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Introducing PHARMAC

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## Introducing PHARMAC

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

#### PHARMAC's role:

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

New Zealand Public Health and Disability Act 2000

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

Further information about PHARMAC and the way we make funding decisions can be found on the PHARMAC website at http://www.pharmac.govt.nz/about.

## **Purpose of the Pharmaceutical Schedule**

The purpose of the Schedule is to list:

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

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

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

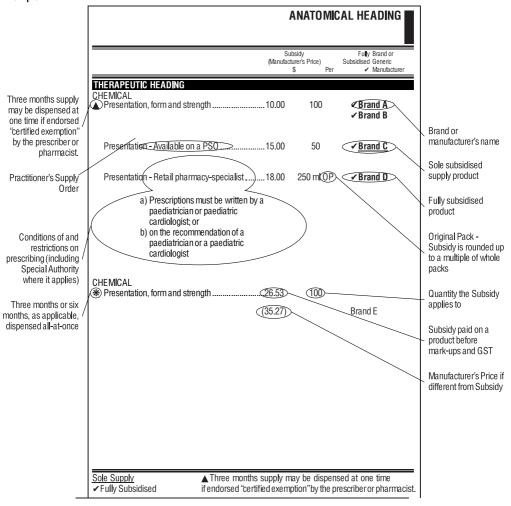
The Pharmaceuticals in this book are listed by therapeutic group, which is based on the WHO Anatomical Therapeutic Chemical (ATC) system. The listings are displayed alphabetically under each heading.

The index lists both chemical entities and product brand names.

## **Explaining pharmaceutical entries**

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

#### Example



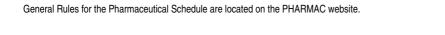
# Glossary

#### **Units of Measure**

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

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

millimoleunit	
Solution	Supp Tab
Trans Dermal Delivery System	TDDS



#### SECTION B: ALIMENTARY TRACT AND METABOLISM

	Subsidy (Manufacturer's Price) \$	Sul Per	osidised G	rand or eneric anufacturer
Antacids and Antiflatulents				
Antacids and Reflux Barrier Agents				
LGINIC ACID Sodium alginate 225 mg and magnesium alginate 87.5 mg p sachet		30	✓ Gavi	scon Infant
ODIUM ALGINATE  Tab 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg - peppermint flavour	1.80 (8.60)	60		scon Double ength
F Oral liq 500 mg with sodium bicarbonate 267 mg and calciul carbonate 160 mg per 10 ml		500 ml	Acide	ex
Phosphate Binding Agents				
LUMINIUM HYDROXIDE  Tab 600 mg CALCIUM CARBONATE  Oral liq 1,250 mg per 5 ml (500 mg elemental per 5 ml)	12.56	100	✓ Alu-	Гab
Subsidy by endorsementOnly when prescribed for children under 12 years of agendorsed accordingly.		500 ml ate bindir	✓ Roxang agent and	
Antidiarrhoeals				
Agents Which Reduce Motility				
OPERAMIDE HYDROCHLORIDE – Up to 30 cap available on Fab 2 mg	10.75	400 400	✓ <u>Nodi</u> ✓ <u>Diam</u>	<u>a</u> nide Relief
Rectal and Colonic Anti-inflammatories				
UDESONIDE  Cap 3 mg - Special Authority see SA1155 below - Retail pharmacy	166.50	90	✓ Ento	cort CIR

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

2 Any of the following:

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

Subsidy		Fully	Brand or	
(Manufacturer's Pric	e)	Subsidised	Generic	
	Per	1	Manufacturer	

continued...

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

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

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

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

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

Note: Clinical trials for Entocort CIR use beyond three months demonstrated no improvement in relapse rate.

#### HYDROCORTISONE ACETATE

Rectal foam 10%, CFC-Free (14 applications)26.55	21.1 g OP	<ul><li>Colifoam</li></ul>
MESALAZINE		
Tab 400 mg49.50	100	✓ Asacol
Tab EC 500 mg49.50	100	✓ Asamax
Tab long-acting 500 mg59.05	100	✓ Pentasa
Tab 800 mg85.50	90	✓ Asacol
Modified release granules, 1 g141.72	120 OP	Pentasa
Enema 1 g per 100 ml41.30	7	✓ Pentasa
Suppos 500 mg22.80	20	✓ Asacol
Suppos 1 g54.60	30	✓ Pentasa
OLSALAZINE		
Tab 500 mg93.37	100	✓ Dipentum
Cap 250 mg53.00	100	✓ Dipentum
SODIUM CROMOGLICATE		
Cap 100 mg92.91	100	✓ Nalcrom
SULFASALAZINE		
* Tab 500 mg14.00	100	✓ Salazopyrin
* Tab EC 500 mg	100	✓ Salazopyrin EN

# Local preparations for Anal and Rectal Disorders

## **Antihaemorrhoidal Preparations**

#### ELLIOCORTOLONE CAPROATE WITH ELLIOCORTOLONE PIVALATE AND CINCHOCAINE

INL	NOTIOUATIVE	ALA I L AIND OI	LUCCOTTOLONE OAI HOATE WITH LUCCOTTOLONE I W
P VIltraproct	30 g OP	6.35	Oint 950 mcg, with fluocortolone pivalate 920 mcg, and cinchocaine hydrochloride 5 mg per g
✓ Ultraproct	12	2.66	Suppos 630 mcg, with fluocortolone pivalate 610 mcg, and cinchocaine hydrochloride 1 mg
P Proctosedyl	30 g OP	15.00	HYDROCORTISONE WITH CINCHOCAINE Oint 5 mg with cinchocaine hydrochloride 5 mg per g
✓ Proctosedyl	12	9.90	Suppos 5 mg with cinchocaine hydrochloride 5 mg per g

<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

## Management of Anal Fissures

GLYCERYL TRINITRATE - Special Authority see SA1329 below - Retail pharmacy

## ⇒SA1329 Special Authority for Subsidy

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

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

	/RRONII	

Inj 200 mcg per ml, 1 ml ampoule – Up to 10 inj available on a
PSO.......17.14 10

HYOSCINE BUTYLBROMIDE

 ★ Tab 10 mg
 8.75
 100
 ✓ Buscopan

 ★ Inj 20 mg, 1 ml - Up to 5 inj available on a PSO
 9.57
 5
 ✓ Buscopan

MEBEVERINE HYDROCHLORIDE

### **Antiulcerants**

## **Antisecretory and Cytoprotective**

MISOPROSTOL

#### **Helicobacter Pylori Eradication**

#### CLARITHROMYCIN

Tab 500 mg − Subsidy by endorsement.......10.40 14 ✓ Apo-Clarithromycin

- a) Maximum of 14 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**

RANITIDINE - Only on a prescription

	Tab 150 mg	12.91	500	Ranitidine Relief
	Tab 300 mg		500	✓ Ranitidine Relief
*	Oral liq 150 mg per 10 ml	5.14	300 ml	✓ Peptisoothe
*	Inj 25 mg per ml, 2 ml	8.75	5	✓ Zantac

## **Proton Pump Inhibitors**

LA	NS	OΡ	RA	١ZC	)LE

*	Cap 15 mg4.58	100	Lanzoi Reliet
*	Cap 30 mg5.41	100	✓ Lanzol Relief

✓ Max Health

		Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
MC	EPRAZOLE				
	For omeprazole suspension refer Standard Formulae, pag			_	
*	Cap 10 mg	1.98	90	•	Omeprazole actavis 10
*	Cap 20 mg	1.96	90	•	Omeprazole actavis
*	Cap 40 mg	3.12	90	✓	Omeprazole actavis 40
*	Powder - Only in combination		5 g	✓	Midwest
	Only in extemporaneously compounded omeprazole s			_	
*	Inj 40 mg ampoule with diluent	33.98	5	•	<u>Dr Reddy's</u> <u>Omeprazole</u>
	NTOPRAZOLE	0.44	100		Dannan Dallaf
	Tab EC 20 mg		100 100		Panzop Relief Panzop Relief
不	Tab EC 40 mg	3.33	100		Panzop Reliei
Si	ite Protective Agents				
0	LLOIDAL BISMUTH SUBCITRATE				
	Tab 120 mg	14.51	50	1	Gastrodenol S29
SUG	CRALFATE				
	Tab 1 g	35.50	120		
	·	(48.28)			Carafate
В	ile and Liver Therapy				
RIF	AXIMIN - Special Authority see SA1461 below - Retail ph	armacy			
	Tab 550 mg		56	1	Xifaxan
nit nep ole Rer	SA1461 Special Authority for Subsidy ial application only from a gastroenterologist, hepatologist atologist. Approvals valid for 6 months where the patient harated doses of lactulose.  newal only from a gastroenterologist, hepatologist or Practificatologist. Approvals valid without further renewal unless neefiting from treatment.	as hepatic encephalopa tioner on the recommen	athy o	lespite an	adequate trial of maximur roenterologist or
D	iabetes				
Н	yperglycaemic Agents				
	70VIDE 0 : 14 # " 0440001   D : "	hormoni			
NΙ	ZOXIDE - Special Authority see SA1320 below - Retail pl	narmacy			

Cap 25 mg	110.00	100	✓ Proglicem S29
Cap 100 mg	280.00	100	✓ Proglicem S29
Oral liq 50 mg per ml	620.00	30 ml OP	✓ Proglycem \$29

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

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

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

#### **GLUCAGON HYDROCHLORIDE**

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

	Subsidy		Fully	Brand or
	(Manufacturer's F		sidised	Generic
	\$	Per		Manufacturer
Inculin Chart acting Drangrations				
Insulin - Short-acting Preparations				
NSULIN NEUTRAL				
Inj human 100 u per ml	25.26	10 ml OP	<b>✓</b>	Actrapid
,			<b>√</b> ⊦	lumulin R
▲ Inj human 100 u per ml, 3 ml	42.66	5	<b>✓</b>	Actrapid Penfill
,			<b>✓</b>	lumulin R
Insulin - Intermediate-acting Preparations				
NSULIN ASPART WITH INSULIN ASPART PROTAMINE				
Inj 100 iu per ml, 3 ml prefilled pen	52.15	5	<b>✓</b> N	NovoMix 30 FlexPen
NSULIN ISOPHANE		-	-	
	17.60	10 ml OP	./ L	Humulin NPH
Inj human 100 u per ml	17.00	10 1111 OF		
Ini human 100 u nay ml. 0 ml	00.00	_		Protaphane
Inj human 100 u per ml, 3 ml	29.86	5		Humulin NPH
			•	Protaphane Penfill
NSULIN ISOPHANE WITH INSULIN NEUTRAL				
Inj human with neutral insulin 100 u per ml	25.26	10 ml OP		lumulin 30/70
			-	Mixtard 30
Inj human with neutral insulin 100 u per ml, 3 ml	42.66	5		lumulin 30/70
				PenMix 30
				PenMix 40
			✓ F	PenMix 50
NSULIN LISPRO WITH INSULIN LISPRO PROTAMINE				
Inj lispro 25% with insulin lispro protamine 75% 100 u per ml,				
3 ml		5	<b>✓</b> ⊦	lumalog Mix 25
Inj lispro 50% with insulin lispro protamine 50% 100 u per ml,		ū		
3 ml		5	<b>✓</b> F	lumalog Mix 50
V 111		<u> </u>	• •	idilialog illix oo
Insulin - Long-acting Preparations				
NSULIN GLARGINE				
▲ Inj 100 u per ml, 10 ml	63.00	1	<b>√</b> I	_antus
Inj 100 u per ml, 3 ml	94 50	5		antus
Inj 100 u per ml, 3 ml disposable pen		5	_	antus SoloStar
L my 100 a por mi, o mi aloposablo por minimi minimi				
Insulin - Rapid Acting Preparations				
NSULIN ASPART				
▲ Inj 100 u per ml, 10 ml	30.03	1	<b>√</b> N	NovoRapid
Inj 100 u per ml, 3 ml	51 10	5		NovoRapid Penfill
Inj 100 u per ml, 3 ml syringe		5		NovoRapid FlexPen
		5	• 1	NOVONAPIU FIEKFEII
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	<b>✓</b>	Apidra SoloStar
NSULIN LISPRO				
▲ Inj 100 u per ml, 10 ml	34.92	10 ml OP	<b>✓</b>	lumalog
▲ Inj 100 u per ml, 3 ml		5	_	lumalog
·				

60

✓ Galvumet

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
Alpha Glucosidase Inhibitors				
ACARBOSE				
* Tab 50 mg		90		Glucobay
* Tab 100 mg		90		Glucobay
	11.24	50	•	Acarbose Mylan S29
(Acarbose Mylan 🕸 Tab 100 mg to be delisted 1 October	2019)			
Oral Hypoglycaemic Agents				
GLIBENCLAMIDE				
* Tab 5 mg	6.00	100	/	<u>Daonil</u>
GLICLAZIDE				
* Tab 80 mg	10.29	500	/	Glizide
GLIPIZIDE				
* Tab 5 mg	3.27	100	1	<u>Minidiab</u>
METFORMIN HYDROCHLORIDE				
* Tab immediate-release 500 mg	8.63	1,000	<b>/</b>	Apotex
	(9.59)			Metchek
Apotex to be Sole Supply on 1 May 2019	7.04			
* Tab immediate-release 850 mg		500		Apotex
Apotex to be Sole Supply on 1 May 2019	(7.82)			Metformin Mylan
(Metchek Tab immediate-release 500 mg to be delisted 1 Ma	av 2010)			
(Metformin Mylan Tab immediate-release 850 mg to be delis	, ,			
PIOGLITAZONE	,,			
* Tab 15 mg	3.47	90	1	Vexazone
* Tab 30 mg		90		Vexazone
* Tab 45 mg		90		Vexazone
VILDAGLIPTIN				
Tab 50 mg	40.00	60	1	Galvus
VILDAGLIPTIN WITH METFORMIN HYDROCHLORIDE				
Tab 50 mg with 1,000 mg metformin hydrochloride	40.00	60	1	Galvumet
Tab 50 mg with 850 mg metformin hydrochloride		60	_	Galvumot

Tab 50 mg with 850 mg metformin hydrochloride .......40.00

<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

## **Diabetes Management**

## **Ketone Testing**

BLOOD KETONE DIAGNOSTIC TEST STRIP - Subsidy by endorsement

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

The prescription must be endorsed accordingly.

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

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

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

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

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

diagnostic test strips \_\_\_\_\_\_20.00 1 OP 

CareSens Dual

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

## **Blood Glucose Testing**

BLOOD GLUCOSE DIAGNOSTIC TEST METER - Subsidy by endorsement

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

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

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

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

Note: Only 1 meter available per PSO

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

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

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

Test strips	50 test OP	✓ CareSens N
		✓ CareSens PRO

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

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

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

Blood g	lucose test stri	os26.20	50 test OP	✓ SensoCard
---------	------------------	---------	------------	-------------

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

## **Insulin Syringes and Needles**

Subsidy is available for disposable insulin syringes, needles, and pen needles if prescribed on the same form as the one used for the supply of insulin or when prescribed for an insulin patient and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of insulin.

octivi civiledelo iviaximam or 100 dev per prescriptio	11		
29 g × 12.7 mm	10.50	100	✓ B-D Micro-Fine
31 g × 5 mm	11.75	100	✓ B-D Micro-Fine
31 g × 6 mm	10.50	100	✓ ABM
31 g × 8 mm	10.50	100	✓ B-D Micro-Fine
		100	✓ B-D Micro-Fine
SULIN SYRINGES, DISPOSABLE WITH ATTACHED NEEDL	E – Maximum of 1	00 dev per p	prescription
Syringe 0.3 ml with 29 g x 12.7 mm needle	13.00	100	✓ B-D Ultra Fine
, ,	1.30	10	
	(1.99)		B-D Ultra Fine
Syringe 0.3 ml with 31 g × 8 mm needle	13.00 <sup>°</sup>	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	13.00	100	B-D Ultra Fine
	1.30	10	
	(1.99)		B-D Ultra Fine
Syringe 0.5 ml with 31 g × 8 mm needle	13.00	100	✓ B-D Ultra Fine II
	1.30	10	
	(1.99)		B-D Ultra Fine II
Syringe 1 ml with 29 g x 12.7 mm needle	13.00	100	B-D Ultra Fine
	1.30	10	
	(1.99)		B-D Ultra Fine
Syringe 1 ml with 31 g × 8 mm needle	13.00	100	✓ B-D Ultra Fine II
	1.30	10	
	(1.99)		B-D Ultra Fine II
	29 g x 12.7 mm	$\begin{array}{c} \text{Syringe 0.3 ml with 29 g \times 12.7 mm needle} & 13.00 \\ & & & & & & \\ & & & & & \\ & & & & &$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

## **Insulin Pumps**

INSULIN PUMP - Special Authority see SA1603 below - Retail pharmacy

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

<ul> <li>c) Maximum of 1 insulin pump per patient each four ye</li> </ul>	ar period.		
Min basal rate 0.001 U/h	4,500.00	1	✓ Tandem t:slim X2
Min basal rate 0.025 U/h	8.800.00	1	✓ MiniMed 640G

#### ⇒SA1603 Special Authority for Subsidy

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

All of the following:

- 1 Patient has permanent neonatal diabetes; and
- 2 A MDI regimen trial is inappropriate; and
- 3 Has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy; and
- 4 Patient/Parent/Guardian has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and

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

continued...

- 5 Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care; and
- 6 Either:
  - 6.1 Applicant is a relevant specialist; or
    - 6.2 Applicant is a nurse practitioner working within their vocational scope.

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

All of the following:

- 1 Patient is continuing to derive benefit according to the treatment plan agreed at induction; and
- 2 Patient remains fully compliant and transition to MDI is considered inappropriate by the treating physician; and
- 3 It has been at least 4 years since the last insulin pump received by the patient or, in the case of patients qualifying under previous pump therapy for the initial application; the pump is due for replacement; and
- 4 Either:
  - 4.1 Applicant is a relevant specialist; or
  - 4.2 Applicant is a nurse practitioner working within their vocational scope.

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

All of the following:

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

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

All of the following:

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

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

All of the following:

1 Patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and

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

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

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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continued...

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

#### **Insulin Pump Consumables**

#### ⇒SA1604 Special Authority for Subsidy

Initial application — (permanent neonatal diabetes) only from a relevant specialist or nurse practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

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

**Renewal — (permanent neonatal diabetes)** only from a relevant specialist or nurse practitioner. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 Patient is continuing to derive benefit according to the treatment plan agreed at induction; and
- 2 Patient remains fully compliant and transition to MDI is considered inappropriate by the treating physician; and
- 3 Fither
  - 3.1 Applicant is a relevant specialist; or
  - 3.2 Applicant is a nurse practitioner working within their vocational scope.

Initial application — (severe unexplained hypoglycaemia) only from a relevant specialist or nurse practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

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

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

- 7 Has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy; and
- 8 Fither:
  - 8.1 Applicant is a relevant specialist; or
  - 8.2 Applicant is a nurse practitioner working within their vocational scope.

**Renewal — (severe unexplained hypoglycaemia)** only from a relevant specialist or nurse practitioner. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 Patient is continuing to derive benefit according to the treatment plan agreed at induction of at least a 50% reduction from baseline in hypoglycaemic events; and
- 2 HbA1c has not increased by more than 5 mmol/mol from baseline; and
- 3 Either:
  - 3.1 Applicant is a relevant specialist; or
  - 3.2 Applicant is a nurse practitioner working within their vocational scope.

Initial application — (HbA1c) only from a relevant specialist or nurse practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

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

**Renewal — (HbA1c)** only from a relevant specialist or nurse practitioner. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 Patient is continuing to derive benefit according to the treatment plan agreed at induction of achieving and maintaining a reduction in HbA1c from baseline of 10 mmol/mol; and
- 2 The number of severe unexplained recurrent hypoglycaemic episodes has not increased from baseline; and
- 3 Either:
  - 3.1 Applicant is a relevant specialist; or
  - 3.2 Applicant is a nurse practitioner working within their vocational scope.

Initial application — (Previous use before 1 September 2012) only from a relevant specialist or nurse practitioner. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 Patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and
- 2 Was already on pump treatment prior to 1 September 2012 and had been evaluated by the multidisciplinary team for their suitability for insulin pump therapy at the time of initiating that pump treatment and continues to benefit from pump treatment; and
- 3 The patient has adhered to an intensive MDI regimen using analogue insulins for at least six months prior to initiating

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	(Manufacturer's Price)		ised	Generic
	\$	Per	1	Manufacturer

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pump therapy; and

- 4 The patient is continuing to derive benefit from pump therapy; and
- 5 The patient had achieved and is maintaining a HbA1c of equal to or less than 80 mmol/mol on pump therapy; and
- 6 The patient has had no increase in severe unexplained hypoglycaemic episodes from baseline; and
- 7 The patient's HbA1c has not deteriorated more than 5 mmol/mol from baseline; and
- 8 Either:
  - 8.1 Applicant is a relevant specialist; or
  - 8.2 Applicant is a nurse practitioner working within their vocational scope.

Renewal — (Previous use before 1 September 2012) only from a relevant specialist or nurse practitioner. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 The patient is continuing to derive benefit according to the treatment plan and has maintained a HbA1c of equal to or less than 80 mmol/mol; and
- 2 The patient's HbA1c has not deteriorated more than 5 mmol/mol from initial application; and
- 3 The patient has not had an increase in severe unexplained hypoglycaemic episodes from baseline; and
- 4 Either:
  - 4.1 Applicant is a relevant specialist: or
  - 4.2 Applicant is a nurse practitioner working within their vocational scope.

INSULIN PUMP ACCESSORIES - Special Authority see SA1604 on page 17 - Retail pharmacy

- a) Maximum of 1 cap per prescription
- b) Only on a prescription
- c) Maximum of 1 prescription per 180 days.

Battery cap ......32.00 1 ✓ Animas Battery Cap

(Animas Battery Cap Battery cap to be delisted 1 October 2019)

INSULIN PUMP CARTRIDGE - Special Authority see SA1604 on page 17 - Retail pharmacy

- a) Maximum of 3 sets per prescription
- b) Only on a prescription
- c) Maximum of 13 packs of cartridge sets will be funded per year.

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

INSULIN PUMP INFUSION SET (STEEL CANNULA) - Special Authority see SA1604 on page 17 - Retail pharmacy

a١	Maximum	of 3 sets	ner nres	crintion

b) Only on a prescription

c)	Maximum	of 13	infusion sets will be funded per year	

	<ul> <li>Maximum of 13 infusion sets will be funded per year.</li> </ul>			
	10 mm steel needle; 29 G; manual insertion; 60 cm tubing x			
	10 with 10 needles	130.00	1 OP	✓ Paradigm Sure-T MMT-884
	10 mm steel needle; 29 G; manual insertion; 60 cm tubing ×			WIWI I -OO4
	10 with 10 needles; luer lock	130.00	1 OP	✓ Sure-T MMT-883
	10 mm steel needle; 29 G; manual insertion; 80 cm tubing x			
	10 with 10 needles	130.00	1 OP	✓ Paradigm Sure-T
				MMT-886
	10 mm steel needle; 29 G; manual insertion; 80 cm tubing x			
	10 with 10 needles; luer lock	130.00	1 OP	✓ Sure-T MMT-885
	6 mm steel cannula; straight insertion; 60 cm grey line $\times$ 10 with			
	10 needles	130.00	1 OP	✓ Contact-D
	6 mm steel needle; 29 G; manual insertion; 60 cm tubing x			
	10 with 10 needles	130.00	1 OP	✓ Paradigm Sure-T MMT-864
	Construction CO on the contract of the contrac			IVIIVI I -864
	6 mm steel needle; 29 G; manual insertion; 60 cm tubing × 10 with 10 needles; luer lock	120.00	1 OP	✓ Sure-T MMT-863
	6 mm steel needle; 29 G; manual insertion; 80 cm tubing x	130.00	TOF	Jule-1 WIWI1-003
	10 with 10 needles	130.00	1 OP	✓ Paradigm Sure-T
				MMT-866
	6 mm steel needle; 29 G; manual insertion; 80 cm tubing ×			
	10 with 10 needles; luer lock	130.00	1 OP	✓ Sure-T MMT-865
	8 mm steel cannula; straight insertion; 110 cm grey line ×			
	10 with 10 needles	130.00	1 OP	✓ Contact-D
	8 mm steel cannula; straight insertion; 60 cm grey line $\times$ 10 with			
	10 needles	130.00	1 OP	✓ Contact-D
	8 mm steel needle; 29 G; manual insertion; 60 cm tubing $\times$			
	10 with 10 needles	130.00	1 OP	✓ Paradigm Sure-T
				MMT-874
	8 mm steel needle; 29 G; manual insertion; 60 cm tubing × 10 with 10 needles; luer lock	120.00	1 OP	✓ Sure-T MMT-873
	8 mm steel needle; 29 G; manual insertion; 80 cm tubing ×	130.00	TOP	Sure-1 WIWI1-073
	10 with 10 needles	130.00	1 OP	✓ Paradigm Sure-T
	10 With 10 Hoodies	100.00	1 01	MMT-876
	8 mm steel needle; 29 G; manual insertion; 80 cm tubing ×			
	10 with 10 needles; luer lock	130.00	1 OP	✓ Sure-T MMT-875
۰.,	ntact-D 6 mm steel cannula: straight insertion: 60 cm gray line > 1		lac to ha dalic	etad 1 October 2010)

(Contact-D 6 mm steel cannula; straight insertion; 60 cm grey line  $\times$  10 with 10 needles to be delisted 1 October 2019) (Contact-D 8 mm steel cannula; straight insertion; 110 cm grey line  $\times$  10 with 10 needles to be delisted 1 October 2019) (Contact-D 8 mm steel cannula; straight insertion; 60 cm grey line  $\times$  10 with 10 needles to be delisted 1 October 2019)

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

INSULIN PUMP INFUSION SET (STEEL CANNULA, STRAIGHT INSERTION) – Special Authority see SA1604 on page 17 – Retail pharmacy

- a) Maximum of 3 sets per prescription
- b) Only on a prescription
- c) Maximum of 13 infusion sets will be funded per year.

c) Maximum of to initiation sets will be funded per year.			
6 mm steel cannula; straight insertion; 60 cm line x 10 with 10 needles	130.00	1 OP	✓ TruSteel
6 mm steel cannula; straight insertion; 81 cm line × 10 with 10 needles	130.00	1 OP	✓ TruSteel
8 mm steel cannula; straight insertion; 60 cm line × 10 with 10 needles	130.00	1 OP	✓ TruSteel
8 mm steel cannula; straight insertion; 81 cm line x 10 with 10 needles	130.00	1 OP	✓ TruSteel

INSULIN PUMP INFUSION SET (TEFLON CANNULA, ANGLE INSERTION WITH INSERTION DEVICE) - Special Authority see SA1604 on page 17 - Retail pharmacy

- a) Maximum of 3 sets per prescription
- b) Only on a prescription
- c) Maximum of 13 infusion sets will be funded per year.
- 13 mm teflon cannula; angle insertion; insertion device; 110 cm 1 OP ✓ Inset 30 13 mm teflon cannula; angle insertion; insertion device; 60 cm ✓ Inset 30 1 OP 13 mm teflon cannula; angle insertion; insertion device; 110 cm 1 OP ✓ AutoSoft 30 13 mm teflon cannula; angle insertion; insertion device; 60 cm line x 10 with 10 needles......140.00 1 OP ✓ AutoSoft 30

(Inset 30 13 mm teflon cannula; angle insertion; insertion device; 110 cm grey line × 10 with 10 needles to be delisted 1 October 2019)

(Inset 30 13 mm teflon cannula; angle insertion; insertion device; 60 cm grey line × 10 with 10 needles to be delisted 1 October 2019)

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

INSULIN PUMP INFUSION SET (TEFLON CANNULA, ANGLE INSERTION) - Special Authority see SA1604 on page 17 - Retail pharmacy

- a) Maximum of 3 sets per prescription
- b) Only on a prescription
- c) Maximum of 13 infusion sets will be funded per year.

<ul> <li>c) Maximum of 13 infusion sets will be funded per year.</li> </ul>			
13 mm teflon cannula; angle insertion; 120 cm line $\times$ 10 with			
10 needles	130.00	1 OP	✓ Paradigm Silhouette MMT-382
13 mm teflon cannula; angle insertion; 45 cm line × 10 with			
10 needles	130.00	1 OP	✓ Paradigm Silhouette MMT-368
13 mm teflon cannula; angle insertion; 60 cm line × 10 with			
10 needles	130.00	1 OP	✓ Paradigm Silhouette MMT-381
13 mm teflon cannula; angle insertion; 80 cm line × 10 with			
10 needles	130.00	1 OP	✓ Paradigm Silhouette MMT-383
17 mm teflon cannula; angle insertion; 110 cm line × 10 with			1111111 000
10 needles	120.00	1 OP	✓ Paradigm Silhouette
TO ficeules	130.00	TOF	MMT-377
17 mm teflon cannula; angle insertion; 110 cm line $\times$ 10 with			
10 needles; luer lock	130.00	1 OP	✓ Silhouette MMT-371
17 mm teflon cannula; angle insertion; 60 cm line × 10 with			
10 needles	130.00	1 OP	✓ Paradigm Silhouette MMT-378
17 mm teflon cannula; angle insertion; 60 cm line × 10 with			
10 needles; luer lock	130.00	1 OP	✓ Silhouette MMT-373
17 mm teflon cannula; angle insertion; 80 cm line × 10 with	100.00	1 01	- Simouette iiiii 1-070
	120.00	1 OP	✓ Paradigm Silhouette
10 needles	130.00	1 05	▼ Faraulylli Silliouelle

MMT-384

1 OP

1 OP

1 OP

✓ Inset II

✓ Paradigm Mio

✓ AutoSoft 90

MMT-965

Mio

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

INSULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIGHT INSERTION WITH INSERTION DEVICE) - Special Authority see SA1604 on page 17 - Retail pharmacy

- a) Maximum of 3 sets per prescription
- b) Only on a prescription
- c) Maximum of 13 infusion sets will be funded per year. 6 mm teflon cannula: straight insertion: insertion device:

clear tubing × 10 with 10 needles......130.00

line x 10 with 10 needles......140.00

6 mm teflon cannula; straight insertion; insertion device; 80 cm

6 mm teflon cannula; straight insertion; insertion device; 45 cm blue tubing × 10 with 10 needles	130.00	1 OP	✓ Paradigm Mio MMT-941
6 mm teflon cannula; straight insertion; insertion device; 45 cm pink tubing × 10 with 10 needles	130.00	1 OP	✓ Paradigm Mio MMT-921
6 mm teflon cannula; straight insertion; insertion device; 60 cm blue tubing × 10 with 10 needles	130.00	1 OP	✓ Paradigm Mio MMT-943
6 mm teflon cannula; straight insertion; insertion device; 60 cm grey line × 10 with 10 needles	140.00	1 OP	✓ Inset II
pink tubing × 10 with 10 needles	130.00	1 OP	✓ Paradigm Mio MMT-923
6 mm teflon cannula; straight insertion; insertion device; 80 cm blue tubing × 10 with 10 needles	130.00	1 OP	✓ Paradigm Mio MMT-945
6 mm teflon cannula; straight insertion; insertion device; 80 cm			

pink tubing × 10 with 10 needles130.00	1 OP	✓ Paradigm Mi MMT-925
9 mm teflon cannula: straight insertion; insertion device:		

110 cm grey line × 10 with 10 needles	140.00	1 OP	✓ Inset II
9 mm teflon cannula; straight insertion; insertion device; 60 cm			
gray line > 10 with 10 needles	140 00	1 OP	✓ Inset II

grey line x 10 with 10 needles140.00	1 01	· moct m
9 mm teflon cannula; straight insertion; insertion device; 80 cm		
clear tubing × 10 with 10 needles130.00	1 OP	✓ Paradigm Mic
		MMT-975

clear tubing x 10 with 10 needles130.00	1 OP	✓ Paradigm Mio MMT-975
6 mm teflon cannula; straight insertion; insertion device; 110 cm line × 10 with 10 needles140.00	1 OP	✓ AutoSoft 90
6 mm teflon cannula; straight insertion; insertion device; 60 cm		

9 mm teflon cannula; straight insertion; insertion device;			
110 cm line × 10 with 10 needles	140.00	1 OP	✓ AutoSoft 90

	(Manufacturer's Price)	Per	Subsidised	Generic Manufacturer	
9 mm teflon cannula; straight insertion; insertion device; 60 cr	n				
line × 10 with 10 needles	140.00	1 OP	✓ A	utoSoft 90	
neat II 6 mm taflon cannula: etraight incertion: incertion device: 1	110 cm grav lina v 1	0 with	10 naadlas t	n ha dalistad 1	October

Subeidy

Fully

Brand or

(Inset II 6 mm teflon cannula; straight insertion; insertion device; 110 cm grey line x 10 with 10 needles to be delisted 1 October 2019)

(Inset II 6 mm teflon cannula; straight insertion; insertion device; 60 cm grey line x 10 with 10 needles to be delisted 1 October 2019)

(Inset II 9 mm teflon cannula; straight insertion; insertion device; 110 cm grey line x 10 with 10 needles to be delisted 1 October 2019)

(Inset II 9 mm teflon cannula; straight insertion; insertion device; 60 cm grey line x 10 with 10 needles to be delisted 1 October 2019)

INSULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIGHT INSERTION) – Special Authority see SA1604 on page 17 – Retail pharmacy

- a) Maximum of 3 sets per prescription
- b) Only on a prescription
- c) Maximum of 13 infusion sets will be funded per year.

6 mm teflon cannula; straight insertion; 110 cm tubing × 10 with 10 needles	30.00	1 OP	✓ Paradigm Quick-Set MMT-398
6 mm teflon cannula; straight insertion; 110 cm tubing x 10 with 10 needles; luer lock	30.00	1 OP	✓ Quick-Set MMT-391
6 mm teflon cannula; straight insertion; 60 cm tubing × 10 with			
10 needles	30.00	1 OP	✓ Paradigm Quick-Set MMT-399
6 mm teflon cannula; straight insertion; 60 cm tubing × 10 with			
10 needles; luer lock	30.00	1 OP	✓ Quick-Set MMT-393
6 mm teflon cannula; straight insertion; 80 cm tubing × 10 with			
10 needles	30.00	1 OP	✓ Paradigm Quick-Set MMT-387
9 mm teflon cannula; straight insertion; 106 cm tubing x 10 with			
10 needles	30.00	1 OP	✓ Paradigm Quick-Set MMT-396
9 mm teflon cannula; straight insertion; 110 cm tubing $\times$ 10 with			
10 needles; luer lock	30.00	1 OP	✓ Quick-Set MMT-390
9 mm teflon cannula; straight insertion; 60 cm tubing × 10 with	00.00	4.00	/ Damadiana Outata Out
10 needles	30.00	1 OP	✓ Paradigm Quick-Set MMT-397
9 mm teflon cannula; straight insertion; 60 cm tubing × 10 with			
10 needles; luer lock	30.00	1 OP	✓ Quick-Set MMT-392
9 mm teflon cannula; straight insertion; 80 cm tubing × 10 with			
10 needles	30.00	1 OP	✓ Paradigm Quick-Set MMT-386

Fully

Brand or

	(Manufacturer's Price)	Si Per	ubsidised	Generic Manufacturer
INSULIN PUMP RESERVOIR - Special Authority see SA1604 on	page 17 – Retail ph	armacy		
a) Maximum of 3 sets per prescription				
b) Only on a prescription				
c) Maximum of 13 packs of reservoir sets will be funded per y	ear.			
10 × luer lock conversion cartridges 1.8 ml for Paradigm pump	s50.00	1 OP	<b>✓</b>	ADR Cartridge 1.8
Cartridge 200 U, luer lock × 10	50.00	1 OP	<b>✓</b>	Animas Cartridge
Cartridge for 5 and 7 series pump; 1.8 ml × 10	50.00	1 OP	<b>✓</b> F	Paradigm
				1.8 Reservoir
Cartridge for 7 series pump; 3.0 ml x 10	50.00	1 OP	<b>✓</b> F	Paradigm
				3.0 Reservoir
Syringe and cartridge for 50X pump, 3.0 ml × 10	50.00	1 OP	<b>√</b> 5	0X 3.0 Reservoir
(Animas Cartridge Cartridge 200 U, luer lock × 10 to be delisted 1	October 2019)			
(50X 3.0 Reservoir Syringe and cartridge for 50X pump, 3.0 ml x 1	0 to be delisted 1 O	ctober 2	2019)	

Subsidy

## **Digestives Including Enzymes**

#### PANCREATIC ENZYME

Cap pancreatin 150 mg (amylase 8,000 Ph Eur U, lipase			
10,000 Ph Eur U, total protease 600 Ph Eur U)	.34.93	100	✓ Creon 10000
Cap pancreatin (175 mg (25,000 U lipase, 22,500 U amylase,			
1,250 U protease))	.94.40	100	Panzytrat
Cap pancreatin 300 mg (amylase 18,000 Ph Eur U, lipase			
25,000 Ph Eur U, total protease 1,000 Ph Eur U)	.94.38	100	✓ Creon 25000
URSODEOXYCHOLIC ACID - Special Authority see SA1739 below -	Retail pharmad	су	
Cap 250 mg	.37.95	100	✓ Ursosan

#### ⇒SA1739 Special Authority for Subsidy

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

Either:

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

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

All of the following:

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

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

Both:

- 1 Primary biliary cholangitis confirmed by antimitochondrial antibody titre (AMA) > 1:80, and raised cholestatic liver enzymes with or without raised serum IqM 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:

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

- 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.

Note: Ursodeoxycholic acid is not an appropriate therapy for patients requiring a liver transplant (bilirubin > 100 micromol/l: decompensated cirrhosis). These patients should be referred to an appropriate transplant centre. Treatment failure -- doubling of serum bilirubin levels, absence of a significant decrease in ALP or ALT and AST, development of varices, ascites or encephalopathy, marked worsening of pruritus or fatique, histological progression by two stages, or to cirrhosis, need for transplantation.

	xau	IW	15	

Bulk-forming Agents			
ISPAGHULA (PSYLLIUM) HUSK – Only on a prescription  * Powder for oral soln  MUCILAGINOUS LAXATIVES WITH STIMULANTS	6.05	500 g OP	✓ Konsyl-D
* Dry		500 g OP	
	(17.32)		Normacol Plus
	2.41 (8.72)	200 g OP	Normacol Plus
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  Not funded for use in the ear.	3.10	200	✓ <u>Laxsol</u>
* Oral drops 10%	3.78	30 ml OP	✓ <u>Coloxyl</u>
Onioid Recentor Antagonists - Perinheral			

Opioid Receptor	Antagonists	- Peripheral
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METHYLNALTREXONE BROMIDE - Special Authority see SA1	691 on the next page	<ul><li>Reta</li></ul>	ul pharmacy
Inj 12 mg per 0.6 ml vial	36.00	1	✓ Relistor
	246 00	7	✓ Relistor

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

#### ⇒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	0.05		4 pou
* Suppos 3.6 g - Only on a prescription	9.25	20	✓ <u>PSM</u>
LACTULOSE – Only on a prescription			
* Oral liq 10 g per 15 ml	3.18	500 ml	✓ Laevolac
MACROGOL 3350 WITH POTASSIUM CHLORIDE, SODIUM BIO	CARBONATE AN	ND SODIUM C	CHLORIDE
Powder for oral soln 13.125 g with potassium chloride 46.6 m	ıa.		
sodium bicarbonate 178.5 mg and sodium chloride 350.7	0.	30	✓ Molaxole
SODIUM ACID PHOSPHATE - Only on a prescription	· ·		
Enema 16% with sodium phosphate 8%	2 50	1	✓ Fleet Phosphate
Zhoma 10/0 Mar oodidin phoophato 0/0		•	Enema
SODIUM CITRATE WITH SODIUM LAURYL SULPHOACETATE	Only on a pro	oorintion	
	, ,	Scription	
Enema 90 mg with sodium lauryl sulphoacetate 9 mg per ml, 5 ml		50	✓ Micolette
5 1111	20.72	30	Wilcolette
Stimulant Laxatives			
Juliulant Laxauves			
BISACODYL - Only on a prescription			
* Tab 5 mg	5.99	200	✓ Lax-Tab
* Suppos 10 mg	3.74	10	✓ Lax-Suppositories
SENNA - Only on a prescription			
* Tab, standardised	2.17	100	
•	(6.84)		Senokot
	0.43	20	
	(1.72)		Senokot

## **Metabolic Disorder Agents**

ALGLUCOSIDASE ALFA - Special Authority see SA1622 below - F	Retail pharmacy		
Ini 50 mg vial	.1.142.60	1	✓ Mvozvme

#### ⇒SA1622 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;
- 2 Any of the following:
  - 2.1 Diagnosis confirmed by documented deficiency of acid alpha-glucosidase by prenatal diagnosis using chorionic

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

continued...

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
- 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.

BETAINE - Special Authority see SA1727 below - Retail pharmacy 180 a OP Cvstadane

#### ⇒SA1727 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.

GALSULFASE - Special Authority see SA1593 below - Retail pharmacy Inj 1 mg per ml, 5 ml vial......2,234.00 ✓ Naglazyme

#### ⇒SA1593 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 Fither:
  - 2.1 Diagnosis confirmed by demonstration of N-acetyl-galactosamine-4-sulfatase (arylsulfatase B) deficiency by either

continued...

enzyme activity assay in leukocytes or skin fibroblasts; or

2.2 Detection of two disease causing mutations and patient has a sibling who is known to have mucopolysaccharidosis VI.

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

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

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

#### ⇒SA1695 Special Authority for Subsidy

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

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

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

### ⇒SA1757 Special Authority for Subsidy

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

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

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

All of the following:

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

#### **⇒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 SA1598 below - Retail pharmacy
Grans 483 mg per g.......1,920.00 174 g OP 

✓ Pheburane

#### ⇒SA1598 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.

#### Gaucher's Disease

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

Brand or Generic Manufacturer

#### ⇒SA0473 Special Authority for Subsidy

Special Authority approved by the Gaucher Treatment Panel

Notes: Subject to a budgetary cap. Applications will be considered and approved subject to funding availability.

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

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

Wellington Email: gaucherpanel@pharmac.govt.nz

TALIGLUCERASE ALFA - Special Authority see SA1734 below - Retail pharmacy

Brand switch fee payable (Pharmacode 2561972) - see page 225 for details

#### ⇒SA1734 Special Authority for Subsidy

Special Authority approved by the Gaucher Treatment Panel

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

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

Wellington Email: gaucherpanel@pharmac.govt.nz

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

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

#### **Access Criteria**

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

- The patient has a diagnosis of symptomatic type 1 or type 3\* Gaucher disease confirmed by the demonstration of specific
  deficiency of glucocerebrosidase in leukocytes or cultured skin fibroblasts, and genotypic analysis; and
- 2) Patient does not have another life-threatening or severe disease where the prognosis is unlikely to be influenced by taliglucerase alfa or might be reasonably expected to compromise a response to therapy with taliglucerase alfa; and
- 3) Taliglucerase alfa is to be administered at a dose no greater than 30 unit/kg every other week rounded to the nearest whole vial (200 units), unless otherwise agreed by PHARMAC; and
- 4) Supporting clinical information including test reports, MRI whole body STIR, serum glucosylsphingosine, haematological data, and other relevant investigations, are submitted to the Gaucher Panel for assessment; and
- 5) Any of the following:
- Patient has haematological complications such as haemoglobin less than 95 g/l, symptomatic anaemia, thrombocytopenia; at least two episodes of severely symptomatic splenic infarcts confirmed with imagery; or massive symptomatic splenomegaly; or
  - 2) Patient has skeletal complications such as acute bone crisis requiring hospitalisation or major pain management strategies; radiological MRI Evidence of incipient destruction of any major joint (e.g. hips or shoulder); spontaneous fractures or vertebral collapse; chronic bone pain not controlled by other pharmaceuticals; or
  - 3) Patient has significant liver dysfunction or hepatomegaly attributable to Gaucher disease; or
  - 4) Patient has reduced vital capacity from clinically significant or progressive pulmonary disease due to Gaucher disease; or
  - Patient is a child and has experienced growth failure with significant decrease in percentile linear growth over a 6-12 month period.

#### \*Unapproved indication

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

Subsidy		Fully	Brand or
(Manufacturer's Price)		Subsidised	Generic
<b>3</b>	Per		Manufacturer

continued...

All of the following:

- Patient has demonstrated a symptomatic improvement or no deterioration in the main symptom for which therapy was initiated; and
- 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 one year and two years since initiation of treatment begins, and two to three yearly thereafter, demonstrate no deterioration shown by the MRI, compared with MRI taken immediately prior to commencement of therapy or adjusted dose; and
- 4) Serum glucosylsphingosine levels taken at least 6 to 12 monthly show a decrease compared with baseline; and
- Patient has not had severe infusion-related adverse reactions which were not preventable by appropriate pre-medication and/or adjustment of infusion rates; and
- Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT; and
- 7) Patient is compliant with regular treatment and taliglucerase alfa is to be administered at a dose no greater than 30 unit/kg every other week rounded to the nearest whole vial (200 units), unless otherwise agreed by PHARMAC; and
- 8) Supporting clinical information including test reports, MRI whole body STIR, serum glucosylsphingosine, haematological data, and other relevant investigations are submitted to the Gaucher Panel for assessment as required.

## **Mouth and Throat**

## Agents Used in Mouth Ulceration

Soln 0.15% - Higher subsidy of \$20.31 per 500 ml with

BENZYDAMINE HYDROCHLORIDE

Endorsement	9.00 (20.31)	500 ml	Difflam
Additional subsidy by endorsement for a patient who har prescription is endorsed accordingly.	, ,	as a result of tre	
CARMELLOSE SODIUM WITH GELATIN AND PECTIN			
Paste		56 g OP	Stomahesive
	4.55	15 g OP	
	(7.90)	5 · OD	Orabase
	1.52	5 g OP	Orabase
Powder	(3.60)	28 g OP	Orabase
rowaei	(10.95)	20 y OF	Stomahesive
CHLORHEXIDINE GLUCONATE			
Mouthwash 0.2%	2.57	200 ml OP	✓ healthE
CHOLINE SALICYLATE WITH CETALKONIUM CHLORIDE			
* Adhesive gel 8.7% with cetalkonium chloride 0.01%	2.06	15 g OP	
	(6.00)		Bonjela
TRIAMCINOLONE ACETONIDE			
Paste 0.1%	5.33	5 g OP	✓ Kenalog in Orabase
Oropharyngeal Anti-infectives			
AMPHOTERICIN B			
Lozenges 10 mg	5.86	20	✓ Fungilin
MICONAZOLE			· · ung
Oral gel 20 mg per g	4.74	40 g OP	✓ <u>Decozol</u>

	Subsidy (Manufacturer's Pr \$		Fully Brand or dised Generic ✓ Manufacturer
NYSTATIN Oral liq 100,000 u per ml	1.95	24 ml OP	✓ <u>Nilstat</u>
Other Oral Agents			
For folinic mouthwash, pilocarpine oral liquid or saliva substitute	formula refer Star	ndard Formulae	e, page 227
HYDROGEN PEROXIDE  * Soln 3% (10 vol) – Maximum of 200 ml per prescription	1.40	100 ml	✓ Pharmacy Health
THYMOL GLYCERIN  * Compound, BPC	9.15	500 ml	✓ <u>PSM</u>
Vitamins			
Vitamin A			
VITAMIN A WITH VITAMINS D AND C  * Soln 1000 u with Vitamin D 400 u and ascorbic acid 30 mg p 10 drops	4.50	10 ml OP	✓ Vitadol C
(Vitadol C Soln 1000 u with Vitamin D 400 u and ascorbic acid 3  Vitamin B	u mg per 10 arops	s to be delisted	T August 2019)
HYDROXOCOBALAMIN  * Inj 1 mg per ml, 1 ml ampoule – Up to 6 inj available on a P PYRIDOXINE HYDROCHLORIDE  a) No more than 100 mg per dose b) Only on a prescription	SO1.89	3	✓ <u>Neo-B12</u>
* Tab 25 mg — No patient co-payment payable      * Tab 50 mg		90 500	✓ <u>Vitamin B6 25</u> ✓ <u>Apo-Pyridoxine</u>
THIAMINE HYDROCHLORIDE - Only on a prescription  * Tab 50 mg	4.89	100	✓ Max Health
VITAMIN B COMPLEX  * Tab, strong, BPC	7.15	500	✓ Bplex
Vitamin C			
ASCORBIC ACID  a) No more than 100 mg per dose b) Only on a prescription  * Tab 100 mg	8.10	500	✓ Cvite
Vitamin D			
ALFACALCIDOL  * Cap 0.25 mcg  * Cap 1 mcg  * Oral drops 2 mcg per ml  CALCITRIOL  * Cap 0.25 mcg  * Cap 0.5 mcg	87.98 60.68	100 100 20 ml OP	✓ One-Alpha ✓ One-Alpha ✓ One-Alpha ✓ One-Alpha ✓ Calcitriol-AFT ✓ Calcitriol-AFT

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

** Cap 1.25 mg (50,000 iu) — Maximum of 12 cap per prescription2.50 12	Multrivitamin Preparations  MULTIVITAMIN RENAL - Special Authority see SA1546 below - Retail pharmacy  * Cap		Subsidy (Manufacturer's Pric	e) Subsi Per	Fully Brand or dised Generic ✓ Manufacturer
MULTIVITAMIN RENAL — Special Authority see SA1546 below — Retail pharmacy  * Cap	MULTIVITAMIN RENAL — Special Authority see SA1546 below — Retail pharmacy  * Cap	* Cap 1.25 mg (50,000 iu) - Maximum of 12 cap per prescripti			
** Cap	** Cap	Multivitamin Preparations			
Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:  Either:  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 m² body surface area (BSA).  MULTIVITAMINS — Special Authority see SA1036 below — Retail pharmacy  * Powder	Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications methe following criteria:    The patient has chronic kidney disease and is receiving either peritoneal dialysis or haemodialysis; or   The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of <   The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of <   The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of <   The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of <   The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of <   The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of <   The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of <   The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of <   The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of <   The patient has patient has had a preaptoval for multivitamins.	* Cap		30	✓ Clinicians Renal Vit
2 The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of < 15 ml/min/1.73 m² body surface area (BSA).  MULTIVITAMINS — Special Authority see SA1036 below — Retail pharmacy  **Powder	2 The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of < 15 ml/min/1.73 m² body surface area (BSA).  MULTIVITAMINS — Special Authority see SA1036 below — Retail pharmacy  **Powder	Initial application from any relevant practitioner. Approvals valid the following criteria:	without further re	newal unless	notified for applications meeting
** Powder	# Powder	2 The patient has chronic kidney disease grade 5, defined a			
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  * Tab (BPC cap strength)	Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where the patient I inborn errors of metabolism.  Renewal from any relevant practitioner. Approvals valid without further renewal unless notified where patient has had a pre approval for multivitamins.  VITAMINS  * Tab (BPC cap strength)	* Powder		200 g OP	✓ Paediatric Seravit
VITAMINS  * Tab (BPC cap strength)	VITAMINS  * Tab (BPC cap strength)	Initial application from any relevant practitioner. Approvals valid inborn errors of metabolism.			·
* Tab (BPC cap strength)	* Tab (BPC cap strength)				
SA1720 below – Retail pharmacy	SA1720 below – Retail pharmacy	* Tab (BPC cap strength)	10.50	1,000	✓ <u>Mvite</u>
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  * Tab eff 1.75 g (1 g elemental)	Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications methodologic riteria:  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  * Tab eff 1.75 g (1 g elemental)		23.40	60	✓ Vitabdeck
CALCIUM CARBONATE         * Tab eff 1.75 g (1 g elemental)       2.07       10       ✓ Calsource         * Tab 1.25 g (500 mg elemental)       7.52       250       ✓ Arrow-Calcium         * Calsource Tab eff 1.75 g (1 g elemental) to be delisted 1 September 2019)         * CALCIUM GLUCONATE       34.24       10       ✓ Hospira         * Inj 10%, 10 ml ampoule       34.24       10       ✓ Max Health 329	CALCIUM CARBONATE         * Tab eff 1.75 g (1 g elemental)       2.07       10       ✓ Calsource         * Tab 1.25 g (500 mg elemental)       7.52       250       ✓ Arrow-Calcium         CALCIUM GLUCONATE         * Inj 10%, 10 ml ampoule       34.24       10       ✓ Hospira         64.00       20       ✓ Max Health (\$29)         (Hospira Inj 10%, 10 ml ampoule to be delisted 1 July 2019)	Initial application from any relevant practitioner. Approvals valid the following criteria: Any of the following:  1 Patient has cystic fibrosis with pancreatic insufficiency; or 2 Patient is an infant or child with liver disease or short gut s		newal unless	notified for applications meeting
CALCIUM CARBONATE  # Tab eff 1.75 g (1 g elemental)	CALCIUM CARBONATE  * Tab eff 1.75 g (1 g elemental)	Minerals			
* Tab eff 1.75 g (1 g elemental)       2.07       10       ✓ Calsource         * Tab 1.25 g (500 mg elemental)       7.52       250       ✓ Arrow-Calcium         * Calsource Tab eff 1.75 g (1 g elemental) to be delisted 1 September 2019)         CALCIUM GLUCONATE       34.24       10       ✓ Hospira         * Inj 10%, 10 ml ampoule       64.00       20       ✓ Max Health 🖘	★ Tab eff 1.75 g (1 g elemental)       2.07       10       ✓ Calsource         ★ Tab 1.25 g (500 mg elemental)       7.52       250       ✓ Arrow-Calcium         (Calsource Tab eff 1.75 g (1 g elemental) to be delisted 1 September 2019)       ✓       CALCIUM GLUCONATE         ★ Inj 10%, 10 ml ampoule       34.24       10       ✓ Hospira         (Hospira Inj 10%, 10 ml ampoule to be delisted 1 July 2019)       ✓       Max Health \$29	Calcium			
★ Inj 10%, 10 ml ampoule       34.24       10       ✓ Hospira         64.00       20       ✓ Max Health \$29	* Inj 10%, 10 ml ampoule	* Tab eff 1.75 g (1 g elemental)	7.52		
(Hospira Inj 10%, 10 ml ampoule to be delisted 1 July 2019)					•
	Fluoride	(Hospira Inj 10%, 10 ml ampoule to be delisted 1 July 2019)			

100

✓ PSM

SODIUM FLUORIDE

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
lodine				
POTASSIUM IODATE  * Tab 253 mcg (150 mcg elemental iodine)	4.69	90	✓ <u>N</u>	euroTabs
Iron				
FERRIC CARBOXYMALTOSE - Special Authority see SA1675 bi Inj 50 mg per ml, 10 ml		acy 1	<b>✓</b> Fe	erinject

Initial application — (serum ferritin less than or equal to 20 mcg/L) from any medical practitioner. Approvals valid for 3 months for applications meeting the following criteria: Both:

- 1 Patient has been diagnosed with iron-deficiency anaemia with a serum ferritin level of less than or equal to 20 mcg/L; and
- 2 Any of the following:
  - 2.1 Patient has been compliant with oral iron treatment and treatment has proven ineffective; or
  - 2.2 Treatment with oral iron has resulted in dose-limiting intolerance; or
  - 2.3 Rapid correction of anaemia is required.

Renewal — (serum ferritin less than or equal to 20 mcg/L) from any medical practitioner. Approvals valid for 3 months for applications meeting the following criteria:

#### Both:

- 1 Patient continues to have iron-deficiency anaemia with a serum ferritin level of less than or equal to 20 mcg/L; and
- 2 A re-trial with oral iron is clinically inappropriate.

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

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

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

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

FERROUS FUMARATE		
* Tab 200 mg (65 mg elemental)	9 100	✓ Ferro-tab
FERROUS FUMARATE WITH FOLIC ACID		
* Tab 310 mg (100 mg elemental) with folic acid 350 mcg4.68	3 60	✓ Ferro-F-Tabs
FERROUS SULPHATE		
* Tab long-acting 325 mg (105 mg elemental)2.06	30	✓ Ferrograd
* Oral liq 30 mg (6 mg elemental) per 1 ml10.80	500 ml	✓ Ferodan

	Subsidy (Manufacturer's Price) \$	Sub Per	Fully sidised	Brand or Generic Manufacturer
IRON POLYMALTOSE				
* Inj 50 mg per ml, 2 ml ampoule	15.22 34.50	5		errum H errosig
(Ferrum H Inj 50 mg per ml, 2 ml ampoule to be delisted 1 July 20	19)			-
Magnesium				
For magnesium hydroxide mixture refer Standard Formulae, page MAGNESIUM SULPHATE	227			
* Inj 2 mmol per ml, 5 ml ampoule	10.21	10	<b>✓</b> <u>D</u>	BL S29 \$29
Zinc				
ZINC SULPHATE  * Cap 137.4 mg (50 mg elemental)	11.00	100	✓ Z	incaps

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

### Antianaemics

### Hypoplastic and Haemolytic

### ⇒SA1775 Special Authority for Subsidy

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

All of the following:

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

Note: Epoetin alfa is indicated in the treatment of anaemia associated with chronic renal failure (CRF) where no cause for anaemia other than CRF is detected and there is adequate monitoring of iron stores and iron replacement therapy.

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

All of the following:

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

Note: Indication marked with \* is an unapproved indication

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

Note: Epoetin alfa is indicated in the treatment of anaemia associated with chronic renal failure (CRF) where no cause for anaemia other than CRF is detected and there is adequate monitoring of iron stores and iron replacement therapy.

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

- 1 The patient's transfusion requirement continues to be reduced with erythropoietin treatment; and
- 2 Transformation to acute myeloid leukaemia has not occurred; and
- 3 The minimum necessary dose of epoetin would be used and will not exceed 80,000 iu per week.

Note: Indication marked with \* is an unapproved indication

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
EPOETIN ALFA - Special Authority see SA1775 on the previous	page – Retail pharm	асу		
Wastage claimable				
Inj 1,000 iu in 0.5 ml, syringe	250.00	6	✓	Binocrit
Inj 2,000 iu in 1 ml, syringe	100.00	6	✓	Binocrit
Inj 3,000 iu in 0.3 ml, syringe	150.00	6	✓	Binocrit
Inj 4,000 iu in 0.4 ml, syringe		6	1	Binocrit
Inj 5,000 iu in 0.5 ml, syringe		6	✓	Binocrit
Inj 6,000 iu in 0.6 ml, syringe	145.00	6	✓	Binocrit
Inj 8,000 iu in 0.8 ml, syringe		6	1	Binocrit
Inj 10,000 iu in 1 ml, syringe		6	1	Binocrit
Inj 40,000 iu in 1 ml, syringe		1	•	Binocrit

### Megaloblastic

FΟ	LIC ACID			
*	Tab 0.8 mg	21.84	1,000	✓ Apo-Folic Acid
*	Tab 5 mg	12.12	500	✓ Apo-Folic Acid
	Oral lig 50 mcg per ml		25 ml OP	✓ Riomed

### Antifibrinolytics, Haemostatics and Local Sclerosants

ELTROMBOPAG - Special Authority see SA1743 below - Retail ph	armacy		
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

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

continued...

3.2 Patient has immune thrombocytopenic purpura\* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding.

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

#### Both:

- 1 Two immunosuppressive therapies have been trialled and failed after therapy of at least 3 months duration; and
- 2 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.

