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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.

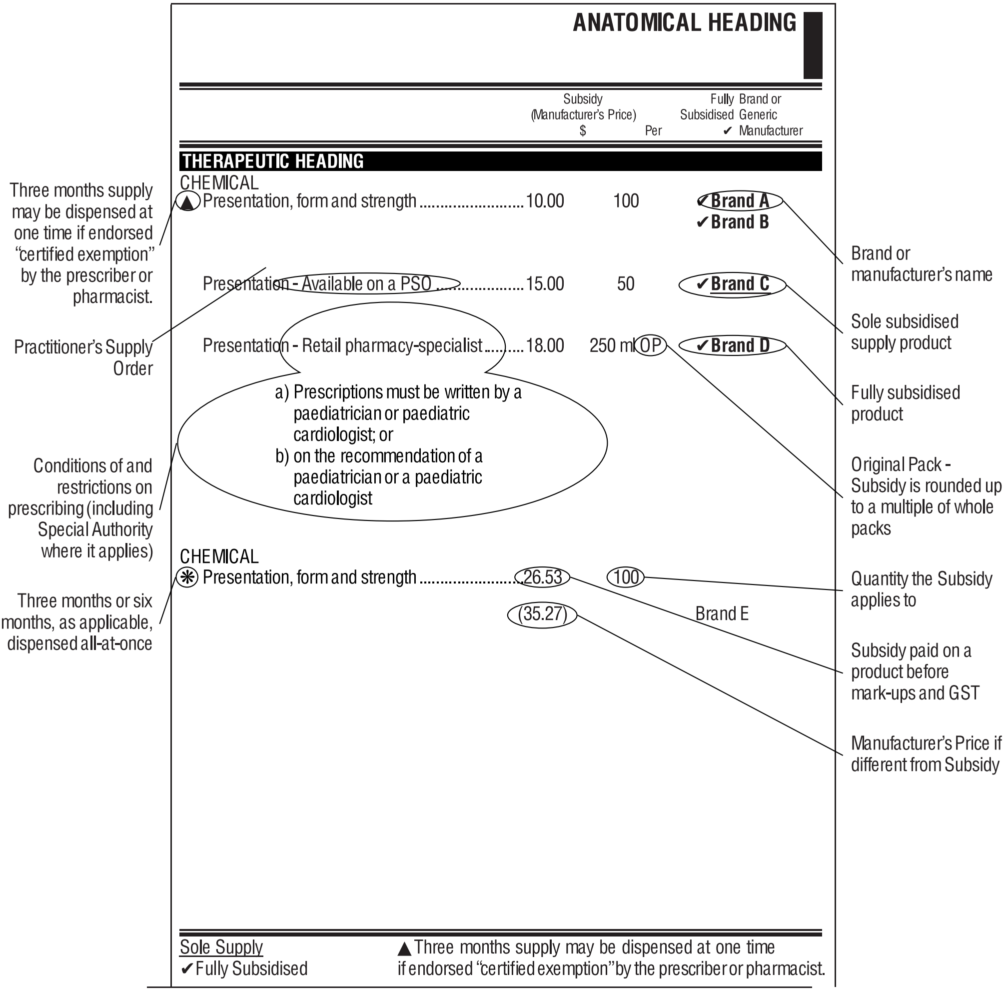
The Pharmaceuticals in this book are listed by therapeutic group, which is based on the WHO Anatomical Therapeutic Chemical (ATC) system. The listings are displayed alphabetically under each heading.

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

gram .... g
kilogram .... kg
international unit .... iu
microgram .... mcg
milligram .... mg
millilitre .... ml
millimole .... mmol
unit .... u

Abbreviations

Ampoule .... Amp
Capsule .... Cap
Cream .... Crm
Device .... Dev
Dispersible .... Disp
Effervescent .... Eff
Emulsion .... Emul
Enteric Coated .... EC
Gelatinous .... Gel
Granules .... Gran
Infusion .... Inf
Injection .... Inj
Liquid .... Liq
Long Acting .... LA
Ointment .... Oint
Sachet .... Sach
Solution .... Soln
Suppository .... Supp
Tablet .... Tab
Tincture .... Tinc
Trans Dermal Delivery System .... TDDS

General Rules for the Pharmaceutical Schedule are located on the PHARMAC website.

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

Antacids and Antiflatulents

Antacids and Reflux Barrier Agents

ALGINIC ACID				
Sodium alginate 225 mg and magnesium alginate 87.5 mg per sachet	5.31	30	✔	**Gaviscon Infant**
SODIUM ALGINATE				
❋ Tab 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg - peppermint flavour	1.80 (8.60)	60		Gaviscon Double Strength
❋ Oral liq 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml	1.50 (4.95)	500 ml		Acidex

Phosphate Binding Agents

ALUMINIUM HYDROXIDE				
❋ Tab 600 mg	12.56	100	✔	**Alu-Tab**
CALCIUM CARBONATE				
Oral liq 1,250 mg per 5 ml (500 mg elemental per 5 ml) – Subsidy by endorsement	39.00	500 ml	✔	**Roxane**

Only when prescribed for patients unable to swallow calcium carbonate tablets or where calcium carbonate tablets are inappropriate and the prescription is endorsed accordingly.

Antidiarrhoeals

Agents Which Reduce Motility

LOPERAMIDE HYDROCHLORIDE – Up to 30 cap available on a PSO				
❋ Tab 2 mg	10.75	400	✔	**Nodia**
❋ Cap 2 mg	6.25	400	✔	**Diamide Relief**

Rectal and Colonic Anti-inflammatories

BUDESONIDE				
Cap 3 mg – Special Authority see SA1155 below – Retail pharmacy	166.50	90	✔	**Entocort CIR**

➽SA1155 Special Authority for Subsidy

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

Both:

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

2 Any of the following:

2.1 Diabetes; or

2.2 Cushingoid habitus; or

2.3 Osteoporosis where there is significant risk of fracture; or

continued…

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

	Subsidy $	Per	Fully Subsidised	Brand
HYDROCORTISONE ACETATE				
Rectal foam 10%, CFC-Free (14 applications)	26.55	21.1 g OP	✔	**Colifoam**
HYDROCORTISONE ACETATE WITH PRAMOXINE HYDROCHLORIDE				
Topical aerosol foam, 1% with pramoxine hydrochloride 1%	26.55	10 g OP	✔	**Proctofoam** S29
MESALAZINE				
Tab 400 mg	49.50	100	✔	**Asacol**
Tab EC 500 mg	49.50	100	✔	**Asamax**
Tab long-acting 500 mg	59.05	100	✔	**Pentasa**
Tab 800 mg	85.50	90	✔	**Asacol**
Modified release granules, 1 g	141.72	120 OP	✔	**Pentasa**
Enema 1 g per 100 ml	41.30	7	✔	**Pentasa**
Suppos 500 mg	22.80	20	✔	**Asacol**
Suppos 1 g	54.60	30	✔	**Pentasa**
OLSALAZINE				
Tab 500 mg	93.37	100	✔	**Dipentum**
Cap 250 mg	53.00	100	✔	**Dipentum**
SODIUM CROMOGLICATE				
Cap 100 mg	92.91	100	✔	**Nalcrom**
SULFASALAZINE				
❋ Tab 500 mg	14.00	100	✔	**Salazopyrin**
❋ Tab EC 500 mg	15.53	100	✔	**Salazopyrin EN**

Local preparations for Anal and Rectal Disorders

Antihaemorrhoidal Preparations

	Subsidy $	Per	Fully Subsidised	Brand
FLUOCORTOLONE CAPROATE WITH FLUOCORTOLONE PIVALATE AND CINCHOCAINE				
Oint 950 mcg, with fluocortolone pivalate 920 mcg, and cinchocaine hydrochloride 5 mg per g	6.35	30 g OP	✔	**Ultraproct**
Suppos 630 mcg, with fluocortolone pivalate 610 mcg, and cinchocaine hydrochloride 1 mg	2.66	12	✔	**Ultraproct**
HYDROCORTISONE WITH CINCHOCAINE				
Oint 5 mg with cinchocaine hydrochloride 5 mg per g	15.00	30 g OP	✔	**Proctosedyl**
Suppos 5 mg with cinchocaine hydrochloride 5 mg per g	9.90	12	✔	**Proctosedyl**

▲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

Management of Anal Fissures

GLYCERYL TRINITRATE – Special Authority see SA1329 below – Retail pharmacy

❋ Oint 0.2%	22.00	30 g OP	✔	**Rectogesic**

➽SA1329 Special Authority for Subsidy
Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has a chronic anal fissure that has persisted for longer than three weeks.

Antispasmodics and Other Agents Altering Gut Motility

GLYCOPYRRONIUM BROMIDE

Inj 200 mcg per ml, 1 ml ampoule – Up to 10 inj available on a PSO	17.14	10	✔	**Max Health**

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

❋ Tab 135 mg	18.00	90	✔	**Colofac**

Antiulcerants

Antisecretory and Cytoprotective

MISOPROSTOL

❋ Tab 200 mcg	41.50	120	✔	**Cytotec**

Helicobacter Pylori Eradication

CLARITHROMYCIN

Tab 500 mg – Subsidy by endorsement	10.40	14	✔	**Apo-Clarithromycin**

a) Maximum of 14 tab per prescription
b) Subsidised only if prescribed for helicobacter pylori eradication and prescription is endorsed accordingly. Note: the prescription is considered endorsed if clarithromycin is prescribed in conjunction with a proton pump inhibitor and either amoxicillin or metronidazole.

H2 Antagonists

FAMOTIDINE – Only on a prescription

❋ Tab 20 mg	49.13	1,000	✔	**Famotidine Hovid** S29

RANITIDINE – Subsidy by endorsement

a) Only on a prescription
b) Subsidy by endorsement – Subsidised for patients who were taking ranitidine prior to 1 November 2019 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of ranitidine.

❋ Tab 150 mg	12.91	500	✔	**Ranitidine Relief**
❋ Tab 300 mg	18.21	500	✔	**Ranitidine Relief**
❋ Oral liq 150 mg per 10 ml	5.14	300 ml	✔	**Peptisoothe**
❋ Inj 25 mg per ml, 2 ml	13.40	5	✔	**Zantac**

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

Proton Pump Inhibitors

LANSOPRAZOLE

❋ Cap 15 mg	4.58	100	✔	Lanzol Relief
❋ Cap 30 mg	5.41	100	✔	Lanzol Relief

OMEPRAZOLE

For omeprazole suspension refer Standard Formulae, page 237

❋ Cap 10 mg	1.98	90	✔	Omeprazole actavis 10
❋ Cap 20 mg	1.96	90	✔	Omeprazole actavis 20
❋ Cap 40 mg	3.12	90	✔	Omeprazole actavis 40
❋ Powder – Only in combination	42.50	5 g	✔	Midwest

Only in extemporaneously compounded omeprazole suspension.

❋ Inj 40 mg ampoule with diluent	33.98	5	✔	Dr Reddy's Omeprazole

PANTOPRAZOLE

❋ Tab EC 20 mg	2.02	100	✔	Panzop Relief
❋ Tab EC 40 mg	2.85	100	✔	Panzop Relief

Site Protective Agents

COLLOIDAL BISMUTH SUBCITRATE

Tab 120 mg	14.51	50	✔	Gastrodenol S29

SUCRALFATE

Tab 1 g	35.50 (48.28)	120		Carafate

Bile and Liver Therapy

RIFAXIMIN – Special Authority see SA1461 below – Retail pharmacy

Tab 550 mg	625.00	56	✔	Xifaxan

➽SA1461 Special Authority for Subsidy

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

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

Diabetes

Hyperglycaemic Agents

DIAZOXIDE – Special Authority see SA1320 on the next page – Retail pharmacy

Cap 25 mg	110.00	100	✔	Proglicem S29
Cap 100 mg	280.00	100	✔	Proglicem S29
Oral liq 50 mg per ml	620.00	30 ml OP	✔	Proglycem S29

▲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

➽SA1320 **Special Authority for Subsidy**
Initial application from any relevant practitioner. Approvals valid for 12 months where used for the treatment of confirmed hypoglycaemia caused by hyperinsulinism.
Renewal from any relevant practitioner. Approvals valid without further renewal unless notified where the treatment remains appropriate and the patient is benefiting from treatment.

GLUCAGON HYDROCHLORIDE				
Inj 1 mg syringe kit – Up to 5 kit available on a PSO	32.00	1	✔	**Glucagen Hypokit**

Insulin - Short-acting Preparations

INSULIN NEUTRAL				
▲ Inj human 100 u per ml	25.26	10 ml OP	✔	**Actrapid**
			✔	**Humulin R**
▲ Inj human 100 u per ml, 3 ml	42.66	5	✔	**Actrapid Penfill**
			✔	**Humulin R**

Insulin - Intermediate-acting Preparations

INSULIN ASPART WITH INSULIN ASPART PROTAMINE				
▲ Inj 100 iu per ml, 3 ml prefilled pen	52.15	5	✔	**NovoMix 30 FlexPen**
INSULIN ISOPHANE				
▲ Inj human 100 u per ml	17.68	10 ml OP	✔	**Humulin NPH**
			✔	**Protaphane**
▲ Inj human 100 u per ml, 3 ml	29.86	5	✔	**Humulin NPH**
			✔	**Protaphane Penfill**
INSULIN ISOPHANE WITH INSULIN NEUTRAL				
▲ Inj human with neutral insulin 100 u per ml	25.26	10 ml OP	✔	**Humulin 30/70**
			✔	**Mixtard 30**
▲ Inj human with neutral insulin 100 u per ml, 3 ml	42.66	5	✔	**Humulin 30/70**
			✔	**PenMix 30**
			✔	**PenMix 40**
			✔	**PenMix 50**
INSULIN LISPRO WITH INSULIN LISPRO PROTAMINE				
▲ Inj lispro 25% with insulin lispro protamine 75% 100 u per ml, 3 ml	42.66	5	✔	**Humalog Mix 25**
▲ Inj lispro 50% with insulin lispro protamine 50% 100 u per ml, 3 ml	42.66	5	✔	**Humalog Mix 50**

Insulin - Long-acting Preparations

INSULIN GLARGINE				
▲ Inj 100 u per ml, 10 ml	63.00	1	✔	**Lantus**
▲ Inj 100 u per ml, 3 ml	94.50	5	✔	**Lantus**
▲ Inj 100 u per ml, 3 ml disposable pen	94.50	5	✔	**Lantus SoloStar**

Insulin - Rapid Acting Preparations

INSULIN ASPART				
▲ Inj 100 u per ml, 10 ml	30.03	1	✔	**NovoRapid**
▲ Inj 100 u per ml, 3 ml	51.19	5	✔	**NovoRapid Penfill**
▲ Inj 100 u per ml, 3 ml syringe	51.19	5	✔	**NovoRapid FlexPen**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
INSULIN GLULISINE				
▲ Inj 100 u per ml, 10 ml	27.03	1	✔	**Apidra**
▲ Inj 100 u per ml, 3 ml	46.07	5	✔	**Apidra**
▲ Inj 100 u per ml, 3 ml disposable pen	46.07	5	✔	**Apidra SoloStar**
INSULIN LISPRO				
▲ Inj 100 u per ml, 10 ml	34.92	10 ml OP	✔	**Humalog**
▲ Inj 100 u per ml, 3 ml	59.52	5	✔	**Humalog**

Alpha Glucosidase Inhibitors

ACARBOSE				
❋ Tab 50 mg	3.50	90	✔	**Glucobay**
	10.47		✔	**Accarb**
❋ Tab 100 mg	6.40	90	✔	**Glucobay**
	20.23		✔	**Accarb**

Oral Hypoglycaemic Agents

GLIBENCLAMIDE				
❋ Tab 5 mg	6.00	100	✔	**Daonil**
GLICLAZIDE				
❋ Tab 80 mg	10.29	500	✔	**Glizide**
GLIPIZIDE				
❋ Tab 5 mg	3.27	100	✔	**Minidiab**
METFORMIN HYDROCHLORIDE				
❋ Tab immediate-release 500 mg	8.63	1,000	✔	**Apotex**
❋ Tab immediate-release 850 mg	7.04	500	✔	**Apotex**
PIOGLITAZONE				
❋ Tab 15 mg	3.47	90	✔	**Vexazone**
❋ Tab 30 mg	5.06	90	✔	**Vexazone**
❋ Tab 45 mg	7.10	90	✔	**Vexazone**
VILDAGLIPTIN				
Tab 50 mg	40.00	60	✔	**Galvus**
VILDAGLIPTIN WITH METFORMIN HYDROCHLORIDE				
Tab 50 mg with 1,000 mg metformin hydrochloride	40.00	60	✔	**Galvumet**
Tab 50 mg with 850 mg metformin hydrochloride	40.00	60	✔	**Galvumet**

▲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

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.

Test strips	15.50	10 strip OP	✔	KetoSens

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 (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic 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
   4) has a genetic or an acquired disorder of glucose homeostasis, excluding type 1 or type 2 diabetes and metabolic syndrome.

   The prescription must be endorsed accordingly. Only one CareSens meter per patient will be subsidised (no repeat prescriptions). Patients already using the CareSens N POP meter and CareSens N meter are not eligible for a new meter, unless they have:
   1) type 1 diabetes; or
   2) permanent neonatal diabetes; or
   3) undergone a pancreatectomy; or
   4) cystic fibrosis-related diabetes.

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

Meter with 50 lancets, a lancing device and 10 diagnostic test strips	10.00	1 OP	✔	**CareSens N**
			✔	**CareSens N POP**
	20.00		✔	**CareSens N Premier**

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:
1) 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
2) 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	10.56	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:
1) 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
2) Prescribed on the same prescription as insulin or a sulphonylurea in which case the prescription is deemed to be endorsed; or
3) Prescribed for a pregnant woman with diabetes and endorsed accordingly; or
4) Prescribed for a patient on home TPN at risk of hypoglycaemia or hyperglycaemia and endorsed accordingly; or
5) Prescribed for a patient with a genetic or an acquired disorder of glucose homeostasis excluding type 1 or type 2 diabetes and metabolic syndrome and endorsed accordingly.

Blood glucose test strips	26.20	50 test OP	✔	**SensoCard**

▲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

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.

INSULIN PEN NEEDLES – Maximum of 200 dev per prescription

	Subsidy $	Per	Fully Subsidised	Brand
✻ 29 g x 12.7 mm	10.50	100	✔	**B-D Micro-Fine**
✻ 31 g x 5 mm	11.75	100	✔	**B-D Micro-Fine**
✻ 31 g x 6 mm	9.50	100	✔	**Berpu**
✻ 31 g x 8 mm	10.50	100	✔	**B-D Micro-Fine**
✻ 32 g x 4 mm	10.50	100	✔	**B-D Micro-Fine**

INSULIN SYRINGES, DISPOSABLE WITH ATTACHED NEEDLE – Maximum of 200 dev per prescription

	Subsidy $	Per	Fully Subsidised	Brand
✻ 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 x 8 mm needle	13.00	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 x 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 x 8 mm needle	13.00	100	✔	**B-D Ultra Fine II**
	1.30	10		
	(1.99)			B-D Ultra Fine II

Insulin Pumps

INSULIN PUMP – Special Authority see SA1603 below – Retail pharmacy

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

	Subsidy $	Per	Fully Subsidised	Brand
Min basal rate 0.025 U/h	8,800.00	1	✔	**MiniMed 640G**
Min basal rate 0.1 U/h	4,500.00	1	✔	**Tandem t:slim X2**

➽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

continued…

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

continued…

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

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 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 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:

continued…

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

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 Either:
  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 Either:
  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

continued…

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

continued…

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 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

continued…

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

continued…

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 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.

Cartridge 300 U, t:lock × 10	50.00	1 OP	✔	**Tandem Cartridge**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
INSULIN PUMP INFUSION SET (STEEL CANNULA) – 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.				
10 mm steel needle; 29 G; manual insertion; 60 cm tubing × 10 with 10 needles	130.00	1 OP	✔	**Paradigm Sure-T MMT-884**
10 mm steel needle; 29 G; manual insertion; 60 cm tubing × 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 × 10 with 10 needles	130.00	1 OP	✔	**Paradigm Sure-T MMT-886**
10 mm steel needle; 29 G; manual insertion; 80 cm tubing × 10 with 10 needles; luer lock	130.00	1 OP	✔	**Sure-T MMT-885**
6 mm steel needle; 29 G; manual insertion; 60 cm tubing × 10 with 10 needles	130.00	1 OP	✔	**Paradigm Sure-T MMT-864**
6 mm steel needle; 29 G; manual insertion; 60 cm tubing × 10 with 10 needles; luer lock	130.00	1 OP	✔	**Sure-T MMT-863**
6 mm steel needle; 29 G; manual insertion; 80 cm tubing × 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 needle; 29 G; manual insertion; 60 cm tubing × 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	130.00	1 OP	✔	**Sure-T MMT-873**
8 mm steel needle; 29 G; manual insertion; 80 cm tubing × 10 with 10 needles	130.00	1 OP	✔	**Paradigm Sure-T 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**
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.				
6 mm steel cannula; straight insertion; 60 cm line × 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 × 10 with 10 needles	130.00	1 OP	✔	**TruSteel**

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

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 line × 10 with 10 needles	140.00	1 OP	✔	**AutoSoft 30**
13 mm teflon cannula; angle insertion; insertion device; 60 cm line × 10 with 10 needles	140.00	1 OP	✔	**AutoSoft 30**

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.

13 mm teflon cannula; angle insertion; 120 cm line × 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 10 needles	130.00	1 OP	✔	**Paradigm Silhouette MMT-377**
17 mm teflon cannula; angle insertion; 110 cm line × 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 10 needles	130.00	1 OP	✔	**Paradigm Silhouette MMT-384**

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

Description	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
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 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 clear tubing × 10 with 10 needles	130.00	1 OP	✔	**Paradigm Mio MMT-965**
6 mm teflon cannula; straight insertion; insertion device; 80 cm pink tubing × 10 with 10 needles	130.00	1 OP	✔	**Paradigm Mio MMT-925**
9 mm teflon cannula; straight insertion; insertion device; 80 cm clear tubing × 10 with 10 needles	130.00	1 OP	✔	**Paradigm Mio MMT-975**
6 mm teflon cannula; straight insertion; insertion device; 110 cm line × 10 with 10 needles	140.00	1 OP	✔	**AutoSoft 90**
6 mm teflon cannula; straight insertion; insertion device; 60 cm line × 10 with 10 needles	140.00	1 OP	✔	**AutoSoft 90**
9 mm teflon cannula; straight insertion; insertion device; 110 cm line × 10 with 10 needles	140.00	1 OP	✔	**AutoSoft 90**
9 mm teflon cannula; straight insertion; insertion device; 60 cm line × 10 with 10 needles	140.00	1 OP	✔	**AutoSoft 90**

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

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.

	Subsidy $	Per	Fully Subsidised	Brand
6 mm teflon cannula; straight insertion; 110 cm tubing × 10 with 10 needles	130.00	1 OP	✔	**Paradigm Quick-Set MMT-398**
6 mm teflon cannula; straight insertion; 110 cm tubing × 10 with 10 needles; luer lock	130.00	1 OP	✔	**Quick-Set MMT-391**
6 mm teflon cannula; straight insertion; 60 cm tubing × 10 with 10 needles	130.00	1 OP	✔	**Paradigm Quick-Set MMT-399**
6 mm teflon cannula; straight insertion; 60 cm tubing × 10 with 10 needles; luer lock	130.00	1 OP	✔	**Quick-Set MMT-393**
6 mm teflon cannula; straight insertion; 80 cm tubing × 10 with 10 needles	130.00	1 OP	✔	**Paradigm Quick-Set MMT-387**
9 mm teflon cannula; straight insertion; 106 cm tubing × 10 with 10 needles	130.00	1 OP	✔	**Paradigm Quick-Set MMT-396**
9 mm teflon cannula; straight insertion; 110 cm tubing × 10 with 10 needles; luer lock	130.00	1 OP	✔	**Quick-Set MMT-390**
9 mm teflon cannula; straight insertion; 60 cm tubing × 10 with 10 needles	130.00	1 OP	✔	**Paradigm Quick-Set MMT-397**
9 mm teflon cannula; straight insertion; 60 cm tubing × 10 with 10 needles; luer lock	130.00	1 OP	✔	**Quick-Set MMT-392**
9 mm teflon cannula; straight insertion; 80 cm tubing × 10 with 10 needles	130.00	1 OP	✔	**Paradigm Quick-Set MMT-386**

INSULIN PUMP RESERVOIR – 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 reservoir sets will be funded per year.

	Subsidy $	Per	Fully Subsidised	Brand
10 × luer lock conversion cartridges 1.8 ml for Paradigm pumps	50.00	1 OP	✔	**ADR Cartridge 1.8**
Cartridge for 5 and 7 series pump; 1.8 ml × 10	50.00	1 OP	✔	**Paradigm 1.8 Reservoir**
Cartridge for 7 series pump; 3.0 ml × 10	50.00	1 OP	✔	**Paradigm 3.0 Reservoir**

Digestives Including Enzymes

PANCREATIC ENZYME

	Subsidy $	Per	Fully Subsidised	Brand
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**

▲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
URSODEOXYCHOLIC ACID – Special Authority see SA1739 below – Retail pharmacy				
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 IgM or, if AMA is negative, by liver biopsy; and
2 Patient not requiring a liver transplant (bilirubin > 100 umol/l; decompensated cirrhosis).

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

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

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

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

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

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

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

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

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 fatigue, histological progression by two stages, or to cirrhosis, need for transplantation.

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

Laxatives

Bulk-forming Agents

ISPAGHULA (PSYLLIUM) HUSK – Only on a prescription

❋ Powder for oral soln	6.05	500 g OP	✔	Konsyl-D

MUCILAGINOUS LAXATIVES WITH STIMULANTS

❋ Dry	6.02 (17.32)	500 g OP		Normacol Plus
	2.41 (8.72)	200 g OP		Normacol Plus

Faecal Softeners

DOCUSATE SODIUM – Only on a prescription

❋ Tab 50 mg	2.31	100	✔	Coloxyl
❋ Tab 120 mg	3.13	100	✔	Coloxyl

DOCUSATE SODIUM WITH SENNOSIDES

❋ Tab 50 mg with sennosides 8 mg	3.10	200	✔	Laxsol

POLOXAMER – Only on a prescription
Not funded for use in the ear.

❋ Oral drops 10%	3.78	30 ml OP	✔	Coloxyl

Opioid Receptor Antagonists - Peripheral

METHYLNALTREXONE BROMIDE – Special Authority see SA1691 below – Retail pharmacy

Inj 12 mg per 0.6 ml vial	36.00	1	✔	Relistor
	246.00	7	✔	Relistor

➽SA1691 Special Authority for Subsidy

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

Both:

1 The patient is receiving palliative care; and

2 Either:

2.1 Oral and rectal treatments for opioid induced constipation are ineffective; or

2.2 Oral and rectal treatments for opioid induced constipation are unable to be tolerated.

Osmotic Laxatives

GLYCEROL

❋ Suppos 3.6 g – Only on a prescription	9.25	20	✔	PSM

LACTULOSE – Only on a prescription

❋ Oral liq 10 g per 15 ml	3.33	500 ml	✔	Laevolac

MACROGOL 3350 WITH POTASSIUM CHLORIDE, SODIUM BICARBONATE AND SODIUM CHLORIDE

Powder for oral soln 13.125 g with potassium chloride 46.6 mg, sodium bicarbonate 178.5 mg and sodium chloride 350.7 mg	6.78	30	✔	Molaxole

SODIUM ACID PHOSPHATE – Only on a prescription

Enema 16% with sodium phosphate 8%	2.50	1	✔	Fleet Phosphate Enema

▲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
SODIUM CITRATE WITH SODIUM LAURYL SULPHOACETATE – Only on a prescription				
Enema 90 mg with sodium lauryl sulphoacetate 9 mg per ml, 5 ml	29.98	50	✔	Micolette

Stimulant Laxatives

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 – Retail pharmacy				
Inj 50 mg vial	1,142.60	1	✔	Myozyme

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

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

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

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
BETAINE – Special Authority see SA1727 below – Retail pharmacy				
Powder for oral soln	575.00	180 g OP	✔	**Cystadane**

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

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

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

IDURSULFASE – Special Authority see SA1623 below – Retail pharmacy				
Inj 2 mg per ml, 3 ml vial	4,608.30	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.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
LARONIDASE – Special Authority see SA1695 below – Retail pharmacy				
Inj 100 U per ml, 5 ml vial	1,335.16	1	✔	**Aldurazyme**

➽SA1695 Special Authority for Subsidy
Initial application only from a metabolic physician. Approvals valid for 24 weeks for applications meeting the following criteria:
All of the following:

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

SAPROPTERIN DIHYDROCHLORIDE – Special Authority see SA1757 below – Retail pharmacy				
Tab soluble 100 mg	1,452.70	30 OP	✔	**Kuvan**

➽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.

SODIUM BENZOATE – Special Authority see SA1599 on the next page – Retail pharmacy				
Soln 100 mg per ml	CBS	100 ml	✔	**Amzoate** S29

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

➽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

TALIGLUCERASE ALFA – Special Authority see SA1734 below – Retail pharmacy

Inj 200 unit vial	1,072.00	1	✔	**Elelyso**

➽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:

1) The patient has a diagnosis of symptomatic type 1 or type 3* Gaucher disease confirmed by the demonstration of specific deficiency of glucocerebrosidase in leukocytes or cultured skin fibroblasts, and genotypic analysis; and
2) Patient does not have another life-threatening or severe disease where the prognosis is unlikely to be influenced by 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:
6)
    1) 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

continued…

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

continued…

4) Patient has reduced vital capacity from clinically significant or progressive pulmonary disease due to Gaucher disease; or
5) 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:

All of the following:

1) Patient has demonstrated a symptomatic improvement or no deterioration in the main symptom for which therapy was initiated; and
2) Patient has demonstrated a clinically objective improvement or no deterioration in haemoglobin levels, platelet counts and liver and spleen size; and
3) Radiological (MRI) signs of bone activity performed at 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
5) Patient has not had severe infusion-related adverse reactions which were not preventable by appropriate pre-medication and/or adjustment of infusion rates; and
6) 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

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised	Brand or Generic Manufacturer
BENZYDAMINE HYDROCHLORIDE				
Soln 0.15% – Higher subsidy of $20.31 per 500 ml with Endorsement	9.00	500 ml		
	(20.31)			Difflam
Additional subsidy by endorsement for a patient who has oral mucositis as a result of treatment for cancer, and the prescription is endorsed accordingly.				
CARMELLOSE SODIUM WITH GELATIN AND PECTIN				
Paste	17.20	56 g OP	✔	**Stomahesive**
	4.55	15 g OP		
	(7.90)			Orabase
	1.52	5 g OP		
	(3.60)			Orabase
Powder	8.48	28 g OP		
	(10.95)			Stomahesive
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**

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

Oropharyngeal Anti-infectives

AMPHOTERICIN B				
Lozenges 10 mg	5.86	20	✔	**Fungilin**
MICONAZOLE				
Oral gel 20 mg per g	4.74	40 g OP	✔	**Decozol**
NYSTATIN				
Oral liq 100,000 u per ml	1.95	24 ml OP	✔	**Nilstat**

Other Oral Agents

For folinic mouthwash, pilocarpine oral liquid or saliva substitute formula refer Standard Formulae, page 237

HYDROGEN PEROXIDE				
❋ Soln 3% (10 vol) – Maximum of 200 ml per prescription	1.40	100 ml	✔	**Pharmacy Health**
(Pharmacy Health Soln 3% (10 vol) to be delisted 1 July 2020)				
THYMOL GLYCERIN				
❋ Compound, BPC	9.15	500 ml	✔	**PSM**

Vitamins

Vitamin A

VITAMIN A WITH VITAMINS D AND C				
❋ Soln 1000 u with Vitamin D 400 u and ascorbic acid 30 mg per 10 drops	4.50	10 ml OP	✔	**Vitadol C**

Vitamin B

HYDROXOCOBALAMIN				
❋ Inj 1 mg per ml, 1 ml ampoule – Up to 6 inj available on a PSO	1.89	3	✔	**Neo-B12**
PYRIDOXINE HYDROCHLORIDE				
a) No more than 100 mg per dose				
b) Only on a prescription				
❋ Tab 25 mg – No patient co-payment payable	2.70	90	✔	**Vitamin B6 25**
❋ Tab 50 mg	13.63	500	✔	**Apo-Pyridoxine**
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	9.90	500	✔	**Cvite**
Cvite to be Sole Supply on 1 March 2020				

▲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

Vitamin D

ALFACALCIDOL

✻ Cap 0.25 mcg	26.32	100	✔	One-Alpha
✻ Cap 1 mcg	87.98	100	✔	One-Alpha
✻ Oral drops 2 mcg per ml	60.68	20 ml OP	✔	One-Alpha

CALCITRIOL

✻ Cap 0.25 mcg	7.95	100	✔	Calcitriol-AFT
✻ Cap 0.5 mcg	13.75	100	✔	Calcitriol-AFT

COLECALCIFEROL

✻ Cap 1.25 mg (50,000 iu) – Maximum of 12 cap per prescription	2.50	12	✔	Vit.D3
✻ Oral liq 188 mcg per ml (7,500 iu per ml)	9.00	4.8 ml OP	✔	Puria

Multivitamin Preparations

MULTIVITAMIN RENAL – Special Authority see SA1546 below – Retail pharmacy

✻ Cap	6.49	30	✔	Clinicians Renal Vit

➽SA1546 Special Authority for Subsidy

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

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 m^2 body surface area (BSA).

MULTIVITAMINS – Special Authority see SA1036 below – Retail pharmacy

✻ Powder	72.00	200 g OP	✔	Paediatric Seravit

➽SA1036 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has inborn errors of metabolism.

Renewal from any relevant practitioner. Approvals valid without further renewal unless notified where patient has had a previous approval for multivitamins.

VITAMINS

✻ Tab (BPC cap strength)	11.45	1,000	✔	Mvite
Mvite to be Sole Supply on 1 March 2020				
✻ Cap (fat soluble vitamins A, D, E, K) – Special Authority see SA1720 below – Retail pharmacy	23.40	60	✔	Vitabdeck

➽SA1720 Special Authority for Subsidy

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

Any of the following:

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

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

Minerals

Calcium

CALCIUM CARBONATE

❋ Tab eff 1.75 g (1 g elemental)	28.40	20	✔	**Calcium Sandoz** S29
❋ Tab 1.25 g (500 mg elemental)	7.52	250	✔	**Arrow-Calcium**

CALCIUM GLUCONATE

❋ Inj 10%, 10 ml ampoule	64.00	20	✔	**Max Health** S29

Fluoride

SODIUM FLUORIDE

❋ Tab 1.1 mg (0.5 mg elemental)	5.75	100	✔	**PSM**

Iodine

POTASSIUM IODATE

❋ Tab 253 mcg (150 mcg elemental iodine)	4.69	90	✔	**NeuroTabs**

Iron

FERRIC CARBOXYMALTOSE – Special Authority see SA1840 below – Retail pharmacy

Inj 50 mg per ml, 10 ml	150.00	1	✔	**Ferinject**

➽SA1840 **Special Authority for Subsidy**

Initial application — (serum ferritin less than or equal to 20 mcg/L) from any relevant 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 relevant 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

continued…

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

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

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

continued…

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.

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
FERROUS FUMARATE				
✻ Tab 200 mg (65 mg elemental)	3.09	100	✔	Ferro-tab
FERROUS FUMARATE WITH FOLIC ACID				
✻ Tab 310 mg (100 mg elemental) with folic acid 350 mcg	4.68	60	✔	Ferro-F-Tabs
FERROUS SULFATE				
✻ Oral liq 30 mg (6 mg elemental) per 1 ml	12.08	500 ml	✔	Ferodan
FERROUS SULPHATE				
✻ Tab long-acting 325 mg (105 mg elemental)	2.06	30	✔	Ferrograd
IRON POLYMALTOSE				
✻ Inj 50 mg per ml, 2 ml ampoule	15.22	5	✔	Ferrum H
	34.50		✔	Ferrosig

(Ferrum H Inj 50 mg per ml, 2 ml ampoule to be delisted 1 February 2020)

Magnesium

For magnesium hydroxide mixture refer Standard Formulae, page 237

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
MAGNESIUM HYDROXIDE				
Suspension 8%	72.20	500 ml	✔	T&R S29
MAGNESIUM SULPHATE				
✻ Inj 2 mmol per ml, 5 ml ampoule	10.21	10	✔	DBL
			✔	DBL S29 S29

Zinc

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
ZINC SULPHATE				
✻ Cap 137.4 mg (50 mg elemental)	11.00	100	✔	Zincaps

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic 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 ✔	Brand or Generic Manufacturer
EPOETIN ALFA – Special Authority see SA1775 on the previous page – Retail pharmacy				
Wastage claimable				
Inj 1,000 iu in 0.5 ml, syringe	250.00	6	✔	Binocrit
Inj 2,000 iu in 1 ml, syringe	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	96.50	6	✔	Binocrit
Inj 5,000 iu in 0.5 ml, syringe	125.00	6	✔	Binocrit
Inj 6,000 iu in 0.6 ml, syringe	145.00	6	✔	Binocrit
Inj 8,000 iu in 0.8 ml, syringe	175.00	6	✔	Binocrit
Inj 10,000 iu in 1 ml, syringe	197.50	6	✔	Binocrit
Inj 40,000 iu in 1 ml, syringe	250.00	1	✔	Binocrit

Megaloblastic

FOLIC ACID				
✻ Tab 0.8 mg	21.84	1,000	✔	Apo-Folic Acid
✻ Tab 5 mg	12.12	500	✔	Apo-Folic Acid
Oral liq 50 mcg per ml	26.00	25 ml OP	✔	Biomed

Antifibrinolytics, Haemostatics and Local Sclerosants

EFTRENONACOG ALFA [RECOMBINANT FACTOR IX] – [Xpharm]

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

Inj 250 iu vial	612.50	1	✔	Alprolix
Inj 500 iu vial	1,225.00	1	✔	Alprolix
Inj 1,000 iu vial	2,450.00	1	✔	Alprolix
Inj 2,000 iu vial	4,900.00	1	✔	Alprolix
Inj 3,000 iu vial	7,350.00	1	✔	Alprolix
ELTROMBOPAG – Special Authority see SA1743 below – Retail pharmacy				
Wastage claimable				
Tab 25 mg	1,550.00	28	✔	Revolade
Tab 50 mg	3,100.00	28	✔	Revolade

➽SA1743 Special Authority for Subsidy

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

All of the following:

1 Patient has had a splenectomy; and

2 Two immunosuppressive therapies have been trialled and failed after therapy of 3 months each (or 1 month for rituximab); and

3 Any of the following:

3.1 Patient has a platelet count of 20,000 to 30,000 platelets per microlitre and has evidence of significant mucocutaneous bleeding; or

3.2 Patient has a platelet count of less than or equal to 20,000 platelets per microlitre and has evidence of active bleeding; or

3.3 Patient has a platelet count of less than or equal to 10,000 platelets per microlitre.

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

Initial application — (idiopathic thrombocytopenic purpura contraindicated to splenectomy) only from a haematologist.

continued…

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

continued…
Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1 Patient has a significant and well-documented contraindication to splenectomy for clinical reasons; and
2 Two immunosuppressive therapies have been trialled and failed after therapy of 3 months each (or 1 month for rituximab); and
3 Either:
   3.1 Patient has immune thrombocytopenic purpura* with a platelet count of less than or equal to 20,000 platelets per microliter; or
   3.2 Patient has immune thrombocytopenic purpura* with a platelet count of 20,000 to 30,000 platelets per microlitre 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. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group. Rare Clinical Circumstances Brand of bypassing agent for > 14 days predicted use. Access to funded treatment for > 14 days predicted use is by named patient application to the Haemophilia Treaters Group, subject to access criteria.

Inj 1 mg syringe	1,178.30	1	✔	**NovoSeven RT**
Inj 2 mg syringe	2,356.60	1	✔	**NovoSeven RT**
Inj 5 mg syringe	5,891.50	1	✔	**NovoSeven RT**
Inj 8 mg syringe	9,426.40	1	✔	**NovoSeven RT**

FACTOR EIGHT INHIBITOR BYPASSING FRACTION – [Xpharm]
For patients with haemophilia. Preferred Brand of bypassing agent for > 14 days predicted use. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

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

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
MOROCTOCOG ALFA [RECOMBINANT FACTOR VIII] – [Xpharm]				
For patients with haemophilia. Rare Clinical Circumstances Brand of short half-life recombinant factor VIII. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group, subject to criteria.				
Inj 250 iu prefilled syringe	287.50	1	✔	**Xyntha**
Inj 500 iu prefilled syringe	575.00	1	✔	**Xyntha**
Inj 1,000 iu prefilled syringe	1,150.00	1	✔	**Xyntha**
Inj 2,000 iu prefilled syringe	2,300.00	1	✔	**Xyntha**
Inj 3,000 iu prefilled syringe	3,450.00	1	✔	**Xyntha**
NONACOG GAMMA, [RECOMBINANT FACTOR IX] – [Xpharm]				
For patients with haemophilia. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.				
Inj 500 iu vial	435.00	1	✔	**RIXUBIS**
Inj 1,000 iu vial	870.00	1	✔	**RIXUBIS**
Inj 2,000 iu vial	1,740.00	1	✔	**RIXUBIS**
Inj 3,000 iu vial	2,610.00	1	✔	**RIXUBIS**
OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (ADVATE) – [Xpharm]				
For patients with haemophilia. Preferred Brand of short half-life recombinant factor VIII. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.				
Inj 250 iu vial	210.00	1	✔	**Advate**
Inj 500 iu vial	420.00	1	✔	**Advate**
Inj 1,000 iu vial	840.00	1	✔	**Advate**
Inj 1,500 iu vial	1,260.00	1	✔	**Advate**
Inj 2,000 iu vial	1,680.00	1	✔	**Advate**
Inj 3,000 iu vial	2,520.00	1	✔	**Advate**
OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (KOGENATE FS) – [Xpharm]				
For patients with haemophilia. Rare Clinical Circumstances Brand of short half-life recombinant factor VIII. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group, subject to criteria.				
Inj 250 iu vial	237.50	1	✔	**Kogenate FS**
Inj 500 iu vial	475.00	1	✔	**Kogenate FS**
Inj 1,000 iu vial	950.00	1	✔	**Kogenate FS**
Inj 2,000 iu vial	1,900.00	1	✔	**Kogenate FS**
Inj 3,000 iu vial	2,850.00	1	✔	**Kogenate FS**
RURIOCTOCOG ALFA PEGOL [RECOMBINANT FACTOR VIII] – [Xpharm]				
For patients with haemophilia A receiving prophylaxis treatment. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management group.				
Inj 250 iu vial	300.00	1	✔	**Adynovate**
Inj 500 iu vial	600.00	1	✔	**Adynovate**
Inj 1,000 iu vial	1,200.00	1	✔	**Adynovate**
Inj 2,000 iu vial	2,400.00	1	✔	**Adynovate**
SODIUM TETRADECYL SULPHATE				
✻ Inj 3% 2 ml	28.50	5		
	(73.00)			Fibro-vein
TRANEXAMIC ACID				
Tab 500 mg	9.45	60	✔	**Mercury Pharma**
	20.67	100	✔	**Cyklokapron**

(Cyklokapron Tab 500 mg to be delisted 1 May 2020)

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

Vitamin K

PHYTOMENADIONE				
Inj 2 mg per 0.2 ml – Up to 5 inj available on a PSO	8.00	5	✔	**Konakion MM**
Inj 10 mg per ml, 1 ml – Up to 5 inj available on a PSO	9.21	5	✔	**Konakion MM**

Antithrombotic Agents

Antiplatelet Agents

ASPIRIN				
❋ Tab 100 mg	10.80	990	✔	**Ethics Aspirin EC**
CLOPIDOGREL				
❋ Tab 75 mg	4.60	84	✔	**Clopidogrel Multichem**
	5.44		✔	**Arrow - Clopid**

(Arrow - Clopid Tab 75 mg to be delisted 1 May 2020)

DIPYRIDAMOLE				
❋ Tab long-acting 150 mg	10.90	60	✔	**Pytazen SR**
PRASUGREL – Special Authority see SA1201 below – Retail pharmacy				
Tab 5 mg	108.00	28	✔	**Effient**
Tab 10 mg	120.00	28	✔	**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:

continued…

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

continued…
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.

Heparin and Antagonist Preparations

DALTEPARIN SODIUM – Special Authority see SA1270 below – 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	60.03	10	✔	**Fragmin**
Inj 10,000 iu per 1 ml graduated syringe	77.55	10	✔	**Fragmin**

(Fragmin Inj 2,500 iu per 0.2 ml prefilled syringe to be delisted 1 April 2020)
(Fragmin Inj 5,000 iu per 0.2 ml prefilled syringe to be delisted 1 April 2020)
(Fragmin Inj 7,500 iu per 0.75 ml graduated syringe to be delisted 1 April 2020)
(Fragmin Inj 10,000 iu per 1 ml graduated syringe to be delisted 1 April 2020)

➽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:
Either:

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:
Either:

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 on the next page – Retail pharmacy

Inj 20 mg in 0.2 ml syringe	27.93	10	✔	**Clexane**
Inj 40 mg in 0.4 ml syringe	37.27	10	✔	**Clexane**
Inj 60 mg in 0.6 ml syringe	56.18	10	✔	**Clexane**
Inj 80 mg in 0.8 ml syringe	74.90	10	✔	**Clexane**
Inj 100 mg in 1 ml syringe	93.80	10	✔	**Clexane**
Inj 120 mg in 0.8 ml syringe	116.55	10	✔	**Clexane**
Inj 150 mg in 1 ml syringe	133.20	10	✔	**Clexane**

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

➽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
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).

HEPARIN SODIUM

Inj 1,000 iu per ml, 5 ml ampoule	58.57	50	✔	**Pfizer**
Inj 5,000 iu per ml, 1 ml	28.40	5	✔	**Hospira**
			✔	**Pfizer**
Inj 5,000 iu per ml, 5 ml ampoule	203.68	50	✔	**Pfizer**
Inj 25,000 iu per ml, 0.2 ml	19.00	5	✔	**Hospira**
	42.40		✔	**Heparin Ratiopharm** S29
	122.00	10	✔	**Wockhardt** S29
	190.00	50	✔	**Pfizer** S29

HEPARINISED SALINE

Inj 10 iu per ml, 5 ml	56.94	50	✔	**Pfizer**

Oral Anticoagulants

DABIGATRAN

Cap 75 mg – No more than 2 cap per day	76.36	60	✔	**Pradaxa**
Cap 110 mg	76.36	60	✔	**Pradaxa**
Cap 150 mg	76.36	60	✔	**Pradaxa**

RIVAROXABAN

Tab 10 mg – No more than 1 tab per day	83.10	30	✔	**Xarelto**
Tab 15 mg – Up to 14 tab available on a PSO	77.56	28	✔	**Xarelto**
Tab 20 mg	77.56	28	✔	**Xarelto**

▲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
WARFARIN SODIUM				
Note: Marevan and Coumadin are not interchangeable.				
✻ Tab 1 mg	3.46	50	✔	**Coumadin**
	7.60	100	✔	**Marevan**
✻ Tab 2 mg	4.31	50	✔	**Coumadin**
✻ Tab 3 mg	11.80	100	✔	**Marevan**
✻ Tab 5 mg	5.93	50	✔	**Coumadin**
	13.50	100	✔	**Marevan**

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**
Inj 480 mcg per 0.5 ml prefilled syringe	161.50	10	✔	**Nivestim**

➽SA1259 Special Authority for Subsidy

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

Any of the following:

1 Prevention of neutropenia in patients undergoing high risk chemotherapy for cancer (febrile neutropenia risk greater than or equal to 20%*); or
2 Peripheral blood stem cell mobilisation in patients undergoing haematological transplantation; or
3 Peripheral blood stem cell mobilisation or bone marrow donation from healthy donors for transplantation; or
4 Treatment of severe chronic neutropenia (ANC < 0.5 $\times 10^9$/L); or
5 Treatment of drug-induced prolonged neutropenia (ANC < 0.5 $\times 10^9$/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				
Inj 6 mg per 0.6 ml syringe	1,080.00	1	✔	**Neulastim**

➽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 PSO	29.50	5	✔	**Biomed**
✻ Inj 50%, 90 ml bottle – Up to 5 inj available on a PSO	14.50	1	✔	**Biomed**
POTASSIUM CHLORIDE				
✻ Inj 75 mg per ml, 10 ml	55.00	50	✔	**AstraZeneca**
			✔	**Potassium Chloride Aguettant** S29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
SODIUM BICARBONATE				
Inj 8.4%, 50 ml	19.95	1	✔	**Biomed**
a) Up to 5 inj available on a PSO b) Not in combination				
Inj 8.4%, 100 ml	20.50	1	✔	**Biomed**
a) Up to 5 inj available on a PSO b) Not in combination				
SODIUM CHLORIDE				
Not funded for use as a nasal drop. Not funded for nebuliser use except when used in conjunction with an antibiotic intended for nebuliser use.				
Inj 0.9%, bag – Up to 2000 ml available on a PSO	1.23	500 ml	✔	**Baxter**
	1.26	1,000 ml	✔	**Baxter**
Only if prescribed on a prescription for renal dialysis, maternity or post-natal care in the home of the patient, or on a PSO for emergency use. (500 ml and 1,000 ml packs)				
Inj 23.4% (4 mmol/ml), 20 ml ampoule	33.00	5	✔	**Biomed**
For Sodium chloride oral liquid formulation refer Standard Formulae, page 237				
Inj 0.9%, 5 ml ampoule – Up to 5 inj available on a PSO	2.80	20	✔	**Fresenius Kabi**
Inj 0.9%, 10 ml ampoule – Up to 5 inj available on a PSO	5.40	50	✔	**Fresenius Kabi**
Inj 0.9%, 20 ml ampoule	5.00	20	✔	**Fresenius Kabi**
TOTAL PARENTERAL NUTRITION (TPN) – Retail pharmacy-Specialist				
Infusion	CBS	1 OP	✔	**TPN**
WATER				
1) On a prescription or Practitioner's Supply Order only when on the same form as an injection listed in the Pharmaceutical Schedule requiring a solvent or diluent; or 2) On a bulk supply order; or 3) When used in the extemporaneous compounding of eye drops; or 4) When used for the dilution of sodium chloride soln 7% for cystic fibrosis patients only.				
Inj 5 ml ampoule – Up to 5 inj available on a PSO	7.00	50	✔	**InterPharma**
Inj 10 ml ampoule – Up to 5 inj available on a PSO	6.63	50	✔	**Pfizer**
Inj 20 ml ampoule – Up to 5 inj available on a PSO	5.00	20	✔	**Fresenius Kabi**
			✔	**Multichem**
	7.50	30	✔	**InterPharma**

Oral Administration

CALCIUM POLYSTYRENE SULPHONATE				
Powder	169.85	300 g OP	✔	**Calcium Resonium**
COMPOUND ELECTROLYTES				
Powder for oral soln – Up to 10 sach available on a PSO	2.30	10	✔	**Enerlyte**
	9.77	50	✔	**Electral**
Electral to be Sole Supply on 1 April 2020				
(Enerlyte Powder for oral soln to be delisted 1 April 2020)				
COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE]				
Soln with electrolytes (2 × 500 ml)	6.55	1,000 ml OP	✔	**Pedialyte - Bubblegum**
PHOSPHORUS				
Tab eff 500 mg (16 mmol)	82.50	100	✔	**Phosphate Phebra**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
POTASSIUM CHLORIDE				
❋ Tab eff 548 mg (14 m eq) with chloride 285 mg (8 m eq)	5.26	60		
	(11.85)			Chlorvescent
❋ Tab long-acting 600 mg (8 mmol)	8.90	200	✔	**Span-K**
SODIUM BICARBONATE				
Cap 840 mg	8.52	100	✔	**Sodibic**
			✔	**Sodibic**
SODIUM POLYSTYRENE SULPHONATE				
Powder	84.65	454 g OP	✔	**Resonium-A**

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

Alpha-Adrenoceptor Blockers

Alpha Adrenoceptor Blockers

DOXAZOSIN				
❋ Tab 2 mg	6.75	500	✔	Apo-Doxazosin
❋ Tab 4 mg	9.09	500	✔	Apo-Doxazosin
PHENOXYBENZAMINE HYDROCHLORIDE				
❋ Cap 10 mg	65.00	30	✔	BNM S29
	216.67	100	✔	Dibenzyline S29
PRAZOSIN				
❋ Tab 1 mg	5.53	100	✔	Apo-Prazosin
❋ Tab 2 mg	7.00	100	✔	Apo-Prazosin
❋ Tab 5 mg	11.70	100	✔	Apo-Prazosin
TERAZOSIN				
❋ Tab 1 mg	0.59	28	✔	Actavis
❋ Tab 2 mg	7.50	500	✔	Apo-Terazosin
❋ Tab 5 mg	10.90	500	✔	Apo-Terazosin

Agents Affecting the Renin-Angiotensin System

ACE Inhibitors

CAPTOPRIL				
❋ Oral liq 5 mg per ml	94.99	95 ml OP	✔	Capoten
Oral liquid restricted to children under 12 years of age.				
CILAZAPRIL				
❋ Tab 0.5 mg	2.09	90	✔	Zapril
❋ Tab 2.5 mg	4.80	90	✔	Zapril
	7.20	200	✔	Apo-Cilazapril
Zapril to be Sole Supply on 1 February 2020				
❋ Tab 5 mg	8.35	90	✔	Zapril
	12.00	200	✔	Apo-Cilazapril
Zapril to be Sole Supply on 1 February 2020				
(Apo-Cilazapril Tab 2.5 mg to be delisted 1 February 2020)				
(Apo-Cilazapril Tab 5 mg to be delisted 1 February 2020)				
ENALAPRIL MALEATE				
❋ Tab 5 mg	1.82	100	✔	Acetec
	3.84		✔	Ethics Enalapril
❋ Tab 10 mg	2.02	100	✔	Acetec
	4.96		✔	Ethics Enalapril
❋ Tab 20 mg	2.42	100	✔	Acetec
	7.12		✔	Ethics Enalapril
(Ethics Enalapril Tab 5 mg to be delisted 1 June 2020)				
(Ethics Enalapril Tab 10 mg to be delisted 1 June 2020)				
(Ethics Enalapril Tab 20 mg to be delisted 1 June 2020)				
LISINOPRIL				
❋ Tab 5 mg	2.07	90	✔	Ethics Lisinopril
❋ Tab 10 mg	2.36	90	✔	Ethics Lisinopril
❋ Tab 20 mg	3.17	90	✔	Ethics Lisinopril

▲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
PERINDOPRIL				
✱ Tab 2 mg	3.75	30	✔	Apo-Perindopril
✱ Tab 4 mg	4.80	30	✔	Apo-Perindopril
QUINAPRIL				
✱ Tab 5 mg	6.01	90	✔	Arrow-Quinapril 5
✱ Tab 10 mg	3.16	90	✔	Arrow-Quinapril 10
✱ Tab 20 mg	4.89	90	✔	Arrow-Quinapril 20

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	3.83	30	✔	Accuretic 10
✱ Tab 20 mg with hydrochlorothiazide 12.5 mg	4.92	30	✔	Accuretic 20

Angiotensin II Antagonists

CANDESARTAN CILEXETIL				
✱ Tab 4 mg	1.90	90	✔	Candestar
✱ Tab 8 mg	2.28	90	✔	Candestar
✱ Tab 16 mg	3.67	90	✔	Candestar
✱ Tab 32 mg	6.39	90	✔	Candestar
LOSARTAN POTASSIUM				
✱ Tab 12.5 mg	1.39	84	✔	Losartan Actavis
✱ Tab 25 mg	1.63	84	✔	Losartan Actavis
✱ Tab 50 mg	2.00	84	✔	Losartan Actavis
✱ 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

continued…

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

continued…

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 117

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
AMIODARONE HYDROCHLORIDE				
▲ Tab 100 mg – Retail pharmacy-Specialist	3.80	30	✔	Aratac
▲ Tab 200 mg – Retail pharmacy-Specialist	5.25	30	✔	Aratac
Inj 50 mg per ml, 3 ml ampoule – Up to 6 inj available on a PSO	9.98	5	✔	Lodi
	11.98	6	✔	Cordarone-X
	16.37	10	✔	Max Health
(Lodi Inj 50 mg per ml, 3 ml ampoule to be delisted 1 February 2020)				
(Cordarone-X Inj 50 mg per ml, 3 ml ampoule to be delisted 1 February 2020)				
ATROPINE SULPHATE				
❋ Inj 600 mcg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	12.07	10	✔	Martindale
DIGOXIN				
❋ Tab 62.5 mcg – Up to 30 tab available on a PSO	7.00	240	✔	Lanoxin PG
❋ Tab 250 mcg – Up to 30 tab available on a PSO	15.20	240	✔	Lanoxin
❋ Oral liq 50 mcg per ml	16.60	60 ml	✔	Lanoxin
			✔	Lanoxin S29 S29
DISOPYRAMIDE PHOSPHATE				
▲ Cap 100 mg	23.87	100	✔	Rythmodan
FLECAINIDE ACETATE – Retail pharmacy-Specialist				
▲ Tab 50 mg	19.95	60	✔	Flecainide BNM
	38.95		✔	Tambocor
Flecainide BNM to be Sole Supply on 1 February 2020				
▲ Cap long-acting 100 mg – Brand switch fee payable (Pharmacode 2577003) - see page 235 for details	39.51	90	✔	Flecainide Controlled Release Teva
▲ Cap long-acting 200 mg – Brand switch fee payable (Pharmacode 2577003) - see page 235 for details	61.06	90	✔	Flecainide Controlled Release Teva
Inj 10 mg per ml, 15 ml ampoule	100.00	5	✔	Tambocor
(Tambocor Tab 50 mg to be delisted 1 February 2020)				

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
MEXILETINE HYDROCHLORIDE				
▲ Cap 150 mg	162.00	100	✔	**Mexiletine Hydrochloride USP** S29
▲ Cap 250 mg	202.00	100	✔	**Mexiletine Hydrochloride USP** S29
PROPAFENONE HYDROCHLORIDE – Retail pharmacy-Specialist				
▲ Tab 150 mg	40.90	50	✔	**Rytmonorm**

Antihypotensives

MIDODRINE – Special Authority see SA1474 below – Retail pharmacy				
Tab 2.5 mg	53.00	100	✔	**Gutron**
Tab 5 mg	79.00	100	✔	**Gutron**

➽SA1474 **Special Authority for Subsidy**

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

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.

Beta-Adrenoceptor Blockers

Beta Adrenoceptor Blockers

ATENOLOL				
✻ Tab 50 mg	4.26	500	✔	**Mylan Atenolol**
✻ Tab 100 mg	7.30	500	✔	**Mylan Atenolol**
✻ Oral liq 25 mg per 5 ml	21.25	300 ml OP	✔	**Atenolol AFT**
Restricted to children under 12 years of age.				
BISOPROLOL FUMARATE				
✻ Tab 2.5 mg	3.53	90	✔	**Bosvate**
✻ Tab 5 mg	5.15	90	✔	**Bosvate**
✻ Tab 10 mg	9.40	90	✔	**Bosvate**
CARVEDILOL				
✻ Tab 6.25 mg	2.24	60	✔	**Carvedilol Sandoz**
✻ Tab 12.5 mg	2.30	60	✔	**Carvedilol Sandoz**
✻ Tab 25 mg	2.95	60	✔	**Carvedilol Sandoz**
CELIPROLOL				
✻ Tab 200 mg	21.40	180	✔	**Celol**
LABETALOL				
Tab 100 mg	11.36	100	✔	**Presolol** S29
Tab 200 mg	29.74	100	✔	**Hybloc**
			✔	**Presolol** S29
✻ Inj 5 mg per ml, 20 ml ampoule	59.06 (88.60)	5		Trandate

(Hybloc Tab 200 mg to be delisted 1 February 2020)

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
METOPROLOL SUCCINATE				
❋ Tab long-acting 23.75 mg	1.03	30	✔	Betaloc CR
❋ Tab long-acting 47.5 mg	1.25	30	✔	Betaloc CR
❋ Tab long-acting 95 mg	1.99	30	✔	Betaloc CR
❋ Tab long-acting 190 mg	3.00	30	✔	Betaloc CR
METOPROLOL TARTRATE				
❋ Tab 50 mg	5.66	100	✔	Apo-Metoprolol
❋ Tab 100 mg	7.55	60	✔	Apo-Metoprolol
❋ Tab long-acting 200 mg	23.40	28	✔	Slow-Lopresor
❋ Inj 1 mg per ml, 5 ml vial	29.50	5	✔	Metroprolol IV Mylan
NADOLOL				
❋ Tab 40 mg	16.69	100	✔	Apo-Nadolol
❋ Tab 80 mg	26.43	100	✔	Apo-Nadolol
PINDOLOL				
❋ Tab 5 mg	13.22	100	✔	Apo-Pindolol
❋ Tab 10 mg	23.12	100	✔	Apo-Pindolol
❋ Tab 15 mg	33.31	100	✔	Apo-Pindolol
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	✔	Cardinol LA
❋ Oral liq 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.

	Subsidy $	Per	Fully Subsidised	Manufacturer
SOTALOL				
❋ Tab 80 mg	32.58	500	✔	Mylan
❋ Tab 160 mg	10.98	100	✔	Mylan
TIMOLOL				
❋ Tab 10 mg	10.55	100	✔	Apo-Timol

Calcium Channel Blockers

Dihydropyridine Calcium Channel Blockers

	Subsidy $	Per	Fully Subsidised	Manufacturer
AMLODIPINE				
❋ Tab 2.5 mg	1.72	100	✔	Apo-Amlodipine
❋ Tab 5 mg	3.33	250	✔	Apo-Amlodipine
❋ Tab 10 mg	4.40	250	✔	Apo-Amlodipine

▲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
FELODIPINE				
✻ 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	4.32	90	✔	Felo 10 ER
NIFEDIPINE				
✻ Tab long-acting 10 mg	10.63	60	✔	Adalat 10
			✔	Adefin S29
✻ Tab long-acting 20 mg	17.72	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

(Adefin XL Tab long-acting 30 mg to be delisted 1 March 2020)

Other Calcium Channel Blockers

DILTIAZEM HYDROCHLORIDE				
✻ Tab 30 mg	4.60	100	✔	Dilzem
✻ Tab 60 mg	8.50	100	✔	Dilzem
✻ Cap long-acting 120 mg	33.42	500	✔	Apo-Diltiazem CD
✻ Cap long-acting 180 mg	50.05	500	✔	Apo-Diltiazem CD
✻ Cap long-acting 240 mg	66.76	500	✔	Apo-Diltiazem CD
PERHEXILINE MALEATE				
✻ Tab 100 mg	62.90	100	✔	Pexsig
VERAPAMIL HYDROCHLORIDE				
✻ Tab 40 mg	7.01	100	✔	Isoptin
✻ Tab 80 mg	11.74	100	✔	Isoptin
✻ Tab long-acting 120 mg	15.20	250	✔	Verpamil SR
	36.02	100	✔	Isoptin Retard S29
			✔	Isoptin 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

(Verpamil SR Tab long-acting 120 mg to be delisted 1 May 2020)

Centrally-Acting Agents

CLONIDINE				
✻ Patch 2.5 mg, 100 mcg per day – Only on a prescription	7.40	4	✔	Mylan
✻ Patch 5 mg, 200 mcg per day – Only on a prescription	10.04	4	✔	Mylan
✻ Patch 7.5 mg, 300 mcg per day – Only on a prescription	12.34	4	✔	Mylan
CLONIDINE HYDROCHLORIDE				
✻ Tab 25 mcg	8.75	112	✔	Clonidine BNM
✻ Tab 150 mcg	34.32	100	✔	Catapres
✻ Inj 150 mcg per ml, 1 ml ampoule	25.96	10	✔	Medsurge
METHYLDOPA				
✻ Tab 250 mg	15.10	100	✔	Methyldopa Mylan
	52.85	500	✔	Methyldopa Mylan S29 S29

✔ fully subsidised
Sole Subsidised Supply
S29 Unapproved medicine supplied under Section 29

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

Diuretics

Loop Diuretics

BUMETANIDE				
❋ Tab 1 mg	16.36	100	✔	**Burinex**
❋ Inj 500 mcg per ml, 4 ml vial	7.95	5	✔	**Burinex**
FUROSEMIDE [FRUSEMIDE]				
Tab 40 mg – Up to 30 tab available on a PSO	7.24	1,000	✔	**Apo-Furosemide**
	(8.00)			Diurin 40
Apo-Furosemide to be Sole Supply on 1 March 2020				
❋ Tab 500 mg	25.00	50	✔	**Urex Forte**
❋ Oral liq 10 mg per ml	11.20	30 ml OP	✔	**Lasix**
❋ Inj 10 mg per ml, 25 ml ampoule	60.65	6	✔	**Lasix**
❋ Inj 10 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	1.15	5	✔	**Frusemide-Claris**

(Diurin 40 Tab 40 mg to be delisted 1 March 2020)

Potassium Sparing Diuretics

AMILORIDE HYDROCHLORIDE				
Oral liq 1 mg per ml	30.00	25 ml OP	✔	**Biomed**
EPLERENONE – Special Authority see SA1728 below – Retail pharmacy				
Tab 50 mg	17.00	30	✔	**Inspra**
Tab 25 mg	11.87	30	✔	**Inspra**

➽SA1728 Special Authority for Subsidy

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

Both:

1. Patient has heart failure with ejection fraction less than 40%; and
2. Either:
   - 2.1 Patient is intolerant to optimal dosing of spironolactone; or
   - 2.2 Patient has experienced a clinically significant adverse effect while on optimal dosing of spironolactone.

METOLAZONE				
Tab 5 mg	CBS	1	✔	**Metolazone** S29
		50	✔	**Zaroxolyn** S29
SPIRONOLACTONE				
❋ Tab 25 mg	4.38	100	✔	**Spiractin**
❋ Tab 100 mg	11.80	100	✔	**Spiractin**
Oral liq 5 mg per ml	30.60	25 ml OP	✔	**Biomed**

Potassium Sparing Combination Diuretics

AMILORIDE HYDROCHLORIDE WITH FUROSEMIDE				
❋ Tab 5 mg with furosemide 40 mg	8.63	28	✔	**Frumil**
AMILORIDE HYDROCHLORIDE WITH HYDROCHLOROTHIAZIDE				
❋ Tab 5 mg with hydrochlorothiazide 50 mg	5.00	50	✔	**Moduretic**

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

Thiazide and Related Diuretics

BENDROFLUMETHIAZIDE [BENDROFLUAZIDE]				
✻ Tab 2.5 mg – Up to 150 tab available on a PSO	12.50	500	✔	Arrow-Bendrofluazide
May be supplied on a PSO for reasons other than emergency.				
✻ Tab 5 mg	20.42	500	✔	Arrow-Bendrofluazide
CHLOROTHIAZIDE				
Oral liq 50 mg per ml	26.00	25 ml OP	✔	Biomed
CHLORTALIDONE [CHLORTHALIDONE]				
✻ Tab 25 mg	6.50	50	✔	Hygroton
INDAPAMIDE				
✻ Tab 2.5 mg	2.60	90	✔	Dapa-Tabs

Lipid-Modifying Agents

Fibrates

BEZAFIBRATE				
✻ Tab 200 mg	19.01	90	✔	Bezalip
✻ Tab long-acting 400 mg	12.89	30	✔	Bezalip Retard
GEMFIBROZIL				
✻ Tab 600 mg	19.56	60	✔	Lipazil

Other Lipid-Modifying Agents

ACIPIMOX				
✻ Cap 250 mg	18.75	30	✔	Olbetam
NICOTINIC ACID				
✻ Tab 50 mg	4.12	100	✔	Apo-Nicotinic Acid
✻ Tab 500 mg	17.89	100	✔	Apo-Nicotinic Acid

Resins

COLESTIPOL HYDROCHLORIDE				
Grans for oral liq 5 g	28.60	30	✔	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	6.96	500	✔	Lorstat
✻ Tab 20 mg	9.99	500	✔	Lorstat
✻ Tab 40 mg	15.93	500	✔	Lorstat
✻ Tab 80 mg	27.19	500	✔	Lorstat

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
PRAVASTATIN – See prescribing guideline on the previous page				
❋ Tab 20 mg	4.72	100	✔	Apo-Pravastatin
❋ Tab 40 mg	8.06	100	✔	Apo-Pravastatin
SIMVASTATIN – See prescribing guideline on the previous page				
❋ Tab 10 mg	0.95	90	✔	Simvastatin Mylan
❋ Tab 20 mg	1.52	90	✔	Simvastatin Mylan
❋ Tab 40 mg	2.63	90	✔	Simvastatin Mylan
❋ Tab 80 mg	6.00	90	✔	Simvastatin Mylan

Selective Cholesterol Absorption Inhibitors

EZETIMIBE – Special Authority see SA1045 below – Retail pharmacy				
❋ Tab 10 mg	2.00	30	✔	Ezetimibe Sandoz

➽SA1045 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 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 × 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 mg	5.15	30	✔	Zimybe
Tab 10 mg with simvastatin 20 mg	6.15	30	✔	Zimybe
Tab 10 mg with simvastatin 40 mg	7.15	30	✔	Zimybe
Tab 10 mg with simvastatin 80 mg	8.15	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

continued…

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

continued…
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.

Nitrates

GLYCERYL TRINITRATE

	Subsidy $	Per	Fully Subsidised	Brand
✻ Oral pump spray, 400 mcg per dose – Up to 250 dose available on a PSO	4.45	250 dose OP	✔	**Nitrolingual Pump Spray**
✻ Oral spray, 400 mcg per dose – Up to 200 dose available on a PSO	4.45	200 dose OP	✔	**Glytrin**
✻ Patch 25 mg, 5 mg per day	15.73	30	✔	**Nitroderm TTS**
✻ Patch 50 mg, 10 mg per day	18.62	30	✔	**Nitroderm TTS**

(Glytrin Oral spray, 400 mcg per dose to be delisted 1 May 2020)

ISOSORBIDE MONONITRATE

	Subsidy $	Per	Fully Subsidised	Brand
✻ Tab 20 mg	18.80	100	✔	**<u>Ismo 20</u>**
✻ Tab long-acting 40 mg	8.20	30	✔	**Ismo 40 Retard**
✻ Tab long-acting 60 mg	8.29	90	✔	**<u>Duride</u>**

Sympathomimetics

ADRENALINE

	Subsidy $	Per	Fully Subsidised	Brand
Inj 1 in 1,000, 1 ml ampoule – Up to 5 inj available on a PSO	4.98	5	✔	**Aspen Adrenaline**
	5.25		✔	**DBL Adrenaline**
Inj 1 in 10,000, 10 ml ampoule – Up to 5 inj available on a PSO	27.00	5	✔	**Hospira**
	49.00	10	✔	**Aspen Adrenaline**

ISOPRENALINE [ISOPROTERENOL]

	Subsidy $	Per	Fully Subsidised	Brand
✻ Inj 200 mcg per ml, 1 ml ampoule	36.80 (164.20)	25		Isuprel

Vasodilators

HYDRALAZINE HYDROCHLORIDE

	Subsidy $	Per	Fully Subsidised	Brand
✻ Tab 25 mg – Special Authority see SA1321 below – Retail pharmacy	CBS	1	✔	**Hydralazine**
		56	✔	**Onelink** S29
		84	✔	**AMDIPHARM** S29
		100	✔	**Onelink** S29
✻ Inj 20 mg ampoule	25.90	5	✔	**Apresoline**

➽SA1321 Special Authority for Subsidy
Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:
Either:

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

MINOXIDIL

	Subsidy $	Per	Fully Subsidised	Brand
▲ Tab 10 mg	70.00	100	✔	**Loniten**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
NICORANDIL				
▲ Tab 10 mg	25.57	60	✔	Ikorel
▲ Tab 20 mg	32.28	60	✔	Ikorel
PAPAVERINE HYDROCHLORIDE				
❋ Inj 12 mg per ml, 10 ml ampoule	217.90	5	✔	Hospira
PENTOXIFYLLINE [OXPENTIFYLLINE]				
Tab 400 mg	42.26	50	✔	Trental 400

Endothelin Receptor Antagonists

AMBRISENTAN – Special Authority see SA1702 below – Retail pharmacy				
Tab 5 mg	4,585.00	30	✔	Volibris
Tab 10 mg	4,585.00	30	✔	Volibris

➽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				
Tab 62.5 mg	141.00	60	✔	Bosentan Dr Reddy's
Tab 125 mg	141.00	60	✔	Bosentan Dr Reddy's

➽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

continued…

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

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

continued…

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:
- 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

SILDENAFIL – Special Authority see SA1825 below – Retail pharmacy

Tab 25 mg	0.64	4	✔	Vedafil
Tab 50 mg	0.64	4	✔	Vedafil
Tab 100 mg	6.60	12	✔	Vedafil

➽SA1825 **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:

continued…

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

continued…

- 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 Either:

- 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
    - 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 (dyn 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.

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

Both:

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

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

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

Nebuliser soln 10 mcg per ml, 2 ml	740.10	30	✔	**Ventavis**

➽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

▲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

Antiacne Preparations

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 88

ADAPALENE

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

	Subsidy $	Per	Fully Subsidised	Brand
Crm 0.1%	22.89	30 g OP	✔	**Differin**
Gel 0.1%	22.89	30 g OP	✔	**Differin**

ISOTRETINOIN – Special Authority see SA1475 below – Retail pharmacy

	Subsidy $	Per	Fully Subsidised	Brand
Cap 5 mg	8.14	60	✔	**Oratane**
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:
Either:

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
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.

TRETINOIN

	Subsidy $	Per	Fully Subsidised	Brand
Crm 0.5 mg per g – Maximum of 50 g per prescription	13.90	50 g OP	✔	**ReTrieve**

Antibacterials Topical

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 88

HYDROGEN PEROXIDE

	Subsidy $	Per	Fully Subsidised	Brand
✻ Crm 1%	8.56	10 g OP	✔	**Crystaderm**
		15 g OP	✔	**Crystaderm**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
MUPIROCIN				
Oint 2%	6.60 (9.26)	15 g OP		Bactroban
a) Only on a prescription				
b) Not in combination				
SODIUM FUSIDATE [FUSIDIC ACID]				
Crm 2%	1.59	5 g OP	✔	**Foban**
a) Maximum of 5 g per prescription				
b) Only on a prescription				
c) Not in combination				
Oint 2%	1.59	5 g OP	✔	**Foban**
a) Maximum of 5 g per prescription				
b) Only on a prescription				
c) Not in combination				
SULFADIAZINE SILVER				
Crm 1%	10.80	50 g OP	✔	**Flamazine**
a) Up to 250 g available on a PSO				
b) Not in combination				

Antifungals Topical

For systemic antifungals, refer to INFECTIONS, Antifungals, page 95

AMOROLFINE				
a) Only on a prescription				
b) Not in combination				
Nail soln 5%	15.95	5 ml OP	✔	**MycoNail**
CICLOPIROX OLAMINE				
a) Only on a prescription				
b) Not in combination				
Nail-soln 8%	5.72	7 ml OP	✔	**Apo-Ciclopirox**
CLOTRIMAZOLE				
❋ Crm 1%	0.70	20 g OP	✔	**Clomazol**
a) Only on a prescription				
b) Not in combination				
❋ Soln 1%	4.36 (7.55)	20 ml OP		Canesten
a) Only on a prescription				
b) Not in combination				
ECONAZOLE NITRATE				
Crm 1%	1.00 (7.48)	20 g OP		Pevaryl
a) Only on a prescription				
b) Not in combination				
Foaming soln 1%, 10 ml sachets	9.89 (17.23)	3		Pevaryl
a) Only on a prescription				
b) Not in combination				

▲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
MICONAZOLE NITRATE				
❋ Crm 2%	0.74	15 g OP	✔	<u>Multichem</u>
a) Only on a prescription b) Not in combination				
❋ Lotn 2%	4.36	30 ml OP		
	(10.03)			Daktarin
a) Only on a prescription b) Not in combination				
❋ Tinct 2%	4.36	30 ml OP		
	(12.10)			Daktarin
a) Only on a prescription b) Not in combination				
NYSTATIN				
Crm 100,000 u per g	1.00	15 g OP		
	(7.90)			Mycostatin
a) Only on a prescription b) Not in combination				

Antipruritic Preparations

CALAMINE				
a) Only on a prescription b) Not in combination				
Crm, aqueous, BP	1.26	100 g	✔	<u>healthE Calamine Aqueous Cream BP</u>
Lotn, BP	12.94	2,000 ml	✔	**PSM**
(PSM Lotn, BP to be delisted 1 July 2020)				
CROTAMITON				
a) Only on a prescription b) Not in combination				
Crm 10%	3.29	20 g OP	✔	<u>Itch-Soothe</u>
MENTHOL – Only in combination				
1) Only in combination with a dermatological base or proprietary Topical Corticosteriod – Plain 2) With or without other dermatological galenicals.				
Crystals	6.92	25 g	✔	**MidWest**
	29.60	100 g	✔	**MidWest**

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

Corticosteroids Topical

For systemic corticosteroids, refer to CORTICOSTEROIDS AND RELATED AGENTS, page 78

Corticosteroids - Plain

BETAMETHASONE DIPROPIONATE				
Crm 0.05%	2.96	15 g OP	✔	**Diprosone**
	8.97	50 g OP	✔	**Diprosone**
Crm 0.05% in propylene glycol base	4.33	30 g OP	✔	**Diprosone OV**
Oint 0.05%	2.96	15 g OP	✔	**Diprosone**
	8.97	50 g OP	✔	**Diprosone**
Oint 0.05% in propylene glycol base	4.33	30 g OP	✔	**Diprosone OV**
(Diprosone OV Crm 0.05% in propylene glycol base to be delisted 1 May 2020)				
BETAMETHASONE VALERATE				
✻ Crm 0.1%	3.45	50 g OP	✔	**Beta Cream**
✻ Oint 0.1%	3.45	50 g OP	✔	**Beta Ointment**
✻ Lotn 0.1%	18.00	50 ml OP	✔	**Betnovate**
CLOBETASOL PROPIONATE				
✻ Crm 0.05%	2.18	30 g OP	✔	**Dermol**
✻ Oint 0.05%	2.12	30 g OP	✔	**Dermol**
CLOBETASONE BUTYRATE				
Crm 0.05%	5.38	30 g OP		
	(7.09)			Eumovate
DIFLUCORTOLONE VALERATE				
Crm 0.1%	8.97	50 g OP		
	(15.86)			Nerisone
Fatty oint 0.1%	8.97	50 g OP		
	(15.86)			Nerisone
HYDROCORTISONE				
✻ Crm 1% – Only on a prescription	3.42	30 g OP	✔	**DermAssist**
	17.15	500 g	✔	**Pharmacy Health**
✻ Powder – Only in combination	49.95	25 g	✔	**ABM**
Up to 5% in a dermatological base (not proprietary Topical Corticosteriod – Plain) with or without other dermatological galenicals				
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	✔	**DP Lotn HC**
HYDROCORTISONE BUTYRATE				
Lipocream 0.1%	3.42	30 g OP	✔	**Locoid Lipocream**
	6.85	100 g OP	✔	**Locoid Lipocream**
Oint 0.1%	13.70	100 g OP	✔	**Locoid**
Milky emul 0.1%	13.70	100 ml OP	✔	**Locoid Crelo**
METHYLPREDNISOLONE ACEPONATE				
Crm 0.1%	4.95	15 g OP	✔	**Advantan**
Oint 0.1%	4.95	15 g OP	✔	**Advantan**

▲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
MOMETASONE FUROATE				
Crm 0.1%	1.51	15 g OP	✔	Elocon Alcohol Free
	2.50	50 g OP	✔	Elocon Alcohol Free
Oint 0.1%	1.51	15 g OP	✔	Elocon
	2.90	50 g OP	✔	Elocon
Lotn 0.1%	6.30	30 ml OP	✔	Elocon
TRIAMCINOLONE ACETONIDE				
Crm 0.02%	6.30	100 g OP	✔	Aristocort
Oint 0.02%	6.35	100 g OP	✔	Aristocort

Corticosteroids - Combination

BETAMETHASONE VALERATE WITH CLIOQUINOL – Only on a prescription				
Crm 0.1% with clioquinol 3%	3.49	15 g OP		
	(4.90)			Betnovate-C
BETAMETHASONE VALERATE WITH SODIUM FUSIDATE [FUSIDIC ACID]				
Crm 0.1% with sodium fusidate (fusidic acid) 2%	3.49	15 g OP		
	(10.45)			Fucicort

a) Maximum of 15 g per prescription
b) Only on a prescription

HYDROCORTISONE WITH MICONAZOLE – Only on a prescription				
❋ Crm 1% with miconazole nitrate 2%	2.00	15 g OP	✔	Micreme H
HYDROCORTISONE WITH NATAMYCIN AND NEOMYCIN – Only on a prescription				
Crm 1% with natamycin 1% and neomycin sulphate 0.5%	3.35	15 g OP	✔	Pimafucort
Oint 1% with natamycin 1% and neomycin sulphate 0.5%	3.35	15 g OP	✔	Pimafucort
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCIN AND NYSTATIN				
Crm 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 mcg per g – Only on a prescription	3.49	15 g OP		
	(6.60)			Viaderm KC

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 prescription is endorsed accordingly.

❋ Handrub 1% with ethanol 70%	4.29	500 ml	✔	healthE
❋ Soln 4% wash	3.98	500 ml	✔	healthE

TRICLOSAN – Subsidy by endorsement

a) Maximum of 500 ml per prescription
b)
   a) Only if prescribed for a patient identified with Methicillin-resistant Staphylococcus aureus (MRSA) prior to elective surgery in hospital and the prescription is endorsed accordingly; or
   b) Only if prescribed for a patient with recurrent Staphylococcus aureus infection and the prescription is endorsed accordingly

Soln 1%	5.90	500 ml OP	✔	healthE

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
Barrier Creams and Emollients				
Barrier Creams				
DIMETHICONE				
❋ Crm 5% pump bottle	4.48	500 ml OP	✔	**healthE Dimethicone 5%**
❋ Crm 10% pump bottle	4.52	500 ml OP	✔	**healthE Dimethicone 10%**
ZINC AND CASTOR OIL				
❋ Oint	4.25	500 g	✔	**Boucher**
Emollients				
AQUEOUS CREAM				
❋ Crm	1.92	500 g	✔	**Boucher**
CETOMACROGOL				
❋ Crm BP	2.48	500 g	✔	**healthE**
CETOMACROGOL WITH GLYCEROL				
Crm 90% with glycerol 10%	2.35	500 ml OP	✔	**Boucher**
	2.82		✔	**Pharmacy Health Sorbolene with Glycerin**
	3.10	1,000 ml OP	✔	**Boucher**
	3.87		✔	**Pharmacy Health Sorbolene with Glycerin**
Boucher to be Sole Supply on 1 March 2020				
(Pharmacy Health Sorbolene with Glycerin Crm 90% with glycerol 10% to be delisted 1 March 2020)				
(Pharmacy Health Sorbolene with Glycerin Crm 90% with glycerol 10% to be delisted 1 March 2020)				
EMULSIFYING OINTMENT				
❋ Oint BP	3.59	500 g	✔	**AFT**
OIL IN WATER EMULSION				
❋ Crm	2.19	500 g	✔	**O/W Fatty Emulsion Cream**
PARAFFIN				
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		
	(11.95)			DP Lotion
	1.40	250 ml OP		
	(4.53)			DP Lotion
	5.60	1,000 ml		
	(20.53)			Alpha-Keri Lotion
	(23.91)			BK Lotion
	1.40	250 ml OP		
	(7.73)			BK Lotion

▲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

Other Dermatological Bases

PARAFFIN

White soft – Only in combination	4.99	450 g	✔	**healthE**
	19.99	2,500 g	✔	**healthE**
	3.58	500 g		
	(7.78)			IPW
	(8.69)			PSM

a) Only in combination with a dermatological galenical or as a diluent for a proprietary Topical Corticosteroid – Plain.
b) healthE to be Sole Supply on 1 April 2020

(IPW White soft to be delisted 1 April 2020)
(PSM White soft to be delisted 1 May 2020)

Minor Skin Infections

POVIDONE IODINE

Oint 10%	3.27	25 g OP	✔	**Betadine**

a) Maximum of 100 g per prescription
b) Only on a prescription

Antiseptic Solution 10%	2.55	100 ml	✔	**Riodine**

Riodine to be Sole Supply on 1 February 2020

Antiseptic soln 10%	3.83	15 ml	✔	**Riodine**
	5.40	500 ml	✔	**Riodine**
	(6.20)			Betadine
	1.28	100 ml		
	(13.27)			Betadine
	0.19	15 ml		
	(7.41)			Betadine

Riodine to be Sole Supply on 1 March 2020

Skin preparation, povidone iodine 10% with 30% alcohol	10.00	500 ml	✔	**Betadine Skin Prep**
	1.63	100 ml		
	(3.48)			Betadine Skin Prep
Skin preparation, povidone iodine 10% with 70% alcohol	1.63	100 ml		
	(6.64)			Pfizer

(Betadine Antiseptic soln 10% to be delisted 1 March 2020)
(Betadine Antiseptic soln 10% to be delisted 1 March 2020)
(Betadine Antiseptic soln 10% to be delisted 1 March 2020)

Parasiticidal Preparations

DIMETHICONE

❋ Lotn 4%	4.98	200 ml OP	✔	**<u>healthE Dimethicone 4% Lotion</u>**

IVERMECTIN – Special Authority see SA1225 on the next page – 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.
3) For the purposes of subsidy of ivermectin, institution means age related residential care facilities, disability care facilities or prisons.

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

➽SA1225 **Special Authority for Subsidy**
Initial application — (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.
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

continued…

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

continued…

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.

PERMETHRIN				
Crm 5%	4.95	30 g OP	✔	Lyderm
Lotn 5%	3.69	30 ml OP	✔	A-Scabies
PHENOTHRIN				
Shampoo 0.5%	11.36	200 ml OP	✔	**Parasidose**

Psoriasis and Eczema Preparations

ACITRETIN – Special Authority see SA1476 below – Retail pharmacy

Cap 10 mg	17.86	60	✔	Novatretin
Cap 25 mg	41.36	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:

Either:

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

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
COAL TAR				
Soln BP – Only in combination	36.25	200 ml	✔	Midwest
1) Up to 10% only in combination with a dermatological base or proprietary Topical Corticosteriod – Plain				
2) With or without other dermatological galenicals.				
COAL TAR WITH ALLANTOIN, MENTHOL, PHENOL AND SULPHUR				
Soln 5% with sulphur 0.5%, menthol 0.75%, phenol 0.5% and allantoin crm 2.5%	6.59	75 g OP		
	(8.00)			Egopsoryl TA
	3.43	30 g OP		
	(4.35)			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 on a prescription				
❋ Soln 2.3% with trolamine laurilsulfate and fluorescein sodium	3.86	500 ml	✔	Pinetarsol
SALICYLIC ACID				
Powder – Only in combination	18.88	250 g	✔	Midwest
			✔	PSM
1) Only in combination with a dermatological base or proprietary Topical Corticosteroid – Plain or collodion flexible				
2) With or without other dermatological galenicals.				
SULPHUR				
Precipitated – Only in combination	6.35	100 g	✔	Midwest
1) Only in combination with a dermatological base or proprietary Topical Corticosteroid – Plain				
2) With or without other dermatological galenicals.				

Scalp Preparations

BETAMETHASONE VALERATE				
❋ Scalp app 0.1%	7.75	100 ml OP	✔	Beta Scalp
CLOBETASOL PROPIONATE				
❋ Scalp app 0.05%	5.69	30 ml OP	✔	Dermol
HYDROCORTISONE BUTYRATE				
Scalp lotn 0.1%	7.30	100 ml OP	✔	Locoid
KETOCONAZOLE				
Shampoo 2%	2.99	100 ml OP	✔	Sebizole
a) Maximum of 100 ml per prescription				
b) Only on a prescription				

▲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

Sunscreens

SUNSCREENS, PROPRIETARY – Subsidy by endorsement

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

Crm	3.30 (5.89)	100 g OP		Hamilton Sunscreen
Lotn,	5.10	200 g OP	✔	**Marine Blue Lotion SPF 50+**

Marine Blue Lotion SPF 50+ to be Sole Supply on 1 March 2020

(Hamilton Sunscreen Crm to be delisted 1 March 2020)

Wart Preparations

For salicylic acid preparations refer to PSORIASIS AND ECZEMA PREPARATIONS, page 66

IMIQUIMOD

Crm 5%, 250 mg sachet	21.72	24	✔	**Perrigo**

PODOPHYLLOTOXIN

Soln 0.5%	33.60	3.5 ml OP	✔	**Condyline**
			✔	**Condyline S29** S29

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

Other Skin Preparations

Antineoplastics

FLUOROURACIL SODIUM

Crm 5%	7.95	20 g OP	✔	**Efudix**

✔ **fully subsidised**
Sole Subsidised Supply
S29 Unapproved medicine supplied under Section 29

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

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

Contraceptives - Non-hormonal

Condoms

CONDOMS

❋ 49 mm – Up to 144 dev available on a PSO	11.42	144	✔	**Moments**
	13.36		✔	**Shield 49**
Moments to be Sole Supply on 1 March 2020				
❋ 53 mm	0.95	10	✔	**Moments**
	1.11	12	✔	**Gold Knight**
	11.64	144	✔	**Moments**
	13.36		✔	**Shield Blue**
a) Maximum of 60 dev per prescription b) Up to 60 dev available on a PSO c) Moments to be Sole Supply on 1 March 2020				
❋ 53 mm (chocolate)	13.36	144	✔	**Gold Knight**
a) Maximum of 60 dev per prescription b) Up to 60 dev available on a PSO				
❋ 53 mm (strawberry)	13.36	144	✔	**Gold Knight**
a) Maximum of 60 dev per prescription b) Up to 60 dev available on a PSO				
❋ 53 mm, 0.05 mm thickness	0.95	10	✔	**Moments**
	11.42	144	✔	**Moments**
a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription c) Moments to be Sole Supply on 1 March 2020				
❋ 53 mm, chocolate, brown	0.95	10	✔	**Moments**
	11.64	144	✔	**Moments**
a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription c) Moments to be Sole Supply on 1 March 2020				
❋ 53 mm, strawberry, red	0.95	10	✔	**Moments**
	11.64	144	✔	**Moments**
a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription c) Moments to be Sole Supply on 1 March 2020				
❋ 56 mm	0.97	10	✔	**Moments**
	11.64	144	✔	**Moments**
	13.36		✔	**Durex Extra Safe**
			✔	**Gold Knight**
a) Maximum of 60 dev per prescription b) Up to 60 dev available on a PSO				
❋ 56 mm, 0.05 mm thickness	1.30	12	✔	**Gold Knight**
	15.57	144	✔	**Gold Knight**
a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription c) Gold Knight to be Sole Supply on 1 March 2020				
❋ 56 mm, 0.08 mm thickness	0.97	10	✔	**Moments**
	11.64	144	✔	**Moments**
a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription c) Moments to be Sole Supply on 1 March 2020				
❋ 56 mm, 0.08 mm thickness, red	0.97	10	✔	**Moments**
	11.64	144	✔	**Moments**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription c) Moments to be Sole Supply on 1 March 2020				
❋ 56 mm, chocolate	1.30	12	✔	**Gold Knight**
	15.57	144	✔	**Gold Knight**
a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription c) Gold Knight to be Sole Supply on 1 March 2020				
❋ 56 mm, shaped	13.36	144		
	(16.08)			Durex Confidence
a) Maximum of 60 dev per prescription b) Up to 60 dev available on a PSO				
❋ 56 mm, strawberry	1.30	12	✔	**Gold Knight**
	15.57	144	✔	**Gold Knight**
a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription c) Gold Knight to be Sole Supply on 1 March 2020				
❋ 60 mm – Up to 144 dev available on a PSO	13.36	144	✔	**Shield XL**

(Shield 49 49 mm to be delisted 1 March 2020)
(Gold Knight 53 mm to be delisted 1 March 2020)
(Shield Blue 53 mm to be delisted 1 March 2020)
(Gold Knight 53 mm (chocolate) to be delisted 1 March 2020)
(Gold Knight 53 mm (strawberry) to be delisted 1 March 2020)
(Durex Extra Safe 56 mm to be delisted 1 March 2020)
(Gold Knight 56 mm to be delisted 1 March 2020)
(Durex Confidence 56 mm, shaped to be delisted 1 March 2020)

Contraceptive Devices

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

❋ IUD 29.1 mm length x 23.2 mm width	18.45	1	✔	**Choice TT380 Short**
❋ IUD 33.6 mm length x 29.9 mm width	18.45	1	✔	**Choice TT380 Standard**
❋ IUD 35.5 mm length x 19.6 mm width	15.50	1	✔	**Choice Load 375**

Contraceptives - Hormonal

Combined Oral Contraceptives

➽SA0500 Special Authority for Alternate Subsidy
Initial application from any medical practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Both:
1 Either:
   1.1 Patient is on a Social Welfare benefit; or
   1.2 Patient has an income no greater than the benefit; and
2 Has tried at least one of the fully funded options and has been unable to tolerate it.

continued…

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

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

continued…

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

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

Notes: The approval numbers of Special Authorities approved after 1 November 1999 are interchangeable between Mercilon and Marvelon.
The additional subsidy will fund Mercilon and Marvelon up to the manufacturer's price for each of these products as identified on the Schedule at 1 November 1999.
Special Authorities approved before 1 November 1999 remain valid until the expiry date and can be renewed providing that women are still either:

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

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

ETHINYLOESTRADIOL WITH DESOGESTREL

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
✳ Tab 20 mcg with desogestrel 150 mcg and 7 inert tab	6.62 (19.80)	84		Mercilon 28

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

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
✳ Tab 30 mcg with desogestrel 150 mcg and 7 inert tab	6.62 (19.80)	84		Marvelon 28

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

ETHINYLOESTRADIOL WITH LEVONORGESTREL

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
✳ Tab 20 mcg with levonorgestrel 100 mcg and 7 inert tablets – Up to 112 tab available on a PSO	2.18	84	✔	**<u>Microgynon 20 ED</u>**
	6.45	112	✔	**Femme-Tab ED**
✳ Tab 50 mcg with levonorgestrel 125 mcg and 7 inert tab – Up to 84 tab available on a PSO	9.45	84	✔	**Microgynon 50 ED**
✳ Tab 30 mcg with levonorgestrel 150 mcg	6.62 (16.50)	63		Microgynon 30

a) Higher subsidy of $15.00 per 63 tab with Special Authority see SA0500 on the previous page
b) Up to 63 tab available on a PSO

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
✳ Tab 30 mcg with levonorgestrel 150 mcg and 7 inert tablets – Up to 112 tab available on a PSO	1.77	84	✔	**<u>Levlen ED</u>**
	6.45	112	✔	**Femme-Tab ED**

ETHINYLOESTRADIOL WITH NORETHISTERONE

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
✳ Tab 35 mcg with norethisterone 1 mg – Up to 63 tab available on a PSO	6.62	63	✔	**Brevinor 1/21**
✳ Tab 35 mcg with norethisterone 1 mg and 7 inert tab – Up to 84 tab available on a PSO Brevinor 1/28 to be Sole Supply on 1 March 2020	6.95	84	✔	**Brevinor 1/28**
✳ Tab 35 mcg with norethisterone 500 mcg – Up to 63 tab available on a PSO	6.62	63	✔	**Brevinor 21**
✳ Tab 35 mcg with norethisterone 500 mcg and 7 inert tab – Up to 84 tab available on a PSO	6.62	84	✔	**Norimin**

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

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

Progestogen-only Contraceptives

➽SA0500 Special Authority for Alternate Subsidy

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

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

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

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

Notes: The approval numbers of Special Authorities approved after 1 November 1999 are interchangeable between Mercilon and Marvelon.
The additional subsidy will fund Mercilon and Marvelon up to the manufacturer's price for each of these products as identified on the Schedule at 1 November 1999.
Special Authorities approved before 1 November 1999 remain valid until the expiry date and can be renewed providing that women are still either:

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

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

	Subsidy $	Per	Fully Subsidised	Brand
LEVONORGESTREL				
✻ Tab 30 mcg	6.62 (16.50)	84		Microlut
a) Higher subsidy of $13.80 per 84 tab with Special Authority see SA0500 above				
b) Up to 84 tab available on a PSO				
✻ Subdermal implant (2 × 75 mg rods) – Up to 3 pack available on a PSO	106.92	1	✔	**Jadelle**
MEDROXYPROGESTERONE ACETATE				
Inj 150 mg per ml, 1 ml syringe – Up to 5 inj available on a PSO	7.98	1	✔	**Depo-Provera**
NORETHISTERONE				
✻ Tab 350 mcg – Up to 84 tab available on a PSO	6.25	84	✔	**Noriday 28**

Emergency Contraceptives

	Subsidy $	Per	Fully Subsidised	Brand
LEVONORGESTREL				
✻ Tab 1.5 mg	4.95	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.				

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

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**

Gynaecological Anti-infectives

ACETIC ACID WITH HYDROXYQUINOLINE AND RICINOLEIC ACID				
Jelly with glacial acetic acid 0.94%, hydroxyquinoline sulphate 0.025%, glycerol 5% and ricinoleic acid 0.75% with applicator	8.43 (24.00)	100 g OP		Aci-Jel
CLOTRIMAZOLE				
❋ Vaginal crm 1% with applicators	2.50	35 g OP	✔	**Clomazol**
❋ Vaginal crm 2% with applicators	3.00	20 g OP	✔	**Clomazol**
MICONAZOLE NITRATE				
❋ Vaginal crm 2% with applicator	3.88	40 g OP	✔	**Micreme**
NYSTATIN				
Vaginal crm 100,000 u per 5 g with applicator(s)	4.45	75 g OP	✔	**Nilstat**

Myometrial and Vaginal Hormone Preparations

ERGOMETRINE MALEATE				
Inj 500 mcg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	105.00	5	✔	**DBL Ergometrine**
OESTRIOL				
❋ Crm 1 mg per g with applicator	6.62	15 g OP	✔	**Ovestin**
❋ Pessaries 500 mcg	6.86	15	✔	**Ovestin**
OXYTOCIN – Up to 5 inj available on a PSO				
Inj 5 iu per ml, 1 ml ampoule	3.98	5	✔	**Oxytocin BNM**
Inj 10 iu per ml, 1 ml ampoule	4.98	5	✔	**Oxytocin BNM**
OXYTOCIN WITH ERGOMETRINE MALEATE – Up to 5 inj available on a PSO				
Inj 5 iu with ergometrine maleate 500 mcg per ml, 1 ml	15.00	5	✔	**Syntometrine**

Pregnancy Tests - hCG Urine

PREGNANCY TESTS - HCG URINE a) Up to 200 test available on a PSO b) Only on a PSO				
Cassette	12.00	40 test OP	✔	**Smith BioMed Rapid Pregnancy Test**

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

Urinary Agents

For urinary tract Infections refer to INFECTIONS, Antibacterials, page 106

5-Alpha Reductase Inhibitors

FINASTERIDE – Special Authority see SA0928 below – Retail pharmacy

✻ Tab 5 mg	4.81	100	✔	Ricit

➽SA0928 Special Authority for Subsidy

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

Both:

1 Patient has symptomatic benign prostatic hyperplasia; and

2 Either:

2.1 The patient is intolerant of non-selective alpha blockers or these are contraindicated; or

2.2 Symptoms are not adequately controlled with non-selective alpha blockers.

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

Alpha-1A Adrenoreceptor Blockers

TAMSULOSIN HYDROCHLORIDE – Special Authority see SA1032 below – Retail pharmacy

✻ Cap 400 mcg	17.73	100	✔	Tamsulosin-Rex

➽SA1032 Special Authority for Subsidy

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

Both:

1 Patient has symptomatic benign prostatic hyperplasia; and

2 The patient is intolerant of non-selective alpha blockers or these are contraindicated.

Other Urinary Agents

OXYBUTYNIN

✻ Tab 5 mg	8.85	500	✔	Apo-Oxybutynin
✻ Oral liq 5 mg per 5 ml	60.40	473 ml	✔	Apo-Oxybutynin

POTASSIUM CITRATE

Oral liq 3 mmol per ml – Special Authority see SA1083 below – Retail pharmacy	31.80	200 ml OP	✔	Biomed

➽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	✔	Ural

SOLIFENACIN SUCCINATE

Tab 5 mg	3.00	30	✔	Solifenacin Mylan
Tab 10 mg	5.50	30	✔	Solifenacin Mylan

▲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
TOLTERODINE – Special Authority see SA1272 below – Retail pharmacy				
Tab 1 mg	14.56	56	✔	**Arrow-Tolterodine**
Tab 2 mg	14.56	56	✔	**Arrow-Tolterodine**

(Arrow-Tolterodine Tab 1 mg to be delisted 1 March 2020)

➽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.

Detection of Substances in Urine

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
ORTHO-TOLIDINE				
❋ Compound diagnostic sticks	7.50 (8.25)	50 test OP		Hemastix
TETRABROMOPHENOL				
❋ Blue diagnostic strips	7.02 (13.92)	100 test OP		Albustix

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

Calcium Homeostasis

CALCITONIN

❋ Inj 100 iu per ml, 1 ml ampoule	121.00	5	✔	**Miacalcic**

CINACALCET – Special Authority see SA1618 below – Retail pharmacy

Tab 30 mg – Wastage claimable	210.30	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

Inj 4 mg per 5 ml, vial – Special Authority see SA1687 below – Retail pharmacy	38.03	1	✔	**Zoledronic acid Mylan**

➽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:

All of the following:

continued…

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

continued…

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

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised	Brand or Generic Manufacturer
BETAMETHASONE SODIUM PHOSPHATE WITH BETAMETHASONE ACETATE				
✻ Inj 3.9 mg with betamethasone acetate 3 mg per ml, 1 ml	19.20 (36.96)	5		Celestone Chronodose
DEXAMETHASONE				
✻ Tab 0.5 mg – Retail pharmacy-Specialist Up to 60 tab available on a PSO	0.99	30	✔	**Dexmethsone**
✻ Tab 4 mg – Retail pharmacy-Specialist Up to 30 tab available on a PSO	1.90	30	✔	**Dexmethsone**
Oral liq 1 mg per ml – Retail pharmacy-Specialist Oral liq prescriptions: 1) Must be written by a Paediatrician or Paediatric Cardiologist; or 2) On the recommendation of a Paediatrician or Paediatric Cardiologist.	45.00	25 ml OP	✔	**Biomed**
DEXAMETHASONE PHOSPHATE Dexamethasone phosphate injection will not be funded for oral use.				
✻ Inj 4 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	14.19	10	✔	**Max Health**
✻ Inj 4 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	25.18	10	✔	**Max Health**
FLUDROCORTISONE ACETATE				
✻ Tab 100 mcg	14.32	100	✔	**Florinef**
HYDROCORTISONE				
✻ Tab 5 mg	8.10	100	✔	**Douglas**
✻ Tab 20 mg	20.32	100	✔	**Douglas**
✻ Inj 100 mg vial a) Up to 5 inj available on a PSO b) Only on a PSO	5.30	1	✔	**Solu-Cortef**
METHYLPREDNISOLONE – Retail pharmacy-Specialist				
✻ Tab 4 mg	112.00	100	✔	**Medrol**
✻ Tab 100 mg	194.00	20	✔	**Medrol**
METHYLPREDNISOLONE (AS SODIUM SUCCINATE) – Retail pharmacy-Specialist				
Inj 40 mg vial	18.90	1	✔	**Solu-Medrol-Act-O-Vial**
Inj 125 mg vial	28.90	1	✔	**Solu-Medrol-Act-O-Vial**
Inj 500 mg vial	22.78	1	✔	**Solu-Medrol-Act-O-Vial**
Inj 1 g vial	27.83	1	✔	**Solu-Medrol**
METHYLPREDNISOLONE ACETATE				
Inj 40 mg per ml, 1 ml vial	44.40	5	✔	**Depo-Medrol**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
PREDNISOLONE				
❋ Oral liq 5 mg per ml – Up to 30 ml available on a PSO	6.00	30 ml OP	✔	Redipred
Restricted to children under 12 years of age.				
PREDNISONE				
❋ Tab 1 mg	10.68	500	✔	Apo-Prednisone
❋ Tab 2.5 mg	12.09	500	✔	Apo-Prednisone
❋ Tab 5 mg – Up to 30 tab available on a PSO	11.09	500	✔	Apo-Prednisone
❋ Tab 20 mg	29.03	500	✔	Apo-Prednisone
TETRACOSACTRIN				
❋ Inj 250 mcg per ml, 1 ml ampoule	75.00	1	✔	AU Synacthen
			✔	Synacthen
❋ Inj 1 mg per ml, 1 ml ampoule	690.00	1	✔	Synacthen Depot
			✔	Synacthene Retard S29
TRIAMCINOLONE ACETONIDE				
Inj 10 mg per ml, 1 ml ampoule	20.80	5	✔	Kenacort-A 10
Inj 40 mg per ml, 1 ml ampoule	51.10	5	✔	Kenacort-A 40

Sex Hormones Non Contraceptive

Androgen Agonists and Antagonists

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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	✔	Depo-Testosterone
TESTOSTERONE ESTERS – Retail pharmacy-Specialist				
Inj 250 mg per ml, 1 ml	12.98	1	✔	Sustanon Ampoules
TESTOSTERONE UNDECANOATE – Retail pharmacy-Specialist				
Cap 40 mg	21.00	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”.

▲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

Oestrogens

OESTRADIOL – See prescribing guideline on the previous page

❋ Tab 1 mg	4.12 (11.10)	28 OP		Estrofem
❋ Tab 2 mg	4.12 (11.10)	28 OP		Estrofem
❋ Patch 25 mcg per day a) No more than 2 patch per week b) Only on a prescription	6.12	8	✔	**Estradot**
❋ Patch 50 mcg per day a) No more than 2 patch per week b) Only on a prescription	7.04	8	✔	**Estradot 50 mcg**
❋ Patch 75 mcg per day a) No more than 2 patch per week b) Only on a prescription	7.91	8	✔	**Estradot**
❋ Patch 100 mcg per day a) No more than 2 patch per week b) Only on a prescription	7.91	8	✔	**Estradot**

OESTRADIOL VALERATE – See prescribing guideline on the previous page

❋ Tab 1 mg	12.36	84	✔	**Progynova**
❋ Tab 2 mg	12.36	84	✔	**Progynova**

OESTROGENS – See prescribing guideline on the previous page

❋ Conjugated, equine tab 300 mcg	3.01 (13.50)	28		Premarin
❋ Conjugated, equine tab 625 mcg	4.12 (13.50)	28		Premarin

Progestogens

MEDROXYPROGESTERONE ACETATE – See prescribing guideline on the previous page

❋ Tab 2.5 mg	3.75	30	✔	**Provera**
❋ Tab 5 mg	14.00	100	✔	**Provera**
❋ Tab 10 mg	7.15	30	✔	**Provera**

Progestogen and Oestrogen Combined Preparations

OESTRADIOL WITH NORETHISTERONE – See prescribing guideline on the previous page

❋ Tab 1 mg with 0.5 mg norethisterone acetate	5.40 (18.10)	28 OP		Kliovance
❋ Tab 2 mg with 1 mg norethisterone acetate	5.40 (18.10)	28 OP		Kliogest
❋ Tab 2 mg with 1 mg norethisterone acetate (10), and 2 mg oestradiol tab (12) and 1 mg oestradiol tab (6)	5.40 (18.10)	28 OP		Trisequens

Other Oestrogen Preparations

ETHINYLOESTRADIOL

❋ Tab 10 mcg	17.60	100	✔	**NZ Medical and Scientific**

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

Other Progestogen Preparations

LEVONORGESTREL				
❋ Intra-uterine device 52 mg	269.50	1	✔	**Mirena**
❋ Intra-uterine device 13.5 mg	215.60	1	✔	**Jaydess**
MEDROXYPROGESTERONE ACETATE				
Tab 100 mg – Retail pharmacy-Specialist	101.00	100	✔	**Provera HD**
NORETHISTERONE				
❋ Tab 5 mg – Up to 30 tab available on a PSO	18.29	100	✔	**Primolut N**
PROGESTERONE				
Cap 100 mg – Special Authority see SA1609 below – Retail pharmacy	16.50	30	✔	**Utrogestan**

➽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 Either:

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.

Thyroid and Antithyroid Agents

CARBIMAZOLE				
❋ Tab 5 mg	10.80	100	✔	**AFT Carbimazole** S29
			✔	**Neo-Mercazole**
LEVOTHYROXINE				
❋ Tab 25 mcg	3.89	90	✔	**Synthroid**
❋ Tab 50 mcg	1.71	28	✔	**Mercury Pharma**
	4.05	90	✔	**Synthroid**
	64.28	1,000	✔	**Eltroxin**
❋ Tab 100 mcg	1.78	28	✔	**Mercury Pharma**
	4.21	90	✔	**Synthroid**
	66.78	1,000	✔	**Eltroxin**

PROPYLTHIOURACIL – Special Authority see SA1199 on the next page – Retail pharmacy

Propylthiouracil is not recommended for patients under the age of 18 years unless the patient is pregnant and other treatments are contraindicated.

Tab 50 mg	35.00	100	✔	**PTU** S29

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

➽SA1199 Special Authority for Subsidy

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

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

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

Trophic Hormones

Growth Hormones

SOMATROPIN (OMNITROPE) – Special Authority see SA1629 below – Retail pharmacy

❋ Inj 5 mg cartridge	34.88	1	✔	Omnitrope
❋ Inj 10 mg cartridge	69.75	1	✔	Omnitrope
❋ Inj 15 mg cartridge	104.63	1	✔	Omnitrope

➽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:
Either:

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

continued…

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

continued…

2 Height velocity is < 25th percentile over 6-12 months using the standards of Tanner and Davies (1985); and
3 A current bone age is < 14 years.

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

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

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

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

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

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

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

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

continued…

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

All of the following:

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

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

All of the following:

1. The patient has a diagnosis of Prader-Willi syndrome that has been confirmed by genetic testing or clinical scoring criteria; and
2. The patient is aged six months or older; and
3. A current bone age is < 14 years (female patients) or < 16 years (male patients); and
4. Sleep studies or overnight oximetry have been performed and there is no obstructive sleep disorder requiring treatment, or if an obstructive sleep disorder is found, it has been adequately treated under the care of a paediatric respiratory physician and/or ENT surgeon; and
5. Either:
   - 5.1 Both:
     - 5.1.1 The patient is aged two years or older; and
     - 5.1.2 There is no evidence of type II diabetes or uncontrolled obesity defined by BMI that has increased by greater than or equal to 0.5 standard deviations in the preceding 12 months; or
   - 5.2 The patient is aged between six months and two years and a thorough upper airway assessment is planned to be undertaken prior to treatment commencement and at six to 12 weeks following treatment initiation.

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

All of the following:

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

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

All of the following:

continued…

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

continued…

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
  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

GOSERELIN

Implant 3.6 mg, syringe	66.48	1	✔	**Zoladex**
Implant 10.8 mg, syringe	177.50	1	✔	**Zoladex**

LEUPRORELIN

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

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

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

Vasopressin Agonists

DESMOPRESSIN ACETATE

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
Tab 100 mcg – Special Authority see SA1401 below – Retail pharmacy	25.00	30	✔	**Minirin**
Tab 200 mcg – Special Authority see SA1401 below – Retail pharmacy	54.45	30	✔	**Minirin**
▲ Nasal drops 100 mcg per ml – Retail pharmacy-Specialist	39.03	2.5 ml OP	✔	**Minirin**
▲ Nasal spray 10 mcg per dose – Retail pharmacy-Specialist	23.95	6 ml OP	✔	**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:

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

CABERGOLINE

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
Tab 0.5 mg – Maximum of 2 tab per prescription; can be waived by Special Authority see SA1370 below	3.75	2	✔	**Dostinex**
	15.20	8	✔	**Dostinex**

➽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

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
Tab 50 mg	29.84	10	✔	**Mylan Clomiphen** S29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
DANAZOL				
Cap 100 mg	19.13	28	✔	**Mylan** S29
	68.33	100	✔	**Azol**
Cap 200 mg	97.83	100	✔	**Azol**
(Azol Cap 100 mg to be delisted 1 June 2020)				
METYRAPONE				
Cap 250 mg – Retail pharmacy-Specialist	520.00	50	✔	**Metopirone**

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

Anthelmintics

ALBENDAZOLE – Special Authority see SA1318 below – Retail pharmacy

Tab 400 mg	469.20	60	✔	**Eskazole** S29

➽SA1318 Special Authority for Subsidy

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

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

MEBENDAZOLE – Only on a prescription

Tab 100 mg	24.19	24	✔	**De-Worm**
Oral liq 100 mg per 5 ml	2.18 (7.17)	15 ml		Vermox

PRAZIQUANTEL

Tab 600 mg	68.00	8	✔	**Biltricide**

Antibacterials

a) For topical antibacterials, refer to DERMATOLOGICALS, page 58
b) For anti-infective eye preparations, refer to SENSORY ORGANS, page 230

Cephalosporins and Cephamycins

CEFACLOR MONOHYDRATE

Cap 250 mg	24.70	100	✔	**Ranbaxy-Cefaclor**
Grans for oral liq 125 mg per 5 ml – Wastage claimable	3.53	100 ml	✔	**Ranbaxy-Cefaclor**
	4.33		✔	**Keflor**

CEFALEXIN

Cap 250 mg	3.33	20	✔	**Cephalexin ABM**
Cap 500 mg	3.95	20	✔	**Cephalexin ABM**
Grans for oral liq 25 mg per ml – Wastage claimable	8.75	100 ml	✔	**Cefalexin Sandoz**
Grans for oral liq 50 mg per ml – Wastage claimable	11.75	100 ml	✔	**Cefalexin Sandoz**

CEFAZOLIN – Subsidy by endorsement

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

Inj 500 mg vial	3.39	5	✔	**AFT**
Inj 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	0.89	1	✔	**Ceftriaxone-AFT**
Inj 1 g vial	3.99	5	✔	**Ceftriaxone-AFT**

CEFUROXIME AXETIL – Subsidy by endorsement

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

Tab 250 mg	45.93	50	✔	**Zinnat**

Zinnat to be Sole Supply on 1 February 2020

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

➠SA1683 Special Authority for Waiver of Rule

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

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

Note: Indications marked with * are unapproved indications.

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

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

Note: Indications marked with * are unapproved indications.

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

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

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

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

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

Tab 250 mg	3.98	14	✔	Apo-Clarithromycin
Grans for oral liq 250 mg per 5 ml – Wastage claimable	192.00	50 ml	✔	Klacid

➠SA1857 Special Authority for Waiver of Rule

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

continued…

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

continued…

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

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

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

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

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
ERYTHROMYCIN (AS LACTOBIONATE)				
Inj 1 g vial	10.00	1	✔	**Erythrocin IV**
ERYTHROMYCIN ETHYL SUCCINATE				
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	✔	**E-Mycin**
a) Up to 300 ml available on a PSO b) Up to 2 x the maximum PSO quantity for RFPP c) Wastage claimable				
Grans for oral liq 400 mg per 5 ml	6.77	100 ml	✔	**E-Mycin**
a) Up to 200 ml available on a PSO b) Wastage claimable				
ERYTHROMYCIN STEARATE				
Tab 250 mg – Up to 30 tab available on a PSO	14.95 (22.29)	100		ERA
Tab 500 mg	29.90 (44.58)	100		ERA
ROXITHROMYCIN				
Tab disp 50 mg	8.29	10	✔	**Rulide D**
Restricted to children under 12 years of age.				
Tab 150 mg	8.28	50	✔	**Arrow-Roxithromycin**
Tab 300 mg	16.33	50	✔	**Arrow-Roxithromycin**

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

Penicillins

AMOXICILLIN				
Cap 250 mg	14.97	500	✔	**Apo-Amoxi**
	22.50		✔	**Alphamox**
a) Up to 30 cap available on a PSO b) Up to 10 x the maximum PSO quantity for RFPP c) Alphamox to be Sole Supply on 1 April 2020				
Cap 500 mg	16.75	500	✔	**Apo-Amoxi**
	36.98		✔	**Alphamox**
a) Up to 30 cap available on a PSO b) Up to 10 x the maximum PSO quantity for RFPP c) Alphamox to be Sole Supply on 1 April 2020				
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				
Grans for oral liq 250 mg per 5 ml	1.31	100 ml	✔	**Alphamox 250**
a) Up to 300 ml available on a PSO b) Up to 10 x the maximum PSO quantity for RFPP c) Wastage claimable				
Inj 250 mg vial	10.67	10	✔	**Ibiamox**
Inj 500 mg vial	12.41	10	✔	**Ibiamox**
Inj 1 g vial – Up to 5 inj available on a PSO	17.29	10	✔	**Ibiamox**
(Apo-Amoxi Cap 250 mg to be delisted 1 April 2020) *(Apo-Amoxi Cap 500 mg to be delisted 1 April 2020)*				
AMOXICILLIN WITH CLAVULANIC ACID				
Tab 500 mg with clavulanic acid 125 mg – Up to 30 tab available on a PSO	1.88	20	✔	**Augmentin**
Grans for oral liq amoxicillin 25 mg with clavulanic acid 6.25 mg per ml	3.83	100 ml	✔	**Augmentin**
a) Up to 200 ml available on a PSO b) Wastage claimable				
Grans for oral liq amoxicillin 50 mg with clavulanic acid 12.5 mg per ml – Up to 200 ml available on a PSO	2.20	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**
BENZYLPENICILLIN SODIUM [PENICILLIN G]				
Inj 600 mg (1 million units) vial – Up to 5 inj available on a PSO	10.35	10	✔	**Sandoz**
	25.88	25	✔	**Pan-Penicillin G Sodium** S29

▲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
FLUCLOXACILLIN				
Cap 250 mg – Up to 30 cap available on a PSO	16.83	250	✔	Staphlex
Cap 500 mg	56.61	500	✔	Staphlex
Grans for oral liq 25 mg per ml	2.29	100 ml	✔	AFT
a) Up to 200 ml available on a PSO 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 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
PHENOXYMETHYLPENICILLIN (PENICILLIN V)				
Cap 250 mg – Up to 30 cap available on a PSO	2.59	50	✔	Cilicaine VK
Cap 500 mg	4.26	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	2.99	100 ml	✔	AFT
a) Up to 200 ml available on a PSO b) Wastage claimable				
Grans for oral liq 250 mg per 5 ml	3.99	100 ml	✔	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	✔	Cilicaine

Tetracyclines

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
DOXYCYCLINE				
❋ Tab 100 mg – Up to 30 tab available on a PSO	64.43	500	✔	Doxine
MINOCYCLINE HYDROCHLORIDE				
❋ Tab 50 mg – Additional subsidy by Special Authority see SA1355 below – Retail pharmacy	5.79 (12.05)	60		Mino-tabs
❋ Cap 100 mg	19.32 (52.04)	100		Minomycin

➽SA1355 Special Authority for Manufacturers Price
Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has rosacea.

TETRACYCLINE – Special Authority see SA1332 below – Retail pharmacy				
Cap 500 mg	46.00	30	✔	Tetracyclin 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 (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer

Other Antibiotics

For topical antibiotics, refer to DERMATOLOGICALS, page 58

CIPROFLOXACIN

Recommended for patients with any of the following:

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

Tab 250 mg – Up to 5 tab available on a PSO	1.45	28	✔	Cipflox
Tab 500 mg – Up to 5 tab available on a PSO	1.99	28	✔	Cipflox
Tab 750 mg	3.15	28	✔	Cipflox

CLINDAMYCIN

Cap hydrochloride 150 mg – Maximum of 4 cap per prescription; can be waived by endorsement - Retail pharmacy - Specialist	4.10	16	✔	**Clindamycin ABM**
	4.61	24	✔	**Dalacin C**

Dalacin C to be Sole Supply on 1 April 2020

Inj phosphate 150 mg per ml, 4 ml ampoule – Retail pharmacy-Specialist	39.00	10	✔	Dalacin C

(Clindamycin ABM Cap hydrochloride 150 mg to be delisted 1 April 2020)

COLISTIN SULPHOMETHATE – Retail pharmacy-Specialist – Subsidy by endorsement

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

Inj 150 mg	65.00	1	✔	**Colistin-Link**

GENTAMICIN SULPHATE

Inj 10 mg per ml, 1 ml ampoule – Subsidy by endorsement	25.00	5	✔	**DBL Gentamicin**

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

Inj 40 mg per ml, 2 ml ampoule – Subsidy by endorsement	17.50	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

Tab 400 mg	52.00	5	✔	**Avelox**

➽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

continued…

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

continued…

1.2.3 Impaired visual acuity (considered to preclude ethambutol use); or
1.2.4 Significant pre-existing liver disease or hepatotoxicity from tuberculosis medications; or
1.2.5 Significant documented intolerance and/or side effects following a reasonable trial of first-line medications; or

2 Mycobacterium avium-intracellulare complex not responding to other therapy or where such therapy is contraindicated.*; or
3 Patient is under five years of age and has had close contact with a confirmed multi-drug resistant tuberculosis case.

Note: Indications marked with * are unapproved indications.

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

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

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

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

PAROMOMYCIN – Special Authority see SA1689 below – Retail pharmacy

Cap 250 mg	126.00	16	✔	**Humatin** S29

➽SA1689 Special Authority for Subsidy

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

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

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

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

PYRIMETHAMINE – Special Authority see SA1328 below – Retail pharmacy

Tab 25 mg	48.00	30	✔	**Daraprim** S29

➽SA1328 Special Authority for Subsidy

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

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

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** S29

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

➽SA1331 Special Authority for Subsidy
Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:
Any of the following:
1 For the treatment of toxoplasmosis in patients with HIV for a period of 3 months; or
2 For pregnant patients for the term of the pregnancy; or
3 For infants with congenital toxoplasmosis until 12 months of age.

TOBRAMYCIN

	Subsidy $	Per	Fully Subsidised	Brand
Inj 40 mg per ml, 2 ml vial – Subsidy by endorsement	15.00	5	✔	**Tobramycin Mylan**

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

	Subsidy $	Per	Fully Subsidised	Brand
Solution for inhalation 60 mg per ml, 5 ml – Subsidy by endorsement	2,200.00	56 dose	✔	**TOBI**

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

TRIMETHOPRIM

	Subsidy $	Per	Fully Subsidised	Brand
❋ Tab 300 mg – Up to 30 tab available on a PSO	16.50	50	✔	**TMP**

TRIMETHOPRIM WITH SULPHAMETHOXAZOLE [CO-TRIMOXAZOLE]

	Subsidy $	Per	Fully Subsidised	Brand
❋ Tab trimethoprim 80 mg and sulphamethoxazole 400 mg – Up to 30 tab available on a PSO	53.96	500	✔	**Trisul**
❋ Oral liq 8 mg sulphamethoxazole 40 mg per ml – Up to 200 ml available on a PSO	2.97	100 ml	✔	**Deprim**

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

	Subsidy $	Per	Fully Subsidised	Brand
Inj 500 mg vial	2.37	1	✔	**Mylan**

Antifungals

a) For topical antifungals refer to DERMATOLOGICALS, page 59
b) For topical antifungals refer to GENITO URINARY, page 74

FLUCONAZOLE

	Subsidy $	Per	Fully Subsidised	Brand
Cap 50 mg – Retail pharmacy-Specialist	2.09	28	✔	**Mylan**
Cap 150 mg – Subsidy by endorsement	0.33	1	✔	**Mylan**

a) Maximum of 1 cap per prescription; can be waived by endorsement - Retail pharmacy - Specialist
b) Patient has vaginal candida albicans and the practitioner considers that a topical imidazole (used intra-vaginally) is not recommended and the prescription is endorsed accordingly; can be waived by endorsement - Retail pharmacy - Specialist.

	Subsidy $	Per	Fully Subsidised	Brand
Cap 200 mg – Retail pharmacy-Specialist	5.08	28	✔	**Mylan**
Powder for oral suspension 10 mg per ml – Special Authority see SA1359 below – Retail pharmacy	34.56	35 ml	✔	**Diflucan S29** S29
	98.50		✔	**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:

continued…

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic 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	4.27	15	✔	Itrazole

Funded for tinea vesicolor where topical treatment has not been successful and diagnosis has been confirmed by mycology, or for tinea unguium 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 liq 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

Tab 200 mg – PCT – Retail pharmacy-Specialist – Subsidy by endorsement	CBS	30	✔	**Link Healthcare** S29
			✔	**Nizoral** S29

Prescriptions must be written by, or on the recommendation of an oncologist

NYSTATIN

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

POSACONAZOLE – Special Authority see SA1285 on the next page – Retail pharmacy

Tab modified-release 100 mg	869.86	24	✔	**Noxafil**
Oral liq 40 mg per ml	761.13	105 ml OP	✔	**Noxafil**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic 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	✔	Deolate
VORICONAZOLE – Special Authority see SA1273 below – Retail pharmacy				
Tab 50 mg	91.00	56	✔	Vttack
Tab 200 mg	350.00	56	✔	Vttack
Powder for oral suspension 40 mg per ml – Wastage claimable	1,437.00	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 (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer

Antimalarials

PRIMAQUINE PHOSPHATE – Special Authority see SA1684 below – Retail pharmacy

Tab 7.5 mg	117.00	56	✔	**Primacin** S29

➽SA1684 Special Authority for Subsidy

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

Both:

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

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

Both:

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

Antiparasitics

Antiprotozoals

QUININE SULPHATE

❋ Tab 300 mg	61.91	500	✔	**Q 300**

Antitrichomonal Agents

METRONIDAZOLE

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
b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or dermatologist.

❋ Cap 50 mg	442.00	100	✔	**Lamprene** S29

CYCLOSERINE – Retail pharmacy-Specialist

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

Cap 250 mg	344.00	60	✔	**Cyclorin** S29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
DAPSONE – Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or dermatologist				
Tab 25 mg	268.50	100	✔	**Dapsone**
Tab 100 mg	329.50	100	✔	**Dapsone**
ETHAMBUTOL HYDROCHLORIDE – Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or respiratory physician				
Tab 100 mg	85.73	100	✔	**EMB Fatol** S29
Tab 400 mg	49.34	56	✔	**Myambutol** S29
ISONIAZID – Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an internal medicine physician, paediatrician, clinical microbiologist, dermatologist or public health physician				
❋ Tab 100 mg	22.00	100	✔	**PSM**
ISONIAZID WITH RIFAMPICIN – Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an internal medicine physician, paediatrician, clinical microbiologist, dermatologist or public health physician				
❋ Tab 100 mg with rifampicin 150 mg	85.54	100	✔	**Rifinah**
❋ Tab 150 mg with rifampicin 300 mg	170.60	100	✔	**Rifinah**
PARA-AMINO SALICYLIC ACID – Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an infectious disease specialist, clinical microbiologist or respiratory physician				
Grans for oral liq 4 g sachet	280.00	30	✔	**Paser** S29
PROTIONAMIDE – Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an infectious disease specialist, clinical microbiologist or respiratory physician				
Tab 250 mg	305.00	100	✔	**Peteha** S29
PYRAZINAMIDE – Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or respiratory physician				
❋ Tab 500 mg	59.00	100	✔	**AFT-Pyrazinamide**
RIFABUTIN – Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, respiratory physician or gastroenterologist				
❋ Cap 150 mg	275.00	30	✔	**Mycobutin**

▲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

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.

	Subsidy $	Per	Fully Subsidised	Brand
✻ Cap 150 mg	55.75	100	✔	Rifadin
✻ Cap 300 mg	116.25	100	✔	Rifadin
✻ Oral liq 100 mg per 5 ml	12.00	60 ml	✔	Rifadin

Antivirals

For eye preparations refer to Eye Preparations, Anti-Infective Preparations, page 230

Hepatitis B Treatment

ADEFOVIR DIPIVOXIL – Special Authority see SA0829 below – Retail pharmacy

	Subsidy $	Per	Fully Subsidised	Brand
Tab 10 mg	670.00	30	✔	Hepsera

➽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 × 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 Either:
  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 × 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

	Subsidy $	Per	Fully Subsidised	Brand
✻ Tab 0.5 mg	52.00	30	✔	Entecavir Sandoz

LAMIVUDINE – Special Authority see SA1685 on the next page – Retail pharmacy

	Subsidy $	Per	Fully Subsidised	Brand
Tab 100 mg	4.20	28	✔	Zetlam
Oral liq 5 mg per ml	270.00	240 ml OP	✔	Zeffix

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic 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 DISOPROXIL
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 104

❋ Tab 245 mg (300.6 mg as a succinate)	38.10	30	✔	Tenofovir Disoproxil Teva

Herpesvirus Treatments

ACICLOVIR

❋ Tab dispersible 200 mg	1.60	25	✔	Lovir
❋ Tab dispersible 400 mg	5.38	56	✔	Lovir
❋ Tab dispersible 800 mg	5.98	35	✔	Lovir

VALACICLOVIR

Tab 500 mg	5.75	30	✔	Vaclovir
Tab 1,000 mg	11.35	30	✔	Vaclovir

VALGANCICLOVIR – Special Authority see SA1404 below – Retail pharmacy

Tab 450 mg	225.00	60	✔	Valganciclovir Mylan

➽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.

Initial application — (Cytomegalovirus in immunocompromised patients) only from a relevant specialist. Approvals valid for

continued…

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

continued…
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

Tab 90 mg with sofosbuvir 400 mg	24,363.46	28	✔	**Harvoni**

➽SA1605 Special Authority for Subsidy
Special Authority approved by the Hepatitis C Treatment Panel (HepCTP)
Notes: By application to the Hepatitis C Treatment Panel (HepCTP).
Applications will be considered by HepCTP and approved subject to confirmation of eligibility.
Application details may be obtained from PHARMAC's website http://www.pharmac.govt.nz/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

HIV Prophylaxis and Treatment

EMTRICITABINE WITH TENOFOVIR DISOPROXIL – Subsidy by endorsement; can be waived by Special Authority see SA1842 on the next page

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 104 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 (300.6 mg as a succinate)	61.15	30	✔	<u>**Teva**</u>

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

➽SA1842 Special Authority for Waiver of Rule
Initial application 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 (refer to local health pathways or https://ashm.org.au/HIV/PrEP/ for training materials); and
2 Patient has undergone testing for HIV, syphilis, Hep B if not immune 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 3 months and is not contraindicated for treatment; and
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 is not at risk of HIV seroconversion; 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
  - 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.

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 (refer to local health pathways or https://ashm.org.au/HIV/PrEP/ for training materials); and
2 Patient has undergone testing for HIV, syphilis, Hep B if not immune 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 and is not contraindicated for treatment; and
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 is not at risk of HIV seroconversion; 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
  - 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.

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

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:

Either:

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

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

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

Initial application — (post-exposure prophylaxis following 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.

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.

continued…

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

continued…
Notes: Tenofovir disoproxil prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals. Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.
Renewal — (Second or subsequent percutaneous exposure) only from a named specialist. Approvals valid for 6 weeks where the patient has percutaneous exposure to blood known to be HIV positive.

Non-nucleosides Reverse Transcriptase Inhibitors

EFAVIRENZ – Special Authority see SA1651 on the previous page – Retail pharmacy

Tab 50 mg	63.38	30	✔	**Stocrin** S29
Tab 200 mg	190.15	90	✔	**Stocrin**
Tab 600 mg	63.38	30	✔	**Stocrin**
Oral liq 30 mg per ml	145.79	180 ml OP	✔	**Stocrin** S29

(Stocrin S29 Tab 50 mg to be delisted 1 April 2020)
(Stocrin S29 Oral liq 30 mg per ml to be delisted 1 August 2020)

ETRAVIRINE – Special Authority see SA1651 on the previous page – Retail pharmacy

Tab 200 mg	770.00	60	✔	**Intelence**

NEVIRAPINE – Special Authority see SA1651 on the previous page – Retail pharmacy

Tab 200 mg	60.00	60	✔	**Nevirapine Alphapharm**
Oral suspension 10 mg per ml	203.55	240 ml	✔	**Viramune Suspension**

Nucleosides Reverse Transcriptase Inhibitors

ABACAVIR SULPHATE – Special Authority see SA1651 on the previous page – Retail pharmacy

Tab 300 mg	180.00	60	✔	**Ziagen**
Oral liq 20 mg per ml	256.31	240 ml OP	✔	**Ziagen**

ABACAVIR SULPHATE WITH LAMIVUDINE – Special Authority see SA1651 on the previous page – Retail pharmacy
Note: abacavir with lamivudine (combination tablets) counts as two anti-retroviral medications for the purposes of the anti-retroviral Special Authority.

Tab 600 mg with lamivudine 300 mg	63.00	30	✔	**Kivexa**

EFAVIRENZ WITH EMTRICITABINE AND TENOFOVIR DISOPROXIL – Special Authority see SA1651 on the previous page – Retail pharmacy
Note: Efavirenz with emtricitabine and tenofovir disoproxil counts as three anti-retroviral medications for the purposes of the anti-retroviral Special Authority

Tab 600 mg with emtricitabine 200 mg and tenofovir disoproxil 245 mg (300 mg as a maleate)	106.88	30	✔	**Mylan**

EMTRICITABINE – Special Authority see SA1651 on the previous page – Retail pharmacy

Cap 200 mg	307.20	30	✔	**Emtriva**

LAMIVUDINE – Special Authority see SA1651 on the previous page – Retail pharmacy

Tab 150 mg	52.50	60	✔	**Lamivudine Alphapharm**
Oral liq 10 mg per ml	102.50	240 ml OP	✔	**3TC**

ZIDOVUDINE [AZT] – Special Authority see SA1651 on the previous page – Retail pharmacy

Cap 100 mg	152.25	100	✔	**Retrovir**
Oral liq 10 mg per ml	30.45	200 ml OP	✔	**Retrovir**

▲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
ZIDOVUDINE [AZT] WITH LAMIVUDINE – Special Authority see SA1651 on page 104 – Retail pharmacy				
Note: zidovudine [AZT] with lamivudine (combination tablets) counts as two anti-retroviral medications for the purposes of the anti-retroviral Special Authority.				
Tab 300 mg with lamivudine 150 mg	33.00	60	✔	Alphapharm

Protease Inhibitors

	Subsidy	Per	Fully Subsidised	Brand
ATAZANAVIR SULPHATE – Special Authority see SA1651 on page 104 – Retail pharmacy				
Cap 150 mg	141.68	60	✔	Teva
Cap 200 mg	188.91	60	✔	Teva
DARUNAVIR – Special Authority see SA1651 on page 104 – Retail pharmacy				
Tab 400 mg	335.00	60	✔	Prezista
Tab 600 mg	476.00	60	✔	Prezista
LOPINAVIR WITH RITONAVIR – Special Authority see SA1651 on page 104 – 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 104 – Retail pharmacy				
Tab 100 mg	43.31	30	✔	Norvir

Strand Transfer Inhibitors

	Subsidy	Per	Fully Subsidised	Brand
DOLUTEGRAVIR – Special Authority see SA1651 on page 104 – Retail pharmacy				
Tab 50 mg	1,090.00	30	✔	Tivicay
RALTEGRAVIR POTASSIUM – Special Authority see SA1651 on page 104 – Retail pharmacy				
Tab 400 mg	1,090.00	60	✔	Isentress
Tab 600 mg	1,090.00	60	✔	Isentress HD

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

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

continued…

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

continued…

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 on the previous page
b) Prescriptions must be written by, or on the recommendation of, an internal medicine physician or ophthalmologist

Inj 3 m iu prefilled syringe	38.00	1	✔	**Roferon-A**

PEGYLATED INTERFERON ALFA-2A – Special Authority see SA1400 below – Retail pharmacy

a) See prescribing guideline on the previous page
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.

Inj 180 mcg prefilled syringe	500.00	4	✔	**Pegasys**

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

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

1 Patient has chronic hepatitis C, genotype 1; and
2 Patient has had previous treatment with pegylated interferon and ribavirin; and
3 Any of the following:

continued…

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

continued…

3.1 Patient has responder relapsed; or
3.2 Patient was a partial responder; or
3.3 Patient received interferon treatment prior to 2004; and

4 Patient is to be treated in combination with boceprevir; and
5 Maximum of 48 weeks therapy.

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

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

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

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

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 guidelines.
- Pegylated Interferon-alfa 2a is not approved for use in children.

Urinary Tract Infections

	Subsidy $	Per	Fully Subsidised	Brand
METHENAMINE (HEXAMINE) HIPPURATE				
✳ Tab 1 g	40.01	100	✔	**Hiprex**
NITROFURANTOIN				
✳ Tab 50 mg – Up to 30 tab available on a PSO	22.20	100	✔	**Nifuran**
✳ Tab 100 mg	37.50	100	✔	**Nifuran**
NORFLOXACIN				
Tab 400 mg – Subsidy by endorsement	135.00	100	✔	**Arrow-Norfloxacin**

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

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

Anticholinesterases

NEOSTIGMINE METILSULFATE				
Inj 2.5 mg per ml, 1 ml ampoule	98.00	50	✔	**AstraZeneca**
PYRIDOSTIGMINE BROMIDE				
▲ Tab 60 mg	45.79	100	✔	**Mestinon**

Non-Steroidal Anti-Inflammatory Drugs

DICLOFENAC SODIUM				
✻ Tab EC 25 mg	1.23	50	✔	**Diclofenac Sandoz**
✻ Tab 50 mg dispersible	1.50	20	✔	**Voltaren D**
✻ Tab EC 50 mg	1.23	50	✔	**Diclofenac Sandoz**
✻ Tab long-acting 75 mg	22.80	500	✔	**Apo-Diclo SR**
✻ Tab long-acting 100 mg	25.15	500	✔	**Apo-Diclo SR**
✻ Inj 25 mg per ml, 3 ml ampoule – Up to 5 inj available on a PSO	13.20	5	✔	**Voltaren**
✻ Suppos 12.5 mg	2.04	10	✔	**Voltaren**
✻ Suppos 25 mg	2.44	10	✔	**Voltaren**
✻ Suppos 50 mg – Up to 10 supp available on a PSO	4.22	10	✔	**Voltaren**
✻ Suppos 100 mg	7.00	10	✔	**Voltaren**
IBUPROFEN				
✻ Tab 200 mg	11.71	1,000	✔	**Relieve**
✻ Tab long-acting 800 mg	7.99	30	✔	**Brufen SR**
✻ Oral liq 20 mg per ml	1.88	200 ml	✔	**Ethics**
KETOPROFEN				
✻ Cap long-acting 200 mg	12.07	28	✔	**Oruvail SR**
MEFENAMIC ACID				
✻ Cap 250 mg	1.25	50		
	(9.16)			Ponstan
	0.50	20		
	(5.60)			Ponstan
NAPROXEN				
✻ Tab 250 mg	32.69	500	✔	**Noflam 250**
✻ Tab 500 mg	22.19	250	✔	**Noflam 500**
✻ Tab long-acting 750 mg	6.16	28	✔	**Naprosyn SR 750**
✻ Tab long-acting 1 g	8.21	28	✔	**Naprosyn SR 1000**
SULINDAC				
✻ Tab 100 mg	8.55	50	✔	**Aclin**
✻ Tab 200 mg	15.10	50	✔	**Aclin**
TENOXICAM				
✻ Tab 20 mg	9.15	100	✔	**Tilcotil**
✻ Inj 20 mg vial	9.95	1	✔	**AFT**

NSAIDs Other

CELECOXIB				
Cap 100 mg	3.63	60	✔	**Celebrex**
			✔	**Celecoxib Pfizer**
Cap 200 mg	2.30	30	✔	**Celebrex**
			✔	**Celecoxib Pfizer**

(Celebrex Cap 100 mg to be delisted 1 September 2020)

▲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

Topical Products for Joint and Muscular Pain

CAPSAICIN

Crm 0.025% – Special Authority see SA1289 below – Retail pharmacy	6.95	25 g OP	✔	**Zostrix**
	9.95	45 g OP	✔	**Zostrix**
	13.27	60 g OP	✔	**Rugby Capsaicin Topical Cream** S29

➽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	7.98	100	✔	**Plaquenil**
LEFLUNOMIDE				
Tab 10 mg	2.90	30	✔	**Apo-Leflunomide**
Tab 20 mg	2.90	30	✔	**Apo-Leflunomide**
PENICILLAMINE				
Tab 125 mg	67.23	100	✔	**D-Penamine**
Tab 250 mg	110.12	100	✔	**D-Penamine**
SODIUM AUROTHIOMALATE				
Inj 10 mg in 0.5 ml ampoule	76.87	10	✔	**Myocrisin**
Inj 20 mg in 0.5 ml ampoule	113.17	10	✔	**Myocrisin**
Inj 50 mg in 0.5 ml ampoule	217.23	10	✔	**Myocrisin**

(Myocrisin Inj 10 mg in 0.5 ml ampoule to be delisted 1 March 2020)
(Myocrisin Inj 20 mg in 0.5 ml ampoule to be delisted 1 March 2020)
(Myocrisin Inj 50 mg in 0.5 ml ampoule to be delisted 1 March 2020)

Drugs Affecting Bone Metabolism

Alendronate for Osteoporosis

ALENDRONATE SODIUM				
✻ Tab 70 mg	2.44	4	✔	**Fosamax**
ALENDRONATE SODIUM WITH COLECALCIFEROL				
✻ Tab 70 mg with colecalciferol 5,600 iu	1.51	4	✔	**Fosamax Plus**

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:

continued…

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

continued…

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

PAMIDRONATE DISODIUM

	Subsidy $	Per	Fully Subsidised	Brand
Inj 3 mg per ml, 10 ml vial	5.98	1	✔	**Pamisol**
Inj 6 mg per ml, 10 ml vial	15.02	1	✔	**Pamisol**
Inj 9 mg per ml, 10 ml vial	17.05	1	✔	**Pamisol**

RALOXIFENE HYDROCHLORIDE – Special Authority see SA1779 on the next page – Retail pharmacy

	Subsidy $	Per	Fully Subsidised	Brand
❋ Tab 60 mg	53.76	28	✔	**Evista**

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

➽SA1779 Special Authority for Subsidy

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

Any of the following:

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

Notes:

a) BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.

b) Evidence suggests that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score less than or equal to -2.5 and, therefore, do not require BMD measurement for raloxifene funding.

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

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

RISEDRONATE SODIUM				
Tab 35 mg	3.10	4	✔	Risedronate Sandoz
TERIPARATIDE – Special Authority see SA1139 below – Retail pharmacy				
Inj 250 mcg per ml, 2.4 ml	490.00	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 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;

continued…

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

continued…

zoledronic acid 5 mg per year. If an intolerance of a severity necessitating permanent treatment withdrawal develops during the use of one antiresorptive agent, an alternate antiresorptive agent must be trialled so that the patient achieves the minimum requirement of 12 months' continuous therapy.

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

d) A maximum of 18 months of treatment (18 cartridges) will be subsidised.

ZOLEDRONIC ACID

Inj 0.05 mg per ml, 100 ml, vial – Special Authority see SA1780 below – Retail pharmacy	60.00	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 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

continued…

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

continued…

- 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:

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

continued…

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

continued…

-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

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
ALLOPURINOL				
❋ Tab 100 mg	4.54	500	✔	DP-Allopurinol
❋ Tab 300 mg	10.35	500	✔	DP-Allopurinol
BENZBROMARONE – Special Authority see SA1537 below – Retail pharmacy				
Tab 100 mg	45.00	100	✔	Benzbromaron AL 100 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.

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/

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
COLCHICINE				
❋ Tab 500 mcg	9.58	100	✔	Colgout

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
FEBUXOSTAT – Special Authority see SA1538 below – Retail 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**

Muscle Relaxants

BACLOFEN				
✻ Tab 10 mg	4.20	100	✔	**Pacifen**
Inj 0.05 mg per ml, 1 ml ampoule – Subsidy by endorsement	11.55	1	✔	**Lioresal Intrathecal**
Subsidised only for use in a programmable pump in patients where oral antispastic agents have been ineffective or have caused intolerable side effects and the prescription is endorsed accordingly.				
Inj 2 mg per ml, 5 ml ampoule – Subsidy by endorsement	372.98	5	✔	**Medsurge**
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.				
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**

✔ **fully subsidised**
Sole Subsidised Supply
S29 Unapproved medicine supplied under Section 29

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

Agents for Parkinsonism and Related Disorders

Dopamine Agonists and Related Agents

AMANTADINE HYDROCHLORIDE				
▲ Cap 100 mg	38.24	60	✔	Symmetrel
APOMORPHINE HYDROCHLORIDE				
▲ Inj 10 mg per ml, 2 ml ampoule	59.50	5	✔	Movapo
BROMOCRIPTINE MESYLATE				
❋ Tab 2.5 mg	32.08	100	✔	Apo-Bromocriptine
ENTACAPONE				
▲ Tab 200 mg	22.00	100	✔	Entapone
LEVODOPA WITH BENSERAZIDE				
❋ Tab dispersible 50 mg with benserazide 12.5 mg	13.25	100	✔	Madopar Rapid
❋ Cap 50 mg with benserazide 12.5 mg	13.75	100	✔	Madopar 62.5
❋ Cap 100 mg with benserazide 25 mg	15.80	100	✔	Madopar 125
❋ Cap long-acting 100 mg with benserazide 25 mg	22.85	100	✔	Madopar HBS
❋ Cap 200 mg with benserazide 50 mg	26.25	100	✔	Madopar 250
LEVODOPA WITH CARBIDOPA				
❋ Tab 100 mg with carbidopa 25 mg	17.97	100	✔	Kinson
			✔	Sinemet
❋ Tab long-acting 100 mg with carbidopa 25 mg	23.84	100	✔	Mylan S29
❋ Tab long-acting 200 mg with carbidopa 50 mg	37.15	100	✔	Sinemet CR
	46.73		✔	Mylan S29
❋ Tab 250 mg with carbidopa 25 mg	32.67	100	✔	Sinemet
PRAMIPEXOLE HYDROCHLORIDE				
▲ Tab 0.25 mg	6.12	100	✔	Ramipex
▲ Tab 1 mg	20.73	100	✔	Ramipex
ROPINIROLE HYDROCHLORIDE				
▲ Tab 0.25 mg	0.71	21	✔	Ropin S29 S29
	2.78	100	✔	Apo-Ropinirole
	2.85	84	✔	Ropin
Ropin to be Sole Supply on 1 March 2020				
▲ Tab 1 mg	3.95	84	✔	Ropin
	5.00	100	✔	Apo-Ropinirole
Ropin to be Sole Supply on 1 March 2020				
▲ Tab 2 mg	5.48	84	✔	Ropin
	7.72	100	✔	Apo-Ropinirole
Ropin to be Sole Supply on 1 March 2020				
▲ Tab 5 mg	12.50	84	✔	Ropin
	16.51	100	✔	Apo-Ropinirole
Ropin to be Sole Supply on 1 March 2020				
(Apo-Ropinirole Tab 0.25 mg to be delisted 1 March 2020)				
(Apo-Ropinirole Tab 1 mg to be delisted 1 March 2020)				
(Apo-Ropinirole Tab 2 mg to be delisted 1 March 2020)				
(Apo-Ropinirole Tab 5 mg to be delisted 1 March 2020)				
SELEGILINE HYDROCHLORIDE				
❋ Tab 5 mg	22.00	100	✔	Apo-Selegiline S29 S29

▲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
TOLCAPONE				
▲ Tab 100 mg	132.50	100	✔	**Tasmar**

Anticholinergics

BENZATROPINE MESYLATE				
Tab 2 mg	7.99	60	✔	**Benztrop**
Inj 1 mg per ml, 2 ml	95.00	5	✔	**Cogentin**
	190.00	10	✔	**Omega**

a) Up to 10 inj available on a PSO
b) Only on a PSO

PROCYCLIDINE HYDROCHLORIDE				
Tab 5 mg	7.40	100	✔	**Kemadrin**

Agents for Essential Tremor, Chorea and Related Disorders

RILUZOLE – Special Authority see SA1403 below – Retail pharmacy
Wastage claimable

Tab 50 mg	130.00	56	✔	**Rilutek**

➽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	✔	**Motetis**

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

Anaesthetics

Local

LIDOCAINE [LIGNOCAINE]				
Gel 2%, tube – Subsidy by endorsement	14.50	30 ml	✔	**Xylocaine 2% Jelly**
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	105.00	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.				
Gel 2%, 11 ml urethral syringe – Subsidy by endorsement	42.00	10	✔	**Instillagel Lido**
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.				
c) Instillagel Lido to be Sole Supply on 1 April 2020				
(Cathejell Gel 2%, 10 ml urethral syringe to be delisted 1 April 2020)				
LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE				
Oral (gel) soln 2%	38.00	200 ml	✔	**Mucosoothe**
Inj 1%, 5 ml ampoule – Up to 25 inj available on a PSO	8.75	25	✔	**Lidocaine-Claris**
	17.50	50		
	(35.00)			Xylocaine
Inj 2%, 5 ml ampoule – Up to 5 inj available on a PSO	8.25	25	✔	**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	6.20	5	✔	**Lidocaine-Claris**
Inj 2%, 20 ml vial – Up to 5 inj available on a PSO	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				
b) Subsidised only if prescribed for urethral or cervical administration and the prescription is endorsed accordingly.				

Topical Local Anaesthetics

➠SA0906 Special Authority for Subsidy

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

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

LIDOCAINE [LIGNOCAINE] – Special Authority see SA0906 above – Retail pharmacy				
Crm 4%	5.40	5 g OP	✔	**LMX4**
	27.00	30 g OP	✔	**LMX4**
LIDOCAINE [LIGNOCAINE] WITH PRILOCAINE – Special Authority see SA0906 above – Retail 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**

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

Analgesics

For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, page 109

Non-opioid Analgesics

For aspirin & chloroform application refer Standard Formulae, page 237

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
ASPIRIN				
❋ Tab dispersible 300 mg – Up to 30 tab available on a PSO	4.50	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.				
Crm 0.075%	12.50	45 g OP	✔	Zostrix HP
NEFOPAM HYDROCHLORIDE				
Tab 30 mg	23.40	90	✔	Acupan
PARACETAMOL				
❋ Tab 500 mg - blister pack – Up to 30 tab available on a PSO	7.12	1,000	✔	Paracetamol Pharmacare
			✔	Pharmacare
❋ Tab 500 mg - bottle pack	6.32	1,000	✔	Pharmacare
❋ Oral liq 120 mg per 5 ml	5.35	1,000 ml	✔	Paracare
a) Up to 200 ml available on a PSO b) Not in combination				
❋ 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	3.29	10	✔	Gacet
❋ Suppos 250 mg	3.79	10	✔	Gacet
❋ Suppos 500 mg	12.40	50	✔	Gacet

Opioid Analgesics

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
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	13.50	100	✔	PSM
DIHYDROCODEINE TARTRATE				
Tab long-acting 60 mg	8.60	60	✔	DHC Continus
FENTANYL				
a) Only on a controlled drug form b) No patient co-payment payable c) Safety medicine; prescriber may determine dispensing 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	9.25	5	✔	Fentanyl Sandoz
Patch 100 mcg per hour	11.40	5	✔	Fentanyl Sandoz

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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).				
e) For methadone hydrochloride oral liquid refer Standard Formulae, page 237				
Tab 5 mg	1.40	10	✔	**Methatabs**
Oral liq 2 mg per ml	5.79	200 ml	✔	**Biodone**
Oral liq 5 mg per ml	5.79	200 ml	✔	**Biodone Forte**
Oral liq 10 mg per ml	6.79	200 ml	✔	**Biodone Extra Forte**
Inj 10 mg per ml, 1 ml	61.00	10	✔	**AFT**
MORPHINE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
Oral liq 1 mg per ml	9.28	200 ml	✔	**RA-Morph**
Oral liq 2 mg per ml	16.24	200 ml	✔	**RA-Morph**
Oral liq 5 mg per ml	19.44	200 ml	✔	**Ordine** S29
			✔	**RA-Morph**
Oral liq 10 mg per ml	27.74	200 ml	✔	**Ordine** S29
			✔	**RA-Morph**
MORPHINE SULPHATE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
Tab immediate-release 10 mg	2.80	10	✔	**Sevredol**
Tab long-acting 10 mg	1.93	10	✔	**Arrow-Morphine LA**
Tab immediate-release 20 mg	5.52	10	✔	**Sevredol**
Tab long-acting 30 mg	2.85	10	✔	**Arrow-Morphine LA**
Tab long-acting 60 mg	5.60	10	✔	**Arrow-Morphine LA**
Tab long-acting 100 mg	6.10	10	✔	**Arrow-Morphine LA**
Cap long-acting 10 mg	2.05	10	✔	**m-Eslon**
Cap long-acting 30 mg	3.00	10	✔	**m-Eslon**
Cap long-acting 60 mg	6.12	10	✔	**m-Eslon**
Cap long-acting 100 mg	7.13	10	✔	**m-Eslon**
Inj 5 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	6.27	5	✔	**DBL Morphine Sulphate**
Inj 10 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	4.47	5	✔	**DBL Morphine Sulphate**
Inj 15 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	4.76	5	✔	**DBL Morphine Sulphate**
Inj 30 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	6.19	5	✔	**DBL Morphine Sulphate**
(Arrow-Morphine LA Tab long-acting 100 mg to be delisted 1 June 2020)				
MORPHINE TARTRATE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
Inj 80 mg per ml, 1.5 ml ampoule	42.72	5	✔	**DBL Morphine Tartrate**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
OXYCODONE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
Tab controlled-release 5 mg	2.15	20	✔	Oxycodone Sandoz
Tab controlled-release 10 mg	2.15	20	✔	Oxycodone Sandoz
Tab controlled-release 20 mg	2.15	20	✔	Oxycodone Sandoz
Tab controlled-release 40 mg	3.20	20	✔	Oxycodone Sandoz
Tab controlled-release 80 mg	10.98	20	✔	Oxycodone Sandoz
Cap immediate-release 5 mg	1.88	20	✔	OxyNorm
Cap immediate-release 10 mg	3.32	20	✔	OxyNorm
Cap immediate-release 20 mg	5.81	20	✔	OxyNorm
Oral liq 5 mg per 5 ml	11.20	250 ml	✔	OxyNorm
Inj 10 mg per ml, 1 ml ampoule	7.28	5	✔	OxyNorm
Inj 10 mg per ml, 2 ml ampoule	14.36	5	✔	OxyNorm
Inj 50 mg per ml, 1 ml ampoule	30.60	5	✔	OxyNorm
PARACETAMOL WITH CODEINE – Safety medicine; prescriber may determine dispensing frequency				
❋ Tab paracetamol 500 mg with codeine phosphate 8 mg	18.21	1,000	✔	Paracetamol + Codeine (Relieve)
PETHIDINE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
Tab 50 mg	4.46	10	✔	PSM
Inj 50 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	4.98	5	✔	DBL Pethidine Hydrochloride
Inj 50 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	5.12	5	✔	DBL Pethidine Hydrochloride
TRAMADOL HYDROCHLORIDE				
Tab sustained-release 100 mg	1.55	20	✔	Tramal SR 100
Tab sustained-release 150 mg	2.10	20	✔	Tramal SR 150
Tab sustained-release 200 mg	2.75	20	✔	Tramal SR 200
Cap 50 mg	2.25	100	✔	Arrow-Tramadol

Antidepressants

Cyclic and Related Agents

AMITRIPTYLINE – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	1.96	100	✔	Arrow-Amitriptyline
Tab 25 mg	1.52	100	✔	Arrow-Amitriptyline
Tab 50 mg	2.51	100	✔	Arrow-Amitriptyline
CLOMIPRAMINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	13.99	100	✔	Apo-Clomipramine
Tab 25 mg	4.73	50	✔	Apo-Clomipramine
	9.46	100	✔	Apo-Clomipramine

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

DOSULEPIN [DOTHIEPIN] HYDROCHLORIDE – Subsidy by endorsement

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

Tab 75 mg	11.19	100	✔	**Dopress**
Cap 25 mg	7.83	50	✔	**Dosulepin Mylan** S29

(Dopress Tab 75 mg to be delisted 1 August 2020)

DOXEPIN HYDROCHLORIDE – Subsidy by endorsement

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

Cap 25 mg	6.86	100	✔	**Anten**
Cap 50 mg	8.55	100	✔	**Anten**

(Anten Cap 25 mg to be delisted 1 April 2020)
(Anten Cap 50 mg to be delisted 1 May 2020)

IMIPRAMINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency

Tab 10 mg	5.48	50	✔	**Tofranil**
	10.96	100	✔	**Tofranil**
Tab 25 mg	8.80	50	✔	**Tofranil**

MAPROTILINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency

Tab 25 mg	7.52	30	✔	**Ludiomil**
	12.53	50	✔	**Ludiomil**
	25.06	100	✔	**Ludiomil**
Tab 75 mg	14.01	20	✔	**Ludiomil**
	21.01	30	✔	**Ludiomil**

NORTRIPTYLINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency

Tab 10 mg	2.44	100	✔	**Norpress**
Tab 25 mg	5.98	180	✔	**Norpress**

Monoamine-Oxidase Inhibitors (MAOIs) - Non Selective

PHENELZINE SULPHATE

❋ Tab 15 mg	70.80	60	✔	**Nardil S29** S29
	118.00	100	✔	**Nardil**

TRANYLCYPROMINE SULPHATE

❋ Tab 10 mg	12.85	28	✔	**Parnate S29** S29
	22.94	50	✔	**Parnate**
	96.00	100	✔	**Parnate S29** S29

Monoamine-Oxidase Type A Inhibitors

MOCLOBEMIDE

❋ Tab 150 mg	6.40	60	✔	**Aurorix**
❋ Tab 300 mg	9.80	60	✔	**Aurorix**

▲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

Selective Serotonin Reuptake Inhibitors

CITALOPRAM HYDROBROMIDE				
❋ Tab 20 mg	1.52	84	✔	PSM Citalopram
ESCITALOPRAM				
❋ 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	2.47	30	✔	**Arrow-Fluoxetine**

Subsidised by endorsement

1) When prescribed for a patient who cannot swallow whole tablets or capsules and the prescription is endorsed accordingly; or
2) When prescribed in a daily dose that is not a multiple of 20 mg in which case the prescription is deemed to be endorsed. Note: Tablets should be combined with capsules to facilitate incremental 10 mg doses.

Cap 20 mg	7.49	90	✔	**Arrow-Fluoxetine**

(Arrow-Fluoxetine Tab dispersible 20 mg, scored to be delisted 1 August 2020)
(Arrow-Fluoxetine Cap 20 mg to be delisted 1 August 2020)

PAROXETINE				
❋ Tab 20 mg	3.61	90	✔	**Loxamine**
	4.02		✔	**Apo-Paroxetine**

Loxamine to be Sole Supply on 1 March 2020
(Apo-Paroxetine Tab 20 mg to be delisted 1 March 2020)

SERTRALINE				
❋ Tab 50 mg	0.92	30	✔	**Setrona**
	3.05	90	✔	**Arrow-Sertraline**

Setrona to be Sole Supply on 1 March 2020

❋ Tab 100 mg	1.61	30	✔	**Setrona**
	5.25	90	✔	**Arrow-Sertraline**

Setrona to be Sole Supply on 1 March 2020
(Arrow-Sertraline Tab 50 mg to be delisted 1 March 2020)
(Arrow-Sertraline Tab 100 mg to be delisted 1 March 2020)

Other Antidepressants

MIRTAZAPINE				
Tab 30 mg	2.63	30	✔	Apo-Mirtazapine
Tab 45 mg	3.48	30	✔	Apo-Mirtazapine
VENLAFAXINE				
❋ Cap 37.5 mg	6.38	84	✔	Enlafax XR
❋ Cap 75 mg	8.11	84	✔	Enlafax XR
❋ Cap 150 mg	11.16	84	✔	Enlafax XR

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

Antiepilepsy Drugs

Agents for Control of Status Epilepticus

CLONAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Inj 1 mg per ml, 1 ml	21.00	5	✔	Rivotril
DIAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
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 procedures”.	11.83	5	✔	Hospira
Rectal tubes 5 mg – Up to 5 tube available on a PSO	40.87	5	✔	Stesolid
Rectal tubes 10 mg – Up to 5 tube available on a PSO	40.87	5	✔	Stesolid
PARALDEHYDE				
❋ Inj 5 ml	1,500.00	5	✔	AFT S29
PHENYTOIN SODIUM				
❋ Inj 50 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	88.63	5	✔	Hospira
❋ Inj 50 mg per ml, 5 ml ampoule – Up to 5 inj available on a PSO	133.92	5	✔	Hospira

Control of Epilepsy

CARBAMAZEPINE				
❋ Tab 200 mg	14.53	100	✔	Tegretol
❋ Tab long-acting 200 mg	16.98	100	✔	Tegretol CR
❋ Tab 400 mg	34.58	100	✔	Tegretol
❋ Tab long-acting 400 mg	39.17	100	✔	Tegretol CR
❋ Oral liq 20 mg per ml	26.37	250 ml	✔	Tegretol
CLOBAZAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	9.12	50	✔	Frisium
CLONAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Oral drops 2.5 mg per ml	7.38	10 ml OP	✔	Rivotril
ETHOSUXIMIDE				
Cap 250 mg	140.88	100	✔	Zarontin
Oral liq 250 mg per 5 ml	56.35	200 ml	✔	Zarontin
GABAPENTIN Note: Not subsidised in combination with subsidised pregabalin				
❋ Cap 100 mg	2.65	100	✔	Apo-Gabapentin
❋ Cap 300 mg	4.07	100	✔	Apo-Gabapentin
❋ Cap 400 mg	5.64	100	✔	Apo-Gabapentin
LACOSAMIDE – Special Authority see SA1125 on the next page – Retail pharmacy				
▲ Tab 50 mg	25.04	14	✔	Vimpat
▲ Tab 100 mg	50.06	14	✔	Vimpat
	200.24	56	✔	Vimpat
▲ Tab 150 mg	75.10	14	✔	Vimpat
	300.40	56	✔	Vimpat
▲ Tab 200 mg	400.55	56	✔	Vimpat

▲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

➽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 $	Per	Fully Subsidised	Brand or Generic Manufacturer
LAMOTRIGINE				
▲ Tab dispersible 2 mg	6.74	30	✔	**Lamictal**
▲ Tab dispersible 5 mg	9.64	30	✔	**Lamictal**
	15.00	56	✔	**Arrow-Lamotrigine**
✻ Tab dispersible 25 mg	2.76	56	✔	**Logem**
✻ Tab dispersible 50 mg	3.31	56	✔	**Logem**
✻ Tab dispersible 100 mg	4.40	56	✔	**Logem**
LEVETIRACETAM				
Tab 250 mg	4.99	60	✔	**Everet**
Tab 500 mg	8.79	60	✔	**Everet**
Tab 750 mg	14.39	60	✔	**Everet**
Tab 1,000 mg	18.59	60	✔	**Everet**
Oral liq 100 mg per ml	44.78	300 ml OP	✔	**Levetiracetam-AFT**
PHENOBARBITONE				
For phenobarbitone oral liquid refer Standard Formulae, page 237				
✻ Tab 15 mg	40.00	500	✔	**PSM**
✻ Tab 30 mg	40.00	500	✔	**PSM**
PHENYTOIN SODIUM				
✻ Tab 50 mg	75.00	200	✔	**Dilantin Infatab**
Cap 30 mg	74.00	200	✔	**Dilantin**
Cap 100 mg	37.00	200	✔	**Dilantin**
✻ Oral liq 30 mg per 5 ml	22.03	500 ml	✔	**Dilantin**
PREGABALIN				
Note: Not subsidised in combination with subsidised gabapentin				
✻ Cap 25 mg	2.25	56	✔	**Pregabalin Pfizer**
✻ Cap 75 mg	2.65	56	✔	**Pregabalin Pfizer**
✻ Cap 150 mg	4.01	56	✔	**Pregabalin Pfizer**
✻ Cap 300 mg	7.38	56	✔	**Pregabalin Pfizer**
PRIMIDONE				
✻ Tab 250 mg	17.25	100	✔	**Apo-Primidone**
	62.00	200	✔	**Mysoline S29** S29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
SODIUM VALPROATE				
Tab 100 mg	13.65	100	✔	Epilim Crushable
Tab 200 mg EC	27.44	100	✔	Epilim
Tab 500 mg EC	52.24	100	✔	Epilim
❋ Oral liq 200 mg per 5 ml	20.48	300 ml	✔	Epilim S/F Liquid
			✔	Epilim Syrup
❋ Inj 100 mg per ml, 4 ml	41.50	1	✔	Epilim IV
STIRIPENTOL – Special Authority see SA1330 below – Retail pharmacy				
Cap 250 mg	509.29	60	✔	Diacomit S29
Powder for oral liq 250 mg sachet	509.29	60	✔	Diacomit S29

➽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:

Both:

1 Patient has confirmed diagnosis of Dravet syndrome; and

2 Seizures have been inadequately controlled by appropriate courses of sodium valproate, clobazam and at least two of the following: topiramate, levetiracetam, ketogenic diet.

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

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
TOPIRAMATE				
▲ Tab 25 mg	11.07	60	✔	Arrow-Topiramate
			✔	Topiramate Actavis
	26.04		✔	Topamax
▲ Tab 50 mg	18.81	60	✔	Arrow-Topiramate
			✔	Topiramate Actavis
	44.26		✔	Topamax
▲ Tab 100 mg	31.99	60	✔	Arrow-Topiramate
			✔	Topiramate Actavis
	75.25		✔	Topamax
▲ Tab 200 mg	55.19	60	✔	Arrow-Topiramate
			✔	Topiramate Actavis
	129.85		✔	Topamax
▲ Sprinkle cap 15 mg	20.84	60	✔	Topamax
▲ Sprinkle cap 25 mg	26.04	60	✔	Topamax
VIGABATRIN – Special Authority see SA1072 below – Retail pharmacy				
▲ 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

continued…

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

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

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

continued…

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:

Both:

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

2 Either:

2.1 Patient is receiving regular automated visual field testing (ideally every 6 months) on an ongoing basis for duration of treatment with vigabatrin; or

2.2 It is impractical or impossible (due to comorbid conditions) to monitor the patient's visual fields.

Notes: 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.

Vigabatrin is associated with a risk of irreversible visual field defects, which may be asymptomatic in the early stages.

Antimigraine Preparations

For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, page 109

Acute Migraine Treatment

ERGOTAMINE TARTRATE WITH CAFFEINE				
Tab 1 mg with caffeine 100 mg	31.00	100	✔	**Cafergot**
			✔	**Cafergot S29** S29
RIZATRIPTAN				
Tab orodispersible 10 mg	5.26	30	✔	**Rizamelt**
SUMATRIPTAN				
Tab 50 mg	24.44	100	✔	**Apo-Sumatriptan**
Tab 100 mg	46.23	100	✔	**Apo-Sumatriptan**
Inj 12 mg per ml, 0.5 ml prefilled pen – Maximum of 10 inj per prescription	42.67	2 OP	✔	**Sun Pharma** S29
	81.15		✔	**Clustran**

Prophylaxis of Migraine

For Beta Adrenoceptor Blockers refer to CARDIOVASCULAR SYSTEM, page 48

PIZOTIFEN				
❋ Tab 500 mcg	23.21	100	✔	**Sandomigran**

Antinausea and Vertigo Agents

For Antispasmodics refer to ALIMENTARY TRACT, page 8

APREPITANT – Special Authority see SA0987 on the next page – Retail pharmacy				
Cap 2 × 80 mg and 1 × 125 mg	84.00	3 OP	✔	**Emend Tri-Pack**

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

➽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.

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
BETAHISTINE DIHYDROCHLORIDE				
❋ Tab 16 mg	2.89	84	✔	Vergo 16
CYCLIZINE HYDROCHLORIDE				
Tab 50 mg	0.55	10	✔	Nausicalm
CYCLIZINE LACTATE				
Inj 50 mg per ml, 1 ml	14.95	5	✔	Nausicalm
DOMPERIDONE				
❋ Tab 10 mg	2.25	100	✔	Pharmacy Health
HYOSCINE HYDROBROMIDE				
❋ Inj 400 mcg per ml, 1 ml ampoule	46.50	5	✔	Hospira
	93.00	10	✔	Martindale S29
Patch 1.5 mg – Special Authority see SA1387 below – Retail pharmacy	14.11	2	✔	Scopoderm TTS

➽SA1387 Special Authority for Subsidy
Initial application from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:
Either:

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

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

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
METOCLOPRAMIDE HYDROCHLORIDE				
❋ Tab 10 mg	1.30	100	✔	Metoclopramide Actavis 10
❋ Inj 5 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	9.50	10	✔	Pfizer
ONDANSETRON				
❋ Tab 4 mg	2.68	50	✔	Onrex
	3.36		✔	Apo-Ondansetron
Onrex to be Sole Supply on 1 April 2020				
❋ Tab disp 4 mg – Up to 10 tab available on a PSO	0.95	10	✔	Ondansetron ODT-ORLA
❋ Tab 8 mg	4.57	50	✔	Onrex
	4.77		✔	Apo-Ondansetron
Onrex to be Sole Supply on 1 April 2020				
❋ Tab disp 8 mg – Up to 10 tab available on a PSO	1.43	10	✔	Ondansetron ODT-DRLA

(Apo-Ondansetron Tab 4 mg to be delisted 1 April 2020)
(Apo-Ondansetron Tab 8 mg to be delisted 1 April 2020)

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
PROCHLORPERAZINE				
❋ Tab 3 mg buccal	5.97 (15.00)	50		Buccastem
❋ Tab 5 mg – Up to 30 tab available on a PSO	6.35	250	✔	Nausafix
❋ Inj 12.5 mg per ml, 1 ml – Up to 5 inj available on a PSO	25.81	10	✔	Stemetil

▲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

Antipsychotics

General

AMISULPRIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 100 mg	5.15	30	✔	Sulprix
Tab 200 mg	14.96	60	✔	Sulprix
Tab 400 mg	29.78	60	✔	Sulprix
Sulprix to be Sole Supply on 1 February 2020				
Oral liq 100 mg per ml	65.53	60 ml	✔	Solian
(Solian Oral liq 100 mg per ml to be delisted 1 July 2020)				
ARIPIPRAZOLE – Safety medicine; prescriber may determine dispensing frequency				
Tab 5 mg	17.50	30	✔	Aripiprazole Sandoz
Tab 10 mg	17.50	30	✔	Aripiprazole Sandoz
Tab 15 mg	17.50	30	✔	Aripiprazole Sandoz
Tab 20 mg	17.50	30	✔	Aripiprazole Sandoz
Tab 30 mg	17.50	30	✔	Aripiprazole Sandoz
CHLORPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg – Up to 30 tab available on a PSO	14.83	100	✔	Largactil
Tab 25 mg – Up to 30 tab available on a PSO	15.62	100	✔	Largactil
Tab 100 mg – Up to 30 tab available on a PSO	36.73	100	✔	Largactil
Inj 25 mg per ml, 2 ml – Up to 5 inj available on a PSO	30.79	10	✔	Largactil
CLOZAPINE – Hospital pharmacy [HP4]				
Safety medicine; prescriber may determine dispensing frequency				
Tab 25 mg	5.69	50	✔	Clozaril
	6.69		✔	Clopine
	11.36	100	✔	Clozaril
	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	34.65	50	✔	Clopine
	69.30	100	✔	Clopine
Suspension 50 mg per ml	17.33	100 ml	✔	Clopine
HALOPERIDOL – Safety medicine; prescriber may determine dispensing frequency				
Tab 500 mcg – Up to 30 tab available on a PSO	6.23	100	✔	Serenace
Tab 1.5 mg – Up to 30 tab available on a PSO	9.43	100	✔	Serenace
Tab 5 mg – Up to 30 tab available on a PSO	29.72	100	✔	Serenace
Oral liq 2 mg per ml – Up to 200 ml available on a PSO	23.84	100 ml	✔	Serenace
Inj 5 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	21.55	10	✔	Serenace
LEVOMEPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Inj 25 mg per ml, 1 ml ampoule	33.50	10	✔	Nozinan
	47.89		✔	Wockhardt
Nozinan to be Sole Supply on 1 April 2020				
(Wockhardt Inj 25 mg per ml, 1 ml ampoule to be delisted 1 April 2020)				
LEVOMEPROMAZINE MALEATE – Safety medicine; prescriber may determine dispensing frequency				
Tab 25 mg	16.10	100	✔	Nozinan
Tab 100 mg	41.75	100	✔	Nozinan

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
LITHIUM CARBONATE – Safety medicine; prescriber may determine dispensing frequency				
Tab 250 mg – Subsidy by endorsement	34.30	500	✔	**Lithicarb FC**
Subsidised for patients who were taking lithium carbonate tab 250 mg prior to 1 January 2020 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of lithium carbonate.				
Tab long-acting 400 mg	72.00	100	✔	**Priadel**
Cap 250 mg	9.42	100	✔	**Douglas**
(Lithicarb FC Tab 250 mg to be delisted 1 November 2020)				
OLANZAPINE – Safety medicine; prescriber may determine dispensing frequency				
Tab 2.5 mg	0.64	28	✔	**Zypine**
Tab 5 mg	1.15	28	✔	**Zypine**
Tab orodispersible 5 mg	1.25	28	✔	**Zypine ODT**
Tab 10 mg	1.65	28	✔	**Zypine**
Tab orodispersible 10 mg	2.05	28	✔	**Zypine ODT**
PERICYAZINE – Safety medicine; prescriber may determine dispensing frequency				
Tab 2.5 mg	10.49	84	✔	**Neulactil**
	12.49	100	✔	**Neulactil**
Tab 10 mg	37.34	84	✔	**Neulactil**
	44.45	100	✔	**Neulactil**
QUETIAPINE – Safety medicine; prescriber may determine dispensing frequency				
Tab 25 mg	1.79	90	✔	**Quetapel**
Tab 100 mg	3.45	90	✔	**Quetapel**
Tab 200 mg	5.75	90	✔	**Quetapel**
Tab 300 mg	9.60	90	✔	**Quetapel**
RISPERIDONE – Safety medicine; prescriber may determine dispensing frequency				
Tab 0.5 mg	1.86	60	✔	**Actavis**
Tab 1 mg	2.06	60	✔	**Actavis**
Tab 2 mg	2.29	60	✔	**Actavis**
Tab 3 mg	2.50	60	✔	**Actavis**
Tab 4 mg	3.43	60	✔	**Actavis**
Oral liq 1 mg per ml	7.66	30 ml	✔	**Risperon**
ZIPRASIDONE – Safety medicine; prescriber may determine dispensing frequency				
Cap 20 mg	14.50	60	✔	**Zusdone**
Cap 40 mg	24.70	60	✔	**Zusdone**
Cap 60 mg	33.80	60	✔	**Zusdone**
Cap 80 mg	39.70	60	✔	**Zusdone**
ZUCLOPENTHIXOL HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	31.45	100	✔	**Clopixol**

Depot Injections

FLUPENTHIXOL DECANOATE – Safety medicine; prescriber may determine dispensing frequency				
Inj 20 mg per ml, 1 ml – Up to 5 inj available on a PSO	13.14	5	✔	**Fluanxol**
Inj 20 mg per ml, 2 ml – Up to 5 inj available on a PSO	20.90	5	✔	**Fluanxol**
Inj 100 mg per ml, 1 ml – Up to 5 inj available on a PSO	40.87	5	✔	**Fluanxol**
HALOPERIDOL DECANOATE – Safety medicine; prescriber may determine dispensing frequency				
Inj 50 mg per ml, 1 ml – Up to 5 inj available on a PSO	28.39	5	✔	**Haldol**
Inj 100 mg per ml, 1 ml – Up to 5 inj available on a PSO	55.90	5	✔	**Haldol Concentrate**
			✔	**Haldol Decanoas** S29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
OLANZAPINE – Special Authority see SA1428 below – Retail pharmacy				
Safety medicine; prescriber may determine dispensing 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
   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.

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

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
RISPERIDONE – Special Authority see SA1427 on the next page – Retail pharmacy				
Safety medicine; prescriber may determine dispensing frequency				
Inj 25 mg vial	135.98	1	✔	Risperdal Consta
Inj 37.5 mg vial	178.71	1	✔	Risperdal Consta
Inj 50 mg vial	217.56	1	✔	Risperdal Consta

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

➽SA1427 Special Authority for Subsidy
Initial application from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Either:
1 The patient has had an initial Special Authority approval for paliperidone depot injection or olanzapine depot injection; or
2 All of the following:
  2.1 The patient has schizophrenia or other psychotic disorder; and
  2.2 Has 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 injectable form before trialing risperidone 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	20.23	100	✔	**Orion**
❋ Tab 10 mg	13.16	100	✔	**Orion**
CLONAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 500 mcg	5.64	100	✔	**Paxam**
Tab 2 mg	10.78	100	✔	**Paxam**
DIAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 2 mg	15.05	500	✔	**Arrow-Diazepam**
Tab 5 mg	16.18	500	✔	**Arrow-Diazepam**
LORAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 1 mg	9.72	250	✔	**Ativan**
Tab 2.5 mg	12.50	100	✔	**Ativan**
OXAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	6.17	100	✔	**Ox-Pam**
Tab 15 mg	8.53	100	✔	**Ox-Pam**

Multiple Sclerosis Treatments

DIMETHYL FUMARATE – Special Authority see SA1559 below – Retail pharmacy Wastage claimable				
Cap 120 mg	520.00	14	✔	**Tecfidera**
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).

continued…

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

continued…

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

The coordinator
Multiple Sclerosis Treatment Assessment Committee
PHARMAC PO Box 10 254
Wellington

Phone: 04 460 4990
Facsimile: 04 916 7571
Email: mstaccoordinator@pharmac.govt.nz

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:

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

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

continued…

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 dimethyl fumarate; or
4) non-compliance with treatment, including refusal to undergo annual assessment.

Note: Switching between natalizumab, fingolimod, dimethyl fumarate, teriflunomide and ocrelizumab 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

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

continued…

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

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:

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
3) intolerance to fingolimod; or
4) non-compliance with treatment, including refusal to undergo annual assessment.

Note: Switching between natalizumab, fingolimod, dimethyl fumarate, teriflunomide and ocrelizumab 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

Inj 20 mg per ml, 15 ml vial	1,750.00	1	✔	**Tysabri**

➽SA1563 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

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

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Wellington	

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

continued…

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;
   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) 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
9) 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.

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

continued…

2) increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment)(see note); or
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, teriflunomide and ocrelizumab 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.

OCRELIZUMAB – Special Authority see SA1867 below – Retail pharmacy

Inj 30 mg per ml, 10 ml vial	9,346.00	1	✔	**Ocrevus**

➽SA1867 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).
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Multiple Sclerosis Treatment Assessment Committee	Facsimile: 04 916 7571
PHARMAC PO Box 10 254	Email: mstaccoordinator@pharmac.govt.nz
Wellington	

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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;

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

continued…

- 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 ocrelizumab; and
g) patients must have not previously had intolerance to ocrelizumab; and
h) 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
3) intolerance to ocrelizumab; or
4) non-compliance with treatment, including refusal to undergo annual assessment.

Note: Switching between natalizumab, fingolimod, dimethyl fumarate, teriflunomide and ocrelizumab 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

Tab 14 mg	1,582.62	28	✔	**Aubagio**

➽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:

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Wellington	

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

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

continued…

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
   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 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
3) intolerance to teriflunomide; or
4) non-compliance with treatment, including refusal to undergo annual assessment.

Note: Switching between natalizumab, fingolimod, dimethyl fumarate, teriflunomide and ocrelizumab 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

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

continued…
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

GLATIRAMER ACETATE – Special Authority see SA1808 below – Retail pharmacy

Inj 40 mg prefilled syringe	2,275.00	12	✔	**Copaxone**

➠SA1808 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).

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, 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. As a new Special Authority approval number is required 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;

continued…

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

continued…

   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; 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
   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 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.

INTERFERON BETA-1-ALPHA – Special Authority see SA1809 below – Retail pharmacy

Inj 6 million iu prefilled syringe	1,170.00	4	✔	**Avonex**
Injection 6 million iu per 0.5 ml pen injector	1,170.00	4	✔	**Avonex Pen**

➽SA1809 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:

continued…

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

continued…

The coordinator
Multiple Sclerosis Treatment Assessment Committee
PHARMAC PO Box 10 254
Wellington

Phone: 04 460 4990
Facsimile: 04 916 7571
Email: mstaccoordinator@pharmac.govt.nz

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).
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, 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. As a new Special Authority approval number is required 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
   g) 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:

continued…

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

continued…

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 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.

INTERFERON BETA-1-BETA – Special Authority see SA1810 below – Retail pharmacy

	Subsidy	Per	Fully Subsidised	Brand
Inj 8 million iu per 1 ml	1,322.89	15	✔	**Betaferon**

➽SA1810 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
Multiple Sclerosis Treatment Assessment Committee
PHARMAC PO Box 10 254
Wellington

Phone: 04 460 4990
Facsimile: 04 916 7571
Email: mstaccoordinator@pharmac.govt.nz

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).

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, 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. As a new Special Authority approval number is required 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:

continued…

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

continued…

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
   g) 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
   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 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

continued…

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

continued…
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.

Sedatives and Hypnotics

MELATONIN – Special Authority see SA1666 below – Retail pharmacy

Tab modified-release 2 mg – No more than 5 tab per day	28.22	30	✔	**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:

All of the following:

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

Note: Indications marked with * are unapproved indications.

MIDAZOLAM – Safety medicine; prescriber may determine dispensing frequency

Inj 1 mg per ml, 5 ml ampoule	4.30	10	✔	**Midazolam-Claris**
Inj 1 mg per ml, 5 ml plastic ampoule – Up to 10 inj available on a PSO	14.90	10	✔	**Pfizer**
On a PSO for status epilepticus use only. PSO must be endorsed for status epilepticus use only.				
Inj 5 mg per ml, 3 ml ampoule	2.50	5	✔	**Midazolam-Claris**
Inj 5 mg per ml, 3 ml plastic ampoule – Up to 5 inj available on a PSO	11.90	5	✔	**Pfizer**
On a PSO for status epilepticus use only. PSO must be endorsed for status epilepticus use only.				

NITRAZEPAM – Subsidy by endorsement

a) Safety medicine; prescriber may determine dispensing frequency
b) Subsidy by endorsement – subsidised for patients who were taking nitrazepam prior to 1 August 2019 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of nitrazepam in the preceding 12 months.

Tab 5 mg	5.22	100	✔	**Nitrados**

(Nitrados Tab 5 mg to be delisted 1 January 2021)

PHENOBARBITONE SODIUM – Special Authority see SA1386 on the next page – Retail pharmacy

Inj 200 mg per ml, 1 ml ampoule	30.00	5	✔	**Aspen** S29

✔ fully subsidised
Sole Subsidised Supply
S29 Unapproved medicine supplied under Section 29

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

➽SA1386 Special Authority for Subsidy
Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:
Both:
1. For the treatment of terminal agitation that is unresponsive to other agents; and
2. The applicant is part of a multidisciplinary team working in palliative care.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised	Brand or Generic Manufacturer
TEMAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	1.27	25	✔	Normison
TRIAZOLAM – Safety medicine; prescriber may determine dispensing 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 dispensing frequency				
Tab 7.5 mg	9.56	500	✔	Zopiclone Actavis

Stimulants/ADHD Treatments

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised	Brand or Generic Manufacturer
ATOMOXETINE – Special Authority see SA1416 below – Retail pharmacy				
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

➽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.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
DEXAMFETAMINE SULFATE – Special Authority see SA1149 below – Retail pharmacy				
a) Only on a controlled drug form				
b) Safety medicine; prescriber may determine dispensing frequency				
Tab 5 mg	20.00	100	✔	PSM

➽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
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.

	Subsidy $	Per	✔	Brand
METHYLPHENIDATE HYDROCHLORIDE – Special Authority see SA1150 below – Retail pharmacy				
a) Only on a controlled drug form				
b) Safety medicine; prescriber may determine dispensing frequency				
Tab immediate-release 5 mg	3.20	30	✔	Rubifen
Tab immediate-release 10 mg	3.00	30	✔	Ritalin
			✔	Rubifen
Tab immediate-release 20 mg	7.85	30	✔	Rubifen
Tab sustained-release 20 mg	10.95	30	✔	Rubifen SR
	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:

continued…

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

continued…
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
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 EXTENDED-RELEASE – Special Authority see SA1151 on the next page – Retail pharmacy

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

Tab extended-release 18 mg	18.20	30	✔	**Methylphenidate ER - Teva**
	58.96		✔	**Concerta**
Tab extended-release 27 mg	22.00	30	✔	**Methylphenidate ER - Teva**
	65.44		✔	**Concerta**
Tab extended-release 36 mg	22.40	30	✔	**Methylphenidate ER - Teva**
	71.93		✔	**Concerta**
Tab extended-release 54 mg	26.40	30	✔	**Methylphenidate ER - Teva**
	86.24		✔	**Concerta**
Cap modified-release 10 mg	15.60	30	✔	**Ritalin LA**
Cap modified-release 20 mg	20.40	30	✔	**Ritalin LA**
Cap modified-release 30 mg	25.52	30	✔	**Ritalin LA**
Cap modified-release 40 mg	30.60	30	✔	**Ritalin LA**

▲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

➽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 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; 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.

MODAFINIL – Special Authority see SA1126 below – Retail pharmacy

Tab 100 mg	64.00	60	✔	**Modavigil**

➽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 Either:
   3.1 An effective dose of a subsidised formulation of methylphenidate or dexamfetamine has been trialled and discontinued because of intolerable side effects; or
   3.2 Methylphenidate and dexamfetamine are contraindicated.

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

Treatments for Dementia

DONEPEZIL HYDROCHLORIDE

❋ Tab 5 mg	4.34	90	✔	**Donepezil-Rex**
❋ Tab 10 mg	6.64	90	✔	**Donepezil-Rex**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
RIVASTIGMINE – Special Authority see SA1488 below – Retail pharmacy				
Patch 4.6 mg per 24 hour	90.00	30	✔	**Exelon**
Patch 9.5 mg per 24 hour	90.00	30	✔	**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

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
BUPRENORPHINE WITH NALOXONE – Special Authority see SA1203 below – Retail pharmacy				
a) No patient co-payment payable				
b) Safety medicine; prescriber may determine dispensing frequency				
Tab sublingual 2 mg with naloxone 0.5 mg	18.37	28	✔	**Buprenorphine Naloxone BNM**
	57.40		✔	**Suboxone**
Buprenorphine Naloxone BNM to be Sole Supply on 1 April 2020				
Tab sublingual 8 mg with naloxone 2 mg	53.12	28	✔	**Buprenorphine Naloxone BNM**
	166.00		✔	**Suboxone**
Buprenorphine Naloxone BNM to be Sole Supply on 1 April 2020				

(Suboxone Tab sublingual 2 mg with naloxone 0.5 mg to be delisted 1 April 2020)
(Suboxone Tab sublingual 8 mg with naloxone 2 mg to be delisted 1 April 2020)

➽SA1203 Special Authority for Subsidy

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

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

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

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

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

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

continued…

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

continued…

and another attempt is planned; and

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

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

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

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

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

BUPROPION HYDROCHLORIDE				
Tab modified-release 150 mg	11.00	30	✔	**Zyban**
DISULFIRAM				
Tab 200 mg	153.00	100	✔	**Antabuse**
NALTREXONE HYDROCHLORIDE – Special Authority see SA1408 below – Retail pharmacy				
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) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
NICOTINE				
a) Nicotine will not be funded in amounts less than 4 weeks of treatment.				
b) Note: Direct Provision by a pharmacist permitted under the provisions in Part I of Section A.				
Patch 7 mg – Up to 28 patch available on a PSO	17.28	28	✔	Habitrol
Patch 7 mg for direct distribution only – [Xpharm]	3.94	7	✔	Habitrol
Patch 14 mg – Up to 28 patch available on a PSO	19.00	28	✔	Habitrol
Patch 14 mg for direct distribution only – [Xpharm]	4.52	7	✔	Habitrol
Patch 21 mg – Up to 28 patch available on a PSO	21.77	28	✔	Habitrol
Patch 21 mg for direct distribution only – [Xpharm]	5.18	7	✔	Habitrol
Lozenge 1 mg – Up to 216 loz available on a PSO	18.27	216	✔	Habitrol
Lozenge 1 mg for direct distribution only – [Xpharm]	3.20	36	✔	Habitrol
Lozenge 2 mg – Up to 216 loz available on a PSO	20.02	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 PSO	36.39	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 PSO	36.39	384	✔	Habitrol
Gum 2 mg (Mint) for direct distribution only – [Xpharm]	8.64	96	✔	Habitrol
Gum 4 mg (Fruit) – Up to 384 piece available on a PSO	42.07	384	✔	Habitrol
Gum 4 mg (Fruit) for direct distribution only – [Xpharm]	10.01	96	✔	Habitrol
Gum 4 mg (Mint) – Up to 384 piece available on a PSO	42.07	384	✔	Habitrol
Gum 4 mg (Mint) for direct distribution only – [Xpharm]	10.01	96	✔	Habitrol
VARENICLINE TARTRATE – Special Authority see SA1845 below – Retail pharmacy				
a) A maximum of 12 weeks' varenicline will be subsidised on each Special Authority approval, including the starter pack				
b) Varenicline will not be funded in amounts less than 4 weeks of treatment.				
c) The 6-month time period in which a patient can receive a funded 12-week course of varenicline tartrate starts from the date the Special Authority is approved.				
Tab 0.5 mg x 11 and 1 mg x 42	25.64	53 OP	✔	Varenicline Pfizer
Tab 1 mg	27.10	56	✔	Varenicline Pfizer

➽SA1845 Special Authority for Subsidy

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

1 Short-term therapy as an aid to achieving abstinence in a patient who has indicated that they are ready to cease smoking; and

2 The patient is part of, or is about to enrol in, a comprehensive support and counselling smoking cessation programme, which includes prescriber or nurse monitoring; and

3 Either:

3.1 The patient has tried but failed to quit smoking after at least two separate trials of nicotine replacement therapy, at least one of which included the patient receiving comprehensive advice on the optimal use of nicotine replacement therapy; or

3.2 The patient has tried but failed to quit smoking using bupropion or nortriptyline; and

4 The patient has not had a Special Authority for varenicline approved in the last 6 months; and

5 Varenicline is not to be used in combination with other pharmacological smoking cessation treatments and the patient has agreed to this; and

6 The patient is not pregnant; and

7 The patient will not be prescribed more than 12 weeks' funded varenicline (see note).

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

1 Short-term therapy as an aid to achieving abstinence in a patient who has indicated that they are ready to cease smoking;

continued…

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

continued…

and

2 The patient is part of, or is about to enrol in, a comprehensive support and counselling smoking cessation programme, which includes prescriber or nurse monitoring; and
3 It has been 6 months since the patient’s previous Special Authority was approved; and
4 Varenicline is not to be used in combination with other pharmacological smoking cessation treatments and the patient has agreed to this; and
5 The patient is not pregnant; and
6 The patient will not be prescribed more than 12 weeks' funded varenicline (see note).

The patient must not have had an approval in the past 6 months.
Notes: a maximum of 12 weeks' varenicline will be subsidised on each Special Authority approval.
This includes the 4-week 'starter' pack.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or 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/m^2 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 Either:
      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 Either:
  2.1 Both:

continued…

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

continued…

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.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised	Brand or Generic Manufacturer
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	✔	**DBL Carboplatin**
	45.20		✔	**Carboplatin Ebewe**
	48.50		✔	**Carbaccord**
Inj 1 mg for ECP	0.10	1 mg	✔	**Baxter**
CARMUSTINE – PCT only – Specialist				
Inj 100 mg vial	1,387.00	1	✔	**BiCNU**
			✔	**Bicnu Heritage** S29
Inj 100 mg for ECP	1,387.00	100 mg OP	✔	**Baxter**
CHLORAMBUCIL – PCT – Retail pharmacy-Specialist				
Tab 2 mg	29.06	25	✔	**Leukeran FC**
CISPLATIN – PCT only – Specialist				
Inj 1 mg per ml, 50 ml vial	12.29	1	✔	**DBL Cisplatin**
	15.00		✔	**Cisplatin Ebewe**
Inj 1 mg per ml, 100 ml vial	19.70	1	✔	**DBL Cisplatin**
	21.00		✔	**Cisplatin Ebewe**
Inj 1 mg for ECP	0.25	1 mg	✔	**Baxter**
CYCLOPHOSPHAMIDE				
Tab 50 mg – PCT – Retail pharmacy-Specialist	79.00	50	✔	**Endoxan** S29
	158.00	100	✔	**Procytox** S29
Wastage claimable				
Inj 1 g vial – PCT – Retail pharmacy-Specialist	35.65	1	✔	**Endoxan**
	127.80	6	✔	**Cytoxan**
Inj 2 g vial – PCT only – Specialist	71.25	1	✔	**Endoxan**
Inj 1 mg for ECP – PCT only – Specialist	0.04	1 mg	✔	**Baxter**
IFOSFAMIDE – PCT only – Specialist				
Inj 1 g	96.00	1	✔	**Holoxan**
Inj 2 g	180.00	1	✔	**Holoxan**
Inj 1 mg for ECP	0.10	1 mg	✔	**Baxter**
LOMUSTINE – PCT – Retail pharmacy-Specialist				
Cap 10 mg	132.59	20	✔	**CeeNU**
Cap 40 mg	399.15	20	✔	**CeeNU**
MELPHALAN				
Tab 2 mg – PCT – Retail pharmacy-Specialist	40.70	25	✔	**Alkeran**
Inj 50 mg – PCT only – Specialist	67.80	1	✔	**Alkeran**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
OXALIPLATIN – PCT only – Specialist				
Inj 100 mg vial	25.01	1	✔	**Oxaliplatin Actavis 100**
	110.00		✔	**Oxaliplatin Ebewe**
Inj 5 mg per ml, 20 ml vial	46.32	1	✔	**Oxaliccord**
			✔	**Oxaliplatin Accord**
Inj 1 mg for ECP	0.48	1 mg	✔	**Baxter**
(Oxaliccord Inj 5 mg per ml, 20 ml vial to be delisted 1 February 2020)				
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 SA1467 below				
Inj 100 mg vial	139.00	1	✔	**Azacitidine Dr Reddy's**
	605.00		✔	**Vidaza**
Inj 1 mg for ECP	1.53	1 mg	✔	**Baxter**

➽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 (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
CALCIUM 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	17.10	5	✔	**Hospira**
Inj 10 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specialist	7.28	1	✔	**Calcium Folinate Sandoz**
Calcium Folinate Sandoz to be Sole Supply on 1 March 2020				
Inj 50 mg – PCT – Retail pharmacy-Specialist	18.25	5	✔	**Calcium Folinate Ebewe**
Inj 10 mg per ml, 10 ml vial – PCT only – Specialist	9.49	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	25.14	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	72.00	1	✔	**Calcium Folinate Sandoz**
Calcium Folinate Sandoz to be Sole Supply on 1 March 2020				
Inj 1 mg for ECP – PCT only – Specialist	0.06	1 mg	✔	**Baxter**
(Calcium Folinate Ebewe Inj 50 mg to be delisted 1 March 2020)				
CAPECITABINE – Retail pharmacy-Specialist				
Tab 150 mg	11.15	60	✔	**Brinov**
Tab 500 mg	62.28	120	✔	**Brinov**
CLADRIBINE – PCT only – Specialist				
Inj 1 mg per ml, 10 ml	5,249.72	7	✔	**Leustatin**
Inj 10 mg for ECP	749.96	10 mg OP	✔	**Baxter**
CYTARABINE				
Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specialist	400.00	5	✔	**Pfizer**
Inj 100 mg per ml, 20 ml vial – PCT – Retail pharmacy-Specialist	41.36	1	✔	**Pfizer**
Inj 1 mg for ECP – PCT only – Specialist	0.25	10 mg	✔	**Baxter**
Inj 100 mg intrathecal syringe for ECP – PCT only – Specialist	80.00	100 mg OP	✔	**Baxter**
FLUDARABINE PHOSPHATE				
Tab 10 mg – PCT – Retail pharmacy-Specialist	412.00	20	✔	**Fludara Oral**
Inj 50 mg vial – PCT only – Specialist	576.45	5	✔	**Fludarabine Ebewe**
Inj 50 mg for ECP – PCT only – Specialist	115.29	50 mg OP	✔	**Baxter**
FLUOROURACIL				
Inj 50 mg per ml, 20 ml vial – PCT only – Specialist	12.00	1	✔	**Fluorouracil Ebewe**
Inj 50 mg per ml, 100 ml vial – PCT only – Specialist	30.00	1	✔	**Fluorouracil Ebewe**
Inj 1 mg for ECP – PCT only – Specialist	0.66	100 mg	✔	**Baxter**
GEMCITABINE HYDROCHLORIDE – PCT only – Specialist				
Inj 1 g, 26.3 ml vial	62.50	1	✔	**DBL Gemcitabine**
Inj 1 g	15.89	1	✔	**Gemcitabine Ebewe**
	349.20		✔	**Gemzar**
Inj 1 mg for ECP	0.02	1 mg	✔	**Baxter**

✔ **fully subsidised**
Sole Subsidised Supply
S29 Unapproved medicine supplied under Section 29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
IRINOTECAN HYDROCHLORIDE – PCT only – Specialist				
Inj 20 mg per ml, 5 ml vial	71.44	1	✔	**Irinotecan Accord** S29
			✔	**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	37.00	25	✔	**Puri-nethol**
Oral suspension 20 mg per ml – Retail pharmacy-Specialist – Special Authority see SA1725 below	428.00	100 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.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
METHOTREXATE				
❋ Tab 2.5 mg – PCT – Retail pharmacy-Specialist	8.05	90	✔	**Trexate**
❋ Tab 10 mg – PCT – Retail pharmacy-Specialist	31.75	90	✔	**Trexate**
❋ Inj 2.5 mg per ml, 2 ml – PCT – Retail pharmacy-Specialist	47.50	5	✔	**Hospira**
❋ Inj 7.5 mg prefilled syringe	14.61	1	✔	**Methotrexate Sandoz**
❋ Inj 10 mg prefilled syringe	14.66	1	✔	**Methotrexate Sandoz**
❋ Inj 15 mg prefilled syringe	14.77	1	✔	**Methotrexate Sandoz**
❋ Inj 20 mg prefilled syringe	14.88	1	✔	**Methotrexate Sandoz**
❋ Inj 25 mg prefilled syringe	14.99	1	✔	**Methotrexate Sandoz**
❋ Inj 30 mg prefilled syringe	15.09	1	✔	**Methotrexate Sandoz**
❋ Inj 25 mg per ml, 2 ml vial – PCT – Retail pharmacy-Specialist	30.00	5	✔	**DBL Methotrexate Onco-Vial**
❋ Inj 25 mg per ml, 20 ml vial – PCT – Retail pharmacy-Specialist	45.00	1	✔	**DBL Methotrexate Onco-Vial**
❋ Inj 100 mg per ml, 10 ml – PCT – Retail pharmacy-Specialist	25.00	1	✔	**Methotrexate Ebewe**
❋ Inj 100 mg per ml, 50 ml vial – PCT – Retail pharmacy-Specialist	79.99	1	✔	**Methotrexate Ebewe**
❋ Inj 1 mg for ECP – PCT only – Specialist	0.06	1 mg	✔	**Baxter**
❋ Inj 5 mg intrathecal syringe for ECP – PCT only – Specialist	4.73	5 mg OP	✔	**Baxter**
PEMETREXED – PCT only – Specialist – Special Authority see SA1679 on the next page				
Inj 100 mg vial	60.89	1	✔	**Juno Pemetrexed**
Inj 500 mg vial	217.77	1	✔	**Juno Pemetrexed**
Inj 1 mg for ECP	0.55	1 mg	✔	**Baxter**

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

➽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:

Both:

1. Patient has been diagnosed with mesothelioma; and
2. Pemetrexed to be administered at a dose of 500 mg/m^2 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^2 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. Either:
   - 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^2 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^2 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
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^2 every 21 days.

	Subsidy $	Per	Fully Subsidised	Brand
THIOGUANINE – PCT – Retail pharmacy-Specialist				
Tab 40 mg	126.31	25	✔	**Lanvis**

Other Cytotoxic Agents

	Subsidy $	Per	Fully Subsidised	Brand
AMSACRINE – PCT only – Specialist				
Inj 50 mg per ml, 1.5 ml ampoule	1,500.00	6	✔	**Amsidine** S29
	4,736.00		✔	**Amsidine** S29
Inj 75 mg	1,250.00	5	✔	**AmsaLyo** S29
ANAGRELIDE HYDROCHLORIDE – PCT – Retail pharmacy-Specialist				
Cap 0.5 mg	CBS	100	✔	**Agrylin** S29
			✔	**Teva** S29
ARSENIC TRIOXIDE – PCT only – Specialist				
Inj 1 mg per ml, 10 ml vial	4,817.00	10	✔	**Phenasen**
Inj 10 mg for ECP	481.70	10 mg OP	✔	**Baxter**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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**
BORTEZOMIB – PCT only – Specialist – Special Authority see SA1576 below				
Inj 3.5 mg vial	1,892.50	1	✔	**Velcade**
Inj 1 mg for ECP	594.77	1 mg	✔	**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 Either:

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**

(Leunase Inj 10,000 iu to be delisted 1 December 2020)
(Baxter Inj 10,000 iu for ECP to be delisted 1 December 2020)

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**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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**
DOCETAXEL – PCT only – Specialist				
Inj 10 mg per ml, 2 ml vial	12.40	1	✔	**DBL Docetaxel**
Inj 20 mg	48.75	1	✔	**Docetaxel Sandoz**
Inj 10 mg per ml, 8 ml vial	26.95	1	✔	**DBL Docetaxel**
Inj 20 mg per ml, 4 ml vial	26.95	1	✔	**Docetaxel Accord** S29
Inj 80 mg	195.00	1	✔	**Docetaxel Sandoz**
Inj 1 mg for ECP	0.55	1 mg	✔	**Baxter**
DOXORUBICIN HYDROCHLORIDE – PCT only – Specialist				
Inj 2 mg per ml, 5 ml vial	10.00	1	✔	**Doxorubicin Ebewe**
Inj 2 mg per ml, 25 ml vial	11.50	1	✔	**Doxorubicin Ebewe**
	17.00		✔	**Arrow-Doxorubicin**
Inj 2 mg per ml, 50 ml vial	23.00	1	✔	**Doxorubicin Ebewe**
Inj 2 mg per ml, 100 ml vial	56.15	1	✔	**Doxorubicin Ebewe**
	65.00		✔	**Arrow-Doxorubicin**
Inj 1 mg for ECP	0.29	1 mg	✔	**Baxter**
EPIRUBICIN HYDROCHLORIDE – PCT only – Specialist				
Inj 2 mg per ml, 5 ml vial	25.00	1	✔	**Epirubicin Ebewe**
Inj 2 mg per ml, 25 ml vial	30.00	1	✔	**Epirubicin Ebewe**
Inj 2 mg per ml, 100 ml vial	85.00	1	✔	**Epirubicin Ebewe**
Inj 1 mg for ECP	0.37	1 mg	✔	**Baxter**
ETOPOSIDE				
Cap 50 mg – PCT – Retail pharmacy-Specialist	340.73	20	✔	**<u>Vepesid</u>**
Cap 100 mg – PCT – Retail pharmacy-Specialist	340.73	10	✔	**<u>Vepesid</u>**
Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specialist	7.90	1	✔	**Rex Medical**
Inj 1 mg for ECP – PCT only – Specialist	0.09	1 mg	✔	**Baxter**
ETOPOSIDE PHOSPHATE – PCT only – Specialist				
Inj 100 mg (of etoposide base)	40.00	1	✔	**Etopophos**
Inj 1 mg (of etoposide base) for ECP	0.47	1 mg	✔	**Baxter**
HYDROXYUREA – PCT – Retail pharmacy-Specialist				
Cap 500 mg	31.76	100	✔	**Hydrea**
IDARUBICIN HYDROCHLORIDE				
Inj 5 mg vial – PCT only – Specialist	93.00	1	✔	**Zavedos**
Inj 10 mg vial – PCT only – Specialist	198.00	1	✔	**Zavedos**
Inj 1 mg for ECP – PCT only – Specialist	21.84	1 mg	✔	**Baxter**
LENALIDOMIDE – Retail pharmacy-Specialist – Special Authority see SA1468 on the next page				
Wastage claimable				
Cap 10 mg	6,207.00	21	✔	**Revlimid**
Cap 15 mg	7,239.18	21	✔	**Revlimid**
Cap 25 mg	7,627.00	21	✔	**Revlimid**

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

➽SA1468 Special Authority for Subsidy

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:
  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
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
2 The treatment remains appropriate and patient is benefitting from treatment.

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

	Subsidy $	Per	Fully Subsidised	Brand or Generic Manufacturer
MESNA				
Tab 400 mg – PCT – Retail pharmacy-Specialist	314.00	50	✔	Uromitexan
Tab 600 mg – PCT – Retail pharmacy-Specialist	448.50	50	✔	Uromitexan
Inj 100 mg per ml, 4 ml ampoule – PCT only – Specialist	177.45	15	✔	Uromitexan
Inj 100 mg per ml, 10 ml ampoule – PCT only – Specialist	407.40	15	✔	Uromitexan
Inj 1 mg for ECP – PCT only – Specialist	2.96	100 mg	✔	Baxter
MITOMYCIN C – PCT only – Specialist				
Inj 5 mg vial	204.08	1	✔	Arrow
Inj 20 mg vial	816.32	1	✔	Omegapharm S29
Inj 1 mg for ECP	42.04	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	5.51	1 mg	✔	Baxter
PACLITAXEL – PCT only – Specialist				
Inj 30 mg	47.30	5	✔	Paclitaxel Ebewe
Inj 100 mg	20.00	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 SA1325 on the next page				
Inj 750 iu per ml, 5 ml vial	3,005.00	1	✔	Oncaspar LYO S29
Inj 3,750 IU per 5 ml	3,005.00	1	✔	Oncaspar S29

(Oncaspar S29 Inj 3,750 IU per 5 ml to be delisted 1 May 2020)

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

➽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
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.

	Subsidy $	Per	Fully Subsidised	Brand
PENTOSTATIN [DEOXYCOFORMYCIN] – PCT only – Specialist				
Inj 10 mg	CBS	1	✔	**Nipent** S29
PROCARBAZINE HYDROCHLORIDE – PCT – Retail pharmacy-Specialist				
Cap 50 mg	980.00	50	✔	**Natulan** S29
TEMOZOLOMIDE – Special Authority see SA1741 on the next page – Retail pharmacy				
Cap 5 mg	9.13	5	✔	**Temaccord**
	10.20		✔	**Orion Temozolomide**
Cap 20 mg	16.38	5	✔	**Temaccord**
	18.30		✔	**Apo-Temozolomide**
			✔	**Orion Temozolomide**
			✔	**Temizole 20** S29
	136.00	14	✔	**Accord** S29
Cap 100 mg	35.98	5	✔	**Temaccord**
	40.20		✔	**Apo-Temozolomide**
			✔	**Orion Temozolomide**
	532.00	14	✔	**Accord** S29
Cap 140 mg	50.12	5	✔	**Temaccord**
	56.00		✔	**Orion Temozolomide**
	400.00		✔	**Amneal** S29
Cap 180 mg	620.00	14	✔	**Accord** S29
Cap 250 mg	86.34	5	✔	**Temaccord**
	96.80		✔	**Orion Temozolomide**
	688.00		✔	**Amneal** S29

(Orion Temozolomide Cap 5 mg to be delisted 1 May 2020)
(Orion Temozolomide Cap 20 mg to be delisted 1 May 2020)
(Temizole 20 S29 Cap 20 mg to be delisted 1 May 2020)
(Orion Temozolomide Cap 100 mg to be delisted 1 May 2020)
(Orion Temozolomide Cap 140 mg to be delisted 1 May 2020)
(Orion Temozolomide Cap 250 mg to be delisted 1 May 2020)

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

➽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/m^2 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/m^2 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:

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 – Special Authority see SA1124 on the next page

Cap 50 mg	378.00	28	✔	**Thalomid**
Cap 100 mg	756.00	28	✔	**Thalomid**

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

➽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.

	Subsidy $	Per	Fully Subsidised	Brand
TRETINOIN				
Cap 10 mg – PCT – Retail pharmacy-Specialist	479.50	100	✔	**Vesanoid**
VENETOCLAX – Retail pharmacy-Specialist – Special Authority see SA1868 below				
Tab 14 x 10 mg, 7 x 50 mg, 21 x 100 mg	1,771.86	42 OP	✔	**Venclexta**
Tab 10 mg	95.78	14 OP	✔	**Venclexta**
Tab 50 mg	239.44	7 OP	✔	**Venclexta**
Tab 100 mg – Wastage claimable	8,209.41	120	✔	**Venclexta**

➽SA1868 Special Authority for Subsidy

Initial application — (relapsed/refractory chronic lymphocytic leukaemia) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 7 months for applications meeting the following criteria:

All of the following:

1. Patient has chronic lymphocytic leukaemia requiring treatment; and
2. Patient has received at least one prior therapy for chronic lymphocytic leukaemia; and
3. Patient has not previously received funded venetoclax; and
4. The patient's disease has relapsed within 36 months of previous treatment; and
5. Venetoclax to be used in combination with six 28-day cycles of rituximab commencing after the 5-week dose titration schedule with venetoclax; and
6. Patient has an ECOG performance status of 0-2.

Renewal — (relapsed/refractory chronic lymphocytic leukaemia) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1. Treatment remains clinically appropriate and the patient is benefitting from and tolerating treatment; and
2. Venetoclax is to be discontinued after a maximum of 24 months of treatment following the titration schedule unless earlier discontinuation is required due to disease progression or unacceptable toxicity.

Initial application — (previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

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

Renewal — (previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where the treatment remains clinically appropriate and the patient is benefitting from and tolerating treatment.

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

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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 – Specialist	4.14	1 mg	✔	**Baxter**
VINCRISTINE SULPHATE				
Inj 1 mg per ml, 1 ml vial – PCT – Retail pharmacy-Specialist	74.52	5	✔	**DBL Vincristine Sulfate**
Inj 1 mg per ml, 2 ml vial – PCT – Retail pharmacy-Specialist	85.61	5	✔	**DBL Vincristine Sulfate**
Inj 1 mg for ECP – PCT only – Specialist	11.30	1 mg	✔	**Baxter**
VINORELBINE – 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		✔	**Vinorelbine Ebewe**
Inj 1 mg for ECP	1.25	1 mg	✔	**Baxter**

Protein-tyrosine Kinase Inhibitors

ALECTINIB – Retail pharmacy-Specialist – Special Authority see SA1870 below				
Cap 150 mg	7,935.00	224	✔	**Alecensa**

➽SA1870 Special Authority for Subsidy

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

All of the following:

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

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

Both:

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

DASATINIB – Special Authority see SA1805 below – Retail pharmacy				
Wastage claimable				
Tab 20 mg	3,774.06	60	✔	**Sprycel**
Tab 50 mg	6,214.20	60	✔	**Sprycel**
Tab 70 mg	7,692.58	60	✔	**Sprycel**

➽SA1805 Special Authority for Subsidy

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

Any of the following:

1 Both:

 1.1 The patient has a diagnosis of chronic myeloid leukaemia (CML) in blast crisis or accelerated phase; and

 1.2 Maximum dose of 140 mg/day; or

2 Both:

 2.1 The patient has a diagnosis of Philadelphia chromosome-positive acute lymphoid leukaemia (Ph+ ALL); and

continued…

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

continued…

2.2 Maximum dose of 140 mg/day; or

3 All of the following:

3.1 The patient has a diagnosis of CML in chronic phase; and

3.2 Maximum dose of 100 mg/day; and

3.3 Any of the following:

3.3.1 Patient has documented treatment failure* with imatinib; or

3.3.2 Patient has experienced treatment-limiting toxicity with imatinib precluding further treatment with imatinib; or

3.3.3 Patient has high-risk chronic-phase CML defined by the Sokal or EURO scoring system; or

3.3.4 Patients is enrolled in the KISS study** and requires dasatinib treatment according to the study protocol.

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

All of the following:

1 Lack of treatment failure while on dasatinib*; and

2 Dasatinib treatment remains appropriate and the patient is benefiting from treatment; and

3 Maximum dasatinib dose of 140 mg/day for accelerated or blast phase CML and Ph+ ALL, and 100 mg/day for chronic phase CML.

Note: *treatment failure for CML as defined by Leukaemia Net Guidelines. **Kinase-Inhibition Study with Sprycel Start-up https://www.cancertrialsnz.ac.nz/kiss/

ERLOTINIB – Retail pharmacy-Specialist – Special Authority see SA1653 below

Tab 100 mg	764.00	30	✔	**Tarceva**
Tab 150 mg	1,146.00	30	✔	**Tarceva**

➽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 Either:

3.1 Patient is treatment naive; or

3.2 Both:

3.2.1 The patient has discontinued gefitinib due to intolerance; and

3.2.2 The cancer did not progress while on gefitinib; and

4 Erlotinib is to be given for a maximum of 3 months.

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

GEFITINIB – Retail pharmacy-Specialist – Special Authority see SA1654 below

Tab 250 mg	1,700.00	30	✔	**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 Either:

2.1 Patient is treatment naive; or

2.2 Both:

continued…

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

continued…

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 MESILATE

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.

	Subsidy	Per	Fully Subsidised	Brand
Tab 100 mg – [Xpharm] – Special Authority see SA1460 below	2,400.00	60	✔	**Glivec**
❋ Cap 100 mg	98.00	60	✔	**Imatinib-AFT**
❋ Cap 400 mg	197.50	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:

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 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

	Subsidy	Per	Fully Subsidised	Brand
Tab 250 mg	1,899.00	70	✔	**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

continued…

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

continued…

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); and
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 below – Retail pharmacy
Wastage claimable

Cap 150 mg	4,680.00	120	✔	**Tasigna**
Cap 200 mg	6,532.00	120	✔	**Tasigna**

➽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:

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:

continued…

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

continued…

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.

RUXOLITINIB – Special Authority see SA1753 below – Retail pharmacy
Wastage claimable

Tab 5 mg	2,500.00	56	✔	**Jakavi**
Tab 15 mg	5,000.00	56	✔	**Jakavi**
Tab 20 mg	5,000.00	56	✔	**Jakavi**

➽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 Authority see SA1266 below – Retail pharmacy

Cap 12.5 mg	2,315.38	28	✔	**Sutent**
Cap 25 mg	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:

continued…

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

continued…
All of the following:

1 The patient has metastatic renal cell carcinoma; and
2 Any of the following:
  2.1 The patient is treatment naive; or
  2.2 The patient has only received prior cytokine treatment; or
  2.3 The patient has only received prior treatment with an investigational agent within the confines of a bona fide clinical trial which has Ethics Committee approval; or
  2.4 Both:
    2.4.1 The patient has discontinued pazopanib within 3 months of starting treatment due to intolerance; and
    2.4.2 The cancer did not progress whilst on pazopanib; and
3 The patient has good performance status (WHO/ECOG grade 0-2); and
4 The disease is of predominant clear cell histology; and
The patient has intermediate or poor prognosis defined as:
5 Any of the following:
  5.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or
  5.2 Haemoglobin level < lower limit of normal; or
  5.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or
  5.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or
  5.5 Karnofsky performance score of less than or equal to 70; or
  5.6 2 or more sites of organ metastasis; and
6 Sunitinib to be used for a maximum of 2 cycles.

Initial application — (GIST) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:
Both:

1 The patient has unresectable or metastatic malignant gastrointestinal stromal tumour (GIST); and
2 Either:
  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

continued…

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

continued…

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 82

ABIRATERONE ACETATE – Retail pharmacy-Specialist – Special Authority see SA1767 below

Wastage claimable

Tab 250 mg	4,276.19	120	✔	**Zytiga**

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

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

All of the following:

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

BICALUTAMIDE

Tab 50 mg	3.80	28	✔	**Binarex**

FLUTAMIDE – Retail pharmacy-Specialist

Tab 250 mg	100.38	84	✔	**Flutamide Mylan** S29
	119.50	100	✔	**Flutamin**

MEGESTROL ACETATE – Retail pharmacy-Specialist

Tab 160 mg	63.53	30	✔	**Apo-Megestrol**

▲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
OCTREOTIDE				
Inj 50 mcg per ml, 1 ml vial	30.64	5	✔	DBL Octreotide
			✔	Octreotide MaxRx S29
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) – Special Authority see SA1016 below – Retail pharmacy				
Inj LAR 10 mg prefilled syringe	1,772.50	1	✔	Sandostatin LAR
Inj LAR 20 mg prefilled syringe	2,358.75	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 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

continued…

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

continued…

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 mg	11.75	60	✔	**Tamoxifen Sandoz**
❋ Tab 20 mg	5.60	60	✔	**Tamoxifen Sandoz**

Aromatase Inhibitors

ANASTROZOLE				
❋ Tab 1 mg	5.04	30	✔	**Rolin**
EXEMESTANE				
❋ Tab 25 mg	14.50	30	✔	**Pfizer Exemestane**
LETROZOLE				
❋ Tab 2.5 mg	4.68	30	✔	**Letrole**

Immunosuppressants

Cytotoxic Immunosuppressants

AZATHIOPRINE – Retail pharmacy-Specialist				
❋ Tab 25 mg	7.35	60	✔	**Azamun**
❋ Tab 50 mg	7.60	100	✔	**Azamun**
❋ Inj 50 mg vial	199.00	1	✔	**Imuran**
MYCOPHENOLATE MOFETIL				
Tab 500 mg	25.00	50	✔	**Cellcept**
Cap 250 mg	25.00	100	✔	**Cellcept**
Powder for oral liq 1 g per 5 ml – Subsidy by endorsement	187.25	165 ml OP	✔	**Cellcept**

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

Fusion Proteins

ETANERCEPT – Special Authority see SA1812 on the next page – Retail pharmacy

Inj 25 mg	799.96	4	✔	**Enbrel**
Inj 50 mg autoinjector	1,599.96	4	✔	**Enbrel**
Inj 50 mg prefilled syringe	1,599.96	4	✔	**Enbrel**

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

➠SA1812 Special Authority for Subsidy

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/m^2 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 joints; 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 — (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

continued…

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

continued…

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 Either:

2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or

2.6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; 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 — (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:

2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or

2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

2.2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and

2.3 A PASI assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and

2.4 The most recent PASI or DLQI assessment is no more than 1 month old at the time of application.

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand 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

continued…

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

continued…

1.2 Either:

1.2.1 The patient has experienced intolerable side effects from adalimumab; or

1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for ankylosing spondylitis; or

2 All of the following:

2.1 Patient has a confirmed diagnosis of ankylosing spondylitis present for more than six months; and

2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and

2.3 Patient has bilateral sacroiliitis demonstrated by plain radiographs, CT or MRI scan; and

2.4 Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and

2.5 Either:

2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following Bath Ankylosing Spondylitis Metrology Index (BASMI) measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or

2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender (see Notes); and

2.6 A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 6 on a 0-10 scale.

Notes: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure must be no more than 1 month old at the time of initial application.

Average normal chest expansion corrected for age and gender:
18-24 years - Male: 7.0 cm; Female: 5.5 cm
25-34 years - Male: 7.5 cm; Female: 5.5 cm
35-44 years - Male: 6.5 cm; Female: 4.5 cm
45-54 years - Male: 6.0 cm; Female: 5.0 cm
55-64 years - Male: 5.5 cm; Female: 4.0 cm
65-74 years - Male: 4.0 cm; Female: 4.0 cm
75+ years - Male: 3.0 cm; Female: 2.5 cm

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

continued…

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

continued…

- 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
   - 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

continued…

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

continued…

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 Either:
   2.1 Both:
      2.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
      2.1.2 Either:
         2.1.2.1 Following each prior etanercept treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-treatment baseline value; or
         2.1.2.2 Following each prior etanercept treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value; or
   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 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:

continued…

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

continued…

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:
Both:

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

Immune Modulators

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised	Brand or Generic Manufacturer
ANTITHYMOCYTE GLOBULIN (EQUINE) – PCT only – Specialist				
Inj 50 mg per ml, 5 ml	2,351.25	5	✔	**ATGAM**
BACILLUS CALMETTE-GUERIN (BCG) VACCINE – PCT only – Specialist				
Subsidised only for bladder cancer.				
Inj 2-8 × 100 million CFU	149.37	1	✔	**OncoTICE**
Inj 40 mg per ml, vial	176.90	3	✔	**SII-Onco-BCG** S29

(SII-Onco-BCG S29 Inj 40 mg per ml, vial to be delisted 1 April 2021)

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

Monoclonal Antibodies

ADALIMUMAB – Special Authority see SA1847 below – Retail pharmacy

Inj 20 mg per 0.4 ml prefilled syringe	1,599.96	2	✔	**Humira**
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	✔	**Humira**

➽SA1847 Special Authority for Subsidy

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.

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 Either:

2.1 Either:

2.1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab; or

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.

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 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.

continued…

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

continued…

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 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 Either:
    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
    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.

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 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 — (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.

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

continued…

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

continued…

1 Both:
  1.1 The patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; and
  1.2 Either:
    1.2.1 The patient has experienced intolerable side effects 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
45-54 years - Male: 6.0 cm; Female: 5.0 cm
55-64 years - Male: 5.5 cm; Female: 4.0 cm
65-74 years - Male: 4.0 cm; Female: 4.0 cm
75+ years - Male: 3.0 cm; Female: 2.5 cm

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

1 Either:
  1.1 Applicant is a rheumatologist; or
  1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with 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.

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

1 Both:

continued…

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

continued…

1.1 The patient has had an initial Special Authority approval for infliximab for chronic ocular inflammation; and
1.2 Either:
1.2.1 The patient has experienced intolerable side effects from infliximab; or
1.2.2 The patient has received insufficient benefit from infliximab to meet the renewal criteria for infliximab for chronic ocular inflammation; or

2 Both:
2.1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and
2.2 Any of the following:
2.2.1 Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective; or
2.2.2 Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or
2.2.3 Patient is under 8 years and treatment with steroids or methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or disease requires control to prevent irreversible vision loss prior to achieving a therapeutic dose of methotrexate.

Renewal — (chronic ocular inflammation) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Both:

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

2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

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 adalimumab is withdrawn.

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.

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

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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.

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 etanercept for juvenile idiopathic arthritis (JIA); 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 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/m^2 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 joints; 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.

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 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 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.

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

continued…

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

continued…

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; or
    2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
  2.5 Any of the following:
    2.5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
    2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or
    2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

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

1 Either:
  1.1 Applicant is a rheumatologist; or
  1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab 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 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.

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.

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

continued…

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

continued…

3 A maximum of 4 doses.

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 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
      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; or
      2.6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; 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.

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 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 Either:

continued…

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

continued…

- 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 Either:

- 4.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
- 4.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

Initial application — (severe Behcet's disease) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

1 The patient has severe Behcet's disease that is significantly impacting the patient's quality of life (see Notes); and

2 Either:

- 2.1 The patient has severe ocular, neurological, gastrointestinal, rheumatological, mucocutaneous and/or vasculitic symptoms and has not responded adequately to treatment with infliximab (see Notes); or
- 2.2 The patient has severe ocular, neurological, gastrointestinal, rheumatological, mucocutaneous and/or vasculitic symptoms and has experienced intolerable side effects from treatment with infliximab; and

3 The patient is experiencing significant loss of quality of life; and

4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Note: 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.

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 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

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 Either:
  - 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
  - 2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; 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

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

continued…

2.3 A PASI assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and

2.4 The most recent PASI or DLQI assessment is no more than 1 month old at the time of application.

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand 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.

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 Either:

2.1.2.1 Following each prior adalimumab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-adalimumab treatment baseline value; or

2.1.2.2 Following each prior adalimumab treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline valuee; 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

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

Either:

1 Both:

1.1 The patient has had an initial Special Authority approval for infliximab for severe ocular inflammation; and

1.2 Either:

1.2.1 The patient has experienced intolerable side effects from infliximab; or

1.2.2 The patient has received insufficient benefit from infliximab to meet the renewal criteria for infliximab for severe ocular inflammation; or

2 Both:

continued…

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

continued…

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

Renewal — (severe ocular inflammation) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Both:
1 Any of the following:
1.1 The patient has had a good clinical response following 3 initial doses; or
1.2 Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
1.3 Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old; and
2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

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 adalimumab is withdrawn.

Initial application — (hidradenitis suppurativa) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:
1 Patient has hidradenitis suppurativa Hurley Stage II or Hurley Stage III lesions in distinct anatomic areas; and
2 Patient has tried, but had an inadequate response to at least a 90 day trial of systemic antibiotics or patient has demonstrated intolerance to or has contraindications for systemic antibiotics; and
3 The patient has 3 or more active lesions (e.g. inflammatory nodules, abscesses, draining fistulae); and
4 The patient has a Dermatology Quality of Life Index of 10 or more and the assessment is no more than 1 month old at time of application; and
5 Following the initial loading doses, adalimumab is to be administered at doses no greater than 40mg every 7 days.

Renewal — (hidradenitis suppurativa) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1 The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline; and
2 The patient has a Dermatology Quality of Life Index improvement of 4 or more from baseline; and
3 Adalimumab is to be administered at doses no greater than 40mg every 7 days. Fortnightly dosing has been considered.

AFLIBERCEPT – Special Authority see SA1772 below – Retail pharmacy

Inj 40 mg per ml, 0.1 ml vial	1,250.00	1	✔	**Eylea**

➽SA1772 Special Authority for Subsidy

Initial application — (wet age related macular degeneration) only from an ophthalmologist. Approvals valid for 3 months for applications meeting the following criteria:
Either:
1 All of the following:
1.1 Any of the following:
1.1.1 Wet age-related macular degeneration (wet AMD); or

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

continued…

- 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 below

Inj 5 mg per ml, 20 ml vial	364.00	1	✔	**Erbitux**
Inj 5 mg per ml, 100 ml vial	1,820.00	1	✔	**Erbitux**
Inj 1 mg for ECP	3.82	1 mg	✔	**Baxter**

➽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:

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

continued…

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 SA1831 below

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
Inj 100 mg	806.00	1	✔	**Remicade**
Inj 1 mg for ECP	8.29	1 mg	✔	**Baxter**

➠SA1831 Special Authority for Subsidy

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
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.

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.

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.

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:

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

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1 Any of the following:
   1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on infliximab; or
   1.2 PCDAI score is 15 or less; or
   1.3 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed; and
2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

Initial application — (Graft vs host disease) from any relevant practitioner. Approvals valid without further renewal unless notified where patient has steroid-refractory acute graft vs. host disease of the gut.

Initial application — (Pulmonary sarcoidosis) from any relevant practitioner. Approvals valid without further renewal unless notified where patient has life-threatening pulmonary sarcoidosis diagnosed by a multidisciplinary team that is refractory to other treatments.

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

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

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

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

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

1 Both:
   1.1 The patient has had an initial Special Authority approval for adalimumab for chronic ocular inflammation; and
   1.2 Either:
      1.2.1 The patient has experienced intolerable side effects from adalimumab; or
      1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for chronic ocular inflammation; or
2 Both:
   2.1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and
   2.2 Any of the following:

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

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

Renewal — (chronic ocular inflammation) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Any of the following:

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

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

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 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).

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.

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

1 Patient has been diagnosed with neurosarcoiosis by a multidisciplinary team; and
2 Patient has CNS involvement; and
3 Patient has steroid-refractory disease; and
4 Either:
4.1 IV cyclophosphamide has been tried; or
4.2 Treatment with IV cyclophosphamide is clinically inappropriate.

Renewal — (neurosarcoidosis) only from a neurologist or Practitioner on the recommendation of a neurologist. Approvals valid

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

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for 18 months for applications meeting the following criteria:
Either:
1 A withdrawal period has been tried and the patient has relapsed; or
2 All of the following:
2.1 A withdrawal period has been considered but would not be clinically appropriate; and
2.2 There has been a marked reduction in prednisone dose; and
2.3 Either:
2.3.1 There has been an improvement in MRI appearances; or
2.3.2 Marked improvement in other symptomology.

Initial application — (plaque psoriasis) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 3 months for applications meeting the following criteria:
Either:
1 Both:
1.1 The patient has had an initial Special Authority approval for adalimumab 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
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.

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:

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

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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.

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

1 Patient was being treated with infliximab prior to 1 February 2019; and

2 Any of the following:

2.1 Rheumatoid arthritis; or
2.2 Ankylosing spondylitis; or
2.3 Psoriatic arthritis; or
2.4 Severe ocular inflammation; or
2.5 Chronic ocular inflammation; or
2.6 Crohn’s disease (adults); or
2.7 Crohn’s disease (children); or
2.8 Fistulising Crohn’s disease; or
2.9 Severe fulminant ulcerative colitis; or
2.10 Severe ulcerative colitis; or
2.11 Plaque psoriasis; or
2.12 Neurosarcoidosis; or
2.13 Severe Behcet’s disease.

Initial application — (psoriatic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:
Both:

1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept 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.

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

1 Either:

1.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or

1.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior infliximab treatment in the opinion of the treating physician; and

2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

Initial application — (rheumatoid arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

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

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All of the following:

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

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

All of the following:

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

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

All of the following:

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

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

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

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

Both:

1 Patient has had a good clinical response to initial treatment with measurably improved quality of life; and
2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

Renewal — (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

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

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

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

Either:

1 Both:
 1.1 The patient has had an initial Special Authority approval for adalimumab for severe ocular inflammation; and
 1.2 Either:
  1.2.1 The patient has experienced intolerable side effects from adalimumab; or
  1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe ocular inflammation; or

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

Renewal — (severe ocular inflammation) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Any of the following:

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

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

Initial application — (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.

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:

All of the following:

1 Patient is continuing to maintain remission and the benefit of continuing infliximab outweighs the risks; and

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

continued…

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.

OBINUTUZUMAB – PCT only – Specialist – Special Authority see SA1627 below

Inj 25 mg per ml, 40 ml vial	5,910.00	1	✔	**Gazyva**
Inj 1 mg for ECP	6.21	1 mg	✔	**Baxter**

➽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
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 × 10^9/L and platelets greater than or equal to 75 × 10^9/L.

OMALIZUMAB – Special Authority see SA1744 below – Retail pharmacy

Inj 150 mg prefilled syringe	450.00	1	✔	**Xolair**
Inj 150 mg vial	450.00	1	✔	**Xolair**

➽SA1744 Special Authority for Subsidy

Initial application — (severe asthma) only from a respiratory specialist or clinical immunologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 Patient must be aged 6 years or older; and
2 Patient has a diagnosis of severe asthma; and
3 Past or current evidence of atopy, documented by skin prick testing or RAST; and
4 Total serum human immunoglobulin E (IgE) between 76 IU/mL and 1300 IU/ml at baseline; and
5 Proven adherence with optimal inhaled therapy including high dose inhaled corticosteroid (budesonide 1,600 mcg per day or fluticasone propionate 1,000 mcg per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 mcg bd or eformoterol 12 mcg bd) for at least 12 months, unless contraindicated or not tolerated; and
6 Either:
   6.1 Patient has received courses of systemic corticosteroids equivalent to at least 28 days treatment in the past

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

continued…

12 months, unless contraindicated or not tolerated; or

6.2 Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral steroids; and

7 Patient has an Asthma Control Test (ACT) score of 10 or less; and

8 Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 26 weeks after the first dose to assess response to treatment.

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

All of the following:

1 Patient must be aged 12 years or older; and

2 Either:

 2.1 Both:

  2.1.1 Patient is symptomatic with Urticaria Activity Score 7 (UAS7) of 20 or above; and

  2.1.2 Patient has a Dermatology life quality index (DLQI) of 10 or greater; or

 2.2 Patient has a Urticaria Control Test (UCT) of 8 or less; and

3 Any of the following:

 3.1 Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and ciclosporin (> 3 mg/kg day) for at least 6 weeks; or

 3.2 Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and at least 3 courses of systemic corticosteroids (> 20 mg prednisone per day for at least 5 days) in the previous 6 months; or

 3.3 Patient has developed significant adverse effects whilst on corticosteroids or ciclosporin; and

4 Either:

 4.1 Treatment to be stopped if inadequate response* following 4 doses; or

 4.2 Complete response* to 6 doses of omalizumab.

Renewal — (severe asthma) only from a clinical immunologist or respiratory specialist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

1 An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and

2 A reduction in the maintenance oral corticosteroid dose or number of exacerbations of at least 50% from baseline.

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

Either:

1 Patient has previously adequately responded* to 6 doses of omalizumab; or

2 Both:

 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 on the next page

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**

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

➽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 relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:
Both:

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 pertuzumab and trastuzumab.

RITUXIMAB – PCT only – Specialist – Special Authority see SA1861 below

Inj 100 mg per 10 ml vial	1,075.50	2	✔	**Mabthera**
Inj 500 mg per 50 ml vial	2,688.30	1	✔	**Mabthera**
Inj 1 mg for ECP	5.64	1 mg	✔	**Baxter**

➽SA1861 Special Authority for Subsidy

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 — (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^2 of body-surface area per week for a total of 4 weeks; and
3 Any of the following:
   3.1 Induction therapy with daily oral or pulse intravenous cyclophosphamide has failed to achieve significant improvement of disease after at least 3 months; or
   3.2 Patient has previously had a cumulative dose of cyclophosphamide > 15 g or a further repeat 3 month induction course of cyclophosphamide would result in a cumulative dose > 15 g; or
   3.3 Cyclophosphamide and methotrexate are contraindicated; or
   3.4 Patient is a female of child-bearing potential; or
   3.5 Patient has a previous history of haemorrhagic cystitis, urological malignancy or haematological malignancy.

Note: Indications marked with * are unapproved indications.

Renewal — (ANCA associated vasculitis) from any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria:
All of the following:

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

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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^2 of body-surface area per week for a total of 4 weeks.

Note: Indications marked with * are unapproved indications.

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

All of the following:

1 The patient has progressive Binet stage A, B or C chronic lymphocytic leukaemia (CLL) requiring treatment; and
2 Any of the following:
  2.1 The patient is rituximab treatment naive; or
  2.2 Either:
    2.2.1 The patient is chemotherapy treatment naive; or
    2.2.2 Both:
      2.2.2.1 The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment; and
      2.2.2.2 The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy; or
  2.3 The patient’s disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; and
3 The patient has good performance status; and
4 Either:
  4.1 The patient does not have chromosome 17p deletion CLL; or
  4.2 Rituximab treatment is to be used in combination with funded venetoclax for relapsed/refractory chronic lymphocytic leukaemia; and
5 Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles; and
6 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration), bendamustine or venetoclax.

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

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

Both:

1 Either:
  1.1 The patient’s disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; or
  1.2 All of the following:
    1.2.1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and
    1.2.2 The patient has had an interval of 36 months or more since commencement of initial rituximab treatment;

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

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and

1.2.3 The patient does not have chromosome 17p deletion CLL; and

1.2.4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustine; and

2 Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles.

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

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

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

2 The patients has responded to the most recent course of rituximab; and

3 The patient has not received rituximab in the previous 6 months.

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

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

2 Either:

2.1 The patient has experienced a severe episode or attack of NMOSD (rapidly progressing symptoms and clinical investigations supportive of a severe attack of NMOSD); or

2.2 All of the following:

2.2.1 The patient has experienced a breakthrough attack of NMOSD; and

2.2.2 The patient is receiving treatment with mycophenolate; and

2.2.3 The patients is receiving treatment with corticosteroids.

Initial application — (Post-transplant) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Both:

1 The patient has B-cell post-transplant lymphoproliferative disorder*; and

2 To be used for a maximum of 8 treatment cycles.

Note: Indications marked with * are unapproved indications.

Renewal — (Post-transplant) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:
All of the following:

1 The patient has had a rituximab treatment-free interval of 12 months or more; and

2 The patient has B-cell post-transplant lymphoproliferative disorder*; and

3 To be used for no more than 6 treatment cycles.

Note: Indications marked with * are unapproved indications.

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

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

2 Either:

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

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2.1 Treatment with corticosteroids and at least one other immunosuppressant for at least a period of 12 months has been ineffective; or

2.2 Both:

2.2.1 Treatment with at least one other immunosuppressant for a period of at least 12 months; and

2.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.

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

1 One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart; and
2 An initial response lasting at least 12 months was demonstrated; and
3 Either:
3.1 The patient has relapsed despite treatment with corticosteroids and at least one other immunosuppressant for a period of at least 12 months; or
3.2 Both:
3.2.1 The patient's myasthenia gravis has relapsed despite treatment with at least one immunosuppressant for a period of at least 12 months; and
3.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.

Initial application — (Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 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/m^2 of body surface area per week for a total of 4 weeks.

Note: Indications marked with * are unapproved indications.

Renewal — (Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS)) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 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/m^2 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; and

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

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2 Treatment with tacrolimus for at least 3 months has been ineffective; and
3 Genetic causes of nephrotic syndrome have been excluded; and
4 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 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/m^2 of body surface area per week for a total of 4 weeks.

Note: Indications marked with * are unapproved indications.

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

1 All of the following:
  1.1 The patient has treatment naive aggressive CD20 positive NHL; and
  1.2 To be used with a multi-agent chemotherapy regimen given with curative intent; and
  1.3 To be used for a maximum of 8 treatment cycles; or
2 Both:
  2.1 The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy; and
  2.2 To be used for a maximum of 6 treatment cycles.

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia

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

1 The patient has had a rituximab treatment-free interval of 12 months or more; and
2 The patient has relapsed refractory/aggressive CD20 positive NHL; and
3 To be used with a multi-agent chemotherapy regimen given with curative intent; and
4 To be used for a maximum of 4 treatment cycles.

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia

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

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

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

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

Initial application — (immune thrombocytopenic purpura (ITP)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:

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

continued…
Both:

1 Either:
  1.1 Patient has immune thrombocytopenic purpura* with a platelet count of less than or equal to 20,000 platelets per microlitre; or
  1.2 Patient has immune thrombocytopenic purpura* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding; and
2 Any of the following:
  2.1 Treatment with steroids and splenectomy have been ineffective; or
  2.2 Treatment with steroids has been ineffective and splenectomy is an absolute contraindication; or
  2.3 Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy).

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/m^2 weekly for 4 weeks) is now planned; or
2 All of the following:
  2.1 Patient was previously treated with rituximab for immune thrombocytopenic purpura*; and
  2.2 An initial response lasting at least 12 months was demonstrated; and
  2.3 Patient now requires repeat treatment.

Note: Indications marked with * are unapproved indications.

Initial application — (indolent, low-grade lymphomas or hairy cell leukaemia*) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:
Either:

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

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

Renewal — (indolent, low-grade lymphomas or hairy cell leukaemia*) from any relevant practitioner. Approvals valid for 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.

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

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

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

Note: Indications marked with * are unapproved indications.

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

Note: Indications marked with * are unapproved indications.

Initial application — (rheumatoid arthritis - TNF inhibitors contraindicated) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

1 Treatment with a Tumour Necrosis Factor alpha inhibitor is contraindicated; and
2 Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses); and
5 Any of the following:
  5.1 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of ciclosporin; or
  5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or
  5.3 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate; and
6 Either:
  6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or
  6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
7 Either:
  7.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
  7.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months; and
8 Either:

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

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- 8.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
- 8.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and

9 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Initial application — (rheumatoid arthritis - prior TNF inhibitor use) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:

1 Both:
- 1.1 The patient has had an initial community Special Authority approval for at least one of etanercept and/or adalimumab for rheumatoid arthritis; and
- 1.2 Either:
  - 1.2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
  - 1.2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept for rheumatoid arthritis; and

2 Either:
- 2.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
- 2.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and

3 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

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

1 Any of the following:
- 1.1 At 4 months following the initial course of rituximab infusions the patient had between a 30% and 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 1.2 At 4 months following the second course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 1.3 At 4 months following the third and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and

2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and

3 Either:
- 3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
- 3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and

4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

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

1 Either:
- 1.1 At 4 months following the initial course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 1.2 At 4 months following the second and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physiciann; 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

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

continued…

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.

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.

Note: Indications marked with * are unapproved indications.

Renewal — (severe cold haemagglutinin disease (CHAD)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 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/m^2 weekly for 4 weeks) is now planned; or
2 All of the following:
   2.1 Patient was previously treated with rituximab for severe cold haemagglutinin disease*; and
   2.2 An initial response lasting at least 12 months was demonstrated; and
   2.3 Patient now requires repeat treatment.

Note: Indications marked with * are unapproved indications.

Initial application — (thrombotic thrombocytopenic purpura (TTP)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 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.

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
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.

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

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

Note: Indications marked with * are unapproved indications.

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

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

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

Note: Indications marked with * are unapproved indications.

Initial application — (warm autoimmune haemolytic anaemia (warm AIHA)) only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 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.

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/m^2 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.

SECUKINUMAB – Special Authority see SA1754 below – Retail pharmacy

Inj 150 mg per ml, 1 ml prefilled syringe	1,599.00	2	✔	**Cosentyx**

➽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

continued…

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

continued…

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 below – Retail pharmacy

Note: Siltuximab is to be administered at doses no greater than 11 mg/kg every 3 weeks.

Inj 100 mg vial	770.57	1	✔	**Sylvant**
Inj 400 mg vial	3,082.33	1	✔	**Sylvant**

➽SA1596 Special Authority for Subsidy

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

All of the following:

1 Patient has severe HHV-8 negative idiopathic multicentric Castleman's Disease; and

2 Treatment with an adequate trial of corticosteroids has proven ineffective; and

3 Siltuximab is to be administered at doses no greater than 11 mg/kg every 3 weeks.

Renewal only from a haematologist or rheumatologist. Approvals valid for 12 months where the treatment remains appropriate and the patient has sustained improvement in inflammatory markers and functional status.

TOCILIZUMAB – PCT only – Special Authority see SA1858 below

Inj 20 mg per ml, 4 ml vial	220.00	1	✔	**Actemra**
Inj 20 mg per ml, 10 ml vial	550.00	1	✔	**Actemra**
Inj 20 mg per ml, 20 ml vial	1,100.00	1	✔	**Actemra**
Inj 1 mg for ECP	2.85	1 mg	✔	**Baxter**

➽SA1858 Special Authority for Subsidy

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

Either:

1 All of the following:

1.1 The patient is enrolled in the Children's Oncology Group AALL1731 trial; and

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

continued…

- 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 (if less than 30kg, maximum of 12 mg/kg); or

2 All of the following:

- 2.1 The patient is enrolled in the Malaghan Institute of Medical Research 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 Either:

- 2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
- 2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis; and

3 Either:

- 3.1 The patient is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor; or
- 3.2 Both:
  - 3.2.1 The patient has been started on rituximab for rheumatoid arthritis in a 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

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

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4 Either:
 4.1 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of ciclosporin alone or in combination with another agent; or
 4.2 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of leflunomide alone or in combination with another agent; and

5 Either:
 5.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints; or
 5.2 Patient has persistent symptoms of poorly controlled and active disease in at least four active joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and

6 Either:
 6.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
 6.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Initial application — (systemic juvenile idiopathic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 Patient diagnosed with systemic juvenile idiopathic arthritis; and
2 Patient has tried and not responded to a reasonable trial of all of the following, either alone or in combination: oral or parenteral methotrexate; non-steroidal anti-inflammatory drugs (NSAIDs); and systemic corticosteroids.

Initial application — (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 Both:
 1.1 Either:
  1.1.1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for adult-onset Still's disease (AOSD); or
  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 Either:
  1.2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
  1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for AOSD; or

2 All of the following:
 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and
 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal antiinflammatory drugs (NSAIDs) and methotrexate; and
 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

Initial application — (polyarticular juvenile idiopathic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

1 Both:
 1.1 The patient has had an initial Special Authority approval for both etanercept and adalimumab for 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

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

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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/m^2 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 Either:
      - 2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; 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:
Either:

1 Following 6 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician.

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

1 Following up to 6 months' initial treatment, the patient has achieved at least an American College of Rheumatology paediatric 30% improvement criteria (ACR Pedi 30) response from baseline; or
2 On subsequent reapplications, the patient demonstrates at least a continuing ACR Pedi 30 response from baseline.

Renewal — (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months where the patient has a sustained improvement in inflammatory markers and functional status.

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

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

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

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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 mg	✔	**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 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

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

continued…

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); and
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.

Note: * For patients with relapsed HER-2 positive disease who have previously received adjuvant trastuzumab for early breast cancer.

TRASTUZUMAB EMTANSINE – PCT only – Specialist – Special Authority see SA1871 below

	Subsidy	Per	Fully Subsidised	Brand
Inj 100 mg vial	2,320.00	1	✔	**Kadcyla**
Inj 160 mg vial	3,712.00	1	✔	**Kadcyla**
Inj 1 mg for ECP	23.20	1 mg	✔	**Baxter**

➽SA1871 Special Authority for Subsidy

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

All of the following:

1 Patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
2 Patient has previously received trastuzumab and chemotherapy, separately or in combination; and
3 Either:
   3.1 The patient has received prior therapy for metastatic disease*; or
   3.2 The patient developed disease recurrence during, or within six months of completing adjuvant therapy*; and
4 Patient has a good performance status (ECOG 0-1); and
5 Either:
   5.1 Patient does not have symptomatic brain metastases; or
   5.2 Patient has brain metastases and has received prior local CNS therapy; and
6 Treatment to be discontinued at disease progression.

Renewal 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:

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

continued…
Both:
1 The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab emtansine; and
2 Treatment to be discontinued at disease progression.

Note: *Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

Programmed Cell Death-1 (PD-1) Inhibitors

NIVOLUMAB – PCT only – Specialist – Special Authority see SA1863 below

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised	Brand or Generic Manufacturer
Inj 10 mg per ml, 4 ml vial	1,051.98	1	✔	**Opdivo**
Inj 10 mg per ml, 10 ml vial	2,629.96	1	✔	**Opdivo**
Inj 1 mg for ECP	27.62	1 mg	✔	**Baxter**

➽SA1863 Special Authority for Subsidy

Initial application — (unresectable or metastatic melanoma) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:
1 Patient has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
2 Patient has measurable disease as defined by RECIST version 1.1; 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 no greater than the equivalent of 3 mg/kg every 2 weeks; 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 or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:
Either:
1 All of the following:
 1.1 Any of the following:
  1.1.1 Patient's disease has had a complete response to treatment according to RECIST criteria (see Note); or
  1.1.2 Patient's disease has had a partial response to treatment according to RECIST criteria (see Note); or
  1.1.3 Patient has stable disease according to RECIST criteria (see Note); and
 1.2 Either:
  1.2.1 Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; or
  1.2.2 Both:
   1.2.2.1 Patient has measurable disease as defined by RECIST version 1.1; and
   1.2.2.2 Patient's disease has not progressed clinically and disease response to treatment has been clearly documented in patient notes; and
 1.3 No evidence of progressive disease according to RECIST criteria (see Note); and
 1.4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; and
 1.5 Nivolumab will be used at a maximum dose of no greater than the equivalent of 3 mg/kg every 2 weeks; or

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

continued…

2 All of the following:
   2.1 Patient has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression; and
   2.2 Patient has signs of disease progression; and
   2.3 Disease has not progressed during previous treatment with nivolumab; and
   2.4 Nivolumab will be used at a maximum dose of no greater than the equivalent of 3 mg/kg every 2 weeks.

Notes: Baseline assessment and 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. Measurable disease includes by CT or MRI imaging or caliper measurement by clinical exam. Target lesion measurements should be assessed using 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.
- 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 – Specialist – Special Authority see SA1862 below

Inj 25 mg per ml, 4 ml vial	4,680.00	1	✔	**Keytruda**
Inj 1 mg for ECP	49.14	1 mg	✔	**Baxter**

➽SA1862 Special Authority for Subsidy

Initial application — (unresectable or metastatic melanoma) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:

1 Patient has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
2 Patient has measurable disease as defined by RECIST version 1.1; 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 no greater than the equivalent of 2 mg/kg every 3 weeks; 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 or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:
Either:

continued…

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

continued…

1 All of the following:
   1.1 Any of the following:
      1.1.1 Patient’s disease has had a complete response to treatment according to RECIST criteria (see Note); or
      1.1.2 Patient’s disease has had a partial response to treatment according to RECIST criteria (see Note); or
      1.1.3 Patient has stable disease according to RECIST criteria (see Note); and
   1.2 Either:
      1.2.1 Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; or
      1.2.2 Both:
         1.2.2.1 Patient has measurable disease as defined by RECIST version 1.1; and
         1.2.2.2 Patient’s disease has not progressed clinically and disease response to treatment has been clearly documented in patient notes; and
   1.3 No evidence of progressive disease according to RECIST criteria (see Note); and
   1.4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; and
   1.5 Pembrolizumab will be used at a maximum dose of no greater than the equivalent of 2 mg/kg every 3 weeks; or

2 All of the following:
   2.1 Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression; and
   2.2 Patient has signs of disease progression; and
   2.3 Disease has not progressed during previous treatment with pembrolizumab; and
   2.4 Pembrolizumab will be used at a maximum dose of no greater than the equivalent of 2 mg/kg every 3 weeks.

Notes: Baseline assessment and 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. Measurable disease includes by CT or MRI imaging or caliper measurement by clinical exam. Target lesion measurements should be assessed using 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.
- 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	177.81	50	✔	**Neoral**
Oral liq 100 mg per ml	198.13	50 ml OP	✔	**Neoral**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
EVEROLIMUS – Special Authority see SA1491 below – Retail pharmacy				
Wastage claimable				
Tab 10 mg	6,512.29	30	✔	**Afinitor**
Tab 5 mg	4,555.76	30	✔	**Afinitor**

➽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

TACROLIMUS – Special Authority see SA1745 below – Retail pharmacy				
Cap 0.5 mg	49.60	100	✔	**Tacrolimus Sandoz**
Cap 0.75 mg	99.30	100	✔	**Tacrolimus Sandoz**
Cap 1 mg	84.30	100	✔	**Tacrolimus Sandoz**
Cap 5 mg	248.20	50	✔	**Tacrolimus 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

▲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

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.

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

Maintenance kit - 6 vials 120 mcg freeze dried venom, with diluent	285.00	1 OP	✔	**Venomil** S29
Treatment kit - 1 vial 550 mcg freeze dried venom, 1 diluent 9 ml, 3 diluent 1.8 ml	305.00	1 OP	✔	**Albey**
Treatment kit - 1 vial 550 mcg freeze dried venom, with diluent	305.00	1 OP	✔	**Hymenoptera** S29

WASP VENOM ALLERGY TREATMENT – Special Authority see SA1367 above – Retail pharmacy

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 freeze dried venom, with diluent	305.00	1 OP	✔	**Hymenoptera** S29
Treatment kit (Yellow jacket venom) - 1 vial 550 mcg freeze dried vespula venom, 1 diluent 9 ml, 1 diluent 1.8 ml	305.00	1 OP	✔	**Albey**
Treatment kit (Yellow jacket venom) - 6 vials 120 mcg freeze dried venom, with diluent	305.00	1 OP	✔	**Venomil** S29

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

Antihistamines

CETIRIZINE HYDROCHLORIDE				
❋ Tab 10 mg	1.12	100	✔	**Zista**
❋ Oral liq 1 mg per ml	2.99	200 ml	✔	**Histaclear**
CHLORPHENIRAMINE MALEATE				
❋ Oral liq 2 mg per 5 ml	9.37	500 ml	✔	**Histafen**
DEXTROCHLORPHENIRAMINE MALEATE				
❋ Tab 2 mg	2.02	40		
	(8.40)			Polaramine
	1.01	20		
	(5.99)			Polaramine
❋ Oral liq 2 mg per 5 ml	1.77	100 ml		
	(10.29)			Polaramine
FEXOFENADINE HYDROCHLORIDE				
❋ Tab 60 mg	4.34	20		
	(8.23)			Telfast
❋ Tab 120 mg	4.74	10		
	(8.23)			Telfast
	14.22	30		
	(26.44)			Telfast
LORATADINE				
❋ Tab 10 mg	1.69	100	✔	**Lorafix**
Lorafix to be Sole Supply on 1 February 2020				
❋ Oral liq 1 mg per ml	2.15	120 ml	✔	**Lorfast**
PROMETHAZINE HYDROCHLORIDE				
❋ Tab 10 mg	1.68	50	✔	**Allersoothe**
❋ Tab 25 mg	1.89	50	✔	**Allersoothe**
❋ Oral liq 1 mg per 1 ml	2.69	100 ml	✔	**Allersoothe**
❋ Inj 25 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	15.54	5	✔	**Hospira**

Inhaled Corticosteroids

BECLOMETHASONE DIPROPIONATE				
Aerosol inhaler, 50 mcg per dose	9.30	200 dose OP	✔	**Qvar**
Aerosol inhaler, 50 mcg per dose CFC-free	8.54	200 dose OP	✔	**Beclazone 50**
Aerosol inhaler, 100 mcg per dose	15.50	200 dose OP	✔	**Qvar**
Aerosol inhaler, 100 mcg per dose CFC-free	12.50	200 dose OP	✔	**Beclazone 100**
Aerosol inhaler, 250 mcg per dose CFC-free	22.67	200 dose OP	✔	**Beclazone 250**
BUDESONIDE				
Powder for inhalation, 100 mcg per dose	17.00	200 dose OP	✔	**Pulmicort Turbuhaler**
Powder for inhalation, 200 mcg per dose	19.00	200 dose OP	✔	**Pulmicort Turbuhaler**
Powder for inhalation, 400 mcg per dose	32.00	200 dose OP	✔	**Pulmicort Turbuhaler**

▲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
FLUTICASONE				
Aerosol inhaler, 50 mcg per dose	4.68	120 dose OP	✔	**Floair**
Aerosol inhaler, 50 mcg per dose CFC-free	7.50	120 dose OP	✔	**Flixotide**
Powder for inhalation, 50 mcg per dose	7.50	60 dose OP	✔	**Flixotide Accuhaler**
Powder for inhalation, 100 mcg per dose	7.50	60 dose OP	✔	**Flixotide Accuhaler**
Aerosol inhaler, 125 mcg per dose	7.22	120 dose OP	✔	**Floair**
Aerosol inhaler, 125 mcg per dose CFC-free	13.60	120 dose OP	✔	**Flixotide**
Aerosol inhaler, 250 mcg per dose	10.18	120 dose OP	✔	**Floair**
Aerosol inhaler, 250 mcg per dose CFC-free	27.20	120 dose OP	✔	**Flixotide**
Powder for inhalation, 250 mcg per dose	13.60	60 dose OP	✔	**Flixotide Accuhaler**

Inhaled Long-acting Beta-adrenoceptor Agonists

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
EFORMOTEROL FUMARATE				
Powder for inhalation, 12 mcg per dose, and monodose device	20.64 (35.80)	60 dose		Foradil
EFORMOTEROL FUMARATE DIHYDRATE				
Powder for inhalation 4.5 mcg per dose, breath activated (equivalent to eformoterol fumarate 6 mcg metered dose)	10.32 (16.90)	60 dose OP		Oxis Turbuhaler
INDACATEROL				
Powder for inhalation 150 mcg	61.00	30 dose OP	✔	**Onbrez Breezhaler**
Powder for inhalation 300 mcg	61.00	30 dose OP	✔	**Onbrez Breezhaler**
SALMETEROL				
Aerosol inhaler CFC-free, 25 mcg per dose	25.00	120 dose OP	✔	**Serevent**
Aerosol inhaler 25 mcg per dose	9.90	120 dose OP	✔	**Meterol**
Powder for inhalation, 50 mcg per dose, breath activated	25.00	60 dose OP	✔	**Serevent Accuhaler**

Inhaled Corticosteroids with Long-Acting Beta-Adrenoceptor Agonists

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
BUDESONIDE WITH EFORMOTEROL				
Aerosol inhaler 100 mcg with eformoterol fumarate 6 mcg	18.23	120 dose OP	✔	**Vannair**
Powder for inhalation 100 mcg with eformoterol fumarate 6 mcg	33.74	120 dose OP	✔	**Symbicort Turbuhaler 100/6**
Aerosol inhaler 200 mcg with eformoterol fumarate 6 mcg	21.40	120 dose OP	✔	**Vannair**
Powder for inhalation 200 mcg with eformoterol fumarate 6 mcg	44.08	120 dose OP	✔	**Symbicort Turbuhaler 200/6**
Powder for inhalation 400 mcg with eformoterol fumarate 12 mcg – No more than 2 dose per day	44.08	60 dose OP	✔	**Symbicort Turbuhaler 400/12**
FLUTICASONE FUROATE WITH VILANTEROL				
Powder for inhalation 100 mcg with vilanterol 25 mcg	44.08	30 dose OP	✔	**Breo Ellipta**
FLUTICASONE WITH SALMETEROL				
Aerosol inhaler 50 mcg with salmeterol 25 mcg	14.58	120 dose OP	✔	**RexAir**
	33.74		✔	**Seretide**
Aerosol inhaler 125 mcg with salmeterol 25 mcg	16.83	120 dose OP	✔	**RexAir**
	44.08		✔	**Seretide**
Powder for inhalation 100 mcg with salmeterol 50 mcg – No more than 2 dose per day	33.74	60 dose OP	✔	**Seretide Accuhaler**
Powder for inhalation 250 mcg with salmeterol 50 mcg – No more than 2 dose per day	44.08	60 dose OP	✔	**Seretide Accuhaler**

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

Beta-Adrenoceptor Agonists

SALBUTAMOL				
Oral liq 400 mcg per ml	20.00	150 ml	✔	**Ventolin**
Infusion 1 mg per ml, 5 ml	118.38	10	✔	**Ventolin**
Inj 500 mcg per ml, 1 ml – Up to 5 inj available on a PSO	53.00	5	✔	**Ventolin**

Inhaled Beta-Adrenoceptor Agonists

SALBUTAMOL				
Aerosol inhaler, 100 mcg per dose CFC free – Up to 1000 dose available on a PSO	3.80	200 dose OP	✔	**Respigen**
			✔	**SalAir**
	(6.00)			Ventolin
Nebuliser soln, 1 mg per ml, 2.5 ml ampoule – Up to 30 neb available on a PSO	3.93	20	✔	**Asthalin**
Nebuliser soln, 2 mg per ml, 2.5 ml ampoule – Up to 30 neb available on a PSO	4.03	20	✔	**Asthalin**
TERBUTALINE SULPHATE				
Powder for inhalation, 250 mcg per dose, breath activated	27.30	200 dose OP	✔	**Bricanyl Turbuhaler**

Anticholinergic Agents

IPRATROPIUM BROMIDE				
Aerosol inhaler, 20 mcg per dose CFC-free – Up to 400 dose available on a PSO	16.20	200 dose OP	✔	**Atrovent**
Nebuliser soln, 250 mcg per ml, 1 ml ampoule – Up to 40 neb available on a PSO	3.35	20	✔	**Univent**
Nebuliser soln, 250 mcg per ml, 2 ml ampoule – Up to 40 neb available on a PSO	11.73	20	✔	**Univent**

Inhaled Beta-Adrenoceptor Agonists with Anticholinergic Agents

SALBUTAMOL WITH IPRATROPIUM BROMIDE				
Aerosol inhaler, 100 mcg with ipratropium bromide, 20 mcg per dose CFC-free	12.19	200 dose OP	✔	**Duolin HFA**
Nebuliser soln, 2.5 mg with ipratropium bromide 0.5 mg per vial, 2.5 ml ampoule – Up to 20 neb available on a PSO	5.20	20	✔	**Duolin**

Long-Acting Muscarinic Antagonists

GLYCOPYRRONIUM – Subsidy by endorsement

a) Inhaled glycopyrronium treatment will not be subsidised if patient is also receiving treatment with subsidised tiotropium or umeclidinium.
b) Glycopyrronium powder for inhalation 50 mcg per dose is subsidised only for patients who have been diagnosed as having COPD using spirometry, and the prescription is endorsed accordingly.

Powder for inhalation 50 mcg per dose	61.00	30 dose OP	✔	**Seebri Breezhaler**

▲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

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 INDACATEROL – Special Authority see SA1584 above – Retail pharmacy

Powder for Inhalation 50 mcg with indacaterol 110 mcg	81.00	30 dose OP	✔	**Ultibro Breezhaler**

TIOTROPIUM BROMIDE WITH OLODATEROL – Special Authority see SA1584 above – Retail pharmacy

Soln for inhalation 2.5 mcg with olodaterol 2.5 mcg	81.00	60 dose OP	✔	**Spiolto Respimat**

UMECLIDINIUM WITH VILANTEROL – Special Authority see SA1584 above – Retail pharmacy

Powder for inhalation 62.5 mcg with vilanterol 25 mcg	77.00	30 dose OP	✔	**Anoro Ellipta**

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

continued…

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

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 SA1864 below
Note: Pirfenidone is not subsidised in combination with subsidised nintedanib.

Tab 801 mg	3,645.00	90	✔	**Esbriet**
Cap 267 mg – Wastage claimable	3,645.00	270	✔	**Esbriet**

➽SA1864 Special Authority for Subsidy
Initial application — (idiopathic pulmonary fibrosis) only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:

1 Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist; and
2 Forced vital capacity is between 50% and 90% predicted; and
3 Pirfenidone is to be discontinued at disease progression (See Note); and
4 Pirfenidone is not to be used in combination with subsidised nintedanib; and
5 Any of the following:
  5.1 The patient has not previously received treatment with nintedanib; or
  5.2 Patient has previously received nintedanib, but discontinued nintedanib within 12 weeks due to intolerance; or
  5.3 Patient has previously received nintedanib, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with nintedanib).

Renewal — (idiopathic pulmonary fibrosis) only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:

1 Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and
2 Pirfenidone is not to be used in combination with subsidised nintedanib; and
3 Pirfenidone is to be discontinued at disease progression (See Note).

Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

Leukotriene Receptor Antagonists

MONTELUKAST

❋ Tab 4 mg	4.25	28	✔	**Montelukast Mylan**
❋ Tab 5 mg	4.25	28	✔	**Montelukast Mylan**
❋ Tab 10 mg	3.95	28	✔	**Montelukast Mylan**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or 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 available on a PSO	124.37	5	✔	**DBL Aminophylline**
THEOPHYLLINE				
❋ Tab long-acting 250 mg	23.02	100	✔	**Nuelin-SR**
❋ Oral liq 80 mg per 15 ml	16.60	500 ml	✔	**Nuelin**

Mucolytics

DORNASE ALFA – Special Authority see SA0611 below – 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 Advisory Panel

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

The Co-ordinator, Cystic Fibrosis Advisory Panel	Phone: (04) 460 4990
PHARMAC, PO Box 10 254	Facsimile: (04) 916 7571
Wellington	Email: CFPanel@pharmac.govt.nz

Prescriptions for patients approved for treatment must be written by respiratory physicians or paediatricians who have experience and expertise in treating cystic fibrosis.

SODIUM CHLORIDE				
Not funded for use as a nasal drop.				
Soln 7%	24.50	90 ml OP	✔	**Biomed**

Nasal Preparations

Allergy Prophylactics

BUDESONIDE				
Metered aqueous nasal spray, 50 mcg per dose	2.59	200 dose OP	✔	**SteroClear**
Metered aqueous nasal spray, 100 mcg per dose	2.87	200 dose OP	✔	**SteroClear**
FLUTICASONE PROPIONATE				
Metered aqueous nasal spray, 50 mcg per dose	1.98	120 dose OP	✔	**Flixonase Hayfever & Allergy**
IPRATROPIUM BROMIDE				
Aqueous nasal spray, 0.03%	4.61	15 ml OP	✔	**Univent**

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

Respiratory Devices

MASK FOR SPACER DEVICE

a) Up to 50 dev available on a PSO
b) Only on a PSO
c) Only for children aged six years and under

Small	2.20	1	✔	**e-chamber Mask**

PEAK FLOW METER

a) Up to 25 dev available on a PSO
b) Only on a PSO

Low range	9.54	1	✔	**Mini-Wright AFS Low Range**
Normal range	9.54	1	✔	**Mini-Wright Standard**

SPACER DEVICE

a) Up to 50 dev available on a PSO
b) Only on a PSO

220 ml (single patient)	2.95	1	✔	**e-chamber Turbo**
510 ml (single patient)	5.12	1	✔	**e-chamber La Grande**
800 ml	6.50	1	✔	**Volumatic**

Respiratory Stimulants

CAFFEINE CITRATE

Oral liq 20 mg per ml (10 mg base per ml)	15.10	25 ml OP	✔	**Biomed**

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

Ear Preparations

ACETIC ACID WITH 1, 2- PROPANEDIOL DIACETATE AND BENZETHONIUM				
For Vosol ear drops with hydrocortisone powder refer Standard Formulae, page 237				
Ear drops 2% with 1, 2-Propanediol diacetate 3% and benzethonium chloride 0.02%	6.97	35 ml OP	✔	**Vosol**
FLUMETASONE PIVALATE				
Ear drops 0.02% with clioquinol 1%	4.46	7.5 ml OP	✔	**Locacorten-Viaform ED's**
			✔	**Locorten-Vioform**
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCIN AND NYSTATIN				
Ear drops 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 mcg per g	5.16	7.5 ml OP	✔	**Kenacomb**

Ear/Eye Preparations

DEXAMETHASONE WITH FRAMYCETIN AND GRAMICIDIN				
Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml	4.50	8 ml OP		
	(9.27)			Sofradex
FRAMYCETIN SULPHATE				
Ear/Eye drops 0.5%	4.13	8 ml OP		
	(8.65)			Soframycin

Eye Preparations

Eye preparations are only funded for use in the eye, unless explicitly stated otherwise.

Anti-Infective Preparations

ACICLOVIR				
✻ Eye oint 3%	14.92	4.5 g OP	✔	**ViruPOS**
CHLORAMPHENICOL				
Eye oint 1%	1.55	5 g OP	✔	**Devatis**
	2.48	4 g OP	✔	**Chlorsig**
Eye drops 0.5%	1.54	10 ml OP	✔	**<u>Chlorafast</u>**
Funded for use in the ear*. Indications marked with * are unapproved indications.				
(Chlorsig Eye oint 1% to be delisted 1 May 2020)				
CIPROFLOXACIN				
Eye drops 0.3% – Subsidy by endorsement	9.99	5 ml OP	✔	**<u>Ciprofloxacin Teva</u>**
When prescribed for the treatment of bacterial keratitis or severe bacterial conjunctivitis resistant to chloramphenicol; or for the second line treatment of chronic suppurative otitis media (CSOM)*; and the prescription is endorsed accordingly. Note: Indication marked with a * is an unapproved indication.				
GENTAMICIN SULPHATE				
Eye drops 0.3%	11.40	5 ml OP	✔	**Genoptic**
PROPAMIDINE ISETHIONATE				
✻ Eye drops 0.1%	2.97	10 ml OP		
	(14.55)			Brolene
SODIUM FUSIDATE [FUSIDIC ACID]				
Eye drops 1%	5.29	5 g OP	✔	**Fucithalmic**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
TOBRAMYCIN				
Eye oint 0.3%	10.45	3.5 g OP	✔	**Tobrex**
Eye drops 0.3%	11.48	5 ml OP	✔	**Tobrex**

Corticosteroids and Other Anti-Inflammatory Preparations

DEXAMETHASONE				
❋ Eye oint 0.1%	5.86	3.5 g OP	✔	**Maxidex**
❋ Eye drops 0.1%	4.50	5 ml OP	✔	**Maxidex**
Ocular implant 700 mcg – Special Authority see SA1680 below – Retail pharmacy	1,444.50	1	✔	**Ozurdex**

➽SA1680 Special Authority for Subsidy

Initial application — (Diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 Patient has diabetic macular oedema with pseudophakic lens; and
2 Patient has reduced visual acuity of between 6/9 - 6/48 with functional awareness of reduction in vision; and
3 Either:
   3.1 Patient's disease has progressed despite 3 injections with bevacizumab; or
   3.2 Patient is unsuitable or contraindicated to treatment with anti-VEGF agents; and
4 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

Renewal — (Diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

1 Patient's vision is stable or has improved (prescriber determined); and
2 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

Initial application — (Women of child bearing age with diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 Patient has diabetic macular oedema; and
2 Patient has reduced visual acuity of between 6/9 - 6/48 with functional awareness of reduction in vision; and
3 Patient is of child bearing potential and has not yet completed a family; and
4 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

Renewal — (Women of child bearing age with diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 Patient's vision is stable or has improved (prescriber determined); and
2 Patient is of child bearing potential and has not yet completed a family; and
3 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

DEXAMETHASONE WITH NEOMYCIN SULPHATE AND POLYMYXIN B SULPHATE				
❋ Eye oint 0.1% with neomycin sulphate 0.35% and polymyxin b sulphate 6,000 u per g	5.39	3.5 g OP	✔	**Maxitrol**
❋ Eye drops 0.1% with neomycin sulphate 0.35% and polymyxin b sulphate 6,000 u per ml	4.50	5 ml OP	✔	**Maxitrol**
DICLOFENAC SODIUM				
Eye drops 0.1%	13.80	5 ml OP	✔	**Voltaren Ophtha**

▲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
FLUOROMETHOLONE				
✻ Eye drops 0.1%	3.09	5 ml OP	✔	**FML**
	5.20		✔	**Flucon**
LEVOCABASTINE				
Eye drops 0.5 mg per ml	8.71	4 ml OP		
	(10.34)			Livostin
LODOXAMIDE				
Eye drops 0.1%	8.71	10 ml OP	✔	**Lomide**
PREDNISOLONE ACETATE				
Eye drops 1%	3.93	10 ml OP	✔	**Prednisolone-AFT**
	7.00	5 ml OP	✔	**Pred Forte**
PREDNISOLONE SODIUM PHOSPHATE – Special Authority see SA1715 below – Retail pharmacy				
Eye drops 0.5%, single dose (preservative free)	38.50	20 dose	✔	**Minims Prednisolone**

➽SA1715 **Special Authority for Subsidy**

Initial application only from an ophthalmologist or optometrist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1. Patient has severe inflammation; and
2. Patient has a confirmed allergic reaction to preservative in eye drops.

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

SODIUM CROMOGLICATE				
Eye drops 2%	1.79	5 ml OP	✔	**Cromal** S29
			✔	**Rexacrom**

Glaucoma Preparations - Beta Blockers

BETAXOLOL				
✻ Eye drops 0.25%	11.80	5 ml OP	✔	**Betoptic S**
✻ Eye drops 0.5%	7.50	5 ml OP	✔	**Betoptic**
TIMOLOL				
✻ Eye drops 0.25%	1.43	5 ml OP	✔	**Arrow-Timolol**
✻ Eye drops 0.5%	1.43	5 ml OP	✔	**Arrow-Timolol**
✻ Eye drops 0.5%, gel forming	3.78	2.5 ml OP	✔	**Timoptol XE**

Glaucoma Preparations - Carbonic Anhydrase Inhibitors

ACETAZOLAMIDE				
✻ Tab 250 mg	17.03	100	✔	**Diamox**
BRINZOLAMIDE				
✻ Eye drops 1%	9.77	5 ml OP	✔	**Azopt**
DORZOLAMIDE HYDROCHLORIDE				
✻ Eye drops 2%	9.77	5 ml OP		
	(17.44)			Trusopt
DORZOLAMIDE WITH TIMOLOL				
✻ Eye drops 2% with timolol 0.5%	2.87	5 ml OP	✔	**Dortimopt**

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

Glaucoma Preparations - Prostaglandin Analogues

BIMATOPROST				
❋ Eye drops 0.03%	3.30	3 ml OP	✔	**Bimatoprost Multichem**
LATANOPROST				
❋ Eye drops 0.005%	1.57	2.5 ml OP	✔	**Teva**
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	✔	**Arrow-Brimonidine**
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%	5.35	15 ml OP	✔	**Isopto Carpine**
❋ Eye drops 4%	7.99	15 ml OP	✔	**Isopto Carpine**
Subsidised for oral use pursuant to the Standard Formulae.				
❋ 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%	17.36	15 ml OP	✔	**Atropt**
CYCLOPENTOLATE HYDROCHLORIDE				
❋ Eye drops 1%	8.76	15 ml OP	✔	**Cyclogyl**
TROPICAMIDE				
❋ Eye drops 0.5%	7.15	15 ml OP	✔	**Mydriacyl**
❋ Eye drops 1%	8.66	15 ml OP	✔	**Mydriacyl**

Preparations for Tear Deficiency

For acetylcysteine eye drops refer Standard Formulae, page 237

HYPROMELLOSE				
❋ Eye drops 0.5%	2.00	15 ml OP		
	(3.92)			Methopt

▲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
HYPROMELLOSE WITH DEXTRAN				
❋ Eye drops 0.3% with dextran 0.1%	2.30	15 ml OP	✔	**Poly-Tears**
POLYVINYL ALCOHOL				
❋ Eye drops 3%	3.68	15 ml OP	✔	**Vistil Forte**
(Vistil Forte Eye drops 3% to be delisted 1 March 2020)				

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.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
CARBOMER – Special Authority see SA1388 above – Retail pharmacy				
Ophthalmic gel 0.3%, 0.5 g	8.25	30	✔	**Poly-Gel**
MACROGOL 400 AND PROPYLENE GLYCOL – Special Authority see SA1388 above – Retail pharmacy				
Eye drops 0.4% and propylene glycol 0.3%, 0.4 ml	4.30	24	✔	**Systane Unit Dose**
SODIUM HYALURONATE [HYALURONIC ACID] – Special Authority see SA1388 above – Retail pharmacy				
Eye drops 1 mg per ml	22.00	10 ml OP	✔	**Hylo-Fresh**
Hylo-Fresh has a 6 month expiry after opening. The Pharmacy Procedures Manual restriction allowing one bottle per month is not relevant and therefore only the prescribed dosage to the nearest OP may be claimed.				

Other Eye Preparations

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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 WOOL FAT				
❋ Eye oint 3% with wool fat 3%	3.63	3.5 g OP	✔	**Poly-Visc**
RETINOL PALMITATE				
Eye oint 138 mcg per g	3.80	5 g OP	✔	**VitA-POS**

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

Various

PHARMACY SERVICES

May only be claimed once per patient.

❋ Brand switch fee	4.50	1 fee	✔	**BSF Flecainide Teva**

The Pharmacode for BSF Flecainide Teva is 2577003 - see also page 47

(BSF Flecainide Teva Brand switch fee to be delisted 1 March 2020)

Agents Used in the Treatment of Poisonings

Antidotes

ACETYLCYSTEINE – Retail pharmacy-Specialist

Inj 200 mg per ml, 10 ml ampoule	58.76	10	✔	**DBL Acetylcysteine**
			✔	**Martindale Pharma** S29

NALOXONE HYDROCHLORIDE

a) Up to 5 inj available on a PSO

b) Only on a PSO

❋ Inj 400 mcg per ml, 1 ml ampoule	22.60	5	✔	**DBL Naloxone Hydrochloride**

Removal and Elimination

CHARCOAL

❋ Oral liq 50 g per 250 ml	43.50	250 ml OP	✔	**Carbosorb-X**

a) Up to 250 ml available on a PSO

b) Only on a PSO

DEFERASIROX – Special Authority see SA1492 below – Retail pharmacy

Wastage claimable

Tab 125 mg dispersible	276.00	28	✔	**Exjade**
Tab 250 mg dispersible	552.00	28	✔	**Exjade**
Tab 500 mg dispersible	1,105.00	28	✔	**Exjade**

➽SA1492 Special Authority for Subsidy

Initial application only from a haematologist. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

1 The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia; and

2 Deferasirox is to be given at a daily dose not exceeding 40 mg/kg/day; and

3 Any of the following:

3.1 Treatment with maximum tolerated doses of deferiprone monotherapy or deferiprone and desferrioxamine combination therapy have proven ineffective as measured by serum ferritin levels, liver or cardiac MRI T2*; or

3.2 Treatment with deferiprone has resulted in severe persistent vomiting or diarrhoea; or

3.3 Treatment with deferiprone has resulted in arthritis; or

3.4 Treatment with deferiprone is contraindicated due to a history of agranulocytosis (defined as an absolute neutrophil count (ANC) of < 0.5 cells per µL) or recurrent episodes (greater than 2 episodes) of moderate neutropenia (ANC 0.5 - 1.0 cells per µL).

Renewal only from a haematologist. Approvals valid for 2 years for applications meeting the following criteria:

Either:

continued…

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

continued…

1. For the first renewal following 2 years of therapy, the treatment has been tolerated and has resulted in clinical improvement in all three parameters namely serum ferritin, cardiac MRI T2* and liver MRI T2* levels; or
2. For subsequent renewals, the treatment has been tolerated and has resulted in clinical stability or continued improvement in all three parameters namely serum ferritin, cardiac MRI T2* and liver MRI T2* levels.

DEFERIPRONE – Special Authority see SA1480 below – Retail pharmacy

Tab 500 mg	533.17	100	✔	**Ferriprox**
Oral liq 100 mg per 1 ml	266.59	250 ml OP	✔	**Ferriprox**

SA1480 Special Authority for Subsidy

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

Either:

1. The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia; or
2. The patient has been diagnosed with chronic iron overload due to acquired red cell aplasia.

DESFERRIOXAMINE MESILATE

✻ Inj 500 mg vial	84.53	10	✔	**DBL Desferrioxamine Mesylate for Inj BP**

SODIUM CALCIUM EDETATE

✻ Inj 200 mg per ml, 5 ml	53.31 (156.71)	6		Calcium Disodium Versenate

Standard Formulae

ACETYLCYSTEINE EYE DROPS

Acetylcysteine inj 200 mg per ml, 10 ml	qs
Suitable eye drop base	qs

ASPIRIN AND CHLOROFORM APPLICATION

Aspirin Soluble tabs 300 mg	12 tabs
Chloroform	to 100 ml

CODEINE LINCTUS (3 mg per 5 ml)

Codeine phosphate	60 mg
Glycerol	40 ml
Preservative	qs
Water	to 100 ml

CODEINE LINCTUS (15 mg per 5 ml)

Codeine phosphate	300 mg
Glycerol	40 ml
Preservative	qs
Water	to 100 ml

FOLINIC MOUTHWASH

Calcium folinate 15 mg tab	1 tab
Preservative	qs
Water	to 500 ml

(Preservative should be used if quantity supplied is for more than 5 days. Maximum 500 ml per prescription.)

MAGNESIUM HYDROXIDE 8% MIXTURE

Magnesium hydroxide paste 29%	275 g
Methyl hydroxybenzoate	1.5 g
Water	to 1,000 ml

METHADONE MIXTURE

Methadone powder	qs
Glycerol	qs
Water	to 100 ml

METHYL HYDROXYBENZOATE 10% SOLUTION

Methyl hydroxybenzoate	10 g
Propylene glycol	to 100 ml

(Use 1 ml of the 10% solution per 100 ml of oral liquid mixture)

OMEPRAZOLE SUSPENSION

Omeprazole capules or powder	qs
Sodium bicarbonate powder BP	8.4 g
Water	to 100 ml

PHENOBARBITONE ORAL LIQUID

Phenobarbitone Sodium	1 g
Glycerol BP	70 ml
Water	to 100 ml

PHENOBARBITONE SODIUM PAEDIATRIC ORAL LIQUID (10 mg per ml)

Phenobarbitone Sodium	400 mg
Glycerol BP	4 ml
Water	to 40 ml

PILOCARPINE ORAL LIQUID

Pilocarpine 4% eye drops	qs
Preservative	qs
Water	to 500 ml

(Preservative should be used if quantity supplied is for more than 5 days.)

SALIVA SUBSTITUTE FORMULA

Methylcellulose	5 g
Preservative	qs
Water	to 500 ml

(Preservative should be used if quantity supplied is for more than 5 days. Maximum 500 ml per prescription.)

SODIUM CHLORIDE ORAL LIQUID

Sodium chloride inj 23.4%, 20 ml	qs
Water	qs

(Only funded if prescribed for treatment of hyponatraemia)

VANCOMYCIN ORAL SOLUTION (50 mg per ml)

Vancomycin 500 mg injection	10 vials
Glycerol BP	40 ml
Water	to 100 ml

(Only funded if prescribed for treatment of Clostridium difficile following metronidazole failure)

VOSOL EAR DROPS
WITH HYDROCORTISONE POWDER 1%

Hydrocortisone powder	1%
Vosol Ear Drops	to 35 ml

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

Extemporaneously Compounded Preparations and Galenicals

BENZOIN

Tincture compound BP	24.42	500 ml		
	(39.90)			Pharmacy Health

(Pharmacy Health Tincture compound BP to be delisted 1 March 2020)

CHLOROFORM

a) Only in combination
b) Maximum of 100 ml per prescription
c) Only in aspirin and chloroform application.
d) Note: This product is no longer being manufactured by the supplier and will be delisted from the Schedule at a date to be determined.

Chloroform BP	25.50	500 ml	✔	**PSM**

CODEINE PHOSPHATE – Safety medicine; prescriber may determine dispensing frequency

Powder – Only in combination	63.09	25 g		
	(90.09)			Douglas

Only in extemporaneously compounded codeine linctus.

COLLODION FLEXIBLE

Note: This product is no longer being manufactured by the supplier and will be delisted from the Schedule at a date to be determined.

Collodion flexible	19.30	100 ml	✔	**PSM**

COMPOUND HYDROXYBENZOATE – Only in combination

Only in extemporaneously compounded oral mixtures.

Soln	30.00	100 ml	✔	**Midwest**

GLYCERIN WITH SODIUM SACCHARIN – Only in combination

Only in combination with Ora-Plus.

Suspension	30.95	473 ml	✔	**Ora-Sweet SF**

GLYCERIN WITH SUCROSE – Only in combination

Only in combination with Ora-Plus.

Suspension	30.95	473 ml	✔	**Ora-Sweet**

GLYCEROL

✻ Liquid – Only in combination	3.28	500 ml	✔	**healthE Glycerol BP**

Only in extemporaneously compounded oral liquid preparations.

MAGNESIUM HYDROXIDE

Paste 29%	22.61	500 g	✔	**PSM**

(PSM Paste 29% to be delisted 1 July 2020)

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	1 g	✔	**AFT**

METHYL HYDROXYBENZOATE

Powder	8.98	25 g	✔	**Midwest**

METHYLCELLULOSE

Powder	36.95	100 g	✔	**MidWest**
Suspension – Only in combination	30.95	473 ml	✔	**Ora-Plus**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
METHYLCELLULOSE WITH GLYCERIN AND SODIUM SACCHARIN – Only in combination				
Suspension	30.95	473 ml	✔	**Ora-Blend SF**
METHYLCELLULOSE WITH GLYCERIN AND SUCROSE – Only in combination				
Suspension	30.95	473 ml	✔	**Ora-Blend**
PHENOBARBITONE SODIUM				
Powder – Only in combination	52.50	10 g	✔	**MidWest**
	325.00	100 g	✔	**MidWest**
Only in children up to 12 years				
PROPYLENE GLYCOL				
Only in extemporaneously compounded methyl hydroxybenzoate 10% solution.				
Liq	11.25	500 ml	✔	**Midwest**
SODIUM BICARBONATE				
Powder BP – Only in combination	10.05	500 g	✔	**Midwest**
Only in extemporaneously compounded omeprazole and lansoprazole suspension.				
SYRUP (PHARMACEUTICAL GRADE) – Only in combination				
Only in extemporaneously compounded oral liquid preparations.				
Liq	14.95	500 ml	✔	**Midwest**
WATER				
Tap – Only in combination	0.00	1 ml	✔	**Tap water**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	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:

Either:

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 SUPPLEMENT – Special Authority see SA1522 above – Hospital pharmacy [HP3]

	Subsidy $	Per	Fully Subsidised	Brand
Powder	5.29	400 g OP	✔	**Polycal**

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

continued…

1 Infant or child aged four years or under; and
2 cystic fibrosis.

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:
Both:

1 infant or child aged four years or under; and
2 Any of the following:
  2.1 cancer in children; or
  2.2 faltering growth; or
  2.3 bronchopulmonary dysplasia; or
  2.4 premature and post premature infants.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:
Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:
Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

CARBOHYDRATE AND FAT SUPPLEMENT – Special Authority see SA1376 on the previous page – Hospital pharmacy [HP3]

Powder (neutral)	60.31	400 g OP	✔	**Duocal Super Soluble Powder**

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

continued…

10 ascites; or
11 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula.
Renewal — (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:
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 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]

	Subsidy $	Per	Fully Subsidised	Brand
Emulsion (neutral)	12.30	200 ml OP	✔	**Calogen**
	30.75	500 ml OP	✔	**Calogen**
Emulsion (strawberry)	12.30	200 ml OP	✔	**Calogen**
Oil	30.00	500 ml OP	✔	**MCT oil (Nutricia)**
Oil, 250 ml	114.92	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 – Special Authority see SA1524 above – Hospital pharmacy [HP3]

	Subsidy $	Per	Fully Subsidised	Brand
Powder	7.90	225 g OP	✔	**Protifar**
	8.95	227 g OP	✔	**Resource Beneprotein**

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

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.

CORD ORAL FEED 1.5KCAL/ML – Special Authority see SA1094 above – Hospital pharmacy [HP3]

Liquid	1.66	237 ml OP	✔	**Pulmocare**

Diabetic Products

➽SA1095 **Special Authority for Subsidy**
Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient is a type I or and II diabetic who is suffering weight loss and malnutrition that requires nutritional support.
Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:
Both:

1. The treatment remains appropriate and the patient is benefiting from treatment; and
2. General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

DIABETIC ENTERAL FEED 1KCAL/ML – Special Authority see SA1095 above – Hospital pharmacy [HP3]

Liquid	7.50	1,000 ml OP	✔	**Diason RTH**
			✔	**Glucerna Select RTH**

DIABETIC ORAL FEED 1KCAL/ML – Special Authority see SA1095 above – Hospital 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)			Sustagen Diabetic

	Subsidy (Manufacturer's Price) $	Per	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 g 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]

Powder (unflavoured)	78.97	400 g OP	✔	**Heparon Junior**

Paediatric Products For Children With Chronic Renal Failure

➽SA1099 Special Authority for Subsidy
Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 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 (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
ENTERAL/ORAL FEED 1KCAL/ML – Special Authority see SA1099 on the previous page – Hospital pharmacy [HP3]				
Liquid	54.00	400 g OP	✔	**Kindergen**

Paediatric Products

➽SA1379 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

1 Child is aged one to ten years; and
2 Any of the following:
   2.1 the child is being fed via a tube or a tube is to be inserted for the purposes of feeding; or
   2.2 any condition causing malabsorption; or
   2.3 faltering growth in an infant/child; or
   2.4 increased nutritional requirements; or
   2.5 the child is being transitioned from TPN or tube feeding to oral feeding.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
PAEDIATRIC ENTERAL FEED 1.5KCAL/ML – Special Authority see SA1379 above – Hospital pharmacy [HP3]				
Liquid	6.00	500 ml OP	✔	**Nutrini Energy RTH**
PAEDIATRIC ENTERAL FEED 1KCAL/ML – Special Authority see SA1379 above – Hospital pharmacy [HP3]				
Liquid	2.68	500 ml OP	✔	**Nutrini RTH**
			✔	**Pediasure RTH**
PAEDIATRIC ENTERAL FEED WITH FIBRE 1.5KCAL/ML – Special Authority see SA1379 above – Hospital pharmacy [HP3]				
Liquid	6.00	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	✔	**Fortini**
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 SA1379 above – Hospital pharmacy [HP3]				
Liquid (unflavoured)	1.60	200 ml OP	✔	**Fortini Multi Fibre**
Liquid (chocolate)	1.60	200 ml OP	✔	**Fortini Multi Fibre**
Liquid (strawberry)	1.60	200 ml OP	✔	**Fortini Multi Fibre**
Liquid (vanilla)	1.60	200 ml OP	✔	**Fortini Multi Fibre**
PEPTIDE-BASED ORAL FEED – Special Authority see SA1379 above – Hospital pharmacy [HP3]				
Powder	43.60	400 g OP	✔	**Peptamen Junior**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic 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 SA1101 above – Hospital pharmacy [HP3]

Liquid	6.08	500 ml OP	✔	**Nepro HP RTH**

RENAL ORAL FEED 1.8 KCAL/ML – Special Authority see SA1101 above – Hospital pharmacy [HP3]

Liquid	2.67	220 ml OP	✔	**Nepro HP (strawberry)**
			✔	**Nepro HP (vanilla)**

RENAL ORAL FEED 2 KCAL/ML – Special Authority see SA1101 above – Hospital pharmacy [HP3]

Liquid	2.88 (3.31)	237 ml OP		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.

ENTERAL/ORAL SEMI-ELEMENTAL FEED 1.5KCAL/ML – Special Authority see SA1377 above – Hospital pharmacy [HP3]

Liquid	18.06	1,000 ml OP	✔	**Vital**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
ORAL ELEMENTAL FEED 0.8KCAL/ML – Special Authority see SA1377 on the previous page – Hospital pharmacy [HP3]				
Liquid (grapefruit), 250 ml carton	171.00	18 OP	✔	**Elemental 028 Extra**
Liquid (pineapple & orange), 250 ml carton	171.00	18 OP	✔	**Elemental 028 Extra**
Liquid (summer fruits), 250 ml carton	171.00	18 OP	✔	**Elemental 028 Extra**
ORAL ELEMENTAL FEED 1KCAL/ML – Special Authority see SA1377 on the previous page – Hospital pharmacy [HP3]				
Powder (unflavoured)	4.50	80 g OP	✔	**Vivonex TEN**
SEMI-ELEMENTAL ENTERAL FEED 1KCAL/ML – Special Authority see SA1377 on the previous page – Hospital pharmacy [HP3]				
Liquid	12.04	1,000 ml OP	✔	**Peptisorb**

Paediatric Products For Children With Low Energy Requirements

➽SA1196 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

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.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
PAEDIATRIC ENTERAL FEED WITH FIBRE 0.76 KCAL/ML – Special Authority see SA1196 above – Hospital pharmacy [HP3]				
Liquid	4.00	500 ml OP	✔	**Nutrini Low Energy Multi Fibre**

Standard Supplements

➽SA1859 Special Authority for Subsidy

Initial application — (Children - indications other than exclusive enteral nutrition for Crohn's disease) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

1. The patient is under 18 years of age; and
2. Any of the following:
   - 2.1 The patient has a condition causing malabsorption; or
   - 2.2 The patient has failure to thrive; or
   - 2.3 The patient has increased nutritional requirements; and
3. Nutrition goal has been set (eg reach a specific weight or BMI).

Renewal — (Children - indications other than exclusive enteral nutrition for Crohn's disease) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

1. The patient is under 18 years of age; and
2. The treatment remains appropriate and the patient is benefiting from treatment; and

continued…

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

continued…

3 A nutrition goal has been set (eg reach a specific weight or BMI).

Initial application — (Children - exclusive enteral nutrition for Crohn's disease) only from a gastroenterologist or dietitian on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1 The patient is under 18 years of age; and
2 It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease; and
3 Dietitians must include the name of the gastroenterologist recommending treatment and the date the gastroenterologist was contacted.

Renewal — (Children - exclusive enteral nutrition for Crohn's disease) from any relevant practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1 The patient is under 18 years of age; and
2 It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease; and
3 General Practitioners and dietitians must include the name of the gastroenterologist recommending treatment and the date the gastroenterologist was contacted.

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

1 Any of the following:
Patient is Malnourished
1.1 Patient has a body mass index (BMI) of less than 18.5 kg/m^2; 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/m^2 and unintentional weight loss greater than 5% within the last 3-6 months; and
2 Any of the following:
Patient has not responded to first-line dietary measures over a 4 week period by:
2.1 Increasing their food intake frequency (eg snacks between meals); or
2.2 Using high-energy foods (e.g. milkshakes, full fat milk, butter, cream, cheese, sugar etc); or
2.3 Using over the counter supplements (e.g. Complan); and
3 A nutrition goal has been set (e.g. to reach a specific weight or BMI).

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

1 A nutrition goal has been set (eg reach a specific weight or BMI); and
2 Any of the following:
Patient is Malnourished
2.1 Patient has a body mass index (BMI) of less than 18.5 kg/m^2; 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^2 and unintentional weight loss greater than 5% within the last 3-6 months.

Initial application — (Short-term medical condition) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:
Any of the following:

1 Is being fed via a nasogastric tube or a nasogastric tube is to be inserted for feeding; or
2 Malignancy and is considered likely to develop malnutrition as a result; or
3 Is undergoing a bone marrow transplant; or
4 Tempomandibular surgery or glossectomy; or
5 Both:
5.1 Pregnant; and

continued…

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

continued…

- 5.2 Any of the following:
  - 5.2.1 Patient is in early pregnancy (< 13 weeks) and has severe clinical hyperemesis gravidarum requiring admission to hospital and is unlikely to meet her nutritional requirements due to continuing hyperemesis gravidarum; or
  - 5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or
  - 5.2.3 Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met.

Renewal — (Short-term medical condition) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:
Any of the following:

1 Is being fed via a nasogastric tube; or
2 Malignancy and is considered likely to develop malnutrition as a result; or
3 Has undergone a bone marrow transplant; or
4 Tempomandibular surgery or glossectomy; or
5 Both:
- 5.1 Pregnant; and
- 5.2 Any of the following:
  - 5.2.1 Patient is in early pregnancy (< 13 weeks) and has severe clinical hyperemesis gravidarum requiring admission to hospital and is unlikely to meet her nutritional requirements due to continuing hyperemesis gravidarum; or
  - 5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or
  - 5.2.3 Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met.

Initial application — (Long-term medical condition) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:
Any of the following:

1 Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube - refer to specific medical condition criteria); or
2 Cystic Fibrosis; or
3 Liver disease; or
4 Chronic Renal failure; or
5 Inflammatory bowel disease; or
6 Chronic obstructive pulmonary disease with hypercapnia; or
7 Short bowel syndrome; or
8 Bowel fistula; or
9 Severe chronic neurological conditions; or
10 Epidermolysis bullosa; or
11 AIDS (CD4 count < 200 cells/mm^3); or
12 Chronic pancreatitis.

Renewal — (Chronic disease OR tube feeding for patients who have previously been funded under Special Authority forms SA0702 or SA0583) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:
Any of the following:

continued…

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

continued…

1 Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube - refer to specific medical condition criteria); or
2 Cystic Fibrosis; or
3 Liver disease; or
4 Chronic Renal failure; or
5 Inflammatory bowel disease; or
6 Chronic obstructive pulmonary disease with hypercapnia; or
7 Short bowel syndrome; or
8 Bowel fistula; or
9 Severe chronic neurological conditions.

ENTERAL FEED 1.5KCAL/ML – Special Authority see SA1859 on page 247 – Hospital pharmacy [HP3]

Liquid	7.00	1,000 ml OP	✔	**Nutrison Energy**

ENTERAL FEED 1KCAL/ML – Special Authority see SA1859 on page 247 – Hospital pharmacy [HP3]

Liquid	1.24	250 ml OP	✔	**Isosource Standard**
	5.29	1,000 ml OP	✔	**Nutrison Standard RTH**
			✔	**Osmolite RTH**

ENTERAL FEED WITH FIBRE 0.83 KCAL/ML – Special Authority see SA1859 on page 247 – Hospital pharmacy [HP3]

Liquid	5.29	1,000 ml OP	✔	**Nutrison 800 Complete Multi Fibre**

ENTERAL FEED WITH FIBRE 1 KCAL/ML – Special Authority see SA1859 on page 247 – Hospital pharmacy [HP3]

Liquid	5.29	1,000 ml OP	✔	**Jevity RTH**
			✔	**Nutrison Multi Fibre**

ENTERAL FEED WITH FIBRE 1.5KCAL/ML – Special Authority see SA1859 on page 247 – Hospital pharmacy [HP3]

Liquid	1.75	250 ml OP	✔	**Ensure Plus HN**
	7.00	1,000 ml OP	✔	**Ensure Plus RTH**
			✔	**Jevity HiCal RTH**
			✔	**Nutrison Energy Multi Fibre**

ORAL FEED (POWDER) – Special Authority see SA1859 on page 247 – 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.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
ORAL FEED 1.5KCAL/ML – Special Authority see SA1859 on page 247 – 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)			Ensure Plus
	(1.26)			Fortisip
Liquid (vanilla) – Higher subsidy of up to $1.33 per 237 ml with Endorsement	0.85	237 ml OP		
	(1.33)			Ensure Plus
	0.72	200 ml OP		
	(1.26)			Ensure Plus
	(1.26)			Fortisip
ORAL FEED WITH FIBRE 1.5 KCAL/ML – Special Authority see SA1859 on page 247 – 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 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 Endorsement	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.

continued…

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

continued…

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

1 Any of the following:
   1.1 any condition causing malabsorption; or
   1.2 faltering growth in an infant/child; or
   1.3 increased nutritional requirements; or
   1.4 fluid restricted; and
2 other lower calorie products have been tried; and
3 patient has substantially increased metabolic requirements or is fluid restricted.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL FEED 2 KCAL/ML – Special Authority see SA1195 on the previous page – Hospital pharmacy [HP3]

Liquid	5.50	500 ml OP	✔	**Nutrison Concentrated**
	11.00	1,000 ml OP	✔	**Two Cal HN RTH**

ORAL FEED 2 KCAL/ML – Special Authority see SA1195 on the previous page – Hospital pharmacy [HP3]

Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, or who have severe epidermolysis bullosa. The prescription must be endorsed accordingly.

Liquid (vanilla) – Higher subsidy of $1.90 per 200 ml with Endorsement	0.96 (1.90)	200 ml OP		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.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
FOOD THICKENER – Special Authority see SA1106 on the previous page – Hospital pharmacy [HP3]				
Powder	6.53	300 g OP	✔	**Nutilis**
	7.25	380 g OP	✔	**Feed Thickener Karicare Aptamil**

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.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
GLUTEN FREE BAKING MIX – Special Authority see SA1729 above – Hospital pharmacy [HP3]				
Powder	2.81 (5.15)	1,000 g OP		Healtheries Simple Baking Mix
GLUTEN FREE BREAD MIX – Special Authority see SA1729 above – Hospital pharmacy [HP3]				
Powder	3.93 (7.32)	1,000 g OP		NZB Low Gluten Bread Mix
	3.51 (10.87)			Horleys Bread Mix
GLUTEN FREE FLOUR – Special Authority see SA1729 above – Hospital pharmacy [HP3]				
Powder	5.62 (18.10)	2,000 g OP		Horleys Flour

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
GLUTEN FREE PASTA – Special Authority see SA1729 on the previous page – Hospital pharmacy [HP3]				
Buckwheat Spirals	2.00 (3.11)	250 g OP		Orgran
Corn and Vegetable Shells	2.00 (2.92)	250 g OP		Orgran
Corn and Vegetable Spirals	2.00 (2.92)	250 g OP		Orgran
Rice and Corn Lasagne Sheets	1.60 (3.82)	200 g OP		Orgran
Rice and Corn Macaroni	2.00 (2.92)	250 g OP		Orgran
Rice and Corn Penne	2.00 (2.92)	250 g OP		Orgran
Rice and Maize Pasta Spirals	2.00 (2.92)	250 g OP		Orgran
Rice and Millet Spirals	2.00 (3.11)	250 g OP		Orgran
Rice and corn spaghetti noodles	2.00 (2.92)	375 g OP		Orgran
Vegetable and Rice Spirals	2.00 (2.92)	250 g OP		Orgran
Italian long style spaghetti	2.00 (3.11)	220 g OP		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

AMINOACID FORMULA WITHOUT METHIONINE – Special Authority see SA1108 above – Hospital pharmacy [HP3]				
Powder	461.94	500 g OP	✔	**XMET Maxamum**

Supplements For MSUD

AMINOACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE – Special Authority see SA1108 above – Hospital pharmacy [HP3]				
Powder	437.22	500 g OP	✔	**MSUD Maxamum**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic 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)	320.00	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	✔	**Easiphen Liquid**
Liquid (juicy tropical) 125 ml	936.00	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	939.00	60 OP	✔	**PKU Lophlex LQ 10**
Liquid (juicy orange) 62.5 ml	939.00	60 OP	✔	**PKU Lophlex LQ 10**
Liquid (juicy berries) 125 ml	936.00	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 SA1108 on the previous page – Hospital pharmacy [HP3]

Powder	8.22	500 g OP	✔	**Loprofin Mix**

LOW PROTEIN PASTA – Special Authority see SA1108 on the previous page – Hospital pharmacy [HP3]

Animal shapes	11.91	500 g OP	✔	**Loprofin**
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) $	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:

Both:

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

2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

LOW CALCIUM INFANT FORMULA – Special Authority see SA1110 above – Hospital pharmacy [HP3]

	Subsidy $	Per	Fully Subsidised	Brand
Powder	44.40	400 g OP	✔	**Locasol**

Gastrointestinal and Other Malabsorptive Problems

AMINO ACID FORMULA – Special Authority see SA1219 below – Hospital pharmacy [HP3]

	Subsidy $	Per	Fully Subsidised	Brand
Powder	43.60	400 g OP	✔	**Alfamino Junior**
Powder (unflavoured)	53.00	400 g OP	✔	**Elecare**
			✔	**Elecare LCP**
			✔	**Neocate Gold**
			✔	**Neocate Junior Unflavoured**
			✔	**Neocate SYNEO**
Powder (vanilla)	53.00	400 g OP	✔	**Elecare**
			✔	**Neocate Junior Vanilla**

➽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 (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
EXTENSIVELY HYDROLYSED FORMULA – Special Authority see SA1557 below – Hospital pharmacy [HP3]				
Powder	15.21	450 g OP	✔	**Aptamil Gold+ Pepti Junior**
	30.42	900 g OP	✔	**Allerpro 1**
			✔	**Allerpro 2**

➽SA1557 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Any of the following:

1 Both:
 1.1 Cows milk formula is inappropriate due to severe intolerance or allergy to its protein content; and
 1.2 Either:
  1.2.1 Soy milk formula has been reasonably trialled without resolution of symptoms; or
  1.2.2 Soy milk formula is considered clinically inappropriate or contraindicated; or
2 Severe malabsorption; or
3 Short bowel syndrome; or
4 Intractable diarrhoea; or
5 Biliary atresia; or
6 Cholestatic liver diseases causing malsorption; or
7 Cystic fibrosis; or
8 Proven fat malabsorption; or
9 Severe intestinal motility disorders causing significant malabsorption; or
10 Intestinal failure; or
11 All of the following:
 11.1 For step down from Amino Acid Formula; and
 11.2 The infant is currently receiving funded amino acid formula; and
 11.3 The infant is to be trialled on, or transitioned to, an extensively hydrolysed formula; and
 11.4 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.

Note: A reasonable trial is defined as a 2-4 week trial, or signs of an immediate IgE mediated allergic reaction.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 An assessment as to whether the infant can be transitioned to a cows milk protein or soy infant formula has been undertaken; and
2 The outcome of the assessment is that the infant continues to require an extensively hydrolysed infant formula; and
3 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.

Fluid Restricted

PAEDIATRIC ORAL/ENTERAL FEED 1 KCAL/ML – Special Authority see SA1698 below – Hospital pharmacy [HP3]				
Liquid	2.35	125 ml OP	✔	**Infatrini**

➽SA1698 Special Authority for Subsidy

Initial application only from a paediatrician, dietitian or general practitioner on the recommendation of a paediatrician or dietitian. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

continued…

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

continued…

1 Patient is fluid restricted or volume intolerant and has been diagnosed with faltering growth; and
2 Patient is under the care of a paediatrician or dietitian who has recommended treatment with a high energy infant formula; and
3 Patient is under 18 months of age or weighs less than 8 kg.

Note: 'Volume intolerant' patients are those who are unable to tolerate an adequate volume of infant formula to achieve expected growth rate. These patients should have first trialled appropriate clinical alternative treatments, such as concentrating, fortifying and adjusting the frequency of feeding.

Renewal only from a paediatrician, dietitian or general practitioner on the recommendation of a paediatrician or dietitian. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 Patient continues to be fluid restricted or volume intolerant and has faltering growth; and
2 Patient is under the care of a hospital paediatrician or dietitian who has recommended treatment with a high energy infant formula; and
3 Patient is under 18 months of age or weighs less than 8 kg.

Note: 'Volume intolerant' patients are those who are unable to tolerate an adequate volume of infant formula to achieve expected growth rate. These patients should have first trialled appropriate clinical alternative treatments, such as concentrating, fortifying and adjusting the frequency of feeding.

Ketogenic Diet

➽SA1197 **Special Authority for Subsidy**

Initial application only from a metabolic physician or paediatric neurologist. Approvals valid for 3 months where the patient has intractable epilepsy, pyruvate dehydrogenase deficiency or glucose transported type-1 deficiency and other conditions requiring a ketogenic diet.

Renewal only from a metabolic physician or paediatric neurologist. Approvals valid for 2 years where the patient is on a ketogenic diet and the patient is benefiting from the diet.

HIGH FAT LOW CARBOHYDRATE FORMULA – Special Authority see SA1197 above – Retail pharmacy

Powder (unflavoured)	35.50	300 g OP	✔	**KetoCal 4:1**
			✔	**Ketocal 3:1**
Powder (vanilla)	35.50	300 g OP	✔	**KetoCal 4:1**

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

Vaccinations

ADULT DIPHTHERIA AND TETANUS VACCINE – [Xpharm]

Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid in 0.5 ml .... 0.00 | 5 | ✔ **ADT Booster**

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
5) 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
2) having one or more household members or carers who within the last 5 years lived in a country with a rate of TB > or equal to 40 per 100,000 for 6 months or longer; or
3) during their first 5 years will be living 3 months or longer in a country with a rate of TB > or equal to 40 per 100,000

Note a list of countries with high rates of TB are available at www.health.govt.nz/tuberculosis (search for downloads) or www.bcgatlas.org/index.php.

Inj Mycobacterium bovis 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 dose for pregnant women in the second or third trimester of each pregnancy; or
2) A single dose for parents or primary caregivers of infants admitted to a Neonatal Intensive Care Unit or Specialist Care Baby Unit for more than 3 days, who had not been exposed to maternal vaccination at least 14 days prior to birth; or
3) A course of up to four doses is funded for children from age 7 up to the age of 18 years inclusive to complete full primary immunisation; or
4) An additional four doses (as appropriate) are funded for (re-)immunisation for patients post haematopoietic stem cell transplantation or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens.

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 haemagluttinin and 2.5 mcg pertactin in 0.5 ml syringe .... 0.00 | 10 | ✔ **Boostrix**
| 1 | ✔ **Boostrix**

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

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
2) A course of four vaccines is funded for catch up programmes for children (to the age of 10 years) to complete full primary immunisation; or
3) An additional four doses (as appropriate) are funded for (re-)immunisation for 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.

Inj 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 poliomyelitis virus in 0.5ml syringe	0.00	10	✔	**Infanrix IPV**

DIPHTHERIA, TETANUS, PERTUSSIS, POLIO, HEPATITIS B AND HAEMOPHILUS INFLUENZAE TYPE B VACCINE – [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 for primary immunisation; or
2) An additional four doses (as appropriate) are funded for (re-)immunisation for children up to and under the age of 10 who are patients post haematopoietic stem cell transplantation, or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens; or
3) Up to five doses for children up to and under the age of 10 receiving solid organ transplantation.

Note: A course of up-to four vaccines is funded for catch up programmes for children (up to and under the age of 10 years) to complete full primary immunisation. Please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.

Inj 30IU diphtheriatoxoid with 40IU tetanustoxoid, 25mcg pertussistoxoid, 25mcg pertussisfilamentoushaemagluttinin, 8 mcgpertactin, 80 D-AgUpoliovirus, 10mcghepatitisBsurfaceantigen in 0.5ml syringe	0.00	10	✔	**Infanrix-hexa**

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-)immunisation for patients post haematopoietic stem cell transplantation, or chemotherapy; functional asplenic; pre or post splenectomy; pre- or post solid organ transplant, pre- or post cochlear implants, renal dialysis and other severely immunosuppressive regimens; or
3) For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

Haemophilus Influenzae type B polysaccharide 10 mcg conjugated to tetanus toxoid as carrier protein 20-40 mcg; prefilled syringe plus vial 0.5 ml	0.00	1	✔	**Hiberix**

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 disease; or
3) One dose of vaccine for close contacts of known hepatitis A cases.

Inj 1440 ELISA units in 1 ml syringe	0.00	1	✔	**Havrix**
Inj 720 ELISA units in 0.5 ml syringe	0.00	1	✔	**Havrix Junior**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic 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 hepatitis B patients or hepatitis B carriers; or
2) for children born to mothers who are hepatitis B surface antigen (HBsAg) positive; or
3) for children up to and under the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination or require a primary course of vaccination; or
4) for HIV positive patients; or
5) for hepatitis C positive patients; or
6) for patients following non-consensual sexual intercourse; or
7) for patients following immunosuppression; or
8) for solid organ transplant patients; or
9) for post-haematopoietic stem cell transplant (HSCT) patients; or
10) following needle stick injury.

Inj 10 mcg per 1 ml vial	0.00	1	✔	**HBvaxPRO**

Funded for patients meeting any of the following criteria:

1) for household or sexual contacts of known acute hepatitis B patients or hepatitis B carriers; or
2) for children born to mothers who are hepatitis B surface antigen (HBsAg) positive; or
3) for children up to and under the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination or require a primary course of vaccination; or
4) for HIV positive patients; or
5) for hepatitis C positive patients; or
6) for patients following non-consensual sexual intercourse; or
7) for patients following immunosuppression; or
8) for solid organ transplant patients; or
9) for post-haematopoietic stem cell transplant (HSCT) patients; or
10) following needle stick injury.

Inj 20 mcg per 1 ml prefilled syringe	0.00	1	✔	**Engerix-B**

Funded for patients meeting any of the following criteria:

1) for household or sexual contacts of known acute hepatitis B patients or hepatitis B carriers; or
2) for children born to mothers who are hepatitis B surface antigen (HBsAg) positive; or
3) for children up to and under the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination or require a primary course of vaccination; or
4) for HIV positive patients; or
5) for hepatitis C positive patients; or
6) for patients following non-consensual sexual intercourse; or
7) for patients following immunosuppression; or
8) for solid organ transplant patients; or
9) for post-haematopoietic stem cell transplant (HSCT) patients; or
10) following needle stick injury; or
11) for dialysis patients; or
12) for liver or kidney transplant patients.

Inj 40 mcg per 1 ml vial	0.00	1	✔	**HBvaxPRO**

Funded for any of the following criteria:

1) for dialysis patients; or
2) for liver or kidney transplant patient.

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

	Subsidy $	Per	Fully Subsidised	Brand
Inj 270 mcg in 0.5 ml syringe	0.00	10	✔	**Gardasil 9**

	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	✔	**Fluarix Tetra**

A) **INFLUENZA VACCINE – child aged 6 months to 35 months**
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) **INFLUENZA VACCINE – pregnant women**
   a) are pregnant

C) 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.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine)	45.00	5	✔	**FluQuadri**
	90.00	10	✔	**Afluria Quad**
			✔	**Influvac Tetra**

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

a) Only on a prescription
b) No patient co-payment payable
c)
   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
            g) are children on long term aspirin, or
            h) have a cochlear implant, or
            i) errors of metabolism at risk of major metabolic decompensation, or
            j) pre and post splenectomy, or
            k) down syndrome, or
         vii) are pregnant; or
      c) children 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.

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

MEASLES, MUMPS AND RUBELLA VACCINE

A) **Measles, mumps and rubella vaccine**

A maximum of two doses for any patient meeting the following criteria:

1) For primary vaccination in children; or
2) For revaccination following immunosuppression; or
3) For any individual susceptible to measles, mumps or rubella; or
4) A maximum of three doses for children who have had their first dose prior to 12 months.

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes. Although a price is listed for the vaccine, doctors can still order measles mumps and rubella vaccine free of charge, as with other Schedule vaccines.

B) Contractors will be entitled to claim payment from the Funder for the supply of measles, mumps and rubella 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 measles, mumps and rubella vaccine listed in the Pharmaceutical Schedule.

C) Contractors can only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

	Subsidy $	Per	Fully Subsidised	Brand
Inj, measles virus 1,000 CCID50, mumps virus 5,012 CCID50, Rubella virus 1,000 CCID50; prefilled syringe/ampoule of diluent 0.5 ml	112.50	5	✔	**MMR II**
	250.00	10	✔	**Priorix**

MENINGOCOCCAL (GROUPS A, C, Y AND W-135) CONJUGATE VACCINE – [Xpharm]

Either:

A) Any of the following:

1) Up to three doses and a booster every five years for patients pre- and post splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre or post solid organ transplant; or
2) One dose for close contacts of meningococcal cases; or
3) A maximum of two doses for bone marrow transplant patients; or
4) A maximum of two doses for patients following immunosuppression*; or

B) Both:

1) Person is aged between 13 and 25 years, inclusive; and
2) Either:
   i) One dose for individuals who are entering within the next three months, or in their first year of living in boarding school hostels, tertiary education halls of residence, military barracks, or prisons; or
   ii) One dose for individuals who are currently living in boarding school hostels, tertiary education halls of residence, military barracks, or prisons, from 1 December 2019 to 30 November 2020.

Note: children under seven years of age require two doses 8 weeks apart, a booster dose three years after the primary series and then five yearly.

*Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.

	Subsidy $	Per	Fully Subsidised	Brand
Inj 4 mcg of each meningococcal polysaccharide conjugated to a total of approximately 48 mcg of diphtheria toxoid carrier per 0.5 ml vial	0.00	1	✔	**Menactra**

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

MENINGOCOCCAL C CONJUGATE VACCINE – [Xpharm]

Any of the following:

1) Up to three doses and a booster every five years for patients pre- and post splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre or post solid organ transplant; or
2) One dose for close contacts of meningococcal cases; or
3) A maximum of two doses for bone marrow transplant patients; or
4) A maximum of two doses for patients following immunosuppression*.

Note: children under seven years of age require two doses 8 weeks apart, a booster dose three years after the primary series and then five yearly.

*Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.

Inj 10 mcg in 0.5 ml syringe	0.00	1	✔	**Neisvac-C**

PNEUMOCOCCAL (PCV10) CONJUGATE VACCINE – [Xpharm]

Either:

1) A primary course of four doses for previously unvaccinated individuals up to the age of 59 months inclusive; or
2) Up to three doses as appropriate to complete the primary course of immunisation for individuals under the age of 59 months who have received one to three doses of PCV13.

Note: please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes

Inj 1 mcg of pneumococcal polysaccharide serotypes 1, 5, 6B, 7F, 9V, 14 and 23F; 3 mcg of pneumococcal polysaccharide serotypes 4, 18C and 19F in 0.5 ml prefilled syringe	0.00	10	✔	**Synflorix**

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

PNEUMOCOCCAL (PCV13) CONJUGATE VACCINE – [Xpharm]

Any of the following:

1) 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
   l) 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, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in 0.5ml syringe	0.00	10	✔	**Prevenar 13**
		1	✔	**Prevenar 13**

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

PNEUMOCOCCAL (PPV23) POLYSACCHARIDE VACCINE – [Xpharm]

Either:

1) Up to three doses (as appropriate) for patients with HIV, for patients post haematopoietic stem cell transplant, or chemotherapy; pre- or post-splenectomy or with functional asplenia, pre- or post-solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, or primary immunodeficiency; or
2) All of the following:
   a) Patient is a child under 18 years for (re-)immunisation; and
   b) Treatment is for a maximum of two doses; and
   c) Any of the following:
      i) on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or
      ii) with primary immune deficiencies; or
      iii) with HIV infection; or
      iv) with renal failure, or nephrotic syndrome; or
      v) who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
      vi) with cochlear implants or intracranial shunts; or
      vii) with cerebrospinal fluid leaks; or
      viii) receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
      ix) with chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or
      x) pre term infants, born before 28 weeks gestation; or
      xi) with cardiac disease, with cyanosis or failure; or
      xii) with diabetes; or
      xiii) with Down syndrome; or
      xiv) who are pre-or post-splenectomy, or with functional asplenia.

Inj 575 mcg in 0.5 ml prefilled syringe (25 mcg of each 23 pneumococcal serotype)	0.00	1	✔	**Pneumovax 23**

POLIOMYELITIS VACCINE – [Xpharm]

Up to three doses for patients meeting either of the following:

1) For partially vaccinated or previously unvaccinated individuals; or
2) For revaccination following immunosuