul> <li>MiniMed Silhouette MMT-377A</li> </ul>
*	17 mm teflon needle, 60 cm tubing x 10130.00	1 OP	<ul> <li>MiniMed Silhouette MMT-378A</li> </ul>
*	6 mm teflon needle, 110 cm tubing x 10130.00	1 OP	MiniMed Quick-Set MMT-398A
*	6 mm teflon needle, 45 cm blue tubing x 10130.00	1 OP	<ul><li>MiniMed Mio MMT-941A</li></ul>
*	6 mm teflon needle, 45 cm pink tubing × 10130.00	1 OP	<ul><li>MiniMed Mio MMT-921A</li></ul>
*	6 mm teflon needle, 60 cm blue tubing x 10130.00	1 OP	<ul><li>MiniMed Mio MMT-943A</li></ul>
*	6 mm teflon needle, 60 cm pink tubing × 10130.00	1 OP	✓ MiniMed Mio  MMT-923A
*	6 mm teflon needle, 60 cm tubing × 10130.00	1 OP	<ul><li>MiniMed Quick-Set MMT-399A</li></ul>
*	6 mm teflon needle, 80 cm blue tubing130.00	1 OP	✓ MiniMed Mio MMT-945A
*	6 mm teflon needle, 80 cm clear tubing × 10130.00	1 OP	✓ MiniMed Mio  MMT-965A
*	6 mm teflon needle, 80 cm pink tubing × 10130.00	1 OP	✓ MiniMed Mio MMT-925A
*	9 mm teflon needle, 110 cm tubing × 10130.00	1 OP	MiniMed Quick-Set MMT-396A
*	9 mm teflon needle, 60 cm tubing × 10130.00	1 OP	✓ MiniMed Quick-Set MMT-397A
*	9 mm teflon needle, 80 cm clear tubing × 10130.00	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 plue 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 Quick-Set MMT-399A 6 mm teflon needle, 60 cm blue tubing 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-95A 6 mm teflon needle, 80 cm clear tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-95A 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, 60 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-975A 9 mm teflon needle, 60 cm tubing × 10 to be delisted 1 October 2026)

		Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
SA	SULIN PUMP INFUSION SET (TEFLON CANNULA, ANGLE IN 2380 on page 18 – 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.		SERTI	ON DEVIC	E) – Special Authority see
	13 mm teflon cannula; angle insertion; insertion device; 110 c line × 10 with 10 needles	182.00	1 OP	✓ A	utoSoft 30
	13 mm teflon cannula; angle insertion; insertion device; 60 cm line × 10 with 10 needles	182.00	1 OP		utoSoft 30
see	SULIN PUMP INFUSION SET (TEFLON CANNULA, FLEXIBLE SA2380 on page 18 – Retail pharmacy  a) Maximum of 5 set per prescription  b) Only on a prescription  c) Maximum of 19 infusion sets will be funded per year.		INSEF	RTION DEV	(ICE) - Special Authority
	6 mm teflon cannula; flexible insertion; insertion device; 46 cm line × 10 with 10 needles	157.00	1 OP	<b>✓</b> m	nylife Inset soft
	6 mm teflon cannula; flexible insertion; insertion device; 60 cm line with integrated inserter × 10 with 10 needles	157.00	1 OP	<b>✓</b> m	nylife Inset soft
*	line × 10 with 10 needles	157.00	1 OP	<b>✓</b> m	nylife Inset soft
*	line × 10 with 10 needles	157.00	1 OP	<b>√</b> m	nylife Inset soft
*	9 mm teflon cannula; flexible insertion; insertion device; 80 cm line x 10 with 10 needles		1 OP	<b>√</b> m	nylife Inset soft
see	SULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIGH SA2380 on page 18 – 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. 6 mm teflon cannula; straight insertion; insertion device;	T INSERTION WITH	inse	rtion de	VICE) - Special Authority
	110 cm line × 10 with 10 needles		1 OP	✓ A	utoSoft 90
	line x 10 with 10 needles		1 OP	<b>✓</b> A	utoSoft 90
	110 cm line × 10 with 10 needles		1 OP	✓ A	utoSoft 90
*	9 mm teflon cannula; straight insertion; insertion device; 60 cr line × 10 with 10 needles		1 OP	✓ A	utoSoft 90
Ref	SULIN PUMP INFUSION SET (TEFLON CANNULA, VARIABLE tail pharmacy  a) Maximum of 5 set per prescription b) Only on a prescription c) Maximum of 19 infusion sets will be funded per year.  13 mm teflon cannula; variable insertion; 60 cm line × 10 with 10 needles	, ,	pecial /	ŕ	e SA2380 on page 18 –

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

INSULIN PUMP RESERVOIR - Special Authority see SA2380 on page 18 - Retail pharmacy

- a) Maximum of 90 cart per prescription
- b) Only on a prescription
- c) Maximum of 360 reservoirs will be funded per year.

*	10 × 1.6 ml glass reservoir for YpsoPump50.00	10 OP	✓ mylife YpsoPump  Reservoir
*	10 × luer lock conversion cartridges 1.8 ml for paradigm pumps50.00	10 OP	✓ ADR Cartridge 1.8
*	Cartridge for 7 series pump; 3.0 ml × 1050.00	10 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 SA2371 below – Retail pharmacy Only on a prescription

	per prescription990.00	1 OP	✓ Dexcom G6
	Maximum of 5 dev will be funded per year.		
*	Sensor (Dexcom G7) - Maximum of 9 dev per prescription110.00	1	Dexcom G7
	Maximum of 40 dev will be funded per year.		
*	Sensor (Freestyle Libre 3 Plus) - Maximum of 6 dev per		
	prescription99.46	1	Freestyle Libre
			3 Plue

Maximum of 28 dev will be funded per year.

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

#### ⇒SA2371 Special Authority for Subsidy

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

#### Both:

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

MMT-332A

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

## **⇒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

1 / WOTE/WIO ENZIME			
Cap pancreatin 150 mg (amylase 8,000 Ph Eur U, lipase			
10,000 Ph Eur U, total protease 600 Ph Eur U)	4.93	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)9	4.38	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)3-	4.93 2	0 g OP 🕠	✓ Creon Micro
URSODEOXYCHOLIC ACID - Special Authority see SA2448 below - Re	etail pharmac	:v	
Cap 250 mg		100	✓ Ursosan

#### ⇒SA2448 Special Authority for Subsidy

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

Either:

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

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

All of the following:

- 1 Patient has chronic severe drug induced cholestatic liver injury; and
- 2 Cholestatic liver injury not due to Total Parenteral Nutrition (TPN) use in adults; and

continued...

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

continued...

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

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

Both:

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

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

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

Both:

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

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

Both:

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

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

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

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

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

## Laxatives

<b>Bulk-forming Agents</b>			
ISPAGHULA (PSYLLIUM) HUSK – Only on a prescription  * Powder for oral soln	22.10	500 g OP	✓ Konsyl-D
Faecal Softeners			
DOCUSATE SODIUM — Only on a prescription  * Tab 50 mg  * Tab 120 mg  DOCUSATE SODIUM WITH SENNOSIDES		100 100	✓ <u>Coloxyl</u> ✓ <u>Coloxyl</u>
Tab 50 mg with sennosides 8 mg  POLOXAMER – Only on a prescription	3.50	200	✓ Laxsol
Not funded for use in the ear.  * Oral drops 10%	4.17	30 ml OP	✓ Coloxyl

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

## **Opioid Receptor Antagonists - Peripheral**

## ⇒SA1691 Special Authority for Subsidy

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

Both:

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

## **Osmotic Laxatives**

GLYCEROL			
* Suppos 2.8/4.0 g - Only on a prescription	12.39	20	<ul><li>Lax-suppositories Glycerol</li></ul>
LACTULOSE - Only on a prescription			
* Oral liq 10 g per 15 ml	6.16	500 ml	✓ Laevolac
MACROGOL 3350 WITH POTASSIUM CHLORIDE, SODIUM B	ICARBONATE AN	ND SODIUM (	CHLORIDE
Powder for oral soln 13.125 g with potassium chloride 46.6 i			
sodium bicarbonate 178.5 mg and sodium chloride 350.		30	✓ APO Health
<b>3</b>	3		Macrogol \$29
	10.15		✓ Molaxole
	12.19		✓ Movicol
(APO Health Macrogol \$29) Powder for oral soln 13.125 g with	potassium chlorid	le 46.6 ma. so	dium bicarbonate 178.5 mg and
sodium chloride 350.7 mg to be delisted 1 January 2026)	potacolam omena	o 10.0 mg, 00	aram broarbonate 17 6.6 mg and
SODIUM ACID PHOSPHATE – Only on a prescription			
Enema 16% with sodium phosphate 8%	3.70	1	✓ Fleet Phosphate
<u> </u>		•	Enema
SODIUM CITRATE WITH SODIUM LAURYL SULPHOACETATI	E Only on a pro	corintion	
Enema 90 mg with sodium lauryl sulphoacetate 9 mg per ml	, ,	Scription	
5 ml		50	✓ Micolette
J III		30	Wilcolette
Stimulant Laxatives			
Cimulant Edxatives			
BISACODYL - Only on a prescription			
* Tab 5 mg		200	<ul><li>Bisacodyl Viatris</li></ul>
* Suppos 10 mg	4.14	10	✓ Lax-Suppositories
SENNA – Only on a prescription			
* Tab, standardised	2.17	100	
•	(9.38)		Senokot
	0.43	20	
	(2.06)		Senokot
SODIUM PICOSULFATE - Special Authority see SA2053 on th	e next page - Re	tail pharmacy	
Oral soln 7.5 mg per ml		30 ml OP	✓ Dulcolax SP Drop

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

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

## ⇒SA2053 Special Authority for Subsidy

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

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

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

## **Metabolic Disorder Agents**

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

## ⇒SA1986 Special Authority for Subsidy

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

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

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

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

RGININE - Special Authority see SA2042 on the next page	– Retail pharmacy		
Tab 1,000 mg	CBS	90	<ul><li>Clinicians</li></ul>
Cap 500 mg		50	✓ Solgar
Powder		400 a	✓ Biomed
		3	

Subsidy
(Manufacturer's Price)
\$ Per

Fully Subsidised Brand or Generic Manufacturer

### ⇒SA2042 Special Authority for Subsidy

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

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

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

### ⇒SA1987 Special Authority for Subsidy

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

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

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

## ⇒SA2039 Special Authority for Subsidy

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

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

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

#### ⇒SA1988 Special Authority for Subsidy

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

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

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

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

continued...

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

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

IDURSULFASE - Special Authority see SA1623 below - Retail pharmacy

✓ Elaprase

## ⇒SA1623 Special Authority for Subsidy

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

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

#### LARONIDASE - Special Authority see SA1695 below - Retail pharmacy ✓ 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
  - - 2.1 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 on the	next page – Retail pha	ırmacy	
Tab 500 mg	CBS	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	✓ Lacuna S29
			✓ Novitium Sugar
			Free S29
Oral liq 500 mg per 10 ml	CBS	300 ml	✓ Balance
(Novitium Sugar Free S29 Oral liq 1 g per 10 ml to be deli	sted 1 February 2026)		

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

## ⇒SA2040 Special Authority for Subsidy

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

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

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

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

## ⇒SA2041 Special Authority for Subsidy

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

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

#### Both:

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

### ⇒SA1989 Special Authority for Subsidy

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

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

**Renewal** only from a metabolic physician or any relevant practitioner on the recommendation of a metabolic physician. Approvals valid for 12 months for applications meeting the following criteria:

#### All of the following:

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

continued...

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

continued...

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

SODIUM BENZOATE - Special Authority see SA1599 below - Retail pharmacy

## ⇒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 below - Retail pharmacy
Grans 483 mg per g......2,016.00 174 g OP 

✓ Pheburane

## ⇒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:

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

TRIENTINE – Special Authority see SA2324 below – Retail pharmacy
Cap 250 mg.......2,022.00 100 ✓ Trientine Waymade

## ⇒SA2324 Special Authority for Subsidy

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

All of the following:

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

#### Gaucher's Disease

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

## **⇒SA2137** Special Authority for Subsidy

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

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

Note: Indication marked with \* is an unapproved indication

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

All of the following:

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

## **Mouth and Throat**

## **Agents Used in Mouth Ulceration**

#### BENZYDAMINE HYDROCHLORIDE

Soln 0.15% - Higher subsidy of \$22.60 per 500 ml with

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

### CARMELLOSE SODIUM WITH GELATIN AND PECTIN

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

Difflam

(M:	Subsidy anufacturer's P	rice) Subs	Fully Brand or sidised Generic
(wa	\$	Per	✓ Manufacturer
RIAMCINOLONE ACETONIDE Paste 0.1%	5.49	5 g OP	✓ Kenalog in Orabase
Oropharyngeal Anti-infectives			
MPHOTERICIN B Lozenges 10 mg	5.86	20	✓ Fungilin
IICONAZOLE Oral gel 20 mg per g	5.19	40 g OP	✓ <u>Decozol</u>
YSTATIN Oral liq 100,000 u per ml	2.22	24 ml OP	✓ <u>Nilstat</u>
Vitamins			
Vitamin B			
YDROXOCOBALAMIN ← Inj 1 mg per ml, 1 ml ampoule – Up to 6 inj available on a PSO.	3.95	3	✓ <u>Hydroxocobalamin</u> <u>Panpharma</u>
YRIDOXINE HYDROCHLORIDE  a) No more than 100 mg per dose b) Only on a prescription			
Tab 25 mg — No patient co-payment payable	3.43 23.45	90 500	✓ <u>Vitamin B6 25</u> ✓ Pyridoxine multichem
HIAMINE HYDROCHLORIDE - Only on a prescription  Tab 50 mg	4.65	100	✓ Thiamine multichem
ITAMIN B COMPLEX  € Tab, strong, BPC	11.25	500	✓ Bplex
Vitamin C			
SCORBIC ACID  a) No more than 100 mg per dose b) Only on a prescription			
Fab 100 mg	16.00	500	✓ Cvite
Vitamin D			
LFACALCIDOL Cap 0.25 mcg Cap 1 mcg Oral drops 2 mcg per ml.	87.98	100 100 20 ml OP	<ul><li>✓ One-Alpha</li><li>✓ One-Alpha</li><li>✓ One-Alpha</li></ul>
ALCITRIOL			·
Cap 0.25 mcg		100	✓ Calcitriol XL S29 ✓ Calcitriol-AFT
Cap 0.5 mcg	13.68	100	<ul><li>✓ Calcitriol XL (\$29)</li><li>✓ Calcitriol-AFT</li></ul>
OLECALCIFEROL  Cap 1.25 mg (50,000 iu) – Maximum of 12 cap per prescription.	3.65	12	✓ <u>Vit.D3</u>
Oral liq 188 mcg per ml (7,500 iu per ml)		5 ml OP	✓ Clinicians

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per Manufacturer **Multivitamin Preparations** MULTIVITAMIN RENAL - Special Authority see SA1546 below - Retail pharmacy 30 ✓ Clinicians Renal Vit. ⇒SA1546 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 The patient has chronic kidney disease and is receiving either peritoneal dialysis or haemodialysis; or 2 The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of < 15 ml/min/1.73 m<sup>2</sup> body surface area (BSA). MULTIVITAMINS - Special Authority see SA1036 below - Retail pharmacy 200 g OP ✓ Paediatric Seravit ⇒SA1036 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has inborn errors of metabolism. Renewal from any relevant practitioner. Approvals valid without further renewal unless notified where patient has had a previous approval for multivitamins. **VITAMINS** 1.000 ✓ Myite \* Cap (fat soluble vitamins A, D, E, K) - Special Authority see Vitabdeck ⇒SA1720 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria: Any of the following: 1 Patient has cystic fibrosis with pancreatic insufficiency; or 2 Patient is an infant or child with liver disease or short gut syndrome; or 3 Patient has severe malabsorption syndrome. **Minerals** Calcium **CALCIUM CARBONATE** 250 ✓ Calci-Tab 500 \* Tab eff 1.25 g (500 mg elemental) - Subsidy by endorsement......260.00 100 ✓ Calcium 500 mg Hexal S29 Subsidy by endorsement - Only when prescribed for paediatric patients (< 5 years) where calcium carbonate oral liquid is considered unsuitable. **CALCIUM GLUCONATE** 10 ✓ Max Health -Hameln S29 lodine

90

✓ NeuroTabs

POTASSIUM IODATE

facturer's Price) \$	Per	sidised •	Generic Manufacturer
3.49	100	✓ <u>F</u>	erro-tab
5.98	100	✓ <u>F</u>	erro-F-Tabs
2.55	30	<b>√</b> F	errograd
			erro-Liquid erodan
March 2026) uary 2026)			
394 below – R 50.00	etail phar 1		erinject
	10.25 2 13.10 5 <i>March 2026)</i> uary 2026) 394 below – R	10.25 250 ml 13.10 500 ml <i>March 2026</i> ) <i>uary 2026</i> ) 394 below – Retail phar	10.25 250 ml

Subsidy

Fully

Brand or

## 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.

continued...

✓ Forrosia

Subsidy	F	ully	Brand or
(Manufacturer's Price)	Subsid		Generic
\$	Per	1	Manufacturer

continued...

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

Both:

37 05

- 1 Patient continues to have iron-deficiency anaemia; and
- 2 A re-trial with oral iron is clinically inappropriate.

IRC	ON POLYMALTOSE
*	Ini 50 mg per ml 2 ml ampoule

* Inj 50 mg per mi, 2 mi ampoule	5	Ferrosig	
Magnesium			
MAGNESIUM HYDROXIDE Suspension 8%33.60	355 ml	✓ Phillips Milk of Magnesia S29	
MAGNESIUM SULPHATE         ★ Inj 2 mmol per ml, 5 ml ampoule       37.53         ★ Inj 2 mmol per ml, 10 ml ampoule       75.06	10 10	✓ <u>Martindale</u> ✓ Inresa S29	
Zinc			
ZINC SULPHATE  * Cap 137.4 mg (50 mg elemental)11.00	100	✓ Zincaps ✓ Zincaps S29 S29	

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

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

## **Antianaemics**

## Hypoplastic and Haemolytic

## ⇒SA2266 Special Authority for Subsidy

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

All of the following:

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

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

All of the following:

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

Note: Indication marked with \* is an unapproved indication

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

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

- 1 The patient's transfusion requirement continues to be reduced with erythropoietin treatment; and
- 2 Transformation to acute myeloid leukaemia has not occurred; and
- 3 The minimum necessary dose of epoetin would be used and will not exceed 80,000 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	<ul><li>Binocrit</li></ul>
Inj 2,000 iu in 1 ml, syringe	100.00	6	<ul><li>Binocrit</li></ul>
Inj 3,000 iu in 0.3 ml, syringe		6	<ul><li>Binocrit</li></ul>
Inj 4,000 iu in 0.4 ml, syringe		6	Binocrit
Inj 5,000 iu in 0.5 ml, syringe		6	Binocrit
Inj 6,000 iu in 0.6 ml, syringe		6	<ul><li>Binocrit</li></ul>
Inj 8,000 iu in 0.8 ml, syringe		6	<ul><li>Binocrit</li></ul>
Inj 10,000 iu in 1 ml, syringe		6	<ul><li>Binocrit</li></ul>
Inj 40,000 iu in 1 ml, syringe		1	Binocrit

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

### **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 Haer	nophilia Management gro	up.	
Inj 250 iu vial	612.50	1	Alprolix
Inj 500 iu vial	1,225.00	1	✓ Alprolix
Inj 1,000 iu vial		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	·	1	Alprolix
ELTROMBOPAG - Special Authority see SA1743 below	- Retail pharmacy		
Wastage claimable			
Tab 25 mg	1,550.00	28	✓ Revolade
Tab 50 mg	3.100.00	28	✓ Revolade

#### ⇒SA1743 Special Authority for Subsidy

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

All of the following:

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

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

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

All of the following:

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

Subsidy		Fully	Brand or
(Manufacturer's Price)		osidised	Generic
<u> </u>	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 \$A2272 below

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

#### ⇒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	·	1	✓ NovoSeven RT
Inj 8 mg syringe	·	1	✓ NovoSeven RT

	Subsidy (Manufacturer's Price)	Sı	Fully bsidised	Brand or Generic
	(Manufacturer 3 i fice)	Per	iD3lul3eu <b>√</b>	Manufacturer
CTOR EIGHT INHIBITOR BYPASSING FRACTION - [X	(pharm]			
For patients with haemophilia. Preferred Brand of bypa				
is managed by the Haemophilia Treaters Group in conj		laemoph		•
Inj 500 U		1		EIBA NF
Inj 1,000 U		1		EIBA NF
Inj 2,500 U	*	1	<b>✓</b> F	EIBA NF
DROCTOCOG ALFA [RECOMBINANT FACTOR VIII] -				
For patients with haemophilia. Rare Clinical Circumsta				
treatment is managed by the Haemophilia Treaters Gro	oup in conjunction with the	National	Haemop	hilia Management Gro
subject to criteria.	007.50			
Inj 250 iu prefilled syringe		1		(yntha
Inj 500 iu prefilled syringe		1		(yntha
Inj 1,000 iu prefilled syringe		1		Yyntha Yyntha
Inj 2,000 iu prefilled syringe		1		Ayntha Kyntha
	•	'	• ^	Ayrılıa
NACOG GAMMA, [RECOMBINANT FACTOR IX] – [Xp		1. 9		
For patients with haemophilia. Access to funded treatn	nent is managed by the Ha	emophil	ia Treate	rs Group in conjunction
with the National Haemophilia Management Group.	070.00			NVIIDIO
Inj 1,000 iu vial		1		RIXUBIS
Inj 2,000 iu vialInj 3,000 iu vial		1		RIXUBIS RIXUBIS
• •	*	ı	• -	IIXUDIS
CTOCOG ALFA [RECOMBINANT FACTOR VIII] (ADVAT				
For patients with haemophilia. Preferred Brand of shor				
managed by the Haemophilia Treaters Group in conjun				•
Inj 500 iu vial		1		dvate
Inj 1,000 iu vial		1		dvate
Inj 2,000 iu vial		1		dvate
Inj 3,000 iu vial	·	1	• •	Advate
TOCOG ALFA [RECOMBINANT FACTOR VIII] (KOGEN				
For patients with haemophilia. Rare Clinical Circumsta				
treatment is managed by the Haemophilia Treaters Gro	oup in conjunction with the	National	Haemop	hilia Management Gro
subject to criteria.				
	007.50	4	./ 1/	Camanata EC
Inj 250 iu vial		1		Cogenate FS
Inj 250 iu vialInj 500 iu vial	475.00	1	✓ K	logenate FS
Inj 250 iu vial	475.00 950.00	1 1	✓ K	Cogenate FS Cogenate FS
Inj 250 iu vial		1 1 1	✓ k ✓ k	Cogenate FS Cogenate FS Cogenate FS
Inj 250 iu vial		1 1	✓ k ✓ k	Cogenate FS Cogenate FS
Inj 250 iu vial	475.00 950.00 1,900.00 2,850.00 R VIII] – [Xpharm]	1 1 1	✓ k ✓ k	Cogenate FS Cogenate FS Cogenate FS Cogenate FS
Inj 250 iu vial		1 1 1 1	✓ k ✓ k	Cogenate FS Cogenate FS Cogenate FS Cogenate FS
Inj 250 iu vial		1 1 1 1 ed treatm	✓ k ✓ k ✓ k nent is ma	Kogenate FS Kogenate FS Kogenate FS Kogenate FS Kogenate FS
Inj 250 iu vial		1 1 1 1 od treatm	✓ k ✓ k ✓ k nent is ma	Kogenate FS
Inj 250 iu vial		1 1 1 1 ed treatm	✓ k ✓ k ✓ k nent is ma	Kogenate FS Kogenate FS Kogenate FS Kogenate FS Kogenate FS Knaged by the Haemor
Inj 250 iu vial		1 1 1 1 1 d treatm	✓ k ✓ k ✓ k nent is ma	Kogenate FS
Inj 250 iu vial		1 1 1 1 od treatm	V K V K V K M M M M M M M M M M M M M M	Kogenate FS Kogena
Inj 250 iu vial		1 1 1 1 1 d treatm	V K V K V K M M M M M M M M M M M M M M	Kogenate FS
Inj 250 iu vial		1 1 1 1 1 d treatm	V K V K V K M M M M M M M M M M M M M M	Kogenate FS Kogena
Inj 250 iu vial		1 1 1 1 1 d treatm	Y K Y K Y K Y K Y K Y K	Kogenate FS Kogena

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
Vitamin K				
PHYTOMENADIONE Inj 2 mg per 0.2 ml - Up to 5 inj available on a PSO	8.00	5	✓ K	Conakion MM Paediatric
Inj 10 mg per ml, 1 ml - Up to 5 inj available on a PSO	9.21	5	<b>✓</b> K	Conakion MM
Antithrombotic Agents				
Antiplatelet Agents				
ASPIRIN  * Tab 100 mg	12.65	990	<b>√</b> <u>E</u>	Ethics Aspirin EC
CLOPIDOGREL  * Tab 75 mg  Arrow - Clopid to be Principal Supply on 1 December 20:		84	<b>✓</b> A	Arrow - Clopid
DIPYRIDAMOLE  Note: No new patients to be initiated on dipyridamole.				
Tab long-acting 150 mg	13.93	60	<b>✓</b> P	ytazen SR
Cap modified-release 200 mg		60	✓ [	Dipyridamole - Strides \$29
(Pytazen SR Tab long-acting 150 mg to be delisted 1 January 20	<i>)</i> 26)			
TICAGRELOR - Special Authority see SA1955 below - Retail pl	harmacy			
* Tab 90 mg	20.35	56	<b>√</b> <u>I</u>	icagrelor Sandoz

#### ⇒SA1955 Special Authority for Subsidy

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

#### Both:

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

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

- 1 Either:
  - 1.1 Patient has had a neurological stenting procedure\* in the last 60 days; or
  - 1.2 Patient is about to have a neurological stenting procedure performed\*; and
- - 2.1 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:

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

continued...

- 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.

## **Heparin and Antagonist Preparations**

ENOXAPARIN SODIUM - Special Authority see SA2152 below - Retail pharmacy

Inj 20 mg in 0.2 ml syringe	21.90	10	✓ Clexane
Inj 40 mg in 0.4 ml syringe	29.74	10	Clexane
Inj 60 mg in 0.6 ml syringe		10	✓ Clexane
Inj 80 mg in 0.8 ml syringe		10	✓ Clexane
Inj 100 mg in 1 ml syringe		10	✓ Clexane
Inj 120 mg in 0.8 ml syringe		10	✓ Clexane Forte
Inj 150 mg in 1 ml syringe		10	✓ Clexane Forte

#### ⇒SA2152 Special Authority for Subsidy

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

Any of the following:

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

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

Any of the following:

1 For the short-term treatment of venous thromboembolism prior to establishing a therapeutic level of oral anti-coagulant

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

continued...

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:

HEPARIN SODIUM

- 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).

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	✓ Wockhardt S29
	103.70		✓ Wockhardt PSF \$29
	127.44	50	✓ Pfizer
Inj 5,000 iu per ml, 5 ml vial	83.00	10	<ul><li>Heparin Sodium Panpharma</li></ul>
Inj 5,000 iu per ml, 1 ml	70.33	5	✓ Hospira
Inj 25,000 iu per ml, 0.2 ml	25.78	5	✓ Hospira
(Pfizer S29 Inj 1,000 iu per ml, 10 ml vial to be delisted 1	January 2026)		
(Wockhardt \$29 Inj 1,000 iu per ml, 5 ml ampoule to be d			
(Wockhardt PSF S29 Inj 1,000 iu per ml, 5 ml ampoule to	be delisted 1 January 20	026)	
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	✓ Pradaxa
Cap 110 mg	27.99	60	✓ Pradaxa
Cap 150 mg		60	✓ Pradaxa
RIVAROXABAN			
Tab 10 mg - No more than 1 tab per day	15.60	30	✓ Xarelto
Tab 15 mg - Up to 14 tab available on a PSO		28	✓ Xarelto
5 1			

Tab 20 mg ...... 14.56

Xarelto

28

	Subsidy		Fully	Brand or
	(Manufacturer's Price)		Subsidised	
	\$	Per	1	Manufacturer
VARFARIN 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	1	Coumadin
★ Tab 3 mg		100	1	Marevan
★ Tab 5 mg		50	1	Coumadin
v	13.50	100	✓	Marevan
Blood Colony-stimulating Factors	13.30	100		Marevaii
	armo ov			
FILGRASTIM – Special Authority see SA1259 below – Retail pha Inj 300 mcg per 0.5 ml prefilled syringe	,	10	1	Nivestim
Inj 480 mcg per 0.5 ml prefiled syringe		10	_	Nivestim
SA1259 Special Authority for Subsidy	100.72	10	•	MINESHIII

### | ⇒SA1259 | Special Authority for Subsidy

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

Any of the following:

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

Inj 6 mg per 0.6 ml syringe .......69.50 ✓ 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	5	✓ Biomed
* Inj 50%, 90 ml bottle - Up to 5 inj available on a PSO17.50	1	✓ Biomed
POTASSIUM CHLORIDE		
* Inj 75 mg per ml, 10 ml65.00	50	Juno
		✓ LumaCina
		✓ Pfizer \$29

	Subsidy (Manufacturer's Price \$	) Per	Fully Subsidised	I Generic
SODIUM BICARBONATE				
Inj 8.4%, 50 ml	24.70	1	•	Biomed
<ul><li>a) Up to 5 inj available on a PSO</li><li>b) Not in combination</li></ul>				
Inj 8.4%, 100 ml	25.31	1	•	Biomed
<ul><li>a) Up to 5 inj available on a PSO</li><li>b) Not in combination</li></ul>				
SODIUM CHLORIDE				
Not funded for use as a nasal drop. Not funded for nebuliser for nebuliser use.	r use except when ι	sed in	conjunction	on with an antibiotic intende
Inj 23.4% (4 mmol/ml), 20 ml ampoule For Sodium chloride oral liquid formulation refer Standar		5 84	•	Biomed
Inj 0.9%, 5 ml ampoule - Up to 5 inj available on a PSO		20	1	Fresenius Kabi
Inj 0.9%, 10 ml ampoule - Up to 5 inj available on a PSO		50	•	Fresenius Kabi
Inj 0.9%, 20 ml ampoule		20		Fresenius Kabi
Inj 0.9%, 1,000 ml bag – Up to 2 bag available on a PSO		1		Baxter
Only if prescribed on a prescription for renal dialysis, ma for emergency use. (500 ml and 1,000 ml packs)		care ii		
Inj 0.9%, 500 ml bag - Up to 4 bag available on a PSO		1		Baxter
Only if prescribed on a prescription for renal dialysis, ma for emergency use. (500 ml and 1,000 ml packs)	ternity or post-natal	care i	n the home	e of the patient, or on a PSC
• , , , , , , , , , , , , , , , , , , ,				
TOTAL PARENTERAL NUTRITION (TPN)				
TOTAL PARENTERAL NUTRITION (TPN) Infusion WATER  1) On a prescription or Practitioner's Supply Order only will		1 OF		TPN Isted in the Pharmaceutic
TOTAL PARENTERAL NUTRITION (TPN) Infusion WATER	hen on the same for e drops; or	m as a	ın injectior	
TOTAL PARENTERAL NUTRITION (TPN) Infusion WATER  1) On a prescription or Practitioner's Supply Order only wl Schedule requiring a solvent or diluent; or 2) On a bulk supply order; or 3) When used in the extemporaneous compounding of ey	hen on the same for e drops; or for cystic fibrosis pa	m as a	n injection only.	n listed in the Pharmaceutic
TOTAL PARENTERAL NUTRITION (TPN) Infusion WATER  1) On a prescription or Practitioner's Supply Order only will Schedule requiring a solvent or diluent; or 2) On a bulk supply order; or 3) When used in the extemporaneous compounding of ey 4) When used for the dilution of sodium chloride soln 7% to	hen on the same for e drops; or for cystic fibrosis pa 7.60	m as a	n injection	n listed in the Pharmaceutic
TOTAL PARENTERAL NUTRITION (TPN) Infusion	hen on the same for e drops; or for cystic fibrosis pa 7.60	m as a tients of	n injection	n listed in the Pharmaceutic Fresenius Kabi Multichem
TOTAL PARENTERAL NUTRITION (TPN) Infusion	hen on the same for e drops; or for cystic fibrosis pa 7.60	m as a tients of	n injection	n listed in the Pharmaceutic Fresenius Kabi Multichem
TOTAL PARENTERAL NUTRITION (TPN) Infusion WATER  1) On a prescription or Practitioner's Supply Order only will Schedule requiring a solvent or diluent; or 2) On a bulk supply order; or 3) When used in the extemporaneous compounding of ey 4) When used for the dilution of sodium chloride soln 7% in the injury of the management of the properties of	hen on the same for e drops; or for cystic fibrosis pa7.605.00	m as a tients of	only.	n listed in the Pharmaceutic Fresenius Kabi Multichem
TOTAL PARENTERAL NUTRITION (TPN) Infusion WATER  1) On a prescription or Practitioner's Supply Order only wis Schedule requiring a solvent or diluent; or 2) On a bulk supply order; or 3) When used in the extemporaneous compounding of ey 4) When used for the dilution of sodium chloride soln 7% in Inj 10 ml ampoule — Up to 5 inj available on a PSO	hen on the same for e drops; or for cystic fibrosis pa7.605.00	m as a tients of 50	only.	risted in the Pharmaceutic Fresenius Kabi Multichem Fresenius Kabi
TOTAL PARENTERAL NUTRITION (TPN) Infusion	hen on the same for e drops; or for cystic fibrosis pa7.60	m as a tients of 50	only.	risted in the Pharmaceutic Fresenius Kabi Multichem Fresenius Kabi
TOTAL PARENTERAL NUTRITION (TPN) Infusion	hen on the same for e drops; or for cystic fibrosis pa7.60	m as a tients of 50 20	only.	Fresenius Kabi Multichem Fresenius Kabi
TOTAL PARENTERAL NUTRITION (TPN) Infusion	e drops; or for cystic fibrosis pa	m as a tients of 50 20	only.	Fresenius Kabi Multichem Fresenius Kabi
TOTAL PARENTERAL NUTRITION (TPN) Infusion	e drops; or for cystic fibrosis pa7.605.00	m as a tients of 50 20	only.	Fresenius Kabi Multichem Fresenius Kabi
TOTAL PARENTERAL NUTRITION (TPN) Infusion	e drops; or for cystic fibrosis pa	m as a state of the state of th	only.	Fresenius Kabi Multichem Fresenius Kabi Calcium Resonium Electral
TOTAL PARENTERAL NUTRITION (TPN) Infusion	e drops; or for cystic fibrosis pa	m as a state of the state of th	only.	Fresenius Kabi Multichem Fresenius Kabi Calcium Resonium Electral
TOTAL PARENTERAL NUTRITION (TPN) Infusion	e drops; or for cystic fibrosis pa	m as a a a a a a a a a a a a a a a a a a	only.	Fresenius Kabi Multichem Fresenius Kabi Calcium Resonium Electral Hydralyte - Lemonade
TOTAL PARENTERAL NUTRITION (TPN) Infusion	e drops; or for cystic fibrosis pa7.60	m as a a a a a a a a a a a a a a a a a a	only.	Fresenius Kabi Multichem Fresenius Kabi Calcium Resonium Electral Hydralyte - Lemonade Phosphate Phebra
TOTAL PARENTERAL NUTRITION (TPN) Infusion	e drops; or for cystic fibrosis pa7.605.00	m as a a a a a a a a a a a a a a a a a a	only.	Fresenius Kabi Multichem Fresenius Kabi Calcium Resonium Electral Hydralyte - Lemonade

	Subsidy (Manufacturer's Price \$	e) Per	Fully Subsidised	Brand or Generic Manufacturer
SODIUM BICARBONATE Cap 840 mg	8.52	100		Sodibic Sodibic
SODIUM POLYSTYRENE SULPHONATE Powder	84.65	454 g C	OP 🗸	Resonium-A

		Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
A	lpha-Adrenoceptor Blockers				
A	Ipha Adrenoceptor Blockers				
DC	XAZOSIN				
*	Tab 2 mg	17.35	500		Doxazosin Clinect
*	Tab 4 mg	20.94	500	/	Doxazosin Clinect
	ENOXYBENZAMINE HYDROCHLORIDE			_	
*	Cap 10 mg	65.00	30	/	BNM S29
	AZOSIN			_	
*	Tab 1 mg	5.53	100	•	Arrotex-Prazosin
		0.00			<b>S29</b> S29
×	Tah 2 mg	9.98	100		Minipress S29 Arrotex-Prazosin
*	Tab 2 mg	7.00	100	•	S29 S29
		13.29		_	Minipress S29
*	Tab 5 mg		100		Arrotex-Prazosin
					<b>S29</b> S29
		22.00		1	Minipress S29
*	Cap 1 mg	15.40	100		Prazosin Mylan S29
*	Cap 2 mg	15.58	100	1	Prazosin Mylan S29
*	Cap 5 mg	23.32	100	1	Prazosin Mylan S29
					-
Α	gents Affecting the Renin-Angiotensin System	1			
A	CE Inhibitors				
CA	PTOPRIL				
	Oral liq 5 mg per ml	86.00 10	0 ml O	P 🗸	DP-Captopril
	Oral liquid restricted to children under 12 years of age.				
ΕN	ALAPRIL MALEATE				
*	Tab 5 mg		90		Acetec
*	Tab 10 mg		90		Acetec
*	Tab 20 mg	2.35	90	•	Acetec
	INOPRIL	10.00	00		Tour Lieine
*	Tab 5 mg Tab 10 mg		90 90	_	Teva Lisinopril Teva Lisinopril
-	Tab 20 mg		90		Teva Lisinopril
	RINDOPRIL				<del></del>
*	Tab 2 mg	1.79	30	1	Coversyl
*	Tab 4 mg		30		Coversyl
*	Tab 8 mg	3.94	30	1	Coversyl

✓ Arrow-Quinapril 5✓ Arrow-Quinapril 10

✓ Arrow-Quinapril 20

90

90

QUINAPRIL

	Subsidy (Manufacturer's Price)		Fully Subsidised	Brand or Generic
	\$	Per	✓	Manufacturer
AMIPRIL				
Cap 1.25 mg	17.25	90	✓.	Γryzan
Cap 2.5 mg		90	✓:	Tryzan
Cap 5 mg	16.88	90	1	Tryzan
Cap 10 mg	17.63	90	1	Γryzan
Angiotensin II Antagonists				
ANDESARTAN CILEXETIL				
Tab 4 mg	2.68	90	1	Candestar
: Tab 8 mg	2.67	90	1	Candestar
: Tab 16 mg	4.22	90	1	Candestar
: Tab 32 mg	5.24	90	1	Candestar
OSARTAN POTASSIUM				
Tab 12.5 mg	2.00	84	✓	Losartan Actavis
: Tab 25 mg	2.29	84	✓ ]	osartan Actavis
: Tab 50 mg	2.86	84	✓ ]	osartan Actavis
Tab 100 mg	4.57	84	✓ ]	Losartan Actavis
Angiotensin II Antagonists with Diuretics				
ANDESARTAN CILEXETIL WITH HYDROCHLOROTHIA	AZIDE			
Tab 16 mg with hydrochlorothiazide 12.5 mg	4.10	30	•	APO-Candesartan HCTZ 16/12.5
Tab 32 mg with hydrochlorothiazide 12.5 mg	5.25	30	✓ /	APO-Candesartan HCTZ 32/12.5
OSARTAN POTASSIUM WITH HYDROCHLOROTHIAZI	DE			
Tab 50 mg with hydrochlorothiazide 12.5 mg	4.00	30	✓ ,	Arrow-Losartan & Hydrochlorothiazide

# **Angiotensin II Antagonists with Neprilysin Inhibitors**

SACUBITRIL WITH VALSARTAN - Special Authority see SA	2302 below – Retail	pharmacy	
Tab 24.3 mg with valsartan 25.7 mg	190.00	56	✓ Entresto 24/26
Tab 48.6 mg with valsartan 51.4 mg	190.00	56	✓ Entresto 49/51
Tab 97.2 mg with valsartan 102.8 mg	190.00	56	✓ Entresto 97/103

#### ⇒SA2302 Special Authority for Subsidy

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

All of the following:

- 1 Patient has heart failure: and
- 2 Any of the following:
  - 2.1 Patient is in NYHA/WHO functional class II; or
  - 2.2 Patient is in NYHA/WHO functional class III; or
  - 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.

	0		E. II.	DI
	Subsidy (Manufacturer's Price)	رم-	Fully Subsidised	
	\$	Per		Manufacturer
Antiarrhythmics				
•				
or lignocaine hydrochloride refer to NERVOUS SYSTEM, Anaes	sthetics, Local, pag	ge 124		
AMIODARONE HYDROCHLORIDE			_	
▲ Tab 100 mg		30		Aratac
Tab 200 mg	5.86	30	•	Aratac
Inj 50 mg per ml, 3 ml ampoule – Up to 10 inj available on a PSO	17.96	10	/	Max Health
TROPINE SULPHATE				
k Inj 600 mcg per ml, 1 ml ampoule − Up to 5 inj available on a	ì			
PSO		10	1	Hikma S29
			✓	Martindale
DIGOXIN				
★ Tab 62.5 mcg – Up to 30 tab available on a PSO	8.58	240	1	Lanoxin PG
* Tab 250 mcg - Up to 30 tab available on a PSO		240	1	Lanoxin
♦ Oral liq 50 mcg per ml		60 ml	1	Lanoxin
			1	Lanoxin S29 S29
DISOPYRAMIDE PHOSPHATE				
▲ Cap 100 mg	23.87	100	/	Rythmodan
	55.90	84		Rythmodan -
				Cheplafarm S29
			1	Rythmodan
				Neon S29
Rythmodan Cap 100 mg to be delisted 1 November 2025)				
FLECAINIDE ACETATE				
▲ Tab 50 mg	19 95	60	1	Flecainide BNM
Cap long-acting 100 mg		90		Flecainide
= cap long assing roomy		00		Controlled
				Release Teva
Cap long-acting 200 mg	54.28	90	1	Flecainide
, 3 3 3				Controlled
				Release Teva
Inj 10 mg per ml, 15 ml ampoule	102.79	5	1	Almarytm S29
, ,	108.16		_	Tambocor
			1	Tambocor
				German S29
IEXILETINE HYDROCHLORIDE				
Cap 150 mg	162 00	100	1	Teva S29
Cap 250 mg		100		Teva S29
	202.00	100	•	I CAQ OF
PROPAFENONE HYDROCHLORIDE	40.00	E0		Dutmonorm
Tab 150 mg	40.90	50		Rytmonorm
Antihypotensives				
MIDODRINE - Special Authority see SA1474 on the next page -	Retail pharmacy			
Tab 2.5 mg	, ,	100	1	Midodrine
· IIIg		100		Medsurge
Tab 5 mg	58.88	100	1	Midodrine
140 0 mg		100	•	Medsurge
4				

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

#### ⇒SA1474 Special Authority for Subsidy

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

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

# **Beta-Adrenoceptor Blockers**

### **Beta Adrenoceptor Blockers**

ATENOLOL			
* Tab 50 mg	11.00	500	✓ <u>Viatris</u>
* Tab 100 mg	18.50	500	<ul> <li>Atenolol Viatris</li> </ul>
* Oral liq 25 mg per 5 ml	49.85	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	2.71	90	✓ Ipca-Bisoprolol
CARVEDILOL			
* Tab 6.25 mg	2.24	60	✓ Carvedilol Sandoz
* Tab 12.5 mg		60	✓ Carvedilol Sandoz
* Tab 25 mg	2.95	60	✓ Carvedilol Sandoz
LABETALOL			
* Tab 100 mg	14.50	100	✓ Trandate
	49.54		✓ Biocon S29
* Tab 200 mg		100	✓ Trandate
· · · · · · · · · · · · · · · · · · ·	42.07		✓ Presolol S29
* Inj 5 mg per ml, 20 ml ampoule		5	110000
, c, po, = c apos.c	(88.60)	ū	Trandate
METOPROLOL SUCCINATE	(55.55)		
* Tab long-acting 23.75 mg	4 20	90	✓ Myloc CR
* Tab long-acting 47.5 mg		90	✓ Myloc CR
* Tab long-acting 95 mg		90	✓ Myloc CR
* Tab long-acting 190 mg		90	✓ Myloc CR
METOPROLOL TARTRATE			<u></u>
* Tab 50 mg	5.66	100	✓ IPCA-Metoprolol
* Tab 100 mg		60	✓ IPCA-Metoprolol
* Tab long-acting 200 mg		28	✓ Slow-Lopresor
* Inj 1 mg per ml, 5 ml vial		5	✓ Metoprolol IV Mylan
		ū	✓ Metoprolol IV Viatris
NADOLOL			
* Tab 40 mg	19 19	100	✓ Nadolol BNM
* Tab 40 mg		100	✓ Nadolol BNM
100 00 mg		100	- Hudoloi Bitiii

	Subsidy (Manufacturer's Price)		Fully Subsidised	Generic
	\$	Per		Manufacturer
PROPRANOLOL				
* Tab 10 mg	7.04	100	✓	<u>Drofate</u>
* Tab 40 mg	8.75	100	✓	IPCA-Propranolol
* Cap long-acting 160 mg	18.17	100	✓	Cardinol LA
♦ Oral lig 4 mg per ml - Special Authority see SA1327 below -	_			
Retail pharmacy		500 n	nl 🗸	Hikma-
,				Propranolol S29
			1	Roxane-
				Propranolol S29

#### ⇒SA1327 Special Authority for Subsidy

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

#### SOTALOL

AMI ODIPINE

*	Tab 80 mg22.5	30	0 🗸 🤄	Sotalol Viatris S29
	40.0	0 50	0 🗸 I	Mylan
*	Tab 160 mg20.0	0 10	0 🗸 1	Mylan

### **Calcium Channel Blockers**

### **Dihydropyridine Calcium Channel Blockers**

*	Tab 2.5 mg	1.45	90	✓ Vasorex
	Tab 5 mg		90	✓ Vasorex
	Tab 10 mg		90	✓ Vasorex
FΕ	LODIPINE			
*	Tab long-acting 2.5 mg	2.18	30	✓ Plendil ER
	Tab long-acting 5 mg		90	✓ Felo 5 ER
	Tab long-acting 10 mg		90	✓ Felo 10 ER

	Subsidy (Manufacturer's Price) \$	Per	Fully Brand or Subsidised Generic Manufacturer	
FEDIPINE				
Tab long-acting 10 mg - Subsidy by endorsement	19.42	56	✓ Tensipine MR1	<b>0</b> S29
Subsidised for patients who were taking nifedipine tab lo endorsed accordingly. Pharmacists may annotate the p dispensing of nifedipine tab long-acting 10 mg.	prescription as endors	ed wh	ere there exists a record of	
Tab long-acting 20 mg		100	✓ Nyefax Retard	
Tab long-acting 30 mg	4.78	14	✓ Mylan Italy (24 release)   S29	hr
	34.10	100	✓ Mylan (24 hr release) \$29	
Tab long-acting 60 mg	52.81	100	✓ Mylan (24 hr release) S29	
Other Calcium Channel Blockers				
LTIAZEM HYDROCHLORIDE				
Cap long-acting 120 mg  Diltiazem CD Clinect to be Principal Supply on 1 Decem		500	✓ Diltiazem CD C	Clinect
Cap long-acting 180 mg		30	✓ Cardizem CD	
Cap long-acting 240 mg		30	✓ Cardizem CD	
Tab 100 mg	62 90	100	✓ Pexsig	
RAPAMIL HYDROCHLORIDE		100	- I oxolg	
Tab 40 mg	7.01	100	✓ Isoptin	
Tab 80 mg		100	✓ Isoptin	
Tab long-acting 120 mg		100	✓ Isoptin Retard	\$29
Tab long doding 120 mg		100	✓ Isoptin SR	
Tab long-acting 240 mg	15.12	30	✓ Isoptin SR	
Inj 2.5 mg per ml, 2 ml ampoule – Up to 5 inj available on a		•		
PSO	25.00	5	✓ Isoptin	
Centrally-Acting Agents				
ONIDINE				
Patch 2.5 mg, 100 mcg per day - Only on a prescription		4	✓ Mylan	
Patch 5 mg, 200 mcg per day - Only on a prescription		4	✓ Mylan	
Patch 7.5 mg, 300 mcg per day – Only on a prescription	17.90	4	✓ <u>Mylan</u>	
ONIDINE HYDROCHLORIDE	oo = :	4	<b>.</b>	
Tab 25 mcg		112	✓ Clonidine Teva	1
Tab 150 mcg		100	✓ <u>Catapres</u>	
Inj 150 mcg per ml, 1 ml ampoule	14.10	5	Catapres	
ETHYLDOPA Tab 250 mg	15.10	100	✓ Methyldopa Vi	atris
Diuretics				
oop Diuretics				
JMETANIDE				
Tab 1 mg	16.36	100	✓ Burinex	
Inj 500 mcg per ml, 4 ml vial		5	✓ Burinex	

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

	Subsidy (Manufacturer's P \$	rice) Subs Per	Fully sidised	Brand or Generic Manufacturer
FUROSEMIDE [FRUSEMIDE] Tab 40 mg - Up to 30 tab available on a PSO* 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	25.00 11.20 60.65	1,000 50 30 ml OP 6 5	✓ [ ✓ ] ✓ ]	PCA-Frusemide Jrex Forte Lasix Lasix Furosemide-Baxter
Potassium Sparing Diuretics				
AMILORIDE HYDROCHLORIDE  Tab 5 mg	171.4135.40 ail pharmacy15.8425.00 valid without further a 40%; and blactone; or adverse effect while4.20140		y I y I g I g I g I g I g I g I g I g I	
Potassium Sparing Combination Diuretics		20 1111 01		Siomeu
AMILORIDE HYDROCHLORIDE WITH FUROSEMIDE  * Tab 5 mg with furosemide 40 mg  AMILORIDE HYDROCHLORIDE WITH HYDROCHLOROTHI  * Tab 5 mg with hydrochlorothiazide 50 mg	AZIDE	28 50	-	Frumil Moduretic
Thiazide and Related Diuretics				
BENDROFLUMETHIAZIDE [BENDROFLUAZIDE]  * Tab 2.5 mg – Up to 150 tab available on a PSO	51.50	500	✓ <u>!</u>	Arrow- Bendrofluazide
May be supplied on a PSO for reasons other than em  * Tab 5 mg	0 ,	500	✓ <u>I</u>	<u>Arrow-</u> <u>Bendrofluazide</u>

CHLORTALIDONE [CHLORTHALIDONE]

25 ml OP

50

✓ Biomed

✓ Hygroton

CHLOROTHIAZIDE

✓ Jinarc

56 OP

	Subsidy		Fully	Brand or	
	(Manufacturer's Price) \$	Per	Subsidised	Generic Manufacturer	
INDAPAMIDE					
* Tab 2.5 mg	16.00	90	✓ <u>D</u>	apa-Tabs	
METOLAZONE					
Tab 5 mg	CBS	50	✓ Z	aroxolyn S29	
Vasopressin receptor antagonists					
TOLVAPTAN - Special Authority see SA2166 below - Retail pha	rmacy				
Tab 15 mg	873.50	28 OP	<b>√</b> Ji	inarc	
Tab 30 mg	873.50	28 OP	<b>√</b> Ji	inarc	
Tab 45 mg + 15 mg		56 OP	✓ J	inarc	
Tab 60 mg + 30 mg	1,747.00	56 OP	<b>√</b> Ji	inarc	

### SA2166 Special Authority for Subsidy

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

1 Patient has a confirmed diagnosis of autosomal dominant polycystic kidney disease; and

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

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

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

Lipid-Modifying Agents		
Fibrates		
BEZAFIBRATE       22.65         Tab 200 mg       22.65         Tab long-acting 400 mg       21.54	90 30	<ul> <li>✓ <u>Bezalip</u></li> <li>✓ <u>Bezalip</u> <u>Retard</u></li> </ul>
Other Lipid-Modifying Agents		
ACIPIMOX	30	✓ Olbetam
Resins		
COLESTYRAMINE Powder for oral suspension 4 g sachet61.50	50	✓ Colestyramine - Mylan S29 ✓ Quantalan sugar free S29

	(Manufacturer's Price)	Per	Subsidised	Generic Manufacturer
HMG CoA Reductase Inhibitors (Statins)				
ATORVASTATIN				
* Tab 10 mg	0.31	30	<b>✓</b> <u>ا</u>	Lorstat
	5.16	500	<b>✓</b> <u>I</u>	Lorstat
* Tab 20 mg	8.12	500	<b>✓</b> <u>I</u>	Lorstat
* Tab 40 mg	13.79	500	✓ [	Lorstat
* Tab 80 mg	25.39	500	✓ [	Lorstat
PRAVASTATIN				
* Tab 20 mg	7.16	100	✓ (	Clinect
* Tab 40 mg		100	✓ (	Clinect
ROSUVASTATIN - Special Authority see SA2093 below - Reta	il pharmacy			
* Tab 5 mg		30	<b>√</b>	Rosuvastatin Viatris
* Tab 10 mg		30	<b>√</b> i	Rosuvastatin Viatris
* Tab 20 mg		30	<b>√</b> i	Rosuvastatin Viatris
* Tab 40 mg		30	<b>√</b> i	Rosuvastatin Viatris
►SA2093 Special Authority for Subsidy				•

Subsidy

Fully

Brand or

SA2093 Special Authority for Subsidy

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

#### Either:

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

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

Both:

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

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

Both:

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

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

Both:

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

	Subsidy (Manufacturer's Pric \$	e) Su Per	Fully ibsidised	Brand or Generic Manufacturer
IMVASTATIN				
₭ Tab 10 mg	1.68	90		Simvastatin Mylan
≰ Tab 20 mg	2.54	90		Simvastatin Viatris Simvastatin Viatris
F Tab 20 mg		90		Simvastatin Viatris
€ Tab 80 mg		90		Simvastatin Viatris
Selective Cholesterol Absorption Inhibitors				
ZETIMIBE				
<b>₭</b> Tab 10 mg	1.76	30	✓	Ezetimibe Sandoz
ZETIMIBE 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	1	Zimybe
Tab 10 mg with simvastatin 80 mg	8.15	30	•	Zimybe
Nitrates				
LYCERYL TRINITRATE				
Oral pump spray, 400 mcg per dose – Up to 250 dose				
available on a PSO	7.48 25	50 dose O	P 🗸	Nitrolingual Pump Spray
▶ Patch 25 mg, 5 mg per day	15.73	30	1	Nitroderm TTS
Patch 50 mg, 10 mg per day		30		Nitroderm TTS
SOSORBIDE MONONITRATE				
₭ Tab 20 mg	22 49	100	1	Ismo 20
F Tab long-acting 40 mg		30		Ismo 40 Retard
Fab long-acting 60 mg		90		<u>Duride</u>
Sympathomimetics				
DRENALINE				
Inj 1 in 1,000, 1 ml ampoule – Up to 5 inj available on a PSO	4.98	5	1	Aspen Adrenaline
, , , , , , , , , , , , , , , , , , ,	13.27	-		DBL Adrenaline
Inj 1 in 10,000, 10 ml ampoule - Up to 5 inj available on a PS	SO27.00	5	✓	Hospira
	49.00	10	1	Aspen Adrenaline
Vasodilators				
IYDRALAZINE HYDROCHLORIDE				
★ Tab 25 mg - Special Authority see SA1321 on the next page	· —			
Retail pharmacy		1	1	Hydralazine
r	- <del>-</del>	56		Onelink S29
		84		AMDIPHARM S29
		100		Camber S29

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

### **⇒SA1321** Special Authority for Subsidy

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

#### Either:

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

#### MINOXIDIL

▲ Tab 10 mg	47.04	60	✓ Minoxidil Roma S29
•	78.40	100	✓ Loniten
NICORANDIL			
▲ Tab 10 mg	27.81	60	✓ Max Health
▲ Tab 20 mg	35.12	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

### **Endothelin Receptor Antagonists**

AMBRISENTAN - Special Authority see SA2486 below - Retai	l pharmacy			
Tab 5 mg	200.00	30	1	Ambrisentan Viatris
Tab 10 mg	200.00	30	1	<b>Ambrisentan Viatris</b>

#### ⇒SA2486 Special Authority for Subsidy

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

#### All of the following:

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

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

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developmental lung disorders including chronic neonatal lung disease; or

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

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

All of the following:

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

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

All of the following:

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

#### 5 Both:

- 5.1 Ambrisentan is to be used as PAH triple therapy; and
- 5.2 Any of the following:
  - 5.2.1 Patient is on the lung transplant list; or
  - 5.2.2 Both:
    - 5.2.2.1 Patient is presenting in NYHA/WHO functional class IV: and
    - 5.2.2.2 Patient has an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease); or
  - 5.2.3 Both:
    - 5.2.3.1 Patient has tried PAH dual therapy for at least three months and remains in an unacceptable risk category according to a validated risk stratification tool\*\*; and
    - 5.2.3.2 Patient does not have major life-threatening comorbidities and triple therapy is not being used in a palliative scenario.

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

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

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

	Subsidy (Manufacturer's Price)		Fully Subsidised	Generic
BOSENTAN - Special Authority see SA2254 below - Retail phar	rmacy			
Tab 62.5 mg	100.00	60	1	Bosentan Dr
				Reddy's
Tab 125 mg	100.00	60	✓	Bosentan Dr
				Reddv's

#### ⇒SA2254 Special Authority for Subsidy

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

#### All of the following:

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

#### 5 Both:

- 5.1 Bosentan is to be used as PAH monotherapy; and
- 5.2 Any of the following:
  - 5.2.1 Patient has experienced intolerable side effects on sildenafil; or
  - 5.2.2 Patient has an absolute contraindication to sildenafil; or
  - 5.2.3 Patient is a child with idiopathic PAH or PAH secondary to congenital heart disease.

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

#### All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH)\*: and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH has been confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and

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

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

All of the following:

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

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

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

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

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

### Phosphodiesterase Type 5 Inhibitors

SILDENAFIL – Special Authority see SA2255 below – Retail ph	armacy		
Tab 25 mg	0.72	4	✓ Vedafil
Tab 50 mg		4	✓ Vedafil
Tab 100 mg		12	✓ Vedafil

### ⇒SA2255 Special Authority for Subsidy

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

All of the following:

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

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

All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH)\*; and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II. III or IV: and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH is confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) of greater than 20 mmHg; and
    - 4.1.3 A pulmonary capillary wedge pressure (PCWP) that is less than or equal to 15 mmHg; and
    - 4.1.4 Pulmonary vascular resistance (PVR) of at least 2 Wood Units or greater than 160 International Units (dyn s cm<sup>-5</sup>); and

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

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

Both:

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

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

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

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

## **Prostacyclin Analogues**

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

#### ⇒SA2256 Special Authority for Subsidy

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

All of the following:

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

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

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guidelines) †; or

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

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

All of the following:

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

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

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

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

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

ILOPROST - Special Authority see SA2257 below - Retail pharmacy

✓ Vebulis

Vebulis to be Principal Supply on 1 December 2025

#### ⇒SA2257 Special Authority for Subsidy

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

All of the following:

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

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(Manufacturer's Price)	Subsidised	Generic
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practitioner on the recommendation of a respiratory specialist, cardiologist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

#### All of the following:

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

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

#### All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH); and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II. III or IV: and
- 4 Any of the following:
  - 4.1 All of the following:
    - 4.1.1 PAH has been confirmed by right heart catheterisation; and
    - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
    - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and

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

continued...

- 4.1.4 A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm<sup>-5</sup>); and
- 4.1.5 Any of the following:
  - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these quidelines) †: or
  - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool\*\*; or
  - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
- 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease; or
- 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
- 5 Both:
  - 5.1 Iloprost is to be used as PAH triple therapy; and
  - 5.2 Any of the following:
    - 5.2.1 Patient is on the lung transplant list; or
    - 5.2.2 Patient is presenting in NYHA/WHO functional class IV; or
    - 5.2.3 Both:
      - 5.2.3.1 Patient has tried PAH dual therapy for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool\*\*; and
      - 5.2.3.2 Patient does not have major life-threatening comorbidities and triple therapy is not being used in a palliative scenario.

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

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

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

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

# **Antiacne Preparations**

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 95

#### **ADAPALENE**

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

22.89	30 g OP	<ul><li>Differin</li></ul>
il pharmacy		
11.26	60	<ul><li>Oratane</li></ul>
18.75	120	✓ Oratane
	120	✓ Oratane
		il pharmacy 6011.26 60

#### ⇒SA2449 Special Authority for Subsidy

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

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

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

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

#### **TRETINOIN**

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

# **Antibacterials Topical**

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 95

HYDROGEN PEROXIDE  * Crm 1%	4.89	15 a OP	✓ Crystaderm
Crystaderm to be Principal Supply on 1 January 2026			<b>,</b>
MUPIROCIN			
Oint 2%	6.60	15 g OP	
	(13.00)	J	Bactroban

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

# **DERMATOLOGICALS**

	Subsidy		Fully Brand or	
	(Manufacturer's F		sidised Generic	
	\$	Per	✓ Manufacturer	
SODIUM FUSIDATE [FUSIDIC ACID]	4.00	5 - OD	/ Falsan	
Crm 2%	1.69	5 g OP	✓ <u>Foban</u>	
b) Only on a prescription				
c) Not in combination				
Oint 2%	1.69	5 g OP	✓ Foban	
a) Maximum of 5 g per prescription				
<ul><li>b) Only on a prescription</li><li>c) Not in combination</li></ul>				
SULFADIAZINE SILVER				
Crm 1%	10.80	50 g OP	✓ Flamazine	
a) Up to 250 g available on a PSO		00 9 0.		
b) Not in combination				
Antifungals Topical				
	100			
For systemic antifungals, refer to INFECTIONS, Antifung	als, page 102			
AMOROLFINE				
a) Only on a prescription     b) Not in combination				
Nail soln 5%	21.87	5 ml OP	✓ MycoNail	
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		
* OOH 1/0	(7.55)	20 1111 01	Canesten	
a) Only on a prescription	,			
b) Not in combination				
ECONAZOLE NITRATE	_			
Crm 1%	8.04	20 g OP	✓ Pevaryl	
a) Only on a prescription     b) Not in combination				
Foaming soln 1%, 10 ml sachets	9.89	3		
	(18.64)		Pevaryl	
a) Only on a prescription				
b) Not in combination				
MICONAZOLE NITRATE  * Crm 2%	0.00	15 a OD	✓ Multichem	
a) Only on a prescription	0.90	15 g OP	▼ <u>munuchem</u>	
b) Not in combination				
* Lotn 2%	4.36	30 ml OP		
	(10.03)		Daktarin	
a) Only on a prescription     b) Not in combination				
* Tinct 2%	4.36	30 ml OP		
	(12.10)	30 01	Daktarin	
a) Only on a prescription	. ,			
b) Not in combination				

✓ healthE Calamine

Aqueous

✓ Itch-Soothe

100 g

20 g OP

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

# **Antipruritic Preparations**

#### CALAMINE

- a) Only on a prescription
- b) Not in combination
- Crm, aqueous, BP......3.45

CROTAMITON

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

Crm 10%......3.49

MENTHOL - Only in combination

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

25 g ✓ MidWest ✓ MidWest 29.60 100 g

### **Corticosteroids Topical**

For systemic corticosteroids, refer to CORTICOSTEROIDS AND RELATED AGENTS, page 84

#### Corticosteroids - Plain

BETAMETHASONE DIPROPIONATE			
Crm 0.05%	2.96	15 g OP	✓ Diprosone
	36.00	50 g OP	✓ Diprosone
Oint 0.05%	2.96	15 g OP	✓ Diprosone
	36.00	50 g OP	✓ Diprosone
Oint 0.05% in propylene glycol base	4.33	30 g OP	Diprosone OV
BETAMETHASONE VALERATE			
* Crm 0.1%	5.85	50 g OP	✓ Beta Cream
* Oint 0.1%	7.90	50 g OP	✓ Beta Ointment
* Lotn 0.1%	30.00	50 ml OP	✓ Betnovate
CLOBETASOL PROPIONATE			
* Crm 0.05%	3.75	30 g OP	✓ Dermol
* Oint 0.05%		30 g OP	✓ Dermol
CLOBETASONE BUTYRATE		Ü	
Crm 0.05%	5.38	30 g OP	
	(10.00)	3 -	Eumovate
HYDROCORTISONE			
* Crm 1% - Only on a prescription	1.78	30 g OP	✓ Ethics
, , ,	20.40	500 g	✓ Noumed
* Powder – Only in combination	49.95	25 g	✓ ABM
Up to 5% in a dermatological base (not proprietary Top galenicals			or without other dermatological
HYDROCORTISONE AND PARAFFIN LIQUID AND LANOLIN			

Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% - Only on

a prescription......12.83 250 ml ✓ DP Lotn HC

	Subsidy (Manufacturer's P \$	rice) Subs	Fully sidised	Brand or Generic Manufacturer
IYDROCORTISONE 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
•		100 1111 01		200014 01010
ETHYLPREDNISOLONE ACEPONATE	4.05	45 00	,	
Crm 0.1%		15 g OP		Advantan
Oint 0.1%	4.95	15 g OP	•	<u>Advantan</u>
IOMETASONE FUROATE				
Crm 0.1%	2.25	15 g OP	1	Elocon Alcohol Free
	3.50	50 g OP	1	Elocon Alcohol Free
Oint 0.1%	2.25	15 g OP		Elocon
	3.50	50 g OP		Elocon
Lotn 0.1%		30 ml OP		Elocon
		00 1111 01		<u></u>
RIAMCINOLONE ACETONIDE	2.42	400 05		Autotoria
Crm 0.02%		100 g OP		Aristocort
Oint 0.02%	6.54	100 g OP	•	Aristocort
Corticosteroids - Combination				
ETAMETHASONE VALERATE WITH SODIUM FUSIDATE	[FUSIDIC ACID]			
Crm 0.1% with sodium fusidate (fusidic acid) 2%		15 g OP		
(	(10.45)	- 3 -		Fucicort
<ul> <li>a) Maximum of 15 g per prescription</li> <li>b) Only on a prescription</li> <li>IYDROCORTISONE WITH MICONAZOLE — Only on a pre-</li> </ul>				
Crm 1% with miconazole nitrate 2%	2.85	15 g OP	•	Micreme H
IYDROCORTISONE WITH NATAMYCIN AND NEOMYCIN Oint 1% with natamycin 1% and neomycin sulphate 0.5%		tion 15 g OP	/	Pimafucort
RIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEON Crm 1 mg with nystatin 100,000 u, neomycin sulphate 2.		IN		
and gramicidin 250 mcg per g - Only on a prescript	ion3.49	15 g OP		
	(9.28)			Viaderm KC
Barrier Creams and Emollients				
Barrier Creams				
IMETHICONE				
Crm 5% pump bottle	4.30	460 g OP	1	healthE
				Dimethicone 5%
Crm 10% pump bottle	4.52	460 g OP	1	healthE
1 1		<b>3</b> -		Dimethicone 10%
INC AND CASTOR OIL				
INC AND CASTOR OIL	4.05	500 m		F
6 Oint	4.25	500 g	•	Evara
Emollients				
QUEOUS CREAM				
€ Crm	1.65	500 g	1	Evara
•		550 g	-	
ETOMACDOCOL				
ETOMACROGOL Crm BP		500 g		Cetomacrogol-AFT

	Subsidy		Fully	Brand or
	(Manufacturer's F	Price) Sub	sidised	Generic
	\$	Per	✓	Manufacturer
OFTOMACDOCOL WITH OLVOFDOL				
CETOMACROGOL WITH GLYCEROL	4.00	400 00	,	_
Crm 90% with glycerol 10%		460 g OP		Evara
	3.25	920 g OP		Evara
Evara to be Principal Supply on 1 December 2025				
EMULSIFYING OINTMENT				
	0.10	F00 =		France Francisife in a
* Oint BP	3.13	500 g	•	Evara Emulsifying
				<u>Ointment</u>
OIL IN WATER EMULSION				
* Crm	2 10	500 g	1	Fatty Emulsion
• • • • • • • • • • • • • • • • • • • •	2.10	000 g	•	Cream (Evara)
				Cieaiii (Evara)
PARAFFIN				
Oint liquid paraffin 50% with white soft paraffin 50%	4.94	500 g OP	1	White Soft Liquid
		ŭ		Paraffin AFT
UREA				
	4.07	400 00		
* Crm 10%	1.37	100 g OP	•	healthE Urea Cream
WOOL FAT WITH MINERAL OIL - Only on a prescription				
* Lotn hydrous 3% with mineral oil	5.60	1,000 ml		
<i>j</i>	(14.96)	.,		DP Lotion
	(20.53)			Alpha-Keri Lotion
	, ,	250 ml OP		Alpha-Ren Lollon
	1.40	250 IIII OP		DD Latina
	(5.87)			DP Lotion
	5.60	1,000 ml		
	(23.91)			BK Lotion
	1.40	250 ml OP		
	(7.73)			BK Lotion
	. ,			
Other Dermatological Bases				
other Bermateregiotal Bacoc				
PARAFFIN				
White soft - Only in combination	4.74	450 g	1	EVARA White Soft
		.00 g		Paraffin
	10.00	0.500 ~	./	
	19.00	2,500 g	v	EVARA White Soft
				<u>Paraffin</u>
Only in combination with a dermatological galenical or a	ıs a diluent for a p	proprietary To	pical C	orticosteroid – Plain.
Minor Skin Infections				
POVIDONE IODINE				
Oint 10%	7.40	65 g OP	1	Betadine
a) Maximum of 130 g per prescription		9		
,				
b) Only on a prescription	4.05	400 :		<b>D</b> ' ''
Antiseptic Solution 10%		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
	(5.15)			

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



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

# **Parasiticidal Preparations**

DIMETHICONE

200 ml OP ✓ healthF Dimethicone 4% Lotion

IVERMECTIN - Special Authority see SA2511 below - Retail pharmacy

✓ Stromectol Tab 3 mg - Up to 100 tab available on a PSO.......17.20

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

#### ⇒SA2511 Special Authority for Subsidy

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

# Fither:

- 1 The person has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
- - 2.1 The person has a confirmed diagnosis of scabies or is a close contact of a scabies case; and
  - - 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; or
- 4 The individual has a travel or residence history that requires presumptive parasite treatment.

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

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

30 ml OP ✓ A-Scabies

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

## **Psoriasis and Eczema Preparations**

ACITRETIN - Special Authority see SA2024 below - Retail pharm	nacy		
Cap 10 mg	26.20	60	✓ Novatretin
Cap 25 mg	57.37	60	✓ <u>Novatretin</u>

#### ⇒SA2024 Special Authority for Subsidy

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

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

BETAMETHASONE DIPROPIONATE WITH CALCIPOTRIOL

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

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

Foam spray 500 mcg with calcipotriol 50 mcg per g59.95	60 g OP	<ul><li>Enstilar</li></ul>
Gel 500 mcg with calcipotriol 50 mcg per g40.92	60 g OP	✓ Daivobet
Oint 500 mcg with calcipotriol 50 mcg per g14.31	30 g OP	Daivobet
CALCIPOTRIOL		
Oint 50 mag par a	120 a OD	✓ Daiyonov

1) Up to 10% only in combination with a dermatological base or proprietary Topical Corticosteriod - Plain

40 g OP

✓ Coco-Scalp

2) With or without other dermatological galenicals.

# COAL TAR WITH ALLANTOIN, MENTHOL, PHENOL AND SULPHUR

Soin 5% with Sulphur 0.5%, mention 0.75%, priend 0.5% and			
allantoin crm 2.5%	6.59	75 a OP	
	(8.00)	- 3 -	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.....7.95

- PIMECROLIMUS Special Authority see SA1970 on the next page 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



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

Pinetarsol

## ⇒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.

1) Only in combination with a dermatological base or proprietary Topical Corticosteroid - Plain or collodion flexible

#### PINE TAR WITH TROLAMINE LAURILSULFATE AND FLUORESCEIN - Only on a prescription \* Soln 2.3% with trolamine laurilsulfate and fluorescein sodium...........5.41 500 ml

SALICYLIC ACID

250 g 

- ✓ Midwest
- 2) With or without other dermatological galenicals.

#### **SULPHUR**

100 a ✓ Midwest

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

#### TACROLIMUS

Oint 0.1% - Special Authority see SA2074 below - Retail 30 q OP ✓ Zematop pharmacy......33.00

- a) Maximum of 30 g per prescription
- b) Note: a maximum of 30 g per prescription and no more than one prescription per 12 weeks.

#### ⇒SA2074 Special Authority for Subsidy

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

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

## Scalp Preparations

BETAMETHASONE VALERATE		
* Scalp app 0.1%	100 ml OP	✓ Beta Scalp
CLOBETASOL PROPIONATE  * Scalp app 0.05%	30 ml OP	✓ Dermol
HYDROCORTISONE BUTYRATE Scalp lotn 0.1%	100 ml OP	✓ Locoid
KETOCONAZOLE Shampoo 2%4.09	100 ml OP	✓ <u>Sebizole</u>

- a) Maximum of 100 ml per prescription
- b) Only on a prescription

## **DERMATOLOGICALS**

Subsidy (Manufacturer's Price) \$

Subsidised Per

Fully

Brand or Generic Manufacturer

## **Sunscreens**

SUNSCREENS, PROPRIETARY - Subsidy by endorsement

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

Lotn,......6.50

200 g OP ✓ Marine Blue Lotion SPF 50+

## **Wart Preparations**

For salicylic acid preparations refer to PSORIASIS AND ECZEMA PREPARATIONS, page 73

**PODOPHYLLOTOXIN** 

✓ Condyline S29 S29

- a) Maximum of 3.5 ml per prescription
- b) Only on a prescription

## **Other Skin Preparations**

### **Antineoplastics**

FΙ	LIORO	IDACII	SODILIM

IMIQUIMOD

IQUIMOD

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

## **GENITO-URINARY SYSTEM**

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

## **Contraceptives - Non-hormonal**

## **Condoms**

-	OMS	14.05	444	/ Mamanta
	mm – Up to 144 dev available on a PSO		144 10	✓ Moments ✓ Moments
r 50	5 [[[[]]	14.25	144	✓ Moments
	a) Maximum of 60 dev per prescription	14.23	144	• WOMENS
	b) Up to 60 dev available on a PSO			
<b>•</b> 53	B mm, 0.05 mm thickness	1 15	10	✓ Moments
	7 mm, 0.00 mm thornood	14.25	144	✓ Moments
	a) Up to 60 dev available on a PSO	11.20		· momonto
	b) Maximum of 60 dev per prescription			
53	B mm, chocolate, brown	1.15	10	✓ Moments
	, , , , , , , , , , , , , , , , , , , ,	14.25	144	✓ Moments
	a) Up to 60 dev available on a PSO			
	b) Maximum of 60 dev per prescription			
- 53	mm, strawberry, red	1.15	10	✓ Moments
	•	14.25	144	✓ Moments
	a) Up to 60 dev available on a PSO			
	b) Maximum of 60 dev per prescription			
56	6 mm	1.15	10	✓ Moments
		14.50	144	✓ Moments
	a) Maximum of 60 dev per prescription			
	b) Up to 60 dev available on a PSO			
56	6 mm, 0.05 mm thickness	2.00	12	Gold Knight
		24.10	144	Gold Knight
	a) Up to 60 dev available on a PSO			
	b) Maximum of 60 dev per prescription			
56	mm, 0.05mm thickness (bulk pack)	20.17	144	Gold Knight
	<ul> <li>a) Maximum of 60 dev per prescription</li> </ul>			
	b) Up to 60 dev available on a PSO			
56	6 mm, 0.08 mm thickness		10	✓ Moments
		14.25	144	✓ Moments
	<ul> <li>a) Up to 60 dev available on a PSO</li> </ul>			
	b) Maximum of 60 dev per prescription			
56	mm, 0.08 mm thickness, red		10	✓ Moments
		14.25	144	✓ Moments
	a) Up to 60 dev available on a PSO			
_	b) Maximum of 60 dev per prescription	4 =0	40	<b>40</b> -1344 1 1 1
56	6 mm, chocolate		12	✓ Gold Knight
	\	21.45	144	Gold Knight
	a) Up to 60 dev available on a PSO			
	b) Maximum of 60 dev per prescription	4 70	10	للماسال المام 🗸
56	6 mm, strawberry		12	✓ Gold Knight
	a) lie to co dou quelleble en a BOO	21.45	144	✓ Gold Knight
	a) Up to 60 dev available on a PSO			
er	b) Maximum of 60 dev per prescription	1 00	12	✓ Cold Knight VI
60	J IIIIII	21.89	144	<ul><li>✓ Gold Knight XL</li><li>✓ Gold Knight XL</li></ul>
	a) Maximum of CO day residential	21.09	144	• Goid Killyfil AL
	a) Maximum of 60 dev per prescription			

### GENITO-URINARY SYSTEM

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

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

#### **Contraceptive Devices**

#### INTRA-UTERINE DEVICE

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

*	IUD 29.1 mm length × 23.2 mm width29.4	80 1	•	Choice 380 7med Nsha Silver/ copper Short
*	IUD 33.6 mm length × 29.9 mm width	80 1	•	TCu 380 Plus Normal
*	IUD 35.5 mm length × 19.6 mm width	00 1	•	Cu 375 Standard

### **Contraceptives - Hormonal**

## **Combined Oral Contraceptives**

## ⇒SA0500 Special Authority for Alternate Subsidy

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

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

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

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

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

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

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

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

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

#### ETHINYLOESTRADIOL WITH DESOGESTREL

★ Tab 20 mcg with desogestrel 150 mcg and 7 inert tab - Up to 84 tab available on a PSO......10.00 84 ✓ Mercilon 28

	Subsidy		Fully	Brand or
	(Manufacturer's Price)		Subsidised	Generic
	\$	Per	•	Manufacturer
ETHINYLOESTRADIOL WITH LEVONORGESTREL				
* Tab 20 mcg with levonorgestrel 100 mcg and 7 inert tablets	_			
Up to 84 tab available on a PSO	1.50	84	1	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 Auth</li> <li>b) Up to 63 tab available on a PSO</li> <li>Tab 30 mcg with levonorgestrel 150 mcg and 7 inert tablets</li> <li>Up to 84 tab available on a PSO</li> </ul>	-	the p	'	oge Oralcon 30 ED
ETHINYLOESTRADIOL WITH NORETHISTERONE				
Tab 35 mcg with norethisterone 1 mg and 7 inert tab - Up to 84 tab available on a PSO		84		Alyacen Brevinor 1/28
Tab 35 mcg with norethisterone 500 mcg and 7 inert tab - U	р			
to 84 tab available on a PSO	21.99	84	✓	Norimin
(Alyacen Tab 35 mcg with norethisterone 1 mg and 7 inert tab to	be delisted 1 January	/ 202	6)	

## **Progestogen-only Contraceptives**

### ⇒SA0500 Special Authority for Alternate Subsidy

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

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

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

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

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

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

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

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

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

#### DESOGESTREL

Tab 75 mcg - Up to 84 tab available on a PSO24	4.50	84	✓ Cerazette
VONORGESTREL			
Tab 30 mcg - Up to 112 tab available on a PSO22	2.00	112	✓ Microlut
Intra-uterine device 52 mg - Up to 25 dev available on a PSO 269	9.50	1	✓ Mirena
Intra-uterine device 13.5 mg - Up to 10 dev available on a			
PSO215	5.60	1	<ul><li>Jaydess</li></ul>
Subdermal implant (2 × 75 mg rods) – Up to 40 impl available			
on a PSO106	6.92	2 OP	✓ <u>Jadelle</u>
	VONORGESTREL  Tab 30 mcg - Up to 112 tab available on a PSO	Tab 30 mcg – Up to 112 tab available on a PSO	VONORGESTREL  Tab 30 mcg – Up to 112 tab available on a PSO22.00  Intra-uterine device 52 mg – Up to 25 dev available on a PSO269.50  Intra-uterine device 13.5 mg – Up to 10 dev available on a PSO215.60  Subdermal implant (2 × 75 mg rods) – Up to 40 impl available

### **GENITO-URINARY SYSTEM**

	Subsidy (Manufacturer's Price) \$	Su Per	Fully bsidised	Brand or Generic Manufacturer
MEDROXYPROGESTERONE ACETATE Inj 150 mg per ml, 1 ml syringe – Up to 5 inj available on a P NORETHISTERONE	SO10.56	1	<b>✓</b> D	epo-Provera
Tab 350 mcg - Up to 84 tab available on a PSO(Norethinderone - CDC Tab 350 mcg to be delisted 1 January 202		84	✓ N	lorethinderone - CDC loriday loriday 28

## **Emergency Contraceptives**

#### LEVONORGESTREL

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

## **Antiandrogen Oral Contraceptives**

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

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

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

#### CYPROTERONE ACETATE WITH ETHINYLOESTRADIOL

## Gynaecological Anti-infectives

ACETIC ACID WITH HYDROXYQUINOLINE AND RICINOLEIC ACID
Jelly with glacial acetic acid 0.94%, hydroxyguinoline sulphate

0.025%, glycerol 5% and ricinoleic acid 0.75% with applicator....8.43 100 g OP Aci-Jel CLOTRIMAZOLE 35 g OP ✓ Clomazol ✓ Clomazol 20 g OP MICONAZOLE NITRATE \* Vaginal crm 2% with applicator .......6.89 Micreme 40 g OP NYSTATIN Vaginal crm 100,000 u per 5 g with applicator(s) ......5.70 75 g OP ✓ Nilstat

## **Myometrial and Vaginal Hormone Preparations**

#### **ERGOMETRINE MALEATE**

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

PSO.......160.00 5 

✓ DBL Ergometrine

Cassette Pregnancy Test

(N	Subsidy Manufacturer's P	rice) Sub-	Fully sidised	Brand or Generic
	\$	Per	1	Manufacturer
OESTRIOL				
* Crm 1 mg per g with applicator	6.95	15 g OP	<b>√</b> <u>C</u>	<u>Ovestin</u>
* Pessaries 500 mcg	7.55	15	<b>√</b> Ç	Ovestin
OXYTOCIN - Up to 5 inj available on a PSO				
Inj 5 iu per ml, 1 ml ampoule	5.98	5	<b>√</b> (	Oxytocin BNM
Inj 10 iu per ml, 1 ml ampoule		5		Dxytocin BNM
OXYTOCIN WITH ERGOMETRINE MALEATE - Up to 5 inj availab				•
Inj 5 iu with ergometrine maleate 500 mcg per ml, 1 ml ampoule		5	<b>√</b> S	Syntometrine

## **Pregnancy Tests - hCG Urine**

## **Urinary Agents**

For urinary tract Infections refer to INFECTIONS, Antibacterials, page 115

## 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 Fither:
  - 2.1 The patient is intolerant of non-selective alpha blockers or these are contraindicated; or
  - 2.2 Symptoms are not adequately controlled with non-selective alpha blockers.

## Alpha-1A Adrenoreceptor Blockers

TAMSULOSIN HYDROCHLORIDE - Special Authority see SA1032 below - Retail pharmacy

## **⇒SA1032** Special Authority for Subsidy

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

#### Both:

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

## **GENITO-URINARY SYSTEM**

(N)	Subsidy lanufacturer's P \$	rice) Subsi Per	Fully dised	Brand or Generic Manufacturer
Other Urinary Agents				
OXYBUTYNIN				
* Tab 5 mg	5.42	100	<b>√</b>	Alchemy Oxybutynin
POTASSIUM CITRATE				
Oral liq 3 mmol per ml – Special Authority see SA1083 below – Retail pharmacy		200 ml OP	<b>✓</b> E	Biomed
⇒SA1083 Special Authority for Subsidy				
<b>Initial application</b> from any relevant practitioner. Approvals valid for Both:	or 12 months f	or applications	meetir	ng the following criteria:
1 The patient has recurrent calcium oxalate urolithiasis; and				
2 The patient has had more than two renal calculi in the two years.				
<b>Renewal</b> from any relevant practitioner. Approvals valid for 2 years benefitting from the treatment.	where the tre	atment remains	appro	opriate and the patient is
SODIUM CITRO-TARTRATE				
* Grans eff 4 g sachets	3.50	28	<b>√</b> [	<u>Jral</u>
SOLIFENACIN SUCCINATE				
Tab 5 mg	1.95	30	<b>√</b> §	Solifenacin succinate Max Health
	3.15		✓ 9	Solifenacin Viatris
Tab 10 mg	3.53	30	✓ 9	Solifenacin

(Solifenacin Viatris Tab 5 mg to be delisted 1 November 2025)

<b>Detection of Substances in Urine</b>	Detection	of Substa	nces in	Urine
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ORTHO-TOLIDINE  * Compound diagnostic sticks	7 50	50 test OP		
- Compound diagnostic sticks	(8.25)	00 1001 01	Hemastix	
TETRABROMOPHENOL  * Blue diagnostic strips	13.92	100 test OP	✓ Albustix	

## **Obstetric Preparations**

## **Antiprogesterones**

		RISTONE	MIFEPRISTC
✓ Mifegyne	1	ab 200 mg - Up to 15 tab available on a PSO83.90	Tab 200
✓ Mifegyne	3	180.00	

succinate Max Health

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

#### Calcium Homeostasis

CALCITONIN  * Inj 100 iu per ml, 1 ml ampoule121.00	5	✓ Miacalcic ✓ Miacalcic S29 S29
CINACALCET – Special Authority see SA2170 below – Retail pharmacy		
Tab 30 mg - Wastage claimable25.24	28	✓ Cinacalet Devatis
Tab 60 mg - Wastage claimable50.47	28	✓ Cinacalet Devatis

⇒SA2170 Special Authority for Subsidy

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

Fither:

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

Renewal — (parathyroid carcinoma or calciphylaxis) only from a nephrologist or endocrinologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 The patient's serum calcium level has fallen to < 3mmol/L: and
- 2 The patient has experienced clinically significant symptom improvement.

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

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

#### All of the following:

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

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

continued...

- 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

## Corticosteroids and Related Agents for Systemic Use

BETAMETHASONE SODIUM PHOSPHATE WITH BETAMETHASONE ACET.  * Inj 3.9 mg with betamethasone acetate 3 mg per ml, 1 ml19.20  (36.96)	ATE 5	Celestone Chronodose
DEXAMETHASONE		
* Tab 0.5 mg - Up to 60 tab available on a PSO1.80	30	✓ Dexmethsone
* Tab 4 mg – Up to 30 tab available on a PSO	30	✓ Dexmethsone
Oral liq 1 mg per ml53.86	25 ml OP	✓ Biomed
DEXAMETHASONE PHOSPHATE		
Dexamethasone phosphate injection will not be funded for oral use.		_
* Inj 4 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO6.88	10	<ul><li>Dexamethasone Medsurge</li></ul>
7.86		✓ Hameln
* Inj 4 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO 10.98	10	<ul><li>Dexamethasone Medsurge</li></ul>
13.10		✓ Hameln
(Hameln Inj 4 mg per ml, 1 ml ampoule to be delisted 1 March 2026) (Hameln Inj 4 mg per ml, 2 ml ampoule to be delisted 1 March 2026) FLUDROCORTISONE ACETATE		
* Tab 100 mcg8.05	100	✓ Florinef
Florinef to be Principal Supply on 1 December 2025		
HYDROCORTISONE		
* Tab 5 mg8.10	100	✓ Douglas
* Tab 20 mg	100	✓ Douglas
<ul><li>Inj 100 mg vial</li></ul>	1	✓ <u>Solu-Cortef</u>
METHYLPREDNISOLONE		
* Tab 4 mg112.00	100	✓ Medrol
* Tab 100 mg223.10	20	✓ Medrol

	Subsidy (Manufacturer's Price \$	) Sub Per	Fully Brand or sidised Generic  Manufacturer
METHYLPREDNISOLONE (AS SODIUM SUCCINATE)			
Inj 40 mg vial	22.30	1	✓ Solu-Medrol-Act- O-Vial
Inj 125 mg vial	34.10	1	✓ Solu-Medrol-Act- O-Vial
Inj 500 mg vial	43.01	1	✓ Solu-Medrol-Act- O-Vial
Inj 1 g vial	52.54	1	✓ Solu-Medrol
METHYLPREDNISOLONE ACETATE			
Inj 40 mg per ml, 1 ml vial	47.06	5	✓ Depo-Medrol
PREDNISOLONE			
Oral liq 5 mg per ml – Up to 30 ml available on a PSO Restricted to children under 12 years of age.	6.00	30 ml OP	✓ Redipred
PREDNISONE			<b>.</b>
F Tab 1 mg		500	✓ 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 ETRACOSACTRIN	50.51	500	✓ Prednisone Clinect
Finj 250 mcg per ml, 1 ml ampoule	86.25	1	✓ Synacthen
for Inj 1 mg per ml, 1 ml ampoule	690.00	1	✓ UK Synacthen ✓ Synacthen Depot ✓ Synacthene Retard \$29
RIAMCINOLONE ACETONIDE			
Inj 10 mg per ml, 1 ml ampoule	21 42	5	✓ Kenacort-A 10
Inj 40 mg per ml, 1 ml ampoule		5	✓ Kenacort-A 40
Sex Hormones Non Contraceptive			
Androgen Agonists and Antagonists			
PROTERONE ACETATE	47.05	50	<b>( 0</b> !!
Tab 50 mg		50	✓ <u>Siterone</u>
Tab 100 mg	31.00	50	✓ <u>Siterone</u>
ESTOSTERONE  Gel (transdermal) 16.2 mg per g, 88 g	52.00	60 OP	✓ Testogel
ESTOSTERONE CIPIONATE		1	
Inj 100 mg per ml, 10 ml vial ESTOSTERONE ESTERS	85.00	1	✓ Depo-Testosterone
Inj 250 mg per ml, 1 ml	12.98	1	✓ Sustanon Ampoules
ESTOSTERONE UNDECANOATE			
	26.00	100	✓ Steril-Gene S29
Cap 40 mg — Subsidy by endorsement		100	
Subsidy by endorsement – subsidised for patients who 1 November 2021 and the prescription is endorsed ac			
where there exists a record of prior dispensing of testo			
Inj 250 mg per ml, 4 ml vial		tap 40 mg	In the preceding 12 months.  ✓ Reandron 1000
my 200 mg per mi, 4 mi viai	00.00	1	- Iteanurun 1000

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

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

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

## **Hormone Replacement Therapy - Systemic**

Oestrogens
------------

C	estrogens			
OE	STRADIOL			
*	Tab 1 mg	4.12	28 OP	
		(11.10)		Estrofem
*	Tab 2 mg	4.12	28 OP	
		(11.10)		Estrofem
*	Gel (transdermal) 0.06% (750 mcg/actuation)	14.25	80 g OP	✓ <u>Estrogel</u>
	Patch 25 mcg per day	8.89	8	<ul><li>Estradiol TDP Mylan</li></ul>
		13.50		✓ Estraderm MX S29
		16.23		✓ Estradot
		21.35		✓ Lyllana
	a) No more than 2 patch per week			
	b) Only on a prescription			
	c) Estradiol TDP Mylan to be Principal Supply on 1 D	ecember 2025		
	Patch 50 mcg per day	9.26	8	<ul><li>Estradiol TDP Mylan</li></ul>
		10.75		✓ Estradiol Viatris
		14.50		✓ Estraderm MX S29
				✓ Estradiol Sandoz
		15.79		✓ Estradot
		21.55		✓ Lyllana
	a) No more than 2 patch per week			•
	b) Only on a prescription			
	c) Estradiol TDP Mylan to be Principal Supply on 1 D	ecember 2025		
	Patch 75 mcg per day		8	<ul><li>Estradiol TDP Mylan</li></ul>
	<b>31</b> ,	11.88		✓ Estradiol Viatris
		14.50		<ul><li>Estradiol Sandoz</li></ul>
		16.53		✓ Estradot
		22.37		✓ Lyllana
	a) No more than 2 patch per week			-
	b) Only on a prescription			
	c) Estradiol TDP Mylan to be Principal Supply on 1 D	ecember 2025		
	Patch 100 mcg per day		8	<ul> <li>Estradiol TDP Mylan</li> </ul>
		12.95		✓ Estradiol Viatris
		14.50		✓ Estradiol Sandoz
		15.50		✓ Estraderm MX S29
		16.18		✓ Estradot
		22.77		✓ Lyllana
				•

	Subsidy		Fully	Brand or
	(Manufacturer's Price	) S Per	ubsidised	Generic Manufacturer
\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	<b>3</b>	Per		Manufacturer
<ul><li>a) No more than 2 patch per week</li><li>b) Only on a prescription</li></ul>				
c) Estradiol TDP Mylan to be Principal Supply on 1 Dec	ember 2025			
(Estraderm MX S29) Patch 25 mcg per day to be delisted 1 Dece				
(Lyllana Patch 25 mcg per day to be delisted 1 December 2025)				
(Estradiol Viatris Patch 50 mcg per day to be delisted 1 December	er 2025)			
(Estraderm MX §29) Patch 50 mcg per day to be delisted 1 Dece	,			
(Estradiol Sandoz Patch 50 mcg per day to be delisted 1 December 1	,			
(Lyllana Patch 50 mcg per day to be delisted 1 December 2025)				
Estradiol Viatris Patch 75 mcg per day to be delisted 1 Decembe	er 2025)			
Estradiol Sandoz Patch 75 mcg per day to be delisted 1 December 1	ber 2025)			
(Lyllana Patch 75 mcg per day to be delisted 1 December 2025)				
(Estradiol Viatris Patch 100 mcg per day to be delisted 1 Decemb				
(Estradiol Sandoz Patch 100 mcg per day to be delisted 1 Decen				
(Estraderm MX S29 Patch 100 mcg per day to be delisted 1 Dec				
(Lyllana Patch 100 mcg per day to be delisted 1 December 2025)	)			
DESTRADIOL VALERATE	40.00	0.4	,	D
* Tab 1 mg	12.36	84	•	Progynova
Progynova to be Principal Supply on 1 December 2025	10.06	0.4	./	Dragumaura
* Tab 2 mg Progynova to be Principal Supply on 1 December 2025	12.30	84	•	Progynova
DESTROGENS	0.01	00		
* Conjugated, equine tab 300 mcg	(19.25)	28		Premarin
* Conjugated, equine tab 625 mcg		28		Fiemann
* Conjugated, equine table25 mog	(19.25)	20		Premarin
	(10.20)			
Progestogens				
MEDROXYPROGESTERONE ACETATE				
* Tab 2.5 mg	6.56	30	1	Provera
	8.75	56	_	Provera
* Tab 5 mg	9.80	56	✓	Provera
	20.13	100		Provera
* Tab 10 mg	10.28	30	•	Provera
Progestogen and Oestrogen Combined Prepara	itions			
DESTRADIOL WITH NORETHISTERONE				
* Tab 1 mg with 0.5 mg norethisterone acetate	5.40	28 OP		
	(18.10)			Kliovance
* Tab 2 mg with 1 mg norethisterone acetate	5.40	28 OP		
	(18.10)			Kliogest
* Tab 2 mg with 1 mg norethisterone acetate (10), and 2 mg				
oestradiol tab (12) and 1 mg oestradiol tab (6)		28 OP		
	(18.10)			Trisequens
Other Oestrogen Preparations				
OESTRIOL				
* Tab 2 mg	7.70	30	1	Ovestin
•	-	-		
		_	_	

	Subsidy		Fully	Brand or
	(Manufacturer's Price)		Subsidised	Generic
	\$	Per		Manufacturer
Other Progestogen Preparations				
MEDROXYPROGESTERONE ACETATE				_
Tab 100 mg	133.57	100	•	Provera HD
NORETHISTERONE				
* Tab 5 mg - Up to 30 tab available on a PSO	5.49	30	✓	Primolut N
PROGESTERONE				
* Cap 100 mg	14.85	30	✓	Utrogestan
				-
Thyroid and Antithyroid Agents				
CARBIMAZOLE				
* Tab 5 mg	7.56	100	✓	Neo-Mercazole
Neo-Mercazole to be Principal Supply on 1 December 20	25			
LEVOTHYROXINE				
* Tab 25 mcg	5.55	90	1	Synthroid
* Tab 50 mcg		28		Mercury Pharma
Ü	5.79	90		Synthroid
	64.28	1,000	<b>/</b>	Eltroxin
* Tablet 50 mcg	12.86	200	✓	Eltroxin
* Tab 100 mcg	1.78	28	✓	Mercury Pharma
	6.01	90	✓	Synthroid
	66.78	1,000	<b>/</b>	Eltroxin
* Tablet 100 mcg	13.36	200	1	Eltroxin
PROPYLTHIOURACIL - Special Authority see SA1199 below - F	Retail pharmacy			
Tab 50 mg		100	1	PTU S29
- CA1100 Chariel Authority for Cubaids				

## **⇒SA1199** Special Authority for Subsidy

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

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

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

## **Trophic Hormones**

#### **Growth Hormones**

SC	MATROPIN (OMNITROPE) - Special Authority see SA2032 below -	Retail pharma	СУ	
*	Inj 5 mg cartridge	30.21	ĺ	✓ Omnitrope
*	Inj 10 mg cartridge	30.21	1	✓ Omnitrope
*	Inj 15 mg cartridge13	39.50	1	✓ Omnitrope

## **⇒SA2032** Special Authority for Subsidy

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

Either:

1 Growth hormone deficiency causing symptomatic hypoglycaemia, or with other significant growth hormone deficient

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

continued...

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

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

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

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4 The patient does not have severe chronic disease (including malignancy or recognized severe skeletal dysplasia) and is not receiving medications known to impair height velocity.

Renewal — (short stature without growth hormone deficiency) only from a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

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

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

All of the following:

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

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

All of the following:

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

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

continued...

- 2 The patient is aged six months or older; and
- 3 A current bone age is < 14 years (female patients) or < 16 years (male patients); and
- 4 Sleep studies or overnight eximetry have been performed and there is no obstructive sleep disorder requiring treatment, or if an obstructive sleep disorder is found, it has been adequately treated under the care of a paediatric respiratory physician and/or ENT surgeon; and
- 5 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:

Subsidy (Manufacturer's Price)	Fully Subsidised	Brand or Generic	
` <b>¢</b> ′	Por 🗸	Manufacturer	

continued...

Any of the following:

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

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

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

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

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

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

## **GnRH Analogues**

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(-)	( ).5	H٠	۲⊢I	IN

Implant 3.6 mg, syringe6	6.48 1	1 ✓ Zoladex
Implant 10.8 mg, syringe136	8.23 1	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 chambe	r syringe - Higher subsidy of
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\$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

Subsidy

Fully

Brand or

	(Manufacturer's Price) \$	Per	Subsidised 🗸	Generic Manufacturer
Vasopressin Agonists				
DESMOPRESSIN Wafer 120 mcg	47.00	30	1	Minirin Melt
DESMOPRESSIN ACETATE				
Tab 100 mcg	25.00	30	<b>✓</b>	Minirin
Tab 200 mcg	54.45	30	✓	Minirin
Inj 4 mcg per ml, 1 ml	67.18	10	✓	Minirin
▲ Nasal spray 10 mcg per dose, 6 ml		60 OF	•	Desmopressin-
				PH&T

## **Other Endocrine Agents**

#### **CABERGOLINE**

### **⇒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.

Cap 250 mg.......558.00

CLOMIFENE CITRATE Tab 50 mg	29.84	10	✓ Mvlan
			Clomiphen S29
METYRAPONE			

50

✓ Metopirone

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

100

✓ Ranbaxy-Cefactor

✓ Cefalexin Sandoz

## **Anthelmintics**

ALBENDAZOLE - Special Authority see SA2512 below - Retail pharmacy

#### **⇒SA2512** Special Authority for Subsidy

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

- 1 The individual has hydatids; or
- 2 The individual has a travel or residence history that requires presumptive parasite treatment.

**Renewal** only from an infectious disease specialist or clinical microbiologist. Approvals valid for 6 months where the treatment remains appropriate and the patient is benefitting from the treatment.

#### MEBENDAZOLE - Only on a prescription

Tab 100 mg	5.18	6	✓ Vermox
Oral liq 100 mg per 5 ml		15 ml	
	(7.83)		Vermox
PRAZIQUANTEL			
Tab 600 mg	68.00	8	✓ Biltricide
•	87.68		✓ Distoside S29
(Biltricide Tab 600 mg to be delisted 1 April 2026)			

### **Antibacterials**

- a) For topical antibacterials, refer to DERMATOLOGICALS, page 67
- b) For anti-infective eye preparations, refer to SENSORY ORGANS, page 277

## **Cephalosporins and Cephamycins**

CEFACLOR MONOHYDRATE	
Can 250 mg	

Grans for oral liq 125 mg per 5 ml - Wastage claimable	100 ml	✓ Ranbaxy-Cefaclor
CEFALEXIN		
Cap 250 mg	20	<ul><li>Cephalexin ABM</li></ul>
Cap 500 mg	20	✓ Cephalexin ABM
Grans for oral lig 25 mg per ml – Wastage claimable7.88	100 ml	✓ Flynn
Grans for oral lig 50 mg per ml — Wastage claimable	100 ml	✓ Flynn

#### CEFAZOLIN - Subsidy by endorsement

Only if prescribed for dialysis or cellulitis in accordance with a Health NZ Hospital approved protocol and the prescription is endorsed accordingly.

11.75

Inj 500 mg vial3.39	5	Cefazolin-AFT
Inj 1 g vial3.59	5	✓ Cefazolin-AFT
Inj 2 g vial7.09	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 fibrosis patient, or the treatment of gonorrhoea, or the treatment of pelvic inflammatory disease, or the treatment of suspected meningococcal disease, and the prescription or PSO is endorsed accordingly.

Inj 500 mg vial	1	✓ Ceftriaxone-AFT
Inj 1 g vial3.49	5	✓ Ceftriaxone-AFT

	(Manufacturer's Price)	Subsid	lised	Generic
	\$	Per	1	Manufacturer
CEFUROXIME AXETIL – Subsidy by endorsement				
Only if prescribed for prophylaxis of endocarditis and the pre	escription is endorsed	accordingly		
Tab 250 mg	CBS	20	✓ A	scend-
				Cefuroxime S29

Subsidy

Fully

Brand or

#### **Macrolides**

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

Tab 250 mg	8.19	30	Apo-Azithromycin
Tab 500 mg - Up to 8 tab available on a PSO		2	✓ Zithromax
Zithromax to be Principal Supply on 1 January 2026			
Grans for oral lig 200 mg per 5 ml (40 mg per ml) – Wastage			
claimable	16.97	15 ml	✓ Zithromax

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

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

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

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

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

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

CLARITHROMYCIN - Maximum of 500 mg per prescription; can be waived by Special Authority see SA1857 on the next page

Tab 250 mg7.31	12	✓ Klaricid S29
8.53	14	✓ Klacid
Grans for oral liq 250 mg per 5 ml - Wastage claimable192.00	50 ml	✓ Klacid

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

### ⇒SA1857 Special Authority for Waiver of Rule

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

Either:

1 Atypical mycobacterial infection; or

ERYTHROMYCIN (AS LACTORIONATE)

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 ome prazole and amoxicillin as part of a triple therapy regimen.

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

Inj 1 g vial	10.00	1	✓ Erythrocin IV
ERYTHROMYCIN ETHYL SUCCINATE			
Tab 400 mg	35.82	100	✓ E-Mycin
Grans for oral liq 200 mg per 5 ml	6.53	100 ml	✓ E-Mycin
Grans for oral liq 400 mg per 5 mla) Up to 200 ml available on a PSO b) Wastage claimable	9.41	100 ml	✓ E-Mycin
ROXITHROMYCIN			
Tab 150 mg	13.19	50	Arrow- Roxithromycin
Tab 300 mg	25.00	50	✓ <u>Arrow-</u> <u>Roxithromycin</u>

	Subsidy		Fully	Brand or
	(Manufacturer's F	Price) Subs	idised	Generic
	\$	Per	1	Manufacturer
Penicillins				
AMOXICILLIN				
Cap 250 mg	54.00	500	✓ N	liro-Amoxicillin
a) Up to 30 cap available on a PSO				
b) Up to 10 x the maximum PSO quantity for RFPP				
Cap 500 mg	41.00	500	✓ N	liro-Amoxicillin
a) Up to 30 cap available on a PSO				
b) Up to 10 x the maximum PSO quantity for RFPP				
Grans for oral liq 125 mg per 5 ml	2.22	100 ml	✓ A	Iphamox 125
a) Up to 200 ml available on a PSO			_	
b) Wastage claimable				
Grans for oral liq 250 mg per 5 ml	2.81	100 ml	✓ A	Iphamox 250
a) Up to 300 ml available on a PSO			_	•
b) Up to 10 x the maximum PSO quantity for RFPP				
c) Wastage claimable				
Inj 250 mg vial	15.97	10	<b>✓</b>	oiamox
Inj 500 mg vial		10	<b>✓</b>	oiamox
Inj 1 g vial - Up to 5 inj available on a PSO	21.64	10	<b>✓</b> II	oiamox
AMOXICILLIN WITH CLAVULANIC ACID				
Tab 500 mg with clavulanic acid 125 mg - Up to 30 tab				
available on a PSO	1 59	10	<b>√</b> 0	uram Duo 500/125
Grans for oral liq amoxicillin 25 mg with clavulanic acid 6.25		10		diam bao ooo, ilo
per ml		100 ml	<b>✓</b> Δ	ugmentin
a) Up to 200 ml available on a PSO		100 1111	· <u>-</u>	agmentin
b) Wastage claimable				
Grans for oral liq amoxicillin 50 mg with clavulanic acid 12.5	ma			
per ml – Up to 200 ml available on a PSO		100 ml OP	J 1	moxiclav Devatis
per fili – op to 200 fili available off a 1 30		100 1111 01	• =	Forte
BENZATHINE BENZYLPENICILLIN				<u>r orto</u>
	40.04	1	./ 0	Senzetacil \$29
Inj 900 mg (1.2 million units) vial	43.24	ı	• •	enzetacii 529
Inj 900 mg (1.2 million units) in 2.3 ml syringe – Up to 5 inj	400.07	10	./ -	Sicillin LA
available on a PSO	432.37	10	• 6	ICIIIIN LA
BENZYLPENICILLIN SODIUM [PENICILLIN G]				
Inj 600 mg (1 million units) vial – Up to 5 inj available on a P	SO 16.50	10	✓ <u>S</u>	andoz
FLUCLOXACILLIN				
Cap 250 mg - Up to 30 cap available on a PSO		250	_	taphlex
Cap 500 mg - Up to 30 cap available on a PSO		500	_	taphlex
Grans for oral liq 25 mg per ml	4.89	100 ml	✓ <u>A</u>	<u>\FT</u>
a) Up to 200 ml available on a PSO				
b) Wastage claimable				
Grans for oral liq 50 mg per ml	5.89	100 ml	✓ A	<u>IFT</u>
a) Up to 200 ml available on a PSO				
b) Wastage claimable	,			
Inj 250 mg vial		10	_	lucloxin
Inj 500 mg vial		10		lucloxin
Inj 1 g vial – Up to 5 inj available on a PSO	6.00	5	<b>✓</b> <u>F</u>	lucil

	Subsidy		Fully	Brand or
	(Manufacturer's Price)	Subs	idised	Generic
	\$	Per	_	Manufacturer
PHENOXYMETHYLPENICILLIN (PENICILLIN V)				
Cap 250 mg - Up to 30 cap available on a PSO	7.68	50	1	Cilicaine VK
Cap 500 mg	13.72	50	1	Cilicaine VK
a) Up to 20 cap available on a PSO				
<li>b) Up to 2 x the maximum PSO quantity for RFPP</li>				
Grans for oral liq 125 mg per 5 ml	5.75	100 ml	1	AFT
a) Up to 200 ml available on a PSO				
b) Wastage claimable				
Grans for oral liq 250 mg per 5 ml	5.89	100 ml	1	AFT
a) Up to 300 ml available on a PSO				
b) Up to 2 x the maximum PSO quantity for RFPP				
c) Wastage claimable				
·, ·······				

## **Tetracyclines**

DO	XYCYCLINE			
*	Tab 100 mg - Up to 30 tab available on a PSO	64.43	500	Doxine
MΙ	NOCYCLINE 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 SA2513 below – Retail pharmacy
Tab 250 mg .......68.44 28

✓ Accord \$29

## ⇒SA2513 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.

Renewal 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, or noncompletion of second line therapy; and
- 2 For use only in combination with bismuth as part of a quadruple therapy regimen.

	Subsidy (Manufacturer's Price \$	e) : Per	Fully Subsidised	Brand or Generic Manufacturer
Other Antibiotics				
For topical antibiotics, refer to DERMATOLOGICALS, page ICIPROFLOXACIN  Recommended for patients with any of the following:  i) microbiologically confirmed and clinically significar ii) prostatitis; or iii) pyelonephritis; or iv) gonorrhoea.		n; or		
Tab 250 mg - Up to 5 tab available on a PSO	1.95	28	<b>√</b>	pca-Ciprofloxacin
Tab 500 mg - Up to 5 tab available on a PSO		28		pca-Ciprofloxacin
Tab 750 mg		28		pca-Ciprofloxacin
CLINDAMYCIN			-	
Cap hydrochloride 150 mg	4 94	24	<b>√</b> [	Dalacin C
Inj 150 mg per ml, 4 ml ampoule		10	_	Hameln
ing too mg por mi, i mi ampoulo	48.78		-	Dalacin C
Hameln Inj 150 mg per ml, 4 ml ampoule to be delisted 1 M			•	Juliuoiii O
COLISTIN SULPHOMETHATE – Retail pharmacy-Specialis Only if prescribed for dialysis or cystic fibrosis patient ar Inj 2 million iu, 10 ml vial	nd the prescription is end		٠.	Colomycin S29
ENTAMICIN SULPHATE			- '	Joinny 0
Inj 40 mg per ml, 2 ml vial – Subsidy by endorsement	36.70	5	✓ (	Cidomycin P/Free S29
Only if prescribed for a dialysis or cystic fibrosis pat endorsed accordingly.	ient or complicated urina	ry tract	infection a	
Inj 10 mg per ml, 1 ml ampoule - Subsidy by endorsem	ent95.00	5	✓ [	DBL Gentamicin
Only if prescribed for a dialysis or cystic fibrosis pat endorsed accordingly.	·	ry tract	infection a	nd the prescription i
Inj 40 mg per ml, 2 ml ampoule - Subsidy by endorsem	ent18.38	10		Gentamicin Amdipharm §29 Pfizer
	91.90	50		Gentamicin Noridem §29
Only if prescribed for a dialysis or cystic fibrosis pat endorsed accordingly.	ient or complicated urina	ry tract	infection a	
Gentamicin Amdipharm 👀 Inj 40 mg per ml, 2 ml ampou Gentamicin Noridem 👀 Inj 40 mg per ml, 2 ml ampoule t				
MOXIFLOXACIN - Special Authority see SA1740 below - F	Retail pharmacy	,		
No patient co-payment payable	p			
T. L. 100	40.00	_		

**⇒SA1740** Special Authority for Subsidy

Tab 400 mg .......42.00

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

Any of the following:

1 Both:

continued...

✓ Avelox

(Manufacturer's Price) Subsidised Generic \$ Per ✔ Manufacturer	Sub	sidy Full	y Brand or
\$ Per ✓ Manufacturer	(Manufactu		
		§ Per •	Manufacturer

continued...

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

Note: Indications marked with \* are unapproved indications.

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

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

All of the following:

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

Initial application — (Penetrating eye injury) only from an ophthalmologist. Approvals valid for 1 month where the patient requires prophylaxis following a penetrating eye injury and treatment is for 5 days only.

Note: Indications marked with \* are unapproved indications.

PAROMOMYCIN - Special Authority see SA1689 below - Retail pharmacy

### ⇒SA1689 Special Authority for Subsidy

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

Fither:

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

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

Either:

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

SODIUM FUSIDATE	[FUSIDIC ACID]
T   050	

SULFADIAZINE SODIUM - Special Authority see SA1331 below - Retail pharmacy

⇒SA1331 Special Authority for Subsidy

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

INFECTIONS - AGENTS FOR SYSTEMIC US	E			
	Subsidy (Manufacturer's Pr	ice) Sub	Fully Brand or sidised Generic Manufactu	rer
continued				
the following criteria: Any of the following:				
For the treatment of toxoplasmosis in patients with HIV for	r a neriod of 3 mo	nths: or		
2 For pregnant patients for the term of the pregnancy; or 3 For infants with congenital toxoplasmosis until 12 months		110, 01		
TOBRAMYCIN				
Inj 40 mg per ml, 2 ml vial - Subsidy by endorsement	15.50	5	✓ Tobramycin	(Viatris)
Only if prescribed for dialysis or cystic fibrosis patient an	d the prescription	is endorsed	accordingly.	
Solution for inhalation 60 mg per ml, 5 ml – Subsidy by	005.00	56 dose	/ Tahuamusim	DNM
endorsementa) Wastage claimable	395.00	56 dose	✓ Tobramycin	BININI
b) Only if prescribed for a cystic fibrosis patient and the	prescription is en	dorsed accor	dinaly.	
TRIMETHOPRIM	p p			
* Tab 300 mg - Up to 30 tab available on a PSO	27.83	50	✓ TMP	
TRIMETHOPRIM WITH SULPHAMETHOXAZOLE [CO-TRIMOX	AZOLE1			
* Tab trimethoprim 80 mg and sulphamethoxazole 400 mg - L	•			
to 30 tab available on a PSO	115.74	500	✓ <u>Trisul</u>	
* Oral liq 8 mg sulphamethoxazole 40 mg per ml – Up to 200				
available on a PSO	4.95	100 ml	✓ Deprim	
VANCOMYCIN – Subsidy by endorsement			for two atms and of Oli	
Only if prescribed for a dialysis or cystic fibrosis patient or for difficile following metronidazole failure and the prescription is			for treatment of Cit	ostriaium
Inj 500 mg vial		1	✓ Mylan	
Antifungals				
a) For topical antifungals refer to DERMATOLOGICALS, page 6	8			
b) For topical antifungals refer to GENITO URINARY, page 80				
FLUCONAZOLE				
Cap 50 mg	4.10	28	✓ Mylan	
Cap 150 mg		1	✓ <u>Mylan</u>	
Cap 200 mg	8.90	28	✓ Mylan	

Powder for oral suspension 10 mg per ml - Special Authority see SA1359 below – Retail pharmacy......129.02 ✓ Diflucan 35 ml

Wastage claimable

### **⇒SA1359** Special Authority for Subsidy

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

Both:

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

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

All of the following:

1 Patient is immunocompromised; and

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

continued...

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

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

Both:

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

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

All of the following:

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

#### ITRACONAZOI F

Cap 100 mg	15	✓ Itraconazole
		Cresent S29
		✓ Itrazole
27.32	60	✓ Itracap \$29
Oral liq 10 mg per ml - Special Authority see SA1322 below -		
Retail pharmacy141.80	150 ml OP	✓ Itraconazole  Kent \$29

(Itracap S29 Cap 100 mg to be delisted 1 December 2025)

### ⇒SA1322 Special Authority for Subsidy

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

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

#### KFTOCONAZOI F

Tab 200 mg - PCT	CBS	30	✓ Burel S29
		100	✓ Strides Shasun S29
			✓ Taro S29
			✓ Teva-
			Ketoconazole S29
NYSTATIN			
Tab 500,000 u	14.16	50	
	(17.09)		Nilstat
Cap 500,000 u	12.81	50	
	(15.47)		Nilstat
POSACONAZOLE - Special Authority see SA2383 on the next page	e – Retail ph	armacy	
Tab modified-release 100 mg	123.60	24	✓ Posaconazole Juno
Posaconazole Juno to be Principal Supply on 1 December 2	2025		
Oral lig 40 mg per ml	308.26	105 ml OP	✓ Devatis
Devatis to be Principal Supply on 1 December 2025			

	Subsidy	F	ully	Brand or
(N	Manufacturer's Price)	Subsid	ised	Generic
	\$	Per	1	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:

TERRINAFINE

- 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	8.97	84	✓ Deolate
VORICONAZOLE - Special Authority see SA2384 on the next page -	Retail pharma	су	
Tab 50 mg	.71.00	56	✓ Vttack
Tab 200 mg	263.00	56	✓ Vttack
Powder for oral suspension 40 mg per ml – Wastage			
claimable	523.22	70 ml	✓ Vfend

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

#### DOIII.

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

#### **Antimalarials**

PRIMAQUINE – Special Authority see SA1684	on the next page – Retail pharmacy		
Tab 15 mg	395.00	100	✓ Bayshore S29
· ·	400.00		✓ Sanofi
			Primaguine S29

Subsidy		Fully	Brand or
(Manufacturer's Price)		Subsidised	Generic
\$	Per	<b>✓</b>	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 Primaguine 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	✓ <u>Metronidamed</u>
Tab 400 mg - Up to 15 tab available on a PSO	4.29	21	✓ <u>Metronidamed</u>
Oral liq benzoate 200 mg per 5 ml	25.00	100 ml	✓ Flagyl-S
Suppos 500 mg	24.48	10	✓ Flagyl
ORNIDAZOLE			
Tab 500 mg	36.52	10	✓ Arrow-Ornidazole

## **Antituberculotics and Antileprotics**

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

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.

"	NFECTIONS - A	GEN	113 FUR	SYSTEMIC USE
	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Generic
DAPSONE – Retail pharmacy-Specialist				
a) No patient co-payment payable				
b) Prescriptions must be written by, or on the recommendation	on of, an infectious d	liseas	e physicia	n, clinical microbiologist or
dermatologist	000.50	400		_
Tab 25 mg Tab 100 mg		100 100		Dapsone Dapsone
3		100	•	Dapsone
ETHAMBUTOL HYDROCHLORIDE – Retail pharmacy-Specialis	it.			
<ul><li>a) No patient co-payment payable</li><li>b) Prescriptions must be written by, or on the recommendati</li></ul>	on of an infactious d	licase	a nhveicia	n clinical microhiologist or
respiratory physician	on or, an inicollous o	iiocao	c priyotola	ii, diiilidai iilididdididgist di
Tab 100 mg	85.73	100	1	EMB Fatol S29
Tab 400 mg		56	1	Myambutol S29
ISONIAZID – Retail pharmacy-Specialist				•
a) No patient co-payment payable				
b) Prescriptions must be written by, or on the recommendati	on of, an internal me	dicine	physiciar	, paediatrician, clinical
microbiologist, dermatologist or public health physician				
* Tab 100 mg		100		Isoniazid Teva S29
	327.41		•	Noumed Isoniazid
ISONIAZID WITH RIFAMPICIN - Retail pharmacy-Specialist				
No patient co-payment payable				
<ul> <li>Prescriptions must be written by, or on the recommendati microbiologist, dermatologist or public health physician</li> </ul>	on or, an internal me	aicine	e pnysiciar	, paediatrician, ciinicai
* Tab 100 mg with rifampicin 150 mg	89 82	100	1	Rifinah
* Tab 150 mg with rifampicin 300 mg		100		Rifinah
LINEZOLID – Special Authority see SA2234 below – Retail phar				
No patient co-payment payable	macy			
Tab 600 mg	194.60	10	✓	Zyvox
Oral liq 20 mg per ml	1,879.00	150 m		Zyvox
<b>⇒SA2234</b> Special Authority for Subsidy				
Initial application — (multi-drug resistant tuberculosis) from	any relevant practition	oner.	Approvals	valid for 18 months for
applications meeting the following criteria:				
Both:	2\. and			
<ol> <li>The person has multi-drug resistant tuberculosis (MDR-TE</li> <li>Ministry of Health's Tuberculosis Clinical Network has rev</li> </ol>		2260	and racom	mande linazolid as nart of
the treatment regimen.	ewed the individual t	Jase c	and recom	menus imezona as part or
PARA-AMINO SALICYLIC ACID – Retail pharmacy-Specialist				
a) No patient co-payment payable				
b) Prescriptions must be written by, or on the recommendati	on of, an infectious d	liseas	e specialis	st. clinical microbiologist or
respiratory physician	,		- opooranc	.,
Grans for oral liq 4 g sachet	280.00	30	✓	Paser S29
PROTIONAMIDE - Retail pharmacy-Specialist				
a) No patient co-payment payable				
b) Prescriptions must be written by, or on the recommendation	on of, an infectious d	liseas	e specialis	t, clinical microbiologist or
respiratory physician			_	
Tab 250 mg	305.00	100	•	Peteha S29

	INFECTIONS - AGENTS FOR SYSTEMIC US	<b>E</b>			
		Subsidy (Manufacturer's Price \$		Fully dised	
PY	RAZINAMIDE - Retail pharmacy-Specialist				
	a) No patient co-payment payable     b) Prescriptions must be written by, or on the recommendation recommendations and the recommendations of the recommendation of the recommendations of the recommendation of the recommendat	on of, an infectious	disease phys	siciar	n, clinical microbiologist or
*	respiratory physician Tab 500 mg	64.95	100	1	AFT-Pyrazinamide
	ABUTIN – Retail pharmacy-Specialist				· · · · · <b>,</b> · · · · · · · · · · · · · · · · · · ·
	a) No patient co-payment payable     b) Prescriptions must be written by, or on the recommendati gastroenterologist	on of, an infectious	disease phys	siciar	n, respiratory physician or
*	Cap 150 mg	353.71	30	1	Mycobutin
	AMPICIN – Subsidy by endorsement				<b>,</b>
	<ul> <li>a) No patient co-payment payable</li> <li>b) For confirmed recurrent Staphylococcus aureus infection antimicrobial based on susceptibilities and the prescriptio Retail pharmacy - Specialist. Specialist must be an interr paediatrician, or public health physician.</li> </ul>	n is endorsed accor nal medicine physici	dingly; can b	e wa nicrol	ived by endorsement - piologist, dermatologist,
	Cap 150 mg		100		Rifadin Rifadin
*	Oral liq 100 mg per 5 ml		60 ml	1	Rifadin Sanofi Rifadin
Α	ntivirals				
For	eye preparations refer to Eye Preparations, Anti-Infective Pre	parations, page 277			
Н	epatitis B Treatment				
	TECAVIR			_	
	Tab 0.5 mg		30	•	Entecavir (Rex)
LAI	MIVUDINE - Special Authority see SA1685 below - Retail ph		20	./	7otlom
	Tab 100 mg Oral lig 5 mg per ml		28 40 ml OP		<u>Zetlam</u> Zeffix
<b>33</b>	SA1685 Special Authority for Subsidy		10 1111 01		20111X
	ial application only from a relevant specialist or medical prac	titioner on the recon	nmendation	of a r	elevant specialist.
App	provals valid for 1 year where used for the treatment or preven	tion of hepatitis B.			
	newal from any relevant practitioner. Approvals valid for 2 year	ars where used for t	he treatment	or p	revention of hepatitis B.
TEI	NOFOVIR DISOPROXIL		مطلاعة المصاميان		
	Tenofovir disoproxil prescribed under endorsement for the treather antiretrovirals for the purposes of Special Authority SA2139.,		ciuaea in the	coui	nt of up to 4 subsidised
*	Tab 245 mg (300 mg as a maleate)		30	1	Tenofovir Disoproxil Viatris
	Tenofovir Disoproxil Viatris to be Principal Supply on 1 D	ecember 2025			
*	Tab 245 mg (300 mg as a fumarate)	13.80	30	✓	Ricovir S29
Н	erpesvirus Treatments				
AC	CLOVIR				
*	Tab dispersible 200 mg	2.05	25	✓	Lovir
*	Tab dispersible 400 mg		56		Lovir
*	Tab dispersible 800 mg	7.43	35		Lovir

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
VALACICLOVIR			4.	
Tab 500 mg		30	_	/aclovir
Tab 1,000 mg	17.78	30	<b>✓</b> <u>V</u>	/aclovir
VALGANCICLOVIR - Special Authority see SA2514 below - Ret Tab 450 mg		60	<b>✓</b> <u>v</u>	<u>/alganciclovir</u> <u>Viatris</u>

#### ⇒SA2514 Special Authority for Subsidy

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

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

#### Fither:

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

#### 2 Both:

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

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

## Both:

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

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

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.

Renewal — (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 re-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:

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

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

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

Both:

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

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

## **Hepatitis C Treatment**

#### GLECAPREVIR WITH PIBRENTASVIR - [Xpharm]

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

Tab 100 mg with pibrentasvir 40 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 http://www.pharmac.govt.nz/mayiret or:

The Coordinator, Hepatitis C Treatment Panel

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

Email: hepcpanel@pharmac.govt.nz

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

## **HIV Prophylaxis and Treatment**

EMTRICITABINE WITH TENOFOVIR DISOPROXIL - Subsidy by endorsement: can be waived by Special Authority see \$A2520 below

- a) Funding for emtricitabine with tenofovir disoproxil for use as PrEP or PEP, should be applied using Special Authority SA2520.
- 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 (when co-prescribed with other antiretrovirals) and percutaneous exposure): Prescription is deemed to be endorsed if emtricitabine with tenofovir disoproxil is co-prescribed with another antiretroviral subsidised under Special Authority SA2139 and the prescription is annotated accordingly by the Pharmacist or endorsed by the prescriber.
  - Note: Emtricitabine with tenofovir disoproxil prescribed under endorsement, for treatment of conditions approved via Special Authority SA2139 (antiretrovirals for confirmed HIV, prevention of maternal transmission, post-exposure prophylaxis following exposure to HIV and percutaneous exposure), is included in the count of up to 4 subsidised antiretrovirals, and counts as two antiretroviral medications, for the purposes of Special Authority SA2139, page 112 There is an approval process to become a named specialist to prescribe antiretroviral therapy in New Zealand. Further information is available on the Pharmac website.

* Tab 200 mg with tenofovir disoproxil 245 mg (300)	mg as a
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✓ Tenofovir Disoproxil **Emtricitabine Viatr** 

Tenofovir Disoproxil Emtricitabine Viatr to be Principal Supply on 1 December 2025

### ⇒SA2520 Special Authority for Subsidy

Initial application — (Pre-exposure prophylaxis) 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 — (Pre-exposure prophylaxis) 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 auidelines:

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

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

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prophylaxis is appropriate; 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:

- DOUI. \_\_
  - 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 appropriate; 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

#### **COVID-19 Treatments**

NIRMATRELVIR WITH RITONAVIR - PCT - Subsidy by endorsement

Subsidised for patients meeting access criteria for oral COVID-19 antiviral treatments (as on <a href="Pharmac's website">Pharmac's website</a>) and where the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed when supplying by Direct Provision under the provisions in Part I of Section A of the Pharmaceutical Schedule.

Tab 150 mg with ritonavir 100 mg	1,274.00	30 OP	1	Paxlovid
Tab 150 mg with ritonavir 100 mg, - [Xpharm]	0.00	30	1	Paxlovid (Pharmac)
(Paxlovid (Pharmac) Tab 150 mg with ritonavir 100 mg, to be	delisted 1 December	2025)		, ,

REMDESIVIR - PCT only

#### **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

Subsidy	F	ully	Brand or
(Manufacturer's Price)	Subsidi	sed	Generic
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applications meeting the following criteria:

Either:

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

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

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

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

Both:

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

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

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

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

Both:

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

	Subsidy (Manufacturer's Price \$	e) Per	Fully Subsidised	
continued where the patient has percutaneous exposure to blood known to	be HIV positive.			
Non-nucleosides Reverse Transcriptase Inhibit	ors			
EFAVIRENZ – Special Authority see SA2139 on page 112 – Ret Note: No new patients to be initiated on efavirenz.  Tab 600 mg		30	•	Efavirenz Milpharm S29
(Efavirenz Milpharm S29 Tab 600 mg to be delisted 1 November ETRAVIRINE – Special Authority see SA2139 on page 112 – Real Tab 200 mg	etail pharmacy 770.00 etail pharmacy 198.25	60 60 240 ml 0	/	Intelence  Nevirapine Viatris  Viramune
				Suspension
Nucleosides Reverse Transcriptase Inhibitors				
ABACAVIR SULPHATE – Special Authority see SA2139 on pag Tab 300 mg  ABACAVIR SULPHATE WITH LAMIVUDINE – Special Authority Note: abacavir with lamivudine (combination tablets) counts anti-retroviral Special Authority.	180.00 see SA2139 on pa as two anti-retrovir	60 age 112 al medio	– Retail pl cations for	the purposes of the
Tab 600 mg with lamivudine 300 mg	35.00	30	•	Abacavir/ Lamivudine Viatris
EFAVIRENZ WITH EMTRICITABINE AND TENOFOVIR DISOPE pharmacy Note: Efavirenz with emtricitabine and tenofovir disoproxil co anti-retroviral Special Authority Tab 600 mg with emtricitabine 200 mg and tenofovir disoprox	ounts as three anti-	retrovira	l medicati	ons for the purposes of the
245 mg (300 mg as a fumarate)		30	_	TEEVIR S29 Triovir S29
Tab 600 mg with emtricitabine 200 mg and tenofovir disoproze 245 mg (300 mg as a maleate)	106.88	30 1 (300 m		Viatris narate) to be delisted 1
January 2026) EMTRICITABINE – Special Authority see SA2139 on page 112 - Cap 200 mg	307.20	30	<b>✓</b>	Emtriva
LAMIVUDINE - Special Authority see SA2139 on page 112 - Re Tab 150 mg Oral liq 10 mg per ml	98.00	60 240 ml C		<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	y 100 200 ml C	_	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	<b>✓</b>	Lamivudine/ Zidovudine Viatris

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
Protease Inhibitors				
ATAZANAVIR SULPHATE - Special Authority see SA2139 on	page 112 – Retail phai	rmacy	/	
Cap 150 mg		60		Atazanavir Mylan
0 000	102.50			Atazanavir Viatris
Cap 200 mg		60	•	Atazanavir Viatris
Atazanavir Mylan Cap 150 mg to be delisted 1 November 2025	,			
DARUNAVIR – Special Authority see SA2139 on page 112 – R	, ,	00		Dawwa a sin Matria
Tab 400 mg		60 60		<u>Darunavir Viatris</u> Darunavir Viatris
Tab 600 mg				Darunavii viatris
OPINAVIR WITH RITONAVIR – Special Authority see SA2139		•		Laninavir/Ditanavir
Tab 100 mg with ritonavir 25 mg	150.00	60	•	Lopinavir/Ritonavir Mylan
Tab 200 mg with ritonavir 50 mg	875.00	120	_	Lopinavir/Ritonavir
rab 200 mg with monavir 50 mg		120	•	Mylan
RITONAVIR - Special Authority see SA2139 on page 112 - Re	stail nharmany			<u>,</u>
Tab 100 mg		30	1	Norvir
rab roomg			-	
Strand Transfer Inhibitors				
OOLUTEGRAVIR - Special Authority see SA2139 on page 112	2 – Retail pharmacy			
Tab 50 mg	1,090.00	30	1	Tivicay
DOLUTEGRAVIR WITH LAMIVUDINE - Special Authority see	SA2139 on page 112 -	- Ret	ail pharma	CV
Tab 50 mg with lamivudine 300 mg		30		Dovato
RALTEGRAVIR POTASSIUM - Special Authority see SA2139	on page 112 – Retail p	harm	acv	
Tab 400 mg		60	•	Isentress
Tab 600 mg	1,090.00	60	1	Isentress HD
Immune Modulators				
PEGYLATED INTERFERON ALFA-2A - Special Authority see	SA2034 below – Retai	l pha	rmacy	

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 135 mcg prefilled syringe	887.35	1	✓ Pegasys (S29) S29
Inj 180 mcg prefilled syringe	748.50	4	✓ Pegasys
	1,355.71		✓ Pegasys S29 S29

#### ⇒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:

Subsidy		Fully	Brand or	Т
(Manufacturer's Price)	S	ubsidised	Generic	
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All of the following:

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

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

All of the following:

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

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

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

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

All of the following:

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

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

Any of the following:

- 1 Patient has a cutaneous T cell lymphoma\*: or
- 2 All of the following:

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

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

All of the following:

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

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**

#### ⇒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> H	liprex
NITROFURANTOIN				
* Tab 50 mg - Up to 30 tab available on a PSO	22.20	100	✓ N	<u>lifuran</u>
* Tab 100 mg	37.50	100	✓ N	lifuran
* Cap modified-release 100 mg - Up to 15 cap available on a				
PSO	81.20	100	✓ N	lacrobid
NORFLOXACIN				
Tab 400 mg - Subsidy by endorsement	245.00	100	✓ A	rrow-Norfloxacin
Only if prescribed for a patient with an uncomplicated uri	nary tract infection th	at is u	ınresponsive	e to a first line agent or

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

Subsidy		Fully Brand or
(Manufacturer's	Price) Sub	osidised Generic
\$	Per	✓ Manufacturer
anticholinesterases		
inicholinesterases		
OSTIGMINE METILSULFATE		
Inj 2.5 mg per ml, 1 ml ampoule48.25	10	✓ Max Health
RIDOSTIGMINE BROMIDE		
Tab 60 mg50.28	100	✓ Mestinon
Ion-Steroidal Anti-Inflammatory Drugs		
CLOFENAC SODIUM		4-11.4
Tab EC 25 mg	50	✓ <u>Diclofenac Sandoz</u>
Tab 50 mg dispersible	20	✓ Voltaren D
Tab EC 50 mg2.19	50	✓ Diclofenac Sandoz
Tab long-acting 75 mg10.00	100	✓ Voltaren SR
Inj 25 mg per ml, 3 ml ampoule – Up to 5 inj available on a PSO 13.20	5	✓ Voltaren
Suppos 12.5 mg2.04	10	✓ Voltaren
Suppos 25 mg2.44	10	✓ Voltaren
Suppos 50 mg - Up to 10 supp available on a PSO4.22	10	✓ Voltaren
Suppos 100 mg7.00	10	✓ Voltaren
JPROFEN		
Tab 200 mg21.40	1.000	✓ Relieve
Tab long-acting 800 mg	30	✓ Ibuprofen SR BNM
Oral liq 20 mg per ml	200 ml	✓ Ethics
	200 1111	Lunes
TOPROFEN		
Cap long-acting 200 mg12.07	28	Oruvail SR
FENAMIC ACID		
Cap 250 mg	50	
(10.82)		Ponstan
0.50	20	· onotall
(7.50)	20	Ponstan
,		i onstan
PROXEN	500	✓ Noflam 250
Tab 250 mg		
Tab 500 mg	250	Noflam 500
Tab long-acting 750 mg	28	✓ Naprosyn SR 750
Tab long-acting 1 g11.50	28	✓ Naprosyn SR 1000
NOXICAM		
Tab 20 mg23.50	100	✓ Tilcotil
Inj 20 mg vial9.95	1	✓ AFT
SAIDs Other		
LECOXIB		
Cap 100 mg3.45	60	✓ Celecoxib Pfizer
3.60	00	✓ Celebrex
	30	✓ Celebrex ✓
	.30	▼ Celebrex
Cap 200 mg	•	✓ Celecoxib Pfizer

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

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

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

#### **CAPSAICIN**

#### **⇒SA1289** Special Authority for Subsidy

**Initial application** from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has osteoarthritis that is not responsive to paracetamol and oral non-steroidal anti-inflammatories are contraindicated.

## **Antirheumatoid Agents**

* Tab 200 mg	7.80	100	✓ <u>Ipca-</u> <u>Hydroxychloroquine</u>
LEFLUNOMIDE			
* Tab 10 mg	6.00	30	✓ Arava
* Tab 20 mg		30	✓ Arava
PENICILLAMINE			
Tab 125 mg	67.23	100	✓ D-Penamine
Tah 250 mg	110 12	100	✓ D-Penamine

## **Drugs Affecting Bone Metabolism**

### Alendronate for Osteoporosis

## ALENDRONATE SODIUM

ALENDRONATE SODIUM WITH COLECALCIFEROL	不	1ab 70 mg3.10	4	rosamax
	AL	ENDRONATE SODIUM WITH COLECALCIFEROL		

#### Other Treatments

DENOSUMAB - Special Authority see SA2441 below - Retail pharmacy

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

 Inj 120 mg per 1.7 ml vial
 500.00
 1
 ✓ Xgeva

 Inj 60 mg per 1 ml prefilled syringe
 250.00
 1
 ✓ Prolia

#### ⇒SA2441 Special Authority for Subsidy

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

All of the following:

- 1 The patient has established osteoporosis; and
- 2 Any of the following:
  - 2.1 History of one significant osteoporotic fracture demonstrated radiologically, with a documented T-Score less than or equal to -2.5, that incorporates BMD measured using dual-energy x-ray absorptiometry (DEXA); or
  - 2.2 History of one significant osteoporotic fracture, demonstrated radiologically, and either the patient is elderly, or

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

#### continued...

- densitometry scanning cannot be performed because of logistical, technical or pathophysiological reasons; or
- 2.3 History of two significant osteoporotic fractures demonstrated radiologically; or
- 2.4 Documented T-Score less than or equal to -3.0; or
- 2.5 A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm that incorporates BMD measured using DEXA; and
- 3 Any of the following:
  - 3.1 Bisphosphonates are contraindicated because the patient's creatinine clearance or eGFR is less than 35 mL/min; or
  - 3.2 The patient has experienced at least two symptomatic new fractures or a BMD loss greater than 2% per year, after at least 12 months' continuous therapy with a funded antiresorptive agent; or
  - 3.3 Bisphosphonates result in intolerable side effects; or
  - 3.4 Intravenous bisphosphonates cannot be administered due to logistical or technical reasons.

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

Both:

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

#### PAMIDRONATE DISODIUM

Inj 3 mg per ml, 10 ml vial	32.49	1	Pamisol
Inj 6 mg per ml, 10 ml vial	88.11	1	✓ Pamisol
Inj 9 mg per ml, 10 ml vial	94.34	1	✓ Pamisol
RALOXIFENE HYDROCHLORIDE - Special Authority see SA1	779 below – Retail	pharmacy	
* Tab 60 mg	53.76	28	<ul><li>Evista</li></ul>

# (Evista Tab 60 mg to be delisted 1 April 2026) 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.

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

#### continued...

- 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**

TERIPARATIDE - Special Authority see SA1139 below - Retail pharmacv 

✓ Teriparatide - Teva

✓ Risedronate Sandoz

### ⇒SA1139 Special Authority for Subsidy

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

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

#### Notes:

- a) The bone mineral density (BMD) measurement used to derive the T-score must be made using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable
- b) Antiresorptive agents and their adequate doses for the purposes of this Special Authority are defined as: alendronate sodium tab 70 mg or tab 70 mg with colecalciferol 5.600 iu once weekly; raloxifene hydrochloride tab 60 mg once daily; zoledronic acid 5 mg per year. If an intolerance of a severity necessitating permanent treatment withdrawal develops during the use of one antiresorptive agent, an alternate antiresorptive agent must be trialled so that the patient achieves the minimum requirement of 12 months' continuous therapy.
- c) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.
- d) A maximum of 18 months of treatment (18 cartridges) will be subsidised.

#### ZOLEDRONIC ACID

✓ Zoledronic Acid **Viatris** 

## Hyperuricaemia and Antigout

#### ALL OPURINOL

1.000 ✓ Ipca-Allopurinol Ipca-Allopurinol 500 BENZBROMARONE - Special Authority see SA1963 below - Retail pharmacy

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 tests.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
COLCHICINE  * Tab 500 mcg	6.00	100	•	Colgout
FEBUXOSTAT – Special Authority see SA2054 below – Retail ph Tab 80 mg Tab 120 mg	4.73	28 28		Febuxostat (Teva) Febuxostat (Teva)

**⇒SA2054** Special Authority for Subsidy

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

#### Both:

- 1 Patient has been diagnosed with gout; and
- 2 Any of the following:
  - 2.1 The patient has a serum urate level greater than 0.36 mmol/l despite treatment with allopurinol at doses of at least 600 mg/day and addition of probenecid at doses of up to 2 g per day or maximum tolerated dose; or
  - 2.2 The patient has experienced intolerable side effects from allopurinol such that treatment discontinuation is required and serum urate remains greater than 0.36 mmol/l despite use of probenecid at doses of up to 2 g per day or maximum tolerated dose: or
  - 2.3 The patient has renal impairment such that probenecid is contraindicated or likely to be ineffective and serum urate remains greater than 0.36 mmol/l despite optimal treatment with allopurinol (see Note); or
  - 2.4 The patient has previously had an initial Special Authority approval for benzbromarone for treatment of gout...

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

Both:

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

Inj 0.05 mg per ml, 1 ml ampoule - Subsidy by endorsement.........11.55

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

100

1

Pacifen

Lioresal Intrathecal

**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**

**BACLOFEN** 

### **Muscle Relaxants**

Subsidised only for use in a programmab caused intolerable side effects and the pr	le pump in patients where oral ar	, ,	ents have been ineffective or have
Inj 2 mg per ml, 5 ml ampoule – Subsidy by 6	endorsement490.91	10	✓ Sintetica Baclofen Intrathecal
Subsidised only for use in a programmab caused intolerable side effects and the pr			ents have been ineffective or have
DANTROLENE			
Cap 25 mg	145.77	100	✓ Dantrium S29 S29
Cap 50 mg	77.00	100	✓ Dantrium
ORPHENADRINE CITRATE			
Tah 100 mg	23 25	100	✓ Norflex

Subsidy (Manufacturer's Price) Fully Subsidised

Brand or Generic Manufacturer

## **Agents for Parkinsonism and Related Disorders**

Dopamine Agonists and Related Agent
-------------------------------------

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	✓ Entacapone Viatris
LEVODOPA WITH BENSERAZIDE	100	<u> </u>
	100	✓ Madopar Rapid
<ul> <li>* Tab dispersible 50 mg with benserazide 12.5 mg</li> <li>* Cap 50 mg with benserazide 12.5 mg</li> <li>13.75</li> </ul>	100	✓ Madopar 62.5
* Cap 100 mg with benserazide 12.5 mg	100	✓ Madopar 125
* Cap long-acting 100 mg with benserazide 25 mg	100	✓ Madopar HBS
* Cap 200 mg with benserazide 50 mg	100	✓ Madopar 250
LEVODOPA WITH CARBIDOPA	100	- maaopai 200
* Tab 100 mg with carbidopa 25 mg26.49	100	✓ Sinemet
* Tab long-acting 200 mg with carbidopa 50 mg	100	✓ Sinemet CR
* Tab 250 mg with carbidopa 25 mg	100	✓ Sinemet
	100	Silieniet
LEVODOPA WITH CARBIDOPA AND ENTACAPONE	400	/ Otalana
* Tab 50 mg with carbidopa 12.5 mg and entacapone 200 mg27.01	100	✓ <u>Stalevo</u>
* Tab 100 mg with carbidopa 25 mg and entacapone 200 mg34.18	100	✓ <u>Stalevo</u>
<ul> <li>Tab 150 mg with carbidopa 37.5 mg and entacapone 200 mg44.96</li> <li>Tab 200 mg with carbidopa 50 mg and entacapone 200 mg51.23</li> </ul>	100 100	<ul><li>✓ <u>Stalevo</u></li><li>✓ Stalevo</li></ul>
	100	Statevo
PRAMIPEXOLE HYDROCHLORIDE		
▲ Tab 0.25 mg	100	✓ Ramipex
Ramipex to be Principal Supply on 1 December 2025	100	/ Daminau
Tab 1 mg	100	✓ Ramipex
Ramipex to be Principal Supply on 1 December 2025		
RASAGILINE		
* Tab 1 mg53.50	30	✓ Azilect S29
ROPINIROLE HYDROCHLORIDE		
▲ Tab 0.25 mg4.05	84	✓ Ropin
▲ Tab 1 mg4.95	84	✓ Ropin
▲ Tab 2 mg6.48	84	✓ Ropin
▲ Tab 5 mg14.50	84	✓ Ropin
TOLCAPONE		
▲ Tab 100 mg	100	✓ Tasmar
•		

## **Anticholinergics**

BENZATROPINE MESYLA	۱L	
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LINZATTIOT INC MEDITATE			
Tab 2 mg	10.99	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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	I Generic
PROCYCLIDINE HYDROCHLORIDE Tab 5 mg	7.40	100		Kemadrin
Agents for Essential Tremor, Chorea and Relate	d Disorders			
RILUZOLE – Special Authority see SA1403 below – Retail pharm Wastage claimable Tab 50 mg	•	56	/	Rilutek
■ SA1403 Special Authority for Subsidy Initial application only from a neurologist or respiratory specialist following criteria: All of the following:	t. Approvals valid for	r 6 m	onths for a	applications meeting the
The patient has amyotrophic lateral sclerosis with disease     The patient has at least 60 percent of predicted forced vita     The patient has not undergone a tracheostomy; and     The patient has not experienced respiratory failure; and     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.				e initial application; and
Renewal from any relevant practitioner. Approvals valid for 18 m All of the following:  1 The patient has not undergone a tracheostomy; and 2 The patient has not experienced respiratory failure; and 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.	onths for applications	s mee	ting the fo	ollowing criteria:
TETRABENAZINE Tab 25 mg	126.02	112	•	Motetis
Anaesthetics	l I			
Local				
LIDOCAINE [LIGNOCAINE]  Gel 2%, tube - Subsidy by endorsement	dministration and the	30 ml e pres 10	cription is	Xylocaine 2% Jelly endorsed accordingly. Instillagel Lido

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

a) Up to 5 each available on a PSO

accordingly.

	Subsidy (Manufacturer's Price	a)	Fully Subsidised	
	\$	Per	oubsidised ✓	Manufacturer
LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE				
Oral (gel) soln 2%	44.00	200 ml	✓	Mucosoothe
Inj 1%, 5 ml ampoule - Up to 25 inj available on a PSO	15.00	25	✓	Lidocaine-Baxter
	17.50	50		
	(35.00)			Xylocaine
Inj 2%, 5 ml ampoule - Up to 5 inj available on a PSO	27.50	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	19.50	5	✓	Lidocaine-Baxter
Inj 2%, 20 ml vial - Up to 5 inj available on a PSO	14.00	5	✓	Lidocaine-Baxter
Inj 10%, 5 ml ampoule - Subsidy by endorsement	CBS	10	1	Xylocard 500 S29
Subsidised only for people receiving palliative care serving	ces where other and	algesic	agents ha	ven't been effective.

## **Topical Local Anaesthetics**

### ⇒SA0906 Special Authority for Subsidy

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

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

LIDOCAINE [LIGNOCAINE] - Special Authority see SA0906	above – Retail pharn	nacy	
Crm 4%	7.60	5 g OP	✓ LMX4
	30.00	30 g OP	✓ LMX4
LIDOCAINE [LIGNOCAINE] WITH PRILOCAINE - Special	Authority see SA0906	above – Reta	il pharmacy
Crm 2.5% with prilocaine 2.5%	45.00	30 g OP	✓ EMLA
Crm 2.5% with prilocaine 2.5% (5 g tubes)	45.00	5	EMLA

## **Analgesics**

For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, page 119

## **Non-opioid Analgesics**

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

## **NERVOUS SYSTEM**

	Subsidy (Manufacturer's Price) \$	) Sub Per	Fully sidised	Brand or Generic Manufacturer
PARACETAMOL				
Tab 500 mg - blister pack		1,000	✓ Pa	<u>icimol</u>
<ul> <li>a) Maximum of 300 tab per prescription; can be waived</li> <li>b) Up to 30 tab available on a PSO</li> <li>c)</li> </ul>	by endorsement			
Subsidy by endorsement for higher quantities i regular daily dosing for one month or greater, a annotate the prescription as endorsed where d     Maximum of 100 tab per dispensing for non-en (for non-endorsed patients), then dispense in rate 500 mg - bottle pack — Maximum of 300 tab per	and the prescription is lispensing history sup adorsed patients. If q	s annotate ports a lo juantities p	d accordi ng-term c prescribed	ingly. Pharmacists may condition. If for more than 100 tabs
prescription; can be waived by endorsement	17.92	1,000	_	oumed Paracetamol
<ol> <li>Subsidy by endorsement for higher quantities is avidaily dosing for one month or greater, and the presprescription as endorsed where dispensing history</li> <li>Maximum of 100 tab per dispensing for non-endornon-endorsed patients), then dispense in repeat d</li> </ol>	scription is annotated supports a long-term sed patients. If quan	I according n condition ntities pres	gly. Phar n. cribed for	macists may annotate the more than 100 tabs (for
Oral liq 120 mg per 5 ml	3.98	200 ml		aracetamol (Ethics)
<ul> <li>a) Maximum of 600 ml per prescription; can be waived</li> <li>b) Up to 200 ml available on a PSO</li> <li>c) Not in combination</li> <li>d)</li> </ul>	by endorsement			,
<ol> <li>Maximum of 200 ml per dispensing for non-end non-endorsed patients), then dispense in reper</li> <li>Subsidy by endorsement for higher quantities i regular daily dosing for one month or greater a Pharmacists may annotate the prescription as condition.</li> </ol>	at dispensing not exc s available for patient nd the prescription is endorsed where disp	eeding 20 ts with lon endorsed ensing his	0 ml per og g term co l or annot story supp	dispensing. Inditions who require ated accordingly. Inditions a long-term
<ul> <li>3) Note: 200 ml presentations of paracetamol oral Pharmacist) under the provisions in Part I of Set</li> <li>4) Note: Direct Provision by a pharmacist of up to conjunction with immunisation of a child under</li> </ul>	ection A o 200 ml permitted ur	nder the pi	rovisions	in Part I of Section A in
Oral liq 250 mg per 5 ml	3.35	200 ml	✓ Pa	
b) Up to 200 ml available on a PSO c) Not in combination				
Maximum of 200 ml per dispensing for non-end non-endorsed patients), then dispense in repeations 2) Subsidy by endorsement for higher quantities i regular daily dosing for one month or greater a	at dispensing not exc s available for patien	eeding 20 ts with lon	0 ml per o g term co	dispensing. Inditions who require

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

4) Note: Direct Provision by a pharmacist of up to 200 ml permitted under the provisions in Part I of Section A in

Pharmacist) under the provisions in Part I of Section A

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
* Suppos 250 mg * Suppos 500 mg		10 50		Gacet Gacet
Opioid Analgesics				
CODEINE PHOSPHATE - Safety medicine; prescriber may det	ermine dispensina fre	auen	CV	
Tab 15 mg		100		Noumed
Tab 30 mg	6.88	100	•	Noumed
Tab 60 mg  Noumed to be Principal Supply on 1 December 2025	13.89	100	•	Noumed
DIHYDROCODEINE TARTRATE  Tab long-acting 60 mg	9.20	60	•	DHC Continus
a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing fr Inj 50 mcg per ml, 2 ml ampoule Inj 50 mcg per ml, 10 ml ampoule Patch 12 mcg per hour Patch 12.5 mcg per hour Patch 50 mcg per hour Patch 75 mcg per hour	4.25 9.41 6.02 6.02 6.91 9.28 15.50	10 10 5 5 5 5		Boucher and Muir Boucher and Muir Fentanyl Sandoz Fentanyl Sandoz Fentanyl Sandoz Fentanyl Sandoz Fentanyl Sandoz
Patch 100 mcg per hour  Fentanyl Sandoz Patch 12.5 mcg per hour to be delisted 1 Nov  METHADONE HYDROCHLORIDE  a) Only on a controlled drug form		5	V	Fentanyl Sandoz
b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing fr Tab 5 mg		10 200 m 200 m 200 m 10		Methadone BNM Biodone Biodone Forte Biodone Extra Forte AFT
MORPHINE HYDROCHLORIDE  a) Only on a controlled drug form  b) No patient co-payment payable  c) Safety medicine; prescriber may determine dispensing from Oral light 1 mg per ml	equency	200 n		RA-Morph
Oral liq 2 mg per ml	23.55 28.20	200 m 200 m	nl 🗸 nl 🗸	RA-Morph

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

200 ml

✓ RA-Morph

	Subsidy		Fully	Brand or
	(Manufacturer's Price) \$	Per	Subsidised	Generic Manufacturer
MODDIJINE CIJI DIJATE	Ψ	1 01		Wandactarci
MORPHINE SULPHATE				
a) Only on a controlled drug form     b) No patient as payment payable.				
b) No patient co-payment payable	aguanav			
c) Safety medicine; prescriber may determine dispensing from		10	./	Sevredol
Tab immediate-release 10 mg		10 10		Sevredol
Tab immediate-release 20 mg Cap long-acting 10 mg		10		m-Eslon
Cap long-acting 10 mg		10		m-Esion
Cap long-acting 60 mg		10		m-Esion
Cap long-acting 100 mg		10		m-Esion
			_	
Oral liq 2 mg per ml		100 m	-	Wockhardt \$29
	29.80			Oramorph
			•	Oramorph CDC
			_	<b>S29</b> S29
Inj 5 mg per ml, 1 ml ampoule – Up to 5 inj available on a PS		5		Medsurge
Inj 10 mg per ml, 1 ml ampoule – Up to 5 inj available on a F		5		Medsurge
Inj 15 mg per ml, 1 ml ampoule – Up to 5 inj available on a F		5		Medsurge
Inj 30 mg per ml, 1 ml ampoule – Up to 5 inj available on a F	PSO7.28	5	✓	Medsurge
OXYCODONE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing from	eauencv			
Tab controlled-release 5 mg		20	1	Oxycodone Sandoz
Tab immediate-release 5 mg		100		Oxycodone Amneal
Tab controlled-release 10 mg		20		Oxycodone Sandoz
Tab immediate-release 10 mg		100		Oxycodone Amneal
Tab controlled-release 20 mg		20		Oxycodone Sandoz
Tab immediate-release 20 mg		100		Oxycodone Amneal
Tab controlled-release 40 mg		20		Oxycodone Sandoz
Tab controlled-release 80 mg		20		Oxycodone Sandoz
Oral lig 1 mg per ml		250 m		Oxycodone Lucis
Inj 10 mg per ml, 1 ml ampoule		5		Hameln
Inj 10 mg per ml, 2 ml ampoule		5		Hameln
Inj 50 mg per ml, 1 ml ampoule		5		Hameln
PARACETAMOL WITH CODEINE – Safety medicine; prescriber				
* Tab paracetamol 500 mg with codeine phosphate 8 mg	31.95	1,000	•	Paracetamol +
				Codeine (Relieve)
PETHIDINE HYDROCHLORIDE				
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>	equency			
Tab 50 mg	8.68	10	✓	Noumed Pethidine
Inj 50 mg per ml, 1 ml ampoule - Up to 5 inj available on a F	PSO 29.88	5	✓	DBL Pethidine
				Hydrochloride
Inj 50 mg per ml, 2 ml ampoule - Up to 5 inj available on a F	PSO30.72	5	1	DBL Pethidine
, , , , , , , , , , , , , , , , , , , ,				Hydrochloride
TRAMADOL HYDROCHLORIDE				-
Tab sustained-release 100 mg	1.95	20	1	Tramal SR 100
Tab sustained-release 150 mg		20		Tramal SR 150
Tab sustained-release 200 mg		20		Tramal SR 200
Cap 50 mg		100		Arrow-Tramadol
Oap 50 mg		100	•	ALLOW-HAIHAUUI

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

	Subsidy		Fully	Brand or
	(Manufacturer's Price)	Sub	sidised	Generic
	\$	Per	•	Manufacturer
Antidepressants				
Cyclic and Related Agents				
AMITRIPTYLINE - Safety medicine; prescriber may determine	dispensing frequency			
Tab 10 mg		100	✓ A	rrow-Amitriptyline
Tab 25 mg	1.99	100	✓ A	rrow-Amitriptyline
Tab 50 mg	3.14	100	✓ A	rrow-Amitriptyline
CLOMIPRAMINE HYDROCHLORIDE - Safety medicine; pres	criher may determine di	snensing	freguer	nev
Tab 25 mg		50		PO Clomipramine
Cap 10 mg		28	_	Clomipramine Teva
(Clomipramine Teva Cap 10 mg to be delisted 1 April 2026)		20	•	nompramme reva
, , ,				
${\tt DOSULEPIN} \ [{\tt DOTHIEPIN}] \ {\tt HYDROCHLORIDE} \ - {\tt Subsidy} \ {\tt by}$				
a) Safety medicine; prescriber may determine dispensing				
<ul><li>b) Subsidy by endorsement – Subsidised for patients who</li></ul>				
2019 and the prescription is endorsed accordingly. Ph		the pres	cription	as endorsed where there
exists a record of prior dispensing of dosulepin [dothier	oin] hydrochloride.			
Tab 75 mg	3.85	30	<b>✓</b> D	osulepin Viatris
Cap 25 mg	7.83	50	<b>✓</b> D	osulepin (
				Viatris S29
IMIPRAMINE HYDROCHLORIDE - Safety medicine; prescrib	er may determine disne	nsina fre	quency	
Tab 10 mg	,	50		ofranil
1 db 10 mg	10.96	100		ofranil
Tab 25 mg		28		nipramine
1 db 25 mg			- "	Crescent S29
	8.80	50	./ т	ofranil
			-	
NORTRIPTYLINE HYDROCHLORIDE - Safety medicine; pre-	•	•		
Tab 10 mg	2.24	50		llegron
	2.46	100		lorpress
Tab 25 mg		50		llegron
	6.29	180	✓ N	lorpress
Monoamine-Oxidase Inhibitors (MAOIs) - Non	Selective			
TRANYLCYPROMINE SULPHATE				
* Tab 10 mg	22 94	50	<b>√</b> p	arnate
74 Tub To Tilg		00		umuto
Monoamine-Oxidase Type A Inhibitors				
MOCLOBEMIDE				
* Tab 150 mg	23.60	60	✓ A	urorix
* Tab 300 mg	38.50	60	✓ A	urorix
Selective Serotonin Reuptake Inhibitors				
Coloration Coloration House to the Coloration Coloratio				
CITALOPRAM HYDROBROMIDE				
* Tab 20 mg	2.86	84	<b>✓</b> 0	Celapram

		Subsidy (Manufacturer's Price) \$	Sub Per	Fully sidised	
ECCITAL ODDAM		Ψ	rei		ivialiulactulei
ESCITALOPRAM  * Tab 10 mg		0.79	28	/	Ipca-Escitalopram
		1.07			Escitalopram (Ethics)
* Tab 20 mg		1.49	28	✓	Ipca-Escitalopram
FLUOXETINE HYDROCHLORIDE					
* Tab dispersible 20 mg, scored – S Subsidised by endorsement	Subsidy by endorsement	2.37	28	•	Fluox
1) When prescribed for a pa	atient who cannot swallow	whole tablets or caps	ules and	the pr	escription is endorsed
accordingly; or  2) When prescribed in a dai endorsed. Note: Tablet:	ily dose that is not a multip s should be combined with	•			•
* Cap 20 mg		3.50	90	1	Arrow-Fluoxetine
PAROXETINE					
* Tab 20 mg			30		Paxtine
(Parting Tab 00 may to be delicted that		4.98	90		Loxamine
(Paxtine Tab 20 mg to be delisted 1 Ma	arch 2026)				
SERTRALINE  * Tab 50 mg		0.00	30	1	Setrona
* Tab 30 mg			30		Setrona
,					
Other Antidepressants					
MIRTAZAPINE				_	
Tab 30 mg		2.34	30	•	Noumed
Noumed to be Principal Supply Tab 45 mg		3.10	30	1	Noumed
Noumed to be Principal Supply					
VENLAFAXINE	,				
* Cap 37.5 mg		8.29	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				
DIAZEPAM – Safety medicine; prescri Inj 5 mg per ml, 2 ml ampoule – S	ubsidy by endorsement		5	1	Hospira
<ul><li>a) Up to 5 inj available on a P</li><li>b) Only on a PSO</li></ul>	SO				
c) PSO must be endorsed "no			_	_	
Rectal tubes 5 mg - Up to 5 tube a	available on a PSO	54.58	5		Stesolid
PHENYTOIN SODIUM					
* Inj 50 mg per ml, 2 ml ampoule – l		104.58	5	1	Hospira
* Inj 50 mg per ml, 5 ml ampoule – U			-		L
PSO			5	✓	Hospira
(Hospira Inj 50 mg per ml, 2 ml ampoul	le to be delisted 1 February	/ 2026)			

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

		Subsidy		Fully	Brand or
		(Manufacturer's Price		sidised	Generic
_		<u> </u>	Per		Manufacturer
_	entrol of Enilopsy				
C	ontrol of Epilepsy				
CA	RBAMAZEPINE				
*	Tab 200 mg	14.53	100	✓ To	egretol
*	Tab long-acting 200 mg	16.98	100	✓ To	egretol CR
		33.96	200		egretol CR
*	Tab 400 mg	34.58	100	✓ To	egretol
*	Tab long-acting 400 mg	39.17	100		egretol CR
*	Oral liq 20 mg per ml		250 ml		egretol
CI	OBAZAM – Safety medicine; prescriber may determine dispe	nsing frequency			
٥٢	Tab 10 mg	. ,	50	✓ F	risium
<u> </u>	· ·		00	• • •	iioiuiii
CL	ONAZEPAM – Safety medicine; prescriber may determine dis		10l OD		
	Oral drops 2.5 mg per ml	7.38	10 ml OP	<b>V</b> K	ivotril
ΕT	HOSUXIMIDE				
	Cap 250 mg	78.89	56	✓ E	ssential
					Ethosuximide S29
		140.88	100	✓ Z	arontin
	Oral liq 250 mg per 5 ml	56.35	200 ml	✓ Z	arontin
(Es	ssential Ethosuximide S29 Cap 250 mg to be delisted 1 Dece				
•	BAPENTIN	,			
G,	Note: Not subsidised in combination with subsidised pregab	olin			
×	Cap 100 mg		100	✓ N	upentin
	. 5		100	_	upentin
*	Cap 400 mg		100	_	upentin
*	Cap 400 mg		100	<u> </u>	<u>upenun</u>
LA	COSAMIDE – Special Authority see SA2267 below – Retail pl	,			
•	Tab 50 mg		14		impat
▲	Tab 100 mg		14		impat
		200.24	56		impat
▲	Tab 150 mg		14		impat
		300.40	56		impat
_	Tab 200 mg	400.55	56	✓ V	impat

Cubaidy

Eully

Drand or

**⇒SA2267** Special Authority for Subsidy

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

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

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

**Renewal** from any relevant practitioner. Approvals valid for 24 months where the patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life compared with that prior to starting lacosamide treatment.

#### **LAMOTRIGINE**

$\blacktriangle$	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

	Subsidy		Fully	
	(Manufacturer's Pri \$	ce) Subs Per	sidised •	Generic Manufacturer
EVETIRACETAM	*			
Tab 250 mg	5.84	60	1	Everet
Tab 500 mg		60		Everet
Tab 750 mg		60		Everet
Tab 1,000 mg		60		Everet
Oral lig 100 mg per ml		300 ml OP		Levetiracetam-AFT
Inj 100 mg per ml, 5 ml vial		10		Levetiracetam-AFT
	00.00	10	•	LCVCtilacctain-Ai i
PHENOBARBITONE	00.4			
For phenobarbitone oral liquid refer Standard Formulae, pa	•		,	
Tab 15 mg	248.50	500	•	Noumed
			_	Phenobarbitone
Tab 30 mg	398.50	500	1	Noumed
				Phenobarbitone
PHENYTOIN SODIUM				
★ Tab 50 mg	75.00	200	1	Dilantin Infatab
Cap 30 mg	74.00	200	1	Dilantin
Cap 100 mg	37.00	200	1	Dilantin
Oral liq 30 mg per 5 ml	22.03	500 ml	1	Dilantin Paediatric
PREGABALIN				
Note: Not subsidised in combination with subsidised gabat	pentin			
Cap 25 mg		56	1	Lyrica
		00		Pregabalin Pfizer
€ Cap 75 mg	2 65	56		Lyrica
- Cap 10 mg		00		Pregabalin Pfizer
Cap 150 mg	4 01	56		Lyrica
· • • • • • • • • • • • • • • • • • • •		00		Pregabalin Pfizer
Cap 300 mg	7.38	56		Lyrica
		00		Pregabalin Pfizer
DIMIDONE				r regusamir inzer
RIMIDONE	07.05	400	,	Duimidono Olinost
€ Tab 250 mg	37.35	100	•	Primidone Clinect
SODIUM VALPROATE				
Tab 100 mg	13.65	100		Epilim Crushable
Tab 200 mg EC		100		Epilim
Tab 500 mg EC	52.24	100		Epilim
♦ Oral liq 200 mg per 5 ml	20.48	300 ml		Epilim S/F Liquid
				Epilim Syrup
k Inj 100 mg per ml, 4 ml	41.50	1	1	Epilim IV
STIRIPENTOL - Special Authority see SA2268 below - Retail	pharmacy			
Cap 250 mg		60	1	Diacomit

#### **⇒SA2268** Special Authority for Subsidy

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

Both:

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



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

continued...

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

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

#### **TOPIRAMATE**

▲ Tab 25 mg	11.07	60	<ul><li>Arrow-Topiramate</li></ul>
			✓ Topiramate Actavis
	26.04		✓ Topamax
▲ Tab 50 mg	18.81	60	✓ Arrow-Topiramate
•			✓ Topiramate Actavis
	44.26		✓ Topamax
▲ Tab 100 mg	31.99	60	✓ Arrow-Topiramate
-			✓ Topiramate Actavis
	75.25		✓ Topamax
▲ Tab 200 mg	55.19	60	✓ Arrow-Topiramate
			✓ Topiramate Actavis
	129.85		✓ Topamax
▲ Sprinkle cap 15 mg	20.84	60	✓ Topamax
▲ Sprinkle cap 25 mg		60	✓ Topamax
VIGABATRIN - Special Authority see SA2088 below - Reta	ail pharmacy		
▲ Tab 500 mg	119.30	100	✓ Sabril
▲ Powder for oral soln 500 mg per sachet	71.58	60	✓ Sabril

#### ⇒SA2088 Special Authority for Subsidy

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

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

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

#### Both:

- 1 The patient has demonstrated a significant and sustained improvement in seizure rate or severity and or quality of life; and
- 2 Either:
  - 2.1 Patient is receiving regular automated visual field testing (ideally every 6 months) on an ongoing basis for duration of treatment with vigabatrin; or
  - 2.2 It is impractical or impossible (due to comorbid conditions) to monitor the patient's visual fields...

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

## **Antimigraine Preparations**

For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, page 119

RIZATRIPTAN Tab orodispersible 10 mg	4.84	30	✓ Rizamelt
SUMATRIPTAN			
Tab 50 mg	14.41	90	<ul><li>Sumagran</li></ul>
Tab 100 mg	22.68	90	✓ Sumagran
Inj 12 mg per ml, 0.5 ml prefilled pen - Maximum of 10 inj per			
prescription	29.80	2 OP	<ul><li>Clustran</li></ul>
Clustran to be Principal Supply on 1 December 2025			

## **Prophylaxis of Migraine**

For Beta Adrenoceptor Blockers refer to CARDIOVASCULAR SYSTEM, page 49

**PIZOTIFEN** 

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

## **Antinausea and Vertigo Agents**

For Antispasmodics refer to ALIMENTARY TRACT, page 8

APREPITANT – Special Authority see SA0987 below – Retail p	oharmacy		
Cap 2 × 80 mg and 1 × 125 mg	21.90	3 OP	✓ Emend Tri-Pack

#### ⇒SA0987 Special Authority for Subsidy

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

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

$\neg$	ALHOTINE		ODIDE
$R \vdash I$		DIHYDROCH	(1211)-

* Tab 16 mg	100	✓ Serc
CYCLIZINE HYDROCHLORIDE		
Tab 50 mg0.66	10	✓ Nausicalm
CYCLIZINE LACTATE		
Inj 50 mg per ml, 1 ml ampoule - Up to 10 inj available on a		
PSO16.36	10	✓ Hameln
DOMPERIDONE		
* Tab 10 mg	100	<ul><li>Domperidone Viatris</li></ul>
Domperidone Viatris to be Principal Supply on 1 December 2025		
HYOSCINE HYDROBROMIDE		
* Inj 400 mcg per ml, 1 ml ampoule93.00	10	✓ Martindale S29
Patch 1 mg per 72 hours - Special Authority see SA1998 on		
the next page – Retail pharmacy	10	<ul><li>Scopolamine Transdermal</li></ul>

**System Viatris** 

135

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

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

### **⇒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	✓ <u>Metoclopramide</u> <u>Actavis 10</u>
* Inj 5 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO7.00 ONDANSETRON	10	✓ Baxter
* Tab 4 mg	50	✓ Periset
Tab disp 4 mg - Up to 10 tab available on a PSO	10	✓ Periset ODT
* Tab 8 mg	50	✓ Periset
Tab disp 8 mg - Up to 10 tab available on a PSO	10	✓ <u>Periset ODT</u>
* Tab 3 mg buccal	50	
(30.00)		Prochlorperazine maleate (Brown & Burk)
* 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

AMISULPRIDE – Safety medicine; prescriber may determine dispensing frequency  Tab 100 mg				
Tab 200 mg       14.47       60       ✓ Sulprix         Tab 400 mg       35.06       60       ✓ Sulprix         ARIPIPRAZOLE – Safety medicine; prescriber may determine dispensing frequency       10.50       30       ✓ Aripiprazole Sandoz         Tab 5 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 10 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 20 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 30 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 30 mg       10.50       30       ✓ Aripiprazole Sandoz         CHLORPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency         Tab 25 mg – Up to 30 tab available on a PSO       15.62       100       ✓ Largactil         Tab 100 mg – Up to 30 tab available on a PSO       36.73       100       ✓ Largactil	AMISULPRIDE - Safety medicine; prescriber may determin	ne dispensing frequency		
Tab 400 mg       35.06       60       ✓ Sulprix         ARIPIPRAZOLE – Safety medicine; prescriber may determine dispensing frequency       10.50       30       ✓ Aripiprazole Sandoz         Tab 5 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 10 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 20 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 30 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 30 mg       10.50       30       ✓ Aripiprazole Sandoz         CHLORPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency         Tab 25 mg – Up to 30 tab available on a PSO       15.62       100       ✓ Largactil         Tab 100 mg – Up to 30 tab available on a PSO       36.73       100       ✓ Largactil	Tab 100 mg	5.84	30	✓ Sulprix
ARIPIPRAZOLE — Safety medicine; prescriber may determine dispensing frequency  Tab 5 mg	Tab 200 mg	14.47	60	✓ Sulprix
Tab 5 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 10 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 15 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 20 mg       10.50       30       ✓ Aripiprazole Sandoz         Tab 30 mg       10.50       30       ✓ Aripiprazole Sandoz         CHLORPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency         Tab 25 mg – Up to 30 tab available on a PSO       15.62       100       ✓ Largactil         Tab 100 mg – Up to 30 tab available on a PSO       36.73       100       ✓ Largactil	Tab 400 mg	35.06	60	✓ Sulprix
Tab 10 mg	ARIPIPRAZOLE - Safety medicine; prescriber may determi	ine dispensing frequenc	у	
Tab 15 mg	Tab 5 mg	10.50	30	Aripiprazole Sandoz
Tab 20 mg	Tab 10 mg	10.50	30	✓ Aripiprazole Sandoz
Tab 30 mg	Tab 15 mg	10.50	30	✓ Aripiprazole Sandoz
CHLORPROMAZINE HYDROCHLORIDE — Safety medicine; prescriber may determine dispensing frequency  Tab 25 mg — Up to 30 tab available on a PSO	Tab 20 mg	10.50	30	✓ Aripiprazole Sandoz
Tab 25 mg − Up to 30 tab available on a PSO	Tab 30 mg	10.50	30	✓ Aripiprazole Sandoz
Tab 100 mg − Up to 30 tab available on a PSO36.73 100 ✓ Largactil	CHLORPROMAZINE HYDROCHLORIDE - Safety medicin	e; prescriber may deter	mine disper	nsing frequency
• 1	Tab 25 mg - Up to 30 tab available on a PSO	15.62	100	✓ Largactil
Inj 25 mg per ml, 2 ml − Up to 5 inj available on a PSO30.79	Tab 100 mg - Up to 30 tab available on a PSO	36.73	100	✓ Largactil
	Inj 25 mg per ml, 2 ml - Up to 5 inj available on a PSO	30.79	10	✓ Largactil

	Subsidy		Fully	Brand or
	(Manufacturer's Price)	) Sub Per	sidised	Generic Manufacturer
CLOZADINE Hamital pharmacy [LID4]	Ψ			
CLOZAPINE – Hospital pharmacy [HP4] Safety medicine; prescriber may determine dispensing frequer	nev			
Tab 25 mg	•	50	1	Clopine
140 20 mg		30		Clozaril
	13.37	100		Clopine
				Clozaril
Tab 50 mg	8.67	50	1	Clopine
ů	17.33	100	1	Clopine
Tab 100 mg	17.33	50	1	Clopine
			✓	Clozaril
	34.65	100	✓	Clopine
				Clozaril
Tab 200 mg	34.65	50	✓	Clopine
	69.30	100	✓	Clopine
Suspension 50 mg per ml	173.30	100 ml	✓	Versacloz
HALOPERIDOL – Safety medicine; prescriber may determine disp	pensina frequency			
Tab 500 mcg - Up to 30 tab available on a PSO		100	1	Serenace
Tab 1.5 mg - Up to 30 tab available on a PSO		100		Serenace
Tab 5 mg - Up to 30 tab available on a PSO		50	1	Serenace
<b>3</b> - 1,	29.72	100	1	Serenace
Oral liq 2 mg per ml - Up to 200 ml available on a PSO	23.84	100 ml	1	Serenace
Inj 5 mg per ml, 1 ml ampoule - Up to 5 inj available on a PSG		10	1	Serenace
EVOMEPROMAZINE - Safety medicine; prescriber may determ	ine dispensina frea	uencv		
Tab 25 mg (33.8 mg as a maleate)		100	1	Nozinan (Swiss)
Tab 25 mg as a maleate		100		Nozinan
Tab 100 mg (135 mg as a maleate)		100		Nozinan (Swiss)
Tab 100 mg as a maleate		100		Nozinan
EVOMEPROMAZINE HYDROCHLORIDE - Safety medicine; pro		mina diana	oncina f	fraguanov
Inj 25 mg per ml, 1 ml ampoule	•	10		Wockhardt
Wockhardt to be Principal Supply on 1 December 2025	20.20	10	•	Wockilalut
ITHIUM CARBONATE – Safety medicine; prescriber may detern			./	Driedel
Tab long-acting 400 mg		100		Priadel
Cap 250 mg		100	•	Douglas
DLANZAPINE – Safety medicine; prescriber may determine dispe			_	
Tab 2.5 mg		30		Zypine
Tab 5 mg		30	_	Zypine
Tab orodispersible 5 mg		28		Zypine ODT
Tab 10 mg		30		Zypine
Tab orodispersible 10 mg	2.89	28		Zypine ODT
PERICYAZINE - Safety medicine; prescriber may determine disp	ensing frequency			
Tab 2.5 mg	13.61	100	✓	Neulactil
Tab 10 mg	48.45	100	1	Neulactil



	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Generic
QUETIAPINE – Safety medicine; prescriber may determine disp Tab 25 mg		30	✓	Quetiapine Viatris \$29
	2.36	90	1	Quetapel
	13.11	500	•	Quetiapine
				Viatris S29
Tab 100 mg	6.40	90	✓	Quetapel
Tab 200 mg	10.97	90	✓	Quetapel
Tab 300 mg	15.83	90	✓	Quetapel
RISPERIDONE - Safety medicine; prescriber may determine di	spensing frequency			
Tab 0.5 mg	2.17	60	✓	Risperidone (Teva)
Tab 1 mg	2.44	60		Risperidone (Teva)
Tab 2 mg	2.72	60	✓	Risperidone (Teva)
Tab 3 mg	4.50	60	✓	Risperidone (Teva)
Tab 4 mg	6.25	60	✓	Risperdal
			✓	Risperidone (Teva)
Oral liq 1 mg per ml	10.29	30 m	<b>✓</b>	Risperon
ZIPRASIDONE - Safety medicine; prescriber may determine dis	spensing frequency			
Cap 20 mg		60	✓	Zusdone
Cap 40 mg	27.41	60	✓	Zusdone
Cap 60 mg	38.39	60	✓	Zusdone
Cap 80 mg	46.55	60	✓	Zusdone
ZUCLOPENTHIXOL HYDROCHLORIDE - Safety medicine; pre	escriber may determin	e disi	pensing fre	equency
Tab 10 mg	•	100		Clopixol

## **Depot Injections**

ARIPIPRAZOLE - Special Authority see SA2395 below -	Retail pharmacy		
Safety medicine; prescriber may determine dispensing	frequency		
Inj 300 mg vial	273.56	1	<ul> <li>Abilify Maintena</li> </ul>
Inj 400 mg vial	341.96	1	✓ Abilify Maintena
0.000			•

#### ⇒SA2395 Special Authority for Subsidy

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

#### Either:

- 1 Fither:
  - 1.1 The patient has had an initial Special Authority approval for risperidone depot injection, paliperidone depot injection or olanzapine depot injection; or
  - 1.2 All of the following:
    - 1.2.1 The patient has schizophrenia or other psychotic disorder; and
    - 1.2.2 The patient has received treatment with oral atypical antipsychotic agents but has been unable to adhere; and
    - 1.2.3 The patient has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in last 12 months; or
- 2 Patient has been unable to access olanzapine depot injection due to supply issues with olanzapine depot injection, or otherwise would have been started on olanzapine depot injection but has been unable to due to supply issues with olanzapine depot injection.

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

#### **NERVOUS SYSTEM**

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

continued...

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 or lnj 20 mg per ml, 1 ml – Up to 5 inj available on a PSO	13.14 20.90	5 7	' Fluanxol ' Fluanxol ' Fluanxol
		•	riudiixoi
HALOPERIDOL DECANOATE - Safety medicine; prescriber may d	etermine aispensin	g rrequency	
Inj 50 mg per ml, 1 ml – Up to 5 inj available on a PSO	28.39	5	' Haldol
Inj 100 mg per ml, 1 ml - Up to 5 inj available on a PSO	55.90	5	Haldol Concentrate
		•	' Haldol
			Decanoas \$29
OLANZAPINE - Special Authority see SA2313 below - Retail pharm	пасу		
a) Safety medicine; prescriber may determine dispensing frequi	ency		
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 Relprevv

## **⇒SA2313** Special Authority for Subsidy

Renewal from any relevant practitioner. Approvals valid for 12 months where the initiation of olanzapine depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of an atypical antipsychotic depot injection.

#### PALIPERIDONE - Special Authority see SA2396 below - Retail pharmacy

ng nequency		
194.25	1	✓ Invega Sustenna
271.95	1	✓ Invega Sustenna
357.42	1	✓ Invega Sustenna
435.12	1	✓ Invega Sustenna
435.12	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: Fither:

- 1 The patient has had an initial Special Authority approval for risperidone depot injection or olanzapine depot injection or aripiprazole depot injection; or
- 2 All of the following:
  - 2.1 The patient has schizophrenia or other psychotic disorder; and
  - 2.2 Has been unable to adhere to treatment using oral atypical antipsychotic agents; and
  - 2.3 Has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in last 12 months.

Renewal from any relevant practitioner. Approvals valid for 12 months where the initiation of paliperidone depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of an atypical antipsychotic depot injection.

### **NERVOUS SYSTEM**

-

#### ⇒SA2167 Special Authority for Subsidy

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

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

**Renewal** from any relevant practitioner. Approvals valid for 12 months where the initiation of paliperidone depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of an atypical antipsychotic depot injection.

RISPERIDONE – Special Authority see SA2397 below – Retail pharmacy

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

### ⇒SA2397 Special Authority for Subsidy

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

- 1 The patient has had an initial Special Authority approval for paliperidone depot injection or olanzapine depot injection or aripiprazole depot injection; or
- 2 All of the following:
  - 2.1 The patient has schizophrenia or other psychotic disorder; and
  - 2.2 Has not been able to adhere with treatment using oral atypical antipsychotic agents; and
  - 2.3 Has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in last 12 months.

**Renewal** from any relevant practitioner. Approvals valid for 12 months where the initiation of risperidone depot injection has been associated with fewer days of intensive intervention than was the case during a corresponding period of time prior to the initiation of an atypical antipsychotic depot injection.

ZUCLOPENTHIXOL DECANOATE - Safety medicine; prescriber may determine dispensing frequency

## **Anxiolytics**

BUSPIRONE HYDROCHLORIDE  * Tab 5 mg  * Tab 10 mg		100 100	✓ Buspirone Viatris ✓ Buspirone Viatris
CLONAZEPAM – Safety medicine; prescriber may determine dispens Tab 500 mcg Tab 2 mg	5.64	100 100	✓ Paxam ✓ Paxam
DIAZEPAM – Safety medicine; prescriber may determine dispensing Tab 2 mg Tab 5 mg	95.00	500 500	✓ <u>Arrow-Diazepam</u> ✓ <u>Arrow-Diazepam</u>
LORAZEPAM – Safety medicine; prescriber may determine dispensir Tab 1 mg Tab 2.5 mg	10.20	250 100	✓ <u>Ativan</u> ✓ <u>Ativan</u>

Subsidy (Manufacturer's Price) \$

Subsidised Per 🗸

Fully

Brand or Generic Manufacturer

## **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 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 approval for ocrelizumab and does not have primary progressive MS.

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

Renewal — (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 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.

DIMETHYL FUMARATE - Special Authority see SA2274 above - Retail pharmacy

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

Cap 120 mg	520.00	14	✓ Tecfidera
Cap 240 mg	2,000.00	56	Tecfidera

### **NERVOUS SYSTEM**

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic \$ Manufacturer FINGOLIMOD - Special Authority see SA2274 on the previous page - Retail pharmacy a) Wastage claimable b) Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted. Cap 0.5 mg......2,200.00 ✓ Gilenva GLATIRAMER ACETATE - Special Authority see SA2274 on the previous page - Retail pharmacy Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted. ✓ Copaxone INTERFERON BETA-1-ALPHA - Special Authority see SA2274 on the previous page - Retail pharmacy Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted. ✓ Avonex INTERFERON BETA-1-BETA - Special Authority see SA2274 on the previous page - Retail pharmacy Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted. ✓ Betaferon NATALIZUMAB - Special Authority see SA2274 on the previous page - Retail pharmacy Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted. ✓ Tvsabri TERIFLUNOMIDE - Special Authority see SA2274 on the previous page - Retail pharmacy a) Wastage claimable b) Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted. ✓ Teriflunomide Sandoz

## **Multiple Sclerosis Treatments - Other**

OCRELIZUMAB - Special Authority see SA2273 below - Retail pharmacy Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

✓ Ocrevus 

#### ⇒SA2273 Special Authority for Subsidy

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

#### 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

#### **NERVOUS SYSTEM**

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

continued...

- 1.4.5 Either:
  - 1.4.5.1 Each significant attack is severe enough to change either the EDSS or at least one of the Kurtze Functional System scores by at least 1 point; or
  - 1.4.5.2 Each significant attack is a recurrent paroxysmal symptom of multiple sclerosis (tonic seizures/spasms, trigeminal neuralgia, Lhermitte's symptom); and
- 1.5 Evidence of new inflammatory activity on an MRI scan within the past 24 months; and
- 1.6 Any of the following:
  - 1.6.1 A sign of that new inflammatory activity on MRI scanning (in criterion 5 immediately above) is a gadolinium enhancing lesion; or
  - 1.6.2 A sign of that new inflammatory activity is a lesion showing diffusion restriction; or
  - 1.6.3 A sign of that new inflammatory is a T2 lesion with associated local swelling; or
  - 1.6.4 A sign of that new inflammatory activity is a prominent T2 lesion that clearly is responsible for the clinical features of a recent attack that occurred within the last 2 years; or
  - 1.6.5 A sign of that new inflammatory activity is new T2 lesions compared with a previous MRI scan; or
- 2 Patient has an active Special Authority approval for either dimethyl fumarate, fingolimod, glatiramer acetate, interferon beta-1-alpha, interferon beta-1-beta, natalizumab or teriflunomide.

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

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

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

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

All of the following:

- 1 Diagnosis of primary progressive multiple sclerosis (PPMS) meets the 2017 McDonald criteria and has been confirmed by a neurologist; and
- 2 Patient has an EDSS 2.0 (score equal to or greater than 2 on pyramidal functions) to EDSS 6.5; and
- 3 Patient has no history of relapsing remitting multiple sclerosis.

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

## **Sedatives and Hypnotics**

MELATONIN - Special Authority see SA2523 below - Retail pharmacy

#### ⇒SA2523 Special Authority for Subsidy

**Initial application** only from a psychiatrist, paediatrician, neurologist, respiratory specialist or any relevant 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\*.



NERVOUS SYSTEM			
	Subsidy (Manufacturer's Price) \$	Fu Subsidise Per	
continued  Renewal only from a psychiatrist, paediatrician, neurologist, respirecommendation of a psychiatrist, paediatrician, neurologist or reapplications meeting the following criteria:  All of the following:			
<ol> <li>Patient is aged 18 years or under*; and</li> <li>Patient has demonstrated clinically meaningful benefit fror</li> <li>Patient has had a trial of funded modified-release melaton recurrence of persistent and distressing insomnia; and</li> <li>Funded modified-release melatonin is to be given at doses</li> <li>Note: Indications marked with * are unapproved indications.</li> </ol>	in discontinuation wit	hin the past 1	, ,
MIDAZOLAM – Safety medicine; prescriber may determine dispe	ensing frequency		
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		✓ Midazolam-Pfizer e only.
Inj 5 mg per ml, 1 ml plastic ampoule - Up to 10 inj available			,
on a PSO			Midazolam-Pfizer
On a PSO for status epilepticus use only. PSO must be Inj 5 mg per ml, 3 ml ampoule			e only. ∕ Midazolam-Baxter
Inj 5 mg per ml, 3 ml plastic ampoule — Up to 5 inj available		5	WIIGAZOIAIII-DAXIEI
a PSOa		5	✓ Midazolam-Pfizer
On a PSO for status epilepticus use only. PSO must be		epilepticus use	e only.
PHENOBARBITONE SODIUM - Special Authority see SA1386 b	oelow – Retail pharma	асу	
Inj 200 mg per ml, 1 ml ampoule	113.37	10	Max Health \$29
■ SA1386 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid the following criteria:  Both:	d without further rene	wal unless no	tified for applications meeting
<ul><li>1 For the treatment of terminal agitation that is unresponsive</li><li>2 The applicant is part of a multidisciplinary team working in</li></ul>		I	
TEMAZEPAM – Safety medicine; prescriber may determine disprate 10 mg		25	✓ <u>Normison</u>
ZOPICLONE – Safety medicine; prescriber may determine dispe Tab 7.5 mg		500	Zopiclone Actavis
Spinal Muscular Atrophy			
NUSINERSEN - PCT only - Special Authority see SA2174 below	v		

 Special Authority see SA2174 below Inj 12 mg per 5 ml vial ......120,000.00 ✓ Spinraza

## **⇒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

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

#### continued...

- 2 Patient is 18 years of age or under; and
- 3 Either
  - 3.1 Patient has experienced the defined signs and symptoms of SMA type I, II or IIIa prior to three years of age; or
  - 3.2 Both:
    - 3.2.1 Patient is pre-symptomatic; and
    - 3.2.2 Patient has three or less copies of SMN2.

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

#### All of the following:

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

## 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 ✓ Evrysdi

## ⇒SA2203 Special Authority for Subsidy

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

# All of the following:

- 1 Patient has genetic documentation of homozygous SMN1 gene deletion, homozygous SMN1 point mutation, or compound heterozygous mutation; and
- 2 Patient is 18 years of age or under; and
- 3 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:

Α

- 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



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

DEXAMFETAMINE SULFATE - Special Authority see SA2410 below - Retail pharmacy

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

### ⇒SA2410 Special Authority for Subsidy

Initial application — (ADHD in patients aged 5 years or over) only from a paediatrician, psychiatrist, medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid without further renewal unless notified for applications meeting the following criteria: All of the following:

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

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

Both:

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

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

LISDEXAMFETAMINE DIMESILATE - Special Authority see SA2415 below - Retail pharmacy

- a) Only on a controlled drug form

### ⇒SA2415 Special Authority for Subsidy

Initial application only from a paediatrician, psychiatrist, medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid without further renewal unless notified for applications meeting the following criteria:

Fither:

- 1 Patient is currently on treatment with lisdexamfetamine dimesilate and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 ADHD (Attention Deficit and Hyperactivity Disorder); and
  - 2.2 Diagnosed according to DSM-V or ICD 11 criteria; and
  - 2.3 Fither:
    - 2.3.1 Applicant is a paediatrician or psychiatrist; or
    - 2.3.2 Applicant is a medical practitioner or nurse practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing; and
  - 2.4 Any of the following:
    - 2.4.1 Patient is taking a currently subsidised formulation of atomoxetine or methylphenidate hydrochloride (extended-release) and has not received sufficient benefit or has experienced intolerable side effects; or
    - 2.4.2 Patient is taking a currently subsidised formulation of dexamfetamine sulfate (immediate-release) which has

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

continued...

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

## METHYLPHENIDATE HYDROCHLORIDE - Special Authority see SA2411 below - Retail pharmacy

- a) Only on a controlled drug form
- b) Safety medicine; prescriber may determine dispensing frequency ✓ Rubifen Tab immediate-release 10 mg......3.00 ✓ Rubifen 30 ✓ Ritalin ✓ Methylphenidate ER 30 - Teva ✓ Rubifen 30 ✓ Rubifen SR 30 30 ✓ Methylphenidate ER - Teva ✓ Methylphenidate ER 30 - Teva 30 ✓ Methylphenidate ER - Teva

# ⇒SA2411 Special Authority for Subsidy

Initial application — (ADHD in patients aged 5 years or over) only from a paediatrician, psychiatrist, medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid without further renewal unless notified for applications meeting the following criteria: All of the following:

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

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

Both:

1 ADHD (Attention Deficit and Hyperactivity Disorder) in patients under 5 years of age; and



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

continued...

2 Diagnosed according to DSM-IV or ICD 10 criteria.

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

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

METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE - Special Authority see SA2450 below - Retail pharmacy

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

b) carety meaning, processing may actomine arepending	,		
Tab extended-release 18 mg	58.96	30	<ul><li>Concerta</li></ul>
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		30	Ritalin LA
Cap modified-release 20 mg		30	Ritalin LA
Cap modified-release 30 mg		30	Ritalin LA
Cap modified-release 40 mg		30	Ritalin LA

# ⇒SA2450 Special Authority for Subsidy

Initial application — (ADHD) only from a paediatrician, psychiatrist, medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 All of the following:
  - 1.1 ADHD (Attention Deficit and Hyperactivity Disorder); and
  - 1.2 Diagnosed according to DSM-IV or ICD 10 criteria; and
  - 1.3 Either:
    - 1.3.1 Applicant is a paediatrician or psychiatrist; or
    - 1.3.2 Applicant is a medical practitioner or nurse practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing; and
  - 1.4 Either:
    - 1.4.1 Patient is taking a currently subsidised formulation of methylphenidate hydrochloride (immediate-release or sustained-release) which has not been effective due to significant administration and/or difficulties with adherence; or
    - 1.4.2 There is significant concern regarding the risk of diversion or abuse of immediate-release methylphenidate hydrochloride; or
- 2 Both:
  - 2.1 Patient meets the Special Authority criteria for SA2411 methylphenidate hydrochloride; and
  - 2.2 Patient is unable to access other methylphenidate hydrochloride presentations under Special Authority criteria SA2411 due to an out of stock (see note).

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

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

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

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

MODAFINIL - Special Authority see SA2451 on the next page - Retail pharmacy

### **NERVOUS SYSTEM**

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

# ⇒SA2451 Special Authority for Subsidy

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

#### Fither:

- 1 All of the following:
  - 1.1 The patient has a diagnosis of narcolepsy and has excessive daytime sleepiness associated with narcolepsy occurring almost daily for three months or more; and
  - 1.2 Either:
    - 1.2.1 The patient has a multiple sleep latency test with a mean sleep latency of less than or equal to 10 minutes and 2 or more sleep onset rapid eye movement periods; or
    - 1.2.2 The patient has at least one of: cataplexy, sleep paralysis or hypnagogic hallucinations; and
  - 1.3 Either:
    - 1.3.1 An effective dose of a subsidised formulation of methylphenidate or dexamfetamine has been trialled and discontinued because of intolerable side effects; or
    - 1.3.2 Methylphenidate and dexamfetamine are contraindicated; or
- 2 Both:
  - 2.1 Patient meets the Special Authority criteria for methylphenidate hydrochloride or methylphenidate hydrochloride extended-release for narcolepsy; and
  - 2.2 Patient is unable to access methylphenidate hydrochloride presentations due to an out of stock (see note).

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

# **Treatments for Dementia**

DONEPEZIL HYDROCHLORIDE			
* Tab 5 mg	3.70	84	✓ Ipca-Donepezil
* Tab 10 mg	5.50	84	✓ Ipca-Donepezil
RIVASTIGMINE - Special Authority see SA2524 below -	Retail pharmacy		
Patch 4.6 mg per 24 hour	49.40	30	Rivastigmine Patch
			<u>BNM 5</u>
Patch 9.5 mg per 24 hour	49.40	30	Rivastigmine Patch
			BNM 10

# **⇒SA2524** 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 is contraindicated to or has experienced intolerable side effects from donepezil tablets.

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

- 1 The treatment remains appropriate; and
- 2 The patient has demonstrated a significant and sustained benefit from treatment.



Subsidy	Fully	Brand or	
(Manufacturer's Price)	Subsidised	Generic	
` ¢ ′	Por ./	Manufacturar	

# **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

28 ✓ Buprenorphine Naloxone BNM

Tab sublingual 8 mg with naloxone 2 mg ......34.00 28 ✓ Buprenorphine Naloxone BNM

## ⇒SA1203 Special Authority for Subsidy

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

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

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

# **BUPROPION HYDROCHLORIDE**

30 Zyban

	Subsidy (Manufacturer's Price)	Suk	Fully	Brand or Generic
	\$	Per	1	Manufacturer
DISULFIRAM				
Tab 200 mg	236.40	100	✓ A	ntabuse
NALTREXONE HYDROCHLORIDE - Special Authority see	SA1408 below – Retail p	harmacy		
Tab 50 mg		30	_	altraccord

⇒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.

28

7

96

✓ Habitrol

✓ Habitrol

✓ Habitrol

**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.

Patch 14 mg - Up to 28 patch available on a PSO ......21.57

Patch 14 mg for direct distribution only - [Xpharm]......12.49

#### 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
- ✓ Habitrol 36 Gum 2 mg (Fruit) - Up to 204 piece available on a PSO ......23.02 204 ✓ Habitrol 96 ✓ Habitrol ✓ Habitrol 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 96 Gum 4 mg (Fruit) - Up to 204 piece available on a PSO ......25.98 204 ✓ Habitrol

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 96 **Habitrol** 

VARENICLINE TARTRATE - Special Authority see SA1845 below - Retail pharmacy

Gum 4 mg (Fruit) for direct distribution only - [Xpharm]...........23.87

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

Tab 0.5 mg × 11 and 1 mg × 42	.16.67	53 OP	Champix
Tab 1 mg		56	Champix

# ⇒SA1845 Special Authority for Subsidy

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



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

continued...

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

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

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

This includes the 4-week 'starter' pack.

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

# **Chemotherapeutic Agents**

# Alkylating Agents

BENDAMUSTINE HYDROCHLORIDE - PCT only - Spe	ecialist - Special Authority	see SA2398	3 below
Inj 25 mg vial	50.05	1	<ul> <li>Bendamustine</li> </ul>
			Sandoz
	77.00		✓ Ribomustin
Inj 100 mg vial	200.20	1	<ul> <li>Bendamustine</li> </ul>
			Sandoz
	308.00		✓ Ribomustin
Inj 1 mg for ECP	2.11	1 mg	✓ Baxter

# ⇒SA2398 Special Authority for Subsidy

Initial application — (CLL\*) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

- All of the following:
  - 1 The patient has chronic lymphocytic leukaemia requiring treatment; and
  - 2 Patient has ECOG performance status of 0-2; and
  - 3 Bendamustine is to be administered at a maximum dose of 100 mg/m² on days 1 and 2 every 4 weeks for a maximum of 6 cycles.

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

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

All of the following:

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

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

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

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

continued...

- 1.2 Bendamustine is to be administered in combination with obinutuzumab for a maximum of 6 cycles; or
- 2 Both:
  - 2.1 Patients have not received a bendamustine regimen within the last 12 months; and
  - 2.2 Either:
    - 2.2.1 Both:
      - 2.2.1.1 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and
      - 2.2.1.2 Patient has had a rituximab treatment-free interval of 12 months or more: or
    - 2.2.2 Bendamustine is to be administered as a monotherapy for a maximum of 6 cycles in rituximab refractory patients.

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

Initial application — (Hodgkin's lymphoma\*) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Patient has Hodgkin's lymphoma requiring treatment; and
- 2 Patient has a ECOG performance status of 0-2; and
- 3 Patient has received one prior line of chemotherapy; and
- 4 Patient's disease relapsed or was refractory following prior chemotherapy; and
- 5 Bendamustine is to be administered in combination with gemcitabine and vinorelbine (BeGeV) at a maximum dose of no greater than 90 mg/m2 twice per cycle, for a maximum of four cycles.

Note: Indications marked with \* are unapproved indications.

BUSULFAN - PCT - Retail pharmacy-Specialist

Boooli 7114 1 01 Hotali priamacy operiano			
Tab 2 mg	89.25	100	✓ Myleran
CARBOPLATIN - PCT only - Specialist			
Inj 10 mg per ml, 45 ml vial	25.73	1	✓ Carboplatin Accord
, ,			✓ DBL Carboplatin
			S29 S29
	32.59		✓ DBL Carboplatin
	48.50		✓ Carbaccord
Inj 1 mg for ECP		1 mg	✓ Baxter
		1 1119	Duxter
CARMUSTINE – PCT only – Specialist	710.00		/ DIONIL
Inj 100 mg vial	710.00	1	✓ BiCNU
Inj 100 mg for ECP	710.00	100 mg OP	✓ Baxter
CHLORAMBUCIL - PCT - Retail pharmacy-Specialist			
Tab 2 mg	29.06	25	<ul><li>Leukeran FC</li></ul>
CISPLATIN - PCT only - Specialist			
Inj 1 mg per ml, 50 ml vial	9.45	1	<ul> <li>Cisplatin Accord</li> </ul>
, -,	15.00		✓ Cisplatin Ebewe
Inj 1 mg per ml, 100 ml vial	18.90	1	✓ Cisplatin Accord
, -,	21.00		✓ Cisplatin Ebewe
	29.66		✓ DBL Cisplatin
Inj 1 mg for ECP	0.19	1 mg	✓ Baxter
CYCLOPHOSPHAMIDE			
Tab 50 mg - PCT - Retail pharmacy-Specialist	145.00	50	✓ Cyclonex
Inj 1 g vial – PCT – Retail pharmacy-Specialist		1	✓ Endoxan
, 5	127.80	6	✓ Cytoxan
Inj 2 g vial - PCT only - Specialist	95.06	1	✓ Endoxan
Inj 1 mg for ECP - PCT only - Specialist		1 mg	✓ Baxter

(	Subsidy Manufacturer's Price)	Sı	Fully ubsidised	
,	\$	Per	•	Manufacturer
FOSFAMIDE - PCT only - Specialist				
Inj 1 g	96.00	1	✓	Holoxan
Inj 2 g		1	✓	Holoxan
Inj 1 mg for ECP	0.10	1 mg	✓	Baxter
LOMUSTINE - PCT - Retail pharmacy-Specialist				
Cap 40 mg	880.00	20	✓	Medac S29
MELPHALAN				
Tab 2 mg - PCT - Retail pharmacy-Specialist	40.70	25	✓	Alkeran
Inj 50 mg - PCT only - Specialist	48.25	1	✓	Melpha
, , ,	67.80		✓	Alkeran
OXALIPLATIN - PCT only - Specialist				
Inj 100 mg vial	25.01	1	✓	Oxaliplatin Actavis
				100
	110.00		✓	Oxaliplatin Ebewe
Inj 5 mg per ml, 20 ml vial	33.35	1	✓	Alchemy Oxaliplatin
	46.32		✓	Oxaliplatin Accord
Inj 1 mg for ECP	0.35	1 mg	✓	Baxter
THIOTEPA - PCT only - Specialist				
Inj 15 mg vial	CBS	1	✓	Bedford S29
, ,			1	Max Health \$29
			1	THIO-TEPA S29
	398.00			Tepadina
Inj 100 mg vial	CBS	1		Max Health \$29
, 5	1,800.00	-		Tepadina
Antimetabolites				
AZACITIDINE - PCT only - Specialist - Special Authority see SA2 Inj 100 mg vial		1	/	Azacitidine Dr

		AZACITIDINE - PCT only - Specialist - Special Authority see SA2479 below
<ul> <li>Azacitidine Dr Reddy's</li> </ul>	1	Inj 100 mg vial50.00
✓ Baxter	1 mg	Inj 1 mg for ECP

# ⇒SA2479 Special Authority for Subsidy

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

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

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

	Subsidy		Fully	Brand or
	(Manufacturer's Price	)	Subsidised	I Generic
	\$	Per		Manufacturer
CALCIUM FOLINATE				
Tab 15 mg - PCT - Retail pharmacy-Specialist	135.33	10	•	DBL Leucovorin Calcium
Inj 3 mg per ml, 1 ml - PCT - Retail pharmacy-Specialist		5		Hospira
Inj 10 mg per ml, 5 ml vial - PCT - Retail pharmacy-Specia	list7.28	1	•	Calcium Folinate Sandoz
			•	Calcium Folinate Sandoz S29 S29
	112.20	5	✓	Eurofolic S29
Inj 50 mg - PCT - Retail pharmacy-Specialist	72.80	10	✓	Leucovorin
				Pharmacia S29
Inj 10 mg per ml, 10 ml vial - PCT only - Specialist	9.49	1	•	Calcium Folinate Sandoz
	163.35	5	✓	Eurofolic S29
Inj 100 mg - PCT only - Specialist	7.33	1	•	Calcium Folinate Ebewe
	94.90	10	•	Leucovorin Pharmacia S29
Inj 300 mg - PCT only - Specialist	21.55	1	•	Leucovorin DBL S29
	22.51		•	Calcium Folinate Ebewe
Inj 10 mg per ml, 35 ml vial - PCT only - Specialist	25.14	1	•	Calcium Folinate Sandoz
			•	Calcium Folinate Sandoz S29 S29
Inj 1 g - PCT only - Specialist	67.51	1	✓	Calcium Folinate Ebewe
Inj 10 mg per ml, 100 ml vial - PCT only - Specialist	72.00	1	•	Calcium Folinate Sandoz
	139.48		1	Eurofolic S29
Inj 1 mg for ECP - PCT only - Specialist	0.14	1 mg	•	Baxter
(Calcium Folinate Sandoz Inj 10 mg per ml, 5 ml vial to be deliste (Calcium Folinate Sandoz S29 S29 Inj 10 mg per ml, 5 ml vial to (Calcium Folinate Sandoz Inj 10 mg per ml, 10 ml vial to be delis (Calcium Folinate Ebewe Inj 100 mg to be delisted 1 November 2	o be delisted 1 Nove sted 1 November 202	mber 2	2025)	
(Calcium Folinate Ebewe Inj 100 mg to be delisted 1 November 2	,			
(Calcium Folinate Sandoz Inj 10 mg per ml, 35 ml vial to be delis		25)		
(Calcium Folinate Sandoz S29 S29 Inj 10 mg per ml, 35 ml vial		,	2025)	
(Calcium Folinate Ebewe Inj 1 g to be delisted 1 November 2025 (Calcium Folinate Sandoz Inj 10 mg per ml, 100 ml vial to be del.	5)		_0_0/	
CAPECITABINE - Retail pharmacy-Specialist				
Tab 150 mg	10.92	60	/	Capecitabine Viatris
Tab 500 mg		120	•	Capecitabine Viatris
CLADRIBINE - PCT only - Specialist				
Inj 1 mg per ml, 10 ml		1		Leustatin
Inj 10 mg for ECP	749.96 1	0 mg (	OP 🗸	Baxter

	Subsidy (Manufacturer's	Dring) Cuba	Fully Brand or sidised Generic
	(Manufacturer s	Price) Subs	✓ Manufacturer
YTARABINE			
Inj 20 mg per ml, 5 ml vial - PCT - Retail pharmacy-Spec	cialist472.00	5	✓ Pfizer
Inj 100 mg per ml, 20 ml vial - PCT - Retail			
pharmacy-Specialist	48.80	1	<ul> <li>Cytarabine DBL</li> </ul>
			✓ Pfizer
Inj 1 mg for ECP - PCT only - Specialist		10 mg	✓ Baxter
Inj 100 mg intrathecal syringe for ECP - PCT only - Spec	cialist94.40	100 mg OP	✓ Baxter
LUDARABINE PHOSPHATE			
Tab 10 mg - PCT - Retail pharmacy-Specialist	412.00	20	✓ Fludara Oral
Inj 50 mg vial - PCT only - Specialist	126.80	1	✓ Fludarabine
			Sagent S29
	634.00	5	✓ Fludarabine Ebewe
Inj 50 mg for ECP - PCT only - Specialist	126.80	50 mg OP	✓ Baxter
Fludarabine Sagent S29 Inj 50 mg vial to be delisted 1 Nove		3 -	
LUOROURACIL			
Inj 50 mg per ml, 20 ml vial – PCT only – Specialist	10.51	1	✓ Fluorouracil Accord
Inj 50 mg per ml, 50 ml vial – PCT only – Specialist		1	✓ Fluorouracil Accord
Inj 50 mg per ml, 100 ml vial – PCT only – Specialist		1	✓ Fluorouracil Accord
Inj 1 mg for ECP – PCT only – Specialist		100 mg	✓ Baxter
EMCITABINE HYDROCHLORIDE - PCT only - Specialist		100 mg	- Bunton
· ·	-\		
Inj 43.3 mg per ml (equivalent to 38 mg per ml gemcitabin 26.3 ml vial		1	✓ DBL Gemcitabine
Inj 1 g		1	✓ Gemcitabine Ebewe
Inj 1 mg for ECP		1 mg	✓ Baxter
, ,	0.02	ring	Daxiei
INOTECAN HYDROCHLORIDE - PCT only - Specialist			
Inj 20 mg per ml, 5 ml vial		1	✓ Accord
	71.44		✓ Irinotecan Actavis
	100.00		
	100.00		✓ Irinotecan-Rex
Inj 20 mg per ml, 25 ml vial		1	✓ Accord S29
Inj 1 mg for ECP	0.54	1 mg	✓ Baxter
ERCAPTOPURINE		_	
Tab 50 mg - PCT - Retail pharmacy-Specialist		25	✓ Puri-nethol
Puri-nethol to be Principal Supply on 1 December 202			
Oral suspension 20 mg per ml – Retail pharmacy-Specia			4
Special Authority see SA1725 below	428.00	100 ml OP	✓ Allmercap
			✓ Xaluprine S29

# ⇒SA1725 Special Authority for Subsidy

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

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

	Subsidy (Manufacturer's Price	1	Fully Subsidised	
	(Manufacturer's Price	Per	Jupainiae0 ✓	Manufacturer
IETHOTREXATE				
€ Tab 2.5 mg – PCT – Retail pharmacy-Specialist	7.80	90	1	Trexate
Tab 10 mg - PCT - Retail pharmacy-Specialist		90		Trexate
Inj 2.5 mg per ml, 2 ml - PCT - Retail pharmacy-Specialist.		5		Methotrexate DBL
Inj 7.5 mg prefilled syringe		1		Methotrexate
ing 7.5 mg promited dynnigo	20.17		•	Sandoz
Inj 10 mg prefilled syringe	19.09	1	1	Methotrexate
ing to mg promised syringe	10.00	'	•	Sandoz
F Inj 15 mg prefilled syringe	24.52	1	1	Methotrexate
ing 15 mg premied synnige	24.55	1	•	Sandoz
Ini 00 ma profilled evringe	16.64	1	./	
Inj 20 mg prefilled syringe	10.04	ı	•	Methotrexate
I lai OE ma profillad auringa	00.70	1		Sandoz Methetrovete
Inj 25 mg prefilled syringe	20.72	I	•	Methotrexate Sandaz
Ini 00 may availled a win as	FF 00		,	Sandoz
Inj 30 mg prefilled syringe	55.00	1	•	Methotrexate
		_		Sandoz
Inj 25 mg per ml, 2 ml vial – PCT – Retail pharmacy-Special	ıst30.00	5	•	Methotrexate DBL
			_	Onco-Vial
Inj 25 mg per ml, 20 ml vial – PCT – Retail pharmacy-Specia	alist45.00	1	/	DBL Methotrexate
				Onco-Vial
Inj 100 mg per ml, 10 ml – PCT – Retail pharmacy-Specialis	t25.00	1	•	Methotrexate Ebewe
Inj 100 mg per ml, 50 ml vial – PCT – Retail				
pharmacy-Specialist		1		Methotrexate Ebewe
Inj 1 mg for ECP - PCT only - Specialist		1 mg		Baxter
Inj 5 mg intrathecal syringe for ECP - PCT only - Specialist	19.06	5 mg O	P 🗸	Baxter
EMETREXED - PCT only - Specialist				
Inj 100 mg vial	8.99	1	✓	Pemetrexed-AFT
•	60.89		✓	Juno Pemetrexed
Inj 500 mg vial	29.99	1	✓	Pemetrexed-AFT
	217.77		✓	Juno Pemetrexed
Inj 1 mg for ECP	0.11	1 mg	✓	Baxter
HIOGUANINE - PCT - Retail pharmacy-Specialist				
Tab 40 mg	126.31	25	/	Lanvis
•				
Other Cytotoxic Agents				
MSACRINE - PCT only - Specialist				
Inj 50 mg per ml, 1.5 ml ampoule	4.736.00	6	1	Amsidine S29
Inj 75 mg	•	5		AmsaLyo S29
		J	•	/ iniouEy o ver
NAGRELIDE HYDROCHLORIDE – PCT – Retail pharmacy-Sp		100	,	A
Cap 0.5 mg	1,1/5.8/	100	•	Agrylin
RSENIC TRIOXIDE - PCT only - Specialist				
Inj 1 mg per ml, 10 ml vial		10		Phenasen
Inj 10 mg for ECP	481.70	I0 mg C	OP 🗸	Baxter
LEOMYCIN SULPHATE - PCT only - Specialist				
Inj 15,000 iu, vial	185.16	1	1	DBL Bleomycin
•				Sulfate
Inj 1,000 iu for ECP	14.32	1,000 i	u 🗸	Baxter
7 7		,	-	

	Subsidy		Fully	/ Brand or
	(Manufacturer's	Price) Subsi		
	\$	Per	1	Manufacturer
BORTEZOMIB - PCT only - Specialist - Special Authority see	SA2355 below			
Inj 3.5 mg vial		1	/	DBL Bortezomib
Inj 1 mg for ECP		1 mg		Baxter
⇒SA2355 Special Authority for Subsidy		9		
	at proofitioner	Annrovala valid w	ithai	ut further renewel unless
Initial application — (plasma cell dyscrasia) from any releval notified where the patient has plasma cell dyscrasia, not includin				
	ig waidenstioni	macrogiobulinae	IIIIa,	requiring treatment.
DACARBAZINE – PCT only – Specialist	70.44		,	DDI December les
Inj 200 mg vial		1		DBL Dacarbazine
Inj 200 mg for ECP	72.11	200 mg OP	•	Baxter
DACTINOMYCIN [ACTINOMYCIN D] - PCT only - Specialist			_	
Inj 0.5 mg vial	255.00	1		Cosmegen
Inj 0.5 mg for ECP	255.00	0.5 mg OP	/	Baxter
DAUNORUBICIN - PCT only - Specialist				
Inj 2 mg per ml, 10 ml	171.93	1	1	Pfizer
Inj 18.7 mg for ECP	171.93	18.7 mg OP	1	Baxter
Inj 20 mg for ECP	171.93	20 mg OP	1	Baxter
Inj 18.7 mg vial	171.93	1	1	Pfizer
(Pfizer Inj 2 mg per ml, 10 ml to be delisted 1 January 2026)				
(Baxter Inj 20 mg for ECP to be delisted 1 January 2026)				
DOCETAXEL - 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		1	1	Docetaxel
, , , , , , , , , , , , , , , , , , , ,				Accord S29
Inj 80 mg	195.00	1	/	Docetaxel Sandoz
Inj 1 mg for ECP		1 mg		Baxter
DOXORUBICIN HYDROCHLORIDE – PCT only – Specialist		9		Suntoi
Inj 2 mg per ml, 5 ml vial	10.00	1	_	Doxorubicin Ebewe
Inj 2 mg per ml, 25 ml vial		1		Doxorubicin Ebewe
inj 2 mg per mi, 23 mi viai	17.00	'		Arrow-Doxorubicin
Inj 2 mg per ml, 50 ml vial		1		Doxorubicin Ebewe
Inj 2 mg per ml, 100 ml vial		1		Arrow-Doxorubicin
11) 2 11g por 111, 100 111 1141	69.99	•		Doxorubicin Ebewe
Inj 1 mg for ECP		1 mg		Baxter
EPIRUBICIN HYDROCHLORIDE - PCT only - Specialist		3		
Inj 2 mg per ml, 5 ml vial	25.00	1	_	Epirubicin Ebewe
Inj 2 mg per ml, 25 ml vial		1		Epirubicin Ebewe
Inj 2 mg per ml, 100 ml vial		1		Epirubicin Ebewe
Inj 1 mg for ECP		1 mg		Baxter
		9		
ETOPOSIDE  Con FO mg	240.72	20	./	Vanasid
Cap 50 mg - PCT - Retail pharmacy-Specialist	340.73	20	•	Vepesid
Cap 100 mg - PCT - Retail pharmacy-Specialist	240.72	10	_	Vepesid
Wastage claimable		10	٠	vepesiu
Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specia	list 7.90	1	/	Rex Medical
Inj 1 mg for ECP - PCT only - Specialist		1 mg		Baxter
		y	-	
ETOPOSIDE PHOSPHATE – PCT only – Specialist	40.00	4	./	Etonophoo
Inj 100 mg (of etoposide base)		1 1 ma		Etopophos Baxter
ווון ו וווש (טו פנטףטפועם טמפט) וטו בטר		1 mg	•	DUALCI

<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
HYDROXYUREA [HYDROXYCARBAMIDE] - PCT - Retail phai Cap 500 mg		100	✓ <u>D</u> e	evatis_
IBRUTINIB - Special Authority see SA2480 below - Retail pharr	nacy			
Tab 140 mg	3,217.00	30	<b>✓</b> Im	nbruvica
Tab 420 mg	9,652.00	30	✓ Im	nbruvica

### ⇒SA2480 Special Authority for Subsidy

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

All of the following:

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

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

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

### IDARUBICIN HYDROCHLORIDE

109.74	1	✓ Zavedos
233.64	1	✓ Zavedos
25.77	1 mg	✓ Baxter
elow – Retail pharr	nacv	
76.92	21	✓ Lenalidomide
		Viatris
50.30	21	✓ Lenalidomide
		Viatris
62.13	21	✓ Lenalidomide
		Viatris
65.09	21	✓ Lenalidomide
		Viatris
	233.64 25.77 lelow – Retail pharr 76.92 50.30	233.64 125.77 1 mg  lelow – Retail pharmacy76.92 2150.30 2150.31 21

### ⇒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:

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

#### continued...

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

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

#### Both:

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

#### **MFSNA**

WEGNA			
Tab 400 mg - PCT - Retail pharmacy-Specialist	314.00	50	<ul><li>Uromitexan</li></ul>
Tab 600 mg - PCT - Retail pharmacy-Specialist	448.50	50	✓ Uromitexan
Inj 100 mg per ml, 4 ml ampoule - PCT only - Specia		15	✓ Uromitexan
Inj 100 mg per ml, 10 ml ampoule – PCT only – Speci		15	✓ Uromitexan
			✓ Baxter
Inj 1 mg for ECP - PCT only - Specialist	2.90	100 mg	Daxiei
MITOMYCIN C - PCT only - Specialist			
Inj 5 mg vial	517.65	1	✓ Accord S29
, 0			✓ Mitomycin
			(Fresenius
			Kabi) \$29
	F0C 00		. ,
	526.00		✓ Mitomycin
			(Sagent) S29
Inj 20 mg vial	1,250.00	1	✓ Teva
Inj 1 mg for ECP		1 mg	✓ Baxter
MITOZANTRONE - PCT only - Specialist			
	07.50	1	✓ Mitozantrone Ebewe
Inj 2 mg per ml, 10 ml vial		•	
Inj 1 mg for ECP	5.51	1 mg	✓ Baxter
NIRAPARIB - Special Authority see SA2325 below - Reta	il pharmacy		
Wastage claimable	,		
Tab 100 mg	13.393.50	84	✓ Zejula
Cap 100 mg		56	✓ Zejula
			,

# SA2325 Special Authority for Subsidy

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

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

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

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

continued...

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 Auth	ority see SA2163 below		
Tab 100 mg	3,701.00	56	✓ Lynparza
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 Fither:
  - 3.1 All of the following:
    - 3.1.1 Patient has newly diagnosed, advanced disease; and
    - 3.1.2 Patient has received one line\*\* of previous treatment with platinum-based chemotherapy; and
    - 3.1.3 Patient's disease must have experienced a partial or complete response to the first-line platinum-based regimen; or
  - 3.2 All of the following:
    - 3.2.1 Patient has received at least two lines\*\* of previous treatment with platinum-based chemotherapy; and
    - 3.2.2 Patient has platinum sensitive disease defined as disease progression occurring at least 6 months after the last dose of the penultimate line\*\* of platinum-based chemotherapy; and
    - 3.2.3 Patient's disease must have experienced a partial or complete response to treatment with the immediately preceding platinum-based regimen; and
    - 3.2.4 Patient has not previously received funded olaparib treatment; and
- 4 Treatment will be commenced within 12 weeks of the patient's last dose of the immediately preceding platinum-based regimen; and
- 5 Treatment to be administered as maintenance treatment; and
- 6 Treatment not to be administered in combination with other chemotherapy.

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

All of the following:

- 1 Treatment remains clinically appropriate and patient is benefitting from treatment; and
- 2 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

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

continued...

- 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 see SA1979 b	elow		
Inj 750 iu per ml, 5 ml vial		1	<ul><li>Oncaspar LYO</li></ul>

⇒SA1979 Special Authority for Subsidy

Initial application — (Acute lymphoblastic leukaemia) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria: Both:

- 1 The patient has newly diagnosed acute lymphoblastic leukaemia; and
- 2 Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol.

Initial application — (Lymphoma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months where the patient has lymphoma requiring L-asparaginase containing protocols (e.g. SMILE).

Renewal — (Acute lymphoblastic leukaemia) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The patient has relapsed acute lymphoblastic leukaemia; and
- 2 Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol.

PENTOSTATIN [DEOXYCOFORMYCIN] – PCT only – Speci		1	✓ Nipent S29
POMALIDOMIDE - Special Authority see SA2354 on the nex	t page – Retail pharr	nacy	
Cap 1 mg		14	✓ Pomolide
, -	71.18	21	✓ Pomolide
Cap 2 mg	94.90	14	✓ Pomolide
	142.35	21	✓ Pomolide
Cap 3 mg	142.35	14	✓ Pomolide
	213.53	21	✓ Pomolide
Cap 4 mg	189.81	14	✓ Pomolide
· -	284.71	21	✓ Pomolide

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

# ⇒SA2354 Special Authority for Subsidy

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

#### Both:

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

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

	50	✓ Natulan S29
	30	• Naturali •
	5	<ul> <li>✓ Temaccord</li> <li>✓ Temozolomide- Taro S29</li> </ul>
	5	✓ Temaccord
		✓ Apo-Temozolomide
35.98	5	✓ Temaccord
40.20		✓ Apo-Temozolomide
50.12	5	✓ Temaccord
	5	✓ Temaccord
	macy-Specialist980.00 - Retail pharmacy9.13	

### ⇒SA2275 Special Authority for Subsidy

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

**Initial application — (neuroendocrine tumours)** only from a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 Patient has been diagnosed with metastatic or unresectable well-differentiated neuroendocrine tumour\*: and
- 2 Temozolomide is to be given in combination with capecitabine; and
- 3 Temozolomide is to be used in 28 day treatment cycles for a maximum of 5 days treatment per cycle at a maximum dose of 200 mg/m² per day; and
- 4 Temozolomide to be discontinued at disease progression.

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

#### Both:

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

**Initial application** — (ewing's sarcoma) only from a relevant specialist. Approvals valid for 9 months where the patient has relapsed/refractory Ewing's sarcoma.

Renewal — (ewing's sarcoma) only from a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

#### Both:

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

Note: Indication marked with a \* is an unapproved indication. Temozolomide is not subsidised for the treatment of relapsed high grade glioma.

	Subsidy (Manufacturer's Price) \$	Per		Brand or Generic Manufacturer
THALIDOMIDE - Retail pharmacy-Specialist - Special Authority				
Cap 50 mg	378.00	28	<b>✓</b> T	halomid
Cap 100 mg	756.00	28	<b>√</b> T	halomid

⇒SA2356 Special Authority for Subsidy

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

**Renewal** from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has obtained a response from treatment during the initial approval period.

Notes: Prescription must be written by a registered prescriber in the thalidomide risk management programme operated by the supplier.

Maximum dose of 400 mg daily as monotherapy or in a combination therapy regimen.

#### **TRFTINOIN**

Cap 10 mg - PCT - Retail pharmacy-Specialist	479.50	100	<ul><li>Vesanoid</li></ul>
Wastage claimable			
VENETOCLAX - Retail pharmacy-Specialist - Special Authority see	SA2481 below		
Tab 14 × 10 mg, 7 × 50 mg, 21 × 100 mg	1,771.86	42 OP	✓ Venclexta
Tab 10 mg	13.68	2 OP	✓ Venclexta
Tab 50 mg	239.44	7 OP	✓ Venclexta
Tab 100 mg - Wastage claimable	8,209.41	120	✓ Venclexta

### ⇒SA2481 Special Authority for Subsidy

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

### All of the following:

- 1 Individual has chronic lymphocytic leukaemia requiring treatment; and
- 2 Individual has received at least one prior therapy for chronic lymphocytic leukaemia; and
- 3 Individual has not previously received funded venetoclax; and
- 4 The individual's disease has relapsed: and
- 5 Venetoclax to be used in combination with six 28-day cycles of rituximab commencing after the 5-week dose titration schedule with venetoclax; and
- 6 Individual has an ECOG performance status of 0-2.

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

### Both:

- 1 Treatment remains clinically appropriate and the individual is benefitting from and tolerating treatment; and
- 2 Venetoclax is to be discontinued after a maximum of 24 months of treatment following the titration schedule unless earlier discontinuation is required due to disease progression or unacceptable toxicity.

Initial application — (previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation\*) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

# All of the following:

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

Renewal — (previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation\*) from any relevant practitioner. Approvals valid for 6 months where the treatment remains clinically appropriate and the patient is benefitting from and tolerating treatment.

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

Initial application — (previously untreated acute myeloid leukaemia) from any relevant practitioner. Approvals valid for 6

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

continued...

months for applications meeting the following criteria:

#### Either

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

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

#### Notes:

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

### VINBLASTINE SULPHATE

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	<ul><li>DBL Vincristine Sulfate</li></ul>
Inj 1 mg for ECP - PCT only - Specialist12.60	1 mg	✓ Baxter
VINORELBINE		
Cap 20 mg32.10	1	✓ Vinorelbine Te Arai
Cap 30 mg42.80	1	✓ Vinorelbine Te Arai
Cap 80 mg80.00	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 - Specialist	1	✓ Navelbine S29 S29
210.00		✓ Vinorelbine Ebewe
Inj 1 mg for ECP - PCT only - Specialist	1 mg	✓ Baxter

# Protein-tyrosine Kinase Inhibitors

ALECTINIB – Retail pharmacy-Specialist – Special Authority see SA1870 below		
Wastage claimable		
Cap 150 mg7,935.00	224	✓ Alecensa

### ⇒SA1870 Special Authority for Subsidy

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

All of the following:

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

Renewal only from a medical oncologist or medical practitioner on the recommendation of a relevant specialist. Approvals valid

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

continued...

for 6 months for applications meeting the following criteria:

#### Roth:

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

# AXITINIB - Special Authority see SA2458 below - Retail pharmacy

Wastage claimable

 Tab 1 mg
 536.40
 28
 ✓ Inlyta

 Tab 5 mg
 2,682.00
 28
 ✓ Inlyta

# ⇒SA2458 Special Authority for Subsidy

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

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

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

# CRIZOTINIB - Special Authority see SA2459 below - Retail pharmacy

Cap 200 mg	7,250.00	60	Xalkori
Cap 250 mg	7,250.00	60	Xalkori

### **⇒SA2459** Special Authority for Subsidy

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

- 1 Patient has locally advanced or metastatic, unresectable, non-squamous non-small cell lung cancer; and
- 2 There is documentation confirming that the patient has a ROS1 rearrangement using an appropriate ROS1 test; and
- 3 Patient has ECOG performance score of 0-3; and
- 4 Baseline measurement of overall tumour burden is documented clinically and radiologically.

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

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

#### DABRAFENIB - Special Authority see SA2494 below - Retail pharmacy

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

### ⇒SA2494 Special Authority for Subsidy

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

# Either:

- 1 The individual is currently on treatment with dabrafenib and trametinib and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Fither:
    - 2.1.1 The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note a); or
    - 2.1.2 Both:
      - 2.1.2.1 The individual has received neoadjuvant treatment with a PD-1/PD-L1 inhibitor; and

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

continued...

- 2.1.2.2 Adjuvant treatment with dabrafenib is required; and
- 2.2 The individual has not received prior funded systemic treatment in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma: and
- 2.3 Treatment must be adjuvant to complete surgical resection; and
- 2.4 Treatment must be initiated within 13 weeks of surgical resection, unless delay is necessary due to post-surgery recovery (see note b); and
- 2.5 The individual has a confirmed BRAF mutation; and
- 2.6 Dabrafenib must be administered in combination with trametinib; and
- 2.7 The individual has ECOG performance score 0-2.

#### Notes:

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

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

Any of the following:

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

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

#### Either:

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

Subsi	idy F	ully Brand o	or
(Manufacture	er's Price) Subsidi	sed Generic	
\$	Per	<ul><li>Manufa</li></ul>	cturer

continued...

2.6.3.3 The individual did not experience disease recurrence within six months of completing adjuvant treatment with a BRAF/MEK inhibitor.

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

Both:

- 1 Any of the following:
  - 1.1 The individual's disease has had a complete response to treatment; or
  - 1.2 The individual's disease has had a partial response to treatment; or
  - 1.3 The individual has stable disease with treatment; and
- 2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period.

# DASATINIB - Special Authority see SA2385 below - Retail pharmacy

Wastag	م ا م	.:	hla
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Tab 20 mg	60	✓ Dasatinib-Teva
Tab 50 mg304.13	60	✓ Dasatinib-Teva
Tab 70 mg415.75	60	✓ Dasatinib-Teva

# ⇒SA2385 Special Authority for Subsidy

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

Any of the following:

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

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

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.

### ERLOTINIB - Retail pharmacy-Specialist - Special Authority see SA2422 below

Tab 100 mg	280.84	30	Alchemy
Tab 150 mg	484.24	30	✓ Alchemy

### ⇒SA2422 Special Authority for Subsidy

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

- 1 Patient has locally advanced or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
- 2 There is documentation confirming that the disease expresses activating mutations of EGFR; and
- 3 Any of the following:
  - 3.1 Patient is treatment naive; or
  - 3.2 Patient has received prior treatment in the adjuvant setting and/or while awaiting EGFR results; or

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

continued...

3.3 Both:

- 3.3.1 The patient has discontinued osimertinib or gefitinib due to intolerance; and
- 3.3.2 The cancer did not progress while on osimertinib or gefitinib.

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

GEFITINIB - Retail pharmacy-Specialist - Special Authority see SA2423 below

Tab 250 mg .......918.00

30 ✓ Iressa

### ⇒SA2423 Special Authority for Subsidy

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

- 1 Patient has locally advanced, or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
- 2 Any of the following:
  - 2.1 Patient is treatment naive; or
  - 2.2 Patient has received prior treatment in the adjuvant setting and/or while awaiting EGFR results; or
  - 2.3 Both:

IMATINIR MESILATE

- 2.3.1 The patient has discontinued osimertinib or erlotinib due to intolerance; and
- 2.3.2 The cancer did not progress whilst on osimertinib or erlotinib; and
- 3 There is documentation confirming that disease expresses activating mutations of EGFR.

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

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

### ⇒SA2442 Special Authority for Subsidy

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

#### Either:

- 1 Patient is currently on treatment with lenvatinib and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 The patient has locally advanced or metastatic differentiated thyroid cancer; and
  - 2.2 Either:
    - 2.2.1 Patient must have symptomatic progressive disease prior to treatment; or
    - 2.2.2 Patient must progressive disease at critical anatomical sites with a high risk of morbidity or mortality where local control cannot be achieved by other measures; and
  - 2.3 Any of the following:
    - 2.3.1 A lesion without iodine uptake in a RAI scan: or

Cap 10 mg......3,407.40

- 2.3.2 Receiving cumulative RAI greater than or equal to 600 mCi; or
- 2.3.3 Experiencing disease progression after a RAI treatment within 12 months; or
- 2.3.4 Experiencing disease progression after two RAI treatments administered within 12 months of each other; and
- 2.4 Patient has thyroid stimulating hormone (TSH) adequately supressed; and

continued...

30

✓ Lenvima

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

continued...

- 2.5 Patient is not a candidate for radiotherapy with curative intent; and
- 2.6 Surgery is clinically inappropriate; and
- 2.7 Patient has an ECOG performance status of 0-2.

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

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

All of the following:

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

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

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

Either:

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

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

MIDOSTAURIN - PCT only - Special Authority see \$A2342 below

Cap 25 mg.......10,981.00 56 **✓ Rydapt** 

# ⇒SA2342 Special Authority for Subsidy

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer	
NILOTINIB - Special Authority see SA2301 below - Retail pharm	nacy				
Wastage claimable					
Cap 150 mg	4,680.00	120	✓ Ta	asigna	
Cap 200 mg	6,532.00	120	✓ Ta	asigna	

# ⇒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.

		SIMERTINIB – Special Authority see SA2418 below – Retail pharmacy	OSIMEF
✓ Tagrisso	30	Tab 40 mg9,310.00	Tab
✓ Tagrisso	30	Tab 80 mg9,310.00	Tab

# ⇒SA2418 Special Authority for Subsidy

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

#### Fither:

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

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

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

Fither:

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

#### continued...

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

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

# PALBOCICLIB - Special Authority see SA2345 below - Retail pharmacy

Wastage claimable			
Tab 75 mg	1,200.00	21	Palbociclib Pfizer
•	4,000.00		✓ Ibrance
Tab 100 mg	1,200.00	21	Palbociclib Pfizer
•	4,000.00		✓ Ibrance
Tab 125 mg	1,200.00	21	Palbociclib Pfizer
•	4.000.00		✓ Ibrance

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

### ⇒SA2345 Special Authority for Subsidy

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

- 1 All of the following:
  - 1.1 Patient has unresectable locally advanced or metastatic breast cancer; and
  - 1.2 There is documentation confirming disease is hormone-receptor positive and HER2-negative; and
  - 1.3 Patient has an ECOG performance score of 0-2; and
  - 1.4 Either:
    - 1.4.1 Disease has relapsed or progressed during prior endocrine therapy; or
    - 1.4.2 Both:
      - 1.4.2.1 Patient is amenorrhoeic, either naturally or induced, with endocrine levels consistent with a postmenopausal or without menstrual-potential state; and
      - 1.4.2.2 Patient has not received prior systemic treatment for metastatic disease; and
  - 1.5 Treatment must be used in combination with an endocrine partner; and
  - 1.6 Patient has not received prior funded treatment with a CDK4/6 inhibitor; or
- 2 All of the following:
  - 2.1 Patient has an active Special Authority approval for ribociclib; and
  - 2.2 Patient has experienced a grade 3 or 4 adverse reaction to ribociclib that cannot be managed by dose reductions and requires treatment discontinuation; and
  - 2.3 Treatment must be used in combination with an endocrine partner; and
  - 2.4 There is no evidence of progressive disease since initiation of ribociclib.

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

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

	Subsidy (Manufacturer's Price)		Fully ubsidised	Brand or Generic	
	\$	Per	•	Manufacturer	
PAZOPANIB - Special Authority see SA2429 below - Retail ph	armacy				
Tab 200 mg	172.88	30	✓ Pa	azopanib Teva	
Tab 400 mg	464.00	30	✓ Pa	azopanib Teva	

⇒SA2429 Special Authority for Subsidy

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

Either:

- 1 All of the following:
  - 1.1 The patient has metastatic renal cell carcinoma of predominantly clear cell histology; and
  - 1.2 Either:
    - 1.2.1 The patient is treatment naive; or
    - 1.2.2 The patient has only received prior cytokine treatment; and
  - 1.3 The patient has an ECOG performance score of 0-2; and The patient has intermediate or poor prognosis defined as:
  - 1.4 Any of the following:
    - 1.4.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or
    - 1.4.2 Haemoglobin level < lower limit of normal: or
    - 1.4.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or
    - 1.4.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or
    - 1.4.5 Karnofsky performance score of less than or equal to 70; or
    - 1.4.6 2 or more sites of organ metastasis; and
  - 1.5 Pazopanib to be used for a maximum of 3 months; or
  - 2 All of the following:
    - 2.1 The patient has metastatic renal cell carcinoma; and
    - 2.2 The patient has discontinued sunitinib within 3 months of starting treatment due to intolerance; and
    - 2.3 The cancer did not progress whilst on sunitinib: and
    - 2.4 Pazopanib to be used for a maximum of 3 months.

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

RIBOCICLIB - Special Authority see SA2495 below - Retail pharmacy

Wastage claimable

✓ Kisqali	,	21	Tab 200 mg1,883.00
✓ Kisqali	,	42	3,767.00
✓ Kisqali	,	63	5,650.00

### ⇒SA2495 Special Authority for Subsidy

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

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

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

#### continued...

- 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 claimable			
Tab 5 mg	2,500.00	56	Jakavi
Tab 10mg	5,000.00	56	Jakavi
Tab 15 mg	5,000.00	56	Jakavi
Tah 20 mg	· ·	56	🗸 .lakavi

# ⇒SA1890 Special Authority for Subsidy

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

- 1 The patient has primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis; and
- 2 Either:
  - 2.1 A classification of risk of intermediate-2 or high-risk myelofibrosis according to either the International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or the Age-Adjusted DIPSS; or
  - 2.2 Both:
    - 2.2.1 A classification of risk of intermediate-1 myelofibrosis according to either the International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or the Age-Adjusted DIPSS; and
    - 2.2.2 Patient has severe disease-related symptoms that are resistant, refractory or intolerant to available therapy;
- 3 A maximum dose of 20 mg twice daily is to be given.

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

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 A maximum dose of 20 mg twice daily is to be given.

SUNITINIB - Special Authority see SA2452 on the ne	ext page - Retail pharmacy		
Cap 12.5 mg	103.11	28	Sunitinib Rex
	208.38		<ul> <li>Sunitinib Pfizer</li> </ul>
Cap 25 mg	203.15	28	Sunitinib Rex
, ,	416.77		<ul> <li>Sunitinib Pfizer</li> </ul>
Cap 50 mg	694.62	28	<ul> <li>Sunitinib Pfizer</li> </ul>

(Sunitinib Pfizer Cap 12.5 mg to be delisted 1 March 2026) (Sunitinib Pfizer Cap 25 mg to be delisted 1 March 2026)

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

# ⇒SA2452 Special Authority for Subsidy

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

Both:

- 1 The patient has metastatic renal cell carcinoma; and
- 2 The patient has not previously received funded sunitinib.

Initial application — (GIST) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 The patient has unresectable or metastatic malignant gastrointestinal stromal tumour (GIST); and
- 2 Either:
  - 2.1 The patient's disease has progressed following treatment with imatinib; or
  - 2.2 The patient has documented treatment-limiting intolerance, or toxicity to, imatinib.

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

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

Both:

The patient has responded to treatment or has stable disease as determined by Choi's modified CT response evaluation criteria as follows:

- 1 Any of the following:
  - 1.1 The patient has had a complete response (disappearance of all lesions and no new lesions); or
  - 1.2 The patient has had a partial response (a decrease in size of 10% or more or decrease in tumour density in Hounsfield Units (HU) of 15% or more on CT and no new lesions and no obvious progression of non measurable disease); or
  - 1.3 The patient has stable disease (does not meet criteria the two above) and does not have progressive disease and no symptomatic deterioration attributed to tumour progression; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

Note: It is recommended that response to treatment be assessed using Choi's modified CT response evaluation criteria (J Clin Oncol, 2007, 25:1753-1759). Progressive disease is defined as either: an increase in tumour size of 10% or more and not meeting criteria of partial response (PR) by tumour density (HU) on CT; or: new lesions, or new intratumoral nodules, or increase in the size of the existing intratumoral nodules.

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

All of the following:

- 1 The patient has unresectable or metastatic malignant gastrointestinal stromal (GIST); and
- 2 The patient is clinically benifiting from treatment and continued treatment remains appropriate; and
- 3 Sunitinib is to be discontinued at progression; and
- 4 The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector.

TRAMETINIB - Special Authority see SA2496 below - Retail pharmacy

 Tab 0.5 mg
 2,370.32
 30
 ✓ Mekinist

 Tab 2 mg
 9,481.29
 30
 ✓ Mekinist

⇒SA2496 Special Authority for Subsidy

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

Fither:

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

#### continued...

- 1 The individual is currently on treatment with dabrafenib and trametinib and met all remaining criteria prior to commencing treatment: or
- 2 All of the following:
  - 2.1 Either:
    - 2.1.1 The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note a); or
    - 2.1.2 Both:
      - 2.1.2.1 The individual has received neoadjuvant treatment with a PD-1/PD-L1 inhibitor; and
      - 2.1.2.2 Adjuvant treatment with trametinib is required; and
  - 2.2 The individual has not received prior funded systemic treatment in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma: and
  - 2.3 Treatment must be adjuvant to complete surgical resection; and
  - 2.4 Treatment must be initiated within 13 weeks of surgical resection, unless delay is necessary due to post-surgery recovery (see note b); and
  - 2.5 The individual has a confirmed BRAF mutation; and
  - 2.6 Trametinib must be administered in combination with dabrafenib; and
  - 2.7 The individual has ECOG performance score 0-2.

### Notes:

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

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

Any of the following:

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

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

### Either:

- 1 The individual is currently on treatment with dabrafenib and trametinib and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
  - 2.2 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
  - 2.3 The individual has ECOG performance score 0-2; and
  - 2.4 The individual has confirmed BRAF mutation: and
  - 2.5 Trametinib must be administered in combination with dabrafenib; and

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- 2.6 Any of the following:
  - 2.6.1 The individual has been diagnosed in the metastatic or unresectable stage III or IV setting; or
  - 2.6.2 The individual did not receive treatment in the adjuvant setting with a BRAF/MEK inhibitor; or
  - 2.6.3 All of the following:
    - 2.6.3.1 The individual received treatment in the adjuvant setting with a BRAF/MEK inhibitor; and
    - 2.6.3.2 The individual did not experience disease recurrence while on treatment with that BRAF/MEK inhibitor; and
    - 2.6.3.3 The individual did not experience disease recurrence within six months of completing adjuvant treatment with a BRAF/MEK inhibitor.

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

Both:

- 1 Any of the following:
  - 1.1 The individual's disease has had a complete response to treatment; or
  - 1.2 The individual's disease has had a partial response to treatment; or
  - 1.3 The individual has stable disease with treatment; and
- 2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period.

# Endocrine Therapy

For GnRH ANALOGUES - refer to HORMONE PREPARATIONS, Trophic Hormones, page 89

ABIRATERONE ACETATE - Retail pharmacy-Specialist - Special Authority see SA2118 below

Wastage claimable

Tab 250 mg .......4,276.19 120 **✓ Zytiga** 

### ⇒SA2118 Special Authority for Subsidy

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

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

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

All of the following:

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

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

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

### All of the following:

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

BICALUTAMIDE			
Tab 50 mg	4.18	28	✓ Binarex
FLUTAMIDE			
Tab 250 mg	. 107.55	90	✓ Prostacur S29
· ·	119.50	100	✓ Flutamin
FULVESTRANT - Retail pharmacy-Specialist - Special Authority see	SA1895 below		
Inj 50 mg per ml, 5 ml prefilled syringe1	,068.00	2	✓ Faslodex

# **⇒SA1895** Special Authority for Subsidy

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

### All of the following:

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

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

### All of the following:

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

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JOINLOIDE			
Inj 100 mcg per ml, 1 ml ampoule	32.71	5	✓ Max Health
, , ,			✓ Octreotide GH \$29
			✓ Sun Pharma S29
Inj 100 mcg per ml, 1 ml vial	48.50	5	✓ Omega S29
Inj 50 mcg per ml, 1 ml vial	27.58	5	✓ Omega S29
Inj 500 mcg per ml, 1 ml vial	113.10	5	✓ Omega S29
Inj 50 mcg per ml, 1 ml ampoule	27.58	5	✓ Max Health
			✓ Octreotide GH \$29
Inj 500 mcg per ml, 1 ml ampoule	113.10	5	Max Health
			✓ Octreotide GH S29
			✓ Sun Pharma S29

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	\$	Per	1	Manufacturer
TAMOXIFEN CITRATE				
* Tab 10 mg	15.00	60	✓ Table 1	amoxifen Sandoz
* Tab 20 mg	5.32	60	✓ Ta	amoxifen Sandoz

# **Long-acting Somatostatin Analogues**

### ⇒SA2445 Special Authority for Subsidy

**Initial application — (Malignant Bowel Obstruction)** from any relevant practitioner. Approvals valid for 2 months for applications meeting the following criteria:

All of the following:

- 1 The patient has nausea\* and vomiting\* due to malignant bowel obstruction\*; and
- 2 Treatment with antiemetics, rehydration, antimuscarinic agents, corticosteroids and analgesics for at least 48 hours has not been successful; and
- 3 Treatment to be given for up to 4 weeks.

Note: Indications marked with \* are unapproved indications.

**Renewal — (Malignant Bowel Obstruction)** from any relevant practitioner. Approvals valid for 3 months where the treatment remains appropriate and the patient is benefiting from treatment.

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

All of the following:

- 1 The patient has acromegaly; and
- 2 Either:
  - 2.1 Treatment with surgery and radiotherapy is not suitable or was unsuccessful; or
  - 2.2 Treatment is for an interim period while awaiting the beneficial effects of radiotherapy; and
- 3 Treatment with a dopamine agonist has been unsuccessful.

Renewal — (Acromegaly) from any relevant practitioner. Approvals valid for 2 years where iGF1 levels have decreased since starting treatment.

Note: In patients with acromegaly, treatment should be discontinued if IGF1 levels have not decreased 3 months after treatment. In patients treated with radiotherapy treatment should be withdrawn every 2 years, for 1 month, for assessment of remission. Treatment should be stopped where there is biochemical evidence of remission (normal IGF1 levels) following treatment withdrawal for at least 4 weeks

**Initial application — (pre-operative acromegaly)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has acromegaly; and
- 2 Patient has a large pituitary tumour, greater than 10 mm at its widest; and
- 3 Patient is scheduled to undergo pituitary surgery in the next six months.

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

Any of the following:

- 1 VIPomas and Glucagonomas for patients who are seriously ill in order to improve their clinical state prior to definitive surgery; or
- 2 Both:
  - 2.1 Gastrinoma: and
  - 2.2 Either:
    - 2.2.1 Surgery has been unsuccessful; or
    - 2.2.2 Patient has metastatic disease after treatment with H2 antagonist or proton pump inhibitors has been unsuccessful: or

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- 3 Both:
  - 3.1 Insulinomas; and
  - 3.2 Surgery is contraindicated or has not been successful; or
- 4 For pre-operative control of hypoglycaemia and for maintenance therapy; or
- 5 Both:
  - 5.1 Carcinoid syndrome (diagnosed by tissue pathology and/or urinary 5HIAA analysis); and
  - 5.2 Disabling symptoms not controlled by maximal medical therapy.

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

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

LANREOTIDE – Special Authority see SA2445 on the previous	<mark>ious page – Retail pha</mark> rn	nacy	
Inj 60 mg per 0.5 ml, 0.5 ml syringe	382.77	1	✓ Mytolac
			✓ Mytolac S29 S29
Inj 90 mg per 0.5 ml, 0.5 ml syringe	562.92	1	✓ Mytolac
Inj 120 mg per 0.5 ml, 0.5 ml syringe	646.70	1	✓ <u>Mytolac</u>
OCTREOTIDE LONG-ACTING - Special Authority see SAZ	2445 on the previous page	ge – Retail	pharmacy
Inj depot 10 mg prefilled syringe	438.40	1	✓ Sandostatin LAR
Inj depot 20 mg prefilled syringe	583.70	1	✓ Sandostatin LAR
Inj depot 30 mg prefilled syringe		1	✓ Sandostatin LAR

### **Aromatase Inhibitors**

ANIAOTDOZOLE

ANASTROZOLE		
* Tab 1 mg	4.39 30	✓ Anatrole
EXEMESTANE		
* Tab 25 mg	9.86 30	✓ Pfizer Exemestane
LETROZOLE		
* Tab 2.5 mg	4.36 28	✓ Accord S29
,	4.67 30	✓ Letrole

## **Immunosuppressants**

# **Cytotoxic Immunosuppressants**

AZATHIOPRINE		
* Tab 25 mg10.15	60	<ul><li>Azamun</li></ul>
* Tab 50 mg	100	<ul><li>Azamun</li></ul>
MYCOPHENOLATE MOFETIL		
Tab 500 mg35.90	50	<ul><li>Cellcept</li></ul>
Cap 250 mg35.90	100	<ul><li>Cellcept</li></ul>
Powder for oral liq 1 g per 5 ml - Subsidy by endorsement187.25	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.

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#### **Fusion Proteins**

FTANFRCEPT	- Special Authority	see SA2399 below	- Retail pharmacy

Inj 25 mg	690.00	4	<ul><li>Enbrel</li></ul>
Inj 25 mg autoinjector	690.00	4	<ul><li>Enbrel</li></ul>
Inj 50 mg autoinjector	1,050.00	4	<ul><li>Enbrel</li></ul>
Inj 50 mg prefilled syringe	· ·	4	Enbrel

### ⇒SA2399 Special Authority for Subsidy

Initial application — (adult-onset Still's disease) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

#### Either:

- 1 Both:
  - 1.1 Either:
    - 1.1.1 The patient has had an initial Special Authority approval for adalimumab for adult-onset Still's disease (AOSD); or
    - 1.1.2 The patient has been started on tocilizumab for AOSD in a Health NZ Hospital; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from adalimumab and/or tocilizumab; or
    - 1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or tocilizumab such that they do not meet the renewal criteria for AOSD: or
- 2 All of the following:
  - 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and
  - 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal anti-inflammatory drugs (NSAIDs) and methotrexate; and
  - 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

Renewal — (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

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

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

#### Either:

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for adalimumab for ankylosing spondylitis; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
    - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for ankylosing spondylitis; or
- 2 All of the following:
  - 2.1 Patient has a confirmed diagnosis of ankylosing spondylitis present for more than six months; and
  - 2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
  - 2.3 Patient has bilateral sacroiliitis demonstrated by plain radiographs, CT or MRI scan; and
  - 2.4 Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal

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anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and

- 2.5 Either:
  - 2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following Bath Ankylosing Spondylitis Metrology Index (BASMI) measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or
  - 2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender (see Notes); and
- 2.6 A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 6 on a 0-10 scale.

Notes: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure must be no more than 1 month old at the time of initial application.

Average normal chest expansion corrected for age and gender:

18-24 years - Male: 7.0 cm; Female: 5.5 cm 25-34 years - Male: 7.5 cm; Female: 5.5 cm 35-44 years - Male: 6.5 cm; Female: 4.5 cm 45-54 years - Male: 6.0 cm; Female: 5.0 cm 55-64 years - Male: 5.5 cm; Female: 4.0 cm 65-74 years - Male: 4.0 cm; Female: 4.0 cm 75+ years - Male: 3.0 cm; Female: 2.5 cm

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

All of the following:

- 1 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:

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- 2.3.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
- 2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or
- 2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

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

Both:

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

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

Fither:

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

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

Both:

- 1 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2 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.

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

Either:

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for adalimumab or secukinumab for psoriatic arthritis; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from adalimumab or secukinumab; or
    - 1.2.2 The patient has received insufficient benefit from adalimumab or secukinumab to meet the renewal criteria for adalimumab or secukinumab for psoriatic arthritis; or
- 2 All of the following:
  - 2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and
  - 2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
  - 2.3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and
  - 2.4 Either:
    - 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints; or
    - 2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
  - 2.5 Any of the following:
    - 2.5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
    - 2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or
    - 2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

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

All of the following:

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

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

All of the following:

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

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

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

#### Either:

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

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

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: Fither:

1 Both:

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- 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
  - 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:

- Botn:
  - 1 Any of the following:
    - 1.1 Both:
      - 1.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
      - 1.1.2 Either:
        - 1.1.2.1 Following each prior etanercept treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-treatment baseline value; or
        - 1.1.2.2 Following each prior etanercept treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value; or
    - 1.2 Both:
      - 1.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
      - 1.2.2 Either:
        - 1.2.2.1 Following each prior etanercept treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
        - 1.2.2.2 Following each prior etanercept treatment course the patient has a reduction of 75% or more in the

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skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or

- 1.3 Both:
  - 1.3.1 Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment; and
  - 1.3.2 Either:
    - 1.3.2.1 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or
    - 1.3.2.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing etanercept; and
- 2 Etanercept to be administered at doses no greater than 50 mg every 7 days.

Note: A treatment course is defined as a minimum of 12 weeks of etanercept treatment

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

All of the following:

- 1 Patient has undifferentiated peripheral spondyloarthritis\* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
- 3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day (or maximum tolerated dose); and
- 4 Patient has tried and not responded to at least three months of leflunomide at a dose of up to 20 mg daily (or maximum tolerated dose); and
- 5 Any of the following:
  - 5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
  - 5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour measured no more than one month prior to the date of this application; or
  - 5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

#### **Immune Modulators**

ANTITHYMOCYTE GLOBULIN (EQUINE) − PCT only − Specialist
Inj 50 mg per ml, 5 ml.......4,439.17 5 ✓ ATGAM

Amgevita

Amgevita

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BACILLUS CALMETTE-GUERIN (BCG) VACCINE – PCT only Subsidised only for bladder cancer.	- Specialist				
Inj 2-8 × 100 million CFU	149.37	1	<b>✓</b> 0	ncoTICE	
Inj 40 mg per ml, vial	182.45	3	<b>√</b> S	II-Onco-BCG S29	
Monoclonal Antibodies					
ADALIMUMAB (AMGEVITA) - Special Authority see SA2525 b	elow - Retail pharmac	y			
Inj 20 mg per 0.4 ml prefilled syringe	190.00	1	✓ A	mgevita	

⇒SA2525 Special Authority for Subsidy

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

Both:

- 1 The patient has severe Behcet's disease\* that is significantly impacting the patient's quality of life; and
- 2 Either:
  - 2.1 The patient has severe ocular, neurological, and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s); or
  - 2.2 The patient has severe gastrointestinal, rheumatological, and/or mucocutaneous symptoms and has not responded adequately to two or more treatments appropriate for the particular symptom(s).

Note: Indications marked with \* are unapproved indications.

Inj 40 mg per 0.8 ml prefilled pen .......375.00

**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

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- lesions have been present for at least 6 months from the time of initial diagnosis; or
- 2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; or
- 2.1.3 Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10; and
- 2.2 Patient has tried, but had an inadequate response to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin. or acitretin: and
- 2.3 A PASI assessment or DLQI assessment has been completed for at least the most recent prior treatment course but no longer than 1 month following cessation of each prior treatment course and is no more than 1 month old at the time of application.

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

Any of the following:

- 1 Both:
  - 1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced a 75% or more reduction in PASI score, or is sustained at this level, when compared with the pre-treatment baseline value; or
    - 1.2.2 The patient has a DLQI improvement of 5 or more, when compared with the pre-treatment baseline value; or
- 2 Both:
  - 2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
  - 2.2 Either:
    - 2.2.1 The patient has experienced reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
    - 2.2.2 The patient has experienced reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre treatment baseline value; or
- 3 Both:
  - 3.1 Patient had severe chronic localised genital or flexural 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 pvoderma gangrenosum\*: and

2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate) and has not received an adequate response.

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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- 1 Patient has active Crohn's disease; and
- 2 Any of the following:
  - 2.1 Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10; or
  - 2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
  - 2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
  - 2.4 Patient has an ileostomy or colostomy and has intestinal inflammation; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids.

Renewal — (Crohn's disease - adults) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 CDAI score has reduced by 100 points from the CDAI score, or HBI score has reduced by 3 points, from when the patient was initiated on adalimumab; or
- 2 CDAI score is 150 or less, or HBI is 4 or less; or
- 3 The patient has demonstrated an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed.

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

All of the following:

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

Renewal — (Crohn's disease - children) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab; or
- 2 PCDAI score is 15 or less; or
- 3 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed.

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

All of the following:

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

Renewal — (Crohn's disease - fistulising) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Fither:

- 1 The number of open draining fistulae have decreased from baseline by at least 50%; or
- 2 There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain.

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

Either:

- 1 The patient has had an initial Special Authority approval for infliximab for chronic ocular inflammation; or
- 2 Both:
  - 2.1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss: and
  - 2.2 Any of the following:
    - 2.2.1 Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven
    - 2.2.2 Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or
    - 2.2.3 Patient is under 8 years and treatment with steroids or methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or disease requires control to prevent irreversible vision loss prior to achieving a therapeutic dose of methotrexate.

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

Any of the following:

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

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

Either:

2 Both:

- 1 Patient has had an initial Special Authority approval for infliximab for severe ocular inflammation; or
- - 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 < 1/2+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
- 3 Following each 2 year treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.

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

Fither:

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#### 1 Both:

- 1.1 Patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; and
- 1.2 Either:
  - 1.2.1 The patient has experienced intolerable side effects; or
  - 1.2.2 The patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis; or
- 2 All of the following:
  - 2.1 Patient has a confirmed diagnosis of ankylosing spondylitis for more than six months; and
  - 2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
  - 2.3 Patient has bilateral sacroiliitis demonstrated by radiology imaging; and
  - 2.4 Patient has not responded adequately to treatment with two or more NSAIDs, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and
  - 2.5 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 BASMI measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or
    - 2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender; and
  - 2.6 A BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment and is no more than 1 month old at the time of application.

Renewal — (ankylosing spondylitis) from any relevant practitioner. Approvals valid for 2 years where treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less.

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

#### 1 Both:

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

Renewal — (Arthritis - oligoarticular course juvenile idiopathic) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

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

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

Either:

- 1 Both:
  - 1.1 Patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA); and
  - 1.2 Fither:
    - 1.2.1 Patient has experienced intolerable side effects; or
    - 1.2.2 Patient has received insufficient benefit to meet the renewal criteria for polyarticular course JIA; or
- 2 All of the following:
  - 2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
  - 2.2 Patient has had polyarticular course JIA for 6 months duration or longer; and
  - 2.3 Any of the following:
    - 2.3.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
    - 2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or
    - 2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

Renewal — (Arthritis - polyarticular course juvenile idiopathic) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

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

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

Either:

- 1 Both:
  - 1.1 Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects; or
    - 1.2.2 The patient has received insufficient benefit from to meet the renewal criteria for psoriatic arthritis; or
- 2 All of the following:
  - 2.1 Patient has had active psoriatic arthritis for six months duration or longer; and
  - 2.2 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
  - 2.3 Patient has tried and not responded to at least three months of sulfasalazine or leflunomide at maximum tolerated doses (unless contraindicated); and
  - 2.4 Either
    - 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
    - 2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
  - 2.5 Any of the following:
    - 2.5.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or

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- 2.5.2 Patient has an ESR greater than 25 mm per hour; or
- 2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

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

Fither:

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

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

Either:

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects; or
    - 1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for rheumatoid arthritis; or
- 2 All of the following:
  - 2.1 Patient has had rheumatoid arthritis (either confirmed by radiology imaging, or the patient is CCP antibody positive) for six months duration or longer; and
  - 2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
  - 2.3 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
  - 2.4 Patient has tried and not responded to at least three months of methotrexate in combination with sulfasalazine and hydroxychloroguine 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 (unless contraindicated); or
    - 2.5.2 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide (unless contraindicated) alone or in combination with methotrexate; and
  - 2.6 Either:
    - 2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
    - 2.6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip.

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

Either:

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

Initial application — (Still's disease - adult-onset (AOSD)) only from a rheumatologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Fither:

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- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for etanercept and/or tocilizumab for AOSD; and
  - 1.2 Either:
    - 1.2.1 Patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
    - 1.2.2 Patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab; or
  - 2 All of the following:
    - 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria; and
    - 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, NSAIDs and methotrexate; and
    - 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

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

All of the following:

- 1 Patient has active ulcerative colitis: and
- 2 Either:
  - 2.1 Patient's SCCAI score is greater than or equal to 4; or
  - 2.2 Patient's PUCAI score is greater than or equal to 20; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from prior therapy with immunomodulators and systemic corticosteroids; and
- 4 Surgery (or further surgery) is considered to be clinically inappropriate.

Renewal — (ulcerative colitis) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 The SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on biologic therapy; or
- 2 The PUCAI score has reduced by 10 points or more from the PUCAI score when the patient was initiation on biologic therapy.

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

All of the following:

- 1 Patient has undifferentiated peripheral spondyloarthritis\* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 2 Patient has tried and not responded to at least three months of each of methotrexate, sulfasalazine and leflunomide, at maximum tolerated doses (unless contraindicated); and
- 3 Any of the following:
  - 3.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
  - 3.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; or
  - 3.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Note: Indications marked with \* are unapproved indications

Renewal — (undifferentiated spondyloarthritis) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

1 Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or

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2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response in the opinion of the treating physician.

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

All of the following:

- 1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
- 2 Patient has axial inflammatory pain for six months or more; and
- 3 Patient is unable to take NSAIDs; and
- 4 Patient has unequivocal 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 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 syringe595.50	2	<ul><li>Humira</li></ul>
Inj 40 mg per 0.4 ml prefilled pen595.50	2	✓ HumiraPen
Inj 40 mg per 0.4 ml prefilled syringe595.50	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:

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All of the following:

- 1 Either:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment: or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

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

Both:

- 1 The patient has had a good clinical response to treatment with measurably improved quality of life; and
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initial application — (Hidradenitis suppurativa) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment: or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 4 Adalimumab to be administered at doses no greater than 40 mg every 7 days. Fortnightly dosing has been considered.

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

All of the following:

- 1 The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline; and
- 2 The patient has a Dermatology Quality of Life Index improvement of 4 or more from baseline; and
- 3 Adalimumab is to be administered at doses no greater than 40mg every 7 days. Fortnightly dosing has been considered.

Initial application — (Psoriasis - severe chronic plaque) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment: or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (Psoriasis - severe chronic plaque) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 Fither:

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- 1.1 Both:
  - 1.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
  - 1.1.2 Fither:
    - 1.1.2.1 Following each prior adalimumab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-adalimumab treatment baseline value; or
    - 1.1.2.2 Following each prior adalimumab treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value; or
- 1.2 Both:
  - 1.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
  - 1.2.2 Either:
    - 1.2.2.1 Following each prior adalimumab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
    - 1.2.2.2 Following each prior adalimumab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-adalimumab treatment baseline value: and
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Initial application — (Pyoderma gangrenosum)** only from a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment: or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 4 A maximum of 8 doses.

**Renewal — (Pyoderma gangrenosum)** only from a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 The patient has demonstrated clinical improvement and continues to require treatment; and
- 2 A maximum of 8 doses.

Initial application — (Crohn's disease - adult) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevitat; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
  - 1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and
- 2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and

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3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (Crohn's disease - adult) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab; or
  - 1.2 CDAI score is 150 or less: or
  - 1.3 The patient has demonstrated an adequate response to treatment, but CDAI score cannot be assessed; and
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initial application — (Crohn's disease - children) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
  - 1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and
- 2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (Crohn's disease - children) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab; or
  - 1.2 PCDAI score is 15 or less; or
  - 1.3 The patient has demonstrated an adequate response to treatment, but PCDAI score cannot be assessed; and
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initial application — (Crohn's disease - fistulising) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
  - 1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and
- 2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (Crohn's disease - fistulising) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 Fither:

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- 1.1 The number of open draining fistulae have decreased from baseline by at least 50%; or
- 1.2 There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain; and
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initial application — (Ocular inflammation – chronic) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with Amgevita, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
  - 1.3 Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment; and
- 2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (Ocular inflammation – chronic) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

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

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

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

All of the following:

- 1 Either:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment: or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita); and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

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

Both:

- 1 Treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less; and
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

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

All of the following:

- 1 Either:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

Renewal — (Arthritis – oligoarticular course juvenile idiopathic) only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months where the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

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

All of the following:

- 1 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.

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Renewal — (Arthritis - polyarticular course juvenile idiopathic) only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months where the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Initial application — (Arthritis - psoriatic) only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Renewal — (Arthritis - psoriatic)** only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria: Both:

- 1 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician; and
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Initial application** — **(Arthritis – rheumatoid)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Either:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment: or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
- 4 Either:
  - 4.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
  - 4.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

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

Both:

- 1 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician; and
- 2 Either:
  - 2.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
  - 2.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

Initial application — (Still's disease – adult-onset (AOSD)) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

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- 1 Either:
  - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment: or
  - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
- 2 Patient has received a maximum of 6 months treatment with Amgevita; and
- 3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

Renewal — (Still's disease – adult-onset (AOSD)) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months where the patient has demonstrated a sustained improvement in inflammatory markers and functional status.

AFLIBERCEPT - Special Authority see SA1772 below - Retail pharmacy

### ⇒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

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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 × 10 9 cells/L in the last 12 months; and
- 5 Patient must be adherent to optimised asthma therapy including inhaled corticosteroids (equivalent to at least 1000 mcg per day of fluticasone propionate) plus long-acting beta-2 agonist, or budesonide/formoterol as part of the anti-inflammatory reliever therapy plus maintenance regimen, unless contraindicated or not tolerated; and
- 6 Either:
  - 6.1 Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral corticosteroids; or
  - 6.2 Patient has received continuous oral corticosteroids of at least the equivalent of 10 mg per day over the previous 3 months; and
- 7 Treatment is not to be used in combination with subsidised mepolizumab; and
- 8 Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment; and
- 9 Either:
  - 9.1 Patient has not previously received an anti-IL5 biological therapy for their severe eosinophilic asthma; or
  - 9.2 Both:
    - 9.2.1 Patient was refractory or intolerant to previous anti-IL5 biological therapy; and
    - 9.2.2 Patient was not eligible to continue treatment with previous anti-IL5 biological therapy and discontinued within 12 months of commencing treatment.

Renewal — (Severe eosinophilic asthma) only from a respiratory physician or clinical immunologist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and
- 2 Either:
  - 2.1 Exacerbations have been reduced from baseline by 50% as a result of treatment with benralizumab; or
  - 2.2 Reduction in continuous oral corticosteroid use by 50% or by 10 mg/day while maintaining or improving asthma control.

# BEVACIZUMAB - PCT only - Special Authority see SA2453 below

Inj 25 mg per ml, 4 ml vial	69.00	1	✓ Vegzelma
Inj 25 mg per ml, 16 ml vial	276.00	1	✓ Vegzelma
Inj 1 mg for ECP	0.71	l mg	✓ Baxter

#### ⇒SA2453 Special Authority for Subsidy

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

Fither:

- 1 Patient is currently on treatment with bevacizumab, and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Patient has locally advanced or metastatic, unresectable hepatocellular carcinoma; and

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

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- 2.2 Patient has preserved liver function (Child-Pugh A); and
- 2.3 Transarterial chemoembolisation (TACE) is unsuitable; and
- 2.4 Any of the following:
  - 2.4.1 Patient has not received prior systemic therapy for the treatment of hepatocellular carcinoma; or
  - 2.4.2 Patient received funded lenvatinib before 1 March 2025; or
  - 2.4.3 Both:
    - 2.4.3.1 Patient has experienced treatment-limiting toxicity from treatment with lenvatinib; and
    - 2.4.3.2 No disease progression since initiation of lenvatinib; and
- 2.5 Patient has an ECOG performance status of 0-2; and
- 2.6 To be given in combination with atezolizumab.

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

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

All of the following:

- 1 Either:
  - 1.1 The patient has FIGO Stage IV epithelial ovarian, fallopian tube, or primary peritoneal cancer; or
  - - 1.2.1 The patient has previously untreated advanced (FIGO Stage IIIB or IIIC) epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
    - 1.2.2 Fither:
      - 1.2.2.1 Debulking surgery is inappropriate; or
      - 1.2.2.2 The cancer is sub-optimally debulked (maximum diameter of any gross residual disease greater than 1cm): and
- 2 Bevacizumab to be administered at a maximum dose of 15 mg/kg every three weeks; and
- 3 18 weeks concurrent treatment with chemotherapy is planned.

Renewal — (advanced or metastatic ovarian cancer) from any relevant practitioner. Approvals valid for 4 months where there is no evidence of disease progression.

Initial application — (Recurrent Respiratory Papillomatosis) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Maximum of 6 doses: and
- 2 The patient has recurrent respiratory papillomatosis; and
- 3 The treatment is for intra-lesional administration.

Renewal — (Recurrent Respiratory Papillomatosis) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Maximum of 6 doses: and
- 2 The treatment is for intra-lesional administration; and
- 3 There has been a reduction in surgical treatments or disease regrowth as a result of treatment.

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

Either:

- 1 Ocular neovascularisation; or
- 2 Exudative ocular angiopathy.

BRENTUXIMAB VEDOTIN - PCT only - Special Authority see \$A2289 on the next page

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## ⇒SA2289 Special Authority for Subsidy

**Initial application** — (relapsed/refractory Hodgkin lymphoma) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 Both:
    - 1.1.1 Patient has relapsed/refractory CD30-positive Hodgkin lymphoma after two or more lines of chemotherapy; and
    - 1.1.2 Patient is ineligible for autologous stem cell transplant; or
  - 1.2 Both:
    - 1.2.1 Patient has relapsed/refractory CD30-positive Hodgkin lymphoma; and
    - 1.2.2 Patient has previously undergone autologous stem cell transplant; and
- 2 Patient has not previously received funded brentuximab vedotin; and
- 3 Response to brentuximab vedotin treatment is to be reviewed after a maximum of 6 treatment cycles; and
- 4 Brentuximab vedotin to be administered at doses no greater than 1.8 mg/kg every 3 weeks.

**Renewal — (relapsed/refractory Hodgkin lymphoma)** from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 Patient has achieved a partial or complete response to brentuximab vedotin after 6 treatment cycles; and
- 2 Treatment remains clinically appropriate and the patient is benefitting from treatment and treatment is being tolerated; and
- 3 Patient is to receive a maximum of 16 total cycles of brentuximab vedotin treatment.

Initial application — (anaplastic large cell lymphoma) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has relapsed/refractory CD30-positive systemic anaplastic large cell lymphoma; and
- 2 Patient has an ECOG performance status of 0-1; and
- 3 Patient has not previously received brentuximab vedotin; and
- 4 Response to brentuximab vedotin treatment is to be reviewed after a maximum of 6 treatment cycles; and
- 5 Brentuximab vedotin to be administered at doses no greater than 1.8 mg/kg every 3 weeks.

Renewal — (anaplastic large cell lymphoma) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 Patient has achieved a partial or complete response to brentuximab vedotin after 6 treatment cycles; and
- 2 Treatment remains clinically appropriate and the patient is benefitting from treatment and treatment is being tolerated; and
- 3 Patient is to receive a maximum of 16 total cycles of brentuximab vedotin treatment.

# CETUXIMAB - PCT only - Specialist - Special Authority see SA2401 below

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Erbitux	1	364.00	Inj 5 mg per ml, 20 ml vial
<ul><li>Erbitux</li></ul>	1	1,820.00	Inj 5 mg per ml, 100 ml vial
✓ Baxter	1 ma	3.82	Ini 1 mg for ECP

#### ⇒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

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4 To be administered in combination with radiation therapy.

Initial application — (colorectal cancer, metastatic) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Patient has metastatic colorectal cancer located on the left side of the colon (see Note); and
- 2 There is documentation confirming disease is RAS and BRAF wild-type; and
- 3 Patient has an ECOG performance score of 0-2; and
- 4 Patient has not received prior funded treatment with cetuximab; and
- 5 Either:
  - 5.1 Cetuximab is to be used in combination with chemotherapy; or
  - 5.2 Chemotherapy is determined to not be in the best interest of the patient based on clinician assessment.

**Renewal — (colorectal cancer, metastatic)** only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where there is no evidence of disease progression.

Note: Left-sided colorectal cancer comprises of the distal one-third of the transverse colon, the splenic flexure, the descending colon, the sigmoid colon, or the rectum.

GEMTUZUMAB OZOGAMICIN − PCT only − Specialist − Special Authority see SA2269 below Inj 5 mg vial .......12,973.00 1 ✓ Mylotarg

## **⇒SA2269** Special Authority for Subsidy

**Initial application** only from a haematologist, paediatric haematologist or paediatric oncologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has not received prior chemotherapy for this condition; and
- 2 Patient has de novo CD33-positive acute myeloid leukaemia; and
- 3 Patient does not have acute promyelocytic leukaemia; and
- 4 Gemtuzumab ozogamicin will be used in combination with standard anthracycline and cytarabine (AraC); and
- 5 Patient is being treated with curative intent; and
- 6 Patient's disease risk has been assessed by cytogenetic testing to be good or intermediate; and
- 7 Patient must be considered eligible for standard intensive remission induction chemotherapy with standard anthracycline and cytarabine (AraC); and
- 8 Gemtuzumab ozogamicin to be funded for one course only (one dose at 3 mg per 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).

INFLIXIMAB - PCT only - Special Authority see SA2487 below

#### ⇒SA2487 Special Authority for Subsidy

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

All of the following:

- 1 Patient has active Crohn's disease; and
- 2 Any of the following:
  - 2.1 Patient has a CDAI score of greater than or equal to 300 or HBI score of greater than or equal to 10; or
  - 2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
  - 2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or

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- 2.4 Patient has an ileostomy or colostomy, and has intestinal inflammation; and
  - 3 Patient has tried but has experienced an inadequate response to, or intolerable side effects from, prior therapy with immunomodulators and corticosteroids.

Renewal — (Crohn's disease (adults)) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 CDAI score has reduced by 100 points from the CDAI score, or HBI score has reduced by 3 points, from when the patient was initiated on infliximab; or
  - 1.2 CDAI score is 150 or less, or HBI is 4 or less; or
  - 1.3 The patient has demonstrated an adequate response to treatment but CDAI score and/or HBI score cannot be assessed: and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

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

All of the following:

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

Renewal — (Crohn's disease (children)) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on infliximab; or
  - 1.2 PCDAI score is 15 or less: or
  - 1.3 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

Initial application — (Graft vs host disease) from any relevant practitioner. Approvals valid without further renewal unless notified where patient has steroid-refractory acute graft vs. host disease of the gut.

Initial application — (Pulmonary sarcoidosis) from any relevant practitioner. Approvals valid without further renewal unless notified where patient has life-threatening pulmonary sarcoidosis diagnosed by a multidisciplinary team that is refractory to other treatments.

Initial application — (acute fulminant ulcerative colitis) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 weeks for applications meeting the following criteria: Both:

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

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

Both:

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

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

All of the following:

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

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

Either:

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for adalimumab for chronic ocular inflammation; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
    - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for chronic ocular inflammation; or
- 2 Both:
  - 2.1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and
  - 2.2 Any of the following:
    - 2.2.1 Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective; or
    - 2.2.2 Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or
    - 2.2.3 Patient is under 8 years and treatment with steroids or methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or disease requires control to prevent irreversible vision loss prior to achieving a therapeutic dose of methotrexate.

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

Any of the following:

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

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

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

Both:

- 1 Patient has confirmed Crohn's disease: and
- 2 Any of the following:
  - 2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
  - 2.2 Patient has one or more rectovaginal fistula(e); or
  - 2.3 Patent has complex peri-anal fistula.

Renewal — (fistulising Crohn's disease) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

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

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

All of the following:

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

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis; and
  - 12 Fither
    - 1.2.1 Patient has experienced intolerable side effects from adalimumab, etanercept or secukinumab; or

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1.2.2 Patient has received insufficient benefit from adalimumab, etanercept or secukinumab to meet the renewal criteria for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis; or

#### 2 All of the following:

- 2.1 Any of the following:
  - 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
  - 2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; or
  - 2.1.3 Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10; and
- 2.2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
- 2.3 A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 2.4 The most recent PASI assessment is no more than 1 month old at the time of initiation.

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand, foot, genital or flexural areas at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and for the face, palm of a hand or sole of a foot the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

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

#### Both:

#### 1 Any of the following:

- 1.1 Both:
  - 1.1.1 Patient had "whole body" severe chronic 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 value: or

#### 1.3 Both:

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

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- 1.3.2.1 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or
- 1.3.2.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing infliximab; and
- 2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

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

#### Both:

- 1 Patient was being treated with infliximab prior to 1 February 2019; and
- 2 Any of the following:
  - 2.1 Rheumatoid arthritis; or
  - 2.2 Ankylosing spondylitis; or
  - 2.3 Psoriatic arthritis; or
  - 2.4 Severe ocular inflammation; or
  - 2.5 Chronic ocular inflammation; or
  - 2.6 Crohn's disease (adults); or
  - 2.7 Crohn's disease (children); or
  - 2.8 Fistulising Crohn's disease; or
  - 2.9 Severe fulminant ulcerative colitis: or
  - 2.10 Severe ulcerative colitis: or
  - 2.11 Plaque psoriasis; or
  - 2.12 Neurosarcoidosis; or
  - 2.13 Severe Behcet's disease.

Initial application — (psoriatic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept and/or secukinumab for psoriatic arthritis; and
- 2 Either:
  - 2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept and/or secukinumab; or
  - 2.2 Following 3-4 months' initial treatment with adalimumab and/or etanercept and/or secukinumab, the patient did not meet the renewal criteria for adalimumab and/or etanercept and/or secukinumab for psoriatic arthritis.

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

Both:

- 1 Either:
  - 1.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  - 1.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior infliximab treatment in the opinion of the treating physician; and
- 2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

Initial application — (rheumatoid arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
- 2 Either:
  - 2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or

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- 2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept; and
- 3 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance.

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

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

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

All of the following:

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

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

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

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

Both:

- 1 Patient has had a good clinical response to initial treatment with measurably improved quality of life; and
- 2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

**Renewal — (fulminant ulcerative colitis)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Where maintenance treatment is considered appropriate, infliximab should be used in combination with immunomodulators and reassessed every 6 months; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

Initial application — (severe ocular inflammation) from any relevant practitioner. Approvals valid for 4 months for applications

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

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meeting the following criteria:

Either:

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for adalimumab for severe ocular inflammation; and
  - 12 Fither
    - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
    - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe 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 inflivimals or
  - 1.2 The PUCAI score has reduced by 10 points or more from the PUCAI score when the patient was initiated on infliximab; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be

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considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

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

All of the following:

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

Note: Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

Initial application — (inflammatory bowel arthritis – axial) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
- 2 Patient has had axial inflammatory pain for six months or more; and
- 3 Patient is unable to take NSAIDs; and
- 4 Patient has unequivocal sacroiliitis demonstrated by radiological imaging or MRI; and
- 5 Patient's disease has not responded adequately to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist; and
- 6 Patient has a BASDAI of at least 6 on a 0 10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment.

Renewal — (inflammatory bowel arthritis – axial) from any relevant practitioner. Approvals valid for 2 years where treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10-point scale, or an improvement in BASDAI of 50%, whichever is less.

Initial application — (inflammatory bowel arthritis – peripheral) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
- 2 Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular; and
- 3 Patient has tried and not experienced a response to at least three months of methotrexate or azathioprine at a maximum tolerated dose (unless contraindicated); and
- 4 Patient has tried and not experienced a response to at least three months of sulfasalazine at a maximum tolerated dose (unless contraindicated); and
- 5 Any of the following:
  - 5.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application: or
  - 5.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; or
  - 5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

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

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**Renewal — (inflammatory bowel arthritis – peripheral)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

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

Initial application — (immune checkpoint inhibitor toxicity in malignancy\*) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The individual requires treatment for moderate to severe autoimmune toxicity following immune checkpoint inhibitor treatment for malignancy; and
- 2 The individual has received insufficient benefit from use of corticosteroids; and
- 3 Infliximab is to be administered at up to 5mg/kg for up to four doses.

Renewal — (immune checkpoint inhibitor toxicity in malignancy\*) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 The individual has shown clinical improvement and ongoing treatment is required; and
- 2 Infliximab is to be administered at up to 5mg/kg for up to a total of 8 doses.

Note: Indications marked with \* are unapproved indications.

INOTUZUMAB OZOGAMICIN - PCT only - Specialist - Special Authority see SA2460 below

Inj 1 mg vial	14,457.00	1	Besponsa
Inj 1 mg for ECP	14,457.00	1 mg	✓ Baxter

## ⇒SA2460 Special Authority for Subsidy

**Initial application** only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has relapsed or refractory CD22-positive B-cell acute lymphoblastic leukaemia/lymphoma, including minimal residual disease: and
- 2 Patient has ECOG performance status of 0-2; and
- 3 Either:
  - 3.1 Both:
    - 3.1.1 Patient has Philadelphia chromosome positive B-Cell ALL; and
    - 3.1.2 Patient has previously received a tyrosine kinase inhibitor; or
  - 3.2 Patient has received one prior line of treatment involving intensive chemotherapy; and
- 4 Treatment is to be administered for a maximum of 3 cycles.

**Renewal** only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient is not proceeding to a stem cell transplant; and
- 2 Either:
  - 2.1 Patient has experienced complete disease response; or
  - 2.2 Patient has experienced complete remission with incomplete haematological recovery; and
- 3 Treatment with inotuzumab ozogamicin is to cease after a total duration of 6 cycles.

MEPOLIZUMAB – Special Authority see SA2331 on the next page – Retail pharmacy

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

⇒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<sup>9</sup> cells/L in the last 12 months; and
- 5 Patient must be adherent to optimised asthma therapy including inhaled corticosteroids (equivalent to at least 1000 mcg per day of fluticasone propionate) plus long acting beta-2 agonist, or budesonide/formoterol as part of the single maintenance and reliever therapy regimen, unless contraindicated or not tolerated; and
- 6 Either:
  - 6.1 Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral corticosteroids; or
  - 6.2 Patient has received continuous oral corticosteroids of at least the equivalent of 10 mg per day over the previous 3 months; and
- 7 Treatment is not to be used in combination with subsidised benralizumab; and
- 8 Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment; and
- 9 Either:
  - 9.1 Patient has not previously received an anti-IL5 biological therapy for their severe eosinophilic asthma; or
  - 9.2 Both:
    - 9.2.1 Patient was refractory or intolerant to previous anti-IL5 biological therapy; and
    - 9.2.2 Patient was not eligible to continue treatment with previous anti-IL5 biological therapy and discontinued within 12 months of commencing treatment.

**Renewal — (Severe eosinophilic asthma)** only from a respiratory physician or clinical immunologist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and
- 2 Either:
  - 2.1 Exacerbations have been reduced from baseline by 50% as a result of treatment with mepolizumab; or
  - 2.2 Reduction in continuous oral corticosteroid use by 50% or by 10 mg/day while maintaining or improving asthma control.

Initial application — (eosinophilic granulomatosis with polyangiitis) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has eosinophilic granulomatosis with polyangiitis; and
- 2 The patient has trialled and not received adequate benefit from at least one of the following for at least three months (unless contraindicated to all): azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate, or rituximab; and
- 3 Fither:
  - 3.1 The patient has trialled prednisone for a minimum of three months and is unable to maintain disease control at

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\$	Per	1	Manufacturer	

continued...

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.

# ⇒SA2155 Special Authority for Subsidy

**Initial application — (chronic lymphocytic leukaemia)** only from a haematologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has progressive Binet stage A, B or C CD20+ chronic lymphocytic leukaemia requiring treatment; and
- 2 The patient is obinutuzumab treatment naive; and
- 3 The patient is not eligible for full dose FCR due to comorbidities with a score > 6 on the Cumulative Illness Rating Scale (CIRS) or reduced renal function (creatinine clearance < 70mL/min); and
- 4 Patient has adequate neutrophil and platelet counts\* unless the cytopenias are a consequence of marrow infiltration by CLL; and
- 5 Patient has good performance status; and
- 6 Obinutuzumab to be administered at a maximum cumulative dose of 8,000 mg and in combination with chlorambucil for a maximum of 6 cycles.

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

\* Neutrophil greater than or equal to  $1.5 \times 10^9$ /L and platelets greater than or equal to  $75 \times 10^9$ /L.

Initial application — (follicular / marginal zone lymphoma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria: All of the following:

- 1 Either:
  - 1.1 Patient has follicular lymphoma; or
  - 1.2 Patient has marginal zone lymphoma; and
- 2 Patient is refractory to or has relapsed within 12 months of a rituximab containing combined chemo-immunotherapy regimen\*; and
- 3 Patient has an ECOG performance status of 0-2; and
- 4 Patient has been previously treated with no more than four chemotherapy regimens; and
- 5 Obinutuzumab to be administered at a maximum dose of 1000 mg for a maximum of 6 cycles in combination with chemotherapy\*.

Note: \* includes unapproved indications

**Renewal — (follicular / marginal zone lymphoma)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 24 months for applications meeting the following criteria: All of the following:

- 1 Patient has no evidence of disease progression following obinutuzumab induction therapy; and
- 2 Obinutuzumab to be administered at a maximum of 1000 mg every 2 months for a maximum of 2 years; and
- 3 Obinutuzumab to be discontinued at disease progression.

OMALIZUMAB - Special Authority see SA1744 on the ne	xt page - Retail pharmacy		
Inj 150 mg prefilled syringe	450.00	1	✓ Xolair
, , , , ,			Xolair AU
Inj 150 mg vial	450.00	1	Xolair

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

# ⇒SA1744 Special Authority for Subsidy

**Initial application — (severe asthma)** only from a respiratory specialist or clinical immunologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

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

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

All of the following:

- 1 Patient must be aged 12 years or older; and
- 2 Either:
  - 2.1 Both:
    - 2.1.1 Patient is symptomatic with Urticaria Activity Score 7 (UAS7) of 20 or above; and
    - 2.1.2 Patient has a Dermatology life quality index (DLQI) of 10 or greater; or
  - 2.2 Patient has a Urticaria Control Test (UCT) of 8 or less; and
- 3 Any of the following:
  - 3.1 Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and ciclosporin (> 3 mg/kg day) for at least 6 weeks; or
  - 3.2 Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and at least 3 courses of systemic corticosteroids (> 20 mg prednisone per day for at least 5 days) in the previous 6 months; or
  - 3.3 Patient has developed significant adverse effects whilst on corticosteroids or ciclosporin; and
- 4 Fither:
  - 4.1 Treatment to be stopped if inadequate response\* following 4 doses; or
  - 4.2 Complete response\* to 6 doses of omalizumab.

**Renewal** — (severe asthma) only from a clinical immunologist or respiratory specialist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and
- 2 A reduction in the maintenance oral corticosteroid dose or number of exacerbations of at least 50% from baseline.

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

Either:

- 1 Patient has previously adequately responded\* to 6 doses of omalizumab; or
- 2 Both:

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

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- 2.1 Patient has previously had a complete response\* to 6 doses of omalizumab; and
- 2.2 Patient has relapsed after cessation of omalizumab therapy.

Note: \*Inadequate response defined as less than 50% reduction in baseline UAS7 and DLQI score, or an increase in Urticaria Control Test (UCT) score of less than 4 from baseline. Patient is to be reassessed for response after 4 doses of omalizumab. Complete response is defined as UAS7 less than or equal to 6 and DLQI less than or equal to 5; or UCT of 16. Relapse of chronic urticaria on stopping prednisone/ciclosporin does not justify the funding of omalizumab.

PALIVIZUMAB - PCT only - Special Authority see SA2419 below

# ⇒SA2419 Special Authority for Subsidy

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

- 1 Palivizumab to be administered during the annual RSV season; and
- 2 Either:
  - 2.1 Both:
    - 2.1.1 Infant was born in the last 12 months; and
    - 2.1.2 Infant was born at less than 32 weeks zero days' gestation; or
    - 2.2 Both:
      - 2.2.1 Child was born in the last 24 months; and
      - 2.2.2 Any of the following:
        - 2.2.2.1 Child has severe lung, airway, neurological or neuromuscular disease that requires ongoing ventilatory/respiratory support (see Note A) in the community; or
        - 2.2.2.2 Both:
          - 2.2.2.2.1 Child has haemodynamically significant heart disease; and
          - 2.2.2.2.2 Any of the following:
            - 2.2.2.2.2.1 Child has unoperated simple congenital heart disease with significant left to right shunt (see Note B): or
            - 2.2.2.2.2.2 Child has unoperated or surgically palliated complex congenital heart disease; or
            - 2.2.2.2.3 Child has severe pulmonary hypertension (see Note C); or
            - 2.2.2.2.2.4 Child has moderate or severe left ventricular (LV) failure (see Note D); or
        - 2.2.2.3 Child has severe combined immune deficiency, confirmed by an immunologist, but has not received a stem cell transplant; or
        - 2.2.2.4 Child has inborn errors of immunity (see Note E) that increase susceptibility to life-threatening viral respiratory infections, confirmed by an immunologist.

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

- 1 Palivizumab to be administered during the annual RSV season; and
- 2 Child was born in the last 24 months; and
- 3 Any of the following:
  - 3.1 Child has severe lung, airway, neurological or neuromuscular disease that requires ongoing ventilatory/respiratory support (see Note A) in the community: or
  - 3.2 Both:
    - 3.2.1 Child has haemodynamically significant heart disease; and
    - 3.2.2 Any of the following:
      - 3.2.2.1 Child has unoperated simple congenital heart disease with significant left to right shunt (see Note B);
      - 3.2.2.2 Child has unoperated or surgically palliated complex congenital heart disease; or

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- 3.2.2.3 Child has severe pulmonary hypertension (see Note C); or
- 3.2.2.4 Child has moderate or severe left ventricular (LV) failure (see Note D); or
- 3.3 Child has severe combined immune deficiency, confirmed by an immunologist, but has not received a stem cell transplant; or
- 3.4 Child has inborn errors of immunity (see Note E) that increase susceptibility to life-threatening viral respiratory infections, confirmed by an immunologist.

#### Notes:

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

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

Inj 30 mg per ml, 14 ml vial	3,927.00	1	Perjeta
Inj 420 mg for ECP	3,927.00	420 mg OP	<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
  - 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.

#### RITLIXIMAB (MARTHERA) - PCT only - Specialist - Special Authority see SA1976 on the next page

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Inj 100 mg per 10 ml vial	1,075.50	2	✓ Mabthera
Inj 500 mg per 50 ml vial	2,688.30	1	✓ Mabthera
Ini 1 mg for FCP	5.64	1 ma	✓ Baxter (Mabthera)

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

## ⇒SA1976 Special Authority for Subsidy

Initial application — (rheumatoid arthritis - TNF inhibitors contraindicated) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Treatment with a Tumour Necrosis Factor alpha inhibitor is contraindicated; and
- 2 Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
- 3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
- 4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses); and
- 5 Any of the following:
  - 5.1 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of ciclosporin; or
  - 5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or
  - 5.3 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate; and
- 6 Either:
  - 6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or
  - 6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 7 Fither:
  - 7.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
  - 7.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months; and
- 8 Either:
  - 8.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
  - 8.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
- 9 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Initial application — (rheumatoid arthritis - prior TNF inhibitor use) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

- 1 Both:
  - 1.1 The patient has had an initial community Special Authority approval for at least one of etanercept and/or adalimumab for rheumatoid arthritis; and
  - 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:

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

RITUXIMAB (RIXIMYO) - PCT only - Specialist - Specia	Authority see SA2497 b	elow	
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)

# ⇒SA2497 Special Authority for Subsidy

Initial application — (ABO-incompatible organ transplant) from any relevant practitioner. Approvals valid without further renewal unless notified where patient is to undergo an ABO-incompatible solid organ transplant\*.

Note: Indications marked with \* are unapproved indications.

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

All of the following:

- 1 Patient has been diagnosed with ANCA associated vasculitis\*; and
- 2 The total rituximab dose would not exceed the equivalent of 375 mg/m<sup>2</sup> of body-surface area per week for a total of 4 weeks; and
- 3 Any of the following:
  - 3.1 Induction therapy with daily oral or pulse intravenous cyclophosphamide has failed to achieve significant improvement of disease after at least 3 months; or
  - 3.2 Patient has previously had a cumulative dose of cyclophosphamide > 15 g or a further repeat 3 month induction

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course of cyclophosphamide would result in a cumulative dose > 15 g; or

- 3.3 Cyclophosphamide and methotrexate are contraindicated; or
- 3.4 Patient is a female of child-bearing potential; or
- 3.5 Patient has a previous history of haemorrhagic cystitis, urological malignancy or haematological malignancy.

Note: Indications marked with \* are unapproved indications.

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

All of the following:

- 1 Patient has been diagnosed with ANCA associated vasculitis\*; and
- 2 Patient has previously responded to treatment with rituximab but is now experiencing an acute flare of vasculitis; and
- 3 The total rituximab dose would not exceed the equivalent of 375 mg/m<sup>2</sup> of body-surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

Initial application — (Antibody-mediated organ transplant rejection) from any relevant practitioner. Approvals valid without further renewal unless notified where patient has been diagnosed with antibody-mediated organ transplant rejection\*.

Note: Indications marked with \* are unapproved indications.

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

All of the following:

- 1 The patient has progressive Binet stage A. B or C chronic lymphocytic leukaemia (CLL) requiring treatment; and
- 2 Any of the following:
  - 2.1 The patient is rituximab treatment naive; or
  - 2.2 Either:
    - 2.2.1 The patient is chemotherapy treatment naive: or
    - 2.2.2 Both:
      - 2.2.2.1 The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment: and
      - 2.2.2.2 The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy; or
  - 2.3 The patient's disease has relapsed and rituximab treatment is to be used in combination with funded venetoclax;
- 3 The patient has good performance status; and
- 4 Either:
  - 4.1 The patient does not have chromosome 17p deletion CLL; or
  - 4.2 Rituximab treatment is to be used in combination with funded venetoclax for relapsed/refractory chronic lymphocytic leukaemia; and
- 5 Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles; and
- 6 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration), bendamustine or venetoclax.

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

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

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- 1 Either:
  - 1.1 The patient's disease has relapsed and rituximab treatment is to be used in combination with funded venetoclax; or
  - 1.2 All of the following:
    - 1.2.1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and
    - 1.2.2 The patient has had an interval of 36 months or more since commencement of initial rituximab treatment;
    - 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 Fither:
  - 2.1 The patient has experienced a severe episode or attack of NMOSD (rapidly progressing symptoms and clinical investigations supportive of a severe attack of NMOSD); or
  - 2.2 All of the following:
    - 2.2.1 The patient has experienced a breakthrough attack of NMOSD; and
    - 2.2.2 The patient is receiving treatment with mycophenolate; and
    - 2.2.3 The patients is receiving treatment with corticosteroids.

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

- 1 One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m2 administered weekly for four weeks; and
- 2 The patients has responded to the most recent course of rituximab; and
- 3 The patient has not received rituximab in the previous 6 months.

Initial application — (Post-transplant) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The patient has B-cell post-transplant lymphoproliferative disorder\*; and
- 2 To be used for a maximum of 8 treatment cycles.

Note: Indications marked with \* are unapproved indications.

Renewal — (Post-transplant) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

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

Note: Indications marked with \* are unapproved indications.

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

- 1 One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart; and
- 2 Fither:
  - 2.1 Treatment with corticosteroids and at least one other immunosuppressant for at least a period of 12 months has been ineffective: or
  - 2.2 Both:
    - 2.2.1 Treatment with at least one other immunosuppressant for a period of at least 12 months; and
    - 2.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.

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

# All of the following:

- 1 One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart; and
- 2 An initial response lasting at least 12 months was demonstrated; and
- 3 Either:
  - 3.1 The patient has relapsed despite treatment with corticosteroids and at least one other immunosuppressant for a period of at least 12 months; or
  - 3.2 Both:
    - 3.2.1 The patient's myasthenia gravis has relapsed despite treatment with at least one immunosuppressant for a period of at least 12 months; and
    - 3.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.

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

All of the following:

- 1 Patient is a child with SDNS\* or FRNS\*; and
- 2 Treatment with steroids for at least a period of 3 months has been ineffective or associated with evidence of steroid toxicity: and
- 3 Treatment with ciclosporin for at least a period of 3 months has been ineffective and/or discontinued due to unacceptable side effects: and
- 4 Treatment with mycophenolate for at least a period of 3 months with no reduction in disease relapses; and
- 5 The total rituximab dose used would not exceed the equivalent of 375 mg/m<sup>2</sup> of body surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

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Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

Note: Indications marked with \* are unapproved indications.

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

Either:

- 1 All of the following:
  - 1.1 The patient has treatment naive aggressive CD20 positive NHL; and
  - 1.2 To be used with a multi-agent chemotherapy regimen given with curative intent; and
  - 1.3 To be used for a maximum of 8 treatment cycles; or
- 2 Both:
  - 2.1 The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy; and
  - 2.2 To be used for a maximum of 6 treatment cycles.

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia

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

All of the following:

- 1 The patient has had a rituximab treatment-free interval of 12 months or more; and
- 2 The patient has relapsed refractory/aggressive CD20 positive NHL; and
- 3 To be used with a multi-agent chemotherapy regimen given with curative intent; and
- 4 To be used for a maximum of 4 treatment cycles.

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia

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

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

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

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All of the following:

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

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

- 1 Fither:
  - 1.1 Patient has immune thrombocytopenic purpura\* with a platelet count of less than or equal to 20,000 platelets per microlitre: or
  - 1.2 Patient has immune thrombocytopenic purpura\* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding; and
- 2 Any of the following:
  - 2.1 Treatment with steroids and splenectomy have been ineffective; or
  - 2.2 Treatment with steroids has been ineffective and splenectomy is an absolute contraindication; or
  - 2.3 Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy); and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

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

Either:

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

Note: Indications marked with \* are unapproved indications.

Initial application — (indolent, low-grade lymphomas or hairy cell leukaemia\*) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

#### Either:

- 1 Both:
  - 1.1 The patient has indolent low grade NHL or hairy cell leukaemia\* with relapsed disease following prior chemotherapy; and
  - 1.2 To be used for a maximum of 6 treatment cycles: or
- 2 Both:
  - 2.1 The patient has indolent, low grade lymphoma or hairy cell leukaemia\* requiring first-line systemic chemotherapy; and
  - 2.2 To be used for a maximum of 6 treatment cycles.

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

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

All of the following:

1 The patient has had a rituximab treatment-free interval of 12 months or more; and

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

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

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

Note: Indications marked with \* are unapproved indications.

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

Note: Indications marked with \* are unapproved indications.

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

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

Note: Indications marked with \* are unapproved indications.

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

Either:

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

Note: Indications marked with \* are unapproved indications.

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

- 1 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks; and
- 2 Either:
  - 2.1 Patient has thrombotic thrombocytopenic purpura\* and has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange; or
  - 2.2 Patient has acute idiopathic thrombotic thrombocytopenic purpura\* with neurological or cardiovascular pathology.

Note: Indications marked with \* are unapproved indications.

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

All of the following:

- 1 Patient was previously treated with rituximab for thrombotic thrombocytopenic purpura\*; and
- 2 An initial response lasting at least 12 months was demonstrated; and

Subsidy		Fully	Brand or
(Manufacturer's Price)	5	Subsidised	Generic
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- 3 Patient now requires repeat treatment; and
- 4 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks.

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

Note: Indications marked with \* are unapproved indications.

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

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

Note: Indications marked with \* are unapproved indications.

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

- 1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m<sup>2</sup> weekly for 4 weeks) is now planned; or
- 2 All of the following:
  - 2.1 Patient was previously treated with rituximab for warm autoimmune haemolytic anaemia\*; and
  - 2.2 An initial response lasting at least 12 months was demonstrated; and
  - 2.3 Patient now requires repeat treatment.

Note: Indications marked with \* are unapproved indications.

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

All of the following:

- 1 Patient has confirmed antisynthetase syndrome; and
- 2 Patient has severe, immediately life or organ threatening disease, including interstitial lung disease; and

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- 3 Either:
  - 3.1 Treatment with at least 3 immunosuppressants (oral steroids, cyclophosphamide, methotrexate, mycophenolate, ciclosporin, azathioprine) has not be effective at controlling active disease; or
  - 3.2 Rapid treatment is required due to life threatening complications; and
- 4 Maximum of four 1.000mg infusions of rituximab.

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

All of the following:

- 1 Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in inflammatory markers, muscle strength and pulmonary function; and
- 2 The patient has not received rituximab in the previous 6 months; and
- 3 Maximum of two cycles of 2 × 1,000mg infusions of rituximab given two weeks apart.

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

All of the following:

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

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

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

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

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

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:

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

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

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

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

Fither:

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

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

Both:

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

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

All of the following:

- 1 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 Fither:

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

#### Notes:

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

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

All of the following:

- 1 Patient has newly diagnosed B-cell acute lymphoblastic leukaemia/lymphoma\*; and
- 2 Treatment must be in combination with an intensive chemotherapy protocol with curative intent; and
- 3 The total rituximab dose would not exceed the equivalent of 375 mg/m<sup>2</sup> per dose for a maximum of 18 doses.

Note: Indications marked with \* are unapproved indications.

Initial application — (desensisation prior to transplant) from any relevant practitioner. Approvals valid for 6 weeks for applications meeting the following criteria:

Both:

- 1 Patient requires desensitisation prior to mismatched allogenic stem cell transplant\*; and
- 2 Patient would receive no more than two doses at 375 mg/m2 of body-surface area.

Note: Indications marked with \* are unapproved indications.

Initial application — (pemiphigus\*) only from a dermatologist or relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Fither:

- 1 All of the following:
  - 1.1 Patient has severe rapidly progressive pemphigus; and
  - 1.2 Is used in combination with systemic corticosteroids (20 mg/day); and
  - 1.3 Any of the following:
    - 1.3.1 Skin involvement is at least 5% body surface area; or
    - 1.3.2 Significant mucosal involvement (10 or more mucosal erosions) or diffuse gingivitis or confluent large erosions: or
    - 1.3.3 Involvement of two or more mucosal sites: or
- 2 Both:
  - 2.1 Patient has pemphigus; and
  - 2.2 Patient has not experienced adequate clinical benefit from systemic corticosteroids (20 mg/day) in combination with a steroid sparing agent, unless contraindicated.

Note: Indications marked with \* are unapproved indications.

Renewal — (pemiphigus\*) only from a dermatologist or relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 Patient has experienced adequate clinical benefit from rituximab treatment, with improvement in symptoms and healing of

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skin ulceration and reduction in corticosteroid requirement; and

2 Patient has not received rituximab in the previous 6 months.

Note: Indications marked with \* are unapproved indications.

Initial application — (immunoglobulin G4-related disease (IgG4-RD\*)) from any relevant practitioner. Approvals valid for 6 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient has confirmed diagnosis of IgG4-RD\*; and
- 2 Either:
  - 2.1 Treatment with corticosteroids and/or disease modifying anti-rheumatic drugs for at least 3 months has been ineffective in lowering corticosteroid dose below 5 mg per day (prednisone equivalent) without relapse; or
  - 2.2 Treatment with corticosteroids and/or disease modifying anti-rheumatic drugs is contraindicated or associated with evidence of toxicity or intolerance; and
- 3 Total rituximab dose used should not exceed a maximum of two 1000 mg infusions of rituximab given two weeks apart.

Note: Indications marked with \* are unapproved indications.

Renewal — (immunoglobulin G4-related disease (IgG4-RD\*)) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 Treatment with rituximab for IgG4-RD\* was previously successful and patient's disease has demonstrated sustained response, but the condition has relapsed; or
  - 1.2 Patient is receiving maintenance treatment for IgG4-RD\*; and
- 2 Rituximab re-treatment not to be given within 6 months of previous course of treatment; and
- 3 Maximum of two 1000 mg infusions of rituximab given two weeks apart.

Note: Indications marked with \* are unapproved indications.

#### ⇒SA2488 Special Authority for Subsidy

Initial application — (severe chronic plaque psoriasis – second-line biologic) only from a dermatologist or any relevant practitioner on the recommendation of a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab or etanercept, or has trialled infliximab in a Health NZ Hospital, for severe chronic plaque psoriasis; and
- 2 Either:
  - 2.1 The patient has experienced intolerable side effects from adalimumab, etanercept or infliximab; or
  - 2.2 The patient has received insufficient benefit from adalimumab, etanercept or infliximab; and
- 3 A Psoriasis Area and Severity Index (PASI) assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 4 The most recent PASI or DQLI assessment is no more than 1 month old at the time of application.

**Initial application** — (severe chronic plaque psoriasis – first-line biologic) only from a dermatologist or any relevant practitioner on the recommendation of a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

1 Any of the following:

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- 1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
- 1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; or
- 1.3 Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10; and
- 2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin: and
- 3 A PASI assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 4 The most recent PASI or DQLI assessment is no more than 1 month old at the time of application.

Note: A treatment course is defined as a minimum of 12 weeks of treatment. "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand. foot, genital or flexural areas, at least 2 of the 3 PASI symptom sub scores for erythema, thickness and scaling are rated as severe or very severe, and for the face, palm of a hand or sole of a foot the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

Renewal — (severe chronic plaque psoriasis – first and second-line biologic) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Fither:
  - 1.1 Either:
    - 1.1.1 Patient's PASI score has reduced by 75% or more (PASI 75) as compared to baseline PASI prior to commencing secukinumab; or
    - 1.1.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing secukinumab; or
  - 1.2 Both:
    - 1.2.1 Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment; and
    - 1.2.2 Either:
      - 1.2.2.1 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or
      - 1.2.2.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing secukinumab; and
- 2 Secukinumab to be administered at a maximum dose of 300 mg monthly.

**Initial application** — **(ankylosing spondylitis – second-line biologic)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 3 months for applications meeting the following criteria: Both:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis; and
- 2 Either:
  - 2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
  - 2.2 Following 12 weeks of adalimumab and/or etanercept treatment, the patient did not meet the renewal criteria for adalimumab and/or etanercept for ankylosing spondylitis.

Renewal — (ankylosing spondylitis – second-line biologic) only from a rheumatologist or medical practitioner on the

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recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Following 12 weeks initial treatment of secukinumab treatment, BASDAI has improved by 4 or more points from pre-secukinumab baseline on a 10 point scale, or by 50%, whichever is less; and
- 2 Physician considers that the patient has benefitted from treatment and that continued treatment is appropriate; and
- 3 Secukinumab to be administered at doses no greater than 300 mg monthly.

Initial application — (psoriatic arthritis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

### Either:

- 1 Both:
  - 1.1 Patient has had an initial Special Authority approval for adalimumab, etanercept or infliximab for psoriatic arthritis; and
  - 1.2 Either:
    - 1.2.1 Patient has experienced intolerable side effects from adalimumab, etanercept or infliximab; or
    - 1.2.2 Patient has received insufficient benefit from adalimumab, etanercept or infliximab to meet the renewal criteria for adalimumab, etanercept or infliximab for psoriatic arthritis; or
- 2 All of the following:
  - 2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and
  - 2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
  - 2.3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and
  - 2.4 Either:
    - 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints; or
    - 2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
  - 2.5 Any of the following:
    - 2.5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
    - 2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or
    - 2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Renewal — (psoriatic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

#### 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.

  SILTIYIMAB Special Authority see SA1596 on the part page Retail pharmacy.

OLI OXIMAB Openial Additionty See Office	on the next page Tretail pharmacy		
Note: Siltuximab is to be administered at o	doses no greater than 11 mg/kg every	3 weeks.	
Inj 100 mg vial	770.57	1	✓ Sylvant
Ini 400 mg vial	3.082.33	1	✓ Sylvant

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# ⇒SA1596 Special Authority for Subsidy

Initial application only from a haematologist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has severe HHV-8 negative idiopathic multicentric Castleman's Disease; and
- 2 Treatment with an adequate trial of corticosteroids has proven ineffective; and
- 3 Siltuximab is to be administered at doses no greater than 11 mg/kg every 3 weeks.

**Renewal** only from a haematologist or rheumatologist. Approvals valid for 12 months where the treatment remains appropriate and the patient has sustained improvement in inflammatory markers and functional status.

# TOCILIZUMAB - PCT only - Special Authority see SA2489 below

Inj 20 mg per ml, 4 ml vial	20.00 1	✓ Actemra
Inj 20 mg per ml, 10 ml vial55	50.00 1	✓ Actemra
Inj 20 mg per ml, 20 ml vial		✓ Actemra
Inj 1 mg for ECP	.2.85 1 mg	✓ Baxter

## ⇒SA2489 Special Authority for Subsidy

Initial application — (cytokine release syndrome) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Fither:

#### 1 Both:

- 1.1 The patient has developed grade 3 or 4 cytokine release syndrome associated with the administration of blinatumomab for the treatment of acute lymphoblastic leukaemia; and
- 1.2 Tocilizumab is to be administered at doses no greater than 8 mg/kg IV for a maximum of 3 doses (if less than 30kg, maximum of 12 mg/kg); or
- 2 All of the following:
  - 2.1 The patient is enrolled in the Malaghan Institute of Medical Research ENABLE trial programme; and
  - 2.2 The patient has developed CRS or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) following CAR T-cell therapy for the treatment of relapsed or refractory B-cell non-Hodgkin lymphoma; and
  - 2.3 Tocilizumab is to be administered according to the consensus guidelines for CRS or ICANS for CAR T-cell therapy at doses no greater than 8 mg/kg IV for a maximum of 3 doses.

Initial application — (previous use) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

#### Both:

- 1 Patient was being treated with tocilizumab prior to 1 February 2019; and
- 2 Any of the following:
  - 2.1 rheumatoid arthritis; or
  - 2.2 systemic juvenile idiopathic arthritis; or
  - 2.3 adult-onset Still's disease; or
  - 2.4 polyarticular juvenile idiopathic arthritis; or
  - 2.5 idiopathic multicentric Castleman's disease.

Initial application — (Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept)) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting 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

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- 2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis; and
- 3 Either:
  - 3.1 The patient is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor; or
  - 3.2 Both:
    - 3.2.1 The patient has been started on rituximab for rheumatoid arthritis in a Health NZ Hospital; and
    - 3.2.2 Fither:
      - 3.2.2.1 The patient has experienced intolerable side effects from rituximab; or
      - 3.2.2.2 At four months following the initial course of rituximab the patient has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis.

Initial application — (Rheumatoid Arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
- 2 Tocilizumab is to be used as monotherapy; and
- 3 Fither:
  - 3.1 Treatment with methotrexate is contraindicated; or
  - 3.2 Patient has tried and did not tolerate oral and/or parenteral methotrexate; and
- 4 Fither:
  - 4.1 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of ciclosporin alone or in combination with another agent; or
  - 4.2 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of leflunomide alone or in combination with another agent; and
- 5 Either:
  - 5.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints;
  - 5.2 Patient has persistent symptoms of poorly controlled and active disease in at least four active joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 6 Fither:
  - 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

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- 1.1.2 The patient has been started on tocilizumab for AOSD in a Health NZ Hospital; and
- 1.2 Either:
  - 1.2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
  - 1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for AOSD; or
- 2 All of the following:
  - 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and
  - 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal antiinflammatory drugs (NSAIDs) and methotrexate; and
  - 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

**Initial application — (polyarticular juvenile idiopathic arthritis)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria: Fither:

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for both etanercept and adalimumab for polyarticular course juvenile idiopathic arthritis (JIA); and
  - 1.2 The patient has experienced intolerable side effects, or has received insufficient benefit from, both etanercept and adalimumab; or
- 2 All of the following:
  - 2.1 Treatment with a tumour necrosis factor alpha inhibitor is contraindicated; and
  - 2.2 Patient has had polyarticular course JIA for 6 months duration or longer; and
  - 2.3 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
  - 2.4 Any of the following:
    - 2.4.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose): or
    - 2.4.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose): or
    - 2.4.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

Initial application — (idiopathic multicentric Castleman's disease) only from a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has severe HHV-8 negative idiopathic multicentric Castleman's disease; and
- 2 Treatment with an adequate trial of corticosteroids has proven ineffective; and
- 3 Tocilizumab to be administered at doses no greater than 8 mg/kg IV every 3-4 weeks.

Initial application — (moderate to severe COVID-19) from any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient has confirmed (or probable) COVID-19; and
- 2 Oxygen saturation of < 92% on room air, or requiring supplemental oxygen; and
- 3 Patient is receiving adjunct systemic corticosteroids, or systemic corticosteroids are contraindicated; and
- 4 Tocilizumab is to be administered at doses no greater than 8mg/kg IV for a maximum of one dose; and
- 5 Tocilizumab is not to be administered in combination with barcitinib.

Renewal — (Rheumatoid Arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Fither:

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- 1 Following 6 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician.

Renewal — (systemic juvenile idiopathic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Fither:

- 1 Following up to 6 months' initial treatment, the patient has achieved at least an American College of Rheumatology paediatric 30% improvement criteria (ACR Pedi 30) response from baseline; or
- 2 On subsequent reapplications, the patient demonstrates at least a continuing ACR Pedi 30 response from baseline.

Renewal — (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months where the patient has a sustained improvement in inflammatory markers and functional status. Renewal — (polyarticular juvenile idiopathic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2 Either:
  - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
  - 2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Renewal — (idiopathic multicentric Castleman's disease) only from a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist. Approvals valid for 12 months where the treatment remains appropriate and the patient has a sustained improvement in inflammatory markers and functional status.

Initial application — (immune checkpoint inhibitor toxicity in malignancy\*) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The individual requires treatment for moderate to severe autoimmune toxicity following immune checkpoint inhibitor treatment for malignancy; and
- 2 The individual has received insufficient benefit from use of corticosteroids; and
- 3 Tocilizumab is to be administered at a maximum dose of 8 mg/kg fortnightly.

Renewal — (immune checkpoint inhibitor toxicity in malignancy\*) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 The individual has shown clinical improvement and ongoing treatment is required; and
- 2 Tocilizumab is to be administered at a maximum dose of 8 mg/kg fortnightly.

Note: Indications marked with \* are unapproved indications.

TRASTUZUMAB (HERZUMA) - PCT only - Special Authority see SA2293 below

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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:

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- 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:

Fither:

- 1 All of the following:
  - 1.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
  - 1.2 The patient received prior adjuvant trastuzumab treatment for early breast cancer; and
  - 1.3 Any of the following:
    - 1.3.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
    - 1.3.2 The patient discontinued lapatinib within 3 months due to intolerable side effects and the cancer did not progress whilst on lapatinib; or
    - 1.3.3 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
  - 1.4 Either:
    - 1.4.1 Trastuzumab will not be given in combination with pertuzumab; or
    - 1.4.2 All of the following:
      - 1.4.2.1 Trastuzumab to be administered in combination with pertuzumab; and
      - 1.4.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
      - 1.4.2.3 The patient has good performance status (ECOG grade 0-1); and
    - 1.5 Trastuzumab to be discontinued at disease progression; or
- 2 All of the following:
  - 2.1 Patient has previously discontinued treatment with trastuzumab in the metastatic setting for reasons other than severe toxicity or disease progression; and
  - 2.2 Patient has signs of disease progression; and
  - 2.3 Disease has not progressed during previous treatment with trastuzumab.

Note: \* For patients with relapsed HER-2 positive disease who have previously received adjuvant trastuzumab for early breast cancer

**Initial application — (metastatic breast cancer)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 Either:
  - 2.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
  - 2.2 The patient discontinued lapatinib within 3 months due to intolerable side effects and the cancer did not progress whilst on lapatinib; and
- 3 Either:
  - 3.1 Trastuzumab will not be given in combination with pertuzumab; or
  - 3.2 All of the following:
    - 3.2.1 Trastuzumab to be administered in combination with pertuzumab; and
    - 3.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer: and
    - 3.2.3 The patient has good performance status (ECOG grade 0-1); and

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continued...

4 Trastuzumab to be discontinued at disease progression.

Renewal — (metastatic breast cancer) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Either:

- 1 All of the following:
  - 1.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
  - 1.2 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
  - 1.3 Trastuzumab to be discontinued at disease progression; or
- 2 All of the following:
  - 2.1 Patient has previously discontinued treatment with trastuzumab for reasons other than severe toxicity or disease progression; and
  - 2.2 Patient has signs of disease progression; and
  - 2.3 Disease has not progressed during previous treatment with trastuzumab.

Initial application — (gastric, gastro-oesophageal junction and oesophageal cancer) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The patient has locally advanced or metastatic gastric, gastro-oesophageal junction or oesophageal cancer expressing HER-2 IHC 2+ FISH+ or IHC3+ (or other current technology); and
- 2 Patient has an ECOG score of 0-2.

Renewal — (gastric, gastro-oesophageal junction and oesophageal cancer) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
- 2 Trastuzumab to be discontinued at disease progression.

#### TRASTUZUMAB DERUXTECAN - PCT only - Special Authority see \$A2420 below

Inj 100 mg per m	2,550.00	1	<ul><li>Enhertu</li></ul>
Inj 1 mg for ECP	 27.05	1 mg	✓ Baxter

## ⇒SA2420 Special Authority for Subsidy

Initial application only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Patient is currently on treatment with trastuzumab deruxtecan and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Patient has metastatic breast cancer expressing HER-2 IHC3+ or ISH+ (including FISH or other current technology); and
  - 2.2 Patient has previously received trastuzumab and chemotherapy, separately or in combination; and
  - 2.3 Either:
    - 2.3.1 The patient has received prior therapy for metastatic disease; or
    - 2.3.2 The patient developed disease recurrence during, or within six months of completing adjuvant therapy; and
  - 2.4 Patient has a good performance status (ECOG 0-1); and
  - 2.5 Patient has not received prior funded trastuzumab deruxtecan treatment; and
  - 2.6 Treatment to be discontinued at disease progression.

**Renewal** only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic \$ Per ✔ Manufacturer
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Both:

- 1 The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab deruxtecan;
- 2 Treatment to be discontinued at disease progression.

Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

## TRASTUZUMAB EMTANSINE - PCT only - Specialist - Special Authority see SA2424 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

# ⇒SA2424 Special Authority for Subsidy

Initial application — (early breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

## All of the following:

- 1 Patient has early breast cancer expressing HER2 IHC3+ or ISH+; and
- 2 Documentation of pathological invasive residual disease in the breast and/or axiliary lymph nodes following completion of surgery; and
- 3 Patient has completed systemic neoadjuvant therapy with trastuzumab and chemotherapy prior to surgery; and
- 4 Disease has not progressed during neoadjuvant therapy; and
- 5 Patient has left ventricular ejection fraction of 45% or greater; and
- 6 Adjuvant treatment with trastuzumab emtansine to be commenced within 12 weeks of surgery; and
- 7 Trastuzumab emtansine to be discontinued at disease progression; and
- 8 Total adjuvant treatment duration must not exceed 42 weeks (14 cycles).

Initial application — (metastatic breast cancer) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 Patient has previously received trastuzumab and chemotherapy, separately or in combination; and
- 3 Fither
  - 3.1 The patient has received prior therapy for metastatic disease\*; or
  - 3.2 The patient developed disease recurrence during, or within six months of completing adjuvant therapy\*; and
- 4 Patient has a good performance status (ECOG 0-1); and
- 5 Either:
  - 5.1 Patient does not have symptomatic brain metastases; or
  - 5.2 Patient has brain metastases and has received prior local CNS therapy; and
- 6 Either:
  - 6.1 Patient has not received prior funded trastuzumab emtansine or trastuzumab deruxtecan treatment; or
  - 6.2 Both:
    - 6.2.1 Patient has discontinued trastuzumab deruxtecan due to intolerance; and
    - 6.2.2 The cancer did not progress while on trastuzumab deruxtecan; and
- 7 Treatment to be discontinued at disease progression.

Renewal — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab emtansine; and
- 2 Treatment to be discontinued at disease progression.

Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

USTEKINUMAB - Special Authority see SA2182 on the next page - Retail pharmacy

Inj 90 mg per ml, 1 ml pre-filled syringe.......4,162.00 1 ✓ Stelara

Subsidy	Fully	Brand or
(Manufacturer's Price)	Subsidised	Generic
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# ⇒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 Fither:
    - 2.2.1 Patient has had an initial approval for prior biologic therapy for Crohn's disease and has experienced intolerable side effects or insufficient benefit to meet renewal criteria: or
    - 2.2.2 Both:
      - 2.2.2.1 Patient meets the initiation criteria for prior biologic therapies for Crohn's disease; and
      - 2.2.2.2 Other biologics for Crohn's disease are contraindicated.

Renewal — (Crohn's disease - adults) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

# Both:

- 1 Any of the following:
  - 1.1 CDAI score has reduced by 100 points, or HBI score has reduced by 3 points, from when the patient was initiated on biologic therapy; or
  - 1.2 CDAI score is 150 or less, or HBI is 4 or less; or
  - 1.3 The patient has experienced an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed; and
- 2 Ustekinumab to be administered at a dose no greater than 90 mg every 8 weeks.

Initial application — (Crohn's disease - children\*) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria: Either:

- 1 Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment; or
- 2 Both:
  - 2.1 Patient has active Crohn's disease: and
  - 2.2 Either:
    - 2.2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria: or
    - 2.2.2 Both:
      - 2.2.2.1 Patient meets the initiation criteria for prior biologic therapies for Crohn's disease; and
      - 2.2.2.2 Other biologics for Crohn's disease are contraindicated.

Note: Indication marked with \* is an unapproved indication.

Renewal — (Crohn's disease - children\*) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

## Both:

- 1 Any of the following:
  - 1.1 PCDAI score has reduced by 10 points from when the patient was initiated on biologic therapy; or
  - 1.2 PCDAI score is 15 or less: or
  - 1.3 The patient has experienced an adequate response to treatment, but CDAI score cannot be assessed; and
- 2 Ustekinumab to administered at a dose no greater than 90 mg every 8 weeks.

Note: Indication marked with \* is an unapproved indication.

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic \$ Per ✔ Manufacturer

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Initial application — (ulcerative colitis) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

# Either:

- 1 Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment; or
- 2 Both:
  - 2.1 Patient has active ulcerative colitis: and
  - 2.2 Fither:
    - 2.2.1 Patient has had an initial approval for prior biologic therapy for ulcerative colitis and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or
    - 2.2.2 Both:
      - 2.2.2.1 Patient meets the initiation criteria for prior biologic therapies for ulcerative colitis; and
      - 2.2.2.2 Other biologics for ulcerative colitis are contraindicated.

**Renewal — (ulcerative colitis)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

#### Both:

- 1 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 Inj 300 mg vial .......3,313.00

✓ Entyvio

# ⇒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;
  - 2.5 Patient has an ileostomy or colostomy, and has intestinal inflammation; and
- 3 Any of the following:
  - 3.1 Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
  - 3.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
  - 3.3 Immunomodulators and corticosteroids are contraindicated.

Renewal — (Crohn's disease - adults) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

### Both:

- 1 Any of the following:
  - 1.1 CDAI score has reduced by 100 points, or HBI score has reduced by 3 points, from when the patient was initiated

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(Manufacturer's Price)	9	Subsidised	Generic	
\$	Per	✓	Manufacturer	

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on biologic therapy; or

- 1.2 CDAI score is 150 or less, or HBI is 4 or less; or
- 1.3 The patient has experienced an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed; and
- 2 Vedolizumab to administered at a dose no greater than 300 mg every 8 weeks.

Initial application — (Crohn's disease - children\*) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Paediatric patient has active Crohn's disease; and
- 2 Any of the following:
  - 2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated); or
  - 2.2 Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30; or
  - 2.3 Patient has extensive small intestine disease; and
- 3 Any of the following:
  - 3.1 Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
  - 3.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
  - 3.3 Immunomodulators and corticosteroids are contraindicated.

Note: Indication marked with \* is an unapproved indication.

Renewal — (Crohn's disease - children\*) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 PCDAI score has reduced by 10 points from when the patient was initiated on biologic therapy; or
  - 1.2 PCDAI score is 15 or less: or
  - 1.3 The patient has experienced an adequate response to treatment, but CDAI score cannot be assessed; and
- 2 Vedolizumab to administered at a dose no greater than 300mg every 8 weeks.

Note: Indication marked with \* is an unapproved indication.

Initial application — (ulcerative colitis) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has active ulcerative colitis; and
- 2 Any of the following:
  - 2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated); or
  - 2.2 Patient has a SCCAI score is greater than or equal to 4: or
  - 2.3 Patient's PUCAI score is greater than or equal to 20\*; and
- 3 Any of the following:
  - 3.1 Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
  - 3.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
  - 3.3 Immunomodulators and corticosteroids are contraindicated.

Note: Indication marked with \* is an unapproved indication.

Renewal — (ulcerative colitis) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

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- 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 Aut	hority see SA2443 below		
Inj 60 mg per ml, 20 ml vial	9,503.00	1	✓ Tecentriq
Inj 1 mg for ECP	8.08	1 mg	✓ Baxter

## ⇒SA2443 Special Authority for Subsidy

Initial application — (non-small cell lung cancer second line monotherapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has locally advanced or metastatic non-small cell lung cancer; and
- 2 Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
- 3 For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
- 4 Patient has an ECOG 0-2: and
- 5 Patient has documented disease progression following treatment with at least two cycles of platinum-based chemotherapy; and
- 6 Atezolizumab is to be used as monotherapy at a dose of 1200 mg every three weeks (or equivalent) for a maximum of 16 weeks; and
- 7 Baseline measurement of overall tumour burden is documented clinically and radiologically.

Renewal — (non-small cell lung cancer second line monotherapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

- 1 Any of the following:
  - 1.1 Patient's disease has had a complete response to treatment; or
  - 1.2 Patient's disease has had a partial response to treatment; or
  - 1.3 Patient has stable disease; and
- 2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; and
- 3 No evidence of disease progression; and
- 4 The treatment remains clinically appropriate and patient is benefitting from treatment; and
- 5 Atezolizumab to be used at a maximum dose of 1200 mg every three weeks (or equivalent); and
- 6 Treatment with atezolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Initial application — (unresectable hepatocellular carcinoma) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Patient is currently on treatment with atezolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Patient has locally advanced or metastatic, unresectable hepatocellular carcinoma; and
  - 2.2 Patient has preserved liver function (Child-Pugh A); and

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- 2.3 Transarterial chemoembolisation (TACE) is unsuitable; and
- 2.4 Any of the following:
  - 2.4.1 Patient has not received prior systemic therapy for the treatment of hepatocellular carcinoma; or
  - 2.4.2 Patient received funded lenvatinib before 1 March 2025; or
  - 2.4.3 Both:
    - 2.4.3.1 Patient has experienced treatment-limiting toxicity from treatment with lenvatinib; and
    - 2.4.3.2 No disease progression since initiation of lenvatinib; and
- 2.5 Patient has an ECOG performance status of 0-2; and
- 2.6 To be given in combination with bevacizumab.

Renewal — (unresectable hepatocellular carcinoma) from any relevant practitioner. Approvals valid for 6 months where there is no evidence of disease progression.

DURVALUMAB - PCT only - Specialist - Special Authority see S	A2425 below		
Inj 50 mg per ml, 10 ml vial	4,700.00	1	Imfinzi
Inj 50 mg per ml, 2.4 ml vial	1,128.00	1	Imfinzi
Inj 1 mg for ECP	9.59	1 mg	<ul><li>Baxter</li></ul>

# ⇒SA2425 Special Authority for Subsidy

Initial application — (Non-small cell lung cancer) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

- 1 Fither:
  - 1.1 Patient has histologically or cytologically documented stage III, locally advanced, unresectable non-small cell lung cancer (NSCLC); or
  - 1.2 Patient has histologically or cytologically documented stage IIb (T1N2a only), locally advanced, unresectable non-small cell lung cancer (NSCLC); and
- 2 Patient has received two or more cycles of platinum-based chemotherapy concurrently with definitive radiation therapy; and
- 3 Patient has no disease progression following the second or subsequent cycle of platinum-based chemotherapy with definitive radiation therapy treatment; and
- 4 Patient has a ECOG performance status of 0 or 1; and
- 5 Patient has completed last radiation dose within 8 weeks of starting treatment with durvalumab; and
- 6 Patient must not have received prior PD-1 or PD-L1 inhibitor therapy for this condition; and
- 7 Either:
  - 7.1 Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks; or
  - 7.2 Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks; and
- 8 Treatment with durvalumab to cease upon signs of disease progression.

Renewal — (Non-small cell lung cancer) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The treatment remains clinically appropriate and the patient is benefitting from treatment; and
- 2 Either:
  - 2.1 Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks; or
  - 2.2 Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks; and
- 3 Treatment with durvalumab to cease upon signs of disease progression; and
- 4 Total continuous treatment duration must not exceed 12 months.

IPILIMUMAB - PCT only - Specialist - Special Authority	y see SA2461 on the next p	page	
Inj 5 mg per ml, 10 ml vial	5,000.00	1	Yervoy
Inj 5 mg per ml, 40 ml vial	20,000.00	1	✓ Yervoy
Inj 1 mg for ECP	106.00	1 mg	✓ Baxter

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(Manufa	cturer's Price) Si	ubsidised	Generic
	\$ Per	✓	Manufacturer

# ⇒SA2461 Special Authority for Subsidy

**Initial application — (renal cell carcinoma)** from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

#### Either:

- 1 The patient is currently on treatment with ipilimumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 The patient has metastatic renal cell carcinoma; and
  - 2.2 The patient is treatment naive; and
  - 2.3 The patient has ECOG performance status 0-2; and
  - 2.4 The disease is predominantly of clear cell histology; and
  - 2.5 Any of the following:
    - 2.5.1 The patient has sarcomatoid histology; or
    - 2.5.2 Haemoglobin levels less than the lower limit of normal; or
    - 2.5.3 Corrected serum calcium level greater than 10 mg/dL (2.5 mmol/L); or
    - 2.5.4 Neutrophils greater than the upper limit of normal; or
    - 2.5.5 Platelets greater than the upper limit of normal; or
    - 2.5.6 Interval of less than 1 year from original diagnosis to the start of systemic therapy; or
    - 2.5.7 Karnofsky performance score of less than or equal to 70; and
  - 2.6 Ipilimumab is to be used at a maximum dose of 1 mg/kg for up to four cycles in combination with nivolumab..

## NIVOLUMAB - PCT only - Specialist - Special Authority see SA2490 below

Inj 10 mg per ml, 4 ml vial	51.98	1 🗸	Opdivo
Inj 10 mg per ml, 10 ml vial2,6	29.96	1	Opdivo
Inj 1 mg for ECP	27.22 1	mg 🗸 I	Baxter

# ⇒SA2490 Special Authority for Subsidy

Initial application — (unresectable or metastatic melanoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
- 2 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
- 3 The individual has ECOG performance 0-2; and
- 4 Either:
  - 4.1 The individual has not received funded pembrolizumab; or
  - 4.2 Both:
    - 4.2.1 The individual has received an initial Special Authority approval for pembrolizumab and has discontinued pembrolizumab within 12 weeks of starting treatment due to intolerance; and
    - 4.2.2 The cancer did not progress while the indvidual was on pembrolizumab; and
- 5 Any of the following:
  - 5.1 The individual has been diagnosed in the metastatic or unresectable stage III or IV setting; or
  - 5.2 The individual did not receive treatment in the perioperative setting with a PD-1/PD-L1 inhibitor; or
  - 5.3 All of the following:
    - 5.3.1 The individual received treatment in the perioperative setting with a PD-1/PD-L1 inhibitor; and
    - 5.3.2 The individual did not experience disease recurrence while on treatment with that PD-1/PD-L1 inhibitor; and
    - 5.3.3 The individual did not experience disease recurrence within six months of completing perioperative treatment with a PD-1/PD-L1 inhibitor.

Renewal — (unresectable or metastatic melanoma, less than 24 months on treatment) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

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- 1 Both:
  - 1.1 Any of the following:
    - 1.1.1 The individual's disease has had a complete response to treatment; or
    - 1.1.2 The individual's disease has had a partial response to treatment; or
    - 1.1.3 The individual has stable disease; and
  - 1.2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; or
  - 2 All of the following:
    - 2.1 The individual has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression; and
    - 2.2 The individual has signs of disease progression; and
    - 2.3 Disease has not progressed during previous treatment with nivolumab.

Renewal — (unresectable or metastatic melanoma, more than 24 months on treatment) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: Both:

- 1 The individual has been on treatment for more than 24 months; and
- - 2.1 Both:
    - 2.1.1 Any of the following:
      - 2.1.1.1 The individual's disease has had a complete response to treatment; or
      - 2.1.1.2 The individual's disease has had a partial response to treatment; or
      - 2.1.1.3 The individual has stable disease; and
    - 2.1.2 Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period; or
  - 2.2 All of the following:
    - 2.2.1 The individual has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression; and
    - 2.2.2 The individual has signs of disease progression; and
    - 2.2.3 Disease has not progressed during previous treatment with nivolumab.

Initial application — (renal cell carcinoma, first line) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

#### Either:

- 1 Patient is currently on treatment with nivolumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 The patient has metastatic renal cell carcinoma; and
  - 2.2 The patient is treatment naive; and
  - 2.3 The patient has ECOG performance status 0-2; and
  - 2.4 The disease is predominantly of clear cell histology; and
  - 2.5 Any of the following:
    - 2.5.1 The patient has sarcomatoid histology; or
    - 2.5.2 Haemoglobin levels less than the lower limit of normal; or
    - 2.5.3 Corrected serum calcium level greater than 10 mg/dL (2.5 mmol/L); or
    - 2.5.4 Neutrophils greater than the upper limit of normal; or
    - 2.5.5 Platelets greater than the upper limit of normal; or
    - 2.5.6 Interval of less than 1 year from original diagnosis to the start of systemic therapy; or
    - 2.5.7 Karnofsky performance score of less than or equal to 70: and

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- 2.6 Nivolumab is to be used in combination with ipilimumab for the first four treatment cycles at a maximum dose of 3 mg/kg; and
- 2.7 Nivolumab is to be used as monotherapy at a maximum maintenance dose of 240 mg every 2 weeks (or equivalent).

**Initial application — (Renal cell carcinoma, second line)** from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has metastatic renal-cell carcinoma; and
- 2 The disease is of predominant clear-cell histology; and
- 3 Patient has ECOG performance status 0-2; and
- 4 Patient has documented disease progression following one or two previous regimens of antiangiogenic therapy; and
- 5 Patient has not previously received a funded immune checkpoint inhibitor; and
- 6 Nivolumab is to be used as monotherapy at a maximum dose of 240 mg every 2 weeks (or equivalent) and discontinued at disease progression.

Renewal — (Renal cell carcinoma) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 Patient's disease has had a complete response to treatment; or
  - 1.2 Patient's disease has had a partial response to treatment; or
  - 1.3 Patient has stable disease; and
- 2 No evidence of disease progression; and
- 3 Nivolumab is to be used as monotherapy at a maximum dose of 240 mg every 2 weeks (or equivalent) and discontinued at disease progression.

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### ⇒SA2498 Special Authority for Subsidy

Initial application — (stage III or IV resectable melanoma - neoadjuvant) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 The individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 The individual has resectable stage IIIB, IIIC, IIID or IV melanoma (excluding uveal) (see note); and
  - 2.2 The individual has not received prior funded systemic treatment in the perioperative setting for their stage IIIB, IIIC, IIID or IV melanoma; and
  - 2.3 Treatment must be prior to complete surgical resection; and
  - 2.4 Pembrolizumab must be administered as monotherapy; and
  - 2.5 The individual has ECOG performance score 0-2; and
  - 2.6 Pembrolizumab to be administered at a fixed dose of 200 mg every 3 weeks (or equivalent).

Renewal — (stage III or IV resectable melanoma - neoadjuvant) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

Any of the following:

1 Both:

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- 1.1 The individual has received neoadjuvant treatment with an immune checkpoint inhibitor; and
- 1.2 The individual meets initial application criteria for pembrolizumab for stage III or IV resected melanoma adjuvant; or

#### 2 Both:

- 2.1 The individual has received neoadjuvant and adjuvant treatment with an immune checkpoint inhibitor; and
- 2.2 The individual meets renewal criteria for pembrolizumab for stage III or IV resected melanoma adjuvant; or

#### 3 All of the following:

- 3.1 The individual has received neoadjuvant and adjuvant treatment with an immune checkpoint inhibitor; and
- 3.2 The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV: and
- 3.3 The individual meets initial application criteria for pembrolizumab for unresectable or metastatic melanoma; or

#### 4 All of the following:

- 4.1 The individual has received neoadjuvant and adjuvant treatment with an immune checkpoint inhibitor; and
- 4.2 The individual has received treatment with an immune checkpoint inhibitor for unresectable or metastatic melanoma; and
- 4.3 The individual meets renewal criteria for pembrolizumab for unresectable or metastatic melanoma.

#### Notes:

- a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition
- b) Initiating treatment within 13 weeks of complete surgical resection means either 13 weeks after resection (primary or lymphadenectomy) or 13 weeks prior to the scheduled date of the resection (primary or lymphadenectomy)

Initial application — (stage III or IV resected melanoma - adjuvant) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: Either:

- 1 The individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 The individual has resected stage IIIB, IIIC, IIID or IV melanoma (excluding uyeal) (see note a); and
  - 2.2 Adjuvant treatment with pembrolizumab is required; and
  - 2.3 The individual has not received prior funded systemic treatment in the adjuvant setting for stage IIIB, IIIC, IIID or IV melanoma; and
  - 2.4 Treatment must be in addition to complete surgical resection; and
  - 2.5 Treatment must be initiated within 13 weeks of complete surgical resection, unless delay is necessary due to post-surgery recovery (see note b); and
  - 2.6 Pembrolizumab must be administered as monotherapy; and
  - 2.7 The individual has ECOG performance score 0-2; and
  - 2.8 Pembrolizumab to be administered at a fixed dose of 200 mg every 3 weeks (or equivalent).

#### Notes:

- a) Stage IIIB, IIIC, IIID or IV melanoma defined as per American Joint Committee on Cancer (AJCC) 8th Edition
- b) Initiating treatment within 13 weeks of complete surgical resection means 13 weeks after resection (primary or lymphadenectomy)

Renewal — (stage III or IV resected melanoma - adjuvant) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

Any of the following:

- 1 All of the following:
  - 1.1 No evidence of disease recurrence; and
  - 1.2 Pembrolizumab must be administered as monotherapy; and
  - 1.3 Pembrolizumab to be administered at a fixed dose of 200 mg every three weeks (or equivalent) for a maximum of 12 months total treatment course, including any systemic neoadjuvant treatment; and

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- 1.4 Treatment to be discontinued at signs of disease recurrence or at completion of 12 months total treatment course (equivalent to 18 cycles at a dose of 200 mg every 3 weeks), including any systemic neoadjuvant treatment; or
- 2 All of the following:
  - 2.1 The individual has received adjuvant treatment with an immune checkpoint inhibitor; and
  - 2.2 The individual has metastatic or unresectable melanoma (excluding uyeal) stage III or IV: and
  - 2.3 The individual meets initial application criteria for pembrolizumab for unresectable or metastatic melanoma; or
- 3 All of the following:
  - 3.1 The individual has received adjuvant treatment with an immune checkpoint inhibitor; and
  - 3.2 The individual has received treatment with an immune checkpoint inhibitor for unresectable or metastatic melanoma; and
  - 3.3 The individual meets renewal criteria for pembrolizumab for unresectable or metastatic melanoma.

Initial application — (unresectable or metastatic melanoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The individual has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
- 2 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
- 3 The individual has ECOG performance score of 0-2; and
- 4 Either:
  - 4.1 The individual has not received funded nivolumab; or
  - 4.2 Both:
    - 4.2.1 The individual has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance; and
    - 4.2.2 The cancer did not progress while the individual was on nivolumab; and
- 5 Any of the following:
  - 5.1 The individual has been diagnosed in the metastatic or unresectable stage III or IV setting; or
  - 5.2 The individual did not receive treatment in the perioperative setting with a PD-1/PD-L1 inhibitor; or
  - 5.3 All of the following:
    - 5.3.1 The individual received treatment in the perioperative setting with a PD-1/PD-L1 inhibitor; and
    - 5.3.2 The individual did not experience disease recurrence while on treatment with that PD-1/PD-L1 inhibitor; and
    - 5.3.3 The individual did not experience disease recurrence within six months of completing perioperative treatment with a PD-1/PD-L1 inhibitor.

Renewal — (unresectable or metastatic melanoma, less than 24 months on treatment) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 Both:
  - 1.1 Any of the following:
    - 1.1.1 The individual's disease has had a complete response to treatment; or
    - 1.1.2 The individual's disease has had a partial response to treatment; or
    - 1.1.3 The individual has stable disease; and
  - 1.2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; or
- 2 All of the following:
  - 2.1 The individual has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression; and
  - 2.2 The individual has signs of disease progression; and
  - 2.3 Disease has not progressed during previous treatment with pembrolizumab.

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Renewal — (unresectable or metastatic melanoma, more than 24 months on treatment) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 The individual has been on treatment for more than 24 months; and
- 2 Either:
  - 2.1 Both:
    - 2.1.1 Any of the following:
      - 2.1.1.1 The individual's disease has had a complete response to treatment; or
      - 2.1.1.2 The individual's disease has had a partial response to treatment; or
      - 2.1.1.3 The individual has stable disease: and
    - 2.1.2 Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period; or
  - 2.2 All of the following:
    - 2.2.1 The individual has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression; and
    - 2.2.2 The individual has signs of disease progression; and
    - 2.2.3 Disease has not progressed during previous treatment with pembrolizumab.

Initial application — (non-small cell lung cancer first-line monotherapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer; and
- 2 Patient has not had chemotherapy for their disease in the palliative setting; and
- 3 Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
- 4 For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
- 5 Pembrolizumab to be used as monotherapy; and
- - 6.1 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

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- 2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; and
- 3 No evidence of disease progression; and
- 4 The treatment remains clinically appropriate and patient is benefitting from treatment; and
- 5 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 6 Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

**Initial application — (non-small cell lung cancer first-line combination therapy)** only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer; and
- 2 The patient has not had chemotherapy for their disease in the palliative setting; and
- 3 Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
- 4 For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
- 5 Pembrolizumab to be used in combination with platinum-based chemotherapy; and
- 6 Patient has an ECOG 0-2: and
- 7 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks; and
- 8 Baseline measurement of overall tumour burden is documented clinically and radiologically.

Renewal — (non-small cell lung cancer first line combination therapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 Patient's disease has had a complete response to treatment; or
  - 1.2 Patient's disease has had a partial response to treatment; or
  - 1.3 Patient has stable disease; and
- 2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period: and
- 3 No evidence of disease progression; and
- 4 The treatment remains clinically appropriate and patient is benefitting from treatment; and
- 5 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 6 Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Initial application — (breast cancer, advanced) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria: 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

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- 2.3 Patient's cancer has confirmed PD-L1 Combined Positive Score (CPS) is greater than or equal to 10; and
- 2.4 Patient has received no prior systemic therapy in the palliative setting; and
- 2.5 Patient has an ECOG score of 0-2; and
- 2.6 Pembrolizumab is to be used in combination with chemotherapy; and
- 2.7 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
- 2.8 Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of

**Renewal — (breast cancer, advanced)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 Patient's disease has had a complete response to treatment; or
  - 1.2 Patient's disease has had a partial response to treatment; or
  - 1.3 Patient has stable disease; and
- 2 No evidence of disease progression; and
- 3 Response to treatment in target lesions has been determined by a comparable radiologic assessment following the most recent treatment period; and
- 4 Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 5 Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Initial application — (head and neck squamous cell carcinoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: Either:

- 1 Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Patient has recurrent or metastatic head and neck squamous cell carcinoma of mucosal origin (excluding nasopharyngeal carcinoma) that is incurable by local therapies; and
  - 2.2 Patient has not received prior systemic therapy in the recurrent or metastatic setting; and
  - 2.3 Patient has a positive PD-L1 combined positive score (CPS) of greater than or equal to 1; and
  - 2.4 Patient has an ECOG performance score of 0-2; and
  - 2.5 Either:
    - 2.5.1 Pembrolizumab to be used in combination with platinum-based chemotherapy; or
    - 2.5.2 Pembrolizumab to be used as monotherapy; and
  - 2.6 Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks.

**Renewal — (head and neck squamous cell carcinoma)** from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 Patient's disease has had a complete response to treatment; or
  - 1.2 Patient's disease has had a partial response to treatment; or
  - 1.3 Patient has stable disease; and
- 2 No evidence of disease progression; and
- 3 Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 4 Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Initial application — (MSI-H/dMMR advanced colorectal cancer) only from a relevant specialist or any relevant practitioner on

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the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

- 1 Individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Either:
    - 2.1.1 Individual has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer: or
    - 2.1.2 Individual has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) unresectable colorectal cancer: and
  - 2.2 Individual is treated with palliative intent; and
  - 2.3 Individual has not previously received funded treatment with pembrolizumab for MSI-H/dMMR advanced colorectal
  - 2.4 Individual has an ECOG performance score of 0-2; and
  - 2.5 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
  - 2.6 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks.

Renewal — (MSI-H/dMMR advanced colorectal cancer) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 No evidence of disease progression; and
- 2 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 3 Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Initial application — (Urothelial carcinoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: 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: Fither:

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- 1 Individual is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Either:
    - 2.1.1 Both:
      - 2.1.1.1 Individual has relapsed/refractory Hodgkin lymphoma after two or more lines of chemotherapy; and
      - 2.1.1.2 Individual is ineligible for autologous stem cell transplant; or
    - 2.1.2 Individual has relapsed/refractory Hodgkin lymphoma and has previously undergone an autologous stem cell transplant; and
  - 2.2 Individual has not previously received funded pembrolizumab for relapsed/refractory Hodgkin lymphoma; and
  - 2.3 Pembrolizumab to be administered at doses no greater than 200 mg once every 3 weeks.

Renewal — (relapsed/refractory Hodgkin lymphoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has received a partial or complete response to pembrolizumab; and
- 2 Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

# Other Immunosuppressants

CICLOSPORIN		
Cap 25 mg44.60	3 50	Neoral
Cap 50 mg	1 50	Neoral
Cap 100 mg177.8	1 50	✓ Neoral
Oral liq 100 mg per ml198.13	3 50 ml OP	✓ Neoral
EVEROLIMUS - Special Authority see SA2414 below - Retail pharmacy		
Wastage claimable		
Tab 10 mg	9 30	<ul><li>Afinitor</li></ul>
Tab 5 mg4,555.76	6 30	✓ Afinitor

#### ⇒SA2414 Special Authority for Subsidy

Initial application only from a neurologist or oncologist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 Patient has tuberous sclerosis: and
- 2 Patient has progressively enlarging sub-ependymal giant cell astrocytomas (SEGAs) that require treatment.

**Renewal** only from a neurologist or oncologist. Approvals valid for 12 months for applications meeting the following criteria: All of the following:

- 1 Documented evidence of SEGA reduction or stabilisation by MRI within the last 3 months; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment; and
- 3 Everolimus to be discontinued at progression of SEGAs.

**Initial application — (renal cell carcinoma)** from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 All of the following:
  - 1.1 The patient has metastatic renal cell carcinoma; and
  - 1.2 The disease is of predominant clear-cell histology; and
  - 1.3 The patient has documented disease progression following one previous line of treatment; and

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- 1.4 The patient has an ECOG performance status of 0-2; and
- 1.5 Everolimus is to be used in combination with lenvatinib; or
- 2 All of the following:
  - 2.1 Patient has received funded treatment with nivolumab for the second line treatment of metastatic renal cell carcinoma; and
  - 2.2 Patient has experienced treatment limiting toxicity from treatment with nivolumab; and
  - 2.3 Everolimus is to be used in combination with lenvatinib; and
  - 2.4 There is no evidence of disease progression.

Renewal — (renal cell carcinoma) from any relevant practitioner. Approvals valid for 4 months where there is no evidence of disease progression.

SIROLIMUS - Special Authority see 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).

Renewal — (severe non-malignant lymphovascular malformations\*) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 Patient's disease has had either a complete response or a partial response to treatment, or patient has stable disease according to RECIST version 1.1 (see Note); or
  - 1.2 Patient's disease has stabilised or responded clinically and disease response to treatment has been clearly documents in patient notes; and
- 2 No evidence of progressive disease; and
- 3 The treatment remains clinically appropriate and the patient is benefitting from the treatment.

Notes: Baseline assessment and disease responses to be assessed according to the Response Evaluation Criteria in Solid

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Tumours (RECIST) version 1.1 (Eisenhauer et al. Eur J Cancer 2009;45:228-47)

Indications marked with \* are unapproved indications

Initial application — (renal angiomyolipoma(s) associated with tuberous sclerosis complex\*) only from a nephrologist or urologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has tuberous sclerosis complex\*; and
- 2 Evidence of renal angiomyolipoma(s) measuring 3 cm or greater and that have shown interval growth.

Renewal — (renal angiomyolipoma(s) associated with tuberous sclerosis complex\*) from any relevant practitioner.

Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Documented evidence of renal angiomyolipoma reduction or stability by magnetic resonance imaging (MRI) or ultrasound; and
- 2 Demonstrated stabilisation or improvement in renal function; and
- The patient has not experienced angiomyolipoma haemorrhage or significant adverse effects to sirolimus treatment; and
   The treatment remains appropriate and the patient is benefitting from treatment.

Note: Indications marked with \* are unapproved indications

Initial application — (refractory seizures associated with tuberous sclerosis complex\*) only from a neurologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has epilepsy with a background of documented tuberous sclerosis complex; and
- 2 Fither:
  - 2.1 Both:
    - 2.1.1 Vigabatrin has been trialled and has not adequately controlled seizures; and
    - 2.1.2 Seizures are not adequately controlled by, or the patient has experienced unacceptable side effects from, optimal treatment with at least two of the following: sodium valproate, topiramate, levetiracetam, carbamazepine, lamotrigine, phenytoin sodium, and lacosamide (see Note); or
  - 2.2 Both:
    - 2.2.1 Vigabatrin is contraindicated; and
    - 2.2.2 Seizures are not adequately controlled by, or the patient has experienced unacceptable side effects from, optimal treatment with at least three of the following: sodium valproate, topiramate, levetiracetam, carbamazepine, lamotrigine, phenytoin sodium, and lacosamide (see Note); and
- 3 Seizures have a significant impact on quality of life; and
- 4 Patient has been assessed and surgery is considered inappropriate for this patient, or the patient has been assessed and would benefit from mTOR inhibitor treatment prior to surgery.

Note: Those of childbearing age potential are not required to trial phenytoin sodium, sodium valproate, or topiramate. Those who can father children are not required to trial sodium valproate.

Renewal — (refractory seizures associated with tuberous sclerosis complex\*) only from a neurologist. Approvals valid for 12 months where demonstrated significant and sustained improvement in seizure rate (e.g. 50% reduction in seizure frequency) or severity and/or patient quality of life compared with baseline prior to starting sirolimus treatment.

Note: Indications marked with \* are unapproved indications

TACROLIMUS - Special Authority see SA2455 on the next page - Retail pharmacy

Cap 0.5 mg	100	✓ Tacrolimus Sandoz
Cap 0.75 mg	100	✓ Tacrolimus Sandoz
Cap 1 mg	100	✓ Tacrolimus Sandoz
Cap 5 mg	50	✓ Tacrolimus Sandoz

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Manufacturer

# ⇒SA2455 Special Authority for Subsidy

Initial application — (organ transplant) only from a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

#### Fither:

- 1 The individual is an organ transplant recipient; or
- 2 The individual is receiving induction therapy for an organ transplant.

Note: Subsidy applies for either primary or rescue therapy.

Initial application — (non-transplant indications\*) only from a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

#### Both:

- 1 Patient requires long-term systemic immunosuppression; and
- 2 Either:
  - 2.1 Ciclosporin has been trialled and discontinued treatment because of unacceptable side effects or inadequate clinical response; or
  - 2.2 Patient is a child with nephrotic syndrome\*.

Note: Indications marked with \* are unapproved indications

# **JAK** inhibitors

UPADACITINIB	<ul> <li>Snecial</li> </ul>	Authority see	SA2483	helow -	Retail nharmacy
UFADACITIND	– ODECIAI	AUTHORITA SEE	JA2400	Delow -	netali bilalillatv

Tab modified-release 15 mg	1,271.00	28	✓ Rinvoq
Tab modified-release 30 mg	2,033.00	28	✓ Rinvoq
Tab modified-release 45 mg	3.049.00	28	✓ Rinvoq

### ⇒SA2483 Special Authority for Subsidy

Initial application — (Rheumatoid Arthritis (previously treated with adalimumab or etanercept)) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 The individual has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
- 1 The individu
  - 2.1 The individual has experienced intolerable side effects with adalimumab and/or etanercept; or
  - 2.2 The individual has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis; and
  - 3 Any of the following:
    - 3.1 Rituximab is not clinically appropriate; or
    - 3.2 The individual is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor; or
    - 3.3 Both:
      - 3.3.1 The individual has been started on rituximab for rheumatoid arthritis in a Health NZ Hospital: and
      - 3.3.2 Either:
        - 3.3.2.1 The individual has experienced intolerable side effects with rituximab; or
        - 3.3.2.2 At four months following the initial course of rituximab the individual has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis.

Renewal — (Rheumatoid Arthritis) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

#### Either:

- 1 Following 6 months' initial treatment, the individual has experienced at least a 50% decrease in active joint count from baseline; or
- 2 On subsequent reapplications, the individual has experienced at least a continuing 30% improvement in active joint count

Subsidy (Manufacturer's Price)		Fully Subsidised	Brand or Generic	
<u> </u>	Per	✓	Manufacturer	

continued...

from baseline

Initial application — (atopic dermatitis) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

#### Either:

- 1 Individual is currently on treatment with upadacitinib for atopic dermatitis and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
  - 2.1 Individual has moderate to severe atopic dermatitis, severity as defined by an Eczema Area and Severity Index (EASI) score of greater than or equal to 16 or a Dermatology Life Quality Index (DLQI) score of greater than or equal to 10; and
  - 2.2 Individual has received insufficient benefit from topical therapy (including topical corticosteroids or topical calcineurin inhibitors) for a 28-day trial within the last 6 months, unless contraindicated to all; and
  - 2.3 Individual has trialled and received insufficient benefit from at least one systemic therapy for a minimum of three months (eg ciclosporin, azathioprine, methotrexate or mycophenolate mofetil), unless contraindicated to all; and
  - 2.4 An EASI assessment or DLQI assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
  - 2.5 The most recent EASI or DQLI assessment is no more than 1 month old at the time of application.

**Renewal — (atopic dermatitis)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

#### Either:

- 1 Individual has received a 75% or greater reduction in EASI score (EASI 75) as compared to baseline EASI prior to commencing upadacitinib; or
- 2 Individual has received a DLQI improvement of 4 or more as compared to baseline DLQI prior to commencing upadacitinib.

**Initial application** — **(Crohn's disease - adult)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

# Either:

- 1 Individual is currently on treatment with upadacitinib for Crohn's disease and met all remaining criteria prior to commencing treatment; or
- 2 Both:
  - 2.1 Individual has active Crohn's disease: and
  - 2.2 Either:
    - 2.2.1 Individual has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or
    - 2.2.2 Both:
      - 2.2.2.1 Individual meets the initiation criteria for prior biologic therapies for Crohn's disease; and
      - 2.2.2.2 Other biologic therapies for Crohn's disease are contraindicated.

Renewal — (Crohn's disease - adult) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 CDAI score has reduced by 100 points from the CDAI score when the individual was initiated on biologic therapy; or
- 2 HBI score has reduced by 3 points from when individual was initiated on biologic therapy; or
- 3 CDAI score is 150 or less; or
- 4 HBI score is 4 or less; or
- 5 The individual has experienced an adequate response to treatment, but CDAI score cannot be assessed.

Initial application — (Crohn's disease - children\*) from any relevant practitioner. Approvals valid for 6 months for applications

Subsidy	Fully		Brand or	
(Manufacturer's Price)	S	ubsidised	Generic	
\$	Per	1	Manufacturer	

continued

meeting the following criteria:

#### Either:

- 1 Individual is currently on treatment with upadacitinib for Crohn's disease and met all remaining criteria prior to commencing treatment; or
- 2 Both:
  - 2.1 Child has active Crohn's disease; and
  - 2.2 Fither:
    - 2.2.1 Child has had an initial approval for prior biologic therapy for Crohn's disease and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or
    - 2.2.2 Both:
      - 2.2.2.1 Child meets the initiation criteria for prior biologic therapies for Crohn's disease; and
      - 2.2.2.2 Other biologic therapies for Crohn's disease are contraindicated.

Renewal — (Crohn's disease - children\*) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 PCDAI score has reduced by 10 points from the child was initiated on treatment; or
- 2 PCDAI score is 15 or less: or
- 3 The child has experienced an adequate response to treatment, but PCDAI score cannot be assessed.

Note: Indications marked with \* are unapproved indications.

Initial application — (ulcerative colitis) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Fither:

#### \_....

- 1 Individual is currently on treatment with upadacitinib for ulcerative colitis and met all remaining criteria prior to commencing treatment; or
- 2 Both:
  - 2.1 Individual has active ulcerative colitis: and
  - 2.2 Either:
    - 2.2.1 Individual has had an initial approval for prior biologic therapy for ulcerative colitis and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or
    - 2.2.2 Both:
      - 2.2.2.1 Individual meets the initiation criteria for prior biologic therapies for ulcerative colitis; and
      - 2.2.2.2 Other biologic therapies for ulcerative colitis are contraindicated.

Renewal — (ulcerative colitis) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

#### Either:

- 1 The SCCAI score has reduced by 2 points or more from the SCCAI score when the individual was initiated on treatment; or
- 2 PUCAI score has reduced by 10 points or more from the PUCAI score when the individual was initiated on treatment.

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic 
\$ Per ✔ Manufacturer

# **Antiallergy Preparations**

### Allergic Emergencies

ADRENALINE - Special Authority see SA2185 below - Retail pharmacy

- a) Maximum of 2 inj per prescription
- Additional prescriptions limited to replacement of up to two devices prior to expiry, or replacement of used device for treatment of anaphylaxis.

#### ⇒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.

	Subsidy		Fully Brand or
	(Manufacturer's Pr	rice) Sub Per	sidised Generic  Manufacturer
BEEVENON ALLEDOV TREATMENT O CLARK S	Ψ		
BEE VENOM ALLERGY TREATMENT – Special Authority see			
Initiation kit - 1 vial freeze dried venom with diluent		1 OP	✓ VENOX S29
Maintenance kit - 1 vial freeze dried venom with diluent	305.00	1 OP	✓ VENOX S29
Maintenance kit - 6 vials 120 mcg freeze dried venom, with			
diluent	285.00	1 OP	✓ Venomil S29
Treatment kit - 1 vial 550 mcg freeze dried venom, 1 diluent			4.41
9 ml, 3 diluent 1.8 ml		1 OP	✓ Albey
Treatment kit - 1 vial 550 mcg freeze dried venom, with dilue	ent305.00	1 OP	✓ Hymenoptera S29
WASP VENOM ALLERGY TREATMENT - Special Authority ser	e SA1367 on the	orevious page	e – Retail pharmacy
Treatment kit (Paper wasp venom) - 1 vial 550 mcg freeze			
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			
dried venom, with diluent		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	431.24	1 OP	✓ Albey
Treatment kit (Yellow jacket venom) - 6 vials 120 mcg freeze			•
dried venom, with diluent		1 OP	✓ Venomil S29
,			
Antihistamines			
CETIRIZINE HYDROCHLORIDE			4 ·
* Tab 10 mg		100	✓ Zista
* Oral liq 1 mg per ml	3.99	200 ml	✓ Histaclear
DEXTROCHLORPHENIRAMINE MALEATE			
* Tab 2 mg	2.02	40	
	(8.40)		Polaramine
	1.01	20	
	(5.99)		Polaramine
* Oral liq 2 mg per 5 ml		100 ml	
	(10.29)		Polaramine
FEXOFENADINE HYDROCHLORIDE			
* Tab 60 mg	4.34	20	
	(8.23)		Telfast
* Tab 120 mg		30	✓ Fexaclear
* Tab 180 mg	4.10	30	✓ Fexaclear
LORATADINE			
* Tab 10 mg		100	✓ Lorafix
* Oral liq 1 mg per ml	1.43	100 ml	<ul><li>Haylor syrup</li></ul>
PROMETHAZINE HYDROCHLORIDE			
* Tab 10 mg	2.19	100	✓ Allersoothe
Allersoothe to be Principal Supply on 1 December 2025			
* Tab 25 mg		100	✓ Allersoothe
Allersoothe to be Principal Supply on 1 December 2025			
* 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	<ul><li>Hospira</li></ul>
			-

<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

Powder for inhalation, 50 mcg per dose, breath activated ......26.25

	\$	Per	✓ Manufacturer
Inhaled Corticosteroids			
BECLOMETHASONE DIPROPIONATE			
Aerosol inhaler, 50 mcg per dose	14.01	200 dose OP	✓ Qvar
Aerosol inhaler, 50 mcg per dose CFC-free	8.54	200 dose OP	✓ Beclazone 50
Aerosol inhaler, 100 mcg per dose	17.52	200 dose OP	✓ Qvar
Aerosol inhaler, 100 mcg per dose CFC-free		200 dose OP	✓ Beclazone 100
Aerosol inhaler, 250 mcg per dose CFC-free	22.67	200 dose OP	✓ Beclazone 250
BUDESONIDE			
Powder for inhalation, 100 mcg per dose	17.00	200 dose OP	✓ Pulmicort
,			Turbuhaler
Powder for inhalation, 200 mcg per dose	19.00	200 dose OP	✓ Pulmicort
• •			Turbuhaler
Powder for inhalation, 400 mcg per dose	32.00	200 dose OP	✓ Pulmicort
,			Turbuhaler
FLUTICASONE			
Aerosol inhaler, 50 mcg per dose	7.19	120 dose OP	✓ Flixotide
Powder for inhalation, 50 mcg per dose		60 dose OP	✓ Flixotide Accuhaler
Powder for inhalation, 100 mcg per dose		60 dose OP	✓ Flixotide Accuhaler
Aerosol inhaler, 125 mcg per dose		120 dose OP	✓ Flixotide
Aerosol inhaler, 250 mcg per dose	24.62	120 dose OP	✓ Flixotide
Powder for inhalation, 250 mcg per dose		60 dose OP	✓ Flixotide Accuhaler
Inhaled Long-acting Beta-adrenoceptor Agonist	S		
EFORMOTEROL FUMARATE DIHYDRATE			
Powder for inhalation 4.5 mcg per dose, breath activated			
(equivalent to eformoterol fumarate 6 mcg metered dose	) 10.32	60 dose OP	
	(16.90)		Oxis Turbuhaler
INDACATEROL			
Powder for inhalation 150 mcg	61.00	30 dose OP	✓ Onbrez Breezhaler
Powder for inhalation 300 mcg		30 dose OP	✓ Onbrez Breezhaler
SALMETEROL			

Subsidy

(Manufacturer's Price)

Fully

Subsidised

Brand or

Generic

120 dose OP

60 dose OP

✓ Serevent✓ Serevent Accuhaler

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic \$
Per ✓ Manufacturer

# Inhaled Corticosteroids with Long-Acting Beta-Adrenoceptor Agonists

RUDES	UNIDE	WITH	<b>FFORM</b> C	TERNI

	220011122 11111121 0111110121102			
*	Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide with 6 mcg eformoterol fumarate metered dose) – Up to 120 dose available on a PSO	41.50	120 dose OP	✓ DuoResp Spiromax
	Powder for inhalation 320 mcg with 9 mcg eformoterol fumarate per dose (equivalent to 400 mcg budesonide with 12 mcg eformoterol fumarate metered dose) – No more than 2			
	dose per day	82.50	120 dose OP	<ul><li>DuoResp Spiromax</li></ul>
*	Aerosol inhaler 100 mcg with eformoterol fumarate 6 mcg - Up			
	to 120 dose available on a PSO	18.23	120 dose OP	✓ Vannair
*	Powder for inhalation 100 mcg with eformoterol fumarate 6 mcg	00.74	100   00	
	- Up to 120 dose available on a PSO	33.74	120 dose OP	✓ Symbicort Turbuhaler 100/6
*	Aerosol inhaler 200 mcg with eformoterol fumarate 6 mcg - Up			
	to 120 dose available on a PSO	21.40	120 dose OP	✓ Vannair
*	Powder for inhalation 200 mcg with eformoterol fumarate 6 mcg			
	– Up to 120 dose available on a PSO	33.74	120 dose OP	✓ Symbicort Turbuhaler 200/6
	Powder for inhalation 400 mcg with eformoterol fumarate			
	12 mcg - No more than 2 dose per day	33.74	60 dose OP	✓ Symbicort Turbuhaler 400/12
FLI	JTICASONE FUROATE WITH VILANTEROL			
	Powder for inhalation 100 mcg with vilanterol 25 mcg	44.08	30 dose OP	✓ Breo Ellipta
FU	JTICASONE WITH SALMETEROL			·
	Aerosol inhaler 50 mcg with salmeterol 25 mcg	25.79	120 dose OP	✓ Seretide
	Aerosol inhaler 125 mcg with salmeterol 25 mcg		120 dose OP	✓ Seretide
	Powder for inhalation 100 mcg with salmeterol 50 mcg - No			
	more than 2 dose per day	33.74	60 dose OP	✓ Seretide Accuhaler
	Powder for inhalation 250 mcg with salmeterol 50 mcg - No			
	more than 2 dose per day	44.08	60 dose OP	<ul> <li>Seretide Accuhaler</li> </ul>

# Beta-Adrenoceptor Agonists

$S\Delta I$		

ALDOTAMOL			
Oral liq 400 mcg per ml	50.00	150 ml	✓ Ventolin
Infusion 1 mg per ml, 5 ml	130.00	10	✓ Ventolin
Inj 500 mcg per ml, 1 ml - Up to 5 inj available on a PSO		5	✓ Ventolin

	Subsidy		Fully Brand or
	(Manufacturer's \$	Price) Subsid	dised Generic  ✓ Manufacturer
	<u> </u>	1 01	- Manufacturor
Inhaled Beta-Adrenoceptor Agonists			
SALBUTAMOL			
Aerosol inhaler, 100 mcg per dose CFC free - Up to 1000 dose available on a PSO	4.18 (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		20	✓ Asthalin ✓ UK Cipla S29
Nebuliser soln, 2 mg per ml, 2.5 ml ampoule – Up to 30 neb available on a PSO		20	✓ Asthalin ✓ UK Cipla S29
TERBUTALINE SULPHATE			
Powder for inhalation, 200 mcg per dose (equivalent to 250 mcg metered dose), breath activated	22.20	120 dose OP	✓ Bricanyl Turbuhaler
Anticholinergic Agents			
IPRATROPIUM BROMIDE  Aerosol inhaler, 20 mcg per dose CFC-free – Up to 400 dos	е		_
available on a PSONebuliser soln, 250 mcg per ml, 2 ml ampoule – Up to 40 ne	16.20	200 dose OP	✓ Atrovent
available on a PSO		20	✓ Accord \$29 ✓ Univent
Inhaled Beta-Adrenoceptor Agonists with Antic	holinergic A	Agents	
SALBUTAMOL WITH IPRATROPIUM BROMIDE			
Aerosol inhaler, 100 mcg with ipratropium bromide, 20 mcg p dose CFC-free Nebuliser soln, 2.5 mg with ipratropium bromide 0.5 mg per	12.19	200 dose OP	✓ Duolin HFA
vial, 2.5 ml ampoule – Up to 20 neb available on a PSO	11.04	20	✓ Duolin
Long-Acting Muscarinic Antagonists			
GLYCOPYRRONIUM – Subsidy by endorsement  a) Inhaled glycopyrronium treatment will not be subsidised i umeclidinium.  b) Glycopyrronium powder for inhalation 50 mcg per dose is having COPD using spirometry if spirometry is possible, a Powder for inhalation 50 mcg per dose	subsidised only and the prescrip	y for patients who	have been diagnosed as
TIOTROPIUM BROMIDE – Subsidy by endorsement  a) Tiotropium treatment will not be subsidised if patient is all			
umeclidinium.  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 deemed.	ave been diagno ccordingly. Pat	osed as having C	OPD using spirometry if
Powder for inhalation, 18 mcg per dose		30 dose 60 dose OP	<ul><li>✓ Spiriva</li><li>✓ Spiriva Respimat</li></ul>

✓ fully subsidised

Principal Supply

Subsidy		Fully	Brand or	
(Manufacturer's Price)	Sı	ubsidised	Generic	
\$	Per	✓	Manufacturer	

UMECLIDINIUM - Subsidy by endorsement

- a) Umeclidinium will not be subsidised if patient is also receiving treatment with subsidised inhaled glycopyrronium or tiotropium bromide.
- b) Umeclidinium powder for inhalation 62.5 mcg per dose is subsidised only for patients who have been diagnosed as having COPD using spirometry if spirometry is possible, and the prescription is endorsed accordingly.

# Long-Acting Muscarinic Antagonists with Long-Acting Beta-Adrenoceptor Agonists

Combination long acting muscarinic antagonist and long acting beta-2 agonist will not be subsidised if patient is also receiving treatment with a combination inhaled corticosteroid and long acting beta-2 agonist.

### ⇒SA1584 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria: Both:

- 1 Patient has been stabilised on a long acting muscarinic antagonist; and
- 2 The prescriber considers that the patient would receive additional benefit from switching to a combination product.

Renewal from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria: Both:

- 1 Patient is compliant with the medication; and
- 2 Patient has experienced improved COPD symptom control (prescriber determined).

GLYCOPYRRONIUM WITH INDACATEROL - Special Authority see SA1584 above - Retail pharmacy

Powder for Inhalation 50 mcg with indacaterol 110 mcg......81.00 30 dose OP 🗸 Ultibro Breezhaler

TIOTROPIUM BROMIDE WITH OLODATEROL - Special Authority see SA1584 above - Retail pharmacy

UMECLIDINIUM WITH VILANTEROL - Special Authority see SA1584 above - Retail pharmacy

Powder for inhalation 62.5 mcg with vilanterol 25 mcg .......77.00 30 dose OP Anoro Ellipta

# Inhaled Corticosteroid with Long-Acting Muscarinic Antagonist and Beta Agonist

BUDESONIDE WITH GLYCOPYRRONIUM AND EFORMOTEROL – Special Authority see SA2421 below – Retail pharmacy Aerosol inhaler budesonide 160 mcg with glycopyrronium

#### ⇒SA2421 Special Authority for Subsidy

**Initial application** from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

#### Both:

- 1 Patient has a diagnosis of COPD confirmed by spirometry or spirometry has been attempted and technically acceptable results are not possible; and
- 2 Either:
  - 2.1 Both:
    - 2.1.1 Patient is currently receiving an inhaled corticosteroid with long acting beta-2 agonist (ICS/LABA) or a long acting muscarinic antagonist with long acting beta-2 agonist (LAMA/LABA); and
    - 2.1.2 Any of the following:

Clinical criteria:

- 2.1.2.1 Patient has a COPD Assessment Test (CAT) score greater than 10; or
- 2.1.2.2 Patient has had 2 or more exacerbations in the previous 12 months; or

Subsidy	Subsidy Fully		Brand or
(Manufacturer's Price)	Subsidised		Generic
<b>3</b>	Per		Manutacturer

continued...

- 2.1.2.3 Patient has had one exacerbation requiring hospitalisation in the previous 12 months; or
- 2.1.2.4 Patient has had an eosinophil count greater than or equal to 0.3 × 10<sup>9</sup> cells/L in the previous 12 months: or
- 2.2 Patient is currently receiving multiple inhaler triple therapy (inhaled corticosteroid with long-acting muscarinic antagonist and long-acting beta-2 agonist - ICS/LAMA/LABA) and met at least one of the clinical criteria above prior to commencing multiple inhaler therapy.

FLUTICASONE FUROATE WITH UMECLIDINIUM AND VILANTEROL - Special Authority see SA2326 below - Retail pharmacy Powder for inhalation fluticasone furoate 100 mcg with

umeclidinium 62.5 mcg and vilanterol 25 mcg.......104.24 30 dose OP ✓ Trelegy Ellipta

### **⇒SA2326** Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

#### Both:

- 1 Patient has a diagnosis of COPD confirmed by spirometry or spirometry has been attempted and technically acceptable results are not possible; and
- 2 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 × 10°9 cells/L in the previous
- 2.2 Patient is currently receiving multiple inhaler triple therapy (inhaled corticosteroid with long acting muscarinic antagonist and long acting beta-2 agonist - ICS/LAMA/LABA) and met at least one of the clinical criteria above prior to commencing multiple inhaler triple therapy.

### Antifibrotics

NINTEDANIB - Special Authority see SA2012 below - Retail pharmacy

Note: Nintedanib not subsidised in combination with subsidised pirfenidone

140to: 14integanib not sabsidised in combination with sai	Joidioca piricriidorio.		
Cap 100 mg	2,554.00	60 OP	Ofev
Cap 150 mg	3,870.00	60 OP	Ofev

#### ⇒SA2012 Special Authority for Subsidy

Initial application — (idiopathic pulmonary fibrosis) only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist; and
- 2 Forced vital capacity is between 50% and 90% predicted; and
- 3 Nintedanib is to be discontinued at disease progression (See Note); and
- 4 Nintedanib is not to be used in combination with subsidised pirfenidone; and
- 5 Any of the following:
  - 5.1 The patient has not previously received treatment with pirfenidone; or

Sub	bsidy F	ully Br	and or
(Manufactu	urer's Price) Subsidis	sed Ge	eneric
•	\$ Per	✓ Ma	anufacturer

continued...

- 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:

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 mg3.10	28	✓ Montelukast Viatris
	Montelukast Viatris to be Principal Supply on 1 December 2025		
*	Tab 5 mg	28	✓ Montelukast Viatris
	Montelukast Viatris to be Principal Supply on 1 December 2025		
*	Tab 10 mg	28	✓ Montelukast Viatris
	Montelukast Viatris to be Principal Supply on 1 December 2025		

Subsidy	Fully	Brand or
(Manufacturer's Price)	Subsidised	Generic
\$	Per 🗸	Manufacturer

# Methylxanthines

A B 4	INIC	וחי	11/1	INIT
AM	HVI(	PF	1 Y I	шль

* Inj 25 mg per ml, 10 ml ampoule - Up to 5 inj available of	n a		
PSO	180.00	5	✓ DBL Aminophylline
THEOPHYLLINE			
* Tab long-acting 250 mg	25.65	100	✓ Nuelin-SR
* Oral lig 80 mg per 15 ml	18 49	500 ml	✓ Nuelin

# **Mucolytics**

DORNASE ALFA − Special Authority see SA1978 below − Retail 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
  - 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 SA2456 below

#### ⇒SA2456 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

1 Patient has been diagnosed with cystic fibrosis; and

Tab elexacaftor 50 mg with tezacaftor 25 mg, ivacaftor 37.5 mg

- 2 Patient is 6 years of age or older; and
- 3 Fither:
  - 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);

Subsidy (Manufacturer's Price)	,	Fully Subsidised	Brand or Generic
 \$	Per	✓	Manufacturer

continued...

and

- 5 The treatment must be the sole funded CFTR modulator therapy for this condition; and
- 6 Treatment with elexacaftor/tezacaftor/ivacaftor must be given concomitantly with standard therapy for this condition.

#### Notes:

 a) Eligible mutations are listed in the Food and Drug Administration (FDA) Trikafta prescribing information https://nctr-crs.fda.gov/fdalabel/services/spl/set-ids/f354423a-85c2-41c3-a9db-0f3aee135d8d/spl-doc

		ly – Specialist – Special Authority see SA2017 below	IVACAFTOR - PCT only - Sp
✓ Kalydeco	56	29,386.00	Tab 150 mg
✓ Kalydeco	56	g, sachet29,386.00	Oral granules 50 mg, sacl
✓ Kalydeco	56	g, sachet29,386.00	Oral granules 75 mg, sacl

#### ⇒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.

# **Nasal Preparations**

# **Allergy Prophylactics**

BUDESONIDE		
Metered aqueous nasal spray, 50 mcg per dose2.59	200 dose OP	✓ <u>SteroClear</u>
Metered aqueous nasal spray, 100 mcg per dose2.89	200 dose OP	✓ <u>SteroClear</u>
FLUTICASONE PROPIONATE		
Metered aqueous nasal spray, 50 mcg per dose2.57	120 dose OP	✓ Flixonase Hayfever
		& Allergy
IPRATROPIUM BROMIDE		
Aqueous nasal spray, 0.03%5.23	15 ml OP	<ul><li>Univent</li></ul>

Oral liq 20 mg per ml (10 mg base per ml)......16.91

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per Manufacturer **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 1 ✓ e-chamber Mask PEAK FLOW METER a) Up to 25 dev available on a PSO b) Only on a PSO ✓ Mini-Wright AFS Low Range Normal range......9.54 ✓ Mini-Wright Standard SPACER DEVICE a) Up to 50 dev available on a PSO b) Only on a PSO ✓ e-chamber Turbo ✓ e-chamber La Grande ✓ Volumatic **Respiratory Stimulants** CAFFEINE CITRATE

25 ml OP

✓ Biomed

			SENSORY ORGANS
	Subsidy (Manufacturer's Pr \$	rice) Subs Per	Fully Brand or idised 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 Ear drops 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 mcg per g		IN 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	4.50 (9.27)	8 ml OP	Otodex \$29
(Otodex \$29 Ear/Eye drops 500 mcg with framycetin sulphate 5 2025) FRAMYCETIN SULPHATE Ear/Eye drops 0.5%	(9.27) mg and gramicio	lin 50 mcg per 8 ml OP	Sofradex ml to be delisted 1 November
Eye Preparations	(8.65)		Soframycin
Eye preparations are only funded for use in the eye, unless explic	citly stated otherw	vise.	
Anti-Infective Preparations			
ACICLOVIR  * Eye oint 3%  CHLORAMPHENICOL  Eye oint 1%	1.55	4.5 g OP	✓ <u>ViruPOS</u> ✓ Devatis
Funded for use in the ear*. Indications marked with * are (Chlorsig Eye drops 0.5% to be delisted 1 March 2026)	1.84	10 ml OP ications.	✓ Chlorsig ✓ Chlorafast
CIPROFLOXACIN  Eye drops 0.3% — Subsidy by endorsement  When prescribed for the treatment of bacterial keratitis o for the second line treatment of chronic suppurative otitis Note: Indication marked with a * is an unapproved indication	r severe bacterial media (CSOM)*		
SODIUM FUSIDATE [FUSIDIC ACID] Eye drops 1%	5.29	5 g OP	✓ Fucithalmic

✓ Fucithalmic Canada (ON) S29 ✓ Fucithalmic Spain S29 **TOBRAMYCIN** 

3.5 g OP 5 ml OP ✓ Tobrex ✓ Tobrex Eye drops 0.3%......11.48



Subsidy Fully E	Brand or
(Manufacturer's Price) Subsidised C	Generic
\$ Per <b>✓</b> M	Manufacturer

# **Corticosteroids and Other Anti-Inflammatory Preparations**

DEXAMETHASONE  * Eye oint 0.1%	5.86	3.5 g OP	✓ Maxidex
* Eye drops 0.1%	4.50	5 ml OP	Maxidex
Ocular implant 700 mcg - Special Authority see SA1680 bel	low		
- Retail pharmacy	1,444.50	1	<ul><li>Ozurdex</li></ul>

### ⇒SA1680 Special Authority for Subsidy

Initial application — (Diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has diabetic macular oedema with pseudophakic lens; and
- 2 Patient has reduced visual acuity of between 6/9 6/48 with functional awareness of reduction in vision; and
- - 3.1 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 eve, and up to a maximum of 3 implants per eye per year.

Initial application — (Women of child bearing age with diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has diabetic macular oedema; and
- 2 Patient has reduced visual acuity of between 6/9 6/48 with functional awareness of reduction in vision; and
- 3 Patient is of child bearing potential and has not yet completed a family; and
- 4 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

Renewal — (Women of child bearing age with diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient's vision is stable or has improved (prescriber determined); and
- 2 Patient is of child bearing potential and has not yet completed a family; and
- 3 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

#### DEXAMETHASONE WITH NEOMYCIN SULPHATE AND POLYMYXIN B SULPHATE

* Eye oint 0.1% with neomycin sulphate 0.35% and polymyxin b			
sulphate 6,000 u per g	5.39	3.5 g OP	✓ Maxitrol
* Eye drops 0.1% with neomycin sulphate 0.35% and polymyxin		-	
b sulphate 6,000 u per ml	4.50	5 ml OP	✓ Maxitrol
DICLOFENAC SODIUM			
Eye drops 0.1%, single dose	1.85	10 dose	<ul> <li>Diclofenac Devatis</li> </ul>
	5.54	30 dose	✓ Diclofenac Devatis
FLUOROMETHOLONE			
* Eye drops 0.1%	3.09	5 ml OP	✓ FML
	5.20		✓ Flucon

	Subsidy		Fully	Brand or
	(Manufacturer's I	Price) Su	bsidised	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
PREDNISOLONE ACETATE				
Eye drops 1%	6.92	10 ml OP	<b>✓</b> P	Prednisolone-AFT
,	7.00	5 ml OP	<b>✓</b> P	Pred Forte
PREDNISOLONE SODIUM PHOSPHATE - Special Authority	see SA1715 belov	v – Retail pha	armacy	
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.

2 91

10 ml OP

2.5 ml OP

✓ Travatan

✓ ∆llerfix

SODIUM CROMOGLICATE	
Eve drops 2%	

Eye drops 2 %	2.91	IU IIII OF	Alleriix
Glaucoma Preparations - Beta Blockers			
BETAXOLOL  * Eye drops 0.25%	7.50 2.42	5 ml OP 5 ml OP	✓ Betoptic S ✓ Betoptic  ✓ Arrow-Timolol ✓ Arrow-Timolol
- Lyo disposition	2.00	0 1111 01	- Miles Timoloi
Glaucoma Preparations - Carbonic Anhydrase Inhibite	ors		
ACETAZOLAMIDE  * Tab 250 mg	3.96	100	✓ <u>Medsurge</u>
# Eye drops 1%  DORZOLAMIDE WITH TIMOLOL	5.11	5 ml OP	✓ Azopt
* Eye drops 2% with timolol 0.5%	3.58	5 ml OP	✓ <u>Dortimopt</u>
Glaucoma Preparations - Prostaglandin Analogues			
BIMATOPROST  * Eye drops 0.03%	5.15	3 ml OP	✓ <u>Lumigan</u>
LATANOPROST  * Eye drops 0.005%	2.08 2	2.5 ml OP	✓ <u>Teva</u>
TRAVOPROST			

<sup>▲</sup>Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

	Subsidy (Manufacturer's Prio \$	ce) Subs	Fully Brand or idised Generic  ✓ Manufacturer					
Glaucoma Preparations - Other								
BRIMONIDINE TARTRATE  * Eye drops 0.2%	5.16	5 ml OP	✓ <u>Arrow-Brimonidine</u>					
BRIMONIDINE TARTRATE WITH TIMOLOL MALEATE  * Eye drops 0.2% with timolol maleate 0.5%	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>					
# Eye drops 1%  * Eye drops 2%  * Eye drops 4%  Subsidised for oral use pursuant to the Standard Formu	5.35 7.99	15 ml OP 15 ml OP 15 ml OP	✓ Isopto Carpine ✓ Isopto Carpine ✓ Isopto Carpine					
PILOCARPINE NITRATE  * Eye drops 2% single dose – Special Authority see SA0895 below – Retail pharmacy		20 dose	✓ Minims Pilocarpine					
▶SA0895 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria: Either:								
Patient has to use an unpreserved solution due to an allergy to the preservative; or     Patient wears soft contact lenses.								
Note: Minims for a general practice are considered to be "tools of trade" and are not approved as special authority items.  Renewal from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is								

# **Mydriatics and Cycloplegics**

benefiting from treatment.

ATROPINE SULPHATE		
* Eye drops 1%18.27	15 ml OP	✓ Atropt
CYCLOPENTOLATE HYDROCHLORIDE		
* Eye drops 1%25.16	15 ml OP	<ul><li>Cyclogyl</li></ul>
TROPICAMIDE		
* Eye drops 0.5%	15 ml OP	✓ Mydriacyl
* Eye drops 1%24.82	15 ml OP	✓ Mydriacyl

# **Preparations for Tear Deficiency**

For acetylcysteine eye drops refer Standard Formulae, page 284

H	I١	1	Ρ	F	lC	M	IEL	_L	0	S	Ε

* Eye drops 0.5%	15 ml OP	✓ Methopt
HYPROMELLOSE WITH DEXTRAN		
* Eve drops 0.3% with dextran 0.1%	15 ml OP	✓ Poly-Tears

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per ✓ Manufacturer

### **Preservative Free Ocular Lubricants**

### ⇒SA2431 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

#### Both:

- 1 Confirmed diagnosis by slit lamp or Schirmer test of severe secretory dry eye; and
- 2 Either:
  - 2.1 Patient is using eye drops more than four times daily on a regular basis; or
  - 2.2 Patient has had a confirmed allergic reaction to preservative in eye drop.

POLYETHYLENE GLYCOL 400 AND PROPYLENE GLYC	COL - Special Authority:	see SA2431	above – Retail pharmacy
Eye drops 0.4% and propylene glycol 0.3%, 0.8 ml	10.78	30	✓ Systane Unit Dose
SODIUM HYALURONATE [HYALURONIC ACID] - Speci	ial Authority see SA2431	above – Ret	ail pharmacy
Eye drops 1 mg per ml	13.58	10 ml OP	✓ Hylo-Fresh
Hylo-Fresh has a 6 month expiry after opening. T	The Pharmacy Procedure	s Manual res	striction allowing one bottle per

month is not relevant and therefore only the prescribed dosage to the nearest OP may be claimed.

# Other Eye Preparations

NAPHAZOLINE HYDROCHLORIDE  * Eye drops 0.1%	15 ml OP	✓ <u>Albalon</u>
OLOPATADINE Eye drops 0.1%	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 g	5 g OP	✓ VitA-POS



VARIOUS			
	Subsidy (Manufacturer's Pric \$		Fully Brand or dised Generic Manufacturer
Various			
PHARMACY SERVICES  * Immunisation administration fee - flu  * Immunisation administration fee - other  * Immunisation co-administration fee - flu and shingles	0.00	1 fee 1 fee 1 fee	✓ Immunisation - Flu ✓ Immunisation Other ✓ Immunisation Flu and Shingles
Agents Used in the Treatment of Poisonings			
Antidotes			
ACETYLCYSTEINE Inj 200 mg per ml, 10 ml ampoule Inj 200 mg per ml, 10 ml vial	52.88	10 10	✓ <u>DBL Acetylcysteine</u> ✓ Martindale Pharma ✓ Hikma Acetylcysteine <sup>\$29</sup>
(Martindale Pharma Inj 200 mg per ml, 10 ml ampoule to be delis NALOXONE HYDROCHLORIDE a) Up to 10 inj available on a PSO b) Only on a PSO		025)	
* Inj 400 mcg per ml, 1 ml ampoule	13.29	5	✓ <u>DBL Naloxone</u> <u>Hydrochloride</u>
Removal and Elimination			
CHARCOAL  * Oral liq 50 g per 250 ml	59.85	250 ml OP	✓ Carbosorb-X
DEFERASIROX – Special Authority see SA1492 below – Retail Wastage claimable	pharmacy		

*	Oral liq 50 g per 250 n	l59.85	250 ml OP	✓ Carbosorb-X
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# 

Tab 125 mg dispersible	276.00	28	<ul><li>Exjade</li></ul>
Tab 250 mg dispersible	552.00	28	<ul><li>Exjade</li></ul>
Tab 500 mg dispersible	1,105.00	28	Exjade

### ⇒SA1492 Special Authority for Subsidy

Initial application only from a haematologist. Approvals valid for 2 years for applications meeting the following criteria: All of the following:

- 1 The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia; and
- 2 Deferasirox is to be given at a daily dose not exceeding 40 mg/kg/day; and
- 3 Any of the following:
  - 3.1 Treatment with maximum tolerated doses of deferiprone monotherapy or deferiprone and desferrioxamine combination therapy have proven ineffective as measured by serum ferritin levels, liver or cardiac MRI T2\*; or
  - 3.2 Treatment with deferiprone has resulted in severe persistent vomiting or diarrhoea; or
  - 3.3 Treatment with deferiprone has resulted in arthritis; or
  - 3.4 Treatment with deferiprone is contraindicated due to a history of agranulocytosis (defined as an absolute neutrophil count (ANC) of < 0.5 cells per μL) or recurrent episodes (greater than 2 episodes) of moderate neutropenia (ANC



Subsidy (Manufacturer's Price)	Sub	Fully sidised	Brand or Generic
\$	Per	1	Manufacturer

continued...

0.5 - 1.0 cells per μL).

**Renewal** only from a haematologist. Approvals valid for 2 years for applications meeting the following criteria: Either:

- 1 For the first renewal following 2 years of therapy, the treatment has been tolerated and has resulted in clinical improvement in all three parameters namely serum ferritin, cardiac MRI T2\* and liver MRI T2\* levels; or
- 2 For subsequent renewals, the treatment has been tolerated and has resulted in clinical stability or continued improvement in all three parameters namely serum ferritin, cardiac MRI T2\* and liver MRI T2\* levels.

DEFERIPRONE	- Special Authority see SA1480 below	<ul> <li>Hetail pharmacy</li> </ul>

Tab 500 mg	533.17	100	✓ Ferriprox
Oral lig 100 mg per 1 ml	266.59	250 ml OP	✓ Ferriprox

### ⇒SA1480 Special Authority for Subsidy

**Initial application** only from a haematologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

#### Either:

- 1 The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia; or
- 2 The patient has been diagnosed with chronic iron overload due to acquired red cell aplasia.

#### DESFERRIOXAMINE MESILATE

* Inj 500 mg vial	332.88	10	✓ DBL  Desferrioxamine  Mesylate for Inj  BP
SODIUM CALCIUM EDETATE  * Inj 200 mg per ml, 5 ml	53 31	6	
4. III 200 IIIg por IIII, 0 III	(156.71)	Ŭ	Calcium Disodium Versenate



# **Standard Formulae**

Statiualu Futiliulae			
ACETYLCYSTEINE EYE DROPS Acetylcysteine inj 200 mg per ml, 10 ml	qs	PHENOBARBITONE SODIUM PAEDIATRIC ORAL mg per ml)	LIQUID (10
Suitable eye drop base	qs	Phenobarbitone Sodium Glycerol BP	400 mg 4 ml
CODEINE LINCTUS (3 mg per 5 ml) Codeine phosphate	60 mg	Water	to 40 ml
Glycerol Preservative	40 ml gs	PILOCARPINE ORAL LIQUID Pilocarpine 4% eye drops	qs
Water	to 100 ml	Preservative	qs
CODEINE LINCTUS (15 mg per 5 ml)		Water (Preservative should be used if quantity supplied is	to 500 ml
Codeine phosphate Glycerol	300 mg 40 ml	than 5 days.)	00.0
Preservative Water	qs to 100 ml	SALIVA SUBSTITUTE FORMULA Methylcellulose	5 g
FOLINIC MOUTHWASH		Preservative Water	qs to 500 ml
Calcium folinate 15 mg tab Preservative Water	1 tab qs to 500 ml	(Preservative should be used if quantity supplied is than 5 days. Maximum 500 ml per prescription.)	or more
(Preservative should be used if quantity supplied is f than 5 days. Maximum 500 ml per prescription.)		SODIUM CHLORIDE ORAL LIQUID Sodium chloride inj 23.4%, 20 ml Water	qs qs
METHYL HYDROXYBENZOATE 10% SOLUTION Methyl hydroxybenzoate	10 g	(Only funded if prescribed for treatment of hyponatra	•
Propylene glycol (Use 1 ml of the 10% solution per 100 ml of oral liqui	to 100 ml	VANCOMYCIN ORAL SOLUTION (25 mg per ml) Vancomycin 500 mg injection Glycerin with sucrose suspension	5 vials 37.5 ml
OMEPRAZOLE SUSPENSION Omeprazole capsules or powder Sodium bicarbonate powder BP Water	qs 8.4 g to 100 ml	Water (Only funded if prescribed for treatment of Clostridiu following metronidazole failure)	to 100 ml
PHENOBARBITONE ORAL LIQUID Phenobarbitone Sodium Glycerol BP Water	1 g 70 ml to 100 ml		

# EXTEMPORANEOUSLY COMPOUNDED PREPARATIONS AND GALENICALS

Subsidy Fully (Manufacturer's Price) Subsidised \$ Per ✓

Brand or Generic Manufacturer

# **Extemporaneously Compounded Preparations and Galenicals**

COLLODION FLEXIBLE  Note: This product is no longer being manufactured by the sup	plior and will h	o dalicted from	m the Schedule at a date to be
determined.	pliel allu wiii L	ie delisted ii oi	ii the Schedule at a date to be
Collodion flexible	19.30	100 ml	✓ PSM
COMPOUND HYDROXYBENZOATE - Only in combination			
Only in extemporaneously compounded oral mixtures.			
Soln	30.00	100 ml	✓ Midwest
GLYCERIN WITH SODIUM SACCHARIN - Only in combination		.=-	
Suspension	30.95	473 ml	✓ Ora-Sweet SF
GLYCERIN WITH SUCROSE – Only in combination	00.05	4701	<b>( 0</b> 0 )
Suspension	30.95	473 ml	✓ Ora-Sweet
GLYCEROL  * Liquid – Only in combination	2 22	500 ml	✓ healthE Glycerol BP
Only in extemporaneously compounded oral liquid preparat		500 1111	• Healthe Glycerol BP
METHYL HYDROXYBENZOATE			
Powder	8.98	25 g	✓ Midwest
METHYLCELLULOSE			
Powder	36.95	100 g	✓ MidWest
Suspension – Only in combination	30.95	473 ml	✓ Ora-Plus
METHYLCELLULOSE WITH GLYCERIN AND SODIUM SACCHAR	RIN – Only in o	combination	
Suspension		473 ml	✓ Ora-Blend SF
METHYLCELLULOSE WITH GLYCERIN AND SUCROSE - Only in		.=-	
Suspension	30.95	473 ml	✓ Ora-Blend
PHENOBARBITONE SODIUM	50.50	40	/ MU-BM
Powder – Only in combination Only in children up to 12 years	52.50	10 g	✓ MidWest
PROPYLENE GLYCOL			
Only in extemporaneously compounded methyl hydroxybenzoa	te 10% solutio	n.	
Lig		500 ml	✓ Midwest
SODIUM BICARBONATE			
Powder BP - Only in combination		500 g	✓ Midwest
Only in extemporaneously compounded omeprazole and la	insoprazole su	spension.	
SYRUP (PHARMACEUTICAL GRADE) - Only in combination			
Only in extemporaneously compounded oral liquid preparations		500 ml	✓ Midwest
Liq	14.95	500 1111	▼ iviidwest
WATER Tap – Only in combination	0.00	1 ml	✓ Tap water
Tup Only in combination		1 1111	- Tup mater

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# **Nutrient Modules**

### Carbohydrate

#### ⇒SA1930 Special Authority for Subsidy

Initial application — (Cystic fibrosis or kidney disease) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria: Fither:

- 1 cystic fibrosis; or
- 2 chronic kidney disease.

Initial application — (Indications other than cystic fibrosis or renal failure) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria: Any of the following:

- 1 cancer in children: or
- 2 cancers affecting alimentary tract where there are malabsorption problems in patients over the age of 20 years; or
- 3 faltering growth in an infant/child; or
- 4 bronchopulmonary dysplasia; or
- 5 premature and post premature infant; or
- 6 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula. Initial application — (Inborn errors of metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified where the patient has inborn errors of metabolism. Renewal — (Cystic fibrosis or renal failure) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria: Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis or renal failure) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria: Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

CARBOHYDRATE SUPPLEMENT - Special Authority see SA1930 above - Hospital pharmacy [HP3]

400 a OP ✓ Polycal Powder .......6.72

# Carbohydrate And Fat

# ⇒SA1376 Special Authority for Subsidy

Initial application — (Cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria: Both:

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- 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

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- 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 Authorit	v see SA2204 on the	previous pa	ge – Hospital r	harmacy [HP3]

Emulsion (neutral)	15.38	200 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 above - Hospital pharmacy [HP3]

	openia riamoni, eee eriise rabeis			
Powder		8.95	227 g OP	<ul> <li>Resource</li> </ul>
			•	Beneprotein
		13.82	225 g OP	✓ Protifar

Subsidy (Manufacturer's Price)

Subsidised Per

Fully

Brand or Generic Manufacturer

# **Oral and Enteral Feeds**

#### **Diabetic Products**

### ⇒SA1095 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient is a type I or and II diabetic who is suffering weight loss and malnutrition that requires nutritional support. Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

#### Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

DIABETIC ENTERAL FEED 1KCAL/ML - Special Authority see \$	SA1095 above – H	ospital phari	macy [HP3]
Liquid, 500 ml bottle	4.65	1 OP	✓ Glucerna Select
DIABETIC ORAL FEED 1KCAL/ML - Special Authority see SA10	95 above – Hosp	ital pharmacy	/ [HP3]
Liquid (strawberry), 200 ml bottle	2.25	1 OP	✓ Diasip
Liquid (vanilla), 200 ml bottle		1 OP	✓ Nutren Diabetes
,	2.25		✓ Diasip

### **Fat Modified Products**

## ⇒SA2205 Special Authority for Subsidy

Initial application — (Inborn errors of metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified where the patient has an inborn error of metabolism. Initial application — (Indications other than errors of inborn metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria: Either:

- 1 Patient has a chyle leak; or
- 2 Modified as a modular feed, made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule, for adults,

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula. Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

#### Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

FAT MODIFIED FEED - Special Authority see SA2205 above - Hospital pharmacy [HP3] 400 a OP Monogen



Subsidy (Manufacturer's Price) Fully Subsidised Per ✓ Brand or Generic Manufacturer

# Paediatric Products For Children Awaiting Liver Transplant

### ⇒SA1098 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient is a child (up to 18 years) who requires a liver transplant.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL FEED 1KCAL/ML - Special Authority see SA1098 above - Hospital pharmacy [HP3]

## Paediatric Products For Children With Chronic Renal Failure

# ⇒SA1099 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient is a child (up to 18 years) with acute or chronic kidney disease.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

#### 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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applications meeting the following criteria:

#### Roth:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

PAEDIATRIC ENTERAL FEED 1.5KCAL/ML - Special Authority se Liquid, 500 ml bottle		the previous pa	age – Hospital pharmacy [HP3]  ✓ Nutrini Energy RTH
PAEDIATRIC ENTERAL FEED 1KCAL/ML - Special Authority see Liquid, 500 ml bottle		ne previous pag 1 OP	e – Hospital pharmacy [HP3]  ✓ Pediasure RTH ✓ Nutrini RTH
PAEDIATRIC ENTERAL FEED WITH FIBRE 1.5KCAL/ML - Speci- pharmacy [HP3]	al Authority se	ee SA1379 on the	he previous page – Hospital
Liquid, 500 ml bottle	7.14	1 OP	<ul><li>Nutrini Energy Multi Fibre</li></ul>
PAEDIATRIC ORAL FEED 1.5KCAL/ML - Special Authority see SA	A1379 on the	previous page -	- Hospital pharmacy [HP3]
Liquid (strawberry), 200 ml bottle	1.90	1 OP	✓ Fortini
Liquid (vanilla), 200 ml bottle		1 OP	✓ Fortini
Liquid (vanilla), 500 ml bottle		1 OP	✓ Pediasure Plus
PAEDIATRIC ORAL FEED 1KCAL/ML - Special Authority see SA1	379 on the pr	revious page – I	Hospital pharmacy [HP3]
Liquid (chocolate), 200 ml bottle		1 OP	✓ Pediasure
Liquid (strawberry), 200 ml bottle		1 OP	✓ Pediasure
Liquid (vanilla), 200 ml bottle		1 OP	✓ Pediasure
Liquid (vanilla), 250 ml can		1 OP	✓ Pediasure
PAEDIATRIC ORAL FEED WITH FIBRE 1.5KCAL/ML - Special Aupharmacy [HP3]	uthority see S	A1379 on the p	revious page – Hospital
Liquid (chocolate), 200 ml bottle	1.90	1 OP	✓ Fortini Multi Fibre
Liquid (strawberry), 200 ml bottle	1.90	1 OP	✓ Fortini Multi Fibre
Liquid (unflavoured), 200 ml bottle		1 OP	✓ Fortini Multi Fibre
Liquid (vanilla), 200 ml bottle	1.90	1 OP	✓ Fortini Multi Fibre
PEPTIDE-BASED ORAL FEED - Special Authority see SA1379 on	the previous	page – Hospita	l pharmacy [HP3]
Powder	43.60	400 g OP	✓ Peptamen Junior

#### **Renal Products**

## ⇒SA1101 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient has acute or chronic kidney disease.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

### Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

RENAL ORAL FEED 1.8 KCAL/ML - Special Authority see SA110	1 above - Hos	pital pharmac	y [HP3]
Liquid, 220 ml bottle	3.31	1 OP	✓ Nepro HP
			(strawberry)
			✓ Nepro HP (vanilla)

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RENAL ORAL FEED 2 KCAL/ML - Special Authority see SA110	1 on the previous page	ge – Hospita	al phar	macy [HP3]
Liquid, 200 ml bottle	13.24	4 OP	✓ N	ovaSource Renal
Liquid (apricot) 125 ml	13.72	4 OP	✓ R	enilon 7.5
Liquid (caramel) 125 ml	13.72	4 OP	✓ R	enilon 7.5

Subsidy

Fully

Brand or

## **Specialised And Elemental Products**

## ⇒SA1377 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 malabsorption; or
- 2 short bowel syndrome; or
- 3 enterocutaneous fistulas: or
- 4 eosinophilic oesophagitis; or
- 5 inflammatory bowel disease: or
- 6 patients with multiple food allergies requiring enteral feeding.

Notes: Each of these products is highly specialised and would be prescribed only by an expert for a specific disorder. The alternative is hospitalisation.

Elemental 028 Extra is more expensive than other products listed in this section and should only be used where the alternatives have been tried first and/or are unsuitable.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL SEMI-ELEMENTAL FEED 1.5KCAL/ML - S Liquid, 1,000 ml bottle		SA1377 abo 1 OP	ve – Hospital pharmacy [HP3]  ✓ Vital
ORAL ELEMENTAL FEED 0.8KCAL/ML - Special Authority s	see SA1377 above – I	Hospital pha	rmacy [HP3]
Liquid (grapefruit), 250 ml carton	179.46	18 OP	✓ Elemental 028 Extra
Liquid (pineapple & orange), 250 ml carton	179.46	18 OP	✓ Elemental 028 Extra
Liquid (summer fruits), 250 ml carton	179.46	18 OP	✓ Elemental 028 Extra
ORAL ELEMENTAL FEED 1KCAL/ML - Special Authority se	e SA1377 above – Ho	spital pharn	nacy [HP3]
Powder (unflavoured), 80 g sachet	4.50	1 OP	✓ Vivonex TEN
SEMI-ELEMENTAL ENTERAL FEED 1KCAL/ML - Special A	uthority see SA1377	above – Hos	spital pharmacy [HP3]
Liquid, 500 ml bottle	7.47	1 OP	<ul><li>Nutrison Advanced</li></ul>
			Peptisorb

# Paediatric Products For Children With Low Energy Requirements

# **⇒SA1196** Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

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- 1 Child aged one to eight years; and
  - 2 The child has a low energy requirement but normal protein and micronutrient requirements.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

PAEDIATRIC ENTERAL FEED WITH FIBRE 0.76 KCAL/ML - Special Authority see SA1196 on the previous page - Hospital pharmacy [HP3]

# Standard Supplements

## ⇒SA1859 Special Authority for Subsidy

Initial application — (Children - indications other than exclusive enteral nutrition for Crohn's disease) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 The patient is under 18 years of age; and
- 2 Any of the following:
  - 2.1 The patient has a condition causing malabsorption; or
  - 2.2 The patient has failure to thrive; or
  - 2.3 The patient has increased nutritional requirements; and
- 3 Nutrition goal has been set (eg reach a specific weight or BMI).

Renewal — (Children - indications other than exclusive enteral nutrition for Crohn's disease) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 The patient is under 18 years of age; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment; and
- 3 A nutrition goal has been set (eg reach a specific weight or BMI).

Initial application — (Children - exclusive enteral nutrition for Crohn's disease) only from a gastroenterologist or dietitian on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 The patient is under 18 years of age; and
- 2 It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease; and
- 3 Dietitians must include the name of the gastroenterologist recommending treatment and the date the gastroenterologist was contacted.

Renewal — (Children - exclusive enteral nutrition for Crohn's disease) from any relevant practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria: All of the following:

- 1 The patient is under 18 years of age; and
- 2 It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease; and
- 3 General Practitioners and dietitians must include the name of the gastroenterologist recommending treatment and the date the gastroenterologist was contacted.

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Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic \$ Per ✔ Manufacturer

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Initial application — (Adults) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

1 Any of the following:

Patient is Malnourished

- 1.1 Patient has a body mass index (BMI) of less than 18.5 kg/m<sup>2</sup>; or
- 1.2 Patient has unintentional weight loss greater than 10% within the last 3-6 months; or
- 1.3 Patient has a BMI of less than 20 kg/m² and unintentional weight loss greater than 5% within the last 3-6 months; and
- 2 Any of the following:

Patient has not responded to first-line dietary measures over a 4 week period by:

- 2.1 Increasing their food intake frequency (eg snacks between meals); or
- 2.2 Using high-energy foods (e.g. milkshakes, full fat milk, butter, cream, cheese, sugar etc); or
- 2.3 Using over the counter supplements (e.g. Complan); and
- 3 A nutrition goal has been set (e.g. to reach a specific weight or BMI).

Renewal — (Adults) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria: Both:

- 1 A nutrition goal has been set (eg reach a specific weight or BMI); and
- 2 Any of the following:

Patient is Malnourished

- 2.1 Patient has a body mass index (BMI) of less than 18.5 kg/m<sup>2</sup>; or
- 2.2 Patient has unintentional weight loss greater than 10% within the last 3-6 months; or
- 2.3 Patient has a BMI of less than 20 kg/m<sup>2</sup> and unintentional weight loss greater than 5% within the last 3-6 months.

**Initial application — (Short-term medical condition)** from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 Is being fed via a nasogastric tube or a nasogastric tube is to be inserted for feeding; or
- 2 Malignancy and is considered likely to develop malnutrition as a result; or
- 3 Is undergoing a bone marrow transplant; or
- 4 Tempomandibular surgery or glossectomy; or
- 5 Both
  - 5.1 Pregnant: and
  - 5.2 Any of the following:
    - 5.2.1 Patient is in early pregnancy (< 13 weeks) and has severe clinical hyperemesis gravidarum requiring admission to hospital and is unlikely to meet her nutritional requirements due to continuing hyperemesis gravidarum; or
    - 5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or
    - 5.2.3 Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met.

**Renewal — (Short-term medical condition)** from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 Is being fed via a nasogastric tube; or
- 2 Malignancy and is considered likely to develop malnutrition as a result; or
- 3 Has undergone a bone marrow transplant; or

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acturer's Price) Subs	sidised	Generic
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- 4 Tempomandibular surgery or glossectomy; or
- 5 Both:
  - 5.1 Pregnant: and
  - 5.2 Any of the following:
    - 5.2.1 Patient is in early pregnancy (< 13 weeks) and has severe clinical hyperemesis gravidarum requiring admission to hospital and is unlikely to meet her nutritional requirements due to continuing hyperemesis gravidarum; or
    - 5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or
    - 5.2.3 Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met.

Initial application — (Long-term medical condition) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

#### Any of the following:

- 1 Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube refer to specific medical condition criteria); or
- 2 Cystic Fibrosis: or
- 3 Liver disease: or
- 4 Chronic Renal failure: or
- 5 Inflammatory bowel disease; or
- 6 Chronic obstructive pulmonary disease with hypercapnia; or
- 7 Short bowel syndrome: or
- 8 Bowel fistula: or
- 9 Severe chronic neurological conditions: or
- 10 Epidermolysis bullosa; or
- 11 AIDS (CD4 count < 200 cells/mm3): or
- 12 Chronic pancreatitis.

Renewal — (Chronic disease OR tube feeding for patients who have previously been funded under Special Authority forms SA0702 or SA0583) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

#### Any of the following:

- 1 Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube refer to specific medical condition criteria); or
- 2 Cystic Fibrosis: or
- 3 Liver disease; or
- 4 Chronic Renal failure; or
- 5 Inflammatory bowel disease; or
- 6 Chronic obstructive pulmonary disease with hypercapnia; or
- 7 Short bowel syndrome; or
- 8 Bowel fistula: or
- 9 Severe chronic neurological conditions.

ENTERAL FEED 1.5KCAL/ML - Special Authority see SA185	9 on page 293 - Ho	spital pharma	acy [HP3]
Liquid, 1,000 ml bottle	8.68	1 OP	✓ Ensure Plus HN RTH
	9.00		✓ Nutrison Energy
Liquid, 250 ml can	2.17	1 OP	✓ Ensure Plus HN
ENTERAL FEED 1KCAL/ML - Special Authority see SA1859	on page 293 – Hosp	oital pharmac	y [HP3]
Liquid, 1,000 ml bottle	6.56	1 OP	✓ Osmolite RTH
•	6.90		✓ Nutrison RTH

	Subsidy		Fully Brand or
	(Manufacturer's Pri		sidised Generic
	\$	Per	✓ Manufacturer
ENTERAL FEED WITH FIBRE 0.83 KCAL/ML - Special Authority	y see SA1859 on		
Liquid, 1,000 ml bottle	9.05	1 OP	✓ Nutrison
			800 Complete
			Multi Fibre
ENTERAL FEED WITH FIBRE 1 KCAL/ML - Special Authority se	ee SA1859 on pag	ge 293 – Hos	pital pharmacy [HP3]
Liquid, 1,000 ml bottle		1 OP	✓ Jevity RTH
	7.21		✓ Nutrison Multi Fibre
ENTERAL FEED WITH FIBRE 1.5KCAL/ML - Special Authority	see SA1859 on pa	age 293 – Ho	ospital pharmacy [HP3]
Liquid, 1,000 ml bottle		1 OP	✓ Jevity HiCal RTH
- <b> </b>			✓ Nutrison Energy
			Multi Fibre
ORAL FEED (POWDER) - Special Authority see SA1859 on page	o 203 – Hospital	nharmacy [H	Dal
Powder (chocolate)		840 g OP	✓ Sustagen Hospital
1 owder (chocolate)	10.00	0+0 g Oi	Formula
	40.00	850 g OP	✓ Ensure
Powder (vanilla)		840 g OP	✓ Sustagen Hospital
1 Owder (Varinia)	10.00	0+0 g Oi	Formula
	40.00	850 g OP	✓ Ensure
ODAL EEED 4 51/041 (ML ) 0 1 1 4 1 1 1 1 0 0 0 0 0 0 0 0 0 0 0 0		•	
ORAL FEED 1.5KCAL/ML - Special Authority see SA1859 on pa			
Additional subsidy by endorsement is available for patients be			
epidermolysis bullosa, or as exclusive enteral nutrition for the			
hypercapnia, defined as CO2 value exceeding 55mmHg. The		st be endorse	ed accordingly.
Liquid (banana), 200 ml bottle - Higher subsidy of up to \$1.7		4.00	
per 1 btl with Endorsement		1 OP	France Dive
	(1.56)		Ensure Plus
1: :1/1	(1.76)		Fortisip
Liquid (chocolate), 200 ml bottle - Higher subsidy of up to	0.70	4.00	
\$1.76 per 1 btl with Endorsement		1 OP	Francis Divis
	(1.56)		Ensure Plus
	(1.76)		Fortisip
Liquid (fruit of the forest), 200 ml bottle – Higher subsidy of			
\$1.56 per 1 btl with Endorsement		1 OP	- D
	(1.56)		Ensure Plus
Liquid (strawberry), 200 ml bottle - Higher subsidy of \$1.76 p			
1 btl with Endorsement		1 OP	
	(1.76)		Fortisip
Liquid (vanilla), 200 ml bottle - Higher subsidy of up to \$1.76			
per 1 btl with Endorsement		1 OP	
	(1.56)		Ensure Plus
	(1.76)		Fortisip
Liquid (vanilla), 237 ml can - Higher subsidy of \$1.65 per			
1 can with Endorsement		1 OP	
	(1.65)		Ensure Plus

	Subsidy		Fully	Brand or
	(Manufacturer's Price)	Sub	sidised	Generic
	\$	Per	1	Manufacturer
ORAL FEED WITH FIBRE 1.5 KCAL/ML - Special Authority se	e SA1859 on page 293	3 – Hospit	tal pharn	nacy [HP3]
Additional subsidy by endorsement is available for patients	being bolus fed throug	h a feedir	ng tube,	or who have severe
epidermolysis bullosa. The prescription must be endorsed	accordingly.			
· ·				

Liquid (chocolate), 200 ml bottle - Higher subsidy of \$1.76 per			
1 btl with Endorsement	0.72	1 OP	
	(1.76)		Fortisip Multi Fibre
Liquid (strawberry), 200 ml bottle - Higher subsidy of \$1.76 per			
1 btl with Endorsement	0.72	1 OP	
	(1.76)		Fortisip Multi Fibre
Liquid (vanilla), 200 ml bottle - Higher subsidy of \$1.76 per			
1 btl with Endorsement	0.72	1 OP	
	(1.76)		Fortisip Multi Fibre

# **High Calorie Products**

### ⇒SA1195 Special Authority for Subsidy

Initial application — (Cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

All of the following:

- 1 Cystic fibrosis; and
- 2 other lower calorie products have been tried; and
- 3 patient has substantially increased metabolic requirements.

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 any condition causing malabsorption; or
  - 1.2 faltering growth in an infant/child; or
  - 1.3 increased nutritional requirements; or
  - 1.4 fluid restricted: and
- 2 other lower calorie products have been tried; and
- 3 patient has substantially increased metabolic requirements or is fluid restricted.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

	Subsidy (Manufacturer's Price) \$		ully Brand or sed Generic  Manufacturer
ENTERAL FEED 2 KCAL/ML - Special Authority see SA1195 o Liquid, 1,000 ml bottle			armacy [HP3]  ✓ Ensure Two Cal HN  RTH
Liquid, 500 ml bottle	6.82	1 OP	✓ Nutrison Concentrated
ORAL FEED 2 KCAL/ML – Special Authority see SA1195 on the Additional subsidy by endorsement is available for patients I epidermolysis bullosa. The prescription must be endorsed a Liquid (vanilla), 200 ml bottle – Higher subsidy of \$2.34 per 1 btl with Endorsement	peing bolus fed throug 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:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

FOOD THICKENER - Special Authority see SA1106 abov	<del>'e</del> – Hospital pharmacy	[HP3]	
Powder	8.29	300 g OP	✓ Nutilis
	24.00	380 g OP	✓ Aptamil Feed
		•	Thickener

# **Gluten Free Foods**

The funding of gluten free foods is no longer being actively managed by Pharmac from 1 April 2011. This means that we are no longer considering the listing of new products, or making subsidy, or other changes to the existing listings. As a result we anticipate that the range of funded items will reduce over time. Management of Coeliac disease with a gluten free diet is necessary for good outcomes. A range of gluten free options are available through retail outlets.

#### ⇒SA1729 Special Authority for Subsidy

Initial application — (all patients) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria: Either:

- 1 Gluten enteropathy has been diagnosed by biopsy; or
- 2 Patient suffers from dermatitis herpetiformis.

Initial application — (paediatric patients diagnosed by ESPGHAN criteria) only from a paediatric gastroenterologist. Approvals valid without further renewal unless notified where the paediatric patient fulfils ESPGHAN criteria for biopsy free diagnosis of coeliac disease.

GLUTEN FREE BAKING MIX – Special Authority see SA1	1729 above – Hospital	pharmacy [HP3]	
Powder	2.81	1,000 g OP	
	(5.15)	•	Healtheries Simple
			Baking Mix

	Subsidy (Manufacturer's P \$		ully Brand or Sed Generic Manufacturer
GLUTEN FREE BREAD MIX - Special Authority see SA1729 or	n the previous pa	ge – Hospital pha	rmacy [HP3]
Powder	3.93	1,000 g OP	
	(7.32)		NZB Low Gluten
			Bread Mix
	3.51		
	(10.87)		Horleys Bread Mix
GLUTEN FREE FLOUR - Special Authority see SA1729 on the	previous page -	Hospital pharmac	cy [HP3]
Powder	5.62	2,000 g OP	
	(18.10)		Horleys Flour

# **Foods And Supplements For Inherited Metabolic Disease**

## ⇒SA2357 Special Authority for Subsidy

**Initial application** from any relevant practitioner. Approvals valid without further renewal unless notified where patient requires dietary management of inherited metabolic disorders.

# **Supplements For Homocystinuria**

AMINOACID FORMULA WITHOUT METHIONINE	<ul> <li>Special Authority see SA2357</li> </ul>	above – F	lospital pharmacy [HP3]
Powder (neutral), 36 g sachets	750.30	30	HCU Anamix Junior
Powder, 12.5 g sachets	349.65	30	✓ HCU Explore 5
Powder, 25 g sachets	1,048.95	30	✓ HCU Express 15
Powder (neutral), can		500 g OP	XMET Maxamum
Powder (unflavoured), can	260.00	400 g OP	HCU Anamix Infant
Liquid (juicy berries), 125 ml bottle	1,684.80	30	✓ HCU Lophlex LQ
Liquid (orange), 125 ml bottle	941.40	36	HCU Anamix Junior
			I O

# Supplements For MSUD and short chain enoyl coA hydratase deficiency

AMINOACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE - Special Authority see \$A2357 above - Hospital pharmacy [HP3]

Powder (neutral) 36 g sachets	750.00	30	<ul><li>MSUD Anamix Junior</li></ul>
Powder, 12.5 g sachets	349.65	30	✓ MSUD Explore 5
Powder, 25 g sachets		30	✓ MSUD Express 15
Powder (neutral), can		500 g OP	✓ MSUD Maxamum
Powder (orange), can	454.71	500 g OP	✓ MSUD Maxamum
Powder (unflavoured), can	260.00	400 g OP	<ul><li>MSUD Anamix Infant</li></ul>
Liquid (orange) 125 ml bottles	941.40	36	<ul><li>MSUD Anamix Junior LQ</li></ul>
Liquid (juicy berries) 125 ml pouches	1,684.80	30	✓ MSUD Lophlex LQ 20

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Manufacturer

# **Supplements For PKU**

AMINOACID FORMULA WITHOUT PHENYLALANINE - Special Authority see SA2357 on the previous page - Hospital pharmacy [HP3]

annacy [in o]			
Tabs		75 OP	Phlexy 10
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 Explore 10
Powder (Orange), 34 g sachets	883.50	30	✓ PKU Express 20
Powder (Raspberry), 25 g sachets		30	✓ PKU Explore 10
Powder (Tropical), 34 g sachets		30	✓ PKU Express 20
Powder (berry) 28 g sachets		30	✓ PKU Lophlex
· ,, •			Powder
Powder (chocolate) 36 g sachet	393.00	30	✓ PKU Anamix Junior
· onser (enessians) so y sasmemment			Chocolate
Powder (neutral) 28 g sachets	936.00	30	✓ PKU Lophlex
1 owder (fleditar) 20 g oddrote		00	Powder
Powder (neutral) 36 g sachets	303.00	30	✓ PKU Anamix Junior
Powder (orange) 28 g sachets		30	✓ PKU Lophlex
rowder (ordrige) 20 g sacriets	930.00	30	Powder
Daviday (avanas) 66 a acabat	000.00	00	
Powder (orange) 36 g sachet	393.00	30	✓ PKU Anamix Junior
			Orange
Powder (unflavoured) 12.5 g sachets		30	✓ PKU First Spoon
Powder (vanilla) 36 g sachet	393.00	30	✓ PKU Anamix Junior
			Vanilla
Infant formula		400 g OP	PKU Anamix Infant
Powder (neutral), 4 × 400 g can	715.16	1,600 g OP	✓ Pku Start
Powder (orange)		500 g OP	XP Maxamum
Powder (unflavoured)		500 g OP	XP Maxamum
Liquid (berry), 125 ml bottle	13.10	1 OP	PKU Anamix Junior
			LQ
Liquid (orange), 125 ml bottle	13.10	1 OP	✓ PKU Anamix Junior
			LQ
Liquid (forest berries), 250 ml carton	540.00	18 OP	✓ Easiphen Liquid
Liquid (juicy tropical) 125 ml		30 OP	✓ PKU Lophlex LQ 20
Oral semi-solid (berries) 109 g		36 OP	✓ PKU Lophlex
, ,	,		Sensation 20
Liquid (juicy berries) 62.5 ml	939.00	60 OP	✓ PKU Lophlex LQ 10
Liquid (juicy berries) 125 ml		30 OP	✓ PKU Lophlex LQ 20
Liquid (juicy orange) 125 ml		30 OP	✓ PKU Lophlex LQ 20
=-q (J)		00 0.	. No Lopinox La Lo

	Subsidy (Manufacturer's Price)		Fully Subsidised	I Generic
	\$	Per	•	Manufacturer
SLYCOMACROPEPTIDE AND AMINO ACID CONTAINS SON	ME PHENYLALANINE	– Spe	ecial Autho	ority see SA2357 on
age 299 – Hospital pharmacy [HP3]	000.00	00	,	BIZII
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
				20 Chocolate
Powder (Chocolate) 35 g sachets	930.00	30	✓	PKU
				sphere20 Chocolate
Powder (Lemon) 35 g sachets	930.00	30	/	PKU
, ,				sphere20 Lemon
Powder (Lemonade) 33.4 g sachets	936.00	30	/	PKU GMPro Ultra
· ondo (25.10.100) oo · g odo.10.51.		•		Lemonade
Powder (Neutral), 15 g sachets	449.28	30	1	PKU Build 10
Powder (Orange), 20 g sachets		60		PKU Restore
Towaci (Grango), 20 g sacricis		00	•	Powder
Powder (Raspberry Lemonade) 31 g sachets	898.56	30	/	PKU Build
. on as: (asp20) _5 g sass.s.		•		20 Raspberry
				Lemonade
Powder (Smooth) 31 g sachets	808 56	30	1	PKU Build
Fowder (Smooth) ST & Sacriets		30	•	20 Smooth
Douglar (Vanilla) 22 a acabata	000 56	20	./	PKU Build 20 Vanilla
Powder (Vanilla) 33 g sachets		30 30		
Powder (neutral), 40 g sachets				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	1	PKU sphere20 Red
1 Owder (Hed Delly) 55 g sacriets		30	•	Berry
Douglar (Vanilla) 25 a cochata	000.00	20	./	PKU
Powder (Vanilla) 35 g sachets	930.00	30	•	
				sphere20 Vanilla
Liquid (neutral), 250 ml carton		18		PKU GMPro LQ
Liquid (original), 250 ml carton	684.45	30 OF	•	PKU Glytactin RTD 15
Liquid (Coffee Mocha), 250 ml carton	601 15	30 OF		PKU Glytactin RTD
Liquid (Conee Mocha), 250 mi canton	004.40	JU UI	-	15 Lite
Limited (alternative) OFO and acceptant	CO4 45	00 01		
Liquid (chocolate), 250 ml carton		30 OF	•	PKU Glytactin RTD 15
Liquid (vanilla), 250 ml carton	684.45	30 OF	•	PKU Glytactin RTD
		J J1	•	15 Lite

# Foods

LOW PROTEIN BAKING MIX - Special Authority see SA2357 on pag	e 299 –	Hospital pharmacy	(HP3]
Powder	8.55	500 g OP	✓ Loprofin Mix

	Subsidy		Fully Brand or
	(Manufacturer's F	Price) Subs Per	idised Generic  Manufacturer
LOW PROTEIN PASTA Special Authority see SA2257 on page	no 200 Hospital		
LOW PROTEIN PASTA – Special Authority see SA2357 on pag		500 g OP	oj <b>✓ Loprofin</b>
Animal shapesLasagne		250 g OP	✓ Loprofin
•		•	
Low protein rice pasta		500 g OP	✓ Loprofin
Macaroni		250 g OP	✓ Loprofin
Penne		500 g OP	✓ Loprofin
Spaghetti		500 g OP	✓ Loprofin
Spirals	12.39	500 g OP	✓ Loprofin
Supplements for Tyrosinaemia			
AMINOACID FORMULA WITHOUT PHENYLALANINE AND TY pharmacy [HP3]	ROSINE - Speci	ial Authority see	e SA2357 on page 299 – Hospi
Powder (Neutral), 12.5 g sachets	349.65	30	✓ TYR Explore 5
Powder (neutral) 36 g sachets		30	✓ TYR Anamix Junior
Powder, can		400 g OP	✓ TYR Anamix Infant
Liquid (juicy berries) 125 ml pouches		30	✓ TYR Lophlex LQ 20
Liquid (orange) 125 ml bottle		36	✓ TYR Anamix Junior
_ 4 ( 3-/			LQ
GLYCOMACROPEPTIDE AND AMINO ACID CONTAINS SOM	E TYROSINE AN	D PHENYLALA	NINE - Special Authority see
SA2357 on page 299 – Hospital pharmacy [HP3]			,
Powder (Red Berry), 35 g sachets	1.398.60	30	✓ TYR Sphere 20
Powder (Vanilla), 35 g sachets		30	✓ TYR Sphere 20
Supplements for Organic Acidaemias  AMINOACID FORMULA WITHOUT ISOLEUCINE, METHIONIN on page 299 – Hospital pharmacy [HP3]	E, THREONINE	AND VALINE -	- Special Authority see SA2357
	000.00	400 00	
Powder, can		400 g OP	✓ MMA/PA Anamix Infant
AMINOACID FORMULA WITHOUT METHIONINE, THREONINI Hospital pharmacy [HP3]	E AND VALINE -	Ū	Infant rity see SA2357 on page 299 -
AMINOACID FORMULA WITHOUT METHIONINE, THREONINI Hospital pharmacy [HP3] Powder (neutral), 18 g sachets	E AND VALINE -	- Special Autho	Infant rity see SA2357 on page 299 -  ✓ MMA/PA Anamix Junior
AMINOACID FORMULA WITHOUT METHIONINE, THREONINI Hospital pharmacy [HP3] Powder (neutral), 18 g sachets	E AND VALINE - 750.30	- Special Autho 30	Infant rity see SA2357 on page 299 -  ✓ MMA/PA Anamix Junior  ✓ MMA/PA Explore 5
AMINOACID FORMULA WITHOUT METHIONINE, THREONINI Hospital pharmacy [HP3] Powder (neutral), 18 g sachets	E AND VALINE - 750.30	- Special Autho	Infant rity see SA2357 on page 299 -  ✓ MMA/PA Anamix Junior
AMINOACID FORMULA WITHOUT METHIONINE, THREONINI Hospital pharmacy [HP3] Powder (neutral), 18 g sachets	E AND VALINE - 750.30	- Special Autho 30	Infant rity see SA2357 on page 299 -  ✓ MMA/PA Anamix Junior  ✓ MMA/PA Explore 5
AMINOACID FORMULA WITHOUT METHIONINE, THREONINI Hospital pharmacy [HP3] Powder (neutral), 18 g sachets	E AND VALINE750.30349.651,048.95	- Special Autho 30 30 30 30	Infant rity see SA2357 on page 299 -  ✓ MMA/PA Anamix Junior  ✓ MMA/PA Explore 5  ✓ MMA/PA Express 15
AMINOACID FORMULA WITHOUT METHIONINE, THREONING Hospital pharmacy [HP3] Powder (neutral), 18 g sachets  Powder, 12.5 g sachets Powder, 25 g sachets  Supplements for Glutaric Aciduria type 1  AMINOACID FORMULA WITHOUT LYSINE – Special Authority	E AND VALINE750.30349.651,048.95  y see SA2357 on	- Special Autho 30 30 30 30	Infant rity see SA2357 on page 299 -  MMA/PA Anamix Junior  MMA/PA Explore 5  MMA/PA Express 15
AMINOACID FORMULA WITHOUT METHIONINE, THREONING Hospital pharmacy [HP3] Powder (neutral), 18 g sachets Powder, 12.5 g sachets Powder, 25 g sachets  Supplements for Glutaric Aciduria type 1  AMINOACID FORMULA WITHOUT LYSINE – Special Authority Powder (neutral), 18 g sachets	E AND VALINE750.30349.651,048.95  y see SA2357 on750.30	- Special Autho 30 30 30 30 page 299 – Hos	Infant rity see SA2357 on page 299 -  ✓ MMA/PA Anamix Junior  ✓ MMA/PA Explore 5  ✓ MMA/PA Express 15  spital pharmacy [HP3]  ✓ GA1 Anamix Junior
AMINOACID FORMULA WITHOUT METHIONINE, THREONING Hospital pharmacy [HP3] Powder (neutral), 18 g sachets Powder, 12.5 g sachets Powder, 25 g sachets  Supplements for Glutaric Aciduria type 1  AMINOACID FORMULA WITHOUT LYSINE – Special Authority Powder (neutral), 18 g sachets	E AND VALINE	- Special Autho 30 30 30 30 page 299 – Hos	Infant rity see SA2357 on page 299 -  ✓ MMA/PA Anamix Junior  ✓ MMA/PA Explore 5  ✓ MMA/PA Express 15  spital pharmacy [HP3]  ✓ GA1 Anamix Junior  ✓ GA Explore 5
AMINOACID FORMULA WITHOUT METHIONINE, THREONING Hospital pharmacy [HP3] Powder (neutral), 18 g sachets Powder, 12.5 g sachets Powder, 25 g sachets  Supplements for Glutaric Aciduria type 1  AMINOACID FORMULA WITHOUT LYSINE – Special Authority Powder (neutral), 18 g sachets	E AND VALINE	- Special Autho 30 30 30 30 page 299 – Hos	Infant rity see SA2357 on page 299 -  ✓ MMA/PA Anamix Junior  ✓ MMA/PA Explore 5  ✓ MMA/PA Express 15  spital pharmacy [HP3]  ✓ GA1 Anamix Junior
AMINOACID FORMULA WITHOUT METHIONINE, THREONING Hospital pharmacy [HP3] Powder (neutral), 18 g sachets	E AND VALINE	- Special Autho 30 30 30 30 page 299 – Hos 30 30 400 g OP	Infant rity see SA2357 on page 299 -  MMA/PA Anamix Junior  MMA/PA Explore 5  MMA/PA Express 15  Spital pharmacy [HP3]  GA1 Anamix Junior  GA Explore 5  GA1 Anamix Infant
AMINOACID FORMULA WITHOUT METHIONINE, THREONING Hospital pharmacy [HP3] Powder (neutral), 18 g sachets	E AND VALINE750.30349.651,048.95  y see SA2357 on750.30349.65260.00	- Special Autho 30 30 30 30 page 299 – Hos 30 30 400 g OP	Infant rity see SA2357 on page 299 -  MMA/PA Anamix Junior  MMA/PA Explore 5  MMA/PA Express 15  Spital pharmacy [HP3]  GA1 Anamix Junior  GA Explore 5  GA1 Anamix Infant
AMINOACID FORMULA WITHOUT METHIONINE, THREONINI Hospital pharmacy [HP3] Powder (neutral), 18 g sachets	E AND VALINE750.30349.651,048.95  y see SA2357 on750.30349.65260.00	- Special Autho 30 30 30 30  page 299 – Hos 30 400 g OP	Infant rity see SA2357 on page 299 -  MMA/PA Anamix Junior  MMA/PA Explore 5  MMA/PA Express 15  Spital pharmacy [HP3]  GA1 Anamix Junior  GA Explore 5  GA1 Anamix Infant  I pharmacy [HP3]
AMINOACID FORMULA WITHOUT METHIONINE, THREONINI Hospital pharmacy [HP3] Powder (neutral), 18 g sachets	E AND VALINE	- Special Autho 30 30 30 30 30  page 299 – Hospita 30 400 g OP	Infant rity see SA2357 on page 299 -  MMA/PA Anamix Junior  MMA/PA Explore 5  MMA/PA Express 15  Spital pharmacy [HP3]  GA1 Anamix Junior  GA Explore 5  GA1 Anamix Infant  I pharmacy [HP3]

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
CITRULLINE – Special Authority see SA2357 on page 299 – Hospital pharmacy [HP3] Powder, 4 g sachets211.45	30	1	Citrulline1000
ISOLEUCINE – Special Authority see SA2357 on page 299 – Hospital pharmacy [HP3 Powder, 4 g sachets141.05	] 30	1	Isoleucine50
LEUCINE – Special Authority see SA2357 on page 299 – Hospital pharmacy [HP3] Powder, 4 g sachets141.05	30	✓	Leucine100
PHENYLALANINE – Special Authority see SA2357 on page 299 – Hospital pharmacy Powder, 4 g sachets141.05	[HP3] 30	•	Phenylalanine50
TYROSINE – Special Authority see SA2357 on page 299 – Hospital pharmacy [HP3] Powder, 4 g sachets211.45	30	✓	Tyrosine1000
VALINE – Special Authority see SA2357 on page 299 – Hospital pharmacy [HP3] Powder, 4 g sachets141.05	30	•	Valine50
Other Fat Modified Products			
ELEMENTAL FEED WITH HIGH MEDIUM CHAIN TRIGLYCERIDES — Special Author pharmacy [HP3]	ity se	e SA2357	7 on page 299 – Hospital
Powder (neutral), 100 g sachets47.01	10	•	Emsogen
Carbohydrate and Fat with added vitamins and minerals			
PROTEIN FREE SUPPLEMENT CONTAINING CARBOHYDRATE, FAT WITH ADDED Authority see SA2357 on page 299 – Hospital pharmacy [HP3]	VIT/	AMINS AN	ND MINERALS - Special
, , , , , , , , , , , , , , , , , , , ,	0 g O	P 🗸	Energivit
Essential Amino Acids			
ESSENTIAL AMINOACID FORMULA - Special Authority see SA2357 on page 299 - Fowder (neutral), can	Hospi 0 g O		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 vocationally registered general practitioner. Approvals valid for 1 year where the patient is an infant suffering from Williams Syndrome and associated hypercalcaemia.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic \$ Per ✔ Manufacturer

# **Gastrointestinal and Other Malabsorptive Problems**

AMINO ACID FORMULA - Special Authority see SA209	2 below – Hospital pharr	nacy [HP3]	
Powder	43.60	400 g OP	<ul><li>✓ Alfamino</li><li>✓ Alfamino Junior</li></ul>
Powder (unflavoured)	55.61	400 g OP	<ul><li>✓ Neocate Gold</li><li>✓ Neocate Junior</li><li>Unflavoured</li></ul>
			✓ Neocate SYNEO
	65.72		✓ Elecare ✓ Elecare LCP
Powder (vanilla)	55.61	400 g OP	✓ Neocate Junior Vanilla
	65.72		✓ Elecare

## ⇒SA2092 Special Authority for Subsidy

**Initial application** — (Infants under 12 months of age) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Any of the following:

- 1 History of anaphylaxis to cow's milk protein formula or dairy products; or
- 2 Eosinophilic oesophagitis; or
- 3 Ultra-short gut; or
- 4 Severe Immune deficiency; or
- 5 Extensively hydrolysed formula has been trialled in an inpatient setting and is clinically inappropriate; or
- 6 Both
  - 6.1 Extensively hydrolysed formula has been reasonably trialled for 2-4 weeks and is inappropriate due to documented severe intolerance or allergy or malabsorption; and
  - 6.2 Either:
    - 6.2.1 The patient has a valid Special Authority approval for extensively hydrolysed formula: approval number; or 6.2.2 Patient has IgE mediated allergy.

Initial application — (Children 12 months of age and over) only from a paediatrician, paediatric gastroenterologist, paediatric immunologist or dietitian on the recommendation of a paediatrician, paediatric gastroenterologist or paediatric immunologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Either:
  - 1.1 Applicant is a paediatrician, paediatric gastroenterologist or paediatric immunologist; or
  - 1.2 Applicant is a dietitian and confirms that a paediatrician, paediatric gastroenterologist or paediatric immunologist has been consulted within the last 12 months and has recommended treatment for the patient; and
- 2 Any of the following:
  - 2.1 History of anaphylaxis to cow's milk protein formula or dairy products; or
  - 2.2 Eosinophilic oesophagitis; or
  - 2.3 Ultra-short gut; or
  - 2.4 Severe Immune deficiency: or
  - 2.5 Extensively hydrolysed formula has been trialled in an inpatient setting and is clinically inappropriate; or
  - 2.6 Both:
    - 2.6.1 Extensively hydrolysed formula has been reasonably trialled for 2-4 weeks and is inappropriate due to documented severe intolerance or allergy or malabsorption; and
    - 2.6.2 Either:
      - 2.6.2.1 The patient has a valid Special Authority approval for extensively hydrolysed formula: approval

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Subsidy	Fully	Brand or	
(Manufacturer's Price)	Subsidised	l 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	Fu	lly Brand or	
(Manufacturer's Price)	Subsidis	ed Generic	
\$	Per	<ul> <li>Manufacturer</li> </ul>	

continued...

All of the following:

- 1 Patient has a valid Special Authority approval for extensively hydrolysed formula (SA1557); and
- 2 Extensively hydrolysed formula (Aptamil Gold+ Pepti Junior, AllerPro SYNEO 1 and 2) is unable to be supplied at this time; and
- 3 The approval only applies to funded dispensings of Neocate Gold and Neocate Syneo.

Note: This criteria is short term funding to cover an out-of-stock situation on some extensively hydrolysed formula powder funded under Special Authority form SA1557. There is no renewal criteria under this restriction.

ENTERAL LIQUID PEPTIDE FORMULA - Special Authority see SA1953 below - Hospital pharmacy [HP3]

Liquid 1 kcal/ml, 500 ml bottle12.44	1 OP	✓ Nutrini Peptisorb
Liquid 1.5 kcal/ml, 500 ml bottle	1 OP	✓ Nutrini Peptisorb
		Energy

## ⇒SA1953 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has impaired gastrointestinal function and either cannot tolerate polymeric feeds, or polymeric feeds are unsuitable; and
- 2 Any of the following:
  - 2.1 Severe malabsorption; or
  - 2.2 Short bowel syndrome: or
  - 2.3 Intractable diarrhoea; or
  - 2.4 Biliary atresia; or
  - 2.5 Cholestatic liver diseases causing malabsorption; or
  - 2.6 Cystic fibrosis; or
  - 2.7 Proven fat malabsorption; or
  - 2.8 Severe intestinal motility disorders causing significant malabsorption; or
  - 2.9 Intestinal failure: or
  - 2.10 Both:
    - 2.10.1 The patient is currently receiving funded amino acid formula; and
    - 2.10.2 The patient is to be trialled on, or transitioned to, an enteral liquid peptide formula; and
- 3 Either:
  - 3.1 A semi-elemental or partially hydrolysed powdered feed has been reasonably trialled and considered unsuitable; or
  - 3.2 For step down from intravenous nutrition.

Note: A reasonable trial is defined as a 2-4 week trial.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 An assessment as to whether the patient can be transitioned to a cows milk protein or soy infant formula or extensively hydrolysed formula has been undertaken; and
- 2 The outcome of the assessment is that the patient continues to require an enteral liquid peptide formula; and
- 3 General practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.

EXTENSIVELY HYDROLYSED FORMULA  – Special A	authority see SA1557 on the	e next page –	Hospital pharmacy [HP3]
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 Either
    - 1.2.1 Soy milk formula has been reasonably trialled without resolution of symptoms; or
    - 1.2.2 Soy milk formula is considered clinically inappropriate or contraindicated; or
- 2 Severe malabsorption; or
- 3 Short bowel syndrome; or
- 4 Intractable diarrhoea; or
- 5 Biliary atresia; or
- 6 Cholestatic liver diseases causing malsorption; or
- 7 Cystic fibrosis: or
- 8 Proven fat malabsorption; or
- 9 Severe intestinal motility disorders causing significant malabsorption; or
- 10 Intestinal failure; or
- 11 All of the following:
  - 11.1 For step down from Amino Acid Formula: and
  - 11.2 The infant is currently receiving funded amino acid formula; and
  - 11.3 The infant is to be trialled on, or transitioned to, an extensively hydrolysed formula; and
  - 11.4 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.

Note: A reasonable trial is defined as a 2-4 week trial, or signs of an immediate IgE mediated allergic reaction.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 An assessment as to whether the infant can be transitioned to a cows milk protein or soy infant formula has been undertaken; and
- 2 The outcome of the assessment is that the infant continues to require an extensively hydrolysed infant formula; and
- 3 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.

#### Fluid Restricted

PAEDIATRIC ORAL/ENTERAL FEED 1 KCAL/ML - Special Authority see SA1698 below - Hospital pharmacy [HP3] Liquid, 125 ml bottle .......2.80 1 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...



Subsidy (Manufacturer's Price)	5	Fully Subsidised	Brand or 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 SA119	7 above – Hospita	al pharmacy [HP3]
Powder (unflavoured)36.92	300 g OP	✓ KetoCal 4:1
	_	✓ Ketocal 3:1
Powder (vanilla)36.92	300 g OP	✓ KetoCal 4:1

# **SECTION I: NATIONAL IMMUNISATION SCHEDULE**

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per Manufacturer

# **Vaccinations**

#### BACILLUS CALMETTE-GUERIN VACCINE - [Xpharm]

For infants at increased risk of tuberculosis. Increased risk is defined as:

- 1) living in a house or family with a person with current or past history of TB; or
- 2) having one or more household members or carers who within the last 5 years lived in a country with a rate of TB > or equal to 40 per 100,000 for 6 months or longer; or
- 3) during their first 5 years will be living 3 months or longer in a country with a rate of TB > or equal to 40 per 100,000 Note a list of countries with high rates of TB are available at www.health.govt.nz/tuberculosis (search for downloads) or www.bcgatlas.org/index.php.

Inj Mycobacterium bovis	s BCG (Bacillus Calmette-Guerin),
Devision strain 4004	Proceedings of the Part of the 1997 and the

Danish strain 1331, live attenuated, vial with diluent.................0.00 10 **▼** BCG Vaccine AJV

## COVID-19 VACCINE - [Xpharm]

Inj 3 mcg bretovameran per 0.3 ml, 0.48 ml vial; infant vaccine,

Up to three doses for previously unvaccinated children aged 6 months - 4 years at high risk of severe illness.

10 **✓ Comirnaty Omicron** (JN.1)

#### Either:

- 1) One dose for previously unvaccinated children aged 5-11 years old; or
- 2) Up to three doses for immunocompromised children aged 5-11 years old.
- Inj 30 mcg bretovameran per 0.3 ml, 0.48 ml vial; adult vaccine,

10 **✓ Comirnaty Omicron** 

(JN.1)

#### Any of the following:

1) One dose for previously unvaccinated people aged 12-15 years old: or

- 2) Up to three doses for immunocompromised people aged 12-15 years old; or
- 3) Up to two doses for previously unvaccinated people 16-29 years old; or
- 4) Up to four doses for people aged 16-29 at high risk of severe illness; or
- 5) One dose for previously unvaccinated people aged 30 and older; or
- 6) One additional dose every 6 months for previously vaccinated people aged 30 years and over additional dose is given at least 6 months after last dose.

Subsidy		Fully	Brand or	
(Manufacturer's Price	e)	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
  - A course of up to four doses is funded for children from age 7 up to the age of 18 years inclusive to complete full primary immunisation; or
  - 4) An additional four doses (as appropriate) are funded for (re-)immunisation for patients post haematopoietic stem cell transplantation or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens; or
  - 5) A single dose for vaccination of patients aged from 65 years old: or
  - 6) A single dose for vaccination of patients aged from 45 years old who have not had 4 previous tetanus doses; or
  - 7) For vaccination of previously unimmunised or partially immunised patients; or
  - 8) For revaccination following immunosuppression; or
  - 9) For boosting of patients with tetanus-prone wounds.

Notes: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

- B) Contractors will be entitled to claim payment from the Funder for the supply of diphtheria, tetanus and pertussis vaccine to patients eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the diphtheria, tetanus and pertussis vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraphs 1 – 9 above.

Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg			
pertussis toxoid, 8 mcg pertussis filamentous			
haemagglutinin and 2.5 mcg pertactin in 0.5 ml prefilled			
syringe	0.00	10	✓ Roostrix

Subsidy (Manufacturer's Price)	S	Fully	Brand or Generic	
\$	Per	✓	Manufacturer	

#### DIPHTHERIA, TETANUS, PERTUSSIS AND POLIO VACCINE

- a) Only on a prescription
- b) No patient co-payment payable

c)

- A) Funded for any of the following:
  - 1) A single dose for children up to the age of 7 who have completed primary immunisation; or
  - A course of four vaccines is funded for catch up programmes for children (to the age of 10 years) to complete full primary immunisation; or
  - 3) An additional four doses (as appropriate) are funded for (re-)immunisation for people post HSCT, or chemotherapy; pre- or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens; or
  - 4) Five doses will be funded for children requiring solid organ transplantation.
- B) Contractors will be entitled to claim payment from the Funder for the supply of Diphtheria, tetanus, pertussis and polio vaccine to people eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Diphtheria, tetanus, pertussis and polio vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

Inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous

haemagglutinin, 8 mcg pertactin and 80 D-antigen units

10 ✓ Infanrix IPV

#### DIPHTHERIA, TETANUS, PERTUSSIS, POLIO, HEPATITIS B AND HAEMOPHILUS INFLUENZAE TYPE B VACCINE

- a) Only on a prescription
- b) No patient co-payment payable

c)

- A) Funded for children meeting any of the following criteria
  - 1) Up to four doses for children under the age of 10 years for primary immunisation; or
  - An additional four doses (as appropriate) for (re-)immunisation of children under the age of 18 years post haematopoietic stem cell transplantation; or
  - 3) An additional four doses (as appropriate) for (re-)immunisation of children under the age of 10 years who are post chemotherapy; pre or post splenectomy; undergoing renal dialysis and other severely immunosuppressive regimens; or
  - 4) Up to five doses for children under the age of 10 years receiving solid organ transplantation.
- B) Contractors will be entitled to claim payment from the Funder for the supply of Diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type b vaccine to people eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type b vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

Note: A course of up-to four vaccines is funded for catch up programmes for children (up to and under the age of 10 years) to complete full primary immunisation. Please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.

Inj 30IU diphtheria with 40IU tetanus and 25mcg pertussis toxoids, 25mcg pertussis filamentous haemagglutinin, 8mcg pertactin, 80D-AgU polio virus, 10mcg hepatitis B antigen, 10mcg H. influenzae type b with tetanus toxoid

10 ✓ Infanrix-hexa

			Subsidy (Manufactured Price)			ully	Brand or
			(Manufacturer's Price) \$	Per	Subsidi	<b>√</b>	Generic Manufacturer
HAEM	OPHII	US INFLUENZAE TYPE B VACCINE					
a)	Only	on a prescription					
b) c)	No p	atient co-payment payable					
,	A)	One dose for people meeting any of the following:					
		<ol> <li>For primary vaccination in children; or</li> </ol>					
		<ol> <li>An additional dose (as appropriate) is funded for transplantation, or chemotherapy; functional as</li> </ol>	` '				•
		transplant, pre or post cochlear implants, renal	dialysis and other se	vere	ly immi	inosu	ppressive regimens; or
		<ol> <li>For use in testing for primary immunodeficiency physician or paediatrician.</li> </ol>	diseases, on the re	comi	nendat	ion of	an internal medicine
	B)	Contractors will be entitled to claim payment from the		•			• • • • • • • • • • • • • • • • • • • •
		vaccine to people eligible under the above criteria pu					'
		for subsidised immunisation, and they may only do s	o in respect of the H	aemo	philus	influe	nzae type b vaccine list
	C)	in the Pharmaceutical Schedule.	aritaria that are say	محمط	hu thai	× 000t	raat which may be a
	C)	Contractors may only claim for populations within the sub-set of the population described in paragraph A a		ereu	by triei	CON	ract, which may be a
Ini	10 m	cg vial with diluent syringe		1		✓ A	ct-HIB
		A VACCINE – [Xpharm]				_	<u></u>
		for patients meeting any of the following criteria:					
		o vaccinations for use in transplant patients; or					
		o vaccinations for use in children with chronic liver dis	sease; or				
3	3) Or	e dose of vaccine for close contacts of known hepatit	is A cases.				

✓ Havrix 1440

✓ Havrix Junior

1

		Subsidy (Manufacturer's Price)	Subsid	Fully dised	Brand or Generic
		\$	Per	1	Manufacturer
HEDATITIC D DECOMPINANT VACCINE	[Vnhorm]				

#### HEPATITIS B RECOMBINANT VACCINE - [Xpharm]

✓ Engerix-B

Funded for patients meeting any of the following criteria:

- 1) for household or sexual contacts of known acute hepatitis B patients or hepatitis B carriers; or
- 2) for children born to mothers who are hepatitis B surface antigen (HBsAq) positive; or
- 3) for children up to and under the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination or require a primary course of vaccination; or
- 4) for HIV positive patients; or
- 5) for hepatitis C positive patients; or
- 6) for patients following non-consensual sexual intercourse; or
- 7) for patients prior to planned immunosuppression for greater than 28 days; or
- 8) for patients following immunosuppression; or
- 9) for solid organ transplant patients; or
- 10) for post-haematopoietic stem cell transplant (HSCT) patients; or
- 11) following needle stick injury.

✓ Engerix-B 

Funded for patients meeting any of the following criteria:

- 1) for household or sexual contacts of known acute hepatitis B patients or hepatitis B carriers; or
- 2) for children born to mothers who are hepatitis B surface antigen (HBsAg) positive; or
- 3) for children up to and under the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination or require a primary course of vaccination; or
- 4) for HIV positive patients; or
- 5) for hepatitis C positive patients; or
- 6) for patients following non-consensual sexual intercourse; or
- 7) for patients prior to planned immunosuppression for greater than 28 days; or
- 8) for patients following immunosuppression; or
- 9) for solid organ transplant patients; or
- 10) for post-haematopoietic stem cell transplant (HSCT) patients; or
- 11) following needle stick injury; or
- 12) for dialysis patients; or
- 13) for liver or kidney transplant patients.

	Subsidy		Fully	Brand or	
(Manufacturer's Price) Subsidised Generic	(Manufacturer's Price)	Sub	sidised	Generic	
\$ Per ✔ Manufacturer	\$	Per	1	Manufacturer	

HUMAN PAPILLOMAVIRUS (6, 11, 16, 18, 31, 33, 45, 52 AND 58) VACCINE [HPV]

- a) Maximum of 1 inj per prescription
- b) Only on a prescription
- c) No patient co-payment payable
- ď
- 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
    - 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.

	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 (2025 formulation)

Subsidy	Fully	Brand or
(Manufacturer's Price)	Subsidised	Generic
\$	Por 🗸	Manufacturer

- a) Maximum of 1 inj per prescription
- b) Only on a prescription
- c) No patient co-payment payable
- ď

### 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)	Subsidised		Generic
 \$	Per	•	

#### MEASLES, MUMPS AND RUBELLA VACCINE

- a) Only on a prescription
- b) No patient co-payment payable
- c)

## A) Measles, mumps and rubella vaccine

A maximum of two doses for any patient meeting the following criteria:

- 1) For primary vaccination in children; or
- 2) For revaccination following immunosuppression; or
- 3) For any individual susceptible to measles, mumps or rubella; or
- 4) A maximum of three doses for children who have had their first dose prior to 12 months.

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes. Although a price is listed for the vaccine, doctors can still order measles mumps and rubella vaccine free of charge, as with other Schedule vaccines.

- B) Contractors will be entitled to claim payment for the supply of measles, mumps and rubella vaccine to patients eligible under the above criteria pursuant to their contract with Health NZ for subsidised immunisation, and they may only do so in respect of the measles, mumps and rubella vaccine listed in the Pharmaceutical Schedule.
- C) Contractors can only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

Inj, measles virus 1,000 CCID50, mumps virus 5,012 CCID50,		
Rubella virus 1,000 CCID50; prefilled syringe/ampoule of		
diluent 0.5 ml	10	Priorix

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic \$ Per ✔ Manufacturer

### MENINGOCOCCAL (GROUPS A, C, Y AND W-135) CONJUGATE VACCINE

Inj 10 mcg of each meningococcal polysaccharide conjugated

a) Only on a prescription

b) No patient co-payment payable

C,

- A) Any of the following:
  - Up to three doses and a booster every five years for patients pre- and post splenectomy and for patients
    with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre or post
    solid organ transplant; or

MenQuadfi

- 2) One dose for close contacts of meningococcal cases of any group; or
- 3) One dose for person who has previously had meningococcal disease of any group; or
- 4) A maximum of two doses for bone marrow transplant patients; or
- 5) A maximum of two doses for person pre- and post-immunosuppression\*; or
- B) Both:
  - 1) Person is aged between 13 and 25 years, inclusive; and
  - 2) Either:
    - One dose for individuals who are entering within the next three months, or in their first year of living in boarding school hostels, tertiary education halls of residence, military barracks, Youth Justice residences, or prisons; or
    - 2) One dose for individuals who turn 13 years of age while living in boarding school hostels.
- C) Contractors will be entitled to claim payment from the Funder for the supply of Meningococcal A, C, Y and W-135 vaccine to patients eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Meningococcal A, C, Y and W-135 vaccine listed in the Pharmaceutical Schedule.
- D) Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraphs A-B above.

Note: children under seven years of age require two doses 8 weeks apart, a booster dose three years after the primary series and then five yearly.

\*Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.

Inj 5 mcg of each meningococcal polysaccharide conjugated to a total of approximately 44 mcg of tetanus toxoid carrier

- 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.

(Ma	Subsidy	Fı	ully	Brand or
	nufacturer's Price)	Subsidis	sed	Generic
	\$	Per	•	Manufacturer

#### MENINGOCOCCAL B MULTICOMPONENT VACCINE

- a) Only on a prescription
- b) No patient co-payment payable
- c) Any of the following:
  - A) A primary course of up to three doses for children up to the age of 59 months inclusive; or
  - B) Both:
    - 1) Person is 5 years 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; or
      - ii) up to two doses and a booster every five years for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited); or
      - iii) up to two doses and a booster every five years pre- or post-solid organ transplant; or
      - iv) up to two doses for close contacts of meningococcal cases of any group; or
      - v) up to two doses for person who has previously had meningococcal disease of any group; or
      - vi) up to two doses for bone marrow transplant patients; or
      - vii) up to two doses for person pre- and post-immunosuppression\*; or
  - C) 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 prison; or
      - ii) Two doses for individuals who turn 13 years of age while living in boarding school hostels.
  - D) 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.
  - E) 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-C above.

\*Immunosuppression due to corticosteroid or other immunosuppressive therapy must be for a period of greater than 28 days.

Inj 175 mcg per 0.5 ml prefilled syringe	0.00	1	✓ Bexsero
		10	✓ Bexsero

			_
Subsidy	Fully	Brand or	Т
(Manufacturer's Price)	Subsidised	Generic	
\$	Per 🗸	Manufacturer	

## PNEUMOCOCCAL (PCV13) CONJUGATE VACCINE

- a) Only on a prescription
- b) No patient co-payment payable
- c)
- A) Any of the following:
  - 1) A course of three doses for previously unvaccinated children up to the age of 59 months inclusive; or
  - Two doses are funded for high risk individuals (over the age of 12 months and under 18 years) who have previously received two doses of the primary course of PCV10: or
  - 3) Up to an additional four doses (as appropriate) are funded for the (re)immunisation of high risk children aged under 5 years with any of the following:
    - a) on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or
    - b) primary immune deficiencies; or
    - c) HIV infection: or
    - d) renal failure, or nephrotic syndrome; or
    - e) who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
    - f) cochlear implants or intracranial shunts; or
    - g) cerebrospinal fluid leaks; or
    - 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 mcq of pneumococcal polysaccharide serotypes 1, 3, 4,

	NATIONAL I	IMMUNISATI	ON SCHEDULE
	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
PNEUMOCOCCAL (PPV23) POLYSACCHARIDE VACCINE Any of the following:	- [Xpharm]		
<ol> <li>Up to three doses (as appropriate) for patients with chemotherapy; pre- or post-splenectomy or with fur complement deficiency (acquired or inherited), coch</li> <li>All of the following:</li> </ol>	nctional asplenia, pre- or p	ost-solid organ t	ransplant, renal dialysis,
<ul> <li>a) Patient is a child under 18 years for (re-)immu</li> <li>b) Treatment is for a maximum of two doses; and</li> <li>c) Any of the following:</li> </ul>			

- i) on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or
  - ii) with primary immune deficiencies; or iii) with HIV infection; or
  - iv) with renal failure, or nephrotic syndrome; or
  - v) who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
  - vi) with cochlear implants or intracranial shunts; or
  - vii) with cerebrospinal fluid leaks; or
  - viii) receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
  - ix) with chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or
  - x) pre term infants, born before 28 weeks gestation; or
  - xi) with cardiac disease, with cyanosis or failure; or
  - xii) with diabetes: or
  - xiii) with Down syndrome; or
  - xiv) who are pre-or post-splenectomy, or with functional asplenia; or
- For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician

Inj 575 mcg in 0.5 ml prefilled syringe (25 mcg of each 23 pneumococcal serotype)	.0.00	1	✓ Pneumovax 23
POLIOMYELITIS VACCINE - [Xpharm]			
Up to three doses for patients meeting either of the following:			
1) For partially vaccinated or previously unvaccinated individuals;	or		
<ol><li>For revaccination following immunosuppression.</li></ol>			
Note: Please refer to the Immunisation Handbook for appropriate so	chedule for cato	h-up progr	rammes.
Ini 80D antigen units in 0.5 ml syringe	.0.00	1	✓ IPOL

Subsidy	Fully	Brand or
(Manufacturer's Price)	Subsidised	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, squeezable tube (PVC free)0.00	10	✓ Rotarix
Oral susp live attenuated human rotavirus 1,000,000 CCID50 per dose, prefilled oral applicator0.00	10	✓ Rotarix

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic \$ Per ✔ Manufacturer	ufacturer's Price) Subsidised Generic
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### 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.

▲Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.

				Subsidy (Manufacturer's Price) \$	Sub Per	Fully osidised	Brand or Generic Manufacturer
ARIC	ELLA	ZOSTER VACCINE [SHIN	GLES VACCINE]				
a)	Only	on a prescription					
b)	No p	atient co-payment payable					
c)							
	A)		ng the following criteria:				
		1) Either:					
		,	all people aged 65 year				
		,		or older with any of the		•	
		, , ,	•	em cell transplant or cell	ular ther	apy; or	
		, , , ,	st-solid organ transplar	,			
		,	ogical malignancies; or ing with poorly controlle				
		, , , ,	. ,	difying anti-rheumatic d	ruge (DM	1ΔRDs _	targeted synthetic
		, ,	•	, ,	٠,		lupus erythematosus or
		<b>0</b> /	id arthritis; or	of for polymyaigia mour	natioa, o	yotonno	apas or ythomatosas or
			kidney disease (CKD	4 or 5): or			
		, ,	nmunodeficiency				
	B)	Contractors will be entitled	to claim payment from	the Funder for the supp	oly of Vai	ricella zo	ster vaccine (Shingles
		vaccine) to patients eligible	under the above criter	ria pursuant to their con	tract with	Health	New Zealand (Health NZ)
		for subsidised immunisation	n, and they may only d	o so in respect of the Va	aricella z	oster va	ccine [Shingles vaccine]
		listed in the Pharmaceutica	al Schedule.				
	C)	Contractors may only clain	n for patient populations	s within the criteria that	are cove	red by th	neir contract, which may be

	-			
Diag	nost	$\cap$ $\Lambda$	MAN	te
	IIUSI	$\sigma_{-}$	S GIL	0

a sub-set of the population described in paragraph A above.

✓ Shingrix

✓ Shingrix

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- Symbols -	Albey	267	Amzoate	3
3TC114	Albustix	82	Anaesthetics	12
- A -	Alchemy Oxaliplatin	155	Anagrelide hydrochloride	15
A-Scabies72	Alchemy Oxybutynin	82	Analgesics	120
Abacavir sulphate114	Aldurazyme	28	Anastrozole	
Abacavir sulphate with	Alecensa		Anatrole	18
lamivudine 114	Alectinib	166	Anoro Ellipta	
Abacavir/Lamivudine Viatris114	Alendronate sodium	120	Antabuse	15
Abilify Maintena138	Alendronate sodium with		Antacids and Antiflatulents	
Abiraterone acetate178	colecalciferol	120	Anthelmintics	9
Acarbose11	Alfacalcidol	32	Antiacne Preparations	
Accarb11	Alfamino	304	Antiallergy Preparations	26
Acetazolamide279	Alfamino Junior	304	Antianaemics	
Acetec	Alginic acid	6	Antiandrogen Oral	
Acetic acid with hydroxyquinoline and	Alglucosidase alfa		Contraceptives	80
ricinoleic acid80	Alkeran		Antiarrhythmics	
Acetylcysteine282	Allegron		Antibacterials	
Aci-Jel80	Allerfix		Antibacterials Topical	
Aciclovir	Allerpro Syneo 1		Anticholinergic Agents	
Infection108	Allerpro Syneo 2		Anticholinesterases	
Sensory277	Allersoothe		Antidepressants	
Acidex6	Allmercap		Antidiarrhoeals	
Acipimox53	Allopurinol		Antiepilepsy Drugs	
Acitretin	Almarytm		Antifibrinolytics, Haemostatics and	
Act-HIB	Alpha-Adrenoceptor Blockers		Local Sclerosants	
Actemra	Alpha-Keri Lotion		Antifibrotics	
Actinomycin D	Alphamox 125		Antifungals	
Actrapid10	Alphamox 250		Antifungals Topical	
Actrapid Penfill	Alprolix		Antihistamines	
Acupan	Alu-Tab		Antihypotensives	
Adalimumab (Amgevita)	Aluminium hydroxide		Antimalarials	
Adalimumab (Humira - Alternative	Alyacen		Antimigraine Preparations	
brand) 197	Amantadine hydrochloride		Antinausea and Vertigo Agents	
Adapalene	Ambrisentan		Antipruritic Preparations	
Adcetris	Ambrisentan Viatris		Antipsychotics	
ADR Cartridge 1.8	Amgevita		Antiretrovirals	
Adrenaline	Amiloride hydrochloride		Antirheumatoid Agents	
Cardiovascular55	Amiloride hydrochloride with	52	S .	
Respiratory266	furosemide	50	Antispasmodics and Other Agents Altering Gut Motility	
Advantan70	Amiloride hydrochloride with	52	,	
Advate	•	E0.	Antithrombotic Agents	41
	hydrochlorothiazide		Antithymocyte globulin	10
Adynovate	Aminophylline		(equine)	
	Amiodarone hydrochloride		Antitrichomonal Agents	100
Affibercept	Amisulpride		Antituberculotics and	40
AFT-Pyrazinamide108	Amitriptyline		Antileprotics	
Agents Affecting the	Amlodipine		Antiulcerants	
Renin-Angiotensin System 46	Amorolfine		Antivirals	
Agents for Parkinsonism and Related	Amoxicillin		Anxiolytics	
Disorders	Amoxicillin with clavulanic acid.		Anzatax	
Agents Used in the Treatment of	Amoxiclav Devatis Forte		Apidra	
Poisonings	Amphotericin B		Apidra SoloStar	
Agrylin	Amsacrine		APO Clomipramine	
Albalon281	AmsaLyo		APO Health Macrogol	2
Albendazole95	Amsidine	158	APO-Atomoxetine	14

Apo-Azithromycin	96	Ativan	140	Benzylpenicillin sodium [Penicillin	
APO-Candesartan HCTZ		Atnahs Olsalazine	8	G]	9
16/12.5	47	Atomoxetine	145	Besponsa	21
APO-Candesartan HCTZ		Atorvastatin	54	Beta Cream	6
32/12.5	47	Atropine sulphate		Beta Ointment	
Apo-Temozolomide	164	Cardiovascular	48	Beta Scalp	7
Apomorphine hydrochloride	124	Sensory	280	Beta-Adrenoceptor Agonists	26
Aprepitant	135	Atropt		Beta-Adrenoceptor Blockers	4
Apresoline		Atrovent		Beta-hCG low sensitivity urine test	1
Aptamil Feed Thickener	298	Augmentin	98	kit	8
Aqueous cream	70	Aurorix	130	Betadine	7
Aratac	48	AutoSoft 30	21	Betadine Skin Prep	
Arava	120	AutoSoft 90	21	Betaferon	
Arginine	26	Avelox	100	Betahistine dihydrochloride	13
Arginine2000	302	Avonex	142	Betaine	2
Aripiprazole	. 136, 138	Axitinib	167	Betamethasone dipropionate	6
Aripiprazole Sandoz	136	Azacitidine	155	Betamethasone dipropionate with	
Aristocort	70	Azacitidine Dr Reddy's	155	calcipotriol	7
Arrotex-Prazosin S29	46	Azamun	181	Betamethasone sodium phosphate	Э
Arrow - Clopid	40	Azathioprine	181	with betamethasone acetate	
Arrow - Lattim	280	Azilect	124	Betamethasone valerate	69, 7
Arrow-Amitriptyline	130	Azithromycin	96	Betamethasone valerate with sodiu	um
Arrow-Bendrofluazide	52	Azopt	279	fusidate [fusidic acid]	7
Arrow-Brimonidine		AZT	114	Betaxolol	27
Arrow-Diazepam	140	- B -		Betnovate	6
Arrow-Doxorubicin	159	B-D Micro-Fine	16	Betoptic	27
Arrow-Fluoxetine	131	B-D Ultra Fine	17	Betoptic S	27
Arrow-Losartan &		B-D Ultra Fine II	17	Bevacizumab	20
Hydrochlorothiazide	47	Bacillus Calmette-Guerin (BCG)		Bexsero	31
Arrow-Norfloxacin		vaccine	189	Bezafibrate	5
Arrow-Ornidazole	106	Bacillus Calmette-Guerin		Bezalip	5
Arrow-Quinapril 10	46	vaccine	309	Bezalip Retard	
Arrow-Quinapril 20		Baclofen	123	Bicalutamide	
Arrow-Quinapril 5		Bactroban	67	Bicillin LA	9
Arrow-Roxithromycin		Balance	28	BiCNU	
Arrow-Timolol		Barrier Creams and Emollients	70	Bile and Liver Therapy	1
Arrow-Topiramate		Bayshore	105	Biltricide	
Arrow-Tramadol		BCG Vaccine AJV		Bimatoprost	
Arsenic trioxide	158	Beclazone 100	268	Binarex	
Asacol	7	Beclazone 250	268	Binocrit	3
Asacol S29	7	Beclazone 50	268	Biocon	
Ascend-Cefuroxime	96	Beclomethasone dipropionate	268	Biodone	12
Ascorbic acid		Bedaquiline		Biodone Extra Forte	
Aspen Adrenaline		Bee venom allergy treatment	267	Biodone Forte	
Aspirin		Bendamustine hydrochloride		Bisacodyl	
Blood	40	Bendamustine Sandoz		Bisacodyl Viatris	
Nervous	126	Bendrofluazide		Bisoprolol fumarate	
Asthalin		Bendroflumethiazide		BK Lotion	
Atazanavir Mylan		[Bendrofluazide]	52	Bleomycin sulphate	
Atazanavir sulphate		Benralizumab		Blood Colony-stimulating	
Atazanavir Viatris		Benzathine benzylpenicillin		Factors	4
Atenolol		Benzatropine mesylate	124	Blood glucose diagnostic test	
Atenolol AFT		Benzbromarone		meter	1
Atenolol Viatris		Benzetacil		Blood glucose diagnostic test	
Atezolizumab		Benztrop		strip	1
ATGAM		Benzydamine hydrochloride		Blood glucose test strips (visually	

impaired)16	Calogen	288	Charcoal	282
Blood Ketone Diagnostic Test	Camber	55	CheckTop	81
Strip 14	Candesartan cilexetil	47	Chemotherapeutic Agents	153
Boostrix310	Candesartan cilexetil with		Chickenpox vaccine	
Bortezomib	hydrochlorothiazide	47	Chlorafast	
Bosentan59	Candestar		Chlorambucil	154
Bosentan Dr Reddy's59	Canesten	68	Chloramphenicol	277
Bplex32	Capecitabine	156	Chlorothiazide	52
Brentuximab Vedotin207	Capecitabine Viatris		Chlorpromazine hydrochloride	
Breo Ellipta269	Capsaicin		Chlorsig	
Brevinor 1/2879	Musculoskeletal	120	Chlortalidone [Chlorthalidone]	
Breztri Aerosphere271	Nervous		Chlorthalidone	
Bricanyl Turbuhaler270	Captopril		Chlorvescent	
Brimonidine tartrate280	Carafate		Choice 380 7med Nsha Silver/co	
Brimonidine tartrate with timolol	Carbaccord		Short	
maleate280	Carbamazepine		Ciclosporin	
Brinzolamide279	Carbimazole		Cidomycin P/Free	
Budesonide	Carboplatin		Cilicaine VK	90
Alimentary6	Carboplatin Accord		Cinacalcet	
Respiratory268, 275	Carbosorb-X		Cinacalet Devatis	
Budesonide Te Arai	Cardinol LA		Ciprofloxacin	
Budesonide with eformoterol269	Cardizem CD		Infection	100
Budesonide with glycopyrronium and	CareSens Dual		Sensory	
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