#### EPTACOG ALFA [RECOMBINANT FACTOR VIIA] - [Xpharm]

For patients with haemophilia, whose funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

Inj 1 mg syringe	1	✓ NovoSeven RT
Inj 2 mg syringe	1	✓ NovoSeven RT
Inj 5 mg syringe	1	✓ NovoSeven RT
Inj 8 mg syringe9,426.40	1	✓ NovoSeven RT

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

For patients with haemophilia, whose funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

Inj 500 U1,450.00	1	FEIBA NF
Inj 1,000 U2,900.00	1	✓ FEIBA NF
Inj 2,500 U	1	✓ FEIBA NF

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

Preferred Brand of recombinant factor VIII for patients with haemophilia from 1 March 2016. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

managed by the maemophilia meaters Group in conjunction with	i ilie ivalionai	Haemophila	. Manayement G
Inj 250 iu prefilled syringe	210.00	1	✓ Xyntha
Inj 500 iu prefilled syringe		1	Xyntha
Inj 1,000 iu prefilled syringe	840.00	1	✓ Xyntha
Inj 2,000 iu prefilled syringe		1	Xyntha
Inj 3,000 iu prefilled syringe		1	Xyntha

	Subsidy		Fully				
	(Manufacturer's Price)	Subs Per	idised •	Generic Manufacturer			
	<del>-</del>	rei	_	Manuacturei			
NONACOG ALFA [RECOMBINANT FACTOR IX] - [Xpharm	]						
For patients with haemophilia, whose funded treatment is	s managed by the Haemo	philia Trea	aters	Group in conjunction with			
the National Haemophilia Management Group.	040.00		,	B			
Inj 250 iu vial		1		BeneFIX			
Inj 500 iu vial		1	_	BeneFIX			
Inj 1,000 iu vial	·	1		BeneFIX			
Inj 2,000 iu vial		1		BeneFIX			
Inj 3,000 iu vial		1		BeneFIX			
NONACOG GAMMA, [RECOMBINANT FACTOR IX] - [Xph	arm]						
For patients with haemophilia, whose funded treatment is	s managed by the Haemo	philia Trea	aters	Group in conjunction with			
the National Haemophilia Management Group.							
Inj 250 iu vial	287.50	1	1	RIXUBIS			
Inj 500 iu vial	575.00	1	1	RIXUBIS			
Inj 1,000 iu vial	1,150.00	1	1	RIXUBIS			
Inj 2,000 iu vial	2,300.00	1	1	RIXUBIS			
Inj 3,000 iu vial	3,450.00	1	1	RIXUBIS			
OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (ADVATE	) – [Xnharm]						
Rare Clinical Circumstances Brand of recombinant factor	,	monhilia fi	rom 1	March 2016 Access to			
funded treatment by application to the Haemophilia Treatment	tmente Panel Annlication	n dataile m	ou he	ohtainad from			
PHARMAC's website http://www.pharmac.govt.nz or:	intento i anei. Applicatioi	i ucialis ii	iay be	5 Obtained Horn			
<del></del> -							
•	Phone: 0800 023 588 O	ption 2					
PHARMAC PO Box 10 254 F	acsimile: (04) 974 4881						
Wellington E	mail: haemophilia@phar	mac.govt.	nz				
·							
Inj 250 iu vial	207.50	1	1	Advate			
•		1		Advate			
Inj 500 iu vial		1		Advate			
Inj 1,000 iu vial Inj 1,500 iu vial		1		Advate			
		1		Advate			
Inj 2,000 iu vial		1					
Inj 3,000 iu vial		ı	•	Advate			
OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (KOGENA							
Second Brand of recombinant factor VIII for patients with							
application to the Haemophilia Treatments Panel. Applic	ation details may be obta	ined from	PHAI	RMAC's website			
http://www.pharmac.govt.nz or:							
The Co-ordinator, Haemophilia Treatments Panel F	Phone: 0800 023 588 O	ption 2					
	acsimile: (04) 974 4881						
	imail: haemophilia@phar	man govt	nz				
Weilington	.maii. <u>naemopiilia@phai</u>	mac.govi.	112				
Inj 250 iu vial		1		Kogenate FS			
Inj 500 iu vial	475.00	1		Kogenate FS			
Inj 1,000 iu vial		1	1	Kogenate FS			
Inj 2,000 iu vial	1,900.00	1	1	Kogenate FS			
Inj 3,000 iu vial	2,850.00	1	1	Kogenate FS			
SODIUM TETRADECYL SULPHATE							
* Inj 3% 2 ml	28.50	5					
	(73.00)	-		Fibro-vein			
TRANEYAMIC ACID	, ,						
TRANEXAMIC ACID	20.67	100	./	Cuklokanron			
Tab 500 mg	20.0/	100	•	Cyklokapron			

✓ Effient

	Subsidy (Manufacturer's Price)	S Per	Fully ubsidised	Brand or Generic Manufacturer
Vitamin K				
PHYTOMENADIONE Inj 2 mg per 0.2 ml — Up to 5 inj available on a PSO Inj 10 mg per ml, 1 ml — Up to 5 inj available on a PSO		5 5	•	Konakion MM Konakion MM
Antithrombotic Agents				
Antiplatelet Agents				
ASPIRIN	12.50	990	<b>√</b> <u>E</u>	Ethics Aspirin EC
* Tab 75 mg	5.44	84	<b>√</b> <u>µ</u>	Arrow - Clopid
DIPYRIDAMOLE  * Tab long-acting 150 mg		60	<b>√</b> <u>F</u>	Pytazen SR
PRASUGREL – Special Authority see SA1201 below – Retail ph Tab 5 mg		28	<b>✓</b> E	Effient

#### ⇒SA1201 Special Authority for Subsidy

Initial application — (coronary angioplasty and bare metal stent) from any relevant practitioner. Approvals valid for 6 months where the patient has undergone coronary angioplasty in the previous 4 weeks and is clopidogrel-allergic\*.

**Initial application** — (drug eluting stent) from any relevant practitioner. Approvals valid for 12 months where the patient has had a drug-eluting cardiac stent inserted in the previous 4 weeks and is clopidogrel-allergic\*.

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

Renewal — (coronary angioplasty and bare metal stent) from any relevant practitioner. Approvals valid for 6 months where the patient has undergone coronary angioplasty or had a bare metal cardiac stent inserted in the previous 4 weeks and is clopidogrel-allergic\*.

Renewal — (drug eluting stent) from any relevant practitioner. Approvals valid for 12 months where had a drug-eluting cardiac stent inserted in the previous 4 weeks and is clopidogrel-allergic\*.

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.

TICAGRELOR – Special Authority see SA1382 below – Retail pharmacy

\* Tab 90 mg ......90.00 56 

Brilinta

### ⇒SA1382 Special Authority for Subsidy

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

#### Both:

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

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.

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

### **Heparin and Antagonist Preparations**

DALTEPARIN SODIUM - Special Authority see SA1270 bel	ow – Retail pharmacy		
Inj 2,500 iu per 0.2 ml prefilled syringe	19.97	10	Fragmin
Inj 5,000 iu per 0.2 ml prefilled syringe	39.94	10	✓ Fragmin
Inj 7,500 iu per 0.75 ml graduated syringe		10	✓ Fragmin
Inj 10,000 iu per 1 ml graduated syringe	77.55	10	✓ Fragmin
Inj 12,500 iu per 0.5 ml prefilled syringe	99.96	10	✓ Fragmin
Inj 15,000 iu per 0.6 ml prefilled syringe	120.05	10	✓ Fragmin
Inj 18,000 iu per 0.72 ml prefilled syringe	158.47	10	✓ Fragmin

#### ⇒SA1270 Special Authority for Subsidy

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

#### Fither:

- 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.

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

#### Any of the following:

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

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

#### Fither:

- 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.

**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, Acute Coronary Syndrome, cardioversion, or prior to oral anti-coagulation).

#### ENOXAPARIN SODIUM - Special Authority see SA1646 below - Retail pharmacy

Entertain fullity control of control of the following	riotali pilarillaoy		
Inj 20 mg in 0.2 ml syringe	27.93	10	<ul><li>Clexane</li></ul>
Inj 40 mg in 0.4 ml syringe		10	<ul><li>Clexane</li></ul>
Inj 60 mg in 0.6 ml syringe		10	<ul><li>Clexane</li></ul>
Inj 80 mg in 0.8 ml syringe	74.90	10	<ul><li>Clexane</li></ul>
Inj 100 mg in 1 ml syringe		10	Clexane
Inj 120 mg in 0.8 ml syringe		10	Clexane
Ini 150 mg in 1 ml syringe		10	✓ Clexane

#### ⇒SA1646 Special Authority for Subsidy

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

Any of the following:

- 1 Low molecular weight heparin treatment is required during a patients pregnancy; or
- 2 For the treatment of venous thromboembolism where the patient has a malignancy; or

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

continued...

3 For the prevention of thrombus formation in the extra-corporeal circulation during haemodialysis.

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

Any of the following:

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

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

Any of the following:

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

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

HEP	١H	N 50	טע	IUIVI	
Ti-	ni 1	$\cap \cap \cap$	i	nor	

DABIGATRAN

inj 1,000 iu per mi, 5 mi ampoule	58.57	50	✔ Pfizer
Inj 5,000 iu per ml, 1 ml	28.40	5	✓ Hospira
Inj 5,000 iu per ml, 5 ml ampoule	203.68	50	✓ Pfizer
Inj 25,000 iu per ml, 0.2 ml		5	✓ Hospira
HEPARINISED SALINE			
Inj 10 ju per ml, 5 ml	56.94	50	✓ Pfizer

# Oral Anticoagulants

	Cap 75 mg - No more than 2 cap per day	76.36	60	✓ Pradaxa
	Cap 110 mg		60	✓ Pradaxa
	Cap 150 mg	76.36	60	✓ Pradaxa
R۱۷	'AROXABAN			
	Tab 10 mg - No more than 1 tab per day	83.10	30	✓ Xarelto
	Tab 15 mg		28	✓ Xarelto
	Tab 20 mg		28	✓ Xarelto
W۸	RFARIN SODIUM			
	Note: Marevan and Coumadin are not interchangeable.			
*	Tab 1 mg	3.46	50	<ul><li>Coumadin</li></ul>
	•	6.86	100	Marevan
*	Tab 2 mg	4.31	50	Coumadin
*	Tab 3 mg		100	Marevan
*	Tab 5 mg	5.93	50	<ul><li>Coumadin</li></ul>
	Ť	11.75	100	✓ Marevan

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

# **Blood Colony-stimulating Factors**

FILGRASTIM - Special Authority see SA1259 below - Retail	pharmacy		
Inj 300 mcg per 0.5 ml prefilled syringe	96.22	10	✓ Nivestim
, , , , , ,	270.00	5	✓ Zarzio
Inj 480 mcg per 0.5 ml prefilled syringe	161.50	10	✓ Nivestim
,	432.00	5	✓ Zarzio

#### ⇒SA1259 Special Authority for Subsidy

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

Any of the following:

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

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

PEGFILGRASTIM - Special Authority see SA1384 below - Retail pharmacy

### **⇒SA1384** 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 20%\*). 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.

# Fluids and Electrolytes

#### Intravenous Administration

GLUCOSE [DEXTROSE]		
* Inj 50%, 10 ml ampoule – Up to 5 inj available on a PSO29.50	5	Biomed
* Inj 50%, 90 ml bottle - Up to 5 inj available on a PSO14.50	1	✓ Biomed
POTASSIUM CHLORIDE		
* Inj 75 mg per ml, 10 ml55.00	50	✓ AstraZeneca
SODIUM BICARBONATE		
Inj 8.4%, 50 ml19.95	1	✓ Biomed
a) Up to 5 inj available on a PSO		
b) Not in combination		
Inj 8.4%, 100 ml20.50	1	Biomed
a) Up to 5 inj available on a PSO		

b) Not in combination

	Subsidy		Fully	Brand or
	(Manufacturer's Pr	rice) Subsid	dised	Generic
	\$	Per	1	Manufacturer
SODIUM CHLORIDE				
Not funded for use as a nasal drop. Only funded for nebulise	eruse when in co	niunction with a	ın ar	ntihiotic intended for
nebuliser use.	or doc when in oo	njunotion with c	iii ui	Illibiolio littoridod foi
Inj 0.9%, bag – Up to 2000 ml available on a PSO	1 23	500 ml	1	Baxter
inj 0.075, bag op to 2000 nii available on a 1 00 iiiiiiiiiiiiii	1.26	1,000 ml		Baxter
Only if prescribed on a prescription for renal dialysis, ma		,		
for emergency use. (500 ml and 1,000 ml packs)			•	, o pa, o a
Inj 23.4% (4 mmol/ml), 20 ml ampoule	33.00	5	1	Biomed
For Sodium chloride oral liquid formulation refer Standar				
Inj 0.9%, 5 ml ampoule - Up to 5 inj available on a PSO	7.00	50	1	InterPharma
			1	Multichem
Inj 0.9%, 10 ml ampoule - Up to 5 inj available on a PSO	6.63	50	1	Pfizer
Inj 0.9%, 20 ml ampoule		20	1	Multichem
•	7.50	30	1	InterPharma
TOTAL PARENTERAL NUTRITION (TPN) - Retail pharmacy-Sp	nacialist			
Infusion		1 OP	1	TPN
		1 01	•	
WATER				
<ol> <li>On a prescription or Practitioner's Supply Order only w</li> </ol>	hen on the same	form as an injed	ction	listed in the Pharmaceutica
Schedule requiring a solvent or diluent; or				
<ol><li>On a bulk supply order; or</li></ol>				
<ol><li>When used in the extemporaneous compounding of ey</li></ol>	e drops; or			
4) When used for the dilution of sodium chloride soln 7% to	for cystic fibrosis	patients only.		
Inj 5 ml ampoule - Up to 5 inj available on a PSO		50	1	<u>InterPharma</u>
Inj 10 ml ampoule - Up to 5 inj available on a PSO	6.63	50	1	Pfizer
Inj 20 ml ampoule - Up to 5 inj available on a PSO	5.00	20	1	Multichem
	7.50	30	1	InterPharma
Oral Administration				
CALCIUM POLYSTYRENE SULPHONATE				
Powder	160.05	300 g OP	./	Calcium Resonium
	109.00	300 g OF	•	Calcium nesomum
COMPOUND ELECTROLYTES			_	
Powder for oral soln — Up to 10 sach available on a PSO	2.30	10	/	<u>Enerlyte</u>
COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE]				
Soln with electrolytes (2 × 500 ml)	6.55	1,000 ml OP	1	Pedialyte -
				Bubblegum
PHOSPHORUS				
Tab eff 500 mg (16 mmol)	82.50	100	1	Phosphate Phebra
1 4 5 1 5 5 5 1 5 5 1 5 1 5 1 5 1 5 1 5				Phosphate-Sandoz
(Phosphate-Sandoz Tab eff 500 mg (16 mmol) to be delisted 1 M	lav 2019)			
POTASSIUM CHLORIDE	, ,			
	E 06	60		
* Tab eff 548 mg (14 m eq) with chloride 285 mg (8 m eq)	5.26 (11.85)	60		Chlorvescent
* Tab long-acting 600 mg (8 mmol)	` ,	200	1	Span-K
	0.30	200	•	оран-к
SODIUM BICARBONATE			_	•
Cap 840 mg	8.52	100		Sodibic
			/	Sodibic
SODIUM POLYSTYRENE SULPHONATE				
Powder	84.65	454 g OP	1	Resonium-A

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

Subsidy (Manufacturer's Price) \$ Per

Fully Subsidised Brand or Generic Manufacturer

# **Alpha-Adrenoceptor Blockers**

## **Alpha Adrenoceptor Blockers**

6.75	500	✓ Apo-Doxazosin
9.09	500	✓ Apo-Doxazosin
65.00	30	✓ BNM S29
216.67	100	✓ Dibenzyline \$29
5.53	100	✓ Apo-Prazosin
7.00	100	✓ Apo-Prazosin
11.70	100	✓ Apo-Prazosin
0.59	28	✓ Actavis
	500	✓ Apo-Terazosin
10.90	500	✓ Apo-Terazosin

# Agents Affecting the Renin-Angiotensin System

#### **ACE Inhibitors**

CAPTOPRIL		
* Oral liq 5 mg per ml94.99	95 ml OP	<ul><li>Capoten</li></ul>
Oral liquid restricted to children under 12 years of age.		
CILAZAPRIL		
* Tab 0.5 mg	90	✓ Zapril
* Tab 2.5 mg7.20	200	✓ Apo-Cilazapril
* Tab 5 mg	200	✓ Apo-Cilazapril
ENALAPRIL MALEATE		
* Tab 5 mg	100	<ul> <li>Ethics Enalapril</li> </ul>
* Tab 10 mg	100	<ul> <li>Ethics Enalapril</li> </ul>
* Tab 20 mg7.12	100	<ul> <li>Ethics Enalapril</li> </ul>
LISINOPRIL		
* Tab 5 mg	90	<ul> <li>Ethics Lisinopril</li> </ul>
* Tab 10 mg2.36	90	✓ Ethics Lisinopril
* Tab 20 mg3.17	90	<ul> <li>Ethics Lisinopril</li> </ul>
PERINDOPRIL		
* Tab 2 mg	30	✓ Apo-Perindopril
* Tab 4 mg4.80	30	✓ Apo-Perindopril
QUINAPRIL		· — ·
* Tab 5 mg	90	✓ Arrow-Quinapril 5
* Tab 10 mg3.16	90	✓ Arrow-Quinapril 10
* Tab 20 mg4.89	90	✓ Arrow-Quinapril 20
-		

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
	Ψ	rei	<u>`</u>	Ivialiulaciulei
ACE Inhibitors with Diuretics				
CILAZAPRIL WITH HYDROCHLOROTHIAZIDE  * Tab 5 mg with hydrochlorothiazide 12.5 mg	10.18	100	•	Apo-Cilazapril/ Hydrochlorothiazide
QUINAPRIL WITH HYDROCHLOROTHIAZIDE  * Tab 10 mg with hydrochlorothiazide 12.5 mg  * Tab 20 mg with hydrochlorothiazide 12.5 mg		30 30		Accuretic 10 Accuretic 20
Angiotensin II Antagonists				
CANDESARTAN CILEXETIL				
* Tab 4 mg	1.90	90	1	Candestar
* Tab 8 mg	2.28	90	•	Candestar
* Tab 16 mg	3.67	90		Candestar
* Tab 32 mg	6.39	90	/	<u>Candestar</u>
LOSARTAN POTASSIUM				
* Tab 12.5 mg		84		Losartan Actavis
* Tab 25 mg		84		Losartan Actavis
* Tab 100 mg		84		Losartan Actavia
* Tab 100 mg	2.31	84	•	Losartan Actavis
Angiotensin II Antagonists with Diuretics				
LOSARTAN POTASSIUM WITH HYDROCHLOROTHIAZIDE Tab 50 mg with hydrochlorothiazide 12.5 mg	1.88	30	•	Arrow-Losartan & Hydrochlorothiazide

# Angiotensin II Antagonists with Neprilysin Inhibitors

SACUBITRIL WITH VALSARTAN - Special Authority see SA1751 below - Retail pharmacy

Note: Due to the angiotensin II receptor blocking activity of sacubitril with valsartan it should not be co-administered with an ACE inhibitor or another ARB.

Tab 24.3 mg with valsartan 25.7 mg	190.00	56	✓ Entresto 24/26
Tab 48.6 mg with valsartan 51.4 mg	190.00	56	✓ Entresto 49/51
Tab 97.2 mg with valsartan 102.8 mg	190.00	56	✓ Entresto 97/103

#### ⇒SA1751 Special Authority for Subsidy

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

- 1 Patient has heart failure; and
- 2 Any of the following:
  - 2.1 Patient is in NYHA/WHO functional class II: or
  - 2.2 Patient is in NYHA/WHO functional class III; or
  - 2.3 Patient is in NYHA/WHO functional class IV; and
- 3 Patient has a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%; and
- 4 Patient is receiving concomitant optimal standard chronic heart failure treatments.

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

## Antiarrhythmics  For lignocaine hydrochloride refer to NERVOUS SYSTEM, Anaesthetics, Local, page 118  ## AMIODARONE HYDROCHLORIDE  ## Tab 100 mg — Retail pharmacy-Specialist		Subsidy (Manufacturer's Price		Fully Subsidised	Generic
or lignocaine hydrochloride refer to NERVOUS SYSTEM, Anaesthetics, Local, page 118  MIODARONE HYDROCHLORIDE  A Tab 100 mg — Retail pharmacy-Specialist		<b>3</b>	Per		Manufacturer
MODARONE HYDROCHLORIDE	Antiarrhythmics				
Tab 100 mg	or lignocaine hydrochloride refer to NERVOUS SYSTEM, Anaest	hetics, Local, page	118		
Tab 200 mg					
Inj 50 mg per ml, 3 ml ampoule — Up to 6 inj available on a PSO					
11.98   6				_	
TROPINE SULPHATE	Inj 50 mg per ml, 3 ml ampoule – Up to 6 inj available on a PS				<del></del>
In   1000 mcg per ml, 1 ml ampoule — Up to 5 inj available on a PSO		11.98	6	•	Cordarone-X
PSO	TROPINE SULPHATE				
State   Stat	€ Inj 600 mcg per ml, 1 ml ampoule - Up to 5 inj available on a				
## Tab 62.5 mcg − Up to 30 tab available on a PSO	PSO	12.07	10	1	<u>Martindale</u>
E Tab 62.5 mcg − Up to 30 tab available on a PSO	IGOXIN				
Tab 250 mcg		6.67	240	/	Lanoxin PG
Section   Sec					
Cap 100 mg			60 m	· •	Lanoxin
A Cap 100 mg	1 01			1	Lanoxin S29 S29
Cap 100 mg	NISODAD VIDA DI OSDITATE				
Cap 150 mg		22.87	100	1	Pythmodan
A Tab 50 mg       38.95       60       ✓ Tambocor         A Cap long-acting 100 mg       38.95       30       ✓ Tambocor CR         A Cap long-acting 200 mg       68.78       30       ✓ Tambocor CR         Inj 10 mg per ml, 15 ml ampoule       52.45       5       ✓ Tambocor         MEXILETINE HYDROCHLORIDE       162.00       100       ✓ Mexiletine         A Cap 150 mg       202.00       100       ✓ Mexiletine         Hydrochloride       USP \$29         PROPAFENONE HYDROCHLORIDE – Retail pharmacy-Specialist       40.90       50       ✓ Rytmonorm         Antihypotensives         MIDODRINE – Special Authority see SA1474 below – Retail pharmacy       53.00       100       ✓ Gutron		20.07	100	•	nyumouan
Cap long-acting 100 mg	, , ,	00.05	00	,	T
Cap long-acting 200 mg       68.78       30       ✓ Tambocor CR         Inj 10 mg per ml, 15 ml ampoule       52.45       5       ✓ Tambocor         MEXILETINE HYDROCHLORIDE       162.00       100       ✓ Mexiletine         Hydrochloride       USP \$29       Wexiletine       Hydrochloride         USP \$29       PROPAFENONE HYDROCHLORIDE – Retail pharmacy-Specialist       ✓ Mexiletine       Hydrochloride         USP \$29       40.90       50       ✓ Rytmonorm     Antihypotensives  MIDODRINE – Special Authority see SA1474 below – Retail pharmacy Tab 2.5 mg       53.00       100       ✓ Gutron	•				
Inj 10 mg per ml, 15 ml ampoule	, , ,				
MEXILETINE HYDROCHLORIDE  Cap 150 mg	, , ,				
Cap 150 mg	, ,	32.43	5	•	Tallibucui
Hydrochloride USP \$29  A Cap 250 mg					
Cap 250 mg	Cap 150 mg	162.00	100	•	
Cap 250 mg					•
Hydrochloride USP \$239  ROPAFENONE HYDROCHLORIDE – Retail pharmacy-Specialist Tab 150 mg					
ROPAFENONE HYDROCHLORIDE – Retail pharmacy-Specialist Tab 150 mg	Cap 250 mg	202.00	100	•	
ROPAFENONE HYDROCHLORIDE – Retail pharmacy-Specialist  Tab 150 mg					•
Tab 150 mg					USP 829
Antihypotensives  #IDODRINE – Special Authority see SA1474 below – Retail pharmacy Tab 2.5 mg53.00 100   Gutron				_	_
IIDODRINE – Special Authority see SA1474 below – Retail pharmacy  Tab 2.5 mg53.00 100 ✓ Gutron	▲ Tab 150 mg	40.90	50	•	Rytmonorm
TIDODRINE – Special Authority see SA1474 below – Retail pharmacy  Tab 2.5 mg53.00 100 ✓ Gutron	Audibumatanahaa				
Tab 2.5 mg53.00 100 <b>✓ Gutron</b>	Antinypotensives				
Tab 2.5 mg53.00 100 <b>✓ Gutron</b>	MDODRINE - Special Authority see SA1474 below - Retail phar	macv			
_			100	1	Gutron
	· ·				

not due to drugs.

Note: Treatment should be started with small doses and titrated upwards as necessary. Hypertension should be avoided, and the usual target is a standing systolic blood pressure of 90 mm Hg.

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

Subsidy (Manufacturer's Price) \$ Per

Fully Subsidised Brand or Generic Manufacturer

# **Beta-Adrenoceptor Blockers**

# **Beta Adrenoceptor Blockers**

ATENOLOL		
* Tab 50 mg4.26	500	✓ Mylan Atenolol
* Tab 100 mg7.30	500	✓ Mylan Atenolol
* Oral liq 25 mg per 5 ml21.25	300 ml OP	✓ Atenolol AFT
Restricted to children under 12 years of age.		
BISOPROLOL FUMARATE		
* Tab 2.5 mg	90	✓ Bosvate
* Tab 5 mg	90	✓ Bosvate
* Tab 10 mg	90	✓ Bosvate
CARVEDILOL		
* Tab 6.25 mg	60	✓ Carvedilol Sandoz
* Tab 12.5 mg	60	✓ Carvedilol Sandoz
* Tab 25 mg	60	✓ Carvedilol Sandoz
C .	00	• Our vealior Suridoz
CELIPROLOL	400	4011
* Tab 200 mg21.40	180	✓ Celol
LABETALOL		
Tab 50 mg8.99	100	✓ Hybloc
Tab 100 mg11.36	100	✓ Hybloc
Tab 200 mg29.74	100	✓ Hybloc
* Inj 5 mg per ml, 20 ml ampoule	5	
(88.60)		Trandate
(Hybloc Tab 50 mg to be delisted 1 August 2019)		
(Hybloc Tab 100 mg to be delisted 1 December 2019)		
(Hybloc Tab 200 mg to be delisted 1 February 2020)		
METOPROLOL SUCCINATE		
* Tab long-acting 23.75 mg	30	✓ Betaloc CR
* Tab long-acting 47.5 mg	30	✓ Betaloc CR
* Tab long-acting 95 mg	30	✓ Betaloc CR
* Tab long-acting 190 mg	30	✓ Betaloc CR
METOPROLOL TARTRATE		
* Tab 50 mg	100	✓ Apo-Metoprolol
* Tab 100 mg	60	✓ Apo-Metoprolol
* Tab long-acting 200 mg	28	✓ Slow-Lopresor
* Inj 1 mg per ml, 5 ml vial	5	✓ Metroprolol IV
Till I mg per mi, 5 mi viai20.30	3	Mylan
NAPOLO		<u>mytun</u>
NADOLOL W. Tab 40 mm	100	Ana Nadalal
* Tab 40 mg	100	✓ Apo-Nadolol
* Tab 80 mg	100	✓ Apo-Nadolol
PINDOLOL		_
* Tab 5 mg	100	✓ Apo-Pindolol
* Tab 10 mg23.12	100	✓ Apo-Pindolol
* Tab 15 mg	100	✓ Apo-Pindolol

<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
PROPRANOLOL				
* Tab 10 mg	4.64	100	✓	Apo-Propranolol
* Tab 40 mg	5.72	100	✓	Apo-Propranolol
* Cap long-acting 160 mg	18.17	100	1	Cardinol LA
* Oral lig 4 mg per ml - Special Authority see SA1327 below -	-			
Retail pharmacy	CBS	500 ml	✓	Roxane 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 ODIDINE

	Tab 80 mg		500 100	✓ <u>Mylan</u> ✓ <u>Mylan</u>
	MOLOL	40.55	100	/ An a Thurst
*	Tab 10 mg	10.55	100	✓ Apo-Timol

# **Calcium Channel Blockers**

### **Dihydropyridine Calcium Channel Blockers**

AIV	ILODIPINE			
*	Tab 2.5 mg	1.72	100	✓ Apo-Amlodipine
*	Tab 5 mg	.3.33	250	✓ Apo-Amlodipine
*	Tab 10 mg		250	✓ Apo-Amlodipine
FΕ	LODIPINE			
*	Tab long-acting 2.5 mg	1.45	30	✓ Plendil ER
*	Tab long-acting 5 mg	.3.93	90	✓ Felo 5 ER
*	Tab long-acting 10 mg		90	Felo 10 ER
NIF	FEDIPINE			
*	Tab long-acting 10 mg	0.63	60	✓ Adalat 10
			,	✓ Adefin S29
*	Tab long-acting 20 mg	9.59	100	✓ Nyefax Retard
*	Tab long-acting 30 mg	3.14	30	✓ Adalat Oros
			,	✓ Adefin XL
*	Tab long-acting 60 mg	5.67	30	✓ Adalat Oros
			,	✓ Adefin XL

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
Other Calcium Channel Blockers				
DILTIAZEM HYDROCHLORIDE				
* Tab 30 mg		100		Dilzem
* Tab 60 mg		100		Dilzem
* Cap long-acting 120 mg		500		Apo-Diltiazem CD
* Cap long-acting 180 mg		500		Apo-Diltiazem CD
* Cap long-acting 240 mg	66.76	500	•	Apo-Diltiazem CD
PERHEXILINE MALEATE  * Tab 100 mg	62.00	100		Pexsig
•	02.90	100	•	rexsig
VERAPAMIL HYDROCHLORIDE				
* Tab 40 mg		100		Isoptin
* Tab 80 mg		100		Isoptin
* Tab long-acting 120 mg		250		Verpamil SR
* Tab long-acting 240 mg	25.00	250	•	Verpamil SR
* Inj 2.5 mg per ml, 2 ml ampoule – Up to 5 inj available on a			_	
PSO	25.00	5	•	Isoptin
Ocademille Action Amonto				
Centrally-Acting Agents				
CLONIDINE				
* Patch 2.5 mg, 100 mcg per day - Only on a prescription	7.40	4	1	Mylan
* Patch 5 mg, 200 mcg per day — Only on a prescription		4		Mylan
* Patch 7.5 mg, 300 mcg per day — Only on a prescription		4	_	Mylan
	12.04	7	•	<u>wytan</u>
CLONIDINE HYDROCHLORIDE	0.75	440	,	O D.
* Tab 25 mcg		112		Clonidine BNM
* Tab 150 mcg		100		Catapres
* Inj 150 mcg per ml, 1 ml ampoule	25.96	10	•	<u>Medsurge</u>
METHYLDOPA			_	
* Tab 250 mg	15.10	100	/	Methyldopa Mylan
Diuretics				
Loop Diuretics				
BUMETANIDE				
* Tab 1 mg	16 36	100	1	Burinex
* Inj 500 mcg per ml, 4 ml vial		5		Burinex
	7.00	J	•	Durinex
FUROSEMIDE [FRUSEMIDE]	0.00	1 000		Dissin 40
* Tab 40 mg - Up to 30 tab available on a PSO		1,000		Diurin 40
* Tab 500 mg		50 0 ml C		Urex Forte Lasix
Oral liq 10 mg per ml     Inj 10 mg per ml, 25 ml ampoule		0 mi C 6		Lasix Lasix
* Inj 10 mg per ml, 2 ml ampoule — Up to 5 inj available on a F		5		Frusemide-Claris
	00 1.20	J	•	Tuscilluc-Olaris
Potassium Sparing Diuretics				
AMILORIDE HYDROCHLORIDE				
Oral liq 1 mg per ml	30.00 2	5 ml C	)P 🗸	Biomed

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
PLERENONE - Special Authority see SA1728 below - Reta		00		In
Tab 50 mg Tab 25 mg		30 30		Inspra Inspra
Special Authority for Subsidy		00		<u>шорги</u>
itial application from any relevant practitioner. Approvals v	alid without further rene	ewal u	nless notifi	ied for applications m
e following criteria:				
oth:	100/			
<ul><li>1 Patient has heart failure with ejection fraction less than</li><li>2 Either:</li></ul>	40%; and			
2.1 Patient is intolerant to optimal dosing of spirono	lactone: or			
2.2 Patient has experienced a clinically significant a		optima	l dosing of	spironolactone.
1ETOLAZONE				
Tab 5 mg	CBS	1	✓	Metolazone S29
		50	1	Zaroxolyn S29
PIRONOLACTONE				
★ Tab 25 mg ★ Tab 100 mg		100		Spiractin
★ Tab 100 mg Oral lig 5 mg per ml		100 5 ml C		Spiractin Biomed
1 01				
Potassium Sparing Combination Diuretics				
MILORIDE HYDROCHLORIDE WITH FUROSEMIDE			_	
* Tab 5 mg with furosemide 40 mg		28	•	Frumil
MILORIDE HYDROCHLORIDE WITH HYDROCHLOROTHIN Tab 5 mg with hydrochlorothiazide 50 mg		50	1	Moduretic
* Tab 5 mg with hydrochlorothiazide 50 mg	5.00	50		Moduretto
Thiazide and Related Diuretics				
ENDROFLUMETHIAZIDE [BENDROFLUAZIDE]				
* Tab 2.5 mg - Up to 150 tab available on a PSO	12.50	500	•	Arrow-
				<u>Bendrofluazide</u>
May be supplied on a PSO for reasons other than em	ergency.			
₹ Tab 5 mg	20.42	500	•	Arrow-
				<u>Bendrofluazide</u>
CHLOROTHIAZIDE				
Oral liq 50 mg per ml	26.00 2	5 ml C	)P 🗸	Biomed
CHLORTALIDONE [CHLORTHALIDONE]			_	
* Tab 25 mg	8.00	50	•	Hygroton
NDAPAMIDE ≮ Tab 2.5 mg	2.60	90		Dapa-Tabs
N 190 C.J IIIU	∠.0∪	30	•	Daha-Tang

מו		

BE	ZAFIBRATE			
*	Tab 200 mg	19.01	90	✓ Bezalip
*	Tab long-acting 400 mg	12.89	30	✓ Bezalip Retard

	Subsidy (Manufacturer's Price) \$	Sul Per	Fully bsidised	Brand or Generic Manufacturer
GEMFIBROZIL * Tab 600 mg	19.56	60	<b>✓</b> <u>L</u>	ipazil
Other Lipid-Modifying Agents				
ACIPIMOX  Cap 250 mg  NICOTINIC ACID  Tab 50 mg  Tab 500 mg	4.12	30 100 100	✓ <u>A</u>	Dibetam po-Nicotinic Acid po-Nicotinic Acid
Resins				
CHOLESTYRAMINE Powder for oral liq 4 g		50	_	Questran-Lite Questran-Lite S29 S29
Questran-Lite Powder for oral liq 4 g to be delisted 1 June 2019 Questran-Lite S29 Powder for oral liq 4 g to be delisted 1 COLESTIPOL HYDROCHLORIDE Grans for oral liq 5 g	June 2019)	30	<b>√</b> C	colestid
HMG CoA Reductase Inhibitors (Statins)				

#### **Prescribing Guidelines**

Treatment with HMG CoA Reductase Inhibitors (statins) is recommended for patients with dyslipidaemia and an absolute 5 year cardiovascular risk of 15% or greater.

ATORVASTATIN – See prescribing guideline above  * Tab 10 mg  * Tab 20 mg  * Tab 40 mg  * Tab 80 mg	9.99 15.93	500 <b>•</b>	Lorstat Lorstat Lorstat Lorstat
PRAVASTATIN – See prescribing guideline above  * Tab 20 mg	4.72		Apo-Pravastatin
* Tab 40 mg	8.06	100	Apo-Pravastatin
SIMVASTATIN – See prescribing guideline above	0.05	90	Simvastatin Mylan
* Tab 10 mg * Tab 20 mg			Simvastatin Mylan
* Tab 40 mg	2.63	90	Simvastatin Mylan
* Tab 80 mg	6.00	90	Simvastatin Mylan

# **Selective Cholesterol Absorption Inhibitors**

EZ	= HIMIBE - Special Authority see SATU45 below - Retail pharmacy			
*	Tab 10 mg	2.00	30	<ul> <li>Ezetimibe Sandoz</li> </ul>

⇒SA1045 Special Authority for Subsidy

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

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

continued...

All of the following:

- 1 Patient has a calculated absolute risk of cardiovascular disease of at least 15% over 5 years; and
- 2 Patient's LDL cholesterol is 2.0 mmol/litre or greater; and
- 3 Any of the following:
  - 3.1 The patient has rhabdomyolysis (defined as muscle aches and creatine kinase more than 10 x normal) when treated with one statin: or
  - 3.2 The patient is intolerant to both simvastatin and atorvastatin; or
  - 3.3 The patient has not reduced their LDL cholesterol to less than 2.0 mmol/litre with the use of the maximal tolerated dose of atorvastatin.

Notes: A patient who has failed to reduce their LDL cholesterol to < 2.0 mmol/litre with the use of a less potent statin should use a more potent statin prior to consideration being given to the use of non-statin therapies.

Other treatment options including fibrates, resins and nicotinic acid should be considered after failure of statin therapy.

If a patient's LDL cholesterol cannot be calculated because the triglyceride level is too high then a repeat test should be performed and if the LDL cholesterol again cannot be calculated then it can be considered that the LDL cholesterol is greater than 2.0 mmol/litre

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

EZETIMIBE WITH SIMVASTATIN - Special Authority see SA1046 below - Retail pharmacy

Tab 10 mg with simvastatin 10 mg5.15	30	Zimybe
Tab 10 mg with simvastatin 20 mg	30	✓ Zimybe
Tab 10 mg with simvastatin 40 mg7.15	30	✓ Zimybe
Tab 10 mg with simvastatin 80 mg8.15	30	✓ Zimybe

#### ⇒SA1046 Special Authority for Subsidy

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

- 1 Patient has a calculated absolute risk of cardiovascular disease of at least 15% over 5 year; and
- 2 Patient's LDL cholesterol is 2.0 mmol/litre or greater; and
- 3 The patient has not reduced their LDL cholesterol to less than 2.0 mmol/litre with the use of the maximal tolerated dose of atorvastatin.

Notes: A patient who has failed to reduce their LDL cholesterol to less than or equal to 2.0 mmol/litre with the use of a less potent statin should use a more potent statin prior to consideration being given to the use of non-statin therapies.

Other treatment options including fibrates, resins and nicotinic acid should be considered after failure of statin therapy. If a patient's LDL cholesterol cannot be calculated because the triglyceride level is too high then a repeat test should be performed and if the LDL cholesterol again cannot be calculated then it can be considered that the LDL cholesterol is greater than

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

#### **Nitrates**

#### GLYCERYL TRINITRATE

GL	ICENTE INIVITATE		
*	Oral pump spray, 400 mcg per dose - Up to 250 dose		
	available on a PSO4.45	250 dose OP	✓ Nitrolingual Pump Spray
*	Oral spray, 400 mcg per dose - Up to 200 dose available on a		
	PSO4.45	200 dose OP	✓ Glytrin
*	Patch 25 mg, 5 mg per day15.73	30	✓ Nitroderm TTS
*	Patch 50 mg, 10 mg per day 18.62	30	✓ Nitroderm TTS

	<u>'</u>	OAIIDIC	VACCOLATIOTOTEM
	Subsidy		Fully Brand or
	(Manufacturer's Price \$	) Sub Per	osidised Generic  Manufacturer
IOOOODDIDE MONONITDATE	Ψ	1 01	- Manadatarer
ISOSORBIDE MONONITRATE  * Tab 20 mg	10 00	100	✓ Ismo 20
* Tab long-acting 40 mg		30	✓ Ismo 40 Retard
* Tab long-acting 60 mg		90	✓ Duride
Sympathomimetics			
ADRENALINE			
Inj 1 in 1,000, 1 ml ampoule - Up to 5 inj available on a F	SO4.98	5	Aspen Adrenaline
	5.25		✓ Hospira
Inj 1 in 10,000, 10 ml ampoule - Up to 5 inj available on a	a PSO27.00	5	✓ Hospira
	49.00	10	Aspen Adrenaline
ISOPRENALINE [ISOPROTERENOL]			
* Inj 200 mcg per ml, 1 ml ampoule	36.80	25	
	(164.20)		Isuprel
Vasodilators			
Vasouliators			
HYDRALAZINE HYDROCHLORIDE			
* Tab 25 mg - Special Authority see SA1321 below - Reta	il		
pharmacy	CBS	1	<ul><li>Hydralazine</li></ul>
		56	✓ Onelink S29
		84	✓ AMDIPHARM \$29
		100	✓ Onelink S29
* Inj 20 mg ampoule	25.90	5	Apresoline
⇒SA1321         Special Authority for Subsidy           Initial application from any relevant practitioner. Approvals the following criteria:           Either:	ralid without further ren	ewal unles	ss notified for applications meetin
<ol> <li>For the treatment of refractory hypertension; or</li> <li>For the treatment of heart failure in combination with a inhibitors and/or angiotensin receptor blockers.</li> </ol>	nitrate, in patients who	are intole	rant or have not responded to AC
MINOXIDIL	70.00	100	/ Lawitan
▲ Tab 10 mg	70.00	100	✓ Loniten
NICORANDIL			
▲ Tab 10 mg		60	✓ Ikorel
▲ Tab 20 mg	33.28	60	✓ Ikorel
PAPAVERINE HYDROCHLORIDE	0.47.00	_	
* Inj 12 mg per ml, 10 ml ampoule	217.90	5	✓ Hospira
PENTOXIFYLLINE [OXPENTIFYLLINE]			4
Tab 400 mg	42.26	50	✓ Trental 400
Endothelin Receptor Antagonists			
AMBRISENTAN - Special Authority see SA1702 on the next	page – Retail pharmac	У	
Tab 5 mg		30	✓ Volibris
Tab 10 mg	4,585.00	30	✓ Volibris

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

Reddy's

### **⇒SA1702** Special Authority for Subsidy

Special Authority approved by the Pulmonary Arterial Hypertension Panel

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

The Coordinator, PAH Panel

PHARMAC. PO Box 10-254. WELLINGTON

Tel: (04) 916 7561, Fax: (04) 974 4858, Email: PAH@pharmac.govt.nz

BOSENTAN - Special Authority see SA1712 below - Retail pharmacy

⇒SA1712 Special Authority for Subsidy

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

All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH)\*; and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice) clinical classifications; and
- 3 PAH is at NYHA/WHO functional class II, III, or IV; and
- 4 Any of the following:
  - 4.1 Both:
    - 4.1.1 Bosentan is to be used as PAH monotherapy; and
    - 4.1.2 Either:
      - 4.1.2.1 Patient is intolerant or contraindicated to sildenafil; or
      - 4.1.2.2 Patient is a child with idiopathic PAH or PAH secondary to congenital heart disease; or
  - 4.2 Both:
    - 4.2.1 Bosentan is to be used as PAH dual therapy; and
    - 4.2.2 Either:
      - 4.2.2.1 Patient has tried a PAH monotherapy for at least three months and failed to respond; or
      - 4.2.2.2 Patient deteriorated while on a PAH monotherapy; or
  - 4.3 Both:
    - 4.3.1 Bosentan is to be used as PAH triple therapy; and
    - 4.3.2 Any of the following:
      - 4.3.2.1 Patient is on the lung transplant list; or
      - 4.3.2.2 Patient is presenting acutely with idiopathic pulmonary arterial hypertension (IPAH) in New York Heart Association/World Health Organization (NYHA/WHO) Functional Class IV; or
      - 4.3.2.3 Patient is deteriorating rapidly to NYHA/WHO Functional Class IV who may be lung transplant recipients in the future, if their disease is stabilised; or
      - 4.3.2.4 Patient has PAH associated with the scleroderma spectrum of diseases (APAHSSD) who have no major morbidities and are deteriorating despite combination therapy.

**Renewal** only from a respiratory specialist, cardiologist or medical practitioner on the recommendation of a respiratory physician or cardiologist. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 Both:
  - 1.1 Bosentan is to be used as PAH monotherapy; and
  - 1.2 Patient is stable or has improved while on bosentan; or
- 2 Both:

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

#### continued...

- 2.1 Bosentan is to be used as PAH dual therapy; and
  - 2.2 Patient has tried a PAH monotherapy for at least three months and either failed to respond or later deteriorated; or

#### 3 Both:

- 3.1 Bosentan is to be used as PAH triple therapy; and
- 3.2 Any of the following:
  - 3.2.1 Patient is on the lung transplant list; or
  - 3.2.2 Patient is presenting acutely with idiopathic pulmonary arterial hypertension (IPAH) in New York Heart Association/World Health Organization (NYHA/WHO) Functional Class IV; or
  - 3.2.3 Patient is deteriorating rapidly to NYHA/WHO Functional Class IV who may be lung transplant recipients in the future, if their disease is stabilised; or
  - 3.2.4 Patient has PAH associated with the scleroderma spectrum of diseases (APAHSSD) who have no major morbidities and are deteriorating despite combination therapy.

### **Phosphodiesterase Type 5 Inhibitors**

SII DENIAFII	- Special Au	thority saa	SA1738 halow -	- Retail pharmacy
SILDLINALIL	- Special Au	uioniv see	SAI / SO DEIUW -	- netali bilalillacv

Tab 25 mg	0.64	4	✓ Vedafil
Tab 50 mg		4	✓ Vedafil
Tab 100 mg		12	✓ Vedafil

#### ⇒SA1738 Special Authority for Subsidy

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

#### All of the following:

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

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

#### All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH)\*; and
- 2 Any of the following:
  - 2.1 PAH is in Group 1 of the WHO (Venice) clinical classifications; or
  - 2.2 PAH is in Group 4 of the WHO (Venice) clinical classifications; or
  - 2.3 PAH is in Group 5 of the WHO (Venice) clinical classifications; and
- 3 Any of the following:
  - 3.1 PAH is in NYHA/WHO functional class II: or
  - 3.2 PAH is in NYHA/WHO functional class III: or
  - 3.3 PAH is in NYHA/WHO functional class IV; and
- 4 Fither:
  - 4.1 All of the following:
    - 4.1.1 Patient has a pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
    - 4.1.2 Either:
      - 4.1.2.1 Patient has a mean pulmonary artery pressure (PAPm) > 25 mmHg; or

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

continued...

4.1.2.2 Patient is peri Fontan repair; and

- 4.1.3 Patient has a pulmonary vascular resistance (PVR) of at least 3 Wood Units or at least 240 International Units (dvn s cm-5); or
- 4.2 Testing for PCWP, PAPm, or PVR cannot be performed due to the patient's young age.

Note: Indications marked with \* are unapproved indications.

### **Prostacyclin Analogues**

EPOPROSTENOL - Special Authority see SA1696 below -	Retail pharmacy		
Inj 500 mcg vial	36.61	1	✓ Veletri
Inj 1.5 mg vial	73.21	1	✓ Veletri

### ⇒SA1696 Special Authority for Subsidy

Special Authority approved by the Pulmonary Arterial Hypertension Panel

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

The Coordinator, PAH Panel

PHARMAC. PO Box 10-254. WELLINGTON

Tel: (04) 916 7561, Fax: (04) 974 4858, Email: PAH@pharmac.govt.nz ILOPROST – Special Authority see SA1705 below – Retail pharmacy

#### ⇒SA1705 Special Authority for Subsidy

Special Authority approved by the Pulmonary Arterial Hypertension Panel

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

The Coordinator, PAH Panel

PHARMAC, PO Box 10-254, WELLINGTON

Tel: (04) 916 7561, Fax: (04) 974 4858, Email: PAH@pharmac.govt.nz

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

# **Antiacne Preparations**

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 87

#### **ADAPALENE**

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

b) Only on a prescription			
Crm 0.1%	22.89	30 g OP	<ul><li>Differin</li></ul>
Gel 0.1%	22.89	30 g OP	✓ Differin
ISOTRETINOIN - Special Authority see SA1475 below - Reta	il pharmacy		
Cap 5 mg	8.14	60	<ul><li>Oratane</li></ul>
Cap 10 mg	13.34	120	✓ Oratane
Cap 20 mg	20.49	120	✓ Oratane

#### ⇒SA1475 Special Authority for Subsidy

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

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

Note: Applicants are recommended to either have used or be familiar with using a decision support tool accredited by their professional body.

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

- 1 Patient is female and has been counselled and understands the risk of teratogenicity if isotretinoin is used during pregnancy and the applicant has ensured that the possibility of pregnancy has been excluded prior to the commencement of the treatment and that the patient is informed that she must not become pregnant during treatment and for a period of one month after the completion of the treatment; or
- Patient is male.

Note: Applicants are recommended to either have used or be familiar with using a decision support tool accredited by their professional body.

#### **TRFTINOIN**

50 q OP ✓ ReTrieve

## **Antibacterials Topical**

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 87

HYDROGEN	PEROXIDE
----------	----------

* Crm 1%	8.56	15 g OP	✓ Crystaderm
MUPIROCIN			
Oint 2%	6.60	15 g OP	
	(9.26)	_	Bactroban

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

### **DERMATOLOGICALS**

	Subsidy (Manufacturer's Pric \$	e) Sub Per	Fully sidised	
ODIUM FUSIDATE [FUSIDIC ACID]				
Crm 2%		5 g OP		Foban
	2.52	15 g OP	/	DP Fusidic Acid Cream
a) Maximum of 15 g per prescription				Cicaiii
b) Only on a prescription				
c) Not in combination				
Oint 2%	1.59	5 g OP	1	Foban
<ul> <li>a) Maximum of 15 g per prescription</li> </ul>				
b) Only on a prescription				
c) Not in combination				
DP Fusidic Acid Cream Crm 2% to be delisted 1 August 2019	)			
ULFADIAZINE SILVER				
Crm 1%	10.80	50 g OP	1	<u>Flamazine</u>
a) Up to 250 g available on a PSO				
b) Not in combination				
Antifungals Topical				
or systemic antifungals, refer to INFECTIONS, Antifungals, p MOROLFINE	age 94			
MOROLFINE  a) Only on a prescription b) Not in combination Nail soln 5%	15.95	5 ml OP	✓	<u>MycoNail</u>
MOROLFINE  a) Only on a prescription b) Not in combination Nail soln 5%	15.95	5 ml OP		MycoNail  Apo-Ciclopirox
MOROLFINE  a) Only on a prescription b) Not in combination Nail soln 5%	15.95	7 ml OP	✓	Apo-Ciclopirox
MOROLFINE  a) Only on a prescription b) Not in combination Nail soln 5%	15.95		✓	
MOROLFINE  a) Only on a prescription b) Not in combination Nail soln 5%	15.95	7 ml OP	✓	Apo-Ciclopirox
MOROLFINE  a) Only on a prescription b) Not in combination Nail soln 5%	15.95 5.72 0.70	7 ml OP 20 g OP	✓	Apo-Ciclopirox
MOROLFINE  a) Only on a prescription b) Not in combination Nail soln 5%		7 ml OP	✓	Apo-Ciclopirox Clomazol
MOROLFINE  a) Only on a prescription b) Not in combination Nail soln 5%	15.95 5.72 0.70	7 ml OP 20 g OP	✓	Apo-Ciclopirox
MOROLFINE  a) Only on a prescription b) Not in combination Nail soln 5%		7 ml OP 20 g OP	✓	Apo-Ciclopirox Clomazol
MOROLFINE  a) Only on a prescription b) Not in combination Nail soln 5%		7 ml OP 20 g OP	<b>✓</b>	Apo-Ciclopirox Clomazol
MOROLFINE  a) Only on a prescription b) Not in combination Nail soln 5%	5.72 0.70 4.36 (7.55)	7 ml OP 20 g OP 20 ml OP	<b>✓</b>	Apo-Ciclopirox Clomazol
MOROLFINE  a) Only on a prescription b) Not in combination Nail soln 5%		7 ml OP 20 g OP	<b>✓</b>	Apo-Ciclopirox Clomazol Canesten
MOROLFINE  a) Only on a prescription b) Not in combination Nail soln 5%	5.72 0.70 4.36 (7.55)	7 ml OP 20 g OP 20 ml OP	<b>✓</b>	Apo-Ciclopirox Clomazol
MOROLFINE  a) Only on a prescription b) Not in combination Nail soln 5%		7 ml OP 20 g OP 20 ml OP	<b>✓</b>	Apo-Ciclopirox Clomazol Canesten
MOROLFINE  a) Only on a prescription b) Not in combination Nail soln 5%		7 ml OP 20 g OP 20 ml OP 20 g OP	<b>✓</b>	Apo-Ciclopirox Clomazol Canesten
MOROLFINE  a) Only on a prescription b) Not in combination Nail soln 5%		7 ml OP 20 g OP 20 ml OP	<b>✓</b>	Apo-Ciclopirox Clomazol Canesten Pevaryl
MOROLFINE  a) Only on a prescription b) Not in combination Nail soln 5%		7 ml OP 20 g OP 20 ml OP 20 g OP	<b>✓</b>	Apo-Ciclopirox Clomazol Canesten

	Subsidy		Fully Brand	d or
	(Manufacturer's F		sidised Gene	ric
	\$	Per	✓ Manu	facturer
MICONAZOLE NITRATE				
* Crm 2%	0.74	15 g OP	✓ Multich	em
a) Only on a prescription				<del></del>
b) Not in combination				
* Lotn 2%	4.36	30 ml OP		
	(10.03)		Daktarir	1
a) Only on a prescription	(10100)		24	
b) Not in combination				
* Tinct 2%	4.36	30 ml OP		
	(12.10)		Daktarir	1
a) Only on a prescription	()			
b) Not in combination				
,				
NYSTATIN Crm 100 000 u por a	1.00	15 a OP		
Crm 100,000 u per g	(7.90)	15 g OP	Mycosta	atin
a) Only an a proparintian	(7.90)		Wycosia	шп
<ul><li>a) Only on a prescription</li><li>b) Not in combination</li></ul>				
b) Not in combination				
Antipruritic Preparations				
Antipiunite Freparations				
CALAMINE				
a) Only on a prescription				
b) Not in combination				
Crm, aqueous, BP	1.26	100 g	✓ healthE	Calamine
		ŭ	Aque	ous Cream
			BP	
Lotn, BP	12.94	2,000 ml	✓ PSM	
CROTAMITON		•		
a) Only on a prescription				
b) Not in combination				
Crm 10%	3 29	20 g OP	✓ Itch-So	nthe
		20 g 01	<u></u>	<u> </u>
MENTHOL – Only in combination				
Only in combination with a dermatological base or p	proprietary Topical C	orticosteriod –	Plain	
<ol><li>With or without other dermatological galenicals.</li></ol>				
0 11		0.5		
Crystals		25 g	✓ MidWes	
	29.60	100 g	✓ MidWes	ST
Carting atomical Taning				
Corticosteroids Topical				
For systemic corticosteroids, refer to CORTICOSTEROIDS A	ND RELATED AGE	NTS, page 77		
Corticosteroids - Plain				
BETAMETHASONE DIPROPIONATE				
Crm 0.05%	2 96	15 g OP	✓ Diproso	ne
VIIII V.VV / V	0.07	10 g O1	/ Diprose	

	exemption" by the prescriber or pharmacist.
— ···· · · · · · · · · · · · · · · · ·	

Crm 0.05% in propylene glycol base ......4.33

Oint 0.05% in propylene glycol base .......4.33

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

✓ Diprosone

✓ Diprosone✓ Diprosone

✓ Diprosone OV

✓ Diprosone OV

50 g OP

30 g OP

15 g OP

50 g OP

30 g OP

8.97

8.97

	Subsidy	a	Fully	
	(Manufacturer's I	Price) Subs Per	idised •	Generic Manufacturer
OFTANAETHA CONE VALEDATE	Ψ	1 01		Manufacturer
BETAMETHASONE VALERATE  * Crm 0.1%	2.45	E0 ~ OB	./	Poto Croom
		50 g OP		Beta Cream
* Oint 0.1%		50 g OP		Beta Ointment
* Lotn 0.1%	18.00	50 ml OP	•	<u>Betnovate</u>
CLOBETASOL PROPIONATE				
* Crm 0.05%	2.20	30 g OP	1	<u>Dermol</u>
* Oint 0.05%	2.20	30 g OP	1	<u>Dermol</u>
CLOBETASONE BUTYRATE		-		
Crm 0.05%	5.38	30 g OP		
0111 0.00 /0	(7.09)	00 g 01		Eumovate
	(7.00)			Lamovato
DIFLUCORTOLONE VALERATE				
Crm 0.1%		50 g OP		
	(15.86)			Nerisone
Fatty oint 0.1%		50 g OP		
	(15.86)			Nerisone
HYDROCORTISONE				
* Crm 1% - Only on a prescription	1.11	30 g OP	/	DermAssist
	16.25	500 g		Pharmacy Health
★ Powder – Only in combination		25 g		ABM
Up to 5% in a dermatological base (not proprietary Topic galenicals			r with	nout other dermatologica
HYDROCORTISONE AND PARAFFIN LIQUID AND LANOLIN				
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% - Only	on			
a prescription	10.57	250 ml	1	DP Lotn HC
HYDROCORTISONE BUTYRATE				
Lipocream 0.1%	2.40	30 g OP	1	Locoid Lipocream
Lipocieani 0.1/6	6.85	•		
Oint 0.1%	0.00		./	•
	12.70	100 g OP		Locoid Lipocream
		100 g OP	✓	Locoid Lipocream Locoid
Milky emul 0.1%		•	✓	Locoid Lipocream
Milky emul 0.1% METHYLPREDNISOLONE ACEPONATE	13.70	100 g OP	1	Locoid Lipocream Locoid Locoid Crelo
Milky emul 0.1%	13.70	100 g OP	1	Locoid Lipocream Locoid
Milky emul 0.1% METHYLPREDNISOLONE ACEPONATE	13.70	100 g OP 100 ml OP	1	Locoid Lipocream Locoid Locoid Crelo
Milky emul 0.1%	13.70	100 g OP 100 ml OP 15 g OP	1	Locoid Lipocream Locoid Locoid Crelo  Advantan
Milky emul 0.1%	13.70 4.95 4.95	100 g OP 100 ml OP 15 g OP 15 g OP	111111111111111111111111111111111111111	Locoid Lipocream Locoid Locoid Crelo  Advantan Advantan
Milky emul 0.1%	13.70 4.95 4.95 1.51	100 g OP 100 ml OP 15 g OP 15 g OP	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Locoid Lipocream Locoid Locoid Crelo  Advantan Advantan Elocon Alcohol Free
Milky emul 0.1%	13.70 4.95 4.95 1.51 2.50	100 g OP 100 ml OP 15 g OP 15 g OP 15 g OP 50 g OP	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Locoid Lipocream Locoid Locoid Crelo  Advantan Advantan Elocon Alcohol Free Elocon Alcohol Free
Milky emul 0.1%		100 g OP 100 ml OP 15 g OP 15 g OP 15 g OP 50 g OP 15 g OP	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Locoid Lipocream Locoid Locoid Crelo  Advantan Advantan  Elocon Alcohol Free Elocon Alcohol Free Elocon
Milky emul 0.1%		100 g OP 100 ml OP 15 g OP 15 g OP 15 g OP 50 g OP 50 g OP 50 g OP	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Locoid Lipocream Locoid Locoid Crelo  Advantan Advantan  Elocon Alcohol Free Elocon Alcohol Free Elocon Elocon
Milky emul 0.1%		100 g OP 100 ml OP 15 g OP 15 g OP 15 g OP 50 g OP 15 g OP	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Locoid Lipocream Locoid Locoid Crelo  Advantan Advantan  Elocon Alcohol Free Elocon Alcohol Free Elocon
Milky emul 0.1%		100 g OP 100 ml OP 15 g OP 15 g OP 50 g OP 50 g OP 50 g OP 30 ml OP	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Locoid Lipocream Locoid Locoid Crelo  Advantan Advantan  Elocon Alcohol Free Elocon Alcohol Free Elocon Elocon Elocon
Milky emul 0.1%		100 g OP 100 ml OP 15 g OP 15 g OP 15 g OP 50 g OP 50 g OP 50 g OP	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Locoid Lipocream Locoid Locoid Crelo  Advantan Advantan  Elocon Alcohol Free Elocon Alcohol Free Elocon Elocon
Milky emul 0.1%		100 g OP 100 ml OP 15 g OP 15 g OP 50 g OP 50 g OP 50 g OP 30 ml OP	\\ \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Locoid Lipocream Locoid Locoid Crelo  Advantan Advantan  Elocon Alcohol Free Elocon Alcohol Free Elocon Elocon Elocon
Milky emul 0.1%		100 g OP 100 ml OP 15 g OP 15 g OP 50 g OP 50 g OP 50 g OP 30 ml OP	\\ \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Locoid Lipocream Locoid Locoid Crelo  Advantan Advantan  Elocon Alcohol Free Elocon Elocon Elocon Elocon Aristocort
Milky emul 0.1%		100 g OP 100 ml OP 15 g OP 15 g OP 50 g OP 50 g OP 50 g OP 30 ml OP	\\ \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Locoid Lipocream Locoid Locoid Crelo  Advantan Advantan  Elocon Alcohol Free Elocon Elocon Elocon Elocon Aristocort
Milky emul 0.1%		100 g OP 100 ml OP 15 g OP 15 g OP 50 g OP 50 g OP 50 g OP 30 ml OP	\\ \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Locoid Lipocream Locoid Locoid Crelo  Advantan Advantan  Elocon Alcohol Free Elocon Elocon Elocon Elocon Aristocort
Milky emul 0.1%		100 g OP 100 ml OP 15 g OP 15 g OP 50 g OP 50 g OP 50 g OP 30 ml OP	\\ \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Locoid Lipocream Locoid Locoid Crelo  Advantan Advantan  Elocon Alcohol Free Elocon Elocon Elocon Elocon Aristocort

	Subsidy		Fully Brand or
	(Manufacturer's F \$	Price) Subs Per	idised Generic  Manufacturer
BETAMETHASONE VALERATE WITH SODIUM FUSIDATE [	FUSIDIC ACIDI		
Crm 0.1% with sodium fusidate (fusidic acid) 2%		15 g OP	
,	(10.45)	ŭ	Fucicort
<ul><li>a) Maximum of 15 g per prescription</li><li>b) Only on a prescription</li></ul>			
HYDROCORTISONE WITH MICONAZOLE - Only on a presented by a presented by the contract of the con	cription		
★ Crm 1% with miconazole nitrate 2%	2.00	15 g OP	✓ Micreme H
HYDROCORTISONE WITH NATAMYCIN AND NEOMYCIN			
Crm 1% with natamycin 1% and neomycin sulphate 0.5%		15 g OP	<ul><li>✓ Pimafucort</li><li>✓ Pimafucort</li></ul>
Oint 1% with natamycin 1% and neomycin sulphate 0.5%		15 g OP	Pimarucort
"RIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOM"		IIN	
Crm 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 and gramicidin 250 mcg per g - Only on a prescription		15 g OP	
and gramicidin 250 mag per g Only on a prescripin	(6.60)	13 9 01	Viaderm KC
	(5.55)		
Disinfecting and Cleansing Agents			
CHLORHEXIDINE GLUCONATE - Subsidy by endorsement			
a) No more than 500 ml per month			
b) Only if prescribed for a dialysis patient and the prescri	ption is endorsed a	ccordinaly.	
Handrub 1% with ethanol 70%		500 ml	✓ healthE
Soln 4% wash	3.98	500 ml	✓ healthE
RICLOSAN - Subsidy by endorsement			
"RICLOSAN - Subsidy by endorsement a) Maximum of 500 ml per prescription b)			
a) Maximum of 500 ml per prescription     b)     a) Only if prescribed for a patient identified with Me		aphylococcus a	ureus (MRSA) prior to elective
a) Maximum of 500 ml per prescription     b)     a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors	sed accordingly; or	. ,	, , ,
a) Maximum of 500 ml per prescription     b)     a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors     b) Only if prescribed for a patient with recurrent Sta	sed accordingly; or	. ,	, ,,
a) Maximum of 500 ml per prescription     b)     a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors     b) Only if prescribed for a patient with recurrent Sta	sed accordingly; or phylococcus aureu	s infection and	the prescription is endorsed
a) Maximum of 500 ml per prescription     b)     a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors     b) Only if prescribed for a patient with recurrent Sta	sed accordingly; or phylococcus aureu	. ,	, ,,
a) Maximum of 500 ml per prescription     b)     a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors     b) Only if prescribed for a patient with recurrent Sta	sed accordingly; or phylococcus aureu	s infection and	the prescription is endorsed
a) Maximum of 500 ml per prescription     b)     a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors     b) Only if prescribed for a patient with recurrent Sta accordingly     Soln 1%	sed accordingly; or phylococcus aureu	s infection and	the prescription is endorsed
a) Maximum of 500 ml per prescription     b)     a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors     b) Only if prescribed for a patient with recurrent Sta accordingly     Soln 1%	sed accordingly; or phylococcus aureu	s infection and	the prescription is endorsed
a) Maximum of 500 ml per prescription b)  a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors b) Only if prescribed for a patient with recurrent Sta accordingly Soln 1%  Barrier Creams and Emollients  Barrier Creams	sed accordingly; or phylococcus aureu	s infection and	the prescription is endorsed
a) Maximum of 500 ml per prescription b)  a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors b) Only if prescribed for a patient with recurrent Sta accordingly Soln 1%  Barrier Creams and Emollients  Barrier Creams	sed accordingly; or aphylococcus aureu	s infection and	the prescription is endorsed
a) Maximum of 500 ml per prescription b)  a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors b) Only if prescribed for a patient with recurrent Sta accordingly Soln 1%  Barrier Creams and Emollients  Barrier Creams  DIMETHICONE Crm 5% pump bottle	sed accordingly; or aphylococcus aureu	s infection and 500 ml OP	the prescription is endorsed  healthE
a) Maximum of 500 ml per prescription b)  a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors b) Only if prescribed for a patient with recurrent Sta accordingly Soln 1%  Barrier Creams and Emollients  Barrier Creams  DIMETHICONE  Crm 5% pump bottle	sed accordingly; or aphylococcus aureu	s infection and 500 ml OP	the prescription is endorsed  healthE  healthE  Dimethicone 5% healthE
a) Maximum of 500 ml per prescription b)  a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors b) Only if prescribed for a patient with recurrent Sta accordingly Soln 1%  Barrier Creams and Emollients  Barrier Creams  DIMETHICONE Crm 5% pump bottle	sed accordingly; or aphylococcus aureu	s infection and 500 ml OP	the prescription is endorsed  healthE  healthE  Dimethicone 5%
a) Maximum of 500 ml per prescription b)  a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors b) Only if prescribed for a patient with recurrent Sta accordingly Soln 1%  Barrier Creams and Emollients  Barrier Creams  DIMETHICONE Crm 5% pump bottle	sed accordingly; or aphylococcus aureu	s infection and 500 ml OP 500 ml OP 500 ml OP	the prescription is endorsed  healthE  healthE  Dimethicone 5% healthE
a) Maximum of 500 ml per prescription b)  a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors b) Only if prescribed for a patient with recurrent Sta accordingly Soln 1%  Barrier Creams and Emollients  Barrier Creams  DIMETHICONE  Crm 5% pump bottle	sed accordingly; or uphylococcus aureu	s infection and 500 ml OP	the prescription is endorsed  healthE  healthE  Dimethicone 5% healthE
a) Maximum of 500 ml per prescription b)  a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors b) Only if prescribed for a patient with recurrent Sta accordingly Soln 1%  Barrier Creams and Emollients  Barrier Creams  DIMETHICONE  Crm 5% pump bottle	sed accordingly; or uphylococcus aureu	s infection and 500 ml OP 500 ml OP 500 ml OP	the prescription is endorsed  healthE  healthE  Dimethicone 5% healthE  Dimethicone 10%
a) Maximum of 500 ml per prescription b)  a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors b) Only if prescribed for a patient with recurrent State accordingly Soln 1%  Barrier Creams and Emollients  Barrier Creams  DIMETHICONE  Crm 5% pump bottle  Crm 10% pump bottle  ZINC AND CASTOR OIL  Oint	sed accordingly; or uphylococcus aureu	s infection and 500 ml OP 500 ml OP 500 ml OP	the prescription is endorsed  healthE  healthE  Dimethicone 5% healthE  Dimethicone 10%
a) Maximum of 500 ml per prescription b)  a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors b) Only if prescribed for a patient with recurrent State accordingly Soln 1%  Barrier Creams and Emollients  Barrier Creams  DIMETHICONE  Crm 5% pump bottle  Crm 10% pump bottle  CINC AND CASTOR OIL  Oint  Emollients	sed accordingly; or aphylococcus aureu	s infection and 500 ml OP 500 ml OP 500 ml OP	the prescription is endorsed  healthE  healthE  Dimethicone 5% healthE  Dimethicone 10%
a) Maximum of 500 ml per prescription b)  a) Only if prescribed for a patient identified with Me surgery in hospital and the prescription is endors b) Only if prescribed for a patient with recurrent Sta accordingly Soln 1%  Barrier Creams and Emollients  Barrier Creams  DIMETHICONE  Crm 5% pump bottle  Crm 10% pump bottle  CINC AND CASTOR OIL  COINT OIL  COINT OIL  COINT OIL  COINT OIL  COULD CREAM	sed accordingly; or aphylococcus aureu	s infection and 500 ml OP 500 ml OP 500 ml OP 500 ml OP	the prescription is endorsed  healthE  implication by

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

# **DERMATOLOGICALS**

	Subsidy		Fully Brand or
	(Manufacturer's \$	Price) Subs Per	idised Generic  Manufacturer
	ų.	rei	• Manuacturer
CETOMACROGOL WITH GLYCEROL			<b></b>
Crm 90% with glycerol 10%	2.82	500 ml OP	✓ Pharmacy Health
			Sorbolene with Glycerin
	3.87	1,000 ml OP	✓ Pharmacy Health
	3.07	1,000 1111 OF	Sorbolene with
			Glycerin
EMULSIFYING OINTMENT			<u>,</u>
* Oint BP	3 59	500 g	✓ AFT
OIL IN WATER EMULSION		000 g	· <u>Al 1</u>
* Crm	2 10	500 g	✓ O/W Fatty Emulsion
· OIII	2.10	300 g	Cream
PARAFFIN			<del></del>
Oint liquid paraffin 50% with white soft paraffin 50%	5.35	500 ml OP	✓ healthE
UREA			
* 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	
The Louis Hydrodo 676 Wild Hillional Olimination	(11.95)	1,000 1111	DP Lotion
	1.40	250 ml OP	
	(4.53)		DP Lotion
	5.60	1,000 ml	
	(20.53)		Alpha-Keri Lotion
	(23.91) 1.40	250 ml OP	BK Lotion
	(7.73)	250 MI OP	BK Lotion
	(7.73)		DIV LOUDII
Other Dermatological Bases			
PARAFFIN			
White soft - Only in combination	20.20	2,500 g	✓ IPW
	3.58	500 g	IDW

(7.78)

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

**IPW** 

Subsidy (Manufacturer's Price) Subsidised Per ✓ Hully Subsidised Per ✓ Manufacturer  Minor Skin Infections  POVIDONE IODINE Oint 10%	_					
Minor Skin Infections		ully Brand or	Fully		idy	Subs
Minor Skin Infections  POVIDONE IODINE Oint 10%					,	· · · · · · · · · · · · · · · · · · ·
POVIDONE IODINE  Oint 10%		✓ Manufacturer		Per		\$ ====================================
Oint 10%						Minor Skin Infections
a) Maximum of 100 g per prescription b) Only on a prescription  Antiseptic soln 10%						POVIDONE IODINE
b) Only on a prescription  Antiseptic soln 10%		✓ Betadine	)P 🗸	25 g O	7 2	Oint 10%3.2
b) Only on a prescription  Antiseptic soln 10%						a) Maximum of 100 g per prescription
1.28   100 ml   (4.20)   Riodine   (4.20)   Riodine   (4.20)   Riodine   (4.20)   Betadine   (13.27)   Betadine   (7.41)   Betadine   (7.41)   Skin preparation, povidone iodine 10% with 30% alcohol   10.00   500 ml   ✓ Betadine Skin Prep   1.63   100 ml						
1.28 100 ml (4.20) Riodine (13.27) Betadine 0.19 15 ml (7.41) Betadine Skin preparation, povidone iodine 10% with 30% alcohol		✓ Betadine	nl 🗸	500 m	0 !	Antiseptic soln 10%6.2
(4.20) Riodine (13.27) Betadine 0.19 15 ml (7.41) Betadine Skin preparation, povidone iodine 10% with 30% alcohol10.00 500 ml 1.63 100 ml		✓ Riodine	✓			
(13.27) Betadine 0.19 15 ml (7.41) Betadine  Skin preparation, povidone iodine 10% with 30% alcohol10.00 500 ml 1.63 100 ml  Betadine Skin Prep			nl	100 m	8	1.2
0.19 15 ml (7.41) Betadine Skin preparation, povidone iodine 10% with 30% alcohol10.00 500 ml 1.63 100 ml		Riodine			0)	(4.2
Skin preparation, povidone iodine 10% with 30% alcohol		Betadine			7)	(13.2
Skin preparation, povidone iodine 10% with 30% alcohol			ıl	15 m	9	0.1
1.63 100 ml					,	•
	<b>;</b> p	Betadine Skin Pre	nl 🗸	500 m	0 !	Skin preparation, povidone iodine 10% with 30% alcohol10.0
(3.48) Retadine Skin Pren			nl	100 m	-	· · · · · · · · · · · · · · · · · · ·
` '	)	Betadine Skin Prep			,	•
Skin preparation, povidone iodine 10% with 70% alcohol1.63			nl	100 m		
(6.04) Orion					,	•
(6.64) Pfizer		Pfizer			,	•
(Orion Skin preparation, povidone iodine 10% with 70% alcohol to be delisted 1 June 2019)			)	2019)	d 1 June .	(Orion Skin preparation, povidone iodine 10% with 70% alcohol to be deliste
Paraciticidal Proparations						Demonitividal Duan austiana

### Parasiticidal Preparations

DIMETHICONE

IVERMECTIN - Special Authority see SA1225 below - Retail pharmacy

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

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

### ⇒SA1225 Special Authority for Subsidy

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

Both:

- 1 Applying clinician has discussed the diagnosis of scabies with a dermatologist, infectious disease physician or clinical microbiologist; and
- 2 Either:
  - 2.1 Both:
    - 2.1.1 The patient is in the community; and
    - 2.1.2 Any of the following:
      - 2.1.2.1 Patient has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
      - 2.1.2.2 The community patient is physically or mentally unable to comply with the application instructions of topical therapy; or

•				
	Subsidy	Fully	Brand or	
	(Manufacturer's Price)	Subsidised	Generic	
	` <b>e</b> ′	Dor 🗸	Manufacturor	

continued...

- 2.1.2.3 The patient has previously tried and failed to clear infestation using topical therapy; or
- 2.2 All of the following:
  - 2.2.1 The Patient is a resident in an institution; and
  - 2.2.2 All residents of the institution with scabies or at risk of carriage are to be treated for scabies concurrently; and
  - 2.2.3 Any of the following:
    - 2.2.3.1 Patient has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
    - 2.2.3.2 The patient is physically or mentally unable to comply with the application instructions of topical therapy; or
    - 2.2.3.3 Previous topical therapy has been tried and failed to clear the infestation.

Note: Ivermectin is no more effective than topical therapy for treatment of standard scabies infestation.

Initial application — (Other parasitic infections) only from an infectious disease specialist, clinical microbiologist or dermatologist. Approvals valid for 1 month for applications meeting the following criteria: Any of the following:

- 1 Filaricides: or
- 2 Cutaneous larva migrans (creeping eruption); or
- 3 Strongyloidiasis.

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

- 1 Applying clinician has discussed the diagnosis of scabies with a dermatologist, infectious disease physician or clinical microbiologist; and
- 2 Either:
  - 2.1 Both:
    - 2.1.1 The patient is in the community; and
    - 2.1.2 Any of the following:
      - 2.1.2.1 Patient has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
      - 2.1.2.2 The community patient is physically or mentally unable to comply with the application instructions of topical therapy: or
      - 2.1.2.3 The patient has previously tried and failed to clear infestation using topical therapy; or
  - 2.2 All of the following:
    - 2.2.1 The Patient is a resident in an institution; and
    - 2.2.2 All residents of the institution with scabies or at risk of carriage are to be treated for scabies concurrently; and
    - 2.2.3 Any of the following:
      - 2.2.3.1 Patient has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
      - 2.2.3.2 The patient is physically or mentally unable to comply with the application instructions of topical therapy; or
      - 2.2.3.3 Previous topical therapy has been tried and failed to clear the infestation.

Note: Ivermectin is no more effective than topical therapy for treatment of standard scabies infestation.

**Renewal — (Other parasitic infections)** only from an infectious disease specialist, clinical microbiologist or dermatologist. Approvals valid for 1 month for applications meeting the following criteria:

Any of the following:

- 1 Filaricides: or
- 2 Cutaneous larva migrans (creeping eruption); or
- 3 Strongyloidiasis.

RME.	

Crm 5%	.4.95	30 g OP	✓ Lyderm
Lotn 5%	.3.69	30 ml OP	✓ A-Scabies

	Subsidy (Manufacturer's Price \$	e) Subs Per	Fully idised	Brand or Generic Manufacturer	
PHENOTHRIN Shampoo 0.5%	11.36 2	200 ml OP	<b>√</b> P	Parasidose	
	11.36 2	200 ml OP	<b>√</b> P	Parasidose	

### Psoriasis and Eczema Preparations

ACITRETIN – Special Authority see SA1476 below – Retail pharmacy		
Cap 10 mg17.86	60	✓ Novatretin
Cap 25 mg41.36	60	✓ Novatretin

#### ⇒SA1476 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 female and has been counselled and understands the risk of teratogenicity if acitretin is used during pregnancy and the applicant has ensured that the possibility of pregnancy has been excluded prior to the commencement of the treatment and that the patient is informed that she must not become pregnant during treatment and for a period of two years after the completion of the treatment; or
  - 3.2 Patient is male.

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

- 1 Patient is female and has been counselled and understands the risk of teratogenicity if acitretin is used during pregnancy and the applicant has ensured that the possibility of pregnancy has been excluded prior to the commencement of the treatment and that the patient is informed that she must not become pregnant during treatment and for a period of two years after the completion of the treatment; or
- 2 Patient is male.

BETAMETHASONE DIPROPIONATE WITH CALCIPOTRIOL						
Gel 500 mcg with calcipotriol 50 mcg per g	52.24	60 g OP	✓ Daivobet			
Oint 500 mcg with calcipotriol 50 mcg per g	19.95	30 g OP	✓ Daivobet			
CALCIPOTRIOL						
Oint 50 mcg per g	45.00	100 g OP	✓ Daivonex			
COAL TAR						
Soln BP - Only in combination	32.95	200 ml	✓ Midwest			
1) Up to 10% only in combination with a dermatological base or proprietary Topical Corticosteriod – Plain						
With or without other dermatological galenicals.						

COAL TAR WITH ALLANTOIN, MENTHOL, PHENOL AND SULPHUR			
Soln 5% with sulphur 0.5%, menthol 0.75%, phenol 0.5% and			
allantoin crm 2.5%	6.59	75 g OP	
	(8.00)	· ·	Egopsoryl TA
	3.43	30 g OP	0, ,
	(4.35)	Ū	Egopsoryl TA
COAL TAR WITH SALICYLIC ACID AND SULPHUR			
Soln 12% with salicylic acid 2% and sulphur 4% oint	4.97	25 g OP	✓ Coco-Scalp
·	7.95	40 g OP	✓ Coco-Scalp
PINE TAR WITH TROLAMINE LAURILSULFATE AND FLUORESCEIN	- Only o	n a prescription	

500 ml

**Pinetarsol** 

Soln 2.3% with trolamine laurilsulfate and fluorescein sodium............3.86

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

# **DERMATOLOGICALS**

	Subsidy (Manufacturer's Price \$		Fully dised	Brand or Generic Manufacturer
SALICYLIC ACID  Powder − Only in combination18.88 250 g ✓ PSM  1) Only in combination with a dermatological base or proprietary Topical Corticosteroid − Plain or collodion flexible				
With or without other dermatological galenicals.  SULPHUR Precipitated – Only in combination	6.35	100 g	<b>✓</b> M	idwest
<ol> <li>Only in combination with a dermatological base or</li> <li>With or without other dermatological galenicals.</li> </ol>	proprietary Topical (	Corticosteroi	d – Pla	in

Scalp Preparations			
BETAMETHASONE VALERATE  * Scalp app 0.1%	7.75	100 ml OP	✓ Beta Scalp
CLOBETASOL PROPIONATE  * Scalp app 0.05%	6.96	30 ml OP	✓ Dermol
HYDROCORTISONE BUTYRATE Scalp lotn 0.1%	7.30	100 ml OP	✓ <u>Locoid</u>
KETOCONAZOLE Shampoo 2%	2.99	100 ml OP	✓ <u>Sebizole</u>
<ul><li>a) Maximum of 100 ml per prescription</li><li>b) Only on a prescription</li></ul>			

# Sunscreens

SUNSCREENS, PROPRIETARY - Subsidy by	endorsement		
Only if prescribed for a patient with severe	photosensitivity secondary to a def	fined clinical co	ondition and the prescription is
endorsed accordingly.			
Crm	3.30	100 g OP	
	(5.89)	3 -	Hamilton Sunscreen
Lotn,	3.30	100 g OP	✓ Marine Blue Lotion
			SPF 50+
	5.10	200 g OP	✓ Marine Blue Lotion SPF 50+

# **Wart Preparations**

For salicylic acid preparations refer to PSORIASIS AND ECZEMA PR	REPARATIO	NS, page 67	
IMIQUIMOD			
Crm 5%, 250 mg sachet	21.72	24	✓ Perrigo
PODOPHYLLOTOXIN			
Soln 0.5%	33.60	3.5 ml OP	<ul><li>Condyline</li></ul>
a) Maximum of 3.5 ml per prescription			

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

## **DERMATOLOGICALS**

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

# **Other Skin Preparations**

## **Antineoplastics**

FLUOROURACIL SODIUM

#### **GENITO-URINARY SYSTEM**

<u> </u>		Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer	
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## **Contraceptives - Non-hormonal**

#### Condoms

CO		

*	49 mm - Up to 144 dev available on a PSO	144	✓ Shield 49
*	53 mm - Up to 144 dev available on a PSO1.11	12	✓ Gold Knight
			✓ Shield Blue
	13.36	144	✓ Shield Blue
*	53 mm (chocolate) – Up to 144 dev available on a PSO1.11	12	✓ Gold Knight
	13.36	144	✓ Gold Knight
*	53 mm (strawberry) - Up to 144 dev available on a PSO1.11	12	✓ Gold Knight
	13.36	144	✓ Gold Knight
*	56 mm - Up to 144 dev available on a PSO1.11	12	✓ Gold Knight
	13.36	144	✓ Durex Extra Safe
			✓ Gold Knight
*	56 mm, shaped - Up to 144 dev available on a PSO1.11	12	✓ Durex Confidence
	13.36	144	✓ Durex Confidence
*	60 mm - Up to 144 dev available on a PSO13.36	144	✓ Shield XL

### **Contraceptive Devices**

#### INTRA-UTERINE DEVICE

- a) Up to 40 dev available on a PSO
- b) Only on a PSO
- ★ IUD 29.1 mm length × 23.2 mm width
   31.60
   1
   ✓ CI

   ★ IUD 33.6 mm length × 29.9 mm width
   31.60
   1
   ✓ CI

- ✓ Choice TT380 Short
- ✓ Choice
- TT380 Standard

  ✓ Choice Load 375

anticonstitues (Ilaumana)

# **Contraceptives - Hormonal**

### **Combined Oral Contraceptives**

### ⇒SA0500 Special Authority for Alternate Subsidy

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

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

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

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

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

			GEI	NITO-UF	RINARY SYSTEM
		Subsidy (Manufacturer's Price)	Per	Fully Subsidised	
COI	ntinued				
	e additional subsidy will fund Mercilon and Marvelon up to the r	manufacturer's price	for ea	ach of thes	e products as identified on
	Schedule at 1 November 1999.				
	ecial Authorities approved before 1 November 1999 remain val	id until the expiry da	te and	d can be re	enewed providing that
WO	men are still either:				
	on a Social Welfare benefit; or     boys on income no greater than the benefit.				
Th	have an income no greater than the benefit.      annywel numbers of Special Authorities approved before 1 N	lavambar 1000 ara ir	-t - r - b	onachla	for products within the
	e approval numbers of Special Authorities approved before 1 N mbined oral contraceptives and progestogen-only contraceptive				
	HINYLOESTRADIOL WITH DESOGESTREL	3 groups, except Lo	ciic a	ina iviiciog	ynon 20 LD
	Tab 20 mcg with desogestrel 150 mcg and 7 inert tab	6.62	84		
~	rab 20 flicg with desogestier 150 flicg and 7 fliert lab	(19.80)	04		Mercilon 28
	a) Higher subsidy of \$13.80 per 84 tab with Special Auth	( /	the r	orevious n	
	b) Up to 84 tab available on a PSO	1011ty 000 07 10000 01		oroviouo pi	490
*	Tab 30 mcg with desogestrel 150 mcg and 7 inert tab	6.62	84		
		(19.80)			Marvelon 28
	<ul> <li>a) Higher subsidy of \$13.80 per 84 tab with Special Auth</li> <li>b) Up to 84 tab available on a PSO</li> </ul>	nority see SA0500 or	the p	orevious pa	age
ET	HINYLOESTRADIOL WITH LEVONORGESTREL				
	Tab 20 mcg with levonorgestrel 100 mcg and 7 inert tablets -	_			
-	Up to 84 tab available on a PSO		84	1	Microgynon 20 ED
*	Tab 50 mcg with levonorgestrel 125 mcg and 7 inert tab - Up				
	to 84 tab available on a PSO		84	✓	Microgynon 50 ED
*	Tab 30 mcg with levonorgestrel 150 mcg	6.62	63		
		(16.50)			Microgynon 30
	a) Higher subsidy of \$15.00 per 63 tab with Special Auth	ority see SA0500 or	the p	orevious p	age
	b) Up to 63 tab available on a PSO				
*	Tab 30 mcg with levonorgestrel 150 mcg and 7 inert tablets -		0.4		Levier FD
	Up to 84 tab available on a PSO	1.//	84	•	<u>Levlen ED</u>
	HINYLOESTRADIOL WITH NORETHISTERONE				
*	Tab 35 mcg with norethisterone 1 mg - Up to 63 tab available		00		Duarda au 4/04
v	on a PSO	0.0∠	63	•	Brevinor 1/21
木	Tab 35 mcg with norethisterone 1 mg and 7 inert tab - Up to 84 tab available on a PSO	6.62	84	1	Brevinor 1/28
*	Tab 35 mcg with norethisterone 500 mcg – Up to 63 tab	0.02	04	•	DICTRIOI 1/20
~	Tab ob mog with horothistorone boo mog op to ob tab	0.00			<b>D</b> 1 04

# **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:

continued...

✓ Brevinor 21

✓ Norimin

63

84

(Brevinor 1/21 Tab 35 mcg with norethisterone 1 mg to be delisted 1 January 2020) (Brevinor 21 Tab 35 mcg with norethisterone 500 mcg to be delisted 1 July 2019)

\* Tab 35 mcg with norethisterone 500 mcg and 7 inert tab - Up

### GENITO-URINARY SYSTEM

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

continued...

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

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

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

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

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

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

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

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

#### LEVONORGESTREL

*	Tab 30 mcg6.62	84
	(16.50)	) Microlut

- a) Higher subsidy of \$13.80 per 84 tab with Special Authority see SA0500 on the previous page
- b) Up to 84 tab available on a PSO

Subdermal implant (2 x 75 mg rods) - Up to 3 pack available

on a PSO	1	✓ Jadelle
MEDROXYPROGESTERONE ACETATE Inj 150 mg per ml, 1 ml syringe – Up to 5 inj available on a PSO7.25	1	✓ Depo-Provera
NORETHISTERONE		
* Tab 350 mcg - Up to 84 tab available on a PSO	84	✓ Noriday 28

### **Emergency Contraceptives**

#### LEVONORGESTREL

*	Tab 1.5 mg4.95	1	✓ Postinor-1
---	----------------	---	--------------

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

# Antiandrogen Oral Contraceptives

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

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

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

#### CYPROTERONE ACETATE WITH ETHINYLOESTRADIOL

\* Tab 2 mg with ethinyloestradiol 35 mcg and 7 inert tabs - Up

to 168 tab available on a PSO.......4.67 168 ✓ Ginet

	Subsidy		Fully E	Brand or
	(Manufacturer's F	rice) Subs	idised (	Generic
	` \$	Per	✓ N	Manufacturer
Gynaecological Anti-infectives				
ACETIC ACID WITH HYDROXYQUINOLINE AND RICINOLEIC A	CID			
Jelly with glacial acetic acid 0.94%, hydroxyquinoline sulphate	)			
0.025%, glycerol 5% and ricinoleic acid 0.75% with applic		100 g OP		
	(24.00)	5	Aci-	اما
	(24.00)		Au	761
CLOTRIMAZOLE				
* Vaginal crm 1% with applicators	1.60	35 g OP	✓ Clor	mazol
* Vaginal crm 2% with applicators	2.10	20 g OP	✓ Clo	mazol
		- 3 -		
MICONAZOLE NITRATE				
* Vaginal crm 2% with applicator	3.88	40 g OP	✓ <u>Mic</u>	<u>reme</u>
NYSTATIN				
Vaginal crm 100,000 u per 5 g with applicator(s)	1.15	75 g OP	✓ Nils	tot
vaginal citil 100,000 u per 5 g with applicator(s)	4.40	73 g OF	V INIIS	<u>iai</u>
Manual dalam I Variant I I amana Barana di ana				
Myometrial and Vaginal Hormone Preparations				
ERGOMETRINE MALEATE				
Inj 250 mcg per ml, 1 ml ampoule - Up to 5 inj available on a				
PSO	454.00	5	✓ Era	onovine S29
Inj 500 mcg per ml, 1 ml ampoule - Up to 5 inj available on a		•	3	
		-	/ DDI	Farmer at days
PSO		5	□BI	<u> Ergometrine</u>
(Ergonovine S29 Inj 250 mcg per ml, 1 ml ampoule to be delisted	i 1 July 2019)			
OESTRIOL				
* Crm 1 mg per g with applicator	6.60	15 g OP	✓ Ove	otin
0, 0 1,		•		
* Pessaries 500 mcg	6.86	15	✓ Ove	<u>stin</u>
OXYTOCIN - Up to 5 inj available on a PSO				
Inj 5 iu per ml, 1 ml ampoule	3.98	5	✓ Oxv	tocin BNM
Inj 10 iu per ml, 1 ml ampoule		5		tocin BNM
, , , , , , , , , , , , , , , , , , , ,		3	V OAY	TOCIII DININI
OXYTOCIN WITH ERGOMETRINE MALEATE - Up to 5 inj availa	able on a PSO			
Inj 5 iu with ergometrine maleate 500 mcg per ml, 1 ml	15.00	5	✓ Syn	tometrine
, , , , , , , , , , , , , , , , , , , ,				
Pregnancy Tests - hCG Urine				
regulator rests - floor offic				
PREGNANCY TESTS - HCG URINE				
a) Up to 200 test available on a PSO				
b) Only on a PSO			_	
Cassette	12.00	40 test OP	✓ Smi	th BioMed Rapid
			Pı	regnancy Test
Urinary Agents				
orman y regards				
For urinary tract Infections refer to INFECTIONS, Antibacterials, p	aga 106			
i or unitary tract infections refer to five EO HONS, Antibacterials, p	ag <del>o</del> 100			
5-Alpha Reductase Inhibitors				
o Alipha Headotado Illilibitoro				
FINASTERIDE - Special Authority see SA0928 on the next page	- Retail nharm	acv		
* Tab 5 mg		100	✓ Rici	+
Tab of the	+.01	100	+ nici	<u>.</u>

### **GENITO-URINARY SYSTEM**

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

### **⇒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.

Note: Patients with enlarged prostates are the appropriate candidates for therapy with finasteride.

### Alpha-1A Adrenoreceptor Blockers

## **⇒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:

OV/VDLIT/AIIAI

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

### **Other Urinary Agents**

*	Tab 5 mg	500 473 ml	✓ Apo-Oxybutynin ✓ Apo-Oxybutynin
	TASSIUM CITRATE	4/3 1111	▼ Apo-OxybutyIIII
PU	Oral lig 3 mmol per ml – Special Authority see SA1083 below –		
	Retail pharmacy31.80	200 ml OP	✓ <u>Biomed</u>
	241000 Chanial Authority for Cubaidy		

#### ⇒SA1083 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 recurrent calcium oxalate urolithiasis; and
- 2 The patient has had more than two renal calculi in the two years prior to the application.

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

#### SODIUM CITRO-TARTRATE

* Grans eff 4 g sachets	2.34 28	✓ <u>Ural</u>
SOLIFENACIN SUCCINATE		
Tab 5 mg	3.00 30	✓ Solifenacin Mylan
Tab 10 mg	5.50 30	✓ Solifenacin Mylan
TOLTERODINE - Special Authority see SA1272 below - Re	tail pharmacy	
Tab 1 mg	14.56 56	✓ Arrow-Tolterodine
Tab 2 mg	14.56 56	✓ Arrow-Tolterodine

### SA1272 Special Authority for Subsidy

**Initial application** from any relevant practitioner. Approvals valid without further renewal unless notified where patient has overactive bladder and a documented intolerance of, or is non-responsive to oxybutynin.

# **GENITO-URINARY SYSTEM**

Albustix

100 test OP

(13.92)

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

# **Detection of Substances in Urine**

\* Blue diagnostic strips......7.02

ORTHO-TOLIDINE	7.50	50 test OP	
* Compound diagnostic sticks		50 lesi OP	
	(8.25)		Hemastix
TETRABROMOPHENOL			

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

# **Calcium Homeostasis**

CALCITONIN		
* Inj 100 iu per ml, 1 ml ampoule12	21.00 5	✓ Miacalcic
CINACALCET - Special Authority see SA1618 below - Retail pharmacy	,	
Tab 30 mg - Wastage claimable21	10.30 28	✓ Sensipar

#### ⇒SA1618 Special Authority for Subsidy

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

#### Either:

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

**Renewal** 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.

#### ZOLEDRONIC ACID



#### ⇒SA1687 Special Authority for Subsidy

**Initial application** — (bone metastases) only from an oncologist, haematologist or palliative care specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

#### Any of the following:

- 1 Patient has hypercalcaemia of malignancy; or
- 2 Both:
  - 2.1 Patient has bone metastases or involvement; and
  - 2.2 Patient has severe bone pain resistant to standard first-line treatments; or
- 3 Both:
  - 3.1 Patient has bone metastases or involvement: and
  - 3.2 Patient is at risk of skeletal-related events pathological fracture, spinal cord compression, radiation to bone or surgery to bone.

**Initial application** — **(early breast cancer)** only from an oncologist or medical practitioner on the recommendation of a oncologist. Approvals valid for 2 years for applications meeting the following criteria:

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

continued...

#### All of the following:

- 1 Treatment to be used as adjuvant therapy for early breast cancer; and
- 2 Patient has been amenorrhoeic for 12 months or greater, either naturally or induced, with endocrine levels consistent with a postmenopausal state; and
- 3 Treatment to be administered at a minimum interval of 6-monthly for a maximum of 2 years.

# Corticosteroids and Related Agents for Systemic Use

BETAMETHASONE SODIUM PHOSPHATE WITH BETAMETHASONE ACETAT	E	
* Inj 3.9 mg with betamethasone acetate 3 mg per ml, 1 ml19.20	5	
(36.96)		Celestone
		Chronodose
DEXAMETHASONE		
* Tab 0.5 mg - Retail pharmacy-Specialist	30	✓ <u>Dexmethsone</u>
Up to 60 tab available on a PSO  * Tab 4 mg - Retail pharmacy-Specialist1.90	30	✓ Dexmethsone
Up to 30 tab available on a PSO	30	Dexilieuisone
Oral liq 1 mg per ml — Retail pharmacy-Specialist45.00	25 ml OP	✓ Biomed
Oral liq prescriptions:		
1) Must be written by a Paediatrician or Paediatric Cardiologist; or		
<ol><li>On the recommendation of a Paediatrician or Paediatric Cardiologis</li></ol>	st.	
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 PSO14.19	10	✓ Max Health
* Inj 4 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO25.18	10	✓ Max Health
FLUDROCORTISONE ACETATE		4
* Tab 100 mcg14.32	100	✓ Florinef
HYDROCORTISONE		
* Tab 5 mg	100	✓ <u>Douglas</u>
* Tab 20 mg20.32 * Inj 100 mg vial	100 1	<ul> <li>✓ <u>Douglas</u></li> <li>✓ Solu-Cortef</li> </ul>
a) Up to 5 inj available on a PSO	'	<u> </u>
b) Only on a PSO		
METHYLPREDNISOLONE – Retail pharmacy-Specialist		
* Tab 4 mg	100	✓ Medrol
* Tab 100 mg194.00	20	✓ Medrol
METHYLPREDNISOLONE (AS SODIUM SUCCINATE) - Retail pharmacy-Speci	alist	
Inj 40 mg vial	1	✓ Solu-Medrol-Act-
, •		O-Vial
l=i 105 === :i=l	4	Calu Madral Ast
Inj 125 mg vial	1	✓ <u>Solu-Medrol-Act-</u> O-Vial
		<u>O-viai</u>
Inj 500 mg vial22.78	1	✓ Solu-Medrol-Act-
		<u>O-Vial</u>
Ini 1 a viol	4	√ Calu Madral
Inj 1 g vial	1	✓ <u>Solu-Medrol</u>
METHYLPREDNISOLONE ACETATE	Е	√ Dana Madral
Inj 40 mg per ml, 1 ml vial44.40	5	✓ Depo-Medrol

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

	Subsidy (Manufacturer's Pri	ce) Subs	Fully	Brand or Generic
	\$	Per	1	Manufacturer
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	<b>√</b> <u>F</u>	Redipred
PREDNISONE         * Tab 1 mg         * Tab 2.5 mg         * Tab 5 mg – Up to 30 tab available on a PSO         * Tab 20 mg	12.09 11.09	500 500 500 500	✓ <u>I</u>	Apo-Prednisone Apo-Prednisone Apo-Prednisone Apo-Prednisone
TETRACOSACTRIN  * Inj 250 mcg per ml, 1 ml ampoule		1	<b>√</b> 9	Synacthen
* Inj 1 mg per ml, 1 ml ampoule	690.00	1	✓ 9	Synacthen S29 S29 Synacthen Depot Synacthene Retard S29
TRIAMCINOLONE ACETONIDE Inj 10 mg per ml, 1 ml ampoule Inj 40 mg per ml, 1 ml ampoule		5 5		Kenacort-A 10 Kenacort-A 40

# **Sex Hormones Non Contraceptive**

## **Androgen Agonists and Antagonists**

CYPROTERONE ACETATE - Retail pharmacy-Specialist			
Tab 50 mg	13.17	50	✓ Siterone
Tab 100 mg	26.75	50	✓ Siterone
TESTOSTERONE			
Patch 5 mg per day	90.00	30	✓ Androderm
TESTOSTERONE CIPIONATE - Retail pharmacy-Specialist			
Inj 100 mg per ml, 10 ml vial	76.50	1	✓ <u>Depo-Testosterone</u>
TESTOSTERONE ESTERS - Retail pharmacy-Specialist			
Inj 250 mg per ml, 1 ml	12.98	1	Sustanon Ampoules
TESTOSTERONE UNDECANOATE - Retail pharmacy-Specia	alist		
Cap 40 mg		60	Andriol Testocaps
Inj 250 mg per ml, 4 ml vial	86.00	1	✓ Reandron 1000

# **Hormone Replacement Therapy - Systemic**

### **Prescribing Guideline**

HRT should be taken at the lowest dose for the shortest period of time necessary to control symptoms. Patients should be reviewed 6 monthly in line with the updated NZGG "Evidence-based Best Practice Guideline on Hormone Replacement Therapy March 2004".

s Price) Su	Fully Brand or ubsidised Generic
Per	✓ Manufacturer
28 OP	
	Estrofem
28 OP	Fatura farms
8	Estrofem  ✓ Estradot
0	Estrauot
8	✓ Estradot 50 mcg
ū	<u> </u>
8	✓ Estradot
8	✓ Estradot
	<u></u>
84	✓ Progynova
84	✓ Progynova
28	
	Premarin
28	
	Premarin
revious page	
30	✓ Provera
100	✓ Provera
30	✓ Provera
previous page	
28 OP	
	Kliovance
28 OP	
	Kliogest
28 OP	
	Trisequens
100	✓ NZ Medical and
100	Scientific
	100

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
OESTRIOL * Tab 2 mg	7.00	30	•	Ovestin

# Other Progestogen Preparations

#### LEVONORGESTREL

#### ⇒SA1608 Special Authority for Subsidy

Initial application — (No previous use) only from a relevant specialist or general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

#### All of the following:

- 1 The patient has a clinical diagnosis of heavy menstrual bleeding; and
- 2 The patient has failed to respond to or is unable to tolerate other appropriate pharmaceutical therapies as per the Heavy Menstrual Bleeding Guidelines; and
- 3 Either:
  - 3.1 serum ferritin level < 16 mcg/l (within the last 12 months); or
  - 3.2 haemoglobin level < 120 g/l.

Note: Applications are not to be made for use in patients as contraception except where they meet the above criteria. **Renewal** only from a relevant specialist or general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

#### Both:

- 1 Either:
  - 1.1 Patient demonstrated clinical improvement of heavy menstrual bleeding; or
  - 1.2 Previous insertion was removed or expelled within 3 months of insertion; and
- 2 Applicant to state date of the previous insertion.

MEDROXYPROGESTERONE ACETATE		
Tab 100 mg - Retail pharmacy-Specialist101.00	100	✓ Provera HD
NORETHISTERONE		
* Tab 5 mg - Up to 30 tab available on a PSO18.29	100	Primolut N
PROGESTERONE		
Cap 100 mg - Special Authority see SA1609 below - Retail		
pharmacy	30	<ul><li>Utrogestan</li></ul>

#### ⇒SA1609 Special Authority for Subsidy

**Initial application** only from an obstetrician or gynaecologist. Approvals valid for 12 months for applications meeting the following criteria:

#### Both:

- 1 For the prevention of pre-term labour\*; and
- 2 Either:
  - 2.1 The patient has a short cervix on ultrasound (defined as < 25 mm at 16 to 28 weeks); or
  - 2.2 The patient has a history of pre-term birth at less than 28 weeks.

**Renewal** only from an obstetrician or gynaecologist. Approvals valid for 12 months for applications meeting the following criteria: All of the following:

- 1 For the prevention of pre-term labour\*; and
- 2 Treatment is required for second or subsequent pregnancy; and
- 3 Fither:
  - 3.1 The patient has a short cervix on ultrasound (defined as < 25 mm at 16 to 28 weeks); or
  - 3.2 The patient has a history of pre-term birth at less than 28 weeks.

Note: Indications marked with \* are unapproved indications.

_		Subsidy (Manufacturer's Price) \$	Su Per	Fully bsidised	Brand or Generic Manufacturer
T	hyroid and Antithyroid Agents				
CA	RBIMAZOLE				
*	Tab 5 mg	10.80	100	✓ A	FT
	•				Carbimazole S29
				✓ N	eo-Mercazole
LE'	VOTHYROXINE				
*	Tab 25 mcg	3.89	90	<b>√</b> S	ynthroid
*	Tab 50 mcg		28	✓ M	ercury Pharma
	·	4.05	90	<b>√</b> S	ynthroid
		64.28	1,000	<b>√</b> E	Itroxin
*	Tab 100 mcg	1.78	28	✓ M	lercury Pharma
		4.21	90	✓ S	ynthroid
		66.78	1,000	<b>√</b> E	Itroxin
PR	OPYLTHIOURACIL - Special Authority see SA1199 below -	Retail pharmacy			
	Propylthiouracil is not recommended for patients under the a treatments are contraindicated.		the pat	ient is pre	gnant and other
	Tab 50 mg	35.00	100	<b>✓</b> P	TU S29

#### ⇒SA1199 Special Authority for Subsidy

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

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

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

# **Trophic Hormones**

#### **Growth Hormones**

SO	MATROPIN (OMNITROPE) - Special Authority see SA1629 below	w – Retail ph	narmacy	
*	Inj 5 mg cartridge	34.88	1	<ul><li>Omnitrope</li></ul>
*	Inj 10 mg cartridge	69.75	1	✓ Omnitrope
	Inj 15 mg cartridge		1	✓ Omnitrope
_	<u>,                                    </u>			

### ⇒SA1629 Special Authority for Subsidy

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

Fither:

- 1 Growth hormone deficiency causing symptomatic hypoglycaemia, or with other significant growth hormone deficient sequelae (e.g. cardiomyopathy, hepatic dysfunction) and diagnosed with GH < 5 mcg/l on at least two random blood samples in the first 2 weeks of life, or from samples during established hypoglycaemia (whole blood glucose < 2 mmol/l using a laboratory device); or</p>
- 2 All of the following:
  - 2.1 Height velocity < 25th percentile for age adjusted for bone age/pubertal status if appropriate over 6 or 12 months using the standards of Tanner and Davies (1985); and</p>
  - 2.2 A current bone age is < 14 years (female patients) or < 16 years (male patients); and
  - 2.3 Peak growth hormone value of < 5.0 mcg per litre in response to two different growth hormone stimulation tests. In

Subsidy		Fully	Brand or	
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\$	Per		Manufacturer	

continued...

- children who are 5 years or older, GH testing with sex steroid priming is required; and
- 2.4 If the patient has been treated for a malignancy, they should be disease free for at least one year based upon follow-up laboratory and radiological imaging appropriate for the malignancy, unless there are strong medical reasons why this is either not necessary or appropriate: and
- 2.5 Appropriate imaging of the pituitary gland has been obtained.

Renewal — (growth hormone deficiency in children) only from a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 A current bone age is 14 years or under (female patients) or 16 years or under (male patients); and
- 2 Height velocity is greater than or equal to 25th percentile for age (adjusted for bone age/pubertal status if appropriate) while on growth hormone treatment, as calculated over six months using the standards of Tanner and Davis (1985); and
- 3 Height velocity is greater than or equal to 2.0 cm per year, as calculated over 6 months; and
- 4 No serious adverse effect that the patients specialist considers is likely to be attributable to growth hormone treatment has occurred; and
- 5 No malignancy has developed since starting growth hormone.

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

All of the following:

- 1 The patient has a post-natal genotype confirming Turner Syndrome; and
- 2 Height velocity is < 25th percentile over 6-12 months using the standards of Tanner and Davies (1985); and
- 3 A current bone age is < 14 years.

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

All of the following:

- 1 Height velocity is greater than or equal to 50th percentile for age (while on growth hormone calculated over 6 to 12 months using the Ranke's Turner Syndrome growth velocity charts); and
- 2 Height velocity is greater than or equal to 2 cm per year, calculated over six months; and
- 3 A current bone age is 14 years or under; and
- 4 No serious adverse effect that the specialist considers is likely to be attributable to growth hormone treatment has occurred; and
- 5 No malignancy has developed since starting growth hormone.

Initial application — (short stature without growth hormone deficiency) only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 The patient's height is more than 3 standard deviations below the mean for age or for bone age if there is marked growth acceleration or delay; and
- 2 Height velocity is < 25th percentile for age (adjusted for bone age/pubertal status if appropriate), as calculated over 6 to 12 months using the standards of Tanner and Davies(1985); and
- 3 A current bone age is < 14 years or under (female patients) or < 16 years (male patients); and
- 4 The patient does not have severe chronic disease (including malignancy or recognized severe skeletal dysplasia) and is not receiving medications known to impair height velocity.

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

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

Subsidy		Fully	Brand or	
(Manufacturer's Price)	Sub	sidised	Generic	
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- 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</p>
- 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 Fither:
  - 6.1 The patient has a GFR less than or equal to 30 ml/min/1.73m<sup>2</sup> as measured by the Schwartz method (Height(cm)/plasma creatinine (umol/l) x 40 = corrected GFR (ml/min/1.73m<sup>2</sup> in a child who may or may not be receiving dialysis; or
  - 6.2 The patient has received a renal transplant and has received < 5mg/ m²/day of prednisone or equivalent for at least 6 months...

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

All of the following:

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

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

All of the following:

- 1 The patient has a diagnosis of Prader-Willi syndrome that has been confirmed by genetic testing or clinical scoring criteria; and
- 2 The patient is aged six months or older; and
- 3 A current bone age is < 14 years (female patients) or < 16 years (male patients); and
- 4 Sleep studies or overnight eximetry have been performed and there is no obstructive sleep disorder requiring treatment, or if an obstructive sleep disorder is found, it has been adequately treated under the care of a paediatric respiratory physician and/or ENT surgeon; and
- 5 Either:
  - 5.1 Both:

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

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- 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:

Either:

- 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

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

### **GnRH Analogues**

30	0	_	<b>¬</b> г	-,	181

Implant 3.6 mg, syringe	66.48	1	✓ Zoladex
Implant 10.8 mg, syringe	177.50	1	✓ Zoladex

#### I FUPRORFI IN

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

Inj 3.75 mg prefilled dual chamber syringe	- Higher subsidy of
\$221.60 ner 1 ini with Endorsement	

\$221.60 per 1 inj with Endorsement	00.48	I	
	(221.60)		Lucrin Depot 1-month

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

(591.68) Lucrin Depot 3-month

# Vasopressin Agonists

### DESMOPRESSIN ACETATE

Tab 100 mcg - Special Authority see SA1401 below - Retail pharmacy	25.00	30	✓ <u>Minirin</u>		
pharmacy per ml — Retail pharmacy-Specialist	39.03	30 2.5 ml OP 6 ml OP	✓ Minirin ✓ Minirin ✓ Desmopressin- PH&T		
Inj 4 mcg per ml, 1 ml – Special Authority see SA1401 below – Retail pharmacy	67.18	10	✓ Minirin		

### ⇒SA1401 Special Authority for Subsidy

Initial application — (Desmopressin tablets for Nocturnal enuresis) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has primary nocturnal enuresis; and
- 2 The nasal forms of desmopressin are contraindicated; and
- 3 An enuresis alarm is contraindicated.

Initial application — (Desmopressin tablets for Diabetes insipidus) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

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

continued...

- 1 The patient has cranial diabetes insipidus; and
- 2 The nasal forms of desmopressin are contraindicated.

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

Initial application — (Desmopressin injection) only from a relevant specialist. Approvals valid for 2 years where the patient cannot use desmopressin nasal spray or nasal drops.

Renewal — (Desmopressin injection) only from a relevant specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

### **Other Endocrine Agents**

#### CABERGOI INF

		Tab 0.5 mg - Maximum of 2 tab per prescription; can be
Dostinex	2	waived by Special Authority see SA1370 below3.75
✓ Dostinex	8	15.20

#### ⇒SA1370 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:

Either:

- 1 pathological hyperprolactinemia; or
- 2 acromegaly\*.

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

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

#### CLOMIFENE CITRATE

Tab 50 mg29	.84 10	✓ Mylan  Clomiphen  S29
DANAZOL		
Cap 100 mg	.33 100	✓ Azol
Cap 200 mg97	.83 100	✓ Azol
METYRAPONE		
Cap 250 mg - Retail pharmacy-Specialist520	.00 50	✓ Metopirone

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

# **Anthelmintics**

ALBENDAZOLE - Special Authority see S	SA1318 below – Retail pharmacy
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### ⇒SA1318 Special Authority for Subsidy

**Initial application** only from an infectious disease specialist or clinical microbiologist. Approvals valid for 6 months where the patient has hydatids.

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

### MEBENDAZOLE - Only on a prescription

Tab 100 mg	24.19	24	De-Worm
Oral liq 100 mg per 5 ml		15 ml	
	(7.17)		Vermox
PRAZIQUANTEL			
Tab 600 mg	68.00	8	<ul> <li>Biltricide</li> </ul>

### **Antibacterials**

- a) For topical antibacterials, refer to DERMATOLOGICALS, page 59
- b) For anti-infective eve preparations, refer to SENSORY ORGANS, page 220

## Cephalosporins and Cephamycins

CEEACI	∩R	MONOHYDRAT	Έ.
CEEACI	חו	IVIOIVOR I DRAI	г

Can 250 mg

σαρ 200 mg 1.70	100	- Italibaky Coluctor
Grans for oral liq 125 mg per 5 ml - Wastage claimable3.53	100 ml	✓ Ranbaxy-Cefaclor
CEFALEXIN		
Cap 250 mg3.50	20	✓ Cephalexin ABM
Cap 500 mg3.95	20	✓ Cephalexin ABM
Grans for oral liq 25 mg per ml - Wastage claimable8.75	100 ml	✓ Cefalexin Sandoz

24 70

100

✓ Ranhaxy-Cefactor

Note: Cefalexin grans for oral liq will not be funded in amounts more than 14 days treatment per dispensing.

Note: Cefalexin grans for oral liq will not be funded in amounts more than 14 days treatment per dispensing.

### CEFAZOLIN - Subsidy by endorsement

Only if prescribed for dialysis or cellulitis in accordance with a DHB approved protocol and the prescription is endorsed accordingly

accordingly.			
Inj 500 mg vial	.3.39	5	✓ AFT
lnj 1 g vial	.3.29	5	✓ 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	1.20	1	DEVA
lnį 1 g vial	0.84	1	✓ DEVA

### CEFUROXIME AXETIL - Subsidy by endorsement

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

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

### **Macrolides**

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

Tab 250 mg	8.19	30	✓ Apo-Azithromycin
5	8.50	6	✓ Zithromax
Tab 500 mg - Up to 8 tab available on a PSO	0.93	2	✓ Apo-Azithromycin
Grans for oral liq 200 mg per 5 ml (40 mg per ml) - Wastage			
claimable	14.38	15 ml	✓ Zithromax

(Zithromax Tab 250 mg to be delisted 1 June 2019)

#### ⇒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 SA1131 below

Tab 250 mg	3.98	14	<ul> <li>Apo-Clarithromycin</li> </ul>
Grans for oral lig 250 mg per 5 ml - Wastage claimable	23.12	50 ml	✓ Klacid

⇒SA1131 Special Authority for Waiver of Rule

Initial application — (Mycobacterial infections) only from a respiratory specialist, infectious disease specialist or paediatrician.

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

continued...

Approvals valid for 2 years for applications meeting the following criteria:

#### Fither.

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

**Renewal — (Mycobacterial infections)** only from a respiratory specialist, infectious disease specialist or paediatrician. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

ERYTHROMYCIN ETHYL SUCCINATE			9
Tab 400 mg	16.95	100	✓ E-Mycin
a) Up to 20 tab available on a PSO			-
b) Up to 2 x the maximum PSO quantity for RFPP			
Grans for oral liq 200 mg per 5 ml	5.00	100 ml	<ul><li>E-Mycin</li></ul>
<ul> <li>a) Up to 300 ml available on a PSO</li> </ul>			
b) Up to 2 x the maximum PSO quantity for RFPP			
c) Wastage claimable			
Grans for oral liq 400 mg per 5 ml	6.77	100 ml	<ul><li>E-Mycin</li></ul>
a) Up to 200 ml available on a PSO			
b) Wastage claimable			
ERYTHROMYCIN LACTOBIONATE			
lnj 1 g	16.00	1	<ul><li>Erythrocin IV</li></ul>
ERYTHROMYCIN STEARATE			
Tab 250 mg - Up to 30 tab available on a PSO	14.95	100	
• ,	(22.29)		ERA
Tab 500 mg	29.90	100	
	(44.58)		ERA
ROXITHROMYCIN			
Tab disp 50 mg	7.19	10	✓ Rulide D
Restricted to children under 12 years of age.			
Tab 150 mg	7.48	50	✓ Arrow-
			Roxithromycin
Tah 300 mg	14 40	50	✓ Arrow-
, ab 555 mg	14.40	50	Roxithromycin
ERYTHROMYCIN STEARATE Tab 250 mg — Up to 30 tab available on a PSO		100 100	ERA ERA  ✓ Rulide D ✓ Arrow- Roxithromycin ✓ Arrow-

	Subsidy (Manufacturer's Prio \$	ce) Subs Per	Fully Brand or sidised Generic Manufacturer	
Penicillins				
AMOXICILLIN				
Cap 250 mg	14.97	500	✓ Apo-Amoxi	
a) Up to 30 cap available on a PSO				
b) Up to 10 x the maximum PSO quantity for RFPP				
Cap 500 mg	16.75	500	✓ Apo-Amoxi	
a) Up to 30 cap available on a PSO				
b) Up to 10 x the maximum PSO quantity for RFPP			4	
Grans for oral liq 125 mg per 5 ml	1.20	100 ml	✓ Alphamox 125	
a) Up to 200 ml available on a PSO				
b) Wastage claimable	4.04	4001	/ Alabaman 050	
Grans for oral liq 250 mg per 5 ml	1.31	100 ml	✓ Alphamox 250	
a) Up to 300 ml available on a PSO				
<ul> <li>b) Up to 10 x the maximum PSO quantity for RFPP</li> <li>c) Wastage claimable</li> </ul>				
Inj 250 mg vial	10.67	10	✓ Ibiamox	
Inj 500 mg vial		10	✓ Ibiamox	
Inj 1 g vial – Up to 5 inj available on a PSO		10	✓ Ibiamox	
AMOXICILLIN WITH CLAVULANIC ACID				
Tab 500 mg with clavulanic acid 125 mg – Up to 30 tab				
available on a PSO	1 99	20	✓ Augmentin	
Grans for oral liq amoxicillin 25 mg with clavulanic acid 6.25		20	Augmentin	
per ml		100 ml	✓ Augmentin	
a) Up to 200 ml available on a PSO		100 1111	Augmentin	
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	✓ Curam	
BENZATHINE BENZYLPENICILLIN				
Inj 900 mg (1.2 million units) in 2.3 ml syringe – Up to 5 inj				
available on a PSO	344 93	10	✓ Bicillin LA	
		10	5 DIOIIIII EA	
BENZYLPENICILLIN SODIUM [PENICILLIN G] Inj 600 mg (1 million units) vial – Up to 5 inj available on a P	SO 10.25	10	✓ Sandoz	
	30 10.33	10	▼ <u>Sanuoz</u>	
FLUCLOXACILLIN	10.00	050	. Clambian	
Cap 250 mg - Up to 30 cap available on a PSO		250 500	✓ Staphlex	
Grans for oral liq 25 mg per ml		100 ml	✓ Staphlex ✓ AFT	
a) Up to 200 ml available on a PSO	2.23	100 1111	Y ALL	
b) Wastage claimable				
Grans for oral liq 50 mg per ml	3.68	100 ml	✓ AFT	
a) Up to 200 ml available on a PSO		100 1111	<u> </u>	
b) Wastage claimable				
Inj 250 mg vial	9.00	10	✓ Flucloxin	
Inj 500 mg vial	9.40	10	✓ Flucloxin	
Inj 1 g vial – Up to 5 inj available on a PSO	5.22	5	✓ Flucil	

	Subsidy (Manufacturer's Price) \$	) Per	Fully Subsidised	I Generic
PHENOXYMETHYLPENICILLIN (PENICILLIN V)				
Cap 250 mg - Up to 30 cap available on a PSO	2.59	50	1	Cilicaine VK
Cap 500 mg		50	✓	Cilicaine VK
a) Up to 20 cap available on a PSO				
b) Up to 2 x the maximum PSO quantity for RFPP				
Grans for oral liq 125 mg per 5 ml	1.48	100 m	<b>/</b>	AFT
a) Up to 200 ml available on a PSO				
b) Wastage claimable				
Grans for oral liq 250 mg per 5 ml	1.58	100 m	ı 🗸	AFT
a) Up to 300 ml available on a PSO				
b) Up to 2 x the maximum PSO quantity for RFPP				
c) Wastage claimable				
PROCAINE PENICILLIN				
Inj 1.5 g in 3.4 ml syringe – Up to 5 inj available on a PSO.	123.50	5	1	Cilicaine
ing 1.5 g in 5.4 mil syninge – op to 5 mj avaliable on a 1 50.	120.00	J		Cilicaine
Tetracyclines				
OOXYCYCLINE				
* Tab 50 mg - Up to 30 tab available on a PSO	2.90	30		
	(6.00)			Doxy-50
★ Tab 100 mg - Up to 30 tab available on a PSO	6.75 <sup>°</sup>	250	1	Doxine
Doxy-50 Tab 50 mg to be delisted 1 January 2020)				
MINOCYCLINE HYDROCHLORIDE				
★ Tab 50 mg - Additional subsidy by Special Authority see				
SA1355 below – Retail pharmacy	5 79	60		
5. 11000 bolow - Hotali pharmacy	(12.05)	00		Mino-tabs
<b>₭</b> Cap 100 mg		100		mino tubo
- Cap 100 mg	(52.04)	100		Minomycin
CA12EE Chariel Authority for Manufacturers Dries	(02.01)			
⇒SA1355 Special Authority for Manufacturers Price	lid without further rea	owol ··	nlaga nati	ind where the notices ha
nitial application from any relevant practitioner. Approvals va	iiu widiout iurdiel felie	ewai u	111622 110[[]	ieu where the patient ha
osacea. "ETRACYCLINE  – Special Authority see SA1332 below – Reta	ail pharmany			
. ETTAO TOLINE — Special Authority See SA 1332 Delow — Net	40.00	20	,	Tatraavalin

TETRACYCLINE - Special Authority see SA1332 below -	- Retail pharmacy		
Cap 500 mg	46.00	30	<ul><li>Tetracyclin</li></ul>
			Wolff S29

## **⇒SA1332** Special Authority for Subsidy

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

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

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

#### Other Antibiotics

For topical antibiotics, refer to DERMATOLOGICALS, page 59

#### **CIPROFLOXACIN**

Recommended for patients with any of the following:

Can hydrochloride 150 mg - Maximum of 4 can per

- i) microbiologically confirmed and clinically significant pseudomonas infection; or
- ii) prostatitis; or
- iii) pyelonephritis; or
- iv) gonorrhoea.

Tab 250 mg - Up to 5 tab available on a PSO1.45	28	✓ Cipflox
Tab 500 mg - Up to 5 tab available on a PSO1.99	28	✓ Cipflox
Tab 750 mg3.15	28	✓ Cipflox

#### CLINDAMYCIN

prescription; can be waived by endorsement - Retail		
pharmacy - Specialist4.10	16	✓ Clindamycin ABM
Inj phosphate 150 mg per ml, 4 ml ampoule - Retail		
pharmacy-Specialist65.00	10	✓ Dalacin C

#### COLISTIN SULPHOMETHATE - Retail pharmacy-Specialist - Subsidy by endorsement

Only if prescribed for dialysis or cystic fibrosis patient and the prescription is endorsed accordingly.

#### GENTAMICIN SULPHATE

Inj 40 mg per ml, 2 ml ampoule − Subsidy by endorsement.............6.00 10 ✓ Pfizer 30.00 50 ✓ Pfizer

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

MOXIFLOXACIN - Special Authority see SA1740 below - Retail pharmacy

No patient co-payment payable

### ⇒SA1740 Special Authority for Subsidy

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

Any of the following:

#### 1 Both:

- 1.1 Active tuberculosis\*: and
- 1.2 Any of the following:
  - 1.2.1 Documented resistance to one or more first-line medications: or
  - 1.2.2 Suspected resistance to one or more first-line medications (tuberculosis assumed to be contracted in an area with known resistance), as part of regimen containing other second-line agents; or
  - 1.2.3 Impaired visual acuity (considered to preclude ethambutol use); or
  - 1.2.4 Significant pre-existing liver disease or hepatotoxicity from tuberculosis medications; or
  - 1.2.5 Significant documented intolerance and/or side effects following a reasonable trial of first-line medications; or

INFECTIONS - AGENTS FOR SYSTEMIC USE					SE E
	Subsidy (Manufacturer's Price \$	) Sub	Fully sidised	Brand or Generic Manufacturer	
continued					
Mycobacterium avium-intracellulare complex not re     Patient is under five years of age and has had clos Note: Indications marked with * are unapproved indication Renewal only from a respiratory specialist or infectious dis remains appropriate and the patient is benefiting from trea Initial application — (Mycoplasma genitalium) only fro sexual health specialist. Approvals valid for 1 month for a All of the following:      1 Has nucleic acid amplification test (NAAT) confirme     2 Either:      2.1 Has tried and failed to clear infection using     2.2 Has laboratory confirmed azithromycin resis	se contact with a confirmed ons. sease specialist. Approvale atment. om a sexual health specialist applications meeting the follow de Mycoplasma genitalium azithromycin; or	multi-drug s valid for 1 t or Practiti owing crite	resistan year wl oner on ria:	t tuberculosis cas here the treatmer the recommenda	se.
3 Treatment is only for 7 days.	Stance, and				
Initial application — (Penetrating eye injury) only from requires prophylaxis following a penetrating eye injury and Note: Indications marked with * are unapproved indication PAROMOMYCIN — Special Authority see SA1689 below—Cap 250 mg	d treatment is for 5 days onlins.  - Retail pharmacy126.00 list, clinical microbiologist o	ly. 16	<b>√</b> H	umatin §29	
Renewal only from an infectious disease specialist, clinica applications meeting the following criteria:  Either:  1 Patient has confirmed cryptosporidium infection; or 2 For the eradication of Entamoeba histolyica carriac	al microbiologist or gastroer	nterologist.	Approv	als valid for 1 mo	nth for
PYRIMETHAMINE – Special Authority see SA1328 below	•				
Tab 25 mg		30 50		araprim \$29 araprim \$29	
■ SA1328 Special Authority for Subsidy Initial application from any relevant practitioner. Approve the following criteria: Any of the following:  1 For the treatment of toxoplasmosis in patients with 2 For pregnant patients for the term of the pregnancy 3 For infants with concenital toxoplasmosis until 12 r	HIV for a period of 3 montly; or		s notified	d for applications	meeting

SODIUM FUSIDATE [FUSIDIC ACID] Tab 250 mg - Retail pharmacy-Specialist......34.50 12 ✓ Fucidin

Prescriptions must be written by, or on the recommendation of, an infectious disease physician or a clinical microbiologist

SULFADIAZINE SODIUM - Special Authority see SA1331 on the next page - Retail pharmacy Tab 500 mg ......543.20 56

✓ Wockhardt \$29

	Subsidy (Manufacturer's Price) \$	Sub Per	Fully sidised	Brand or Generic Manufacturer
■ SA1331 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid the following criteria: Any of the following:  1 For the treatment of toxoplasmosis in patients with HIV for 2 For pregnant patients for the term of the pregnancy; or	a period of 3 month		ss notified	d for applications meeting
3 For infants with congenital toxoplasmosis until 12 months ( TOBRAMYCIN	or age.			
Inj 40 mg per ml, 2 ml vial - Subsidy by endorsement Only if prescribed for dialysis or cystic fibrosis patient and		5 endorsed		<b>obramycin Mylan</b> Igly.
Solution for inhalation 60 mg per ml, 5 ml — Subsidy by endorsement	•	6 dose	✓ Tordinaly.	ОВІ
TRIMETHOPRIM	p		3-7-	
* Tab 300 mg - Up to 30 tab available on a PSO	16.50	50	<b>√</b> <u>T</u>	<u>MP</u>
TRIMETHOPRIM WITH SULPHAMETHOXAZOLE [CO-TRIMOX/	AZOLE]			
* Tab trimethoprim 80 mg and sulphamethoxazole 400 mg - L to 30 tab available on a PSO	22.90	500	<b>✓</b> T	risul
Oral liq 8 mg sulphamethoxazole 40 mg per ml – Up to 200 r available on a PSO		100 ml	<b>✓</b> D	eprim
VANCOMYCIN – Subsidy by endorsement			_	
Only if prescribed for a dialysis or cystic fibrosis patient or for	prophylaxis of endo	carditis or	for treat	tment of Clostridium
difficile following metronidazole failure and the prescription is	endorsed according			
Inj 500 mg vial	2.37	1	✓ M	<u>lylan</u>
Antifungals				
a) For topical antifungals refer to DERMATOLOGICALS, page 60 b) For topical antifungals refer to GENITO URINARY, page 73	)			
FLUCONAZOLE				
Cap 50 mg - Retail pharmacy-Specialist		28		<u>lylan</u>
Cap 150 mg - Subsidy by endorsement		. 1	_	lylan
<ul><li>a) Maximum of 1 cap per prescription; can be waived by</li><li>b) Patient has vaginal candida albicans and the practitio</li></ul>				

#### F

not recommended and the prescription is endorsed accordingly; can be waived by endorsement - Retail pharmacy -

✓ Mylan Cap 200 mg - Retail pharmacy-Specialist ......5.08 Powder for oral suspension 10 mg per ml - Special Authority

see SA1359 below – Retail pharmacy......34.56 98.50

35 ml ✓ Diflucan S29 S29 ✓ Diflucan

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:

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

continued...

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

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

All of the following:

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

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

Both:

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

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

All of the following:

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

#### ITRACONAZOLE

Cap 100 mg - Subsidy by endorsement ......2.79 15 ✓ Itrazole

Funded for tinea vesicolor where topical treatment has not been successful and diagnosis has been confirmed by mycology, or for tinea unquium where terbinafine has not been successful in eradication or the patient is intolerant to terbinafine and diagnosis has been confirmed by mycology and the prescription is endorsed accordingly. Can be waived by endorsement - Retail pharmacy - Specialist Specialist must be an infectious disease physician, clinical microbiologist, clinical immunologist or dermatologist.

Oral lig 10 mg per ml - Special Authority see SA1322 below -Retail pharmacy......141.80

150 ml OP ✓ Sporanox

### ⇒SA1322 Special Authority for Subsidy

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

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

#### KETOCONAZOLE

NY

Tab 200 mg - PCT - Retail pharmacy-Specialist - Subsi endorsement	, ,	30	✓ Link Healthcare \$29 ✓ Nizoral \$29
Prescriptions must be written by, or on the recommer	ndation of an oncologis	st	
'STATIN			
Tob 500 000	1/16	EΩ	

Tab 500,000 u	14.16	50	
	(17.09)		Nilstat
Cap 500,000 u	12.81	50	
	(15.47)		Nilstat

POSACONAZOLE - Special Authority see SA1285 on the next page - Retail pharmacy Tab modified-release 100 mg......869.86

Noxafil ✓ Noxafil 105 ml OP

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

#### **⇒SA1285** Special Authority for Subsidy

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

#### Either:

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

#### **TERBINAFINE**

*	Tab 250 mg	.1.33	14	✓ <u>Deolate</u>
VO	RICONAZOLE - Special Authority see SA1273 below - Retail pharm	nacy		
	Tab 50 mg	91.00	56	✓ Vttack
	Tab 200 mg	50.00	56	✓ Vttack
	Powder for oral suspension 40 mg per ml - Wastage			
	claimable1,43	37.00	70 ml	✓ Vfend

#### ⇒SA1273 Special Authority for Subsidy

Initial application — (invasive fungal infection) only from a haematologist, infectious disease specialist or clinical microbiologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient is immunocompromised; and
- 2 Applicant is part of a multidisciplinary team including an infectious disease specialist; and
- 3 Any of the following:
  - 3.1 Patient has proven or probable invasive aspergillus infection; or
  - 3.2 Patient has possible invasive aspergillus infection; or
  - 3.3 Patient has fluconazole resistant candidiasis: or
  - 3.4 Patient has mould strain such as Fusarium spp. and Scedosporium spp.

Renewal — (invasive fungal infection) only from a haematologist, infectious disease specialist or clinical microbiologist. Approvals valid for 3 months for applications meeting the following criteria:

### All of the following:

- 1 Patient is immunocompromised; and
- 2 Applicant is part of a multidisciplinary team including an infectious disease specialist; and
- 3 Any of the following:
  - 3.1 Patient continues to require treatment for proven or probable invasive aspergillus infection; or
  - 3.2 Patient continues to require treatment for possible invasive aspergillus infection; or
  - 3.3 Patient has fluconazole resistant candidiasis; or
  - 3.4 Patient has mould strain such as Fusarium spp. and Scedosporium spp.

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

# Antimalarials

PRIMAQUINE PHOSPHATE - Special Authority see SA1684 below - Retail pharmacy

### SA1684 Special Authority for Subsidy

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

#### Both:

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

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

#### Both:

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

### **Antiparasitics**

### **Antiprotozoals**

QUININE SULPHATE

### **Antitrichomonal Agents**

TRO		

Tab 200 mg – Up to 30 tab available on a PSO	10.45	100	✓ Trichozole
Tab 400 mg - Up to 15 tab available on a PSO	18.15	100	✓ Trichozole
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	23.00	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.

#### CLOFAZIMINE - Retail pharmacy-Specialist

- a) No patient co-payment payable
- 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
- Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or respiratory physician.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
DAPSONE - Retail pharmacy-Specialist				
a) No patient co-payment payable				
<li>b) Prescriptions must be written by, or on the recommend dermatologist</li>	ation of, an infectious di	seas	e physician,	clinical microbiologist or
Tab 25 mg	268.50	100		apsone
Tab 100 mg	329.50	100	✓ D	apsone
ETHAMBUTOL HYDROCHLORIDE - Retail pharmacy-Specia	alist			
<ul> <li>a) No patient co-payment payable</li> </ul>				
<ul> <li>Prescriptions must be written by, or on the recommend respiratory physician</li> </ul>	ation of, an infectious di	seas	e physician,	clinical microbiologist or
Tab 100 mg	85.73	100	✓ E	MB Fatol S29
Tab 400 mg	49.34	56	✓ M	lyambutol S29
ISONIAZID - Retail pharmacy-Specialist				
a) No patient co-payment payable				
<ul> <li>Prescriptions must be written by, or on the recommend microbiologist, dermatologist or public health physician</li> </ul>	ation of, an internal med	dicine	physician, p	paediatrician, clinical
* Tab 100 mg	22.00	100	<b>✓</b> <u>P</u>	<u>SM</u>
ISONIAZID WITH RIFAMPICIN - Retail pharmacy-Specialist				
<ul> <li>a) No patient co-payment payable</li> <li>b) Prescriptions must be written by, or on the recommend microbiologist, dermatologist or public health physician</li> </ul>	ation of, an internal med	dicine	physician, p	paediatrician, clinical
* Tab 100 mg with rifampicin 150 mg		100	<b>✓</b> R	ifinah
* Tab 150 mg with rifampicin 300 mg	170.60	100	✓ R	ifinah
PARA-AMINO SALICYLIC ACID - Retail pharmacy-Specialist				
a) No patient co-payment payable				
b) Specialist must be an infectious disease specialist, clin	ical microbiologist or res	spirat	ory specialis	t.
Grans for oral liq 4 g sachet	280.00	30	<b>√</b> P	aser S29
PROTIONAMIDE - Retail pharmacy-Specialist				
<ul> <li>a) No patient co-payment payable</li> </ul>				
b) Specialist must be an infectious disease specialist, clin	ŭ			
Tab 250 mg	305.00	100	<b>✓</b> P	eteha S29
PYRAZINAMIDE - Retail pharmacy-Specialist				
<ul> <li>a) No patient co-payment payable</li> </ul>				
<li>b) Prescriptions must be written by, or on the recommend respiratory physician</li>	ation of, an infectious di	seas	e physician,	clinical microbiologist or
* Tab 500 mg	59.00	100	✓ A	FT-Pyrazinamide
RIFABUTIN – Retail pharmacy-Specialist				•
a) No patient co-payment payable				
b) Prescriptions must be written by, or on the recommend gastroenterologist	ation of, an infectious di	seas	e physician,	respiratory physician or
* Cap 150 mg				

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

#### RIFAMPICIN - Subsidy by endorsement

- a) No patient co-payment payable
- b) For confirmed recurrent Staphylococcus aureus infection in combination with other effective anti-staphylococcal antimicrobial based on susceptibilities and the prescription is endorsed accordingly; can be waived by endorsement -Retail pharmacy - Specialist. Specialist must be an internal medicine physician, clinical microbiologist, dermatologist, paediatrician, or public health physician.

*	Cap 150 mg55.75	100	1	Rifadin
*	Cap 300 mg116.25	100	1	Rifadin
*	Oral liq 100 mg per 5 ml12.00	60 ml	1	Rifadin

### **Antivirals**

For eye preparations refer to Eye Preparations, Anti-Infective Preparations, page 220

### **Hepatitis B Treatment**

### **⇒SA0829** Special Authority for Subsidy

**Initial application** only from a gastroenterologist or infectious disease specialist. Approvals valid for 1 year for applications meeting the following criteria:

#### All of the following:

- 1 Patient has confirmed Hepatitis B infection (HBsAg+); and Documented resistance to lamivudine, defined as:
- 2 Patient has raised serum ALT (> 1 x ULN); and
- 3 Patient has HBV DNA greater than 100,000 copies per mL, or viral load 10 fold or higher over nadir; and
- 4 Detection of M204I or M204V mutation; and
- 5 Fither:
  - 5.1 Both
    - 5.1.1 Patient is cirrhotic; and
    - 5.1.2 adefovir dipivoxil to be used in combination with lamivudine: or
  - 5.2 Both:
    - 5.2.1 Patient is not cirrhotic; and
    - 5.2.2 adefovir dipivoxil to be used as monotherapy.

**Renewal** only from a gastroenterologist or infectious disease specialist. Approvals valid for 2 years where in the opinion of the treating physician, treatment remains appropriate and patient is benefiting from treatment.

Notes: Lamivudine should be added to adefovir dipivoxil if a patient develops documented resistance to adefovir dipivoxil, defined as:

- i) raised serum ALT (> 1 x ULN); and
- ii) HBV DNA greater than 100,000 copies per mL, or viral load 10 fold or higher over nadir; and
- iii) Detection of N236T or A181T/V mutation.

Adefovir dipivoxil should be stopped 6 months following HBeAg seroconversion for patients who were HBeAg+ prior to commencing adefovir dipivoxil.

The recommended dose of adefovir dipivoxil is no more than 10mg daily.

In patients with renal insufficiency adefovir dipivoxil dose should be reduced in accordance with the datasheet guidelines. Adefovir dipivoxil should be avoided in pregnant women and children.

#### **ENTECAVIR**

* Tab 0.5 mg	52.00	30	✓ Entecavir Sandoz
LAMIVUDINE - Special Authority see SA1685 on the next page	- Retail pharma	су	
Tab 100 mg	4.20	28	✓ Zetlam
Oral liq 5 mg per ml	270.00	240 ml OP	✓ Zeffix

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

### ⇒SA1685 Special Authority for Subsidy

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

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

Tenofovir disoproxil prescribed under endorsement for the treatment of HIV is included in the count of up to 4 subsidised antiretrovirals for the purposes of Special Authority SA1651., page 103

### **Herpesvirus Treatments**

#### ACICLOVIR

*	Tab dispersible 200 mg	1.60	25	<ul><li>Lovir</li></ul>
	Tab dispersible 400 mg		56	✓ Lovir
	Tab dispersible 800 mg		35	✓ Lovir
۷A	LACICLOVIR			
	Tab 500 mg	5.75	30	✓ Vaclovir
	Tab 1,000 mg	11.35	30	✓ Vaclovir
۷A	LGANCICLOVIR - Special Authority see SA1404 below - Retain	il pharmacy		
	Tab 450 mg	225.00	60	✓ Valganciclovir  Mylan
		1,050.00		✓ Valcyte

### ⇒SA1404 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:

#### Both:

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

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 6 months for applications meeting the following criteria:

#### Both:

- 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.

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

continued...

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

#### Both:

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

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

Both:

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

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

### **Hepatitis C Treatment**

### GLECAPREVIR WITH PIBRENTASVIR - [Xpharm]

Note the supply of treatment is via PHARMAC's approved direct distribution supply. Further details can be found on PHARMAC's website https://www.pharmac.govt.nz/hepatitis-c-treatments

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

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

No patient co-payment payable

### SA1605 Special Authority for Subsidy

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

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

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

Application details may be obtained from PHARMAC's website http://www.pharmac.govt.nz/hepatitis-c-treatments 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 
S Per ✔ Manufacturer

✓ Teva

# **HIV Prophylaxis and Treatment**

EMTRICITABINE WITH TENOFOVIR DISOPROXIL - Subsidy by endorsement; can be waived by Special Authority see SA1714 below

below
Endorsement for treatment of HIV: Prescription is deemed to be endorsed if emtricitabine with tenofovir disoproxil is co-prescribed with another antiretroviral subsidised under Special Authority SA1651 and the prescription is annotated accordingly by the Pharmacist or endorsed by the prescriber.

Note: Emtricitabine with tenofovir disoproxil prescribed under endorsement for the treatment of HIV is included in the count of up to 4 subsidised antiretrovirals, and counts as two antiretroviral medications, for the purposes of Special Authority SA1651, page 103 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

### ⇒SA1714 Special Authority for Waiver of Rule

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

Both:

- 1 Patient has tested HIV negative; and
- 2 Either:
  - 2.1 All of the following:
    - 2.1.1 Patient is male or transgender; and
    - 2.1.2 Patient has sex with men; and
    - 2.1.3 Patient is likely to have multiple episodes of condomless anal intercourse in the next 3 months; and
    - 2.1.4 Any of the following:
      - 2.1.4.1 Patient has had at least one episode of condomless receptive anal intercourse with one or more casual male partners in the last 3 months; or
      - 2.1.4.2 A diagnosis of rectal chlamydia, rectal gonorrhoea, or infectious syphilis within the last 3 months; or
      - 2.1.4.3 Patient has used methamphetamine in the last three months; or
  - 2.2 All of the following:
    - 2.2.1 Patient has a regular partner who has HIV infection; and
    - 2.2.2 Partner is either not on treatment or has a detectable viral load; and
    - 2.2.3 Condoms have not been consistently used.

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

- 1 Applicant has an up to date knowledge of the safety issues and is competent to prescribe pre-exposure prophylaxis; and
- 2 Patient has undergone testing for HIV, syphilis, and a full STI screen in the previous two weeks; and
- 3 Patient has had renal function testing (creatinine, phosphate and urine protein/creatinine ratio) within the last 12 months;
- 4 Patient has received advice regarding the reduction of risk of HIV and sexually transmitted infections and how to reduce those risks; and
- 5 Patient has tested HIV negative; and
- 6 Either:
  - 6.1 All of the following:
    - 6.1.1 Patient is male or transgender; and
    - 6.1.2 Patient has sex with men: and
    - 6.1.3 Patient is likely to have multiple episodes of condomless anal intercourse in the next 3 months; and

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

continued...

- 6.1.4 Any of the following:
  - 6.1.4.1 Patient has had at least one episode of condomless receptive anal intercourse with one or more casual male partners in the last 3 months; or
  - 6.1.4.2 A diagnosis of rectal chlamydia, rectal gonorrhoea, or infectious syphilis within the last 3 months; or
  - 6.1.4.3 Patient has used methamphetamine in the last three months; or
- 6.2 All of the following:
  - 6.2.1 Patient has a regular partner who has HIV infection; and
  - 6.2.2 Partner is either not on treatment or has a detectable viral load; and
  - 6.2.3 Condoms have not been consistently used.

### **Antiretrovirals**

#### ⇒SA1651 Special Authority for Subsidy

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

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

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

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

Fither:

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

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

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

Initial application — (post-exposure prophylaxis following non-occupational exposure to HIV) only from a named specialist. Approvals valid for 4 weeks for applications meeting the following criteria:

Both:

- 1 Treatment course to be initiated within 72 hours post exposure; and
- 2 Any of the following:
  - 2.1 Patient has had unprotected receptive anal intercourse with a known HIV positive person; or
  - 2.2 Patient has shared intravenous injecting equipment with a known HIV positive person; or
  - 2.3 Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required.

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

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

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Renewal — (second or subsequent post-exposure prophylaxis) only from a named specialist. Approvals valid for 4 weeks for applications meeting the following criteria:

- Both:
  - 1 Treatment course to be initiated within 72 hours post exposure; and
  - 2 Any of the following:
    - 2.1 Patient has had unprotected receptive anal intercourse with a known HIV positive person; or
    - 2.2 Patient has shared intravenous injecting equipment with a known HIV positive person; or
    - 2.3 Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required.

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

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

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

# Non-nucleosides Reverse Transcriptase Inhibitors

crin S29
crin
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crin \$29
elence
<u>virapine</u>
lphapharm
amune Juspension

# **Nucleosides Reverse Transcriptase Inhibitors**

ABACAVIR SULPHATE – Special Authority see SA1651 on the	e previous page –	Retail pharmac	у
Tab 300 mg	229.00	60	✓ Ziagen
Ziagen to be Sole Supply on 1 July 2019			· ·
Oral liq 20 mg per ml	256.31	240 ml OP	✓ Ziagen
ABACAVIR SULPHATE WITH LAMIVUDINE - Special Authori	ity see SA1651 on	the previous pa	age - Retail pharmacy
Note: abacavir with lamivudine (combination tablets) count	ts as two anti-retro	viral medication	ns for the purposes of the
anti-retroviral Special Authority.			
Tab 600 mg with lamivudine 300 mg	427.29	30	✓ Kivexa
Kivexa to be Sole Supply on 1 July 2019			

	Subsidy	)	Fully Brand or
	(Manufacturer's P	Price) Subsi Per	dised Generic  ✓ Manufacturer
FEAVIDENT WITH EATTHOUTABLE AND TENOCOUR DIOODS	т.		
EFAVIRENZ WITH EMTRICITABINE AND TENOFOVIR DISOPR	OXIL – Speciai	Authority see	SA 1651 on page 103 – Retail
pharmacy Note: Efavirenz with emtricitabine and tenofovir disoproxil co anti-retroviral Special Authority	unts as three ar	nti-retroviral med	dications for the purposes of the
Tab 600 mg with emtricitabine 200 mg and tenofovir disoprox	il		
245 mg (300 mg as a fumarate)		30	✓ Atripla
Tab 600 mg with emtricitabine 200 mg and tenofovir disoprox		00	· /mpm
245 mg (300 mg as a maleate)		30	✓ Mylan
EMTRICITABINE – Special Authority see SA1651 on page 103 –		W	,
Cap 200 mg		30	✓ Emtriva
LAMIVUDINE - Special Authority see SA1651 on page 103 - Re		00	- 2000
Tab 150 mg		60	✓ Lamivudine
Tab 150 mg	52.50	00	Alphapharm
Oral liq 10 mg per ml	102 50	240 ml OP	✓ 3TC
. •			- 010
ZIDOVUDINE [AZT] – Special Authority see SA1651 on page 103		100	✓ Retrovir
Cap 100 mg Oral lig 10 mg per ml		200 ml OP	✓ 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	33.00	60	✓ <u>Alphapharm</u>
Protease Inhibitors			
ATAZANAVIR SULPHATE - Special Authority see SA1651 on pa	age 103 - Retail	pharmacy	
Cap 150 mg		60 ′	✓ Teva
, -	568.34		✓ Reyataz
Cap 200 mg	188.91	60	✓ Teva
	757.79		✓ Reyataz
DARUNAVIR - Special Authority see SA1651 on page 103 - Ret	ail pharmacy		
Tab 400 mg	335.00	60	✓ Prezista
Tab 600 mg	476.00	60	✓ Prezista
LOPINAVIR WITH RITONAVIR - Special Authority see SA1651	on page 103 – F	Retail pharmacy	
Tab 100 mg with ritonavir 25 mg	183.75	60	✓ Kaletra
Tab 200 mg with ritonavir 50 mg	463.00	120	✓ Kaletra
Oral liq 80 mg with ritonavir 20 mg per ml	735.00	300 ml OP	✓ Kaletra
RITONAVIR - Special Authority see SA1651 on page 103 - Reta	ail pharmacy		
Tab 100 mg	43.31	30	✓ Norvir
Norvir to be Sole Supply on 1 July 2019			
Strand Transfer Inhibitors			
DOLUTEGRAVIR - Special Authority see SA1651 on page 103 -	- Retail pharmad	CV	
Tab 50 mg		30	✓ Tivicay
RALTEGRAVIR POTASSIUM – Special Authority see SA1651 or	•		··· <b>,</b>
Tab 400 mg Tab 400 mg		60	✓ Isentress

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

## **Immune Modulators**

#### Guidelines for the use of interferon in the treatment of hepatitis C:

Physicians considering treatment of patients with hepatitis C should discuss cases with a gastroenterologist or an infectious disease physician. All subjects undergoing treatment require careful monitoring for side effects.

Patients should be otherwise fit.

Hepatocellular carcinoma should be excluded by ultrasound examination and alpha-fetoprotein level.

#### **Criteria for Treatment**

- 1) Diagnosis
  - Anti-HCV positive on at least two occasions with a positive PCR for HCV-RNA and preferably confirmed by a supplementary RIBA test; or
  - . PCR-RNA positive for HCV on at least 2 occasions if antibody negative; or
  - Anti-HCV positive on at least two occasions with a positive supplementary RIBA test with a negative PCR for HCV RNA but with a liver biopsy consistent with 2(b) following.

#### **Exclusion Criteria**

- Autoimmune liver disease. (Interferon may exacerbate autoimmune liver disease as well as other autoimmune diseases such as thyroid disease).
- 2) Pregnancy.
- 3) Neutropenia ( $< 2.0 \times 10^9$ ) and/or thrombocytopenia.
- 4) Continuing alcohol abuse and/or continuing intravenous drug users.

#### Dosage

The current recommended dosage is 3 million units of interferon alfa-2a or interferon alfa-2b administered subcutaneously 3 times a week for 52 weeks (twelve months)

#### **Exit Criteria**

The patient's response to interferon treatment should be reviewed at either three or four months. Interferon treatment should be discontinued in patients who do not show a substantial reduction (50%) in their mean pre-treatment ALT level at this stage.

INTERFERON ALFA-2A - PCT - Retail pharmacy-Specialist

- a) See prescribing guideline above
- b) Prescriptions must be written by, or on the recommendation of, an internal medicine physician or ophthalmologist

#### INTERFERON ALFA-2B - PCT - Retail pharmacy-Specialist

- a) See prescribing guideline above
- b) Prescriptions must be written by, or on the recommendation of, an internal medicine physician or ophthalmologist
- Inj 18 m iu, 1.2 ml multidose pen.
   206.71
   1
   ✓ Intron-A

   Inj 30 m iu, 1.2 ml multidose pen.
   344.52
   1
   ✓ Intron-A

   Inj 60 m iu, 1.2 ml multidose pen.
   689.04
   1
   ✓ Intron-A
- (Intron-A Inj 18 m iu, 1.2 ml multidose pen to be delisted 1 May 2019)

(Intron-A Ini 30 m iu. 1.2 ml multidose pen to be delisted 1 May 2019)

(Intron-A Inj 60 m iu, 1.2 ml multidose pen to be delisted 1 May 2019)

PEGYLATED INTERFERON ALFA-2A - Special Authority see SA1400 on the next page - Retail pharmacy

- a) See prescribing guideline above
- b) Note: PHARMAC will consider funding ribavirin for the small group of patients who have a clinical need for ribavirin and meet Special Authority criteria. Please contact the Hepatitis C Coordinator at PHARMAC on 0800-023-588 option 4.

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

#### ⇒SA1400 Special Authority for Subsidy

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

Both:

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

#### Notes:

- Consider stopping treatment if there is absence of a virological response (defined as at least a 2-log reduction in viral load) following 12 weeks of treatment since this is predictive of treatment failure.
- Consider reducing treatment to 24 weeks if serum HCV RNA level at Week 4 is undetectable by sensitive PCR assay (less than 50IU/ml) AND Baseline serum HCV RNA is less than 400,000IU/ml

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

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 Fithou
  - 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

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

#### continued...

- 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.

#### Notes:

- Approved dose is 180 mcg once weekly.
- The recommended dose of Pegylated Interferon alfa-2a is 180 mcg once weekly.
- In patients with renal insufficiency (calculated creatinine clearance less than 50ml/min), Pegylated Interferon-alfa 2a dose should be reduced to 135 mcg once weekly.
- In patients with neutropaenia and thrombocytopaenia, dose should be reduced in accordance with the datasheet quidelines.
- Pegylated Interferon-alfa 2a is not approved for use in children.

# **Urinary Tract Infections**

HEXAMINE HIPPURATE			
* Tab 1 g	18.40	100	
•	(40.01)		Hiprex
NITROFURANTOIN			
* Tab 50 mg	22.20	100	✓ Nifuran
* Tab 100 mg		100	✓ Nifuran
NORFLOXACIN			
Tab 400 mg - Subsidy by endorsement			

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

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Per ✓ Manufacturer  \$ Anticholinesterases	
\$ Per  ✓ Manufacturer	
Anticholinesterases	
Anticholinesterases	
Anticholinesterases	
NEOSTIGMINE METILSULFATE	
PYRIDOSTIGMINE BROMIDE	
▲ Tab 60 mg	
Non-Steroidal Anti-Inflammatory Drugs	
DIOLOFFINA CODILIA	
DICLOFENAC SODIUM	
<b>★</b> Tab EC 25 mg	)Z
<b>★</b> Tab 50 mg dispersible	
<b>★</b> Tab EC 50 mg	<u>)Z</u>
Tab long-acting 75 mg	
<b>★</b> Tab long-acting 100 mg	
* 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 mg	
<b>※</b> Suppos 100 mg7.00 10 <b>✓ Voltaren</b>	
IBUPROFEN	
* Tab 200 mg11.71 1,000 ✓ Relieve	
<b>★</b> Tab long-acting 800 mg	
* Oral lig 20 mg per ml	
2.39 ✓ Fenpaed	
•	
KETOPROFEN	
* Cap long-acting 200 mg         12.07         28         ✓ Oruvail SR	
MEFENAMIC ACID	
* Cap 250 mg	
(9.16) Ponstan	
0.50 20	
(5.60) Ponstan	
, ,	
NAPROXEN	
* Tab 250 mg	
<b>★</b> Tab 500 mg	
<b>★</b> Tab long-acting 750 mg	
<b>★</b> Tab long-acting 1 g	0
SULINDAC	
* Tab 100 mg8.55 50 ✓ Aclin	
* Tab 200 mg15.10 50 ✓ Aclin	
TENOXICAM	
<b>★</b> Tab 20 mg10.95 100 <b>✓ Tilcotil</b>	
<b>※</b> Inj 20 mg vial	
NSAIDs Other	
OF! FOOVID	
CELECOXIB	
Cap 100 mg	
✓ <u>Celecoxib Pfizer</u>	
Cap 200 mg	
(Celebrex Cap 100 mg to be delisted 1 September 2019)	

<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

# **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**

HYDROXYCHLOROQUINE  * Tab 200 mg	100	✓ <u>Plaquenil</u>
LEFLUNOMIDE		
Tab 10 mg2.90	30	✓ Apo-Leflunomide
Tab 20 mg2.90	30	✓ Apo-Leflunomide
PENICILLAMINE		
Tab 125 mg67.23	100	✓ D-Penamine
Tab 250 mg110.12	100	✓ D-Penamine
SODIUM AUROTHIOMALATE		
Inj 10 mg in 0.5 ml ampoule76.87	10	✓ Myocrisin
Inj 20 mg in 0.5 ml ampoule113.17	10	✓ Myocrisin
Inj 50 mg in 0.5 ml ampoule217.23	10	✓ Myocrisin

# **Drugs Affecting Bone Metabolism**

# Alendronate for Osteoporosis

ALENDOONATE CODILIN

* Tab 70 mg2.44	4	✓ Fosamax
Fosamax to be Sole Supply on 1 May 2019		
ALENDRONATE SODIUM WITH COLECALCIFEROL		
* Tab 70 mg with colecalciferol 5,600 iu1.51	4	Fosamax Plus
Fosamax Plus to be Sole Supply on 1 May 2019		

# **Alendronate for Paget's Disease**

# **⇒SA0949** Special Authority for Subsidy

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

- 1 Paget's disease; and
- 2 Any of the following:
  - 2.1 Bone or articular pain; or
  - 2.2 Bone deformity: or
  - 2.3 Bone, articular or neurological complications; or
  - 2.4 Asymptomatic disease, but risk of complications due to site (base of skull, spine, long bones of lower limbs); or
  - 2.5 Preparation for orthopaedic surgery.

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

### **Other Treatments**

DENOSUMAB – Special Authority see SA1777 below – Retail pharmacy
Inj 60 mg prefilled syringe.......326.00 1 ✓ Prolia

### ⇒SA1777 Special Authority for Subsidy

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

### All of the following:

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

#### Notes:

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

	Subsidy (Manufacturer's Price)	Su Per	Fully bsidised	Brand or Generic Manufacturer	
PAMIDRONATE DISODIUM					
Inj 3 mg per ml, 10 ml vial	5.98	1	<b>✓</b> <u>P</u>	Pamisol Pamisol	
Inj 6 mg per ml, 10 ml vial	15.02	1	<b>✓</b> P	Pamisol	
Inj 9 mg per ml, 10 ml vial		1	<b>✓</b> P	Pamisol	
RALOXIFENE HYDROCHLORIDE - Special Authority see SA17	79 below – Retail pha	armacv			
* Tab 60 mg		28	<b>√</b> E	Evista	

#### ⇒SA1779 Special Authority for Subsidy

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

Any of the following:

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

#### Notes:

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

RISEDRONATE SODIUM  Tab 35 mg	.3.80	4	✓ Risedronate Sandoz
TERIPARATIDE – Special Authority see SA1139 below – Retail pharma			
Inj 250 mcg per ml, 2.4 ml49	90.00	1	✓ Forteo

### 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

Subsic		Fully	Brand or
(Manufacture	r's Price) Subs	idised	Generic
\$	Per	1	Manufacturer

continued...

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

Ini 0.05 mg per ml. 100 ml. vial - Special Authority see

100 ml OP ✓ Aclasta

### **⇒SA1780** Special Authority for Subsidy

Initial application — (Paget's disease) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 Paget's disease; and
- 2 Any of the following:
  - 2.1 Bone or articular pain: or
  - 2.2 Bone deformity: or
  - 2.3 Bone, articular or neurological complications; or
  - 2.4 Asymptomatic disease, but risk of complications; or
  - 2.5 Preparation for orthopaedic surgery; and
- 3 The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period.

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

- 1 Any of the following:
  - 1.1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) greater than or equal to 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -2.5) (see Note); or
  - 1.2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
  - 1.3 History of two significant osteoporotic fractures demonstrated radiologically; or
  - 1.4 Documented T-Score less than or equal to -3.0 (see Note); or
  - 1.5 A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or
  - 1.6 Patient has had a Special Authority approval for alendronate (Underlying cause Osteoporosis) prior to 1 February 2019 or has had a Special Authority approval for raloxifene; and
- 2 The patient will not be prescribed more than 5 mg of zoledronic acid in a 12-month period.

Initial application — (Underlying cause - glucocorticosteroid therapy) from any relevant practitioner. Approvals valid for 1

Subsidy	F	ully	Brand or
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year for applications meeting the following criteria:

All of the following:

- 1 The patient is receiving systemic glucocorticosteroid therapy (greater than or equal to 5 mg per day prednisone equivalents) and has already received or is expected to receive therapy for at least three months; and
- 2 Any of the following:
  - 2.1 The patient has documented BMD greater than or equal to 1.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -1.5) (see Note); or
  - 2.2 The patient has a history of one significant osteoporotic fracture demonstrated radiologically; or
  - 2.3 The patient has had a Special Authority approval for alendronate (Underlying cause glucocorticosteroid therapy) prior to 1 February 2019 or has had a Special Authority approval for raloxifene; and
- 3 The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period.

Renewal — (Paget's disease) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 The patient has relapsed (based on increases in serum alkaline phosphatase); or
  - 1.2 The patient's serum alkaline phosphatase has not normalised following previous treatment with zoledronic acid; or
  - 1.3 Symptomatic disease (prescriber determined); and
- 2 The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period.

The patient must not have had more than 1 prior approval in the last 12 months.

Renewal — (Underlying cause was, and remains, glucocorticosteroid therapy) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria: Both:

- 1 The patient is continuing systemic glucocorticosteriod therapy (greater than or equal to 5 mg per day prednisone equivalents); and
- 2 The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period.

The patient must not have had more than 1 prior approval in the last 12 months.

Renewal — (Underlying cause was glucocorticosteroid therapy but patient now meets the 'Underlying cause osteoporosis' criteria) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) greater than or equal to 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -2.5) (see Note); or
  - 1.2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
  - 1.3 History of two significant osteoporotic fractures demonstrated radiologically; or
  - 1.4 Documented T-Score less than or equal to -3.0 (see Note); or
  - 1.5 A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or
  - 1.6 The patient has had a Special Authority approval for alendronate (Underlying was glucocorticosteroid therapy but patient now meets the 'Underlying cause - Osteoporosis' criteria) prior to 1 February 2019 or has had a Special Authority approval for raloxifene; and
- 2 The patient will not be prescribed more than 5 mg of zoledronic acid in a 12-month period.

Notes:

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

continued...

- a) BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA).
   Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.
- b) Evidence suggests that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score less than or equal to -2.5 and, therefore, do not require BMD measurement for treatment with bisphosphonates.
- c) Osteoporotic fractures are the incident events for severe (established) osteoporosis and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -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.

# Hyperuricaemia and Antigout

* Tab 100 mg	4.54	500	✓ <u>DP-Allopurinol</u>
* Tab 300 mg	10.35	500	✓ DP-Allopurinol
BENZBROMARONE - Special Authority see SA1537 below	- Retail pharmacy		
Tab 100 mg	45.00	100	<ul> <li>Benzbromaron AL</li> </ul>
			<b>100</b> S29

### ⇒SA1537 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 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 Both:
    - 2.3.1 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 Notes); and
    - 2.3.2 The patient has a rate of creatinine clearance greater than or equal to 20 ml/min; or
  - 2.4 All of the following:
    - 2.4.1 The patient is taking azathioprine and requires urate-lowering therapy; and
    - 2.4.2 Allopurinol is contraindicated; and
    - 2.4.3 Appropriate doses of probenecid are ineffective or probenecid cannot be used due to reduced renal function; and
- 3 The patient is receiving monthly liver function tests.

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

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Notes: Benzbromarone has been associated with potentially fatal hepatotoxicity.

In chronic renal insufficiency, particularly when the glomerular filtration rate is 30 ml/minute or less, probenecid may not be effective. Optimal treatment with allopurinol in patients with renal impairment is defined as treatment to the creatinine clearance-adjusted dose of allopurinol then, if serum urate remains greater than 0.36 mmol/l, a gradual increase of the dose of allopurinol to 600 mg or the maximum tolerated dose.

The New Zealand Rheumatology Association has developed information for prescribers which can be accessed from its website at www.rheumatology.org.nz/home/resources-2/

#### COLCHICINE

* Tab 500 mcg	9.58	100	✓ Colgout
FEBUXOSTAT - Special Authority see SA1538 below - Retail p	pharmacy		
Tab 80 mg	39.50	28	✓ Adenuric
Tab 120 mg	39.50	28	✓ Adenuric

### ⇒SA1538 Special Authority for Subsidy

Initial application 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).

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

Note: In chronic renal insufficiency, particularly when the glomerular filtration rate is 30 ml/minute or less, probenecid may not be effective. The efficacy and safety of febuxostat have not been fully evaluated in patients with severe renal impairment (creatinine clearance less than 30 ml/minute). No dosage adjustment of febuxostat is necessary in patients with mild or moderate renal impairment. Optimal treatment with allopurinol in patients with renal impairment is defined as treatment to the creatinine clearance-adjusted dose of allopurinol then, if serum urate remains greater than 0.36 mmol/l, a gradual increase of the dose of allopurinol to 600 mg or the maximum tolerated dose.

### **PROBENECID**

*	Tab 500 mg	55.00	100	✓ Probenecid-AFT
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### Muscle Relaxants

# BACLOFEN

ĸ	Tab 10 mg4.	20 100	✓ Pacifen	
	Inj 0.05 mg per ml, 1 ml ampoule - Subsidy by endorsement11.	55 1	✓ Lioresal	Intrathecal
	Subsidised only for use in a programmable pump in patients where	oral antispastic	agents have been in	neffective or have
	caused intolerable side effects and the prescription is endorsed ac	cordingly.		
	Ini 2 mg ner ml 5 ml amnoule – Subsidy by endorsement 372	98 5	✓ Medsura	Δ

74.60 (209.29)Lioresal Intrathecal

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

b) Medsurge to be Sole Supply on 1 July 2019

(Lioresal Intrathecal Inj 2 mg per ml, 5 ml ampoule to be delisted 1 July 2019)

/ Danifar

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Generic
DANTROLENE				
Cap 25 mg	65.00	100	✓	Dantrium
				Dantrium S29 S29
Cap 50 mg	77.00	100	/	Dantrium
ORPHENADRINE CITRATE Tab 100 mg	18.54	100	/	Norflex

Subsidy (Manufacturer's Price) Fully Subsidised Per

Brand or Generic Manufacturer

# **Agents for Parkinsonism and Related Disorders**

**Dopamine Agonists and Related Agents** 

AMANTADINE HYDROCHLORIDE  A Cap 100 mg38.24	60	✓ Symmetrel
APOMORPHINE HYDROCHLORIDE	00	· Cymmetrer
	5	✓ Movapo
▲ Inj 10 mg per ml, 2 ml ampoule119.00	5	♥ Movapo
BROMOCRIPTINE MESYLATE		
* Tab 2.5 mg32.08	100	Apo-Bromocriptine
ENTACAPONE		
▲ Tab 200 mg22.00	100	✓ Entapone
LEVODOPA WITH BENSERAZIDE		
* Tab dispersible 50 mg with benserazide 12.5 mg	100	✓ Madopar Rapid
* Cap 50 mg with benserazide 12.5 mg13.75	100	✓ Madopar 62.5
* Cap 100 mg with benserazide 25 mg	100	✓ Madopar 125
* Cap long-acting 100 mg with benserazide 25 mg22.85	100	✓ Madopar HBS
* Cap 200 mg with benserazide 50 mg26.25	100	✓ Madopar 250
LEVODOPA WITH CARBIDOPA		
* Tab 100 mg with carbidopa 25 mg	100	✓ Kinson
		✓ Sinemet
* Tab long-acting 200 mg with carbidopa 50 mg37.15	100	✓ Sinemet CR
* Tab 250 mg with carbidopa 25 mg	100	✓ Sinemet
(Kinson Tab 100 mg with carbidopa 25 mg to be delisted 1 June 2019)		<del></del>
PRAMIPEXOLE HYDROCHLORIDE		
▲ Tab 0.25 mg	100	✓ Ramipex
▲ Tab 1 mg	100	✓ Ramipex
ROPINIROLE HYDROCHLORIDE		<del></del>
▲ Tab 0.25 mg	100	✓ Apo-Ropinirole
▲ Tab 1 mg	100	✓ Apo-Ropinirole
▲ Tab 2 mg	100	✓ Apo-Ropinirole

Antichol	linergics
AIILICIIO	micigica

**TOLCAPONE** 

SELEGILINE HYDROCHLORIDE

BENZATROPINE MESYLATE			
Tab 2 mg	7.99	60	✓ Benztrop
Inj 1 mg per ml, 2 ml		5	✓ Cogentin
	190.00	10	✓ Omega
<ul><li>a) Up to 10 inj available on a PSO</li><li>b) Only on a PSO</li></ul>			•
PROCYCLIDINE HYDROCHLORIDE Tab 5 mg	7.40	100	✓ Kemadrin

▲ Tab 5 mg .......16.51

100

100

100

✓ Apo-Ropinirole

✓ Apo-Selegiline

S29 S29

✓ Tasmar

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

# Agents for Essential Tremor, Chorea and Related Disorders

RILUZOLE - Special Authority see SA1403 below - Retail pharmacy

Wastage claimable

### ⇒SA1403 Special Authority for Subsidy

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

### All of the following:

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

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

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

#### **TETRABENAZINE**

Tab 25 mg .......91.10 112 ✓ <u>Motetis</u>

### Anaesthetics

#### Local

#### LIDOCAINE [LIGNOCAINE]

- a) Up to 150 ml available on a PSO
- b) Subsidised only if prescribed for urethral or cervical administration and the prescription is endorsed accordingly.

Gel 2%, 10 ml urethral syringe — Subsidy by endorsement...............81.50 10 

Pfizer 
160.00 25 
Cathejell

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

	Subsidy (Manufacturer's Price \$	) Subs	Fully sidised	
LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE				
Oral (gel) soln 2%	38.00	200 ml	1	Mucosoothe
Inj 1%, 5 ml ampoule - Up to 25 inj available on a PSO	8.75	25	1	Lidocaine-Claris
	17.50	50		
	(35.00)			Xylocaine
Inj 2%, 5 ml ampoule - Up to 5 inj available on a PSO	6.75	25	1	Lidocaine-Claris
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 Lidocaine-Claris to be Sole Supply on 1 July 2019	6.20	5	•	Lidocaine-Claris
Inj 2%, 20 ml vial – Up to 5 inj available on a PSO Lidocaine-Claris to be Sole Supply on 1 July 2019	6.45	5	•	Lidocaine-Claris
LIDOCAINE [LIGNOCAINE] WITH CHLORHEXIDINE				
Gel 2% with chlorhexidine 0.05%, 10 ml urethral syringes –				
Subsidy by endorsement	81.50	10	✓	Pfizer
a) Up to 5 each available on a PSO				

# **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.

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

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

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

# **Analgesics**

For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, page 109

# Non-opioid Analgesics

For aspirin & chloroform application refer Standard Formulae, page 227

ASPI	RI	N
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\* Tab dispersible 300 mg - Up to 30 tab available on a PSO...............3.90 100 ✓ Ethics Aspirin CAPSAICIN - Subsidy by endorsement

Subsidised only if prescribed for post-herpetic neuralgia or diabetic peripheral neuropathy and the prescription is endorsed accordingly. 45 g OP ✓ Zostrix HP

NEFOPAM HYDROCHLORIDE

90 ✓ Acupan

		Subsidy		Fully	
		(Manufacturer's P		bsidised	
		\$	Per		Manufacturer
PAF	RACETAMOL				
	Tab 500 mg - blister pack		100		Priceline
		7.12	1,000	/	Paracetamol
					Pharmacare
					<u>Pharmacare</u>
				/	Pharmacy Health
	a) Maximum of 300 tab per prescription; can be waived	by endorsement			
	b) Up to 30 tab available on a PSO				
	<ul> <li>c)</li> <li>1) Subsidy by endorsement for higher quantities is</li> </ul>				
	supports a long-term condition.  2) Maximum of 100 tab per dispensing for non-end (for non-endorsed patients), then dispense in re	peat dispensing	not exceed	ing 100	tab per dispensing.
	Tab 500 mg - bottle pack		1,000		<u>Pharmacare</u>
*	Oral liq 120 mg per 5 ml	5.35	1,000 ml	/	<u>Paracare</u>
	<ul> <li>a) Up to 200 ml available on a PSO</li> </ul>				
	b) Not in combination			_	
K	Oral liq 250 mg per 5 ml	5.81	1,000 ml		Paracare Double
					Strength
	a) Up to 100 ml available on a PSO				
	b) Not in combination			_	_
	Suppos 125 mg		10		Gacet
	Suppos 250 mg		10		Gacet
*	Suppos 500 mg		50		Gacet
	Gacet to be Sole Supply on 1 May 2019	(12.60)			Paracare

(Priceline Tab 500 mg - blister pack to be delisted 1 August 2019) (Paracare Suppos 500 mg to be delisted 1 May 2019)

# **Opioid Analgesics**

CODEINE PHOSPHATE – Safety medicine; prescriber may	determine dispensing	frequency	
Tab 15 mg	5.75	100	✓ PSM
Tab 30 mg	6.80	100	✓ PSM
Tab 60 mg		100	✓ PSM
DIHYDROCODEINE TARTRATE			
Tab long-acting 60 mg	9.55	60	✓ DHC Continus
FENTANYL			
a) Only on a controlled drug form			
b) No patient co-payment payable			
c) Safety medicine; prescriber may determine dispensin	g frequency		
Inj 50 mcg per ml, 2 ml ampoule	3.56	10	✓ Boucher and Muir
Inj 50 mcg per ml, 10 ml ampoule	9.41	10	✓ Boucher and Muir
Patch 12.5 mcg per hour	2.95	5	✓ Fentanyl Sandoz
Patch 25 mcg per hour	3.66	5	✓ Fentanyl Sandoz
Patch 50 mcg per hour	6.65	5	✓ Fentanyl Sandoz
Patch 75 mcg per hour		5	✓ Fentanyl Sandoz
Patch 100 mcg per hour	11.40	5	✓ Fentanyl Sandoz

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	Subsidy		Fully	
	(Manufacturer's Price		Subsidised	
	\$	Per		Manufacturer
METHADONE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing free	auencv			
d) Extemporaneously compounded methadone will only be re	eimbursed at the ra	te of th	e cheapes	st form available
(methadone powder, not methadone tablets).				
e) For methadone hydrochloride oral liquid refer Standard Fo	rmulae, page 227			
Tab 5 mg		10	/	Methatabs
Oral lig 2 mg per ml		200 m		Biodone
Oral lig 5 mg per ml		200 m		Biodone Forte
Oral liq 10 mg per ml		200 m		Biodone Extra Forte
Inj 10 mg per ml, 1 ml		10		AFT
MORPHINE HYDROCHLORIDE				
a) Only on a controlled drug form     b) No neticet as payment payable.				
b) No patient co-payment payable	~			
Safety medicine; prescriber may determine dispensing fre- Oral lig 1 mg per ml		200 m		DA Marah
Oral liq 1 mg per ml		200 m	_	RA-Morph RA-Morph
Oral liq 5 mg per ml	19.44	200 m		Ordine \$29
•				RA-Morph
Oral liq 10 mg per ml	27.74	200 m		Ordine S29
			•	RA-Morph
MORPHINE SULPHATE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
<ul> <li>Safety medicine; prescriber may determine dispensing free</li> </ul>				
Tab immediate-release 10 mg		10		Sevredol
Tab long-acting 10 mg		10		Arrow-Morphine LA
Tab immediate-release 20 mg		10		Sevredol
Tab long-acting 30 mg		10		Arrow-Morphine LA
Tab long-acting 60 mg		10		Arrow-Morphine LA
Tab long-acting 100 mg	6.10	10		Arrow-Morphine LA
Cap long-acting 10 mg		10		m-Eslon
Cap long-acting 30 mg		10		m-Eslon
Cap long-acting 60 mg		10		m-Eslon
Cap long-acting 100 mg		10		m-Eslon
Inj 5 mg per ml, 1 ml ampoule – Up to 5 inj available on a PS	O6.27	5	•	DBL Morphine
		_		<u>Sulphate</u>
Inj 10 mg per ml, 1 ml ampoule – Up to 5 inj available on a P	SO 4.47	5	•	DBL Morphine
			_	<u>Sulphate</u>
Inj 15 mg per ml, 1 ml ampoule – Up to 5 inj available on a P	SO4.76	5	•	DBL Morphine
			_	<u>Sulphate</u>
Inj 30 mg per ml, 1 ml ampoule – Up to 5 inj available on a P	SO6.19	5	/	DBL Morphine
				<u>Sulphate</u>
MORPHINE TARTRATE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing free	quency			
Inj 80 mg per ml, 1.5 ml ampoule		5	1	DBL Morphine
				<u>Tartrate</u>

	Subsidy		Fully	
	(Manufacturer's Price) \$	Per	Subsidised	Generic Manufacturer
OXYCODONE HYDROCHLORIDE	<u> </u>			a.iaiaaia.o.
a) Only on a controlled drug form     b) No patient on payment payable				
b) No patient co-payment payable	fraguancy			
c) Safety medicine; prescriber may determine dispensing	requericy	00		Owner dama Candan
Tab controlled-release 5 mg		20		Oxycodone Sandoz
	2.63			BNM
Tab controlled-release 10 mg		20		Oxycodone Sandoz
	2.76		_	BNM
Tab controlled-release 20 mg		20		Oxycodone Sandoz
	4.72		/	BNM
Tab controlled-release 40 mg	3.20	20	✓	Oxycodone Sandoz
	7.69		✓	BNM
Tab controlled-release 80 mg	10.98	20	✓	Oxycodone Sandoz
-	14.11		✓	BNM
Cap immediate-release 5 mg	1.88	20	1	OxyNorm
Cap immediate-release 10 mg		20		OxyNorm
Cap immediate-release 20 mg		20		OxyNorm
Oral liq 5 mg per 5 ml		250 m		OxyNorm
Inj 10 mg per ml, 1 ml ampoule		5		OxyNorm
Inj 10 mg per ml, 2 ml ampoule		5		OxyNorm
Inj 50 mg per ml, 1 ml ampoule		5	_	OxyNorm
		-		
* Tab paracetamol 500 mg with codeine phosphate 8 mg		1,000		Paracetamol + Codeine (Relieve)
* Tab paracetamol 500 mg with codeine phosphate 8 mg PETHIDINE HYDROCHLORIDE				Paracetamol +
<ul> <li>Tab paracetamol 500 mg with codeine phosphate 8 mg</li> <li>PETHIDINE HYDROCHLORIDE         <ul> <li>a) Only on a controlled drug form</li> </ul> </li> </ul>				Paracetamol +
<ul> <li>Tab paracetamol 500 mg with codeine phosphate 8 mg</li> <li>PETHIDINE HYDROCHLORIDE         <ul> <li>a) Only on a controlled drug form</li> <li>b) No patient co-payment payable</li> </ul> </li> </ul>	18.21			Paracetamol +
<ul> <li>* Tab paracetamol 500 mg with codeine phosphate 8 mg</li> <li>PETHIDINE HYDROCHLORIDE         <ul> <li>a) Only on a controlled drug form</li> <li>b) No patient co-payment payable</li> <li>c) Safety medicine; prescriber may determine dispensing</li> </ul> </li> </ul>	frequency	1,000	•	Paracetamol + Codeine (Relieve)
* Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form  b) No patient co-payment payable  c) Safety medicine; prescriber may determine dispensing  Tab 50 mg	frequency4.46	1,000		Paracetamol + Codeine (Relieve)  PSM
<ul> <li>* Tab paracetamol 500 mg with codeine phosphate 8 mg</li> <li>PETHIDINE HYDROCHLORIDE         <ul> <li>a) Only on a controlled drug form</li> <li>b) No patient co-payment payable</li> <li>c) Safety medicine; prescriber may determine dispensing</li> </ul> </li> </ul>	frequency4.46	1,000		Paracetamol + Codeine (Relieve)  PSM DBL Pethidine
* Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency 4.46 a PSO4.98	1,000	<i>y</i>	Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride
* Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency 4.46 a PSO4.98	1,000	<i>y</i>	Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride DBL Pethidine
* Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency 4.46 a PSO4.98	1,000	<i>y</i>	Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride
* Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency 4.46 a PSO4.98 a PSO5.12	1,000	<i>y</i>	Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride DBL Pethidine
* Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency 4.46 a PSO4.98 a PSO5.12	1,000	<i>V</i>	Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride DBL Pethidine
* Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency 4.46 a PSO4.98 a PSO5.12	1,000 10 5 5		Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride DBL Pethidine Hydrochloride
* Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency 4.46 a PSO4.98 a PSO5.12	1,000 10 5 5		Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride DBL Pethidine Hydrochloride Tramal SR 100
Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency 	1,000 10 5 5 20 20 20		Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride DBL Pethidine Hydrochloride Tramal SR 100 Tramal SR 150 Tramal SR 200
Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency 	1,000 10 5 5 20 20		Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride DBL Pethidine Hydrochloride Tramal SR 100 Tramal SR 150
* Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency 	1,000 10 5 5 20 20 20		Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride DBL Pethidine Hydrochloride Tramal SR 100 Tramal SR 150 Tramal SR 200
Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency 	1,000 10 5 5 20 20 20		Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride DBL Pethidine Hydrochloride Tramal SR 100 Tramal SR 150 Tramal SR 200
* Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency 	1,000 10 5 5 20 20 20		Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride DBL Pethidine Hydrochloride Tramal SR 100 Tramal SR 150 Tramal SR 200
* Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency	1,000 10 5 5 20 20 20		Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride DBL Pethidine Hydrochloride  Tramal SR 100 Tramal SR 150 Tramal SR 200 Arrow-Tramadol
* Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency	1,000 10 5 5 20 20 20		Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride DBL Pethidine Hydrochloride Tramal SR 100 Tramal SR 150 Tramal SR 200
Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency	10 5 5 20 20 1000		Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride DBL Pethidine Hydrochloride  Tramal SR 100 Tramal SR 150 Tramal SR 200 Arrow-Tramadol
Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg Inj 50 mg per ml, 1 ml ampoule — Up to 5 inj available on a  Inj 50 mg per ml, 2 ml ampoule — Up to 5 inj available on a  IRAMADOL HYDROCHLORIDE Tab sustained-release 100 mg Tab sustained-release 150 mg Tab sustained-release 200 mg Cap 50 mg  Antidepressants  Cyclic and Related Agents  AMITRIPTYLINE — Safety medicine; prescriber may determine Tab 10 mg Tab 25 mg	frequency	10 5 5 20 20 100 100 100 100 100 100 100 100 1		Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride DBL Pethidine Hydrochloride  Tramal SR 100 Tramal SR 150 Tramal SR 200 Arrow-Tramadol  Arrow-Amitriptyline Arrow-Amitriptyline
Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency	1000 5 5 20 20 20 100 100 100 100		Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride DBL Pethidine Hydrochloride  Tramal SR 100 Tramal SR 150 Tramal SR 200 Arrow-Tramadol  Arrow-Amitriptyline Arrow-Amitriptyline Arrow-Amitriptyline
Tab paracetamol 500 mg with codeine phosphate 8 mg  PETHIDINE HYDROCHLORIDE  a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency	1,000 10 5 5 20 20 20 100 100 100 100 100 dispen	y y y y y y y y sing frequ	Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride DBL Pethidine Hydrochloride  Tramal SR 100 Tramal SR 150 Tramal SR 200 Arrow-Tramadol  Arrow-Amitriptyline Arrow-Amitriptyline Arrow-Amitriptyline ency
b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing Tab 50 mg	frequency	1000 5 5 20 20 20 100 100 100 100	y y y y y y y y y y y y y y y y y y y	Paracetamol + Codeine (Relieve)  PSM DBL Pethidine Hydrochloride DBL Pethidine Hydrochloride  Tramal SR 100 Tramal SR 150 Tramal SR 200 Arrow-Tramadol  Arrow-Amitriptyline Arrow-Amitriptyline Arrow-Amitriptyline

<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	
DOSULEPIN [DOTHIEPIN] HYDROCHLORIDE - Safety medic	ine; prescriber may de	eterm	ine dispen	sing frequency
Tab 75 mg		100	1	Dopress
Cap 25 mg	6.45	100	✓	Dopress
DOXEPIN HYDROCHLORIDE - Subsidy by endorsement				
a) Safety medicine; prescriber may determine dispensing fi	roguenov.			
		, , , , ,	hlavida nvi	ar to 1 March 2010 and the
b) Subsidy by endorsement – Subsidised for patients who				
prescription is endorsed accordingly. Pharmacists may	annotate the prescript	ion as	s endorsed	a where there exists a reco
of prior dispensing of doxepin hydrochloride.				
Cap 10 mg		100		Anten
Cap 25 mg	6.86	100		Anten
Cap 50 mg	8.55	100	✓	Anten
(Anten Cap 10 mg to be delisted 1 January 2020)				
Anten Cap 25 mg to be delisted 1 April 2020)				
Anten Cap 50 mg to be delisted 1 May 2020)				
, ,			,	
MIPRAMINE HYDROCHLORIDE – Safety medicine; prescribe				•
Tab 10 mg		50		Tofranil
	10.96	100		Tofranil
Tab 25 mg	8.80	50	✓	Tofranil
MAPROTILINE HYDROCHLORIDE - Safety medicine; prescrib	er may determine disi	oensi	na freauer	ncv
Tab 25 mg		30		Ludiomil
1 ab 25 mg	12.53	50		Ludiomil
	25.06	100		Ludiomil
Tab 75 mg		20		Ludiomil
Tab 75 mg				
	21.01	30		Ludiomil
NORTRIPTYLINE HYDROCHLORIDE - Safety medicine; preso	criber may determine of	dispe	nsing freq	uency
Tab 10 mg	3.22	100	✓	Norpress
Tab 25 mg	7.08	180	✓	Norpress
Monoamine-Oxidase Inhibitors (MAOIs) - Non S	Selective			
PHENELZINE SULPHATE				
* Tab 15 mg	110 00	100	_	Nardil
	110.00	100	•	Ivaluii
FRANYLCYPROMINE SULPHATE				
* Tab 10 mg	22.94	50	•	Parnate
Monoamine-Oxidase Type A Inhibitors				
MOCLOBEMIDE				
	6.40	60	.,	Aurorix
* Tab 150 mg		60	•	Aurorix
	53.33	500		
	(85.10)			Apo-Moclobemide
Aurorix to be Sole Supply on 1 July 2019				
* Tab 300 mg	9.80	60	✓	Aurorix
	16.33	100		
	(30.70)			Apo-Moclobemide
Aurorix to be Sole Supply on 1 July 2019	, ,			
'Apo-Moclobemide Tab 150 mg to be delisted 1 July 2019)				

	Subsidy (Manufacturer's Price) \$	Ful Subsidise Per •	
Selective Serotonin Reuptake Inhibitors			
CITALOPRAM HYDROBROMIDE  * Tab 20 mg	1.52	84	PSM Citalopram
* Tab 10 mg	1.11	28	Escitalopram- Apotex
* Tab 20 mg	1.90	28	Escitalopram- Apotex
FLUOXETINE HYDROCHLORIDE  * Tab dispersible 20 mg, scored – Subsidy by endorsement.  Subsidised by endorsement	2.47	30	Arrow-Fluoxetine
<ol> <li>When prescribed for a patient who cannot swallow accordingly; or</li> <li>When prescribed in a daily dose that is not a mult endorsed. Note: Tablets should be combined with</li> </ol>	iple of 20 mg in which	case the pres	cription is deemed to be
* Cap 20 mg	1.99	90	Arrow-Fluoxetine
* Tab 20 mg	4.02	90	Apo-Paroxetine
* Tab 50 mg * Tab 100 mg			Arrow-Sertraline Arrow-Sertraline
Other Antidepressants			
MIRTAZAPINE			Apo-Mirtazapine Apo-Mirtazapine
* Cap 37.5 mg			Enlafax XR
* Cap 150 mg			Enlafax XR Enlafax XR
Antiepilepsy Drugs			
Agents for Control of Status Epilepticus			
CLONAZEPAM – Safety medicine; prescriber may determine d Inj 1 mg per ml, 1 ml		5	' Rivotril
DIAZEPAM – Safety medicine; prescriber may determine dispe Inj 5 mg per ml, 2 ml ampoule – Subsidy by endorsement a) Up to 5 inj available on a PSO b) Only on a PSO c) PSO must be endorsed "not for anaesthetic proced	11.83	5	' Hospira
Rectal tubes 5 mg - Up to 5 tube available on a PSO	40.87		Stesolid
Rectal tubes 10 mg - Up to 5 tube available on a PSO PARALDEHYDE	40.87	5	Stesolid
* Inj 5 ml	1,500.00	5	AFT S29

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

	Subsidy		Fully	Brand or
	(Manufacturer's Price \$	e) Sub: Per	sidised •	Generic Manufacturer
PHENYTOIN SODIUM	<del>`</del>			
* Inj 50 mg per ml, 2 ml ampoule – Up to 5 inj available on a	PSO88.63	5	<b>✓</b> H	lospira
* Inj 50 mg per ml, 5 ml ampoule – Up to 5 inj available on a				
PSO		5	<b>✓</b> H	lospira
Control of Epilepsy				
CARBAMAZEPINE				
* Tab 200 mg	14.53	100	✓ T	egretol
* Tab long-acting 200 mg	16.98	100	<b>✓</b> T	egretol CR
* Tab 400 mg	34.58	100	<b>✓</b> T	egretol
* Tab long-acting 400 mg	39.17	100	<b>✓</b> T	egretol CR
* Oral liq 20 mg per ml	26.37	250 ml	<b>✓</b> T	egretol
CLOBAZAM - Safety medicine; prescriber may determine disp	ensina freauency			
Tab 10 mg		50	<b>√</b> F	risium
CLONAZEPAM – Safety medicine; prescriber may determine d				
Oral drops 2.5 mg per ml		10 ml OP	<b>√</b> F	Rivotril
	7.00	10 1111 01	• 1	iivoti ii
ETHOSUXIMIDE Con 250 mg	001.75	000	./ 7	arontin .
Cap 250 mg		200		aronun Zarontin
Oral liq 250 mg per 5 ml	50.35	200 ml	• 2	arontin
GABAPENTIN				
Note: Not subsidised in combination with subsidised prega				
* Cap 100 mg		100	_	Apo-Gabapentin
* Cap 300 mg		100	_	Apo-Gabapentin
* Cap 400 mg	5.64	100	✓ <u>A</u>	Apo-Gabapentin
LACOSAMIDE - Special Authority see SA1125 below - Retail	pharmacy			
▲ Tab 50 mg	25.04	14	✓ V	/impat
▲ Tab 100 mg	50.06	14	✓ V	/impat
	200.24	56		/impat
▲ Tab 150 mg		14		/impat
	300.40	56		/impat
▲ Tab 200 mg	400.55	56	✓ V	/impat

**⇒SA1125** 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 partial-onset 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: "Optimal treatment" is defined as treatment which is indicated and clinically appropriate for the patient, given in adequate doses for the patient's age, weight and other features affecting the pharmacokinetics of the drug with good evidence of compliance. Women of childbearing age are not required to have a trial of sodium valproate.

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

Note: As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anticonvulsant therapy and have assessed quality of life from the patient's perspective.

	Subsidy (Manufacturer's Pr	riaa)	Fully	
	(Manufacturer's Pi \$	rice) Per	Subsidised <	Manufacturer
AMOTRIGINE	<u> </u>			
Tab dispersible 2 mg	6.74	30	1	Lamictal
Tab dispersible 5 mg		30		Lamictal
t ab dioportion of my	15.00	56		Arrow-Lamotrigine
Tab dispersible 25 mg		56		Logem
Tab dioporoible 20 mg	20.40	00		Arrow-Lamotrigine
	29.09			Lamictal
Tab dispersible 50 mg		56		Logem
rab dispersible 50 mg	34.70	50		Arrow-Lamotrigine
	47.89			Lamictal
Tob dispersible 100 mg		EC		
Tab dispersible 100 mg		56		Logem
	59.90			Arrow-Lamotrigine
	79.16		•	Lamictal
EVETIRACETAM				
Tab 250 mg	24.03	60		Everet
Tab 500 mg	28.71	60	✓	Everet
Tab 750 mg	45.23	60	✓	Everet
Tab 1,000 mg	59.12	60	1	Everet
Oral liq 100 mg per ml	44.78	300 ml (	OP 🗸	Levetiracetam-AFT
HENOBARBITONE				
	2 2000 207			
For phenobarbitone oral liquid refer Standard Formulae		E00	./	PSM
← Tab 15 mg		500		
₹ Tab 30 mg	40.00	500	•	PSM
HENYTOIN SODIUM				
₹ Tab 50 mg	50.51	200	✓	Dilantin Infatab
Cap 30 mg	22.00	200	✓	Dilantin
Cap 100 mg	19.79	200	✓	Dilantin
Oral lig 30 mg per 5 ml		500 m	· •	Dilantin
REGABALIN				
Note: Not subsidised in combination with subsidised g	ahanantin			
Cap 25 mg	•	56	1	Pregabalin Pfizer
1 5		56		Pregabalin Pfizer
Cap 75 mg				
Cap 150 mg		56		Pregabalin Pfizer
Cap 300 mg		56	•	Pregabalin Pfizer
RIMIDONE				
₹ Tab 250 mg	17.25	100	✓	Apo-Primidone
	62.00	200	1	Mysoline S29 S29
ODIUM VALPROATE				•
Tab 100 mg	12.65	100	./	Enilim Cruchabla
•				Epilim Crushable
Tab 200 mg EC		100		Epilim
Tab 500 mg EC		100		Epilim
Oral liq 200 mg per 5 ml	20.48	300 m		Epilim S/F Liquid
				Epilim Syrup
f Inj 100 mg per ml, 4 ml	41.50	1	/	Epilim IV
TIRIPENTOL - Special Authority see SA1330 on the nex	t page – Retail pharma	CV		
Cap 250 mg		60	1	Diacomit \$29
-		60		Diacomit \$29
Powder for oral liq 250 mg sachet	509.29	UO	•	DIACOIIIII 258



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

## **⇒SA1330** Special Authority for Subsidy

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

Roth

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

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

#### **TOPIRAMATE**

	Tab 25 mg	11.07	60	✓ Arrow-Topiramate
	·			✓ Topiramate Actavis
		26.04		✓ Topamax
$\blacktriangle$	Tab 50 mg	18.81	60	Arrow-Topiramate
	v			✓ Topiramate Actavis
		44.26		✓ Topamax
$\blacktriangle$	Tab 100 mg	31.99	60	Arrow-Topiramate
				✓ Topiramate Actavis
		75.25		✓ Topamax
$\blacktriangle$	Tab 200 mg	55.19	60	Arrow-Topiramate
	3			✓ Topiramate Actavis
		129.85		✓ Topamax
$\blacktriangle$	Sprinkle cap 15 mg	20.84	60	✓ Topamax
$\blacktriangle$	Sprinkle cap 25 mg	26.04	60	✓ Topamax
VIC	GABATRIN - Special Authority see SA1072 below -	Retail pharmacy		
<b>_</b>	Tab 500 mg	119.30	100	✓ Sabril

### ⇒SA1072 Special Authority for Subsidy

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

- 1 Either:
  - 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; 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.

Notes: ``Optimal treatment with other antiepilepsy agents" is defined as treatment with other antiepilepsy agents which are indicated and clinically appropriate for the patient, given in adequate doses for the patient's age, weight, and other features affecting the pharmacokinetics of the drug with good evidence of compliance.

Vigabatrin is associated with a risk of irreversible visual field defects, which may be asymptomatic in the early stages. **Renewal** from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

			NER	VOUS SYSTEM
	Subsidy (Manufacturer's Price)	Subsi Per	Fully dised	Brand or Generic Manufacturer
continued Both:				
<ul><li>1 The patient has demonstrated a significant and sustained</li><li>2 Either:</li></ul>	improvement in seizu	ire rate or s	severity	y and or quality of life; and
2.1 Patient is receiving regular automated visual field t	testing (ideally every 6	6 months) o	on an c	ongoing basis for duration
of treatment with vigabatrin; or  2.2 It is impractical or impossible (due to comorbid cor	nditions) to monitor the	e natient's	visual f	fields
Notes: As a guideline, clinical trials have referred to a notional 5	,			
anticonvulsant therapy and have assessed quality of life from the			,	
Vigabatrin is associated with a risk of irreversible visual field defe	ects, which may be as	ymptomatio	c in the	e early stages.
Antimigraine Preparations				
For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, pa	age 109			
Acute Migraine Treatment				
ERGOTAMINE TARTRATE WITH CAFFEINE				
Tab 1 mg with caffeine 100 mg	31.00	100		afergot
			<b>√</b> C	afergot S29 S29
RIZATRIPTAN				
Tab orodispersible 10 mg	5.26	30	<b>✓</b> <u>R</u>	<u>izamelt</u>
SUMATRIPTAN	04.44	100		
Tab 100 mg		100 100		. <u>po-Sumatriptan</u> .po-Sumatriptan
Tab 100 mg		100	• <u>A</u>	po-oumanipian
prescription		2 OP	<b>✓</b> C	lustran
r ···· r··		-	✓ S	un Pharma S29

<b>Prophy</b>	laxis o	of Migraine
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For Beta Adrenoceptor Blockers refer to CARDIOVASCULAR SYSTEM, page 49

**PIZOTIFFN** 

\* Tab 500 mcg......23.21

✓ Sandomigran

100

✓ Sandomigran S29 S29

# **Antinausea and Vertigo Agents**

For Antispasmodics refer to ALIMENTARY TRACT, page 8

APREPITANT - Special Authority see SA0987 below - Retail pharmacy

Cap 2 × 80 mg and 1 × 125 mg......84.00

3 OP ✓ Emend Tri-Pack

# ⇒SA0987 Special Authority for Subsidy

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

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

#### BETAHISTINE DIHYDROCHLORIDE

✓ Vergo 16

	Subsidy (Manufacturer's Price)	Per	Fully Subsidised	
CYCLIZINE HYDROCHLORIDE				
Tab 50 mg	0.55	10	/	<u>Nausicalm</u>
CYCLIZINE LACTATE				
Inj 50 mg per ml, 1 ml	14.95	5	✓	Nausicalm
DOMPERIDONE				
* Tab 10 mg	2.25	100	1	Pharmacy Health
	(3.20)			Prokinex
Pharmacy Health to be Sole Supply on 1 June 2019				
(Prokinex Tab 10 mg to be delisted 1 June 2019)				
HYOSCINE HYDROBROMIDE				
* Inj 400 mcg per ml, 1 ml ampoule	46.50	5	✓	Hospira
	93.00	10	1	Martindale S29
Patch 1.5 mg - Special Authority see SA1387 below - Retai	il			
pharmacy	14.11	2	•	Scopoderm TTS

# ⇒SA1387 Special Authority for Subsidy

METACI ODDAMIDE LIVODOCI II ODIDE

**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.

ME *	Tab 10 mg1.30	100	✓ <u>Metoclopramide</u> Actavis 10
	Inj 5 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO 13.56 DANSETRON	10	✓ Pfizer
*	Tab 4 mg	50	✓ Apo-Ondansetron
*	Tab disp 4 mg	10	✓ Ondansetron ODT-ORLA
*	Tab 8 mg4.77	50	✓ Apo-Ondansetron
*	Tab disp 8 mg	10	✓ Ondansetron ODT-DRLA
PR	OCHLORPERAZINE		
*	Tab 3 mg buccal	50	
	(15.00)		Buccastem
*	Tab 5 mg - Up to 30 tab available on a PSO6.35	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 determin	e dispensing frequency	/	
Tab 100 mg	4.56	30	✓ Sulprix
Tab 200 mg	14.75	60	✓ Sulprix
Tab 400 mg	27.70	60	✓ Sulprix
Oral liq 100 mg per ml		60 ml	✓ Solian

	Subsidy		Fully Brand or
	(Manufacturer's Price) \$	Per	Subsidised Generic  Manufacturer
	*	rei	- IManulaciulei
ARIPIPRAZOLE – Safety medicine; prescriber may determine			
Tab 5 mg		30	✓ Aripiprazole Sando
Tab 10 mg		30	✓ Aripiprazole Sando
Tab 15 mg		30	✓ Aripiprazole Sando
Tab 20 mg		30	✓ Aripiprazole Sando
Tab 30 mg		30	<ul> <li>Aripiprazole Sando</li> </ul>
CHLORPROMAZINE HYDROCHLORIDE - Safety medicine; p		ne dis	
Tab 10 mg - Up to 30 tab available on a PSO		100	<ul><li>Largactil</li></ul>
Tab 25 mg - Up to 30 tab available on a PSO		100	✓ Largactil
Tab 100 mg - Up to 30 tab available on a PSO		100	✓ Largactil
Inj 25 mg per ml, 2 ml - Up to 5 inj available on a PSO	25.66	10	✓ Largactil
CLOZAPINE - Hospital pharmacy [HP4]			
Safety medicine; prescriber may determine dispensing frequency	uency		
Tab 25 mg	5.69	50	✓ Clozaril
	6.69		Clopine
	11.36	100	<ul><li>Clozaril</li></ul>
	13.37		Clopine
Tab 50 mg	8.67	50	Clopine
	17.33	100	Clopine
Tab 100 mg	14.73	50	Clozaril
	17.33		Clopine
	29.45	100	✓ Clozaril
	34.65		✓ Clopine
Tab 200 mg		50	✓ Clopine
	69.30	100	✓ Clopine
Suspension 50 mg per ml	17.33	100 m	nl Clopine
HALOPERIDOL - Safety medicine; prescriber may determine of	dispensing frequency		
Tab 500 mcg - Up to 30 tab available on a PSO		100	✓ Serenace
Tab 1.5 mg - Up to 30 tab available on a PSO		100	✓ Serenace
Tab 5 mg - Up to 30 tab available on a PSO		100	✓ Serenace
Oral liq 2 mg per ml — Up to 200 ml available on a PSO	23.84	100 m	<u></u>
Inj 5 mg per ml, 1 ml ampoule - Up to 5 inj available on a F	PSO21.55	10	✓ Serenace
LEVOMEPROMAZINE HYDROCHLORIDE - Safety medicine;	prescriber may detern	nine d	lispensing frequency
Inj 25 mg per ml, 1 ml ampoule	47.89	10	✓ Wockhardt
LEVOMEPROMAZINE MALEATE - Safety medicine; prescribe	er may determine dispe	ensino	a frequency
Tab 25 mg		100	✓ Nozinan
Tab 100 mg		100	✓ Nozinan
LITHIUM CARBONATE - Safety medicine; prescriber may dete		HODO	v.
Tab 250 mg		500	✓ Lithicarb FC
Tab long-acting 400 mg		100	✓ Priadel
Cap 250 mg		100	✓ Douglas
			2019.110
OLANZAPINE – Safety medicine; prescriber may determine dis		00	./ Zunina
Tab 2.5 mg		28	✓ Zypine ✓ Zypine
Tab orodispersible 5 mg		28 28	✓ Zypine ✓ Zypine ODT
Tab orodispersible 5 mg Tab 10 mg		28	✓ <u>Zypine ODT</u> ✓ Zypine
Tab orodispersible 10 mg		28	✓ <u>Zypine</u> ✓ Zypine ODT
rab orogispersible to my	2.00	20	▼ Zypine OD1

	Subsidy		Fully	Brand or
	(Manufacturer's Price)	_	Subsidised	
	\$	Per		Manufacturer
ERICYAZINE - Safety medicine; prescriber may determine dis	spensing frequency			
Tab 2.5 mg	10.49	84	✓	Neulactil
	12.49	100	1	Neulactil
Tab 10 mg	37.34	84	1	Neulactil
	44.45	100	✓	Neulactil
UETIAPINE - Safety medicine; prescriber may determine disp	ensina frequency			
Tab 25 mg	0 ,	90	1	Quetapel
Tab 100 mg		90	_	Quetapel
Tab 200 mg	5.75	90	1	Quetapel
Tab 300 mg	9.60	90	✓	Quetapel
ISPERIDONE - Safety medicine; prescriber may determine di	spensing frequency			
Tab 0.5 mg	, , ,	60	1	Actavis
Tab 1 mg		60	1	Actavis
Tab 2 mg		60	1	Actavis
Tab 3 mg		60	1	Actavis
Tab 4 mg	3.43	60	1	Actavis
Oral liq 1 mg per ml	7.66	30 m	· •	Risperon
IPRASIDONE - Safety medicine; prescriber may determine di	spensing frequency			
Cap 20 mg	,	60	1	Zusdone
Cap 40 mg		60	_	Zusdone
Cap 60 mg		60	_	Zusdone
Cap 80 mg		60	_	Zusdone
UCLOPENTHIXOL HYDROCHLORIDE - Safety medicine; pre		a die		
Tab 10 mg	•	100		Clopixol
- Tab 10 mg		100		Olopinol

# **Depot Injections**

FLUPENTHIXOL DECANOATE - Safety medicine; presi	, ,		'
Inj 20 mg per ml, 1 ml – Up to 5 inj available on a PS	6O13.14	5	✓ Fluanxol
Inj 20 mg per ml, 2 ml - Up to 5 inj available on a PS	SO20.90	5	✓ Fluanxol
Inj 100 mg per ml, 1 ml - Up to 5 inj available on a F	SO40.87	5	✓ Fluanxol
HALOPERIDOL DECANOATE - Safety medicine; presci	riber may determine disper	nsing frequ	iency
Inj 50 mg per ml, 1 ml - Up to 5 inj available on a PS	SO28.39	5	✓ Haldol
Inj 100 mg per ml, 1 ml - Up to 5 inj available on a F	SO55.90	5	✓ Haldol Concentrate
, , ,			✓ Haldol
			Decanoas \$29
OLANZAPINE - Special Authority see SA1428 below - F	Retail pharmacy		
Safety medicine; prescriber may determine dispensir	ng frequency		
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

**⇒SA1428** Special Authority for Subsidy

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

- 1 The patient has had an initial Special Authority approval for paliperidone depot injection or risperidone depot injection; or
- 2 All of the following:
  - 2.1 The patient has schizophrenia; and

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

- 2.2 The patient has tried but failed to comply with treatment using oral atypical antipsychotic agents; and
- 2.3 The patient has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in the last 12 months.

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

Note: The patient should be monitored for post-injection syndrome for at least two hours after each injection.

PALIPERIDONE - Special Authority see SA1429 below - Retail pharmacy

Safety medicine; prescriber may determine dispensing frequency

Inj 25 mg syringe	194.25	1	✓ Invega Sustenna
Inj 50 mg syringe	271.95	1	✓ Invega Sustenna
Inj 75 mg syringe	357.42	1	✓ Invega Sustenna
Inj 100 mg syringe	435.12	1	✓ Invega Sustenna
Inj 150 mg syringe	435.12	1	✓ Invega Sustenna

### ⇒SA1429 Special Authority for Subsidy

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

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

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

Note: Paliperidone depot injection should ideally be used as monotherapy (i.e. without concurrent use of any other antipsychotic medication). In some cases, it may be clinically appropriate to attempt to treat a patient with typical antipsychotic agents in depot injectable form before trialling paliperidone depot injection.

#### PIPOTHIAZINE PALMITATE - Subsidy by endorsement

- a) Safety medicine; prescriber may determine dispensing frequency
- b) Subsidised for patients who were taking pipothiazine palmitate prior to 1 August 2014 and the prescription or PSO is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of pipothiazine palmitate.

Inj 50 mg per ml, 1 ml	<ul> <li>Up to 5 inj available on a PSO</li> </ul>	178.48	10	Piportil
Inj 50 mg per ml, 2 ml	– Up to 5 inj available on a PSO	353.32	10	✓ Piportil

(Piportil Inj 50 mg per ml, 1 ml to be delisted 1 June 2019) (Piportil Inj 50 mg per ml, 2 ml to be delisted 1 June 2019)

RISPERIDONE - Special Authority see SA1427 below - Retail pharmacy

SPERIDONE – Special Authority see SA1427 below – Retail pharmac
Safety medicine: prescriber may determine dispensing frequency

Safety medicine, prescriber may determine dispensing ne	quency		
Inj 25 mg vial	135.98	1	Risperdal Consta
Inj 37.5 mg vial	178.71	1	✓ Risperdal Consta
Inj 50 mg vial		1	✓ Risperdal Consta

# **⇒SA1427** Special Authority for Subsidy

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

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

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

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

Note: Risperidone depot injection should ideally be used as monotherapy (i.e. without concurrent use of any other antipsychotic medication). In some cases, it may be clinically appropriate to attempt to treat a patient with typical antipsychotic agents in depot injection.

ZUCLOPENTHIXOL DECANOATE - Safety medicine; prescriber may determine dispensing frequency

Inj 200 mg per ml, 1 ml − Up to 5 inj available on a PSO.......19.80 5 Clopixol

# **Anxiolytics**

BUSPIRONE HYDROCHLORIDE		
* Tab 5 mg	100	✓ Orion
* Tab 10 mg13.16	100	✓ Orion
CLONAZEPAM - Safety medicine; prescriber may determine dispensing frequency		
Tab 500 mcg5.64	100	✓ Paxam
Tab 2 mg10.78	100	✓ Paxam
DIAZEPAM – Safety medicine; prescriber may determine dispensing frequency		
Tab 2 mg	500	✓ Arrow-Diazepam
Tab 5 mg16.18	500	✓ Arrow-Diazepam
LORAZEPAM – Safety medicine; prescriber may determine dispensing frequency		
Tab 1 mg	250	✓ Ativan
Tab 2.5 mg12.50	100	✓ Ativan
OXAZEPAM – Safety medicine; prescriber may determine dispensing frequency		
Tab 10 mg	100	✓ Ox-Pam
Tab 15 mg8.53	100	✓ Ox-Pam
•		

# **Multiple Sclerosis Treatments**

DIMETHYL FUMARATE - Special Authority see SA	1559 below – Retail pharmacy		
Wastage claimable			
Cap 120 mg	520.00	14	<ul><li>Tecfidera</li></ul>
Cap 240 mg	2,000.00	56	✓ Tecfidera

### ⇒SA1559 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

Notes: Special Authority approved by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (below).

Application details may be obtained from PHARMAC's website <a href="http://www.pharmac.govt.nz">http://www.pharmac.govt.nz</a> or:

Subsidy Fully (Manufacturer's Price) Subsidised Per

Brand or Generic Manufacturer

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The coordinator Phone: 04 460 4990

Multiple Sclerosis Treatment Assessment Committee Facsimile: 04 916 7571

PHARMAC PO Box 10 254 Email: mstaccoordinator@pharmac.govt.nz

Wellington

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

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

#### **Entry Criteria**

- a) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
- b) patients must have Clinically Definite Relapsing Remitting MS with or without underlying progression; and
- c) patients must have:
  - a) EDSS score 0 4.0 and:
    - Experienced at least 1 significant relapse of MS in the previous 12 months or 2 significant relapses in the
      past 24 months; and
    - Evidence of new inflammatory activity on an MR scan within the past 24 months, any of the following:
      - i) a gadolinium enhancing lesion; or
      - ii) a Diffusion Weighted Imaging positive lesion; or
      - iii) a T2 lesion with associated local swelling; or
      - iv) a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse; or v) new T2 lesions compared with a previous MR scan; and
- d) A significant relapse must:
  - a) be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
  - b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);
  - c) last at least one week:
  - d) start at least one month after the onset of a previous relapse;
  - e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least 1 point:
  - f) be distinguishable from the effects of general fatigue; and
  - g) not be associated with a fever (T> 37.5°C); and
- e) applications must be made by the patient's neurologist or general physician; and
- f) patients must have no previous history of lack of response to dimethyl fumarate; and
- g) patients must have not previously had intolerance to dimethyl fumarate; and
- h) patient must not be co-prescribed beta interferon or glatiramer acetate.

#### Stopping Criteria

### Any of the following:

- Confirmed progression of disability that is sustained for six months. Progression of disability is defined as progress by any
  of the following EDDSS points:
  - a) from starting at EDSS 0 increasing to (i.e. stopping on reaching) EDSS 3.0; or
  - b) 1.0 to 3.0; or
  - c) 1.5 to 3.5; or
  - d) 2.0 to 4.0; or
  - e) 2.5 to 4.5; or
  - f) 3.0 to 4.5; or



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

continued...

a) 3.5 to 4.5; or

- h) 4.0 to 4.5.
- 2) increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment)(see note); or
- 3) intolerance to dimethyl fumarate; or
- 4) non-compliance with treatment, including refusal to undergo annual assessment.

Note: Switching between natalizumab, fingolimod, dimethyl fumarate and teriflunomide is permitted provided the EDSS stopping criteria are not met. Switching to interferon or glatiramer acetate is only permitted provided the EDSS stopping criteria are not met and both fingolimod and natalizumab are either not tolerated or treatment with both agents would be clinically inappropriate. Continued relapses on treatment would be expected to lead to a switch of treatment provided the stopping criteria are not met. If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse for recovery to occur.

FINGOLIMOD - Special Authority see SA1562 below - Retail pharmacy

Wastage claimable

Cap 0.5 mg.......2,200.00 28 **✓ Gilenya** 

### ⇒SA1562 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

Notes: Special Authority approved by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (below).

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

The coordinator Phone: 04 460 4990

Multiple Sclerosis Treatment Assessment Committee Facsimile: 04 916 7571

PHARMAC PO Box 10 254 Email: mstaccoordinator@pharmac.govt.nz

Wellington

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

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

### **Entry Criteria**

- 1) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
- 2) patients must have Clinically Definite Relapsing Remitting MS with or without underlying progression; and
- 3) patients must have:
  - a) EDSS score 0 4.0 and:
    - Experienced at least 1 significant relapse of MS in the previous 12 months or 2 significant relapses in the
      past 24 months; and
    - Evidence of new inflammatory activity on an MR scan within the past 24 months, any of the following:
      - i) a gadolinium enhancing lesion; or
      - ii) a Diffusion Weighted Imaging positive lesion; or
      - iii) a T2 lesion with associated local swelling; or
      - iv) a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse; or
      - v) new T2 lesions compared with a previous MR scan; and
- 4) A significant relapse must:
  - a) be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
  - b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);

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

continued...

- c) last at least one week;
- d) start at least one month after the onset of a previous relapse;
- e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least 1 point;
- f) be distinguishable from the effects of general fatigue; and
- g) not be associated with a fever (T> 37.5°C); and
- 5) applications must be made by the patient's neurologist or general physician; and
- 6) patients must have no previous history of lack of response to fingolimod; and
- 7) patients must have not previously had intolerance to fingolimod; and
- 8) patient must not be co-prescribed beta interferon or glatiramer acetate.

### **Stopping Criteria**

# Any of the following:

- Confirmed progression of disability that is sustained for six months. Progression of disability is defined as progress by any
  of the following EDDSS points:
  - a) from starting at EDSS 0 increasing to (i.e. stopping on reaching) EDSS 3.0; or
  - b) 1.0 to 3.0; or
  - c) 1.5 to 3.5; or
  - d) 2.0 to 4.0; or
  - e) 2.5 to 4.5; or
  - f) 3.0 to 4.5; or
  - g) 3.5 to 4.5; or
  - h) 4.0 to 4.5.
- 2) increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment)(see note); or
- 3) intolerance to fingolimod; or
- 4) non-compliance with treatment, including refusal to undergo annual assessment.

Note: Switching between natalizumab, fingolimod, dimethyl fumarate and teriflunomide is permitted provided the EDSS stopping criteria are not met. Switching to interferon or glatiramer acetate is only permitted provided the EDSS stopping criteria are not met and both fingolimod and natalizumab are either not tolerated or treatment with both agents would be clinically inappropriate. Continued relapses on treatment would be expected to lead to a switch of treatment provided the stopping criteria are not met. If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse for recovery to occur.

NATALIZUMAB - Special Authority see SA1563 below - Retail pharmacy

### ⇒SA1563 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

Notes: Special Authority approved by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (below).

Application details may be obtained from PHARMAC's website <a href="http://www.pharmac.govt.nz">http://www.pharmac.govt.nz</a> or:

The coordinator Phone: 04 460 4990

Multiple Sclerosis Treatment Assessment Committee Facsimile: 04 916 7571

PHARMAC PO Box 10 254 Email: mstaccoordinator@pharmac.govt.nz

Wellington

Completed application forms must be sent to the coordinator for MSTAC and will be considered by MSTAC at the next practicable

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



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

#### **Entry Criteria**

- 1) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
- 2) patients must have Clinically Definite Relapsing Remitting MS with or without underlying progression; and
- 3) patients must have:
  - a) EDSS score 0 4.0 and:
    - Experienced at least 1 significant relapse of MS in the previous 12 months or 2 significant relapses in the past 24 months; and
    - Evidence of new inflammatory activity on an MR scan within the past 24 months, any of the following:
      - i) a gadolinium enhancing lesion; or
      - ii) a Diffusion Weighted Imaging positive lesion; or
      - iii) a T2 lesion with associated local swelling; or
      - iv) a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse; or
      - v) new T2 lesions compared with a previous MR scan; and
- 4) A significant relapse must:
  - a) be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria):
  - b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);
  - c) last at least one week;
  - d) start at least one month after the onset of a previous relapse;
  - e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least
  - f) be distinguishable from the effects of general fatigue; and
  - a) not be associated with a fever (T> 37.5°C); and
- 5) applications must be made by the patient's neurologist or general physician; and
- 6) treatment must be initiated and supervised by a neurologist who is registered in the Tysabri Australasian Prescribing Programme operated by the supplier; and
- 7) patients must have no previous history of lack of response to natalizumab; and
- 8) patients must have not previously had intolerance to natalizumab; and
- a) Patient is JC virus negative, or
  - b) Patient is JC virus positive and has given written informed consent acknowledging an understanding of the risk of progressive multifocal leucoencephalopathy (PML) associated with natalizumab
- 10) patient must not be co-prescribed beta interferon or glatiramer acetate.

#### Stopping Criteria

#### Any of the following:

- 1) Confirmed progression of disability that is sustained for six months. Progression of disability is defined as progress by any of the following EDDSS points:
  - a) from starting at EDSS 0 increasing to (i.e. stopping on reaching) EDSS 3.0; or
  - b) 1.0 to 3.0: or
  - c) 1.5 to 3.5; or
  - d) 2.0 to 4.0; or
  - e) 2.5 to 4.5; or
  - f) 3.0 to 4.5; or
  - g) 3.5 to 4.5; or
  - h) 4.0 to 4.5.
- 2) increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment)(see note); or

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

continued...

- 3) intolerance to natalizumab; or
- 4) non-compliance with treatment, including refusal to undergo annual assessment.

Note: Natalizumab can only be dispensed from a pharmacy registered in the Tysabri Australasian Prescribing Programme operated by the supplier.

Switching between natalizumab, fingolimod, dimethyl fumarate and teriflunomide is permitted provided the EDSS stopping criteria are not met. Switching to interferon or glatiramer acetate is only permitted provided the EDSS stopping criteria are not met and both fingolimod and natalizumab are either not tolerated or treatment with both agents would be clinically inappropriate.

Continued relapses on treatment would be expected to lead to a switch of treatment provided the stopping criteria are not met. If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse for recovery to occur.

TERIFLUNOMIDE - Special Authority see SA1560 below - Retail pharmacy

Wastage claimable

### ⇒SA1560 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

Notes: Special Authority approved by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (below).

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

The coordinator Phone: 04 460 4990

Multiple Sclerosis Treatment Assessment Committee Facsimile: 04 916 7571

PHARMAC PO Box 10 254 Email: mstaccoordinator@pharmac.govt.nz

Wellington

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

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

### **Entry Criteria**

- 1) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
- 2) patients must have Clinically Definite Relapsing Remitting MS with or without underlying progression; and
- 3) patients must have:
  - a) EDSS score 0 4.0 and:
    - Experienced at least 1 significant relapse of MS in the previous 12 months or 2 significant relapses in the past 24 months; and
    - Evidence of new inflammatory activity on an MR scan within the past 24 months, any of the following:
      - i) a gadolinium enhancing lesion; or
      - ii) a Diffusion Weighted Imaging positive lesion; or
      - iii) a T2 lesion with associated local swelling; or
      - iv) a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse; or
      - v) new T2 lesions compared with a previous MR scan; and
- 4) A significant relapse must:
  - a) be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
  - b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);
  - c) last at least one week;



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

- d) start at least one month after the onset of a previous relapse;
- e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least 1 point:
- f) be distinguishable from the effects of general fatigue; and
- g) not be associated with a fever (T> 37.5°C); and
- 5) applications must be made by the patient's neurologist or general physician; and
- 6) patients must have no previous history of lack of response to teriflunomide; and
- 7) patients must have not previously had intolerance to teriflunomide; and
- 8) patient must not be co-prescribed beta interferon or glatinamer acetate.

# **Stopping Criteria**

### Any of the following:

- 1) Confirmed progression of disability that is sustained for six months. Progression of disability is defined as progress by any of the following EDDSS points:
  - a) from starting at EDSS 0 increasing to (i.e. stopping on reaching) EDSS 3.0; or
  - b) 1.0 to 3.0; or
  - c) 1.5 to 3.5: or
  - d) 2.0 to 4.0; or
  - e) 2.5 to 4.5; or
  - f) 3.0 to 4.5; or
  - a) 3.5 to 4.5; or
  - h) 4.0 to 4.5.
- 2) increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment)(see note); or
- 3) intolerance to teriflunomide; or
- 4) non-compliance with treatment, including refusal to undergo annual assessment.

Note: Switching between natalizumab, fingolimod, dimethyl fumarate and teriflunomide is permitted provided the EDSS stopping criteria are not met. Switching to interferon or glatiramer acetate is only permitted provided the EDSS stopping criteria are not met and both fingolimod and natalizumab are either not tolerated or treatment with both agents would be clinically inappropriate. Continued relapses on treatment would be expected to lead to a switch of treatment provided the stopping criteria are not met. If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse for recovery to occur.

# Other Multiple Sclerosis Treatments

### ⇒SA1564 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

Notes: Special Authority approved by the Multiple Sclerosis Treatment Assessment Committee (MSTAC), Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria

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

The coordinator Phone: 04 460 4990 Multiple Sclerosis Treatment Assessment Committee Facsimile: 04 916 7571

PHARMAC PO Box 10 254 Email: mstaccoordinator@pharmac.govt.nz

Wellington

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

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

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

Only glatiramer acetate inj 40 mg prefilled syringe will be subsidised if dispensed in a community pharmacy. The other agents will NOT be subsidised if dispensed from a community or hospital pharmacy. Regular supplies will be distributed to all approved patients or their clinicians by courier.

Prescribers must send quarterly prescriptions for approved patients to the MSTAC coordinator.

Only prescriptions for 6 million iu of interferon beta-1-alpha per week, or 8 million iu of interferon beta-1-beta every other day, 20 mg glatiramer acetate daily or 40 mg glatiramer acetate 3 times weekly will be subsidised.

Switching between treatments is permitted within the 12 month approval period without reapproval by MSTAC. The MSTAC coordinator should be notified of the change and a new prescription provided.

# **Entry Criteria**

- 1) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
- 2) patients must have Clinically Definite Relapsing Remitting MS with or without underlying progression; and
- 3) patients must have:
  - a) EDSS score 0 4.0 and:
    - Experienced at least 1 significant relapse of MS in the previous 12 months or 2 significant relapses in the past 24 months; and
    - Evidence of new inflammatory activity on an MR scan within the past 24 months, any of the following:
      - i) a gadolinium enhancing lesion; or
      - ii) a Diffusion Weighted Imaging positive lesion; or
      - iii) a T2 lesion with associated local swelling; or
      - iv) a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse; or
      - v) new T2 lesions compared with a previous MR scan; and
- 4) A significant relapse must:
  - a) be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
  - b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);
  - c) last at least one week;
  - d) start at least one month after the onset of a previous relapse;
  - e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least 1 point:
  - f) be distinguishable from the effects of general fatigue; and
  - a) not be associated with a fever (T> 37.5°C); and
- 5) applications must be made by the patient's neurologist; and
- 6) patients must have no previous history of lack of response to beta-interferon or glatiramer acetate; and
- 7) patients must have either:
  - a) intolerance to both natalizumab and fingolimod; or
  - b) treatment with both natalizumab and fingolimod is considered clinically inappropriate; and
- 8) patient will not be co-prescribed natalizumab or fingolimod.

### Stopping Criteria

#### Any of the following:

- 1) Confirmed progression of disability that is sustained for six months during a minimum of one year of treatment. Progression of disability is defined as progress by any of the following EDDSS Points:
  - a) from starting at EDSS 0 increasing to (i.e. stopping on reaching) EDSS 3.0; or
  - b) 1.0 to 3.0: or
  - c) 1.5 to 3.5; or

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

- d) 2.0 to 4.0; or
- e) 2.5 to 4.5; or
- f) 3.0 to 4.5; or
- g) 3.5 to 4.5; or
- h) 4.0 to 4.5.
- increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment)(see note); or
- 3) intolerance to interferon beta-1-alpha, and/or interferon beta-1-beta and/or glatiramer acetate; or
- 4) non-compliance with treatment, including refusal to undergo annual assessment.

Note: Treatment with interferon beta -1-beta, interferon beta-1-alpha and glatiramer acetate, is permitted only if treatment with both natalizumab and fingolimod is not tolerated or treatment with both would be clinically inappropriate. Beta-interferon or glatiramer acetate will not be funded as second line treatments if EDSS progression has occurred on treatment with natalizumab or fingolimod. Patients who have an increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment) and who do not meet the EDSS Stopping Criteria at annual review may switch from either of the beta-interferon's [interferon beta-1-beta or interferon beta-1-alpha] to glatiramer acetate or vice versa. Patients may switch from either of the beta-interferon's [interferon beta-1-beta or interferon beta-1-alpha] to glatiramer acetate or vice versa for increased relapses only once, after which they will be required to stop funded treatment if they meet any of the Stopping Criteria at annual review (including the criterion relating to increasing relapse rate over 12 months of treatment). If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse for recovery to occur. In this setting anti-JCV antibody positive status may be accepted as a clinically inappropriate reason for treatment with natalizumab.

GLATIRAMER ACETATE – Special Authority see SA1564	on page 140 – Retail pr	narmacy	
Inj 20 mg prefilled syringe - [Xpharm]	2,250.00	28	Copaxone
Inj 40 mg prefilled syringe - No patient co-payment pa	yable2,275.00	12	Copaxone
(Copaxone Inj 20 mg prefilled syringe to be delisted 1 July 2	2019)		
INTERFERON BETA-1-ALPHA - [Xpharm] - Special Author	ority see SA1564 on pag	ge 140	
Inj 6 million iu prefilled syringe	1,170.00	4	✓ Avonex
Injection 6 million iu per 0.5 ml pen injector		4	Avonex Pen
INTERFERON BETA-1-BETA - [Xpharm] - Special Author	ity see SA1564 on page	140	
Inj 8 million iu per 1 ml	1,322.89	15	Betaferon

# **Sedatives and Hypnotics**

0 ✓ Circadin

#### ⇒SA1666 Special Authority for Subsidy

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

All of the following:

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

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

Subsidy (Manufacturer's Price \$	e) Per	Fully Subsidised	Brand or Generic Manufacturer	
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## All of the following:

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

Note: Indications marked with \* are unapproved indications.

MIDAZOLAM - Safety medicine; prescriber may determine dispensing frequen	су	
Inj 1 mg per ml, 5 ml ampoule4.30	10	Midazolam-Claris
Inj 1 mg per ml, 5 ml plastic ampoule - Up to 10 inj available		
on a PSO14.90	10	✓ Pfizer
On a PSO for status epilepticus use only. PSO must be endorsed for s	status epilepticu	ıs use only.
Inj 5 mg per ml, 3 ml ampoule2.50	5	Midazolam-Claris
Inj 5 mg per ml, 3 ml plastic ampoule — Up to 5 inj available on		
a PSO11.90	5	✓ Pfizer
On a PSO for status epilepticus use only. PSO must be endorsed for s	status epilepticu	ıs use only.
NITRAZEPAM - Safety medicine; prescriber may determine dispensing freque	ncv	
Tab 5 mg5.22	100	✓ Nitrados
PHENOBARBITONE SODIUM - Special Authority see SA1386 below - Retail	pharmacy	
Inj 200 mg per ml, 1 ml ampoule30.00	5	✓ Aspen S29
46.20	10	✓ Martindale \$29

(Martindale \$29 Inj 200 mg per ml, 1 ml ampoule to be delisted 1 June 2019)

# ⇒SA1386 Special Authority for Subsidy

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

### Both:

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

TEMAZEPAM – Safety medicine; prescriber may determine dispe	ensing frequency		
Tab 10 mg	1.27	25	✓ <u>Normison</u>
TRIAZOLAM - Safety medicine; prescriber may determine disper	nsing frequency		
Tab 125 mcg	5.10	100	
•	(9.85)		Hypam
Tab 250 mcg	4.10	100	••
,	(11.20)		Hypam
ZOPICLONE - Safety medicine; prescriber may determine disper	nsing frequency		
Tab 7.5 mg	9.56	500	✓ Zopiclone Actavis

# Stimulants/ADHD Treatments

ATOMOXETINE - Special Authority see SA1416 on the	next page - Retail pharma	су	
Cap 10 mg	107.03	28	✓ Strattera
Cap 18 mg	107.03	28	✓ Strattera
Cap 25 mg	107.03	28	✓ Strattera
Cap 40 mg	107.03	28	✓ Strattera
Cap 60 mg	107.03	28	✓ Strattera
Cap 80 mg	139.11	28	✓ Strattera
Cap 100 mg	139.11	28	✓ Strattera

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

### ⇒SA1416 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 ADHD (Attention Deficit and Hyperactivity Disorder) diagnosed according to DSM-IV or ICD 10 criteria; and
- 2 Once-daily dosing; and
- 3 Any of the following:
  - 3.1 Treatment with a subsidised formulation of a stimulant has resulted in the development or worsening of serious adverse reactions or where the combination of subsidised stimulant treatment with another agent would pose an unacceptable medical risk; or
  - 3.2 Treatment with a subsidised formulation of a stimulant has resulted in worsening of co-morbid substance abuse or there is a significant risk of diversion with subsidised stimulant therapy; or
  - 3.3 An effective dose of a subsidised formulation of a stimulant has been trialled and has been discontinued because of inadequate clinical response; or
  - 3.4 Treatment with a subsidised formulation of a stimulant is considered inappropriate because the patient has a history of psychoses or has a first-degree relative with schizophrenia; and
- 4 The patient will not be receiving treatment with atomoxetine in combination with a subsidised formulation of a stimulant, except for the purposes of transitioning from subsidised stimulant therapy to atomoxetine.

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

Note: A "subsidised formulation of a stimulant" refers to currently subsidised methylphenidate hydrochloride tablet formulations (immediate-release, sustained-release and extended-release) or dexamfetamine sulphate tablets.

DEXAMFETAMINE SULFATE - Special Authority see SA1149 below - Retail pharmacy

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

# ⇒SA1149 Special Authority for Subsidy

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

All of the following:

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

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

Both:

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

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

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

Both:

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

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

continued...

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

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

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

METHYLPHENIDATE HYDROCHLORIDE - Special Authority see SA1150 below - Retail pharmacy

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

b) Galety medianic, presented may determine dispen	oning in equently		
Tab immediate-release 5 mg	3.20	30	Rubifen
Tab immediate-release 10 mg		30	Ritalin
•			<ul><li>Rubifen</li></ul>
Tab immediate-release 20 mg	7.85	30	<ul><li>Rubifen</li></ul>
Tab sustained-release 20 mg		30	Rubifen SR
v	50.00	100	Ritalin SR

#### ⇒SA1150 Special Authority for Subsidy

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

All of the following:

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

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

Both:

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

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

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

Both:

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

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

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



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

METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE - Special Authority see SA1151 below - Retail pharmacy

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

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

#### ⇒SA1151 Special Authority for Subsidy

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

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

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

Both:

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

#### ⇒SA1126 Special Authority for Subsidy

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

All of the following:

- 1 The patient has a diagnosis of narcolepsy and has excessive daytime sleepiness associated with narcolepsy occurring almost daily for three months or more; and
- 2 Either:
  - 2.1 The patient has a multiple sleep latency test with a mean sleep latency of less than or equal to 10 minutes and 2 or more sleep onset rapid eye movement periods; or
  - 2.2 The patient has at least one of: cataplexy, sleep paralysis or hypnagogic hallucinations; and
- 3 Fither:

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

continued...

- 3.1 An effective dose of a subsidised formulation of methylphenidate or dexamfetamine has been trialled and discontinued because of intolerable side effects; or
- 3.2 Methylphenidate and dexamfetamine are contraindicated.

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

#### Treatments for Dementia

DONEPEZIL HYDROCHLORIDE	
<b>★</b> Tab 5 mg	Donepezil-Rex
<b>★</b> Tab 10 mg	Donepezil-Rex
RIVASTIGMINE - Special Authority see SA1488 below - Retail pharmacy	
Patch 4.6 mg per 24 hour	Exelon
	Exelon

#### **⇒SA1488** Special Authority for Subsidy

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

- 1 The patient has been diagnosed with dementia; and
- 2 The patient has experienced intolerable nausea and/or vomiting from donepezil tablets.

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

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

# **Treatments for Substance Dependence**

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

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

✓ Suboxone	28	57.40	Tab sublingual 2 mg with naloxone 0.5 mg
✓ Suboxone	28	166.00	Tab sublingual 8 mg with naloxone 2 mg

#### ⇒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



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

continued...

criteria:

All of the following:

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

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

All of the following:

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

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

All of the following:

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

BUPROPION HYDROCHLORIDE			
Tab modified-release 150 mg	11.00	30	✓ Zyban
DISULFIRAM			
Tab 200 mg	75.57	100	Antabuse
NALTREXONE HYDROCHLORIDE - Special Authority see SA1408	oelow – Retail ph	narmacy	
Tab 50 mg	.112.55	30	✓ Naltraccord

#### ⇒SA1408 Special Authority for Subsidy

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

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

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

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

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

#### NICOTINE

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

b) Note. Direct i lovision by a pharmacist permitted under the provisions		JULIOTI A.
Patch 7 mg - Up to 28 patch available on a PSO16.00	28	✓ <u>Habitrol</u>
Patch 7 mg for direct distribution only - [Xpharm]3.94	7	✓ <u>Habitrol</u>
Patch 14 mg - Up to 28 patch available on a PSO17.59	28	✓ <u>Habitrol</u>
Patch 14 mg for direct distribution only - [Xpharm]4.52	7	✓ <u>Habitrol</u>
Patch 21 mg - Up to 28 patch available on a PSO20.16	28	✓ <u>Habitrol</u>
Patch 21 mg for direct distribution only - [Xpharm]5.18	7	✓ Habitrol
Lozenge 1 mg - Up to 216 loz available on a PSO16.61	216	✓ Habitrol
Lozenge 1 mg for direct distribution only - [Xpharm]3.20	36	✓ Habitrol
Lozenge 2 mg - Up to 216 loz available on a PSO18.20	216	✓ Habitrol
Lozenge 2 mg for direct distribution only - [Xpharm]3.24	36	✓ Habitrol
Gum 2 mg (Fruit) - Up to 384 piece available on a PSO33.69	384	✓ Habitrol
Gum 2 mg (Fruit) for direct distribution only - [Xpharm]8.64	96	✓ Habitrol
Gum 2 mg (Mint) - Up to 384 piece available on a PSO33.69	384	✓ <u>Habitrol</u>
Gum 2 mg (Mint) for direct distribution only - [Xpharm]8.64	96	✓ <u>Habitrol</u>
Gum 4 mg (Fruit) - Up to 384 piece available on a PSO38.95	384	✓ <u>Habitrol</u>
Gum 4 mg (Fruit) for direct distribution only - [Xpharm]10.01	96	✓ <u>Habitrol</u>
Gum 4 mg (Mint) - Up to 384 piece available on a PSO38.95	384	✓ <u>Habitrol</u>
Gum 4 mg (Mint) for direct distribution only - [Xpharm]10.01	96	✓ Habitrol

VARENICLINE TARTRATE - Special Authority see SA1771 below - Retail pharmacy

a) A maximum of 12 weeks' varenicline will be subsidised on each Special Authority approval, including the starter pack

b) Varenicline will not be funded in amounts less than 4 weeks of treatment.

by varoniomic vim not be landed in amounte lees than 1 week	one or troutinoint.		
Tab 0.5 mg × 11 and 1 mg × 42	25.64	53 OP	✓ Varenicline Pfizer
Varenicline Pfizer to be Sole Supply on 1 June 2019			
Tab 1 mg	27.10	56	✓ Varenicline Pfizer
•	13.55	28	
	(67.74)		Champix
	27.10	56	•
	(135.48)		Champix
Varenicline Pfizer to be Sole Supply on 1 June 2019	, ,		·
Tab 0.5 mg × 11 and 1 mg × 14	12.09	25 OP	
-	(60.48)		Champix

(Champix Tab 1 mg to be delisted 1 June 2019)

(Champix Tab 1 mg to be delisted 1 June 2019)

(Champix Tab 0.5 mg  $\times$  11 and 1 mg  $\times$  14 to be delisted 1 June 2019)

#### ⇒SA1771 Special Authority for Subsidy

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

- 1 Short-term therapy as an aid to achieving abstinence in a patient who has indicated that they are ready to cease smoking;
- 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



Subs (Manufactur		
\$	Per	Manufacturer

continued...

- 3.2 The patient has tried but failed to quit smoking using bupropion or nortriptyline; and
- 4 The patient has not used funded varenicline in the last 12 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 The patient has not used funded varenicline in the last 12 months; 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 12 months.

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

This includes the 4-week 'starter' pack.

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

# **Chemotherapeutic Agents**

# Alkylating Agents

BENDAMUSTINE HYDROCHLORIDE - PCT only - Specialist - Special Authority see SA1667 below

Inj 25 mg vial	271.35	1	✓ Ribomustin
Inj 100 mg vial	1,085.38	1	✓ Ribomustin
Inj 1 mg for ECP	11.40	1 mg	✓ Baxter

#### ⇒SA1667 Special Authority for Subsidy

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

All of the following:

- 1 The patient has Binet stage B or C, or progressive stage A chronic lymphocytic leukaemia requiring treatment; and
- 2 The patient is chemotherapy treatment naive; and
- 3 The patient is unable to tolerate toxicity of full-dose FCR; and
- 4 Patient has ECOG performance status 0-2; and
- 5 Patient has a Cumulative Illness Rating Scale (CIRS) score of < 6; and
- 6 Bendamustine is to be administered at a maximum dose of 100 mg/m² on days 1 and 2 every 4 weeks for a maximum of 6 cycles.

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

Initial application — (Indolent, Low-grade lymphomas) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria: All of the following:

- 1 The patient has indolent low grade NHL requiring treatment; and
- 2 Patient has a WHO performance status of 0-2; and
- 3 Either:
  - 3.1 Both:
    - 3.1.1 Patient is treatment naive; and
    - 3.1.2 Bendamustine is to be administered for a maximum of 6 cycles (in combination with rituximab when CD20+); or
  - 3.2 All of the following:
    - 3.2.1 Patient has relapsed refractory disease following prior chemotherapy; and
    - 3.2.2 The patient has not received prior bendamustine therapy; and
    - 3.2.3 Fither:
      - 3.2.3.1 Both:
        - 3.2.3.1.1 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and
        - 3.2.3.1.2 Patient has had a rituximab treatment-free interval of 12 months or more: or
      - 3.2.3.2 Bendamustine is to be administered as a monotherapy for a maximum of 6 cycles in rituximab refractory patients.

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

Both:

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

Subsi	idy	Fully Bra	nd or
(Manufacture	er's Price) Subs	sidised Ger	neric
\$	Per	✓ Mai	nufacturer

- 2.1.1 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and
- 2.1.2 Patient has had a rituximab treatment-free interval of 12 months or more; or
- 2.2 Bendamustine is to be administered as a monotherapy for a maximum of 6 cycles in rituximab refractory patients.
  Note: 'indolent, low-grade lymphomas' includes follicular, mantle cell, marginal zone and lymphoplasmacytic/ Waldenstrom's macroglobulinaemia.

BUSULFAN - PCT - Retail pharmacy-Specialist			
Tab 2 mg	89.25	100	✓ Myleran
CARBOPLATIN - PCT only - Specialist			
Inj 10 mg per ml, 45 ml vial	32.59	1	<ul> <li>DBL Carboplatin</li> </ul>
	45.20		Carboplatin Ebewe
	48.50		<ul> <li>Carbaccord</li> </ul>
Inj 1 mg for ECP	0.08	1 mg	✓ Baxter
CARMUSTINE - PCT only - Specialist			
Inj 100 mg vial	532.00	1	✓ BiCNU
,	1.380.00		✓ Emcure \$29
Inj 100 mg for ECP	1,380.00	100 mg OP	✓ Baxter
(BiCNU Inj 100 mg vial to be delisted 1 July 2019)	,	3 -	
CHLORAMBUCIL - PCT - Retail pharmacy-Specialist			
Tab 2 mg	29.06	25	✓ Leukeran FC
CISPLATIN - PCT only - Specialist			
Inj 1 mg per ml, 50 ml vial	12 29	1	✓ DBL Cisplatin
ing i mg por mi, oo mi vidi	15.00	•	✓ Cisplatin Ebewe
Inj 1 mg per ml, 100 ml vial		1	✓ DBL Cisplatin
., ,	21.00	·	✓ Cisplatin Ebewe
Inj 1 mg for ECP		1 mg	✓ Baxter
CYCLOPHOSPHAMIDE		J	
Tab 50 mg - PCT - Retail pharmacy-Specialist	70.00	50	✓ Endoxan S29
rab 50 mg 1 01 Hetali phamacy opecialist	158.00	100	✓ Procytox S29
Wastage claimable	156.00	100	♥ Procylox 329
Inj 1 g vial – PCT – Retail pharmacy-Specialist	35.65	1	✓ Endoxan
inj i g viai – i o i – netali pharmacy-opecialist	127.80	6	✓ Cytoxan
Inj 2 g vial - PCT only - Specialist		1	✓ Endoxan
Inj 1 mg for ECP – PCT only – Specialist		1 mg	✓ Baxter
IFOSFAMIDE – PCT only – Specialist		9	- Duxtor
Inj 1 g	06.00	1	✓ Holoxan
Inj 2 g		1	✓ Holoxan
Inj 1 mg for ECP		1 mg	✓ Baxter
	0.10	ring	▼ Daxtel
LOMUSTINE – PCT – Retail pharmacy-Specialist	100.50	00	✓ OneAllI
Cap 10 mg		20	✓ CeeNU
Cap 40 mg	399.15	20	✓ CeeNU
MELPHALAN			
Tab 2 mg - PCT - Retail pharmacy-Specialist		25	✓ Alkeran
Inj 50 mg - PCT only - Specialist	67.80	1	✓ Alkeran

	Subsidy		Fully	
	(Manufacturer's Price)		Subsidised	
	\$	Per		Manufacturer
OXALIPLATIN - PCT only - Specialist				
Inj 100 mg vial	25.01	1	•	Oxaliplatin Actavis
, ,				100 <sup>.</sup>
	110.00		1	Oxaliplatin Ebewe
Inj 5 mg per ml, 20 ml vial	46.32	1	•	Oxaliccord
Inj 1 mg for ECP	0.48	1 mg	·	Baxter
THIOTEPA - PCT only - Specialist				
Inj 15 mg vial	CBS	1	•	Bedford S29
, •			/	THIO-TEPA S29
			/	Tepadina S29
Inj 100 mg vial	CBS	1	✓	Tepadina S29
Antimetabolites				
AZACITIDINE - PCT only - Specialist - Special Authority see SA	1467 bolow			
Inj 100 mg vial		1	_	Azacitidine Dr
iiij 100 iiig viai	139.00	1	•	Reddy's
	605.00		/	Vidaza
Inj 1 mg for ECP		1 mg		Baxter
,		9	, -	

# ⇒SA1467 Special Authority for Subsidy

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

#### All of the following:

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

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

#### Both:

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

	Subsidy		Fully	
	(Manufacturer's Pr \$	ice) Su Per	bsidised •	
LCIUM FOLINATE				
Tab 15 mg - PCT - Retail pharmacy-Specialist	104.26	10	✓	DBL Leucovorin Calcium
Inj 3 mg per ml, 1 ml $-$ PCT $-$ Retail pharmacy-Specialist Inj 10 mg per ml, 5 ml vial $-$ PCT $-$ Retail pharmacy-Specialis		5 1		Hospira Calcium Folinate Sandoz
Inj 50 mg - PCT - Retail pharmacy-Specialist	18.25	5	✓	Calcium Folinate Ebewe
Inj 10 mg per ml, 10 ml vial - PCT only - Specialist	7.30	1	✓	Calcium Folinate Sandoz
Inj 100 mg - PCT only - Specialist	7.33	1	✓	Calcium Folinate Ebewe
Inj 300 mg - PCT only - Specialist	22.51	1	✓	Calcium Folinate Ebewe
Inj 10 mg per ml, 35 ml vial - PCT only - Specialist	20.95	1	✓	Calcium Folinate Sandoz
Inj 1 g - PCT only - Specialist	67.51	1	✓	Calcium Folinate Ebewe
Inj 10 mg per ml, 100 ml vial - PCT only - Specialist	60.00	1	✓	Calcium Folinate Sandoz
Inj 1 mg for ECP - PCT only - Specialist PECITABINE - Retail pharmacy-Specialist	0.06	1 mg	•	Baxter
Tab 150 mg	11.15	60	1	Brinov
Tab 500 mg		120		Brinov
ADRIBINE - PCT only - Specialist				
Inj 1 mg per ml, 10 ml	5,249.72	7	1	Leustatin
Inj 10 mg for ECP		10 mg OP	✓	Baxter
TARABINE				
Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specialis Inj 100 mg per ml, 20 ml vial – PCT – Retail	st400.00	5	✓	Pfizer
pharmacy-Specialist	41.36	1	✓	Pfizer
Inj 1 mg for ECP - PCT only - Specialist		10 mg	✓	Baxter
Inj 100 mg intrathecal syringe for ECP – PCT only – Specialis JDARABINE PHOSPHATE		100 mg OP	<b>✓</b>	Baxter
Tab 10 mg - PCT - Retail pharmacy-Specialist		20	✓	Fludara Oral
Inj 50 mg vial – PCT only – Specialist		5		Fludarabine Ebewe
Inj 50 mg for ECP - PCT only - Specialist  JOROURACIL	105.00	50 mg OP	•	Baxter
Inj 50 mg per ml, 20 ml vial - PCT only - Specialist	12.00	1	1	Fluorouracil Ebewe
Inj 50 mg per ml, 100 ml vial - PCT only - Specialist	30.00	1	1	Fluorouracil Ebewe
Inj 1 mg for ECP - PCT only - Specialist	0.66	100 mg	1	Baxter
MCITABINE HYDROCHLORIDE - PCT only - Specialist				
Inj 1 g, 26.3 ml vial	62.50	1	1	DBL Gemcitabine
Inj 1 g		1	•	Gemcitabine Ebewe
	349.20			Gemzar
	8 36	1	1	Gemcitabine Ebewe
Inj 200 mg		•		
Inj 200 mg	78.00	1 mg		Gemzar Baxter

	Subsidy (Manufacturer's Price \$	e) Per	Fully Subsidised	d Generic
IRINOTECAN HYDROCHLORIDE - PCT only - Specialist				
Inj 20 mg per ml, 5 ml vial	71.44	1	•	Irinotecan Actavis 100
	100.00		•	Irinotecan-Rex
Inj 1 mg for ECP	0.75	1 mg	•	Baxter
MERCAPTOPURINE				
Tab 50 mg - PCT - Retail pharmacy-Specialist Puri-nethol to be Sole Supply on 1 July 2019	37.00	25	•	Puri-nethol
Oral suspension 20 mg per ml - Retail pharmacy-Specialist	_			
Special Authority see SA1725 below	428.00 1	00 ml (	OP 🗸	Allmercap

#### ⇒SA1725 Special Authority for Subsidy

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

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

			(A)	

*	Tab 2.5 mg - PCT - Retail pharmacy-Specialist8.05	90	✓ Trexate
*	Tab 10 mg - PCT - Retail pharmacy-Specialist31.75	90	✓ Trexate
*	Inj 2.5 mg per ml, 2 ml - PCT - Retail pharmacy-Specialist47.50	5	✓ Hospira
*	Inj 7.5 mg prefilled syringe14.61	1	✓ Methotrexate
			Sandoz
*	Inj 10 mg prefilled syringe14.66	1	✓ Methotrexate
			Sandoz
*	Inj 15 mg prefilled syringe14.77	1	✓ Methotrexate
	, 01		Sandoz
*	Inj 20 mg prefilled syringe14.88	1	✓ Methotrexate
	, 01		Sandoz
*	Inj 25 mg prefilled syringe14.99	1	✓ Methotrexate
	, - 5, , 5		Sandoz
*	Inj 30 mg prefilled syringe15.09	1	✓ Methotrexate
	, 01		Sandoz
*	Inj 25 mg per ml, 2 ml vial – PCT – Retail pharmacy-Specialist30.00	5	✓ DBL Methotrexate
	, - <b>3</b> ,		Onco-Vial
*	Inj 25 mg per ml, 20 ml vial - PCT - Retail pharmacy-Specialist45.00	1	✓ DBL Methotrexate
	, - <b>3</b> ,		Onco-Vial
*	Inj 100 mg per ml, 10 ml - PCT - Retail pharmacy-Specialist25.00	1	✓ Methotrexate Ebewe
*	Inj 100 mg per ml, 50 ml vial – PCT – Retail		
	pharmacy-Specialist	1	✓ Methotrexate Ebewe
*	· · · · · ·	1 ma	✓ Baxter
*	Inj 5 mg intrathecal syringe for ECP - PCT only - Specialist4.73	5 mg ÖP	✓ Baxter
PF	METREXED - PCT only - Specialist - Special Authority see SA1679 below	<b>J</b> -	
٠ ـ	Inj 100 mg vial	1	✓ Juno Pemetrexed
	Inj 500 mg vial217.77	1	✓ Juno Pemetrexed
	Inj 1 mg for ECP0.55	1 mg	✓ Baxter
		9	_4/101

## ⇒SA1679 Special Authority for Subsidy

**Initial application — (mesothelioma)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria:

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

continued...

Both:

- 1 Patient has been diagnosed with mesothelioma; and
- 2 Pemetrexed to be administered at a dose of 500 mg/m<sup>2</sup> every 21 days in combination with cisplatin or carboplatin for a maximum of 6 cycles.

Renewal — (mesothelioma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria: All of the following:

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and the patient is benefitting from treatment; and
- 3 Pemetrexed to be administered at a dose of 500mg/m<sup>2</sup> every 21 days for a maximum of 6 cycles.

Initial application — (non-small cell lung carcinoma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria: Both:

- 1 Patient has locally advanced or metastatic non-squamous non-small cell lung carcinoma; and
- - 2.1 Both:
    - 2.1.1 Patient has chemotherapy-naïve disease; and
    - 2.1.2 Pemetrexed is to be administered at a dose of 500 mg/m<sup>2</sup> every 21 days in combination with cisplatin or carboplatin for a maximum of 6 cycles; or
  - 2.2 All of the following:
    - 2.2.1 Patient has had first-line treatment with platinum based chemotherapy; and
    - 2.2.2 Patient has not received prior funded treatment with pemetrexed; and
    - 2.2.3 Pemetrexed is to be administered at a dose of 500 mg/m<sup>2</sup> every 21 days for a maximum of 6 cycles.

Renewal — (non-small cell lung carcinoma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria: All of the following:

1 No evidence of disease progression; and

THIOGUANINE - PCT - Retail pharmacy-Specialist

- 2 The treatment remains appropriate and the patient is benefitting from treatment; and
- 3 Pemetrexed is to be administered at a dose of 500mg/m<sup>2</sup> every 21 days.

Tab 40 mg	126.31	25	✓ Lanvis
Other Cytotoxic Agents			
AMSACRINE - PCT only - Specialist			
Inj 50 mg per ml, 1.5 ml ampoule	1,500.00	6	✓ Amsidine S29
Inj 75 mg	1,250.00	5	✓ AmsaLyo S29
ANAGRELIDE HYDROCHLORIDE - PCT - Retail pharmacy-Speci	ialist		
Cap 0.5 mg	CBS	100	✓ Agrylin S29
			✓ Teva S29
ARSENIC TRIOXIDE - PCT only - Specialist			
Inj 1 mg per ml, 10 ml vial		10	✓ Phenasen
Inj 10 mg	4,817.00	10	✓ AFT S29
(AFT S29 Inj 10 mg to be delisted 1 September 2019)			
BLEOMYCIN SULPHATE - PCT only - Specialist			
Inj 15,000 iu, vial	161.01	1	✓ DBL Bleomycin Sulfate
Inj 1,000 iu for ECP	12.45	1,000 iu	✓ Baxter

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer	
BORTEZOMIB - PCT only - Specialist - Special Authority see	SA1576 below				
Inj 3.5 mg vial	1,892.50	1	<b>✓</b> V	/elcade	
Inj 1 mg for ECP	594.77	1 mg	<b>√</b> E	Baxter	

⇒SA1576 Special Authority for Subsidy

Initial application — (Treatment naive multiple myeloma/amyloidosis) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Either:
  - 1.1 The patient has treatment-naive symptomatic multiple myeloma; or
  - 1.2 The patient has treatment-naive symptomatic systemic AL amyloidosis \*; and
- 2 Maximum of 9 treatment cycles.

Note: Indications marked with \* are unapproved indications.

Initial application — (Relapsed/refractory multiple myeloma/amyloidosis) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria:

All of the following:

- 1 Fither:
  - 1.1 The patient has relapsed or refractory multiple myeloma; or
  - 1.2 The patient has relapsed or refractory systemic AL amyloidosis \*; and
- 2 The patient has received only one prior front line chemotherapy for multiple myeloma or amyloidosis; and
- 3 The patient has not had prior publicly funded treatment with bortezomib; and
- 4 Maximum of 4 treatment cycles.

Note: Indications marked with \* are unapproved indications.

Renewal — (Relapsed/refractory multiple myeloma/amyloidosis) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria:

Both:

- 1 The patient's disease obtained at least a partial response from treatment with bortezomib at the completion of cycle 4; and
- 2 Maximum of 4 further treatment cycles (making a total maximum of 8 consecutive treatment cycles).

Notes: Responding relapsed/refractory multiple myeloma patients should receive no more than 2 additional cycles of treatment beyond the cycle at which a confirmed complete response was first achieved. A line of therapy is considered to comprise either:

- a) a known therapeutic chemotherapy regimen and supportive treatments; or
- b) a transplant induction chemotherapy regimen, stem cell transplantation and supportive treatments.

Refer to datasheet for recommended dosage and number of doses of bortezomib per treatment cycle.

COLASPASE [L-ASPARAGINASE] – PCT only – Specialist Inj 10,000 iu	102.32	1	✓ Leunase
Inj 10,000 iu for ECP	102.32	10,000 iu OP	✓ Baxter
DACARBAZINE - PCT only - Specialist			
Inj 200 mg vial	58.06	1	DBL Dacarbazine
	580.60	10	✓ Dacarbazine APP S29
Inj 200 mg for ECP	58.06	200 mg OP	✓ Baxter
DACTINOMYCIN [ACTINOMYCIN D] - PCT only - Specialist			
Inj 0.5 mg vial	166.75	1	✓ Cosmegen
Inj 0.5 mg for ECP	166.75	0.5 mg OP	✓ Baxter
DAUNORUBICIN - PCT only - Specialist			
Inj 2 mg per ml, 10 ml	130.00	1	✓ Pfizer
Inj 20 mg for ECP	130.00	20 mg OP	✓ Baxter

	Subsidy		Fully	
	(Manufacturer's P		Subsidised	
	\$	Per		Manufacturer
OCETAXEL - PCT only - Specialist				
Inj 10 mg per ml, 2 ml vial		1	✓	DBL Docetaxel
Inj 20 mg	48.75	1	✓	Docetaxel Sandoz
Inj 10 mg per ml, 8 ml vial		1	✓	DBL Docetaxel
Inj 80 mg	195.00	1	✓	Docetaxel Sandoz
Inj 1 mg for ECP	0.55	1 mg	1	Baxter
DOXORUBICIN HYDROCHLORIDE - PCT only - Specialist		_		
Inj 2 mg per ml, 5 ml vial	10.00	1	1	Doxorubicin Ebewe
Inj 2 mg per ml, 25 ml vial		1		Doxorubicin Ebewe
11] 2 11g pci 111, 20 111 via	17.00	i		Arrow-Doxorubicin
Inj 2 mg per ml, 50 ml vial		1		Doxorubicin Ebewe
Inj 2 mg per ml, 100 ml vial		i		Doxorubicin Ebewe
IIIJ 2 IIIg pei IIII, 100 IIII viai	65.00	'		Arrow-Doxorubicin
Inj 1 mg for ECP		1 mg	_	Baxter
	0.29	ring	•	Daxiei
EPIRUBICIN HYDROCHLORIDE – PCT only – Specialist			_	
Inj 2 mg per ml, 5 ml vial		1		Epirubicin Ebewe
Inj 2 mg per ml, 25 ml vial		1		Epirubicin Ebewe
	32.50	1		Epirubicin Ebewe
Inj 2 mg per ml, 50 ml vial				
Inj 2 mg per ml, 100 ml vial	85.00	1		Epirubicin Ebewe
Inj 2 mg per ml, 100 ml vial Inj 1 mg for ECP	85.00 0.37	1 1 mg		Epirubicin Ebewe Baxter
Inj 2 mg per ml, 100 ml vial	85.00 0.37	-		
Inj 2 mg per ml, 100 ml vial Inj 1 mg for ECP	85.00 0.37	-		
Inj 2 mg per ml, 100 ml vial Inj 1 mg for ECP Epirubicin Ebewe Inj 2 mg per ml, 50 ml vial to be delisted 1 Ju ETOPOSIDE	85.00 0.37 ne 2019)	-	✓	Baxter
Inj 2 mg per ml, 100 ml vial Inj 1 mg for ECP Epirubicin Ebewe Inj 2 mg per ml, 50 ml vial to be delisted 1 Ju ETOPOSIDE Cap 50 mg – PCT – Retail pharmacy-Specialist	85.00 0.37 ne 2019)	1 mg	✓	
Inj 2 mg per ml, 100 ml vial		1 mg	,	Baxter
Inj 2 mg per ml, 100 ml vial		1 mg	<i>y y</i>	Baxter Vepesid Vepesid
Inj 2 mg per ml, 100 ml vial	85.00 0.37 ne 2019) 340.73 340.73 alist7.90	1 mg 20 10 1	<i>y y y</i>	Baxter Vepesid
Inj 2 mg per ml, 100 ml vial	85.00 0.37 ne 2019) 340.73 340.73 alist7.90	1 mg 20 10	<i>y y y</i>	Baxter Vepesid Vepesid Rex Medical
Inj 2 mg per ml, 100 ml vial		1 mg 20 10 1 mg	<i>y y y y y</i>	Baxter  Vepesid  Vepesid  Rex Medical  Baxter
Inj 2 mg per ml, 100 ml vial		1 mg 20 10 1 mg	<i>y y y y y</i>	Baxter  Vepesid  Vepesid  Rex Medical  Baxter  Etopophos
Inj 2 mg per ml, 100 ml vial		1 mg 20 10 1 mg	<i>y y y y y</i>	Baxter  Vepesid  Vepesid  Rex Medical  Baxter
Inj 2 mg per ml, 100 ml vial		1 mg 20 10 1 mg 1 mg 1 mg	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Baxter  Vepesid  Vepesid  Rex Medical  Baxter  Etopophos  Baxter
Inj 2 mg per ml, 100 ml vial		1 mg 20 10 1 mg	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Baxter  Vepesid  Vepesid  Rex Medical  Baxter  Etopophos
Inj 2 mg per ml, 100 ml vial		1 mg 20 10 1 mg 1 mg 1 mg	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Baxter  Vepesid  Vepesid  Rex Medical  Baxter  Etopophos  Baxter
Inj 2 mg per ml, 100 ml vial		1 mg 20 10 1 mg 1 mg 1 mg	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Baxter  Vepesid  Vepesid  Rex Medical  Baxter  Etopophos  Baxter
Inj 2 mg per ml, 100 ml vial		1 mg 20 10 1 mg 1 mg 1 mg 1 mg	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Baxter  Vepesid  Vepesid  Rex Medical  Baxter  Etopophos  Baxter  Hydrea
Inj 2 mg per ml, 100 ml vial		1 mg 20 10 1 mg 1 mg 1 mg 1 mg 100 1	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Baxter  Vepesid  Vepesid  Rex Medical  Baxter  Etopophos  Baxter  Hydrea  Zavedos
Inj 2 mg per ml, 100 ml vial		1 mg 20 10 1 mg 1 mg 1 mg 100 1 mg 100 1 mg	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Baxter  Vepesid  Vepesid  Rex Medical  Baxter  Etopophos  Baxter  Hydrea  Zavedos Zavedos
Inj 2 mg per ml, 100 ml vial		1 mg 20 10 1 mg 1 mg 1 mg 100 1 mg 100 1 mg	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Baxter  Vepesid  Vepesid  Rex Medical  Baxter  Etopophos  Baxter  Hydrea  Zavedos Zavedos
Inj 2 mg per ml, 100 ml vial		1 mg 20 10 1 mg 1 mg 1 mg 100 1 mg 100 1 mg	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Baxter  Vepesid  Vepesid  Rex Medical  Baxter  Etopophos  Baxter  Hydrea  Zavedos  Zavedos  Baxter
Inj 2 mg per ml, 100 ml vial		1 mg 20 10 1 mg 1 mg 1 mg 100 1 mg 100 1 mg 100 21	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Baxter  Vepesid  Vepesid  Rex Medical  Baxter  Etopophos  Baxter  Hydrea  Zavedos  Zavedos  Baxter  Revlimid
Inj 2 mg per ml, 100 ml vial		1 mg 20 10 1 mg 1 mg 1 mg 100 1 mg 100 1 mg	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Baxter  Vepesid  Vepesid  Rex Medical  Baxter  Etopophos  Baxter  Hydrea  Zavedos  Zavedos  Baxter

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

All of the following:

- 1 Patient has relapsed or refractory multiple myeloma with progressive disease; and
- 2 Either:

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

continued...

- 2.1 Lenalidomide to be used as third line\* treatment for multiple myeloma; or
- 2.2 Both:
  - 2.2.1 Lenalidomide to be used as second line treatment for multiple myeloma; and
  - 2.2.2 The patient has experienced severe (grade 3 or higher), dose limiting, peripheral neuropathy with either bortezomib or thalidomide that precludes further treatment with either of these treatments; and

273.00

50

✓ Uromitevan

3 Lenalidomide to be administered at a maximum dose of 25 mg/day in combination with dexamethasone.

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

1 No evidence of disease progression; and

Tah 400 mg - PCT - Retail pharmacy-Specialist

2 The treatment remains appropriate and patient is benefitting from treatment.

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

#### **MFSNA**

rab 400 mg – PCT – netali pharmacy-specialist	2/3.00	30	♥ Uronniexan
Tab 600 mg - PCT - Retail pharmacy-Specialist	407.50	50	✓ Uromitexan
Inj 100 mg per ml, 4 ml ampoule - PCT only - Spec	ialist161.25	15	✓ Uromitexan
Inj 100 mg per ml, 10 ml ampoule - PCT only - Spe	ecialist370.35	15	✓ Uromitexan
Inj 1 mg for ECP - PCT only - Specialist		100 mg	✓ Baxter
MITOMYCIN C - PCT only - Specialist			
Inj 5 mg vial	204.08	1	✓ Arrow
Inj 1 mg for ECP		1 mg	✓ Baxter
MITOZANTRONE - PCT only - Specialist			
Inj 2 mg per ml, 10 ml vial	97.50	1	✓ Mitozantrone Ebewe
Inj 1 mg for ECP		1 mg	✓ Baxter
PACLITAXEL - PCT only - Specialist			
Inj 30 mg	47.30	5	✓ Paclitaxel Ebewe
Inj 100 mg		1	✓ Paclitaxel Ebewe
•	91.67		✓ Paclitaxel Actavis
Inj 150 mg	26.69	1	✓ Paclitaxel Ebewe
. •	137.50		✓ Anzatax
			✓ Paclitaxel Actavis
Inj 300 mg	35.35	1	✓ Paclitaxel Ebewe
	275.00		✓ Anzatax
			✓ Paclitaxel Actavis
Inj 1 mg for ECP	0.19	1 mg	✓ Baxter
PEGASPARGASE - PCT only - Special Authority see S	SA1325 below		
Inj 3,750 IU per 5 ml	3,005.00	1	✓ Oncaspar S29

# ⇒SA1325 Special Authority for Subsidy

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

- - 1 The patient has newly diagnosed acute lymphoblastic leukaemia; and
  - 2 Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol; and

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

continued...

3 Treatment is with curative intent.

**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:

All of the following:

- 1 The patient has relapsed acute lymphoblastic leukaemia; and
- 2 Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol; and
- 3 Treatment is with curative intent.

PENTOSTATIN [DEOXYCOFORMYCIN] – PCT only – Specialist Inj 10 mgCB.	S 1	/	Nipent \$29
PROCARBAZINE HYDROCHLORIDE - PCT - Retail pharmacy-Specialist			
Cap 50 mg980.	00 5	0	Natulan S29
TEMOZOLOMIDE - Special Authority see SA1741 below - Retail pharmac	;y		
Cap 5 mg10.	20 5	· •	Orion
			Temozolomide
Cap 20 mg18.	30 5	· •	Orion
			Temozolomide
		✓	Temizole 20 S29
Cap 100 mg40.	20 5	· •	Orion
			<u>Temozolomide</u>
Cap 140 mg56.	00 5	· •	Orion
			Temozolomide
Cap 250 mg96.	30 5	· •	Orion
			Temozolomide

#### ⇒SA1741 Special Authority for Subsidy

Initial application — (high grade gliomas) only from a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 Patient has newly diagnosed glioblastoma multiforme; or
  - 1.2 Patient has newly diagnosed anaplastic astrocytoma\*; and
- 2 Temozolomide is to be (or has been) given concomitantly with radiotherapy; and
- 3 Following concomitant treatment temozolomide is to be used for a maximum of 5 days treatment per cycle, at a maximum dose of 200 mg/m² per day.

**Initial application — (neuroendocrine tumours)** only from a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 Patient has been diagnosed with metastatic or unresectable well-differentiated neuroendocrine tumour\*; and
- 2 Temozolomide is to be given in combination with capecitabine; and
- 3 Temozolomide is to be used in 28 day treatment cycles for a maximum of 5 days treatment per cycle at a maximum dose of 200 mg/m² per day; and
- 4 Temozolomide to be discontinued at disease progression.

**Initial application** — (ewing's sarcoma) only from a relevant specialist. Approvals valid for 9 months where the patient has relapsed/refractory Ewing's sarcoma.

Renewal — (high grade gliomas) only from a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Either:

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

continued...

- 1 Both:
  - 1.1 Patient has glioblastoma multiforme; and
  - 1.2 The treatment remains appropriate and the patient is benefitting from treatment; or
- 2 All of the following:
  - 2.1 Patient has anaplastic astrocytoma\*: and
  - 2.2 The treatment remains appropriate and the patient is benefitting from treatment; and
  - 2.3 Adjuvant temozolomide is to be used for a maximum of 24 months.

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

Both:

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

**Renewal — (ewing's sarcoma)** only from a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

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

Note: Indication marked with a \* is an unapproved indication. Temozolomide is not subsidised for the treatment of relapsed high grade glioma.

THALIDOMIDE - Retail pharmacy-Specialist - Speci	ial Authority see SA1124 below		
Cap 50 mg	378.00	28	Thalomid
Cap 100 mg	756.00	28	Thalomid

#### ⇒SA1124 Special Authority for Subsidy

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

Either:

- 1 The patient has multiple myeloma; or
- 2 The patient has systemic AL amyloidosis\*.

**Renewal** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid without further renewal unless notified where the patient has obtained a response from treatment during the initial approval period.

Notes: Prescription must be written by a registered prescriber in the thalidomide risk management programme operated by the supplier.

Maximum dose of 400 mg daily as monotherapy or in a combination therapy regimen.

Indication marked with \* is an unapproved indication.

#### **TRFTINOIN**

Cap 10 mg - PCT - Retail pharmacy-Specialist479.50	100	✓ Vesanoid
VINBLASTINE SULPHATE		
Inj 1 mg per ml, 10 ml vial - PCT - Retail pharmacy-Specialist 186.46	5	✓ Hospira
Inj 1 mg for ECP - PCT only - Specialist4.14	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-Specialist85.61	5	<ul><li>DBL Vincristine Sulfate</li></ul>
Inj 1 mg for ECP - PCT only - Specialist11.30	1 mg	✓ Baxter

	Subsidy		Fully	Brand or
	(Manufacturer's Price)		Subsidised	I Generic
	\$	Per	✓	Manufacturer
/INORELBINE - PCT only - Specialist				
Inj 10 mg per ml, 1 ml vial	12.00	1	✓	Navelbine
	42.00		✓	Vinorelbine Ebewe
Inj 10 mg per ml, 5 ml vial	56.00	1	✓	Navelbine
, .,	210.00		1	Vinorelbine Ebewe
Inj 1 mg for ECP	0.90	1 mg	<b>/</b>	Baxter
Protein-tyrosine Kinase Inhibitors  DASATINIB – [Xpharm] – Special Authority see SA0976 below				
Tab 20 mg	3,774.06	60	1	Sprycel
Tab 50 mg	,	60		Sprycel
Tab 70 mg		60		Sprycel
Tab 100 mg		30		Sprycel
⇒SA0976 Special Authority for Subsidy				

Special Authority approved by the CML/GIST Co-ordinator

Notes: Application details may be obtained from PHARMAC's website http://www.pharmac.govt.nz, and prescriptions should be sent to:

The CML/GIST Co-ordinator Phone: (04) 460 4990 **PHARMAC** Facsimile: (04) 916 7571

PO Box 10 254 Email: cmlgistcoordinator@pharmac.govt.nz

Wellington

#### Special Authority criteria for CML - access by application

- a) Funded for patients with diagnosis (confirmed by a haematologist) of a chronic myeloid leukaemia (CML) in blast crisis, accelerated phase, or in chronic phase.
- b) Maximum dose of 140 mg/day for accelerated or blast phase, and 100 mg/day for chronic phase CML.
- c) Subsidised for use as monotherapy only.
- d) Initial approvals valid seven months.
- e) Subsequent approval(s) are granted on application and are valid for six months. The first reapplication (after seven months) should provide details of the haematological response. The third reapplication should provide details of the cytogenetic response after 14-18 months from initiating therapy. All other reapplications should provide details of haematological response, and cytogenetic response if such data is available. Applications to be made and subsequent prescriptions can be written by a haematologist or an oncologist.

Note: Dasatinib is indicated for the treatment of adults with chronic, accelerated or blast phase CML with resistance or intolerance to prior therapy including imatinib.

#### Guideline on discontinuation of treatment for patients with CML

- a) Prescribers should consider discontinuation of treatment if, after 6 months from initiating therapy, a patient did not obtain a haematological response as defined as any one of the following three levels of response:
  - 1) complete haematologic response (as characterised by an absolute neutrophil count (ANC) > 1.5 × 10<sup>9</sup>/L, platelets > 100 × 10<sup>9</sup>/L, absence of peripheral blood (PB) blasts, bone marrow (BM) blasts < 5% (or FISH Ph+ 0-35%) metaphases), and absence of extramedullary disease); or
  - 2) no evidence of leukaemia (as characterised by an absolute neutrophil count (ANC) > 1.0 × 10<sup>9</sup>/L, platelets > 20 × 10<sup>9</sup>/L, absence of peripheral blood (PB) blasts, bone marrow (BM) blasts < 5% (or FISH Ph+ 0-35% metaphases), and absence of extramedullary disease); or
  - 3) return to chronic phase (as characterised by BM and PB blasts < 15%, BM and PB blasts and promyelocytes < 30%, PB basophils < 20% and absence of extramedullary disease other than spleen and liver).
- b) Prescribers should consider discontinuation of treatment if, after 18 months from initiating therapy, a patient did not obtain a major cytogenetic response defined as 0-35% Ph+ metaphases.

	Subsidy (Manufacturer's Price)	S	Fully ubsidised	Brand or Generic	
	\$	Per	✓	Manufacturer	
ERLOTINIB - Retail pharmacy-Specialist - Special Authority see	SA1653 below				
Tab 100 mg	764.00	30	✓ Ta	arceva	
Tab 150 mg	1,146.00	30	✓ Ta	arceva	
- CA4CEO Cusadal Authority for Cubaday					

#### SA1653 Special Authority for Subsidy

Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

#### All of the following:

- 1 Patient has locally advanced or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
- 2 There is documentation confirming that the disease expresses activating mutations of EGFR tyrosine kinase; and
- - 3.1 Patient is treatment naive; or
  - 3.2 Both:
    - 3.2.1 The patient has discontinued defitinib due to intolerance; and
    - 3.2.2 The cancer did not progress while on gefitinib; and
- 4 Erlotinib is to be given for a maximum of 3 months.

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

GEFITINIB - Retail pharmacy-Specialist - Special Authority see SA1654 below

✓ Iressa

#### ⇒SA1654 Special Authority for Subsidy

Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

#### All of the following:

- 1 Patient has locally advanced, or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
- - 2.1 Patient is treatment naive; or
  - 2.2 Both:
    - 2.2.1 The patient has discontinued erlotinib due to intolerance; and
    - 2.2.2 The cancer did not progress whilst on erlotinib; and
  - 3 There is documentation confirming that disease expresses activating mutations of EGFR tyrosine kinase; and
  - 4 Gefitinib is to be given for a maximum of 3 months.

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

#### IMATINIB MESII ATE

Note: Imatinib-AFT is not a registered for the treatment of Gastro Intestinal Stromal Tumours (GIST). The Glivec brand of imatinib mesilate (supplied by Novartis) remains fully subsidised under Special Authority for patients with unresectable and/or metastatic malignant GIST, see SA1460 in Section B of the Pharmaceutical Schedule.

Tab 100 mg - [Xpharm] - Special Authority see SA1460

	below2,400.00	60	✓ Glivec
*	Cap 100 mg98.00	60	✓ Imatinib-AFT
*	Cap 400 mg197.50	30	✓ Imatinib-AFT

#### ⇒SA1460 Special Authority for Subsidy

Special Authority approved by the CML/GIST Co-ordinator

Notes: Application details may be obtained from PHARMAC's website http://www.pharmac.govt.nz, and prescriptions should be sent to:

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

continued...

The CMI /GIST Co-ordinator Phone: (04) 460 4990 **PHARMAC** Facsimile: (04) 916 7571

PO Box 10 254 Email: cmlgistcoordinator@pharmac.govt.nz

Wellington

#### Special Authority criteria for GIST – access by application

Funded for patients:

- a) With a diagnosis (confirmed by an oncologist) of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST).
- b) Maximum dose of 400 mg/day.
- c) Applications to be made and subsequent prescriptions can be written by an oncologist.
- d) Initial and subsequent applications are valid for one year. The re-application criterion is an adequate clinical response to the treatment with imatinib (prescriber determined).

LAPATINIB DITOSYLATE - Special Authority see SA1191 below - Retail pharmacy

Tykerb

#### ⇒SA1191 Special Authority for Subsidy

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

- 1 All of the following:
  - 1.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
  - 1.2 The patient has not previously received trastuzumab treatment for HER 2 positive metastatic breast cancer; and
  - 1.3 Lapatinib not to be given in combination with trastuzumab; and
  - 1.4 Lapatinib to be discontinued at disease progression; or
- 2 All of the following:
  - 2.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
  - 2.2 The patient started trastuzumab for metastatic breast cancer but discontinued trastuzumab within 3 months of starting treatment due to intolerance; and
  - 2.3 The cancer did not progress whilst on trastuzumab; and
  - 2.4 Lapatinib not to be given in combination with trastuzumab; and
  - 2.5 Lapatinib to be discontinued at disease progression.

Renewal — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology);
- 2 The cancer has not progressed at any time point during the previous 12 months whilst on lapatinib; and
- 3 Lapatinib not to be given in combination with trastuzumab; and
- 4 Lapatinib to be discontinued at disease progression.

NILOTINIB - Special Authority see SA1489 on the next page - Retail pharmacy

Wastage claimable

Cap 150 mg	4,680.00	120	✓ Tasigna
Cap 200 mg	6,532.00	120	✓ Tasigna

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

## ⇒SA1489 Special Authority for Subsidy

Initial application only from a haematologist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Patient has a diagnosis of chronic myeloid leukaemia (CML) in blast crisis, accelerated phase, or in chronic phase; and
- 2 Either:
  - 2.1 Patient has documented CML treatment failure\* with imatinib; or
  - 2.2 Patient has experienced treatment limiting toxicity with imatinib precluding further treatment with imatinib; and
- 3 Maximum nilotinib dose of 800 mg/day; and
- 4 Subsidised for use as monotherapy only.

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

**Renewal** only from a haematologist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 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.

PAZOPANIB - Special Authority see SA1190 below - Retail pharmacy

Tab 200 mg	1,334.70	30	✓ Votrient
Tab 400 mg	2,669.40	30	✓ Votrient

#### ⇒SA1190 Special Authority for Subsidy

Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist.

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

All of the following:

- 1 The patient has metastatic renal cell carcinoma; and
- 2 Any of the following:
  - 2.1 The patient is treatment naive: or
  - 2.2 The patient has only received prior cytokine treatment; or
  - 2.3 Both:
    - 2.3.1 The patient has discontinued sunitinib within 3 months of starting treatment due to intolerance; and
    - 2.3.2 The cancer did not progress whilst on sunitinib; and
- 3 The patient has good performance status (WHO/ECOG grade 0-2); and
- 4 The disease is of predominant clear cell histology; and

The patient has intermediate or poor prognosis defined as:

- 5 Any of the following:
  - 5.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or
  - 5.2 Haemoglobin level < lower limit of normal; or
  - 5.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or
  - 5.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or
  - 5.5 Karnofsky performance score of less than or equal to 70; or
  - 5.6 2 or more sites of organ metastasis; and
- 6 Pazopanib to be used for a maximum of 3 months.

**Renewal** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

#### Both:

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

Notes: Pazopanib treatment should be stopped if disease progresses.

Poor prognosis patients are defined as having at least 3 of criteria 5.1-5.6. Intermediate prognosis patients are defined as having 1 or 2 of criteria 5.1-5.6.

	Subsidy (Manufacturer's Price) \$	S Per	Fully Subsidised	Brand or Generic Manufacturer
RUXOLITINIB – Special Authority see SA1753 below – Retail ph Wastage claimable	armacy			
Tab 5 mg	2,500.00	56	✓ Ja	akavi
Tab 15 mg	5,000.00	56	✓ Ja	akavi
Tab 20 mg	5,000.00	56	✓ Ja	akavi

#### ⇒SA1753 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 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; and
- 3 A maximum dose of 20 mg twice daily is to be given.

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

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 A maximum dose of 20 mg twice daily is to be given.

SUNITINIB - Special Authori	see SA1266 below -	Retail pharmacy
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Cap 12.5 mg	2,315.38	28	✓ Sutent
, ,	4,630.77	28	✓ Sutent
Cap 50 mg	9.261.54	28	✓ Sutent

# **⇒SA1266** Special Authority for Subsidy

Initial application — (RCC) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

#### All of the following:

- 1 The patient has metastatic renal cell carcinoma; and
- 2 Any of the following:
  - 2.1 The patient is treatment naive; or
  - 2.2 The patient has only received prior cytokine treatment; or
  - 2.3 The patient has only received prior treatment with an investigational agent within the confines of a bona fide clinical trial which has Ethics Committee approval; or
  - 2.4 Both:
    - 2.4.1 The patient has discontinued pazopanib within 3 months of starting treatment due to intolerance; and
    - 2.4.2 The cancer did not progress whilst on pazopanib; and
- 3 The patient has good performance status (WHO/ECOG grade 0-2); and
- 4 The disease is of predominant clear cell histology; and The patient has intermediate or poor prognosis defined as:
- 5 Any of the following:
  - 5.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or
  - 5.2 Haemoglobin level < lower limit of normal; or
  - 5.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or
  - 5.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or
  - 5.5 Karnofsky performance score of less than or equal to 70; or
  - 5.6 2 or more sites of organ metastasis; and
- 6 Sunitinib to be used for a maximum of 2 cycles.

Initial application — (GIST) only from a relevant specialist or medical practitioner on the recommendation of a relevant

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

- 1 The patient has unresectable or metastatic malignant gastrointestinal stromal tumour (GIST); and 2 Fither:
  - 2.1 The patient's disease has progressed following treatment with imatinib; or
  - 2.2 The patient has documented treatment-limiting intolerance, or toxicity to, imatinib.

**Renewal — (RCC)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

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

Notes: Sunitinib treatment should be stopped if disease progresses.

Poor prognosis patients are defined as having at least 3 of criteria 5.1-5.6. Intermediate prognosis patients are defined as having 1 or 2 of criteria 5.1-5.6

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

Both:

The patient has responded to treatment or has stable disease as determined by Choi's modified CT response evaluation criteria as follows:

- 1 Any of the following:
  - 1.1 The patient has had a complete response (disappearance of all lesions and no new lesions); or
  - 1.2 The patient has had a partial response (a decrease in size of 10% or more or decrease in tumour density in Hounsfield Units (HU) of 15% or more on CT and no new lesions and no obvious progression of non measurable disease): or
  - 1.3 The patient has stable disease (does not meet criteria the two above) and does not have progressive disease and no symptomatic deterioration attributed to tumour progression; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

Note: It is recommended that response to treatment be assessed using Choi's modified CT response evaluation criteria (J Clin Oncol, 2007, 25:1753-1759). Progressive disease is defined as either: an increase in tumour size of 10% or more and not meeting criteria of partial response (PR) by tumour density (HU) on CT; or: new lesions, or new intratumoral nodules, or increase in the size of the existing intratumoral nodules.

# **Endocrine Therapy**

For GnRH ANALOGUES - refer to HORMONE PREPARATIONS, Trophic Hormones, page 81

ABIRATERONE ACETATE - Retail pharmacy-Specialist - Special Authority see SA1767 below

Wastage claimable

#### ⇒SA1767 Special Authority for Subsidy

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

- 1 Patient has prostate cancer; and
- 2 Patient has metastases; and
- 3 Patient's disease is castration resistant; and
- 4 Fither:

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

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

All of the following:

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

# **BICALUTAMIDE**

Tab 50 mg	3.80	28	✓ Binarex
FLUTAMIDE - Retail pharmacy-Specialist			
Tab 250 mg	16.50	30	✓ Flutamide
			Mylan S29
	46.20	84	✓ Flutamide
			Mylan S29
	55.00	100	✓ Flutamin
MEGESTROL ACETATE - Retail pharmacy-Specialist			
Tab 160 mg	63.53	30	✓ Apo-Megestrol
OCTREOTIDE			
Inj 50 mcg per ml, 1 ml vial	30.64	5	✓ DBL Octreotide
Inj 100 mcg per ml, 1 ml vial	18.69	5	✓ DBL Octreotide
Inj 500 mcg per ml, 1 ml vial	72.50	5	✓ DBL Octreotide
OCTREOTIDE LAR (SOMATOSTATIN ANALOGUE) - Sp.	ecial Authority see SA10	16 below -	Retail pharmacy
Inj LAR 10 mg prefilled syringe	1,772.50	1	✓ Sandostatin LAR
Inj LAR 20 mg prefilled syringe		1	Sandostatin LAR
Inj LAR 30 mg prefilled syringe	2,951.25	1	Sandostatin LAR

#### **⇒SA1016** Special Authority for Subsidy

Initial application — (Malignant Bowel Obstruction) from any relevant practitioner. Approvals valid for 2 months for applications meeting the following criteria:

All of the following:

- 1 The patient has nausea\* and vomiting\* due to malignant bowel obstruction\*; and
- 2 Treatment with antiemetics, rehydration, antimuscarinic agents, corticosteroids and analgesics for at least 48 hours has failed: and
- 3 Octreotide to be given at a maximum dose 1500 mcg daily for up to 4 weeks.

Note: Indications marked with \* are unapproved indications.

Renewal — (Malignant Bowel Obstruction) from any relevant practitioner. Approvals valid for 3 months where the treatment

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remains appropriate and the patient is benefiting from treatment.

Initial application — (Acromegaly) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 The patient has acromegaly; and
- 2 Any of the following:
  - 2.1 Treatment with surgery, radiotherapy and a dopamine agonist has failed; or
  - 2.2 Treatment with octreotide is for an interim period while awaiting the effects of radiotherapy and a dopamine agonist has failed: or
  - 2.3 The patient is unwilling, or unable, to undergo surgery and/or radiotherapy.

**Renewal — (Acromegaly)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 IGF1 levels have decreased since starting octreotide; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

Note: In patients with Acromegaly octreotide treatment should be discontinued if IGF1 levels have not decreased after 3 months treatment. In patients treated with radiotherapy octreotide treatment should be withdrawn every 2 years, for 1 month, for assessment of remission. Octreotide treatment should be stopped where there is biochemical evidence of remission (normal IGF1 levels) following octreotide treatment withdrawal for at least 4 weeks

Initial application — (Other Indications) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 VIPomas and Glucagonomas for patients who are seriously ill in order to improve their clinical state prior to definitive surgery; or
- 2 Both:
  - 2.1 Gastrinoma; and
  - 2.2 Either:
    - 2.2.1 Patient has failed surgery; or
    - 2.2.2 Patient in metastatic disease after H2 antagonists (or proton pump inhibitors) have failed; or
- 3 Both:
  - 3.1 Insulinomas; and
  - 3.2 Surgery is contraindicated or has failed; or
- 4 For pre-operative control of hypoglycaemia and for maintenance therapy; or
- 5 Both:
  - 5.1 Carcinoid syndrome (diagnosed by tissue pathology and/or urinary 5HIAA analysis); and
  - 5.2 Disabling symptoms not controlled by maximal medical therapy.

Note: The use of octreotide in patients with fistulae, oesophageal varices, miscellaneous diarrhoea and hypotension will not be funded as a Special Authority item

Renewal — (Other Indications) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

#### TAMOXIFEN CITRATE

*	Tab 10 mg1	1.75	60	1	Tamoxifen Sandoz
*	Tab 20 mg	5.60	60	1	Tamoxifen Sandoz

#### **Aromatase Inhibitors**

ANA	STROZOLE				
*	Tab 1 mg	 5.0	)4	30	✓ Rolin
EXE	MESTANE				
*	Tab 25 mg	 14.5	50	30	✓ Pfizer Exemestane

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

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	\$	Per	<b>✓</b>	Manufacturer
LETROZOLE				
* Tab 2.5 mg	4.68	30	1	<u>Letrole</u>
Immunosuppressants				
Cytotoxic Immunosuppressants				
AZATHIOPRINE – Retail pharmacy-Specialist				
* Tab 25 mg	9.66	100	✓	<u>lmuran</u>
* Tab 50 mg	10.58	100	✓	lmuran
* Inj 50 mg vial		1	1	lmuran
MYCOPHENOLATE MOFETIL				
Tab 500 mg	25.00	50	✓	Cellcept
Cap 250 mg		100	1	Cellcept
Powder for oral liq 1 g per 5 ml - Subsidy by endorsement	187.25 16	35 ml C	OP 🗸	Cellcept
Mycophenolate powder for oral liquid is subsidised only for	or patients unable to	swall	ow tablets	and capsules, and when

#### **Fusion Proteins**

ETANERCEPT – Special Authority see SA1620 below – Retail pl	harmacy		
Inj 25 mg	799.96	4	<ul><li>Enbrel</li></ul>
Inj 50 mg autoinjector	1,599.96	4	<ul><li>Enbrel</li></ul>
Inj 50 mg prefilled syringe	1,599.96	4	<ul><li>Enbrel</li></ul>

#### ⇒SA1620 Special Authority for Subsidy

the prescription is endorsed accordingly.

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

Either:

#### 1 Both:

- 1.1 The patient has had an initial Special Authority approval for adalimumab for 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 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 diagnosed with Juvenile Idiopathic Arthritis (JIA); and
- 2.3 Patient has had severe active polyarticular course JIA for 6 months duration or longer; and
- 2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m² weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and
- 2.5 Both:
  - 2.5.1 Either:
    - 2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender ioints: or
    - 2.5.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and

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2.5.2 Physician's global assessment indicating severe disease.

Initial application — (rheumatoid 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 for rheumatoid arthritis: 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 rheumatoid arthritis: or
- 2 All of the following:
  - 2.1 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
  - 2.2 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 oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
  - 2.4 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
  - 2.5 Any of the following:
    - 2.5.1 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
    - 2.5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or
    - 2.5.3 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
  - 2.6 Fither:
    - 2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints:
    - 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; and
  - 2.7 Fither:
    - 2.7.1 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
    - 2.7.2 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.

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

1 Both:

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

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- 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 15, where lesions have been present for at least 6 months from the time of initial diagnosis; or
- 2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
- 2.2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
- 2.3 A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 2.4 The most recent PASI assessment is no more than 1 month old at the time of application.

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 15, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment. 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 Fither:
    - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
    - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for ankylosing spondylitis; or
- 2 All of the following:
  - 2.1 Patient has a confirmed diagnosis of ankylosing spondylitis present for more than six months; and
  - 2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
  - 2.3 Patient has bilateral sacroiliitis demonstrated by plain radiographs, CT or MRI scan; and
  - 2.4 Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and
  - 2.5 Either:
    - 2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following Bath Ankylosing Spondylitis Metrology Index (BASMI) measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or
    - 2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender (see Notes); and
  - 2.6 A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 6 on a 0-10 scale.

Notes: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure must be no more than 1 month old at the time of initial application.

Average normal chest expansion corrected for age and gender:

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

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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

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 for psoriatic arthritis; 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 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.

**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 4 doses.

Note: Indications marked with \* are unapproved indications.

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 DHB hospital in accordance with the HML rules; and

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- 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 — (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:

All of the following:

- 1 Either:
  - 1.1 Applicant is a named specialist or rheumatologist; or
  - 1.2 Applicant is a Practitioner and confirms that a named specialist or rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance: and
- 3 Either:
  - 3.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline: or
  - 3.2 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 — (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 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 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 3 Either:
  - 3.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  - 3.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 4 Etanercept to be administered at doses no greater than 50 mg every 7 days.

Renewal — (severe chronic plaque psoriasis) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 Applicant is a dermatologist; or
  - 1.2 Applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 Fither:
  - 2.1 Both:

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- 2.1.1 Patient had "whole body" severe chronic plague psoriasis at the start of treatment; and
- 2.1.2 Following each prior etanercept treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-treatment baseline value; or
- 2.2 Both:
  - 2.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
  - 2.2.2 Fither:
    - 2.2.2.1 Following each prior etanercept treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
    - 2.2.2.2 Following each prior etanercept treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; and
- 3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

Note: A treatment course is defined as a minimum of 12 weeks of etanercept treatment

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

All of the following:

- 1 Either:
  - 1.1 Applicant is a rheumatologist; or
  - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 Following 12 weeks' initial treatment and for subsequent renewals, treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less; and
- 3 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and
- 4 Etanercept to be administered at doses no greater than 50 mg every 7 days.

**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.

**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 4 doses.

**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:

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(Manufacturer's Price)	Subsidised	Generic
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Both:

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

#### **Immune Modulators**

ANTITHYMOCYTE GLOBULIN (EQUINE) - PCT only - Spec	eialist		
Inj 50 mg per ml, 5 ml	2,351.25	5	✓ ATGAM
BACILLUS CALMETTE-GUERIN (BCG) VACCINE - PCT onl	y – Specialist		
Subsidised only for bladder cancer.			
Inj 2-8 × 100 million CFU	149.37	1	✓ OncoTICE
Inj 40 mg per ml, vial	162.70	3	✓ SII-Onco-BCG S29
(SII-Onco-BCG \$29) Ini 40 mg per ml vial to be delisted 1 Jan	nuary 2020)		

#### Monoclonal Antibodies

ADALIMUMAB - Special Authority see SA1742 below - Re	tail pharmacy		
Inj 20 mg per 0.4 ml prefilled syringe	1,599.96	2	<ul><li>Humira</li></ul>
Inj 40 mg per 0.8 ml prefilled pen	1,599.96	2	✓ HumiraPen
Inj 40 mg per 0.8 ml prefilled syringe	1,599.96	2	<ul><li>Humira</li></ul>

#### ⇒SA1742 Special Authority for Subsidy

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

#### Fither:

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from etanercept; or
    - 1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for rheumatoid arthritis: or
- 2 All of the following:
  - 2.1 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
  - 2.2 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 oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
  - 2.4 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
  - 2.5 Any of the following:
    - 2.5.1 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
    - 2.5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or

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- 2.5.3 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
- 2.6 Either:
  - 2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints;
  - 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; and
- 2.7 Either:
  - 2.7.1 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
  - 2.7.2 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.

**Initial application — (Crohn's disease - adults)** only from a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has severe active Crohn's disease: and
- 2 Any of the following:
  - 2.1 Patient has a Crohn's Disease Activity Index (CDAI) score of greater than or equal to 300; or
  - 2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
  - 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 systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and
- 4 Surgery (or further surgery) is considered to be clinically inappropriate.

Initial application — (Crohn's disease - children) only from a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Paediatric patient has severe active Crohn's disease; and
- 2 Fither:
  - 2.1 Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30; or
  - 2.2 Patient has extensive small intestine disease; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and
- 4 Surgery (or further surgery) is considered to be clinically inappropriate.

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

Either:

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

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- 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 15, where lesions have been present for at least 6 months from the time of initial diagnosis: or
- 2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
- 2.2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
- 2.3 A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 2.4 The most recent PASI assessment is no more than 1 month old at the time of application.

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 15, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment. 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 etanercept for ankylosing spondylitis; and
  - 1.2 Fither:
    - 1.2.1 The patient has experienced intolerable side effects from etanercept; or
    - 1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept 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 plain radiographs, CT or MRI scan; and
  - 2.4 Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and
  - 2.5 Either:
    - 2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following Bath Ankylosing Spondylitis Metrology Index (BASMI) measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or
    - 2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the following 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

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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

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 etanercept for psoriatic arthritis; and
- 1.2 Either:
  - 1.2.1 The patient has experienced intolerable side effects from etanercept; or
  - 1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for psoriatic arthritis; or

#### 2 All of the following:

- 2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and
- 2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
- 2.3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and
- 2.4 Either:
  - 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints;
  - 2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 2.5 Any of the following:
  - 2.5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
  - 2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or
  - 2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

**Initial application — (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 etanercept for juvenile idiopathic arthritis (JIA); and
- 1.2 Fither:
  - 1.2.1 The patient has experienced intolerable side effects from etanercept; or
  - 1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for juvenile idiopathic arthritis; 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 diagnosed with JIA; and
- 2.3 Patient has had severe active polyarticular course JIA for 6 months duration or longer; and
- 2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m² weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and

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2.5 Both:

2.5.1 Either:

- 2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender ioints: or
- 2.5.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and
- 2.5.2 Physician's global assessment indicating severe disease.

Initial application — (fistulising Crohn's disease) only from a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has confirmed Crohn's disease; and
- 2 Either:
  - 2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
  - 2.2 Patient has one or more rectovaginal fistula(e); and
- 3 A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application; and
- 4 The patient will be assessed for response to treatment after 4 months' adalimumab treatment (see Note).

Note: A maximum of 4 months' adalimumab will be subsidised on an initial Special Authority approval for fistulising Crohn's disease.

**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, ciclosporin, azathioprine, or methotrexate) and not received an adequate response; and
- 3 A maximum of 4 doses.

Note: Note: Indications marked with \* are unapproved indications.

**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 Fither:
    - 1.1.1 The patient has had an initial Special Authority approval for etanercept for adult-onset Still's disease (AOSD); or
    - 1.1.2 The patient has been started on tocilizumab for AOSD in a DHB hospital in accordance with the HML rules; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
    - 1.2.2 The patient has received insufficient benefit from at least a three-month trial of etanercept 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 — (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:

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- 1 Either:
  - 1.1 Applicant is a rheumatologist; or
  - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
  - 2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
  - 3 Fither:
    - 3.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
    - 3.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
  - 4 Fither:
    - 4.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
    - 4.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

Renewal — (Crohn's disease - adults) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 Applicant is a gastroenterologist; or
  - 1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Fither:
  - 2.1 Either:
    - 2.1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab;
    - 2.1.2 CDAI score is 150 or less; or
  - 2.2 Both:
    - 2.2.1 The patient has demonstrated an adequate response to treatment but CDAI score cannot be assessed; and
    - 2.2.2 Applicant to indicate the reason that CDAI score cannot be assessed; and
- 3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (Crohn's disease - children) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Fither:
  - 1.1 Applicant is a gastroenterologist; or
  - 1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Either:
  - 2.1 Fither:
    - 2.1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab; or
    - 2.1.2 PCDAI score is 15 or less: or
  - 2.2 Both:
    - 2.2.1 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed; and

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- 2.2.2 Applicant to indicate the reason that PCDAI score cannot be assessed; and
- 3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (severe chronic plaque psoriasis) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 Applicant is a dermatologist; or
  - 1.2 Applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Either:
  - 2.1 Both:
    - 2.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
    - 2.1.2 Following each prior adalimumab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-adalimumab treatment baseline value; or
  - 2.2 Both:
    - 2.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
    - 2.2.2 Either:
      - 2.2.2.1 Following each prior adalimumab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
      - 2.2.2.2 Following each prior adalimumab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-adalimumab treatment baseline value; and
- 3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Note: A treatment course is defined as a minimum of 12 weeks adalimumab treatment

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

All of the following:

- 1 Either:
  - 1.1 Applicant is a rheumatologist; or
  - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Following 12 weeks' initial treatment and for subsequent renewals, treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less; and
- 3 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and
- 4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

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

All of the following:

- 1 Either:
  - 1.1 Applicant is a rheumatologist; or
  - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Fither:

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- 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician; and
- 3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (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:

All of the following:

- 1 Fither:
  - 1.1 Applicant is a named specialist or rheumatologist; or
  - 1.2 Applicant is a Practitioner and confirms that a named specialist or rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 3 Fither:
  - 3.1 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
  - 3.2 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 — (fistulising Crohn's disease) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Either:
  - 1.1 Applicant is a gastroenterologist; or
  - 1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Either:
  - 2.1 The number of open draining fistulae have decreased from baseline by at least 50%; or
  - 2.2 There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain.

**Renewal — (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 4 doses.

**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 adalimumab treatment; and
- 2 The patient has a sustained improvement in inflammatory markers and functional status.

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

## ⇒SA1772 Special Authority for Subsidy

Initial application — (wet age related macular degeneration) only from an ophthalmologist. Approvals valid for 3 months for applications meeting the following criteria:

#### Either:

- 1 All of the following:
  - 1.1 Any of the following:
    - 1.1.1 Wet age-related macular degeneration (wet AMD); or
    - 1.1.2 Polypoidal choroidal vasculopathy; or
    - 1.1.3 Choroidal neovascular membrane from causes other than wet AMD; and
  - 1.2 Either:
    - 1.2.1 The patient has developed severe endophthalmitis or severe posterior uveitis following treatment with bevacizumab; or
    - 1.2.2 There is worsening of vision or failure of retina to dry despite three intraocular injections of bevacizumab four weeks apart; and
  - 1.3 There is no structural damage to the central fovea of the treated eye; and
  - 1.4 Patient has not previously been treated with ranibizumab for longer than 3 months; or
- 2 Either:
  - 2.1 Patient has current approval to use ranibizumab for treatment of wAMD and was found to be intolerant to ranibizumab within 3 months: or
  - 2.2 Patient has previously\* (\*before June 2018) received treatment with ranibizumab for wAMD and disease was stable while on treatment.

**Initial application — (diabetic macular oedema)** only from an ophthalmologist. Approvals valid for 4 months for applications meeting the following criteria:

#### All of the following:

- 1 Patient has centre involving diabetic macular oedema (DMO); and
- 2 Patient's disease is non responsive to 4 doses of intravitreal bevacizumab when administered 4-6 weekly; and
- 3 Patient has reduced visual acuity between 6/9 6/36 with functional awareness of reduction in vision; and
- 4 Patient has DMO within central OCT (ocular coherence tomography) subfield > 350 micrometers; and
- 5 There is no centre-involving sub-retinal fibrosis or foveal atrophy.

**Renewal — (wet age related macular degeneration)** only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

#### All of the following:

- 1 Documented benefit must be demonstrated to continue; and
- 2 Patient's vision is 6/36 or better on the Snellen visual acuity score; and
- 3 There is no structural damage to the central fovea of the treated eye.

Renewal — (diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

#### All of the following:

- 1 There is stability or two lines of Snellen visual acuity gain; and
- 2 There is structural improvement on OCT scan (with reduction in intra-retinal cysts, central retinal thickness, and sub-retinal fluid): and
- 3 Patient's vision is 6/36 or better on the Snellen visual acuity score; and
- 4 There is no centre-involving sub-retinal fibrosis or foveal atrophy; and
- 5 After each consecutive 12 months treatment with (2nd line anti-VEGF agent), patient has retrialled with at least one injection of bevacizumab and had no response.

CETUXIMAB - PCT only - Specialist - Special Authority see SA1697 on the next page

Inj 5 mg per ml, 20 ml vial	364.00	1	Erbitux
Inj 5 mg per ml, 100 ml vial	1,820.00	1	<ul><li>Erbitux</li></ul>
Inj 1 mg for ECP	3.82	1 mg	Baxter

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## ⇒SA1697 Special Authority for Subsidy

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

All of the following:

- 1 Patient has locally advanced, non-metastatic, squamous cell cancer of the head and neck; and
- 2 Patient is contraindicated to, or is intolerant of, cisplatin; and
- 3 Patient has good performance status; and
- 4 To be administered in combination with radiation therapy.

INFLIXIMAB - PCT only - Special Authority see SA1778 below

Inj 100 mg	806.00	1	Remicade
Inj 1 mg for ECP	8.29	1 mg	✓ Baxter

## ⇒SA1778 Special Authority for Subsidy

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 — (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 — (rheumatoid arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

#### All of the following:

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

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:

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

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 for psoriatic arthritis; and
- 2 Either:
  - 2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
  - 2.2 Following 3-4 months' initial treatment with adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept for psoriatic arthritis.

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

Both:

- 1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and
- 2 Any of the following:
  - 2.1 Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptomst; or
  - 2.2 Patient developed new inflammatory symptoms while receiving high dose steroids; or
  - 2.3 Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms.

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

Both:

- 1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and
- 2 Any of the following:
  - 2.1 Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective; or
  - 2.2 Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose: or
  - 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.

Initial application — (Crohn's disease (adults)) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has severe active Crohn's disease: and
- 2 Any of the following:
  - 2.1 Patient has a Crohn's Disease Activity Index (CDAI) score of greater than or equal to 300; or
  - 2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
  - 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

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- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and
- 4 Surgery (or further surgery) is considered to be clinically inappropriate; and
- 5 Patient must be reassessed for continuation after 3 months of therapy.

Initial application — (Crohn's disease (children)) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Paediatric patient has severe active Crohn's disease; and
- 2 Either:
  - 2.1 Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30; or
  - 2.2 Patient has extensive small intestine disease; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and
- 4 Surgery (or further surgery) is considered to be clinically inappropriate; and
- 5 Patient must be reassessed for continuation after 3 months of therapy.

Initial application — (fistulising Crohn's disease) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 Patient has confirmed Crohn's disease; and
- 2 Fither:
  - 2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
  - 2.2 Patient has one or more rectovaginal fistula(e).

Initial application — (acute severe fulminant ulcerative colitis) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 weeks for applications meeting the following criteria:

Both:

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

Initial application — (severe ulcerative colitis) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has histologically confirmed ulcerative colitis; and
- 2 Either:
  - 2.1 Patient is 18 years or older and the Simple Clinical Colitis Activity Index (SCCAI) is greater than or equal to 4; or
  - 2.2 Patient is under 18 years and the Paediatric Ulcerative Colitis Activity Index (PUCAI) score is greater than or equal to 65; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses for an adequate duration (unless contraindicated) and corticosteroids: and
- 4 Surgery (or further surgery) is considered to be clinically inappropriate.

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

Fither:

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for adalimumab or etanercept for severe chronic plaque psoriasis; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from adalimumab or etanercept; or

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- 1.2.2 The patient has received insufficient benefit from adalimumab or etanercept to meet the renewal criteria for adalimumab or etanercept for severe chronic plaque psoriasis; or
- 2 All of the following:
  - 2.1 Either:
    - 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 15, where lesions have been present for at least 6 months from the time of initial diagnosis: or
    - 2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
  - 2.2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
  - 2.3 A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course: and
  - 2.4 The most recent PASI assessment is no more than 1 month old at the time of initiation.

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 15, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

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.

**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 Fither:
  - 2.1 The patient has severe ocular, neurological and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s) (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.

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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.

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.

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

Both:

- 1 Fither:
  - 1.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  - 1.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior 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.

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 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), following 12 months' treatment; or</p>
- 3 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, following 12 months' treatment.

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.

**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 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), following 12 months' treatment; or</p>
- 3 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, following 12 months' treatment.

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

Renewal — (Crohn's disease (adults)) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on infliximab; or
  - 1.2 CDAI score is 150 or less: or
  - 1.3 The patient has demonstrated an adequate response to treatment but CDAI score cannot be assessed; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

Renewal — (Crohn's disease (children)) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on infliximab; or
  - 1.2 PCDAI score is 15 or less; or
  - 1.3 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

Renewal — (fistulising Crohn's disease) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 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.

Renewal — (severe fulminant ulcerative colitis) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Where maintenance treatment is considered appropriate, infliximab should be used in combination with immunomodulators and reassessed every 6 months; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

Renewal — (severe ulcerative colitis) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

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All of the following:

- 1 Patient is continuing to maintain remission and the benefit of continuing infliximab outweighs the risks; and
- 2 Either:
  - 2.1 Patient is 18 years or older and the SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab; or
  - 2.2 Patient is under 18 years and the PUCAI score has reduced by 30 points or more from the PUCAI score when the patient was initiated on infliximab; and
- 3 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

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

Both:

- 1 Either:
  - 1.1 Both:
    - 1.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
    - 1.1.2 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; and
- 2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

**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.

**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.

OBINUTUZUMAB - PCT only - Specialist - Special Authority see SA1627 on the next page

Inj 25 mg per ml, 40 ml vial	5,910.00	1	✓ Gazyva
Inj 1 mg for ECP	6.21	1 mg	Baxter

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

## **⇒SA1627** Special Authority for Subsidy

Initial application — (chronic lymphocytic leukaemia) only from a haematologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has progressive Binet stage A, B or C CD20+ chronic lymphocytic leukaemia requiring treatment; and
- 2 The patient is obinutuzumab treatment naive; and
- 3 The patient is not eligible for full dose FCR due to comorbidities with a score > 6 on the Cumulative Illness Rating Scale (CIRS) or reduced renal function (creatinine clearance < 70mL/min); and</p>
- 4 Patient has adequate neutrophil and platelet counts\* unless the cytopenias are a consequence of marrow infiltration by CLL; and
- 5 Patient has good performance status; and
- 6 Obinutuzumab to be administered at a maximum cumulative dose of 8,000 mg and in combination with chlorambucil for a maximum of 6 cycles.

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

\* Neutrophil greater than or equal to  $1.5 \times 10^9$ /L and platelets greater than or equal to  $75 \times 10^9$ /L.

OMALIZUMAB - Special Authority see SA1744 below - Retail pharmacy

## ⇒SA1744 Special Authority for Subsidy

**Initial application — (severe asthma)** only from a respiratory specialist or clinical immunologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

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

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

All of the following:

- 1 Patient must be aged 12 years or older; and
- 2 Either:
  - 2.1 Both:

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- 2.1.1 Patient is symptomatic with Urticaria Activity Score 7 (UAS7) of 20 or above; and
- 2.1.2 Patient has a Dermatology life quality index (DLQI) of 10 or greater; or
- 2.2 Patient has a Urticaria Control Test (UCT) of 8 or less; and
- 3 Any of the following:
  - 3.1 Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and ciclosporin (> 3 mg/kg day) for at least 6 weeks; or
  - 3.2 Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and at least 3 courses of systemic corticosteroids (> 20 mg prednisone per day for at least 5 days) in the previous 6 months; or
  - 3.3 Patient has developed significant adverse effects whilst on corticosteroids or ciclosporin; and
- 4 Fither:
  - 4.1 Treatment to be stopped if inadequate response\* following 4 doses: or
  - 4.2 Complete response\* to 6 doses of omalizumab.

Renewal — (severe asthma) only from a clinical immunologist or respiratory specialist. Approvals valid for 2 years for applications meeting the following criteria:

#### Both:

- 1 An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and
- 2 A reduction in the maintenance oral corticosteroid dose or number of exacerbations of at least 50% from baseline.

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

#### Either:

- 1 Patient has previously adequately responded\* to 6 doses of omalizumab; or
- 2 Both:
  - 2.1 Patient has previously had a complete response\* to 6 doses of omalizumab; and
  - 2.2 Patient has relapsed after cessation of omalizumab therapy.

Note: \*Inadequate response defined as less than 50% reduction in baseline UAS7 and DLQI score, or an increase in Urticaria Control Test (UCT) score of less than 4 from baseline. Patient is to be reassessed for response after 4 doses of omalizumab. Complete response is defined as UAS7 less than or equal to 6 and DLQI less than or equal to 5; or UCT of 16. Relapse of chronic urticaria on stopping prednisone/ciclosporin does not justify the funding of omalizumab.

PERTUZUMAB - PCT only - Specialist - Special Authority see SA1606 below

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

### ⇒SA1606 Special Authority for Subsidy

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

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 Either:
  - 2.1 Patient is chemotherapy treatment naïve; or
  - 2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
- 3 The patient has good performance status (ECOG grade 0-1); and
- 4 Pertuzumab to be administered in combination with trastuzumab; and
- 5 Pertuzumab maximum first dose of 840 mg, followed by maximum of 420 mg every 3 weeks; and
- 6 Pertuzumab to be discontinued at disease progression.

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

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relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

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

RITUXIMAB - PCT only - Specialist - Special Authority see SA1783 below

075.50 2 <b>✓ Mabthera</b>	Inj 100 mg per 10 ml vial
688.30 1 <b>✓ Mabthera</b>	Inj 500 mg per 50 ml vial2,688.30
5.64 1 mg <b>✓ Baxter</b>	Inj 1 mg for ECP5.64

## ⇒SA1783 Special Authority for Subsidy

Initial application — (Antibody-mediated renal transplant rejection) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid without further renewal unless notified where patient has been diagnosed with antibody-mediated renal transplant rejection\*.

Note: Indications marked with \* are unapproved indications.

Initial application — (ABO-incompatible renal transplant) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid without further renewal unless notified where patient is to undergo an ABO-incompatible renal transplant\*.

Note: Indications marked with \* are unapproved indications.

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 rituximab prior to 1 February 2019; and
- 2 Any of the following:
  - 2.1 haemophilia with inhibitors; or
  - 2.2 rheumatoid arthritis: or
  - 2.3 severe cold haemagglutinin disease (CHAD); or
  - 2.4 warm autoimmune haemolytic anaemia (warm AIHA); or
  - 2.5 immune thrombocytopenic purpura (ITP); or
  - 2.6 thrombotic thrombocytopenic purpura (TTP); or
  - 2.7 pure red cell aplasia (PRCA); or
  - 2.8 ANCA associated vasculitis; or
  - 2.9 treatment refractory systemic lupus erythematosus (SLE); or
  - 2.10 steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS).

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.

**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.

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:

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Fither:

1 Both:

- 1.1 The patient has indolent low grade NHL or hairy cell leukaemia\* with relapsed disease following prior chemotherapy; and
  - 1.2 To be used for a maximum of 6 treatment cycles; or
- 2 Both:
  - 2.1 The patient has indolent, low grade lymphoma or hairy cell leukaemia\* requiring first-line systemic chemotherapy; 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.

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

Fither:

- 1 All of the following:
  - 1.1 The patient has treatment naive aggressive CD20 positive NHL; and
  - 1.2 To be used with a multi-agent chemotherapy regimen given with curative intent; and
  - 1.3 To be used for a maximum of 8 treatment cycles; or
  - 2 Both:
    - 2.1 The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy; and
    - 2.2 To be used for a maximum of 6 treatment cycles.

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia **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 The patient is rituximab treatment naive; and
  - 3 Either:
    - 3.1 The patient is chemotherapy treatment naive; or
    - 3.2 Both:
      - 3.2.1 The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment: and
      - 3.2.2 The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy; and
  - 4 The patient has good performance status; and
  - 5 The patient does not have chromosome 17p deletion CLL; and
  - 6 Rituximab to be administered in combination with fludarabine and cyclophosphamide or bendamustine for a maximum of 6 treatment cycles; and
  - 7 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustine.

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.

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:

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- 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.

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 hydroxychloroguine sulphate (at maximum tolerated doses); and
- 5 Any of the following:
  - 5.1 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of ciclosporin; or
  - 5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or
  - 5.3 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate; and
- 6 Either:
  - 6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or
  - 6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 7 Either:
  - 7.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
  - 7.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months; and
- 8 Either:
  - 8.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
  - 8.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
- 9 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Initial application — (severe cold haemagglutinin disease (CHAD)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:

Both:

- 1 Patient has cold haemagglutinin disease\*; and
- 2 Patient has severe disease which is characterized by symptomatic anaemia, transfusion dependence or disabling circulatory symptoms.

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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 4 weeks for applications meeting the following criteria:

Both:

- 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.

Note: Indications marked with \* are unapproved indications.

Initial application — (immune thrombocytopenic purpura (ITP)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:

Both:

- 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).

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 4 weeks for applications meeting the following criteria: Either:

- 1 Patient has thrombotic thrombocytopenic purpura\* and has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange; or
- 2 Patient has acute idiopathic thrombotic thrombocytopenic purpura\* with neurological or cardiovascular pathology.

Note: Indications marked with \* are unapproved indications.

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.

Initial application — (ANCA associated vasculitis) from any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient has been diagnosed with ANCA associated vasculitis\*: and
- 2 The total rituximab dose would not exceed the equivalent of 375 mg/m<sup>2</sup> of body-surface area per week for a total of 4 weeks; and
- 3 Any of the following:
  - 3.1 Induction therapy with daily oral or pulse intravenous cyclophosphamide has failed to achieve significant improvement of disease after at least 3 months; or
  - 3.2 Patient has previously had a cumulative dose of cyclophosphamide > 15 g or a further repeat 3 month induction course of cyclophosphamide would result in a cumulative dose > 15 g; or
  - 3.3 Cyclophosphamide and methotrexate are contraindicated; or
  - 3.4 Patient is a female of child-bearing potential; or

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3.5 Patient has a previous history of haemorrhagic cystitis, urological malignancy or haematological malignancy.

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.

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 4 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/m² of body surface area per week for a total of 4 weeks

Note: Indications marked with \* are unapproved indications.

Initial application — (Steroid resistant nephrotic syndrome (SRNS)) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 4 weeks for applications meeting the following criteria:

All of the following:

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

Note: Indications marked with \* are unapproved indications.

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

All of the following:

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

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.

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Note: Indications marked with \* are unapproved indications.

Renewal — (indolent, low-grade lymphomas or hairy cell leukaemia\*) 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 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.

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

**Renewal — (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's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and
- 2 The patient has had an interval of 36 months or more since commencement of initial rituximab treatment; and
- 3 The patient does not have chromosome 17p deletion CLL; and
- 4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustine; and
- 5 Rituximab to be administered in combination with fludarabine and cyclophosphamide or bendamustine 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.

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

All of the following:

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

Renewal — (rheumatoid arthritis - re-treatment in 'responders' to rituximab) only from a rheumatologist or Practitioner on

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the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

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

Renewal — (severe cold haemagglutinin disease (CHAD)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 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.

Renewal — (warm autoimmune haemolytic anaemia (warm AIHA)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria: Either:

- 1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m² weekly for 4 weeks) is now planned; or
- 2 All of the following:
  - 2.1 Patient was previously treated with rituximab for warm autoimmune haemolytic anaemia\*; and
  - 2.2 An initial response lasting at least 12 months was demonstrated; and
  - 2.3 Patient now requires repeat treatment.

Note: Indications marked with \* are unapproved indications.

Renewal — (immune thrombocytopenic purpura (ITP)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 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.

**Renewal — (thrombotic thrombocytopenic purpura (TTP))** only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria: All of the following:

1 Patient was previously treated with rituximab for thrombotic thrombocytopenic purpura\*; and

Subsidy	Fully	Brand or	
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- 2 An initial response lasting at least 12 months was demonstrated; and
- 3 Patient now requires repeat treatment.

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.

Renewal — (ANCA associated vasculitis) from any relevant practitioner. Approvals valid for 4 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.

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.

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 4 weeks for applications meeting the following criteria:

All of the following:

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

Note: Indications marked with \* are unapproved indications.

Renewal — (Steroid resistant nephrotic syndrome (SRNS)) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 4 weeks for applications meeting the following criteria:

All of the following:

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

Note: Indications marked with \* are unapproved indications.

SECUKINUMAB - Special Authority see SA1754 on the next page - Retail pharmacy

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

## **⇒SA1754** Special Authority for Subsidy

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

All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab or etanercept, or has trialled infliximab in a DHB hospital in accordance with the General Rules of the Pharmaceutical Schedule, for severe chronic 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. Approvals valid for 4 months for applications meeting the following criteria:

## All of the following:

- 1 Either:
  - 1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
  - 1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
- 2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin: and
- 3 A PASI assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course: and
- 4 The most recent PASI or DQLI assessment is no more than 1 month old at the time of application.

Note: A treatment course is defined as a minimum of 12 weeks of treatment. "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom sub scores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

Renewal — (severe chronic plaque psoriasis – first and second-line biologic) only from a dermatologist or medical practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

#### Both:

- 1 Either:
  - 1.1 Patient's PASI score has reduced by 75% or more (PASI 75) as compared to baseline PASI prior to commencing secukinumab; or
  - 1.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing secukinumab; and
- 2 Secukinumab to be administered at a maximum dose of 300 mg monthly.

SILTUXIMAB – Special Authority see SA1596 on the next page – Retail pharmacy

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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 Author	ority see SA1781 below
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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 vial1,10		✓ Actemra
Inj 1 mg for ECP	.2.85 1 mg	✓ Baxter

### ⇒SA1781 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:

#### Littlet.

- 1 All of the following:
  - 1.1 The patient is enrolled in the Children's Oncology Group AALL1331 trial; and
  - 1.2 The patient has developed grade 3 or 4 cytokine release syndrome associated with the administration of blinatumomab for the treatment of acute lymphoblastic leukaemia; and
  - 1.3 Tocilizumab is to be administered at doses no greater than 8 mg/kg IV for a maximum of 3 doses; or
- 2 All of the following:
  - 2.1 The patient is enrolled in the Malaghan Institute of Medical Research Phase I ENABLE trial; and
  - 2.2 The patient has developed CRS or CAR T-Cell Related Encephalopathy Syndrome (CRES) associated with the administration of CAR T-cell therapy for the treatment of relapsed or refractory B-cell non-Hodgkin lymphoma; and
  - 2.3 Tocilizumab is to be administered according to the consensus guidelines for CRS and CRES for CAR T-cell therapy (Neelapu et al. Nat Rev Clin Oncol 2018;15:47-62) at doses no greater than 8 mg/kg IV for a maximum of 3 doses.

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

#### Both:

- 1 Patient was being treated with tocilizumab prior to 1 February 2019; and
- 2 Any of the following:
  - 2.1 rheumatoid arthritis; or
  - 2.2 systemic juvenile idiopathic arthritis; or
  - 2.3 adult-onset Still's disease; or
  - 2.4 polyarticular juvenile idiopathic arthritis; or
  - 2.5 idiopathic multicentric Castleman's disease.

Initial application — (Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept)) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
- 2 Fither
  - 2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or

Subsidy	Fully	Brand 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 DHB hospital in accordance with the Section H rules; and
    - 3.2.2 Either:
      - 3.2.2.1 The patient has experienced intolerable side effects from rituximab; or
      - 3.2.2.2 At four months following the initial course of rituximab the patient has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis.

Initial application — (Rheumatoid Arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
- 2 Tocilizumab is to be used as monotherapy; and
- 3 Either:
  - 3.1 Treatment with methotrexate is contraindicated: or
  - 3.2 Patient has tried and did not tolerate oral and/or parenteral methotrexate; and
- 4 Fither
  - 4.1 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of ciclosporin alone or in combination with another agent; or
  - 4.2 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of leflunomide alone or in combination with another agent; and
- 5 Either:
  - 5.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints; or
  - 5.2 Patient has persistent symptoms of poorly controlled and active disease in at least four active joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 6 Either:
  - 6.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
  - 6.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Initial application — (systemic juvenile idiopathic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient diagnosed with systemic juvenile idiopathic arthritis; and
- 2 Patient has tried and not responded to a reasonable trial of all of the following, either alone or in combination: oral or parenteral methotrexate; non-steroidal anti-inflammatory drugs (NSAIDs); and systemic corticosteroids.

Initial application — (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Fither:

- 1 Both:
  - 1.1 Fither:

Subsidy	Fı	ılly	Brand or	
(Manufacturer's Price)	Subsidis	ed	Generic	
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- 1.1.1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for adult-onset Still's disease (AOSD); or
- 1.1.2 The patient has been started on tocilizumab for AOSD in a DHB hospital in accordance with the General Rules of the Pharmaceutical Schedule; and
- 1.2 Fither:
  - 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 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 severe active polyarticular course JIA for 6 months duration or longer; and
  - 2.3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m² weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and
  - 2.4 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
  - 2.5 Both:
    - 2.5.1 Fither:
      - 2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender ioints: or
      - 2.5.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and
    - 2.5.2 Physician's global assessment indicating severe disease.

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.

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:

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

TRASTUZUMAB - PCT only - Specialist - Special Authority see SA1632 below

Inj 150 mg vial	1,350.00	1	✓ Herceptin
Inj 440 mg vial	3,875.00	1	✓ Herceptin
Inj 1 mg for ECP	9.36	1 ma	✓ Baxter

### ⇒SA1632 Special Authority for Subsidy

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

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 Either:
  - 2.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
  - 2.2 Both:
    - 2.2.1 The patient started lapatinib treatment for metastatic breast cancer but discontinued lapatinib within 3 months of starting treatment due to intolerance; and
    - 2.2.2 The cancer did not progress whilst on lapatinib; and
- 3 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

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

continued...

at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and

- 3.2.3 The patient has good performance status (ECOG grade 0-1); and
- 4 Trastuzumab not to be given in combination with lapatinib; and
- 5 Trastuzumab to be discontinued at disease progression.

Renewal — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
- 3 Trastuzumab not to be given in combination with lapatinib; and
- 4 Trastuzumab to be discontinued at disease progression.

Initial application — (early breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 15 months for applications meeting the following criteria:

All of the following:

- 1 The patient has early breast cancer expressing HER 2 IHC 3+ or ISH + (including FISH or other current technology); and
- 2 Maximum cumulative dose of 106 mg/kg (12 months' treatment); and
- 3 Any of the following:
  - 3.1 9 weeks' concurrent treatment with adjuvant chemotherapy is planned; or
  - 3.2 12 months' concurrent treatment with adjuvant chemotherapy is planned; or
  - 3.3 12 months' sequential treatment following adjuvant chemotherapy is planned; or
  - 3.4 12 months' treatment with neoadjuvant and adjuvant chemotherapy is planned; or
  - 3.5 Other treatment regimen, in association with adjuvant chemotherapy, is planned.

Renewal — (early breast cancer\*) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology);
- 2 The patient received prior adjuvant trastuzumab treatment for early breast cancer; and
- 3 Any of the following:
  - 3.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
  - 3.2 Both:
    - 3.2.1 The patient started lapatinib treatment for metastatic breast cancer but discontinued lapatinib within 3 months of starting treatment due to intolerance; and
    - 3.2.2 The cancer did not progress whilst on lapatinib; or
  - 3.3 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
- 4 Either:
  - 4.1 Trastuzumab will not be given in combination with pertuzumab; or
  - 4.2 All of the following:
    - 4.2.1 Trastuzumab to be administered in combination with pertuzumab; and
    - 4.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
    - 4.2.3 The patient has good performance status (ECOG grade 0-1); and
- 5 Trastuzumab not to be given in combination with lapatinib; and
- 6 Trastuzumab to be discontinued at disease progression.

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

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Note: \* For patients with relapsed HER-2 positive disease who have previously received adjuvant trastuzumab for early breast cancer.

## Programmed Cell Death-1 (PD-1) Inhibitors

NIVOLUMAB - PCT only - Specialist - Special Authority see SA1656 below

Inj 10 mg per ml, 4 ml vial	1,051.98	1	<ul><li>Opdivo</li></ul>
Inj 10 mg per ml, 10 ml vial	2,629.96	1	✓ Opdivo
Ini 1 ma for ECP	27.62	1 ma	✓ Baxter

### ⇒SA1656 Special Authority for Subsidy

Initial application — (unresectable or metastatic melanoma) only from a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has metastatic or unresectable melanoma stage III or IV; and
- 2 Patient has measurable disease as defined by the presence of at least one CT or MRI measurable lesion; and
- 3 The patient has ECOG performance score of 0-2; and
- 4 Either:
  - 4.1 Patient has not received funded pembrolizumab; or
  - 4.2 Both:
    - 4.2.1 Patient has received an initial Special Authority approval for pembrolizumab and has discontinued pembrolizumab within 12 weeks of starting treatment due to intolerance; and
    - 4.2.2 The cancer did not progress while the patient was on pembrolizumab; and
- 5 Nivolumab is to be used at a maximum dose of 3 mg/kg every 2 weeks for a maximum of 12 weeks (6 cycles); and
- 6 Baseline measurement of overall tumour burden is documented (see Note); and
- 7 Documentation confirming that the patient has been informed and acknowledges that the initial funded treatment period of nivolumab will not be continued beyond 12 weeks (6 cycles) if their disease progresses during this time.

Renewal — (unresectable or metastatic melanoma) only from 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 according to RECIST criteria (see Note; or
  - 1.2 Patient's disease has had a partial response to treatment according to RECIST criteria (see Note); or
  - 1.3 Patient has stable disease according to RECIST criteria (see Note); and
- 2 Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; and
- 3 No evidence of progressive disease according to RECIST criteria (see Note); and
- 4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; and
- 5 Nivolumab will be used at a maximum dose of 3 mg/kg every 2 weeks for a maximum of 12 weeks (6 cycles).

Notes: Disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer EA, et al. Eur J Cancer 2009;45:228-47). Assessments of overall tumour burden and measurable disease to be undertaken on a minimum of one lesion and maximum of 5 target lesions (maximum two lesions per organ). Target lesions should be selected on the basis of their size (lesions with the longest diameter), be representative of all involved organs, and suitable for reproducible repeated measurements. Target lesion measurements should be assessed using CT or MRI imaging with the same method of assessment and the same technique used to characterise each identified and reported lesion at baseline and every 12 weeks. Response definitions as follows:

Complete Response: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target)
must have reduction in short axis to < 10 mm.</li>

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

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- Partial Response: At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters
- Progressive Disease: At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression).
- Stable Disease: Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease.

PEMBROLIZUMAB - PCT only - Specia	alist – Special Authority see SA1657 below		
Inj 50 mg vial	2,340.00	1	✓ Keytruda
Inj 1 mg for ECP	49.14	1 mg	✓ Baxter

### ⇒SA1657 Special Authority for Subsidy

Initial application — (unresectable or metastatic melanoma) only from a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has metastatic or unresectable melanoma stage III or IV; and
- 2 Patient has measurable disease as defined by the presence of at least one CT or MRI measurable lesion; and
- 3 The patient has ECOG performance score of 0-2; and
- 4 Either:
  - 4.1 Patient has not received funded nivolumab; or
  - 4.2 Both:
    - 4.2.1 Patient has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance; and
    - 4.2.2 The cancer did not progress while the patient was on nivolumab; and
- 5 Pembrolizumab is to be used at a maximum dose of 2 mg/kg every 3 weeks for a maximum of 12 weeks (4 cycles); and
- 6 Baseline measurement of overall tumour burden is documented (see Note); and
- 7 Documentation confirming that the patient has been informed and acknowledges that the initial funded treatment period of pembrolizumab will not be continued beyond 12 weeks (4 cycles) if their disease progresses during this time.

Renewal — (unresectable or metastatic melanoma) only from 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 according to RECIST criteria (see Note); or
  - 1.2 Patient's disease has had a partial response to treatment according to RECIST criteria (see Note); or
  - 1.3 Patient has stable disease according to RECIST criteria (see Note); and
- 2 Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; and
- 3 No evidence of progressive disease according to RECIST criteria (see Note); and
- 4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; and
- 5 Pembrolizumab will be used at a maximum dose of 2 mg/kg every 3 weeks for a maximum of 12 weeks (4 cycles).

Notes: Disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer EA, et al. Eur J Cancer 2009;45:228-47). Assessments of overall tumour burden and measurable disease to be undertaken on a minimum of one lesion and maximum of 5 target lesions (maximum two lesions per organ). Target lesions should be selected on the basis of their size (lesions with the longest diameter), be representative of all involved organs, and suitable for reproducible repeated measurements. Target lesion measurements should be assessed using CT or MRI imaging with the same method of assessment and the same technique used to characterise each identified and reported lesion at baseline and every 12 weeks. Response definitions as follows:

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

#### continued...

- Complete Response: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target)
  must have reduction in short axis to < 10 mm.</li>
- Partial Response: At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
- Progressive Disease: At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression).
- Stable Disease: Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease.

## Other Immunosuppressants

#### **CICLOSPORIN**

Cap 25 mg	44.63	50	Neoral
Cap 50 mg	88.91	50	✓ Neoral
Cap 100 mg		50	✓ Neoral
Oral lig 100 mg per ml	198 13	50 ml OP	✓ Neoral

### EVEROLIMUS - Special Authority see SA1491 below - Retail pharmacy

Wastao	e claim	ahle
vvasiau	e ciaiii	Iable

wasiaye ciaimable			
Tab 10 mg	6,512.29	30	<ul><li>Afinitor</li></ul>
Tab 5 mg	4,555.76	30	<ul><li>Afinitor</li></ul>

## **⇒SA1491** Special Authority for Subsidy

**Initial application** only from a neurologist or oncologist. Approvals valid for 3 months for applications meeting the following criteria:

#### Both:

- 1 Patient has tuberous sclerosis; and
- 2 Patient has progressively enlarging sub-ependymal giant cell astrocytomas (SEGAs) that require treatment.

**Renewal** only from a neurologist or oncologist. Approvals valid for 12 months for applications meeting the following criteria: All of the following:

- 1 Documented evidence of SEGA reduction or stabilisation by MRI within the last 3 months; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment; and
- 3 Everolimus to be discontinued at progression of SEGAs.

Note: MRI should be performed at minimum once every 12 months, more frequent scanning should be performed with new onset of symptoms such as headaches, visual complaints, nausea or vomiting, or increase in seizure activity.

## SIROLIMUS - Special Authority see SA0866 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

### ⇒SA0866 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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
TACROLIMUS – Special Authority see SA1745 below – Retail ph Cap 0.5 mg	55.64 111.28	100 100 50	<b>✓</b> T	Facrolimus Sandoz Facrolimus Sandoz Facrolimus Sandoz

⇒SA1745 Special Authority for Subsidy

**Initial application — (organ transplant)** only from a relevant specialist. Approvals valid without further renewal unless notified where the patient is an organ transplant recipient.

Note: Subsidy applies for either primary or rescue therapy.

Initial application — (non-transplant indications\*) only from a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 Patient requires long-term systemic immunosuppression; and
- 2 Ciclosporin has been trialled and discontinued treatment because of unacceptable side effects or inadequate clinical response.

Note: Indications marked with \* are unapproved indications

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

# **Antiallergy Preparations**

## Allergic Emergencies

ICATIBANT - Special Authority see SA1558 below - Retail pharmacy

Inj 10 mg per ml, 3 ml prefilled syringe......2,668.00 1 ✓ Firazyr

#### ⇒SA1558 Special Authority for Subsidy

Initial application only from a clinical immunologist or relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

#### Both:

- 1 Supply for anticipated emergency treatment of laryngeal/oro-pharyngeal or severe abdominal attacks of acute hereditary angioedema (HAE) for patients with confirmed diagnosis of C1-esterase inhibitor deficiency; and
- 2 The patient has undergone product training and has agreed upon an action plan for self-administration.

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

## Allergy Desensitisation

## **⇒SA1367** Special Authority for Subsidy

**Initial application** only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria: Both:

- 1 RAST or skin test positive; and
- 2 Patient has had severe generalised reaction to the sensitising agent.

Maintenance kit - 6 vials 120 mcg freeze dried venom, with

**Renewal** only from a relevant specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

BEE VENOM ALLERGY TREATMENT - Special Authority see SA1367 above - Retail pharmacy

diluent	285.00	1 OP	✓ Venomil S29
Treatment kit - 1 vial 550 mcg freeze dried venom, 1 diluen	t		
9 ml, 3 diluent 1.8 ml	305.00	1 OP	✓ Albey
Treatment kit - 1 vial 550 mcg freeze dried venom, with dilu	ent305.00	1 OP	✓ Hymenoptera S29
WASP VENOM ALLERGY TREATMENT - Special Authority se	ee SA1367 above -	- Retail pharr	macy
Treatment kit (Paper wasp venom) - 1 vial 550 mcg freeze			
dried polister venom, 1 diluent 9 ml, 1 diluent 1.8 ml	305.00	1 OP	✓ Albey
Treatment kit (Paper wasp venom) - 1 vial 550 mcg freeze			
dried venom, with diluent	305.00	1 OP	✓ Hymenoptera S29
Treatment kit (Paper wasp venom) - 6 vials 120 mcg freeze			
dried venom, with diluent	305.00	1 OP	✓ Venomil S29
Treatment kit (Yellow Jacket venom) - 1 vial 550 mcg freez			
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, 1 diluent 1.8 ml		1 OP	✓ Albey
Treatment kit (Yellow jacket venom) - 6 vials 120 mcg freez			
dried venom, with diluent	305.00	1 OP	✓ Venomil S29

	Subsidy		Fully Brand or
	(Manufacturer's Pri		idised Generic
	\$	Per	✓ Manufacturer
Antihistamines			
Anumstanines			
CETIRIZINE HYDROCHLORIDE			
* Tab 10 mg	1.01	100	✓ Zista
* Oral lig 1 mg per ml		200 ml	✓ Histaclear
CHLORPHENIRAMINE MALEATE			
* Oral lig 2 mg per 5 ml	8.06	500 ml	✓ Histafen
DEXTROCHLORPHENIRAMINE MALEATE			
* Tab 2 mg	2.02	40	
* Tab 2 Hig	(8.40)	40	Polaramine
	1.01	20	i diaramine
	(5.99)	20	Polaramine
* Oral liq 2 mg per 5 ml		100 ml	rolaramino
The Oral lig 2 mg por o mil	(10.29)	100 1111	Polaramine
FEXOFENADINE HYDROCHLORIDE	(10.20)		rolarammo
	4.24	20	
* Tab 60 mg	(8.23)	20	Telfast
* Tab 120 mg	, ,	10	Tellast
* Tab 120 Hg	(8.23)	10	Telfast
	14.22	30	Tellast
	(26.44)	00	Telfast
LORATADINE	(20.11)		rondor
* Tab 10 mg	1 20	100	✓ Lorafix
		120 ml	✓ Lorfast
	2.10	120 1111	LUITASL
PROMETHAZINE HYDROCHLORIDE	4.00	50	/ Allows a sthe
* Tab 10 mg		50	✓ <u>Allersoothe</u>
* Tab 25 mg		50	✓ <u>Allersoothe</u>
* Oral liq 1 mg per 1 ml		100 ml 5	✓ <u>Allersoothe</u>
* Inj 25 mg per ml, 2 ml ampoule – Up to 5 inj available on a	PSU 15.54	5	✓ Hospira
Inhaled Corticosteroids			
Illidied Corticosteroids			
BECLOMETHASONE DIPROPIONATE			
Aerosol inhaler, 50 mcg per dose		200 dose OP	✓ Qvar
Aerosol inhaler, 50 mcg per dose CFC-free	8.54 2	200 dose OP	✓ Beclazone 50
Aerosol inhaler, 100 mcg per dose	15.50 2	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 2	200 dose OP	✓ Beclazone 250
BUDESONIDE			
Powder for inhalation, 100 mcg per dose	17.00 2	200 dose OP	✓ Pulmicort
•			Turbuhaler
Powder for inhalation, 200 mcg per dose	19.00 2	200 dose OP	✓ Pulmicort
, 01			Turbuhaler
Powder for inhalation, 400 mcg per dose	32.00 2	200 dose OP	✓ Pulmicort
			Turbuhaler

		Subsidy				ully	
		(Manufacturer's \$	Price)	Per	Subsid	ised •	Generic Manufacturer
1	ITICASONE	Ψ		1 61		_	IVIALIAIAOLAI GI
L	JTICASONE Aerosol inhaler, 50 mcg per dose	1 60	120	dose	ΛP	J	Floair
	Aerosol inhaler, 50 mcg per dose CFC-free			dose dose			Flixotide
	Powder for inhalation, 50 mcg per dose			uose dose	-		Flixotide Accuhaler
	Powder for inhalation, 100 mcg per dose			dose	-		Flixotide Accuhaler
	Aerosol inhaler, 125 mcg per dose			dose	-		Floair
	Aerosol inhaler, 125 mcg per dose CFC-free			dose	-		Flixotide
	Aerosol inhaler, 250 mcg per dose			dose	-		Floair
	Aerosol inhaler, 250 mcg per dose CFC-free			dose			Flixotide
	Powder for inhalation, 250 mcg per dose			dose	-		Flixotide Accuhaler
li	haled Long-acting Beta-adrenoceptor Agonisi	ts					
	ORMOTEROL FUMARATE						
	Powder for inhalation, 12 mcg per dose, and monodose devi	ce20.64	60	) dos	е		
	2	(35.80)	3.		-		Foradil
ΞF	ORMOTEROL FUMARATE DIHYDRATE						
	Powder for inhalation 4.5 mcg per dose, breath activated						
	(equivalent to eformoterol fumarate 6 mcg metered dose	e)10.32	60 (	dose	OP		
	, ,	(16.90)					Oxis Turbuhaler
Иι	DACATEROL	. ,					
. 41	Powder for inhalation 150 mcg	61.00	30 (	lose	OP	/	Onbrez Breezhaler
	Powder for inhalation 300 mcg		•	dose	•		Onbrez Breezhaler
۰.	•		50 (		٠.	-	JDI DI DI OLI IGIOI
SΑ	LMETEROL  Agreed inhalor CEC from 25 mag per door	05.00	100	doss	OΡ	.,	Caravant
	Aerosol inhaler CFC-free, 25 mcg per dose			dose	-		Serevent
	Aerosol inhaler 25 mcg per dose			dose dose			Meterol Serevent Accuhaler
	Powder for inhalation, 50 mcg per dose, breath activated	25.00	00 (	JUSE	UF	•	Serevent Accumater
lr	haled Corticosteroids with Long-Acting Beta-	Adrenocep	tor A	gon	ists		
ЗU	DESONIDE WITH EFORMOTEROL						
	Aerosol inhaler 100 mcg with eformoterol fumarate 6 mcg			dose	-		Vannair
	Powder for inhalation 100 mcg with eformoterol fumarate 6 m	ncg33.74	120	dose	OP	/	Symbicort
	Assessed Subselve 000 meanwith of the state	64.46	400	.i.	00	,	Turbuhaler 100/6
	Aerosol inhaler 200 mcg with eformoterol fumarate 6 mcg			dose	-		Vannair
	Powder for inhalation 200 mcg with eformoterol fumarate 6 m	ncg 44.08	120	dose	U۲	•	Symbicort
	<b>2</b>						Turbuhaler 200/6
	Powder for inhalation 400 mcg with eformoterol fumarate				0.0		•
	12 mcg - No more than 2 dose per day	44.08	60 (	dose	OP	•	Symbicort
							Turbuhaler 400/12
FL	JTICASONE FUROATE WITH VILANTEROL						
	Powder for inhalation 100 mcg with vilanterol 25 mcg	44.08	30 (	dose	OP	1	Breo Ellipta
-LI	JTICASONE WITH SALMETEROL						
_	Aerosol inhaler 50 mcg with salmeterol 25 mcg	14.58	120	dose	OP	1	RexAir
		33.74	_,		-		Seretide
	Aerosol inhaler 125 mcg with salmeterol 25 mcg		120	dose	OP		RexAir
		44.08	_,		-		Seretide
	Powder for inhalation 100 mcg with salmeterol 50 mcg - No						
	more than 2 dose per day		60 (	dose	OP	1	Seretide Accuhaler
	Powder for inhalation 250 mcg with salmeterol 50 mcg – No		50 (		٥.	-	
	i owaei ioi iiinaialion 200 mcg willi Saimeleioi 00 mcg - No			dose	<b>O</b> D	./	Seretide Accuhaler
	more than 2 dose per day	/ / NO	EU -				

	Subsidy		Fully	Brand or
	(Manufacturer's I		dised	Generic
	\$	Per		Manufacturer
Beta-Adrenoceptor Agonists				
SALBUTAMOL				
Oral liq 400 mcg per ml	20.00	150 ml	11	/entolin
Infusion 1 mg per ml, 5 ml		10	• 1	CITOIII
musion i mg per mi, 5 mi	(130.21)	10	١	/entolin
Inj 500 mcg per ml, 1 ml - Up to 5 inj available on a PSO	` ,	5		/entolin
Inhaled Beta-Adrenoceptor Agonists			•	· • · · · · · · · · · · · · · · · · · ·
illialed bela-Adienoceptor Agonists				
SALBUTAMOL				
Aerosol inhaler, 100 mcg per dose CFC free - Up to 1000				
dose available on a PSO	3.80	200 dose OP	<b>√</b> F	Respigen
				SalAir
	(6.00)		-	/entolin
Nebuliser soln, 1 mg per ml, 2.5 ml ampoule - Up to 30 neb	(0.00)		,	Cittoliii
available on a PSO	2.02	20	.//	Asthalin
	3.93	20	· <u>·</u>	ASUIAIIII
Nebuliser soln, 2 mg per ml, 2.5 ml ampoule – Up to 30 neb	4.00	00		N = 41: = 11:
available on a PSO	4.03	20	• 1	<u>Asthalin</u>
TERBUTALINE SULPHATE				
Powder for inhalation, 250 mcg per dose, breath activated	27.30	200 dose OP	<b>✓</b> E	Bricanyl Turbuhaler
Anticholinergic Agents				
IPRATROPIUM BROMIDE				
Aerosol inhaler, 20 mcg per dose CFC-free – Up to 400 dose				
available on a PSO		200 dose OP	•	Atrovent
Nebuliser soln, 250 mcg per ml, 1 ml ampoule - Up to 40 ne				
available on a PSO		20	<b>√</b> [	<u> Inivent</u>
Nebuliser soln, 250 mcg per ml, 2 ml ampoule - Up to 40 ne	b			
available on a PSO	3.52	20	<b>√</b> [	<u>Jnivent</u>
Inhaled Beta-Adrenoceptor Agonists with Anticl	nolinergic A	gents		
SALBUTAMOL WITH IPRATROPIUM BROMIDE				
Aerosol inhaler, 100 mcg with ipratropium bromide, 20 mcg p	or			
dose CFC-free		200 dose OP	<b>√</b> Γ	Duolin HFA
Nebuliser soln, 2.5 mg with ipratropium bromide 0.5 mg per	12.10	200 0030 01	٠.	Zuoliii III A
vial, 2.5 ml ampoule – Up to 20 neb available on a PSO	5 20	20	<b>/</b> [	Duolin
viai, 2.3 iiii airipodie – op to 20 neb avaliable on a 1 30		20	• •	<del>Juonin</del>
Long-Acting Muscarinic Antagonists				
Long Adding mucouring Amagomoto				
GLYCOPYRRONIUM – Subsidy by endorsement				
a) Inhaled glycopyrronium treatment will not be subsidised if	patient is also	receiving treatme	nt wit	h subsidised tiotropium or
umeclidinium.	-	-		•
b) Glycopyrronium powder for inhalation 50 mcg per dose is	subsidised only	for patients who	have	been diagnosed as
having COPD using spirometry, and the prescription is en				ŭ
Powder for inhalation 50 mcg per dose		30 dose OP	19	Seebri Breezhaler
<b>3</b> 1				

Subsidy	Fu	ly Brand or	
(Manufacturer's P	rice) Subsidise	ed Generic	
\$	Per	Manufacturer	

### TIOTROPIUM BROMIDE - Subsidy by endorsement

- a) Tiotropium treatment will not be subsidised if patient is also receiving treatment with subsidised inhaled glycopyrronium or umeclidinium.
- b) Tiotropium bromide is subsidised only for patients who have been diagnosed as having COPD using spirometry, and the prescription is endorsed accordingly. Patients who had tiotropium dispensed before 1 October 2018 with a valid Special Authority are deemed endorsed.

Powder for inhalation, 18 mcg per dose	50.37	30 dose	✓ Spiriva
Soln for inhalation 2.5 mcg per dose	50.37	60 dose OP	✓ Spiriva Respimat

### 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, and the prescription is endorsed accordingly.

Powder for inhalation 62.5 mcg per dose .......61.50 30 dose OP ✓ Incruse Ellipta

## 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 INDACAT	EROL - Special Authority see SA1584	above – Retail pha	rmacy
Powder for Inhalation 50 mcg with	indacaterol 110 mcg81.00	30 dose OP	✓ Ultibro Breezhaler
TIOTROPIUM BROMIDE WITH OLOD	ATEROL - Special Authority see SA15	84 above – Retail p	harmacy
Soln for inhalation 2.5 mcg with old	odaterol 2.5 mcg81.00	60 dose OP	✓ Spiolto Respimat
LIMECLIDINILIM WITH VII ANTEDOL	Chariel Authority and CA1E94 above	Datail pharmany	

### Antifibrotics

NINTEDANIB - Special Authority see SA1755 below - Retail pharmacy

Note: Nintedanib not subsidised in combination with subsidised pirfenidone.

Cap 100 mg	2,554.00	60 OP	Ofev
Cap 150 mg	3,870.00	60 OP	Ofev

### ⇒SA1755 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

#### RESPIRATORY SYSTEM AND ALLERGIES

|--|

#### continued...

- 2 Forced vital capacity is between 50% and 90% predicted; and
- 3 Nintedanib is to be discontinued at disease progression (See Note); and
- 4 Nintedanib is not to be used in combination with subsidised pirfenidone; and
- 5 Any of the following:
  - 5.1 The patient has not previously received treatment with pirfenidone; or
  - 5.2 Patient has previously received pirfenidone, but discontinued pirfenidone within 12 weeks due to intolerance; or
  - 5.3 Patient has previously received pirfenidone, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with pirfenidone).

**Renewal — (idiopathic pulmonary fibrosis)** only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

#### All of the following:

- 1 Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and
- 2 Nintedanib is not to be used in combination with subsidised pirfenidone; and
- 3 Nintedanib is to be discontinued at disease progression (See Note).

Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

#### PIRFENIDONE - Retail pharmacy-Specialist - Special Authority see SA1748 below

Note: Pirfenidone is not subsidised in combination with subsidised nintedanib.

#### ⇒SA1748 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 80% 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	INTELUKAST			
*	Tab 4 mg	5.25	28	✓ Apo-Montelukast
*	Tab 5 mg	5.50	28	✓ Apo-Montelukast
*	Tab 10 mg	5.65	28	✓ Accord S29
	· ·			✓ Apo-Montelukast

#### RESPIRATORY SYSTEM AND ALLERGIES

RESPIRATORY SYSTEM AND ALLI	ERGIES		
	Subsidy (Manufacturer's \$	Price) Subsi Per	Fully Brand or dised Generic  Manufacturer
Mast Cell Stabilisers			
NEDOCROMIL			
Aerosol inhaler, 2 mg per dose CFC-free	28.07	112 dose OP	✓ Tilade
SODIUM CROMOGLICATE Aerosol inhaler, 5 mg per dose CFC-free	28.07	112 dose OP	✓ Intal Forte CFC Free
Methylxanthines			
AMINOPHYLLINE			
* Inj 25 mg per ml, 10 ml ampoule – Up to 5 inj av		_	<b>4 5 5 1 1 1 1 1 1</b>
PSO THEOPHYLLINE	124.37	5	✓ <u>DBL Aminophylline</u>
* Tab long-acting 250 mg	21.51	100	✓ Nuelin-SR
* Oral liq 80 mg per 15 ml		500 ml	✓ Nuelin
Mucolytics			
DORNASE ALFA – Special Authority see SA0611 be	elow – Retail pharmacy		
Nebuliser soln, 2.5 mg per 2.5 ml ampoule	250.00	6	✓ Pulmozyme
SA0611 Special Authority for Subsidy Special Authority approved by the Cystic Fibrosis Adv Notes: Application details may be obtained from PH/		w.pharmac.govt.	nz or:
The Co-ordinator, Cystic Fibrosis Advisory Panel	Phone: (04) 460 4990		_
PHARMAC, PO Box 10 254	Facsimile: (04) 916 757	1	
Wellington	Email: <u>CFPanel@pharm</u>	ac.govt.nz	
Prescriptions for patients approved for treatment mus and expertise in treating cystic fibrosis.	st be written by respiratory p	ohysicians or pae	diatricians who have experience
SODIUM CHLORIDE  Not funded for use as a nasal drop.			
Soln 7%	23.50	90 ml OP	✓ Biomed
Nasal Preparations			
Allergy Prophylactics			
BECLOMETHASONE DIPROPIONATE			
Metered aqueous nasal spray, 50 mcg per dose	2.35 (5.26)	200 dose OP	Alanase
Metered aqueous nasal spray, 100 mcg per dose	e2.46 (6.00)	200 dose OP	Alanase
(Alanase Metered aqueous nasal spray, 50 mcg per (Alanase Metered aqueous nasal spray, 100 mcg per			
BUDESONIDE	0.50	000 de 05	( Otana Otana
Metered aqueous nasal spray, 50 mcg per dose Metered aqueous nasal spray, 100 mcg per dose		200 dose OP 200 dose OP	✓ <u>SteroClear</u> ✓ <u>SteroClear</u>
FLUTICASONE PROPIONATE	4.00	400   00	<b>4</b> =

Metered aqueous nasal spray, 50 mcg per dose ......1.98

✓ Flixonase Hayfever & Allergy

120 dose OP

## RESPIRATORY SYSTEM AND ALLERGIES

✓ Biomed

25 ml OP

	Subsidy		Fully	Brand or
	(Manufacturer's Pri		sidised	Generic
	\$	Per	✓	Manufacturer
PRATROPIUM BROMIDE				
Aqueous nasal spray, 0.03%	4.61	15 ml OP	<b>√</b> <u>U</u>	<u>Inivent</u>
Respiratory Devices				
MASK FOR SPACER DEVICE				
a) Up to 50 dev available on a PSO				
b) Only on a PSO				
<ul> <li>c) Only for children aged six years and under</li> </ul>				
Small	2.20	1	<b>√</b> e	-chamber Mask
PEAK FLOW METER				
a) Up to 25 dev available on a PSO				
b) Only on a PSO				
Low range	9.54	1	✓ N	lini-Wright AFS Low Range
Normal range	9.54	1	✓ N	lini-Wright
				Standard
SPACER DEVICE				
a) Up to 50 dev available on a PSO				
b) Only on a PSO			_	
220 ml (single patient)		1	•	-chamber Turbo
510 ml (single patient)	5.12	1	<b>✓</b> e	-chamber La Grande
800 ml	6.50	1	<b>✓</b> V	olumatic
Respiratory Stimulants				
CAFFEINE CITRATE				
PAFFEINE OH MATE			_	

Oral liq 20 mg per ml (10 mg base per ml)......14.85

	Subsidy		Fully	Brand or
	(Manufacturer's Pri	ice) Sul	bsidised	Generic
	\$	Per	1	Manufacturer
	· · ·			
Ear Preparations				
ACCTIC ACID MITH 4 O DECEMBEDIOL DIACCTATE AND DE	NZETLIONILIM			
ACETIC ACID WITH 1, 2- PROPANEDIOL DIACETATE AND BE				
For Vosol ear drops with hydrocortisone powder refer Standa	ırd Formulae, <mark>pag</mark>	je 227		
Ear drops 2% with 1, 2-Propanediol diacetate 3% and				
benzethonium chloride 0.02%	6 97	35 ml OP	<b>✓</b> \	/osol
		00 1111 01	•	70001
FLUMETASONE PIVALATE				
Ear drops 0.02% with clioquinol 1%	4.46	7.5 ml OP	✓ L	_ocacorten-Viaform
				ED's
			./ 1	ocorten-Vioform
			V L	-ocorten-violoriii
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCI	N AND NYSTATI	N		
Ear drops 1 mg with nystatin 100,000 u, neomycin sulphate				
	E 40	7.5		( l
2.5 mg and gramicidin 250 mcg per g	5.16	7.5 ml OP	<b>V</b> F	(enacomb
Ear/Eye Preparations				
, ,				
DEXAMETHASONE WITH FRAMYCETIN AND GRAMICIDIN				
Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and				
	4.50	0 1 OD		
gramicidin 50 mcg per ml		8 ml OP	_	
	(9.27)		5	Sofradex
FRAMYCETIN SULPHATE				
Ear/Eye drops 0.5%	4.10	8 ml OP		
Edi/Eye drops 0.5%		o IIII OF	_	
	(8.65)		5	Soframycin
Eye Preparations				
,				
Eye preparations are only funded for use in the eye, unless explic	ritly stated otherw	ise		
Lyc proparations are only fanded for doe in the eye, amoss expite	nily stated strict w	100.		
Anti-Infective Preparations				
And intective i reparations				
ACICLOVIR				
* Eye oint 3%	14.00	4 E a OD	./ \	/im.DOS
* Eye oint 3%	14.92	4.5 g OP	<u> </u>	<u>/iruPOS</u>
CHLORAMPHENICOL				
Eye oint 1%	2.48	4 g OP	10	Chlorsig
Eye drops 0.5%		10 ml OP	_	Chlorafast
			• •	Jilloralast
Funded for use in the ear*. Indications marked with * are	anapproved indi	icaliulis.		
CIPROFLOXACIN				
Eye drops 0.3% - Subsidy by endorsement	9 99	5 ml OP	10	Ciprofloxacin Teva
When prescribed for the treatment of bacterial keratitis o			_	
for the second line treatment of chronic suppurative otitis		and the pre	scription	is endorsed accordingly.
Note: Indication marked with a * is an unapproved indication	ation.			
GENTAMICIN SULPHATE				
	11.40	E ml OD	./ (	Conontio
Eye drops 0.3%	11.40	5 ml OP	• (	Genoptic
PROPAMIDINE ISETHIONATE				
* Eye drops 0.1%	2.97	10 ml OP		
=,	(14.55)			Brolene
	(17.55)			21010110
SODIUM FUSIDATE [FUSIDIC ACID]				
Eye drops 1%	5.29	5 g OP	<b>√</b> F	Fucithalmic
•		-		

	Subsidy (Manufacturer's P	trico) Cut	Fully	Brand or Generic	
	(Manufacturer S F	Per	JSIUISEU	Manufacturer	
TOBRAMYCIN					
Eye oint 0.3%	10.45	3.5 g OP	<b>✓</b> T	obrex	
Eye drops 0.3%	11.48	5 ml OP	<b>✓</b> T	obrex	
Corticosteroids and Other Anti-Inflammatory Pr	reparations				
DEXAMETHASONE					
* Eye oint 0.1%	5.86	3.5 g OP	✓ N	laxidex	
* Eye drops 0.1%	4.50	5 ml OP	✓ N	laxidex	
Ocular implant 700 mcg - Special Authority see SA1680 bel	low				
– Retail pharmacy	1,444.50	1	<b>√</b> (	)zurdex	

⇒SA1680 Special Authority for Subsidy

**Initial application — (Diabetic macular oedema)** only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

#### All of the following:

- 1 Patient has diabetic macular oedema with pseudophakic lens; and
- 2 Patient has reduced visual acuity of between 6/9 6/48 with functional awareness of reduction in vision; and
- 3 Fither
  - 3.1 Patient's disease has progressed despite 3 injections with bevacizumab; or
  - 3.2 Patient is unsuitable or contraindicated to treatment with anti-VEGF agents; and
- 4 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

Renewal — (Diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

#### Both:

- 1 Patient's vision is stable or has improved (prescriber determined); and
- 2 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

**Initial application — (Women of child bearing age with diabetic macular oedema)** only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

#### All of the following:

- 1 Patient has diabetic macular oedema: and
- 2 Patient has reduced visual acuity of between 6/9 6/48 with functional awareness of reduction in vision; and
- 3 Patient is of child bearing potential and has not yet completed a family; and
- 4 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

Renewal — (Women of child bearing age with diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

#### All of the following:

- 1 Patient's vision is stable or has improved (prescriber determined); and
- 2 Patient is of child bearing potential and has not vet completed a family: and
- 3 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

#### DEXAMETHASONE WITH NEOMYCIN SULPHATE AND POLYMYXIN B SULPHATE

*	Eye oint 0.1% with neomycin sulphate 0.35% and polymyxin b			
	sulphate 6,000 u per g5	.39	3.5 g OP	✓ Maxitrol
*	Eye drops 0.1% with neomycin sulphate 0.35% and polymyxin b sulphate 6,000 u per ml4	.50	5 ml OP	✓ Maxitrol
DIC	CLOFENAC SODIUM			
	Eye drops 0.1%13	3.80	5 ml OP	✓ Voltaren Ophtha

	Subsidy		Fully	Brand or
	(Manufacturer's P	rice) Subs Per	idised •	Generic Manufacturer
ELLIOPOMETUOLONE	Ψ	1 01		Manadataro
FLUOROMETHOLONE				
* Eye drops 0.1%	3.09	5 ml OP	<b>√</b> F	ML
	5.20		<b>√</b> F	lucon
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%	3 93	10 ml OP	<b>✓</b> P	rednisolone-AFT
Lyo dropo 170	7.00	5 ml OP		red Forte
	7.00	3 IIII OF	• -	Teu Forte
PREDNISOLONE SODIUM PHOSPHATE - Special Authority se	ee SA1715 below	- Retail pharn	nacy	
Eye drops 0.5%, single dose (preservative free)	38.50	20 dose	✓ N	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.

DORZOLAMIDE WITH TIMOLOL  * Eye drops 2% with timolol 0.5%	7 5 ml OP	✓ Dortimopt
DORZOLAMIDE WITH TIMOLOL	4)	Trusopt
* Eye drops 2%		T
DORZOLAMIDE HYDROCHLORIDE		
* Eye drops 1%	7 5 ml OP	✓ Azopt
BRINZOLAMIDE		
* Tab 250 mg17.0	3 100	✓ Diamox
ACETAZOLAMIDE		
Glaucoma Preparations - Carbonic Anhydrase Inhibitors		
* Eye drops 0.5%, gel forming3.7	8 2.5 ml OP	✓ <u>Timoptol XE</u>
* Eye drops 0.5%	3 5 ml OP	✓ Arrow-Timolol
* Eye drops 0.25%, gel forming		✓ Timoptol XE
* Eye drops 0.25%	3 5 ml OP	✓ Arrow-Timolol
TIMOLOL		
* Eye drops 0.5%	0 5 ml OP	✓ Betagan
LEVOBUNOLOL	0 5 1 O.D.	/ Data was
* Eye drops 0.5%7.5	0 5 ml OP	✓ Betoptic
* Eye drops 0.25%		✓ Betoptic S
BETAXOLOL		
Glaucoma Preparations - Beta Blockers		
Eye drops 2%	5 5 ml OP	✓ Rexacrom
SODIUM CROMOGLICATE		

	Subsidy		Fully Brand or
	(Manufacturer's Pi	rice) Subs Per	idised Generic  ✓ Manufacturer
	Ψ	1 01	- Iviarialacturer
Glaucoma Preparations - Prostaglandin Analog	ues		
BIMATOPROST			
* Eye drops 0.03%	3.30	3 ml OP	✓ Bimatoprost
•			Multichem
	(3.65)		Bimatoprost Actavis
(Bimatoprost Actavis Eye drops 0.03% to be delisted 1 May 2019	9) `´´		·
LATANOPROST			
* Eye drops 0.005%	1.50	2.5 ml OP	✓ Hysite
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	1.57		✓ Teva
Teva to be Sole Supply on 1 July 2019			
(Hysite Eye drops 0.005% to be delisted 1 July 2019)			
TRAVOPROST			
* Eye drops 0.004%	7.30	5 ml OP	✓ Travopt
,	19.50	2.5 ml OP	✓ Travatan
Glaucoma Preparations - Other			
BRIMONIDINE TARTRATE			
* Eye drops 0.2%	4.29	5 ml OP	✓ <u>Arrow-Brimonidine</u>
BRIMONIDINE TARTRATE WITH TIMOLOL MALEATE			
* Eye drops 0.2% with timolol maleate 0.5%	18.50	5 ml OP	✓ Combigan
PILOCARPINE HYDROCHLORIDE			-
* Eye drops 1%	4.26	15 ml OP	✓ Isopto Carpine
* Eye drops 2%		15 ml OP	✓ Isopto Carpine
* Eye drops 4%		15 ml OP	✓ Isopto Carpine
Subsidised for oral use pursuant to the Standard Formul	ae.		
* Eye drops 2% single dose – Special Authority see SA0895			
below – Retail pharmacy	31.95	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:

- 1 Patient has to use an unpreserved solution due to an allergy to the preservative; or
- 2 Patient wears soft contact lenses.

Note: Minims for a general practice are considered to be "tools of trade" and are not approved as special authority items. **Renewal** from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Mydriatics and Cycloplegics		
ATROPINE SULPHATE  * Eye drops 1%	15 ml OP	✓ Atropt
CYCLOPENTOLATE HYDROCHLORIDE  * Eye drops 1%8.76	15 ml OP	✓ Cyclogyl
TROPICAMIDE	15 ml OP	✓ Mydriacyl
* Eye drops 1%	15 ml OP	✓ Mydriacyl



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

## **Preparations for Tear Deficiency**

For acetylcysteine eye drops refer Standard Formulae, page 227

HYPROMELLOSE

HTPROWELLOSE			
* Eye drops 0.5%	2.00	15 ml OP	
, .	(3.92)		Methopt
HYPROMELLOSE WITH DEXTRAN			
* Eye drops 0.3% with dextran 0.1%	2.30	15 ml OP	✓ Poly-Tears
POLYVINYL ALCOHOL			
* Eye drops 1.4%	2.62	15 ml OP	✓ Vistil
* Eve drops 3%	3.68	15 ml OP	✓ Vistil Forte

#### **Preservative Free Ocular Lubricants**

#### ⇒SA1388 Special Authority for Subsidy

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

- 1 Confirmed diagnosis by slit lamp of severe secretory dry eye; and
- 2 Either:
  - 2.1 Patient is using eye drops more than four times daily on a regular basis; or
  - 2.2 Patient has had a confirmed allergic reaction to preservative in eye drop.

Renewal from any relevant practitioner. Approvals valid for 24 months where the patient continues to require lubricating eye drops and has benefited from treatment.

CARBOMER – Special Authority see SA1388 above – Retail phar Ophthalmic gel 0.3%, 0.5 g		30	✓ Poly-Gel				
MACROGOL 400 AND PROPYLENE GLYCOL – Special Authority Eye drops 0.4% and propylene glycol 0.3%, 0.4 ml							
SODIUM HYALURONATE [HYALURONIC ACID] – Special Authority see SA1388 above – Retail pharmacy Eye drops 1 mg per ml							
Hylo-Fresh has a 6 month expiry after opening. The Phar month is not relevant and therefore only the prescribed do							

## **Other Eye Preparations**

NAPHAZOLINE HYDROCHLORIDE  * Eye drops 0.1%4.15	15 ml OP	✓ Naphcon Forte
OLOPATADINE  Eye drops 0.1%10.00	5 ml OP	✓ Patanol
PARAFFIN LIQUID WITH SOFT WHITE PARAFFIN  * Eye oint with soft white paraffin	3.5 g OP	✓ Refresh Night Time
PARAFFIN LIQUID WITH WOOL FAT  * Eye oint 3% with wool fat 3%	3.5 g OP	✓ Poly-Visc
RETINOL PALMITATE  Eye oint 138 mcg per g3.80	5 g OP	✓ VitA-POS

✓ BSF Elelyso

Hydrochloride

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

1 fee

#### **Various**

#### PHARMACY SERVICES

May only be claimed once per patient.

The Pharmacode for BSF Elelyso is 2561972 - see also page 31

(BSF Elelyso Brand switch fee to be delisted 1 June 2019)

## **Agents Used in the Treatment of Poisonings**

#### **Antidotes**

OFTYL OVOTEINE

*	Inj 400 mcg per ml, 1 ml ampoule	22.60	5	DBL Naloxone
	b) Only on a PSO			
	a) Up to 5 inj available on a PSO			
NAL	OXONE HYDROCHLORIDE			
	Inj 200 mg per ml, 10 ml ampoule	58.76	10	✓ DBL Acetylcysteine
	ETYLCYSTEINE - Retail pharmacy-Specialist			_

#### Removal and Elimination

#### CHARCOAL

*	Oral liq 50 g per 250 ml43.50	250 ml OP	✓ Carbosorb-X
	a) Up to 250 ml available on a PSO		

b) Only on a PSO

# Wastage claimable 276.00 28 ✓ Exjade Tab 125 mg dispersible 276.00 28 ✓ Exjade Tab 250 mg dispersible 552.00 28 ✓ Exjade Tab 500 mg dispersible 1,105.00 28 ✓ Exjade

#### ⇒SA1492 Special Authority for Subsidy

Initial application only from a haematologist. Approvals valid for 2 years for applications meeting the following criteria: All of the following:

- 1 The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia; and
- 2 Deferasirox is to be given at a daily dose not exceeding 40 mg/kg/day; and
- 3 Any of the following:
  - 3.1 Treatment with maximum tolerated doses of deferiprone monotherapy or deferiprone and desferrioxamine combination therapy have proven ineffective as measured by serum ferritin levels, liver or cardiac MRI T2\*; or
  - 3.2 Treatment with deferiprone has resulted in severe persistent vomiting or diarrhoea; or
  - 3.3 Treatment with deferiprone has resulted in arthritis; or

DEFERASIROX - Special Authority see SA1492 below - Retail pharmacy

3.4 Treatment with deferiprone is contraindicated due to a history of agranulocytosis (defined as an absolute neutrophil count (ANC) of < 0.5 cells per μL) or recurrent episodes (greater than 2 episodes) of moderate neutropenia (ANC 0.5 - 1.0 cells per μL).</p>

**Renewal** only from a haematologist. Approvals valid for 2 years for applications meeting the following criteria: Either:

- 1 For the first renewal following 2 years of therapy, the treatment has been tolerated and has resulted in clinical improvement in all three parameters namely serum ferritin, cardiac MRI T2\* and liver MRI T2\* levels; or
- 2 For subsequent renewals, the treatment has been tolerated and has resulted in clinical stability or continued improvement in all three parameters namely serum ferritin, cardiac MRI T2\* and liver MRI T2\* levels.

## **VARIOUS**

	Subsidy (Manufacturer's Pric \$	e) S Per	Fully Subsidised	Brand or Generic Manufacturer	
DEFERIPRONE - Special Authority see SA1480 below - Retail	pharmacy				
Tab 500 mg	533.17	100	<b>√</b> F	erriprox	
Oral liq 100 mg per 1 ml	266.59	250 ml O	)P <b> </b>	erriprox	
- CA4400 Consist Authority for Cubaldy				-	

#### ⇒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.

* Inj 500 mg vial	51.52	10	✓ Desferal
	84.53		✓ DBL  Desferrioxamine  Mesylate for Inj  BP
DBL Desferrioxamine Mesylate for Inj BP to be Sole (Desferal Inj 500 mg vial to be delisted 1 June 2019)	Supply on 1 June 2019	)	
SODIUM CALCIUM EDETATE  * Inj 200 mg per ml, 5 ml	53.31	6	
	(156.71)		Calcium Disodium

Versenate

Omeprazole capules or powder

Sodium bicarbonate powder BP

Water

Standard Formulae			
ACETYLCYSTEINE EYE DROPS Acetylcysteine inj 200 mg per ml, 10 ml Suitable eye drop base	qs qs	PHENOBARBITONE ORAL LIQUID Phenobarbitone Sodium Glycerol BP Water	1 g 70 ml to 100 ml
ASPIRIN AND CHLOROFORM APPLICATION Aspirin Soluble tabs 300 mg Chloroform	12 tabs to 100 ml	PHENOBARBITONE SODIUM PAEDIATRIC ORAL mg per ml)	LIQUID (10
CODEINE LINCTUS PAEDIATRIC (3 mg per 5 ml) Codeine phosphate Glycerol Preservative Water	60 mg 40 ml qs to 100 ml	Phenobarbitone Sodium Glycerol BP Water  PILOCARPINE ORAL LIQUID Pilocarpine 4% eye drops	400 mg 4 ml to 40 ml
CODEINE LINCTUS DIABETIC (15 mg per 5 ml) Codeine phosphate Glycerol Preservative Water	300 mg 40 ml qs to 100 ml	Preservative Water (Preservative should be used if quantity supplied is than 5 days.)  SALIVA SUBSTITUTE FORMULA	
FOLINIC MOUTHWASH Calcium folinate 15 mg tab Preservative Water (Preservative should be used if quantity supplied is than 5 days. Maximum 500 ml per prescription.)	1 tab qs to 500 ml for more	Methylcellulose Preservative Water (Preservative should be used if quantity supplied is than 5 days. Maximum 500 ml per prescription.) SODIUM CHLORIDE ORAL LIQUID	5 g qs to 500 ml for more
MAGNESIUM HYDROXIDE 8% MIXTURE Magnesium hydroxide paste 29% Methyl hydroxybenzoate Water	275 g 1.5 g to 1,000 m	Sodium chloride inj 23.4%, 20 ml Water (Only funded if prescribed for treatment of hyponatra IJ VANCOMYCIN ORAL SOLUTION (50 mg per ml) Vancomycin 500 mg injection	qs qs aemia) 10 vials
METHADONE MIXTURE Methadone powder Glycerol Water	qs qs to 100 ml	Glycerol BP Water (Only funded if prescribed for treatment of Clostridiu following metronidazole failure)	40 ml to 100 ml
METHYL HYDROXYBENZOATE 10% SOLUTION Methyl hydroxybenzoate Propylene glycol (Use 1 ml of the 10% solution per 100 ml of oral liqu	10 g to 100 ml id mixture)	VOSOL EAR DROPS WITH HYDROCORTISONE POWDER 1% Hydrocortisone powder Vosol Ear Drops	1% to 35 ml
OMEPRAZOLE SUSPENSION			

qs

8.4 g to 100 ml

#### EXTEMPORANEOUSLY COMPOUNDED PREPARATIONS AND GALENICALS

Subsidy

Fully

Brand or

(Manufacturer's Price) Subsidised Generic Manufacturer Extemporaneously Compounded Preparations and Galenicals BENZOIN Tincture compound BP......24.42 500 ml (39.90)Pharmacy Health 2.44 50 ml (5.10)Pharmacy Health CHI OROFORM a) Only in combination b) Maximum of 100 ml per prescription c) Only in aspirin and chloroform application. 500 ml ✓ PSM CODEINE PHOSPHATE - Safety medicine; prescriber may determine dispensing frequency (90.09)Douglas Only in extemporaneously compounded codeine linctus diabetic or codeine linctus paediatric. **COLLODION FLEXIBLE** Collodion flexible 19.30 ✓ PSM 100 ml COMPOUND HYDROXYBENZOATE - Only in combination Only in extemporaneously compounded oral mixtures. 100 ml ✓ Midwest ✓ David Craiq 34.18 GLYCERIN WITH SODIUM SACCHARIN - Only in combination Only in combination with Ora-Plus. Suspension.......30.95 473 ml ✓ Ora-Sweet SF Ora-Sweet SF to be Sole Supply on 1 July 2019 GLYCERIN WITH SUCROSE - Only in combination Only in combination with Ora-Plus. Suspension......30.95 ✓ Ora-Sweet 473 ml Ora-Sweet to be Sole Supply on 1 July 2019 **GLYCEROL** 500 ml ✓ healthE Glycerol BP Only in extemporaneously compounded oral liquid preparations. MAGNESIUM HYDROXIDE 500 q PSM METHADONE HYDROCHLORIDE a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing frequency d) Extemporaneously compounded methadone will only be reimbursed at the rate of the cheapest form available (methadone powder, not methadone tablets). Powder 7.84 ✓ AFT 1 g

Midwest to be Sole Supply on 1 July 2019

METHYL HYDROXYBENZOATE

✓ Midwest

25 a

## EXTEMPORANEOUSLY COMPOUNDED PREPARATIONS AND GALENICALS

	Subsidy		Fully	Brand or
	(Manufacturer's Pi		sidised	Generic
	\$	Per	1	Manufacturer
THYLCELLULOSE				
Powder	36.95	100 g	<b>✓</b> I	MidWest
MidWest to be Sole Supply on 1 July 2019				
Suspension - Only in combination	30.95	473 ml	✓ (	Ora-Plus
Ora-Plus to be Sole Supply on 1 July 2019				
THYLCELLULOSE WITH GLYCERIN AND SODIUM SACCH	ARIN - Only in o	combination		
Suspension	30.95	473 ml	✓ (	Ora-Blend SF
Ora-Blend SF to be Sole Supply on 1 July 2019				
THYLCELLULOSE WITH GLYCERIN AND SUCROSE - Onl	ly in combination			
Suspension	30.95	473 ml	✓ (	Ora-Blend
Ora-Blend to be Sole Supply on 1 July 2019				
ENOBARBITONE SODIUM				
Powder - Only in combination	52.50	10 g	<b>√</b> I	MidWest
•	325.00	100 g	<b>✓</b> [	MidWest
Only in children up to 12 years				
DPYLENE GLYCOL				
Only in extemporaneously compounded methyl hydroxybenz	oate 10% solution	n.		
Liq	11.25	500 ml	<b>✓</b> I	Midwest
DIUM BICARBONATE				
Powder BP - Only in combination	8.95	500 g	<b>✓</b> I	Midwest
,	9.80	3		
	(29.50)		[	David Craig
Only in extemporaneously compounded omeprazole and	d lansoprazole su	spension.		
RUP (PHARMACEUTICAL GRADE) – Only in combination				
Only in extemporaneously compounded oral liquid preparation	ons.			
Liq		2,000 ml	<b>✓</b> I	Midwest
TEB		•		
Tap – Only in combination	0.00	1 ml	<b>/</b> 1	Γap water

Subsidy (Manufacturer's Price) Fully Subsidised Per

Brand or Generic Manufacturer

## **Nutrient Modules**

#### Carbohydrate

#### ⇒SA1522 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 inborn errors of metabolism: or
- 7 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 — (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 And Fat

#### **⇒SA1376** Special Authority for Subsidy

Initial application — (Cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

continued...

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

- 1 Infant or child aged four years or under; and
- 2 cystic fibrosis.

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 infant or child aged four years or under; and
- 2 Any of the following:
  - 2.1 cancer in children; or
  - 2.2 faltering growth; or
  - 2.3 bronchopulmonary dysplasia; or
  - 2.4 premature and post premature infants.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

#### Fat

## **⇒SA1523** Special Authority for Subsidy

**Initial application** — (Inborn errors of metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient has inborn errors of metabolism.

Initial application — (Indications other than inborn errors of metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria: Any of the following:

- 1 faltering growth in an infant/child; or
- 2 bronchopulmonary dysplasia; or
- 3 fat malabsorption; or
- 4 lymphangiectasia; or
- 5 short bowel syndrome: or
- 6 infants with necrotising enterocolitis; or
- 7 biliary atresia; or
- 8 for use in a ketogenic diet; or
- 9 chyle leak; or

continued...

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

- 10 ascites: or
- 11 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula. **Renewal — (Inborn errors of metabolism)** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than inborn errors of metabolism) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

FAT SUPPLEMENT – Special Authority see SA1523 on the previous page – Hospital pharmacy [HP3]

Emulsion (neutral)12.30	200 ml OP	✓ Calogen
30.75	500 ml OP	✓ Calogen
Emulsion (strawberry)12.30	200 ml OP	✓ Calogen
Oil30.00	500 ml OP	✓ MCT oil (Nutricia)
Oil, 250 ml114.92	4 OP	✓ Liquigen

#### **Protein**

#### ⇒SA1524 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 protein losing enteropathy; or
- 2 high protein needs; or
- 3 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula. **Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

PROTEIN SUPPLEMENT	<ul> <li>Special Authority see SA1524 above – Hospital p</li> </ul>	narmacy [HP3]	
Powder	7.90	225 g OP	✓ Protifar
	8.95	227 g OP	✓ Resource
		•	Beneprotein

Subsidy (Manufacturer's Price) Fully Subsidised Per

Brand or Generic Manufacturer

Sustagen Diabetic

## Oral Supplements/Complete Diet (Nasogastric/Gastrostomy Tube Feed)

#### **Respiratory Products**

#### ⇒SA1094 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 CORD and hypercapnia, defined as a CO2 value exceeding 55 mmHg.

**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 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 Auth		- Hospital pharm 1,000 ml OP	nacy [HP3]  ✓ Diason RTH ✓ Glucerna Select RTH
DIABETIC ORAL FEED 1KCAL/ML - Special Authority	y see SA1095 above – Ho	spital pharmacy	[HP3]
Liquid (strawberry)	1.50	200 ml OP	✓ Diasip
Liquid (vanilla)	1.50	200 ml OP	✓ Diasip
, ,	1.88	250 ml OP	✓ Glucerna Select
	1.78	237 ml OP	
	(2.10)		Resource Diabetic

(2.10)



Subsidy (Manufacturer's Price) Fully Subsidised

Brand or Generic Manufacturer

#### Fat Modified Products

#### ⇒SA1525 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 Patient has metabolic disorders of fat metabolism: or
- 2 Patient has a chyle leak; or
- 3 Modified as a modular feed, made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule, for adults.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula. **Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

#### Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

FAT MODIFIED FEED − Special Authority see SA1525 above − Hospital pharmacy [HP3]

Powder .......60.48 400 q OP

✓ Monogen

## **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.

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

#### **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 applications meeting the following criteria:

#### Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

PAEDIATRIC ENTERAL FEED 1.5KCAL/ML - Special Authority see SA1379 ab Liquid	oove – Hospital pharmacy [HP3] 500 ml OP ✓ Nutrini Energy RTH
PAEDIATRIC ENTERAL FEED 1KCAL/ML - Special Authority see \$A1379 abov Liquid2.68	ve – Hospital pharmacy [HP3] 500 ml OP  ✓ Nutrini RTH ✓ Pediasure RTH
PAEDIATRIC ENTERAL FEED WITH FIBRE 1.5KCAL/ML – Special Authority st Liquid	ee SA1379 above – Hospital pharmacy [HP3] 500 ml OP ✓ Nutrini Energy Multi Fibre
PAEDIATRIC ORAL FEED 1.5KCAL/ML - Special Authority see SA1379 above	- Hospital pharmacy [HP3]
Liquid (strawberry)1.60	200 ml OP Fortini
Liquid (vanilla)1.60	200 ml OP <b>✓ Fortini</b>
PAEDIATRIC ORAL FEED 1KCAL/ML - Special Authority see SA1379 above -	Hospital pharmacy [HP3]
Liquid (chocolate)1.07	200 ml OP ✓ Pediasure
Liquid (strawberry)1.07	200 ml OP ✓ Pediasure
Liquid (vanilla)1.07	200 ml OP ✓ Pediasure
1.34	250 ml OP ✓ Pediasure
PAEDIATRIC ORAL FEED WITH FIBRE 1.5KCAL/ML - Special Authority see S	SA1379 above – Hospital pharmacy [HP3]
Liquid (unflavoured)1.60	200 ml OP ✓ Fortini Multi Fibre
Liquid (chocolate)	200 ml OP ✓ Fortini Multi Fibre
Liquid (strawberry)1.60	200 ml OP ✓ Fortini Multi Fibre
Liquid (vanilla)	200 ml OP ✓ Fortini Multi Fibre
PEPTIDE-BASED ORAL FEED - Special Authority see SA1379 above - Hospita	al pharmacy [HP3]
Powder	400 g OP ✓ Peptamen Junior
1 044001	Too g or - i epiamen damoi

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

#### **Renal Products**

#### ⇒SA1101 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient has acute or chronic kidney disease.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

#### Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

RENAL ENTERAL FEED 1.8 KCAL/ML - Special Authority see Liquid			nacy [HP3]  Nepro HP RTH
RENAL ORAL FEED 1.8 KCAL/ML – Special Authority see SA Liquid		spital pharmacy 220 ml OP	[HP3]  ✓ Nepro HP  (strawberry)  ✓ Nepro HP (vanilla)
RENAL ORAL FEED 2 KCAL/ML - Special Authority see SA11	01 above - Hospi	ital pharmacy [H	HP3]
Liquid	2.88	237 ml OP	
	(3.31)		NovaSource Renal
Liquid (apricot) 125 ml	11.52	4 OP	✓ Renilon 7.5
Liquid (caramel) 125 ml	11.52	4 OP	✓ Renilon 7.5

## **Specialised And Elemental Products**

#### SA1377 Special Authority for Subsidy

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 malabsorption; or
- 2 short bowel syndrome; or
- 3 enterocutaneous fistulas: or
- 4 eosinophilic oesophagitis; or
- 5 inflammatory bowel disease; or
- 6 patients with multiple food allergies requiring enteral feeding.

Notes: Each of these products is highly specialised and would be prescribed only by an expert for a specific disorder. The alternative is hospitalisation.

Elemental 028 Extra is more expensive than other products listed in this section and should only be used where the alternatives have been tried first and/or are unsuitable.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

#### Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Brand or

Fully

	(Manufacturer's F	Price) Subsi	dised Generic  ✓ Manufacturer
ENTERAL/ORAL SEMI-ELEMENTAL FEED 1.5KCAL/ML — Spe pharmacy [HP3] Liquid	·	e SA1377 on the 1,000 ml OP	e previous page – Hospital  Vital
ORAL ELEMENTAL FEED 0.8KCAL/ML — Special Authority see Liquid (grapefruit), 250 ml carton Liquid (pineapple & orange), 250 ml carton Liquid (summer fruits), 250 ml carton	171.00	previous page – 18 OP 18 OP 18 OP	Hospital pharmacy [HP3] ✓ Elemental 028 Extra ✓ Elemental 028 Extra ✓ Elemental 028 Extra
ORAL ELEMENTAL FEED 1KCAL/ML - Special Authority see S Powder (unflavoured)		evious page – H 80 g OP	Hospital pharmacy [HP3]  Vivonex TEN
SEMI-ELEMENTAL ENTERAL FEED 1KCAL/ML - Special Auth [HP3] Liquid	•	7 on the previou 1,000 ml OP	s page – Hospital pharmacy  ✓ Peptisorb

Subsidy

## Paediatric Products For Children With Low Energy Requirements

#### ⇒SA1196 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 Child aged one to eight years; and
- 2 The child has a low energy requirement but normal protein and micronutrient requirements.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

#### Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

## Standard Supplements

## **⇒SA1554** Special Authority for Subsidy

Initial application — (Children - indications other than exclusive enteral nutrition for Crohn's disease) 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 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) only from a dietitian, relevant

continued...

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

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: 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) only from a gastroenterologist, dietitian on the recommendation of a gastroenterologist or vocationally registered general practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 The patient is under 18 years of age; and
- 2 It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease; and
- 3 General Practitioners and dietitians must include the name of the gastroenterologist recommending treatment and the date the gastroenterologist was contacted.

**Initial application** — (Adults) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

1 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) 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:

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.

continued...

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

Initial application — (Short-term medical condition) 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 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) 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:

Any of the following:

- 1 Is being fed via a nasogastric tube; or
- 2 Malignancy and is considered likely to develop malnutrition as a result; or
- 3 Has undergone a bone marrow transplant; or
- 4 Tempomandibular surgery or glossectomy; or
- 5 Both:
  - 5.1 Pregnant: and
  - 5.2 Any of the following:
    - 5.2.1 Patient is in early pregnancy (< 13 weeks) and has severe clinical hyperemesis gravidarum requiring admission to hospital and is unlikely to meet her nutritional requirements due to continuing hyperemesis gravidarum; or
    - 5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or
    - 5.2.3 Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met.

**Initial application** — (**Long-term medical condition**) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria: Any of the following:

- 1 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

continued...

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

- 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) 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 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 SA15 Liquid			[HP3] ✓ Nutrison Energy
ENTERAL FEED 1KCAL/ML - Special Authority see SA155 Liquid	1 0		HP3]  ✓ Isosource Standard ✓ Nutrison Standard RTH ✓ Osmolite RTH
ENTERAL FEED WITH FIBRE 0.83 KCAL/ML - Special Au Liquid	•	n page 237 – Hos 1,000 ml OP	
ENTERAL FEED WITH FIBRE 1 KCAL/ML - Special Autho Liquid			al pharmacy [HP3]  Jevity RTH  Nutrison Multi Fibro
ENTERAL FEED WITH FIBRE 1.5KCAL/ML - Special Auth Liquid		250 ml OP	ital pharmacy [HP3]  ✓ Ensure Plus HN  ✓ Ensure Plus RTH  ✓ Jevity HiCal RTH  ✓ Nutrison Energy  Multi Fibre

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

ORAL FEED (POWDER) - Special Authority see SA1554 on page 237 - Hospital pharmacy [HP3]

Note: Higher subsidy for Sustagen Hospital Formula will only be reimbursed for patients with both a valid Special Authority number and an appropriately endorsed prescription.

Powder (chocolate) - Higher subsidy of up to \$26.00 per 850 g			
with Endorsement	26.00	850 g OP	✓ Ensure
	9.54	840 g OP	
	(26.00)		Sustagen Hospital
			Formula Active

Additional subsidy by endorsement is available for patients with fat malabsorption, fat intolerance or chyle leak. The prescription must be endorsed accordingly.

Powder (vanilla) - Higher subsidy of up to \$26.00 per 850 g			
with Endorsement	8.54	857 g OP	✓ Fortisip
	26.00	850 g OP	✓ Ensure
	9.54	840 g OP	
	(26.00)	· ·	Sustagen Hospital
			Formula Active

Additional subsidy by endorsement is available for patients with fat malabsorption, fat intolerance or chyle leak. The prescription must be endorsed accordingly.

#### ORAL FEED 1.5KCAL/ML - Special Authority see SA1554 on page 237 - Hospital pharmacy [HP3]

Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, who have severe epidermolysis bullosa, or as exclusive enteral nutrition in children under the age of 18 years for the treatment of Crohn's disease. The prescription must be endorsed accordingly.

Liquid (banana) - Higher subsidy of \$1.26 per 200 ml with			
Endorsement	0.72	200 ml OP	
	(1.26)		Ensure Plus
	(1.26)		Fortisip
Liquid (chocolate) - Higher subsidy of \$1.26 per 200 ml with			
Endorsement	0.72	200 ml OP	
	(1.26)		Ensure Plus
	(1.26)		Fortisip
Liquid (fruit of the forest) - Higher subsidy of \$1.26 per 200 ml	` ,		·
with Endorsement.	0.72	200 ml OP	
	(1.26)		Ensure Plus
Liquid (strawberry) - Higher subsidy of \$1.26 per 200 ml with	( -/		
Endorsement	0.72	200 ml OP	
	(1.26)	200 0.	Ensure Plus
	(1.26)		Fortisip
Liquid (vanilla) - Higher subsidy of up to \$1.33 per 237 ml with	(::=0)		. 0.110.p
Endorsement	0.85	237 ml OP	
Litationicit	(1.33)	207 1111 01	Ensure Plus
	0.72	200 ml OP	Liiduic i iud
	(1.26)	200 1111 01	Ensure Plus
	(1.26)		Fortisip
	(1.20)		Fortisib

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

ORAL FEED WITH FIBRE 1.5 KCAL/ML - Special Authority see SA1554 on page 237 - Hospital pharmacy [HP3]

Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, or who have severe epidermolysis bullosa. The prescription must be endorsed accordingly.

Liquid (chocolate) - Higher subsidy of \$1.26 per 200 ml with

Liquid (chocolate) – Higher subsidy of \$1.26 per 200 mi with			
Endorsement	0.72	200 ml OP	
	(1.26)		Fortisip Multi Fibre
Liquid (strawberry) - Higher subsidy of \$1.26 per 200 ml with			
Endorsement	0.72	200 ml OP	
	(1.26)		Fortisip Multi Fibre
Liquid (vanilla) - Higher subsidy of \$1.26 per 200 ml with			
Endorcement	0.72	200 ml OP	

(1.26)

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.

ENTERAL FEED 2 KCAL/ML – Special Authority see	SA1195 above – Hospital p	harmacy [HP3]	
Liquid	5.50	500 ml OP	✓ Nutrison
·			Concentrated
	11.00	1,000 ml OP	✓ Two Cal HN RTH

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

ORAL FEED 2 KCAL/ML - Special Authority see SA1195 on the previous page - Hospital pharmacy [HP3]

Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, or who have severe epidermolysis bullosa. The prescription must be endorsed accordingly.

Liquid (vanilla) - Higher subsidy of \$1.90 per 200 ml with

90) Two Cal HN

#### **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.

#### **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.

GUITEN ERFE BAKING MIX - Special Authority see SA1729 above - Hospital pharmacy (HP3)

acorem i file barring with - special authority see sa	1729 above – Hospital	priarriacy [i ii o]	
Powder	2.81	1,000 g OP	
	(5.15)	-	Healtheries Simple Baking Mix
GLUTEN FREE BREAD MIX - Special Authority see SA1	1729 above – Hospital p	harmacy [HP3]	
Powder	3.93	1,000 g OP	
	(7.32)	-	NZB Low Gluten Bread Mix
	3.51		
	(10.87)		Horleys Bread Mix

	Subsidy (Manufacturer's F \$		Fully Brand or lised Generic  Manufacturer
GLUTEN FREE FLOUR - Special Authority see SA1729 on	the previous page -	Hospital pharma	acy [HP3]
Powder	5.62	2,000 g OP	,
	(18.10)		Horleys Flour
GLUTEN FREE PASTA – Special Authority see SA1729 on	the previous page -	Hospital pharma	cv [HP3]
Buckwheat Spirals		250 g OP	, 1
'	(3.11)	Ü	Orgran
Corn and Vegetable Shells	2.00 <sup>°</sup>	250 g OP	· ·
•	(2.92)	•	Orgran
Corn and Vegetable Spirals	2.00	250 g OP	-
	(2.92)		Orgran
Rice and Corn Lasagne Sheets	1.60	200 g OP	
	(3.82)		Orgran
Rice and Corn Macaroni	2.00	250 g OP	
	(2.92)		Orgran
Rice and Corn Penne	2.00	250 g OP	
	(2.92)		Orgran
Rice and Maize Pasta Spirals		250 g OP	
	(2.92)		Orgran
Rice and Millet Spirals		250 g OP	
	(3.11)		Orgran
Rice and corn spaghetti noodles		375 g OP	_
	(2.92)		Orgran
Vegetable and Rice Spirals		250 g OP	
	(2.92)	05	Orgran
Italian long style spaghetti		220 g OP	•
	(3.11)		Orgran

## Foods And Supplements For Inborn Errors Of Metabolism

#### ⇒SA1108 Special Authority for Subsidy

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

Any of the following:

- 1 Dietary management of homocystinuria; or
- 2 Dietary management of maple syrup urine disease; or
- 3 Dietary management of phenylketonuria (PKU); or
- 4 For use as a supplement to the Ketogenic diet in patients diagnosed with epilepsy.

## **Supplements For Homocystinuria**

## **Supplements For MSUD**

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

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

## **Supplements For PKU**

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

Tabs	99.00	75 OP	✓ Phlexy 10
Powder (chocolate) 36 g sachet	393.00	30	✓ PKU Anamix Junior Chocolate
Powder (unflavoured) 27.8 g sachets	936.00	30	✓ PKU Lophlex Powder
Powder (unflavoured) 36 g sachets	393.00	30	PKU Anamix Junior
Powder (vanilla) 36 g sachet	393.00	30	✓ PKU Anamix Junior Vanilla
Infant formula	174.72	400 g OP	✓ PKU Anamix Infant
Powder (orange)	320.00	500 g OP	✓ XP Maxamum
Powder (unflavoured)		500 g OP	✓ XP Maxamum
Liquid (berry)	13.10	125 ml OP	✓ PKU Anamix Junior LQ
Liquid (orange)	13.10	125 ml OP	✓ PKU Anamix Junior LQ
Liquid (unflavoured)	13.10	125 ml OP	✓ PKU Anamix Junior LQ
Liquid (forest berries), 250 ml carton	540.00	18 OP	<ul> <li>Easiphen Liquid</li> </ul>
Liquid (juicy tropical) 125 ml		30 OP	✓ PKU Lophlex LQ 20
Oral semi-solid (berries) 109 g	1,123.20	36 OP	✓ PKU Lophlex Sensation 20
Liquid (juicy berries) 62.5 ml	939.00	60 OP	✓ PKU Lophlex LQ 10
Liquid (juicy citrus) 62.5 ml		60 OP	✓ PKU Lophlex LQ 10
Liquid (juicy orange) 62.5 ml		60 OP	✓ PKU Lophlex LQ 10
Liquid (juicy berries) 125 ml		30 OP	✓ PKU Lophlex LQ 20
Liquid (juicy orange) 125 ml	936.00	30 OP	✓ PKU Lophlex LQ 20

## Foods

LOW PROTEIN BAKING MIX - Special Authority see	e SA1108 on the previous pa	ige – Hospital p	harmacy [HP3]
Powder	8.22	500 g OP	<ul><li>Loprofin Mix</li></ul>
LOW PROTEIN PASTA - Special Authority see SA1	108 on the previous page - I	Hospital pharm	acy [HP3]
Animal shapes	11.91	500 g OP	<ul><li>Loprofin</li></ul>
Lasagne	5.95	250 g OP	✓ Loprofin
Low protein rice pasta	11.91	500 g OP	✓ Loprofin
Macaroni	5.95	250 g OP	✓ Loprofin
Penne	11.91	500 g OP	✓ Loprofin
Spaghetti	11.91	500 g OP	✓ Loprofin
Spirals	11.91	500 g OP	✓ Loprofin



Subsidy (Manufacturer's Price) Su \$ Per

Fully Subsidised

Brand or Generic Manufacturer

## Infant Formulae

## For Williams Syndrome

#### ⇒SA1110 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient is an infant suffering from Williams Syndrome and associated hypercalcaemia.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

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.

LOW CALCIUM INFANT FORMULA - Special Authority see SA1110 above - Hospital pharmacy [HP3]
Powder .......44.40 400 g OP ✓ Locasol

## **Gastrointestinal and Other Malabsorptive Problems**

AMINO ACID FORMULA - Special Authority see SA1219 below -	Hospital phar	macy [HP3]	
Powder	43.60	400 g OP	Alfamino Junior
	53.00		✓ Neocate LCP
Powder (unflavoured)	53.00	400 g OP	✓ Elecare
,		J	✓ Elecare LCP
			✓ Neocate Gold
			<ul> <li>Neocate Junior Unflavoured</li> </ul>
			✓ Neocate SYNEO
Powder (vanilla)	53.00	400 g OP	✓ Elecare
,		J	✓ Neocate Junior Vanilla

(Neocate LCP Powder to be delisted 1 May 2019)

#### **⇒SA1219** 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 Extensively hydrolysed formula has been reasonably trialled and is inappropriate due to documented severe intolerance or allergy or malabsorption; or
- 2 History of anaphylaxis to cows milk protein formula or dairy products; or
- 3 Eosinophilic oesophagitis.

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 infant can be transitioned to a cows milk protein, soy, or extensively hydrolysed infant formula has been undertaken; and
- 2 The outcome of the assessment is that the infant continues to require an amino acid infant formula; and
- 3 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

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

EXTENSIVELY HYDROLYSED FORMULA - Special Authority see SA1557 below - Hospital pharmacy [HP3]

#### ⇒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

#### ⇒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;

continued...



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

and

3 Patient is under 18 months of age or weighs less than 8 kg.

Note: "Volume intolerant" patients are those who are unable to tolerate an adequate volume of infant formula to achieve expected growth rate. These patients should have first trialled appropriate clinical alternative treatments, such as concentrating, fortifying and adjusting the frequency of feeding.

Renewal only from a paediatrician, dietitian or general practitioner on the recommendation of a paediatrician or dietitian.

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.

✓ KetoCal 4:1

**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 - Speci	al Authority see SA1197	' <mark>above – Ret</mark> ail	pharmacy
Powder (unflavoured)	35.50	300 g OP	✓ KetoCal 4:1
		-	✓ Ketocal 3:1

#### **SECTION I: NATIONAL IMMUNISATION SCHEDULE**

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

#### **Vaccinations**

#### ADULT DIPHTHERIA AND TETANUS VACCINE - [Xpharm]

Any of the following:

- 1) For vaccination of patients aged 45 and 65 years old; or
- 2) For vaccination of previously unimmunised or partially immunised patients: or
- 3) For revaccination following immunosuppression; or
- 4) For boosting of patients with tetanus-prone wounds; or
- For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

#### BACILLUS CALMETTE-GUERIN VACCINE - [Xpharm]

For infants at increased risk of tuberculosis. Increased risk is defined as:

- 1) living in a house or family with a person with current or past history of TB; or
- having one or more household members or carers who within the last 5 years lived in a country with a rate of TB > or equal to 40 per 100,000 for 6 months or longer; or
- 3) during their first 5 years will be living 3 months or longer in a country with a rate of TB > or equal to 40 per 100,000 Note a list of countries with high rates of TB are available at www.health.govt.nz/tuberculosis (search for downloads) or www.bcgatlas.org/index.php.

Inj Mycobacterium bovis BCG (Bacillus Calmette-Guerin),

Danish strain 1331, live attenuated, vial with diluent......0.00 10 

✓ BCG Vaccine

#### DIPHTHERIA. TETANUS AND PERTUSSIS VACCINE - [Xpharm]

Funded for any of the following criteria:

- 1) A single vaccine for pregnant woman between gestational weeks 28 and 38; or
- A course of up to four vaccines is funded for children from age 7 up to the age of 18 years inclusive to complete full primary immunisation; or
- 3) 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.

Notes: Tdap is not registered for patients aged less than 10 years. Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg

pertussis toxoid, 8 mcg pertussis filamentous

#### DIPHTHERIA, TETANUS, PERTUSSIS AND POLIO VACCINE - [Xpharm]

Funded for any of the following:

- 1) A single dose for children up to the age of 7 who have completed primary immunisation; or
- 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
- An additional four doses (as appropriate) are funded for (re-)immunisation for patients post HSCT, or chemotherapy; pre- or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens; or
- 4) Five doses will be funded for children requiring solid organ transplantation.

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

Ini 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg

pertussis toxoid, 25 mcg pertussis filamentous

haemagluttinin, 8 mcg pertactin and 80 D-antigen units

NATIONAL IMMUNISATION SCHEDULE			
(N	Subsidy flanufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
DIPHTHERIA, TETANUS, PERTUSSIS, POLIO, HEPATITIS B AND [Xpharm] Funded for patients meeting any of the following criteria:  1) Up to four doses for children up to and under the age of 10 2) An additional four doses (as appropriate) are funded for (r 10 who are patients post haematopoietic stem cell transplated post solid organ transplant, renal dialysis and other severe 3) Up to five doses for children up to and under the age of 10 Note: A course of up-to four vaccines is funded for catch up protocomplete full primary immunisation. Please refer to the Immuniprogrammes.  Inj 30IU diphtheriatoxoid with 40IU tetanustoxoid, 25mcg pertussistoxoid, 25mcg pertussisfilamentoushaemagluttinin, 8 mcgpertactin, 80 D-AgUpoliovirus, 10mcghepatitisBsurfaceantigen in	0 for primary immu e-)immunisation fo antation, or chemo ely immunosuppres 0 receiving solid or ogrammes for child	nisation; or r children up to a therapy; pre or po ssive regimens; or gan transplantatio Iren (up to and un	nd under the age of ost splenectomy; pre- or r on. der the age of 10 years)
O.5ml syringe  HAEMOPHILUS INFLUENZAE TYPE B VACCINE – [Xpharm] One dose for patients meeting any of the following:  1) For primary vaccination in children; or 2) An additional dose (as appropriate) is funded for (re-)imme transplantation, or chemotherapy; functional asplenic; pre or post cochlear implants, renal dialysis and other severel 3) For use in testing for primary immunodeficiency diseases, paediatrician.	unisation for patien or post splenecton y immunosuppress	nts post haematop ny; pre- or post so sive regimens; or	olid organ transplant, pre-
Haemophilus Influenzae type B polysaccharide 10 mcg conjugated to tetanus toxoid as carrier protein 20-40 mcg; prefilled syringe plus vial 0.5 ml  HEPATITIS A VACCINE – [Xpharm] Funded for patients meeting any of the following criteria:  1) Two vaccinations for use in transplant patients; or 2) Two vaccinations for use in children with chronic liver dise 3) One dose of vaccine for close contacts of known hepatitis	ase; or	1 <b>✓</b> <u>H</u>	<u>iberix</u>

✓ Havrix

✓ Havrix Junior

1

## NATIONAL IMMUNISATION SCHEDULE

	Subsidy		Fully	Brand or
	(Manufacturer's Price)		Subsidised	Generic
	\$	Per		Manufacturer
HEPATITIS B RECOMBINANT VACCINE - [Xpharm]				
Inj 5 mcg per 0.5 ml vial	0.00	1	✓	HBvaxPRO
Funded for patients meeting any of the following criteria:				
1) for household or sexual contacts of known acute he	epatitis B patients or h	nepat	itis B carrie	ers; or
2) for children born to mothers who are hepatitis B sur				
3) for children up to and under the age of 18 years inc	lusive who are consid	dered	not to hav	e achieved a positive
serology and require additional vaccination or requi	re a primary course of	of vac	cination; o	r
<ol><li>for HIV positive patients; or</li></ol>				
5) for hepatitis C positive patients; or				
6) for patients following non-consensual sexual interconsensual sexual sexual interconsensual sexual sexua	ourse; or			
7) for patients following immunosuppression; or				
8) for solid organ transplant patients; or				
for post-haematopoietic stem cell transplant (HSCT	) patients; or			
<ol><li>following needle stick injury.</li></ol>				
lai 40 man and malaid	0.00	4		UDDDO
Inj 10 mcg per 1 ml vial	0.00	1	•	HBvaxPRO
Funded for patients meeting any of the following criteria:	natitia D nationta ar k		itia D agresia	
for household or sexual contacts of known acute he     for shildren herr to methors who are hepatitis B au				ers; or
<ol> <li>for children born to mothers who are hepatitis B sui</li> <li>for children up to and under the age of 18 years inc</li> </ol>				ve achieved a nocitive
serology and require additional vaccination or requi				•
for HIV positive patients; or	ic a primary course c	n vac	onation, o	
5) for hepatitis C positive patients; or				
for patients following non-consensual sexual interce	ourse: or			
7) for patients following immunosuppression; or	,			
8) for solid organ transplant patients; or				
9) for post-haematopoietic stem cell transplant (HSCT	) patients; or			
<ol><li>following needle stick injury.</li></ol>				
Inj 20 mcg per 1 ml prefilled syringe	0.00	1	/	Engerix-B
Funded for patients meeting any of the following criteria:				
<ol> <li>for household or sexual contacts of known acute he</li> </ol>				ers; or
2) for children born to mothers who are hepatitis B sur				
3) for children up to and under the age of 18 years inc				
serology and require additional vaccination or requi	re a primary course of	of vac	cination; o	r
4) for HIV positive patients; or				
5) for hepatitis C positive patients; or				
6) for patients following non-consensual sexual interco	ourse; or			
<ul><li>7) for patients following immunosuppression; or</li><li>8) for solid organ transplant patients; or</li></ul>				
9) for post-haematopoietic stem cell transplant (HSCT	) nationts: or			
10) following needle stick injury; or	) patients, or			
11) for dialysis patients; or				
12) for liver or kidney transplant patients.				
,				
Inj 40 mcg per 1 ml vial	0.00	1	1	HBvaxPRO
Funded for any of the following criteria:				
1) for dialysis patients; or				
<ol> <li>for liver or kidney transplant patient.</li> </ol>				

#### NATIONAL IMMUNISATION SCHEDULE

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

HUMAN PAPILLOMAVIRUS (6, 11, 16, 18, 31, 33, 45, 52 AND 58) VACCINE [HPV] - [Xpharm]

Any of the following:

- 1) Maximum of two doses for children aged 14 years and under; or
- 2) Maximum of three doses for patients meeting any of the following criteria:
  - 1) People aged 15 to 26 years inclusive; or
  - 2) Either:

People aged 9 to 26 years inclusive

- 1) Confirmed HIV infection; or
- 2) Transplant (including stem cell) patients: or
- 3) Maximum of four doses for people aged 9 to 26 years inclusive post chemotherapy

	MATIONAL			011 001125022
	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
INFLUENZA VACCINE				
Inj 60 mcg in 0.5 ml syringe (paediatric quadrivalent vaccine)	_			
[Xpharm]	9.00	1	<b>√</b> F	luarix Tetra
A) INFLUENZA VACCINE – child aged 6 months to				

is available each year for patients aged 6 months to 35 months who meet the following criteria, as set by PHARMAC:

- i) have any of the following cardiovascular diseases
  - a) ischaemic heart disease, or
  - b) congestive heart failure, or
  - c) rheumatic heart disease, or
  - d) congenital heart disease, or
  - e) cerebo-vascular disease; or
- ii) have either of the following chronic respiratory diseases:
  - a) asthma, if on a regular preventative therapy, or
  - b) other chronic respiratory disease with impaired lung function; or
- iii) have diabetes: or
- iv) have chronic renal disease; or
- v) have any cancer, excluding basal and squamous skin cancers if not invasive; or
- vi) have any of the following other conditions:
  - a) autoimmune disease, or
  - b) immune suppression or immune deficiency, or
  - c) HIV, or
  - d) transplant recipients, or
  - e) neuromuscular and CNS diseases/disorders, or
  - f) haemoglobinopathies, or
  - g) on long term aspirin, or
  - h) have a cochlear implant, or
  - i) errors of metabolism at risk of major metabolic decompensation, or
  - j) pre and post splenectomy, or
  - k) down syndrome, or
- vii) have been hospitalised for respiratory illness or have a history of significant respiratory illness;

Unless meeting the criteria set out above, the following conditions are excluded from funding:

- a) asthma not requiring regular preventative therapy.
- b) hypertension and/or dyslipidaemia without evidence of end-organ disease.
- B) Doctors are the only Contractors entitled to claim payment from the Funder for the supply of influenza vaccine inj 60 mcg in 0.5 ml syringe (paediatric quadrivalent vaccine) to patients eligible under the above criteria for subsidised immunisation and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.

Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine)90.00 10 ✓ Influvac Tetr	Inj 60 mcg in 0.5 ml syringe	(quadrivalent vaccine)	90.00	10	✓ Influvac Tetra
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Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Manufacturer

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

#### A) INFLUENZA VACCINE – people 3 years and over

is available each year for patients aged 3 years and over who meet the following criteria, as set by PHARMAC:

- a) all people 65 years of age and over; or
- b) people under 65 years of age who:
  - i) have any of the following cardiovascular diseases:
    - a) ischaemic heart disease, or
    - b) congestive heart failure, or
    - c) rheumatic heart disease, or
    - d) congenital heart disease, or
    - e) cerebo-vascular disease; or
  - ii) have either of the following chronic respiratory diseases:
    - a) asthma, if on a regular preventative therapy, or
    - b) other chronic respiratory disease with impaired lung function; or
  - iii) have diabetes; or
  - iv) have chronic renal disease: or
  - v) have any cancer, excluding basal and squamous skin cancers if not invasive; or
  - vi) have any of the following other conditions:
    - a) autoimmune disease, or
    - b) immune suppression or immune deficiency, or
    - c) HIV, or
    - d) transplant recipients, or
    - e) neuromuscular and CNS diseases/disorders, or
    - f) haemoglobinopathies, or
    - a) are children on long term aspirin, or
    - h) have a cochlear implant, or
    - i) errors of metabolism at risk of major metabolic decompensation, or
    - j) pre and post splenectomy, or
    - k) down syndrome, or
  - vii) are pregnant; or
- c) children aged four years or less (but over three years) who have been hospitalised for respiratory illness or have a history of significant respiratory illness;

Unless meeting the criteria set out above, the following conditions are excluded from funding:

- a) asthma not requiring regular preventative therapy.
- b) hypertension and/or dyslipidaemia without evidence of end-organ disease.
- B) Contractors will be entitled to claim payment from the Funder for the supply of influenza vaccine to patients eligible under the above criteria pursuant to their contract with their DHB for subsidised immunisation, and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

#### MEASLES, MUMPS AND RUBELLA VACCINE - [Xpharm]

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.

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

(I	Subsidy Manufacturer's Price) \$	Su Per	Fully ubsidised	Brand or Generic Manufacturer	
MENINGOCOCCAL (GROUPS A, C, Y AND W-135) CONJUGATE Any of the following:	VACCINE - [Xpha	arm]			
1) Up to three doses and a booster every five years for patie or anatomic asplenia, HIV, complement deficiency (acqui 2) One dose for close contacts of meningococcal cases; or 3) A maximum of two doses for bone marrow transplant pati 4) A maximum of two doses for patients following immunosu. Note: children under seven years of age require two doses 8 v series and then five yearly.  *Immunosuppression due to steroid or other immunosuppression in 4 mcg of each meningococcal polysaccharide conjugated to	red or inherited), or lents; or uppression*. veeks apart, a boos ve therapy must be	pre or p	oost solid e three ye	organ transplant; o	or ry
a total of approximately 48 mcg of diphtheria toxoid carrier per 0.5 ml vial		1	✓ <u>M</u>	lenactra	
MENINGOCOCCAL C CONJUGATE VACCINE – [Xpharm]  Any of the following:  1) Up to three doses and a booster every five years for patie or anatomic asplenia, HIV, complement deficiency (acqui 2) One dose for close contacts of meningococcal cases; or 3) A maximum of two doses for bone marrow transplant pati 4) A maximum of two doses for patients following immunosu Note: children under seven years of age require two doses 8 v series and then five yearly.  *Immunosuppression due to steroid or other immunosuppression 10 mcg in 0.5 ml syringe	red or inherited), or lents; or uppression*. veeks apart, a boos ve therapy must be	pre or p	e three ye	organ transplant; o	or ry
PNEUMOCOCCAL (PCV10) CONJUGATE VACCINE – [Xpharm] Either:  1) A primary course of four doses for previously unvaccinate 2) Up to three doses as appropriate to complete the primary 59 months who have received one to three doses of PCV Note: please refer to the Immunisation Handbook for the appre Inj 1 mcg of pneumococcal polysaccharide serotypes 1, 5, 6B,	course of immunis	ation for	r individua	als under the age o	f
7F, 9V, 14 and 23F; 3 mcg of pneumococcal polysaccharide serotypes 4, 18C and 19F in 0.5 ml	0.00	10	<b>√</b> °	vnfloriv	

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

### PNEUMOCOCCAL (PCV13) CONJUGATE VACCINE - [Xpharm]

Any of the following:

- One dose is funded for high risk children (over the age of 17 months and under 18 years) who have previously received four doses of PCV10: or
- 2) Up to an additional four doses (as appropriate) are funded for high risk children aged under 5 years for (re-)immunisation of patients with any of the following:
  - a) on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or
  - b) with primary immune deficiencies; or
  - c) with HIV infection; or
  - d) with renal failure, or nephrotic syndrome; or
  - e) who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
  - f) with cochlear implants or intracranial shunts; or
  - g) with cerebrospinal fluid leaks; or
  - h) receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
  - i) with chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or
  - j) pre term infants, born before 28 weeks gestation; or
  - k) with cardiac disease, with cyanosis or failure; or
  - I) with diabetes; or
  - m) with Down syndrome; or
  - n) who are pre-or post-splenectomy, or with functional asplenia; or
- 3) Up to an additional four doses (as appropriate) are funded for (re-)immunisation of patients 5 years and over with HIV, for patients pre or post haematopoietic stem cell transplantation, or chemotherapy; pre- or post splenectomy; functional asplenia, pre- or post- solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, or primary immunodeficiency; or
- 4) For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

Note: please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes

Inj 30.8 mcg of pneumococcal polysaccharide serotypes 1, 3, 4,

	NATIONAL	IMMUNISATI	ON SCHEDULE
	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
PNEUMOCOCCAL (PPV23) POLYSACCHARIDE VACCINE Either:	- [Xpharm]		
<ol> <li>Up to three doses (as appropriate) for patients with chemotherapy; pre- or post-splenectomy or with fun complement deficiency (acquired or inherited), coch</li> <li>All of the following:</li> </ol>	ctional asplenia, pre- or lear implants, or primary	oost-solid organ t	transplant, 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 radiat immune response; or ii) with primary immune deficiencies; or iii) with HIV infection; or iv) with renal failure, or nephrotic syndrome. v) who are immune-suppressed following o	or	·	
or vi) with cochlear implants or intracranial shu vii) with cerebrospinal fluid leaks; or viii) receiving corticosteroid therapy for more prednisone of 2 mg/kg per day or greate	ints; or than two weeks, and wh	o are on an equi	valent daily dosage of
20 mg or greater; or ix) with chronic pulmonary disease (includin x) pre term infants, born before 28 weeks g xi) with cardiac disease, with cyanosis or fai xii) with diabetes; or xiii) with Down syndrome; or xiv) who are pre-or post-splenectomy, or with	estation; or ilure; or	gh-dose corticost	eroid therapy); or
Inj 575 mcg in 0.5 ml prefilled syringe (25 mcg of each 23 pneumococcal serotype)	ing:	1 <b>✓</b> <u>F</u>	Pneumovax 23
For revaccination following immunosuppression.     Note: Please refer to the Immunisation Handbook for appling 80D antigen units in 0.5 ml syringe			nes. <b>POL</b>
ROTAVIRUS ORAL VACCINE – [Xpharm]  Maximum of two doses for patients meeting the following:  1) first dose to be administered in infants aged under 1  2) no vaccination being administered to children aged	4 weeks of age; and		
Oral susp live attenuated human rotavirus			

10

✓ Rotarix

1,000,000 CCID50 per dose, prefilled oral applicator......0.00

	Subsidy (Manufacturer's Price) \$	Subsid Per	Fully dised	Brand or Generic Manufacturer
VARICELLA VACCINE [CHICKENPOX VACCINE] – [Xpharm] Either:				
1) Maximum of one dose for primary vaccination for eithe	r:			
a) Any infant born on or after 1 April 2016; or				
<li>b) For previously unvaccinated children turning 11 y varicella infection (chickenpox), or</li>	ears old on or after 1	July 2017,	who h	ave not previously had a
2) Maximum of two doses for any of the following:				
a) Any of the following for non-immune patients:				
<ul><li>i) with chronic liver disease who may in future</li><li>ii) with deteriorating renal function before trans</li></ul>		nsplantatio	n; or	
iii) prior to solid organ transplant; or				
iv) prior to any elective immunosuppression*, o				
v) for post exposure prophylaxis who are imm				lint nu
b) For patients at least 2 years after bone marrow tr				
<ul> <li>c) For patients at least 6 months after completion of</li> <li>d) For HIV positive non immune to varicella with mil</li> </ul>				
e) For patients with inborn errors of metabolism at r varicella, or				
<li>f) For household contacts of paediatric patients wheimmune compromise where the household conta</li>	ct has no clinical histo	ry of varice	lla, or	
<li>g) For household contacts of adult patients who have immunocompromised, or undergoing a procedure has no clinical history of varicella.</li>				
* immunosuppression due to steroid or other immunosuppre	ssive therapy must be	for a treatr	nent p	eriod of greater than
28 days			·	•
Inj 2000 PFU prefilled syringe plus vial	0.00	1		<u>arilrix</u>
		10	✓ V	<u>arilrix</u>
VARICELLA ZOSTER VIRUS (OKA STRAIN) LIVE ATTENUATE Funded for patients meeting either of the following criteria:	ED VACCINE [SHINGI	LES VACC	INE] -	- [Xpharm]
1) One dose for all people aged 65 years; or				
2) One dose for all people aged between 66 and 80 years	s inclusive from 1 April	l 2018 and	31 Ma	rch 2020.
Inj 19,400 PFU prefilled syringe plus vial	0.00	1 10		ostavax ostavax
Diagnostic Agents				
TUBERCULIN PPD [MANTOUX] TEST - [Xpharm]				

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Apo-Clomipramine	123	Arrow-Sertraline		Beclazone 250	
Apo-Diclo SR		Arrow-Timolol	222	Beclazone 50	213
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Apo-Gabapentin		Arsenic trioxide		Bendamustine hydrochloride	
Apo-Leflunomide		Asacol		Bendrofluazide	
Apo-Megestrol		Asamax		Bendroflumethiazide	
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Apo-Ropinirole		Sensory		Betadine Skin Prep	
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Apo-Sumatriptan		Atrovent		Betagan	
Apo-Terazosin		Aubagio		Betahistine dihydrochloride	
Apo-Timol		Augmentin		Betaine	
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Arrow-Calcium	34	AZT	105	Betnovate	62
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Clexane		Condoms		DBL Aminophylline	
Clindamycin		Condyline		DBL Bleomycin Sulfate	
Clindamycin ABM		Contact-D		DBL Carboplatin	
Clinicians Renal Vit		Contraceptives - Hormonal		DBL Cisplatin	
Clobazam		Contraceptives - Non-hormonal.		DBL Dacarbazine	
Clobetasol propionate		Copaxone		DBL Desferrioxamine Mesylate for	
Clobetasone butyrate		Cordarone-X		BP	•
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Genito-Urinary		Cosentyx		DBL Gentamicin	
Clomifene citrate		Cosmegen		DBL Leucovorin Calcium	
Clomipramine hydrochloride		Coumadin		DBL Methotrexate Onco-Vial	
Clonazepam125-		Creon 10000		DBL Morphine Sulphate	
Clonidine		Creon 25000		DBL Morphine Tartrate	
Clonidine BNM		Crotamiton		DBL Naloxone Hydrochloride	
Clonidine hydrochloride		Crystaderm		DBL Octreotide	
Clopidogrel		Curam		DBL Pethidine Hydrochloride	
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Rizatriptan	129	Sildenafil	57	Spiractin	5
Roferon-A	106	Silhouette MMT-371	22	Spiriva	21
Rolin	169	Silhouette MMT-373	22	Spiriva Respimat	21
Ropinirole hydrochloride	118	Siltuximab	202	Spironolactone	5
Rotarix	257	Simvastatin	53	Sporanox	9
Rotavirus oral vaccine	257	Simvastatin Mylan	53	Sprycel	16
Roxane		Sinemet		Staphlex	9
Alimentary	6	Sinemet CR		Stemetil	130
Cardiovascular		Sirolimus	210	SteroClear	
Roxithromycin		Siterone	78	Stesolid	12
Rubifen		Slow-Lopresor	49	Stimulants/ADHD Treatments	14
Rubifen SR	145	Smith BioMed Rapid Pregnancy		Stiripentol	12
Rulide D	<mark>89</mark>	Test	73	Stocrin	
Ruxolitinib	166	Sodibic	45	Stomahesive	3
Rythmodan	48	Sodium acid phosphate	27	Strattera	14
Rytmonorm		Sodium alginate		Stromectol	6
-8-		Sodium aurothiomalate		Suboxone	14
Sabril	128	Sodium benzoate	30	Sucralfate	
Sacubitril with valsartan	47	Sodium bicarbonate		Sulfadiazine Silver	6
SalAir	215	Blood	44–45	Sulfadiazine sodium	9
Salazopyrin	7	Extemporaneous		Sulfasalazine	
Salazopyrin EN		Sodium calcium edetate		Sulindac	10
Salbutamol		Sodium chloride		Sulphur	
Salbutamol with ipratropium		Blood	45	Sulprix	
bromide	215	Respiratory		Sumatriptan	12
Salicylic acid		Sodium citrate with sodium laury		Sunitinib	16
Salmeterol		sulphoacetate		Sunscreens	
Sandomigran		Sodium citro-tartrate		Sunscreens, proprietary	
Sandomigran S29		Sodium cromoglicate		Sure-T MMT-863	2
Sandostatin LAR		Alimentary	7	Sure-T MMT-865	2
Sapropterin dihydrochloride		Respiratory		Sure-T MMT-873	2
Scalp Preparations		Sensory		Sure-T MMT-875	
Scopoderm TTS		Sodium fluoride		Sure-T MMT-883	
Sebizole		Sodium Fusidate [fusidic acid]		Sure-T MMT-885	
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Senna		acid]	224	Sutent	
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SensoCard		Sodium tetradecyl sulphate		Symbicort Turbuhaler 200/6	21
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Synacthen	78	Thiotepa	153	gramicidin, neomycin and ny	statin
Synacthen Depot	78	Thymol glycerin	33	Dermatological	
Synacthen S29	78	Thyroid and Antithyroid Agents	81	Sensory	
Synacthene Retard		Ticagrelor		Triazolam	
Synflorix		Tilade		Trichozole	9
Synthroid		Tilcotil	109	Triclosan	6
Syntometrine		Timolol		Trimethoprim	9
Syrup (pharmaceutical grade)		Cardiovascular	50	Trimethoprim with	
Systane Unit Dose		Sensory		sulphamethoxazole	
- T -		Timoptol XE		[Co-trimoxazole]	9
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Tacrolimus Sandoz	211	Tiotropium bromide with		Trisul	
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Tambocor		Tivicay		Tropicamide	
Tambocor CR		TMP		Trusopt	
Tamoxifen citrate		TOBI		TruSteel	
Tamoxifen Sandoz		Tobramycin		Truvada	
Tamsulosin hydrochloride		Infection	94	Tuberculin PPD [Mantoux] test	
Tamsulosin-Rex		Sensory		Tubersol	
Tandem Cartridge		Tobramycin Mylan		Two Cal HN	
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Telfast		Topiramate		Univent	
Temazepam		Topiramate Actavis		Ural	
Temizole 20		Total parenteral nutrition (TPN)		Urea	
Temozolomide		TPN		Urex Forte	
Tenofovir disoproxil		Tramadol hydrochloride		Urinary Agents	
Tenofovir Disoproxil Teva		Tramal SR 100		Urinary Tract Infections	
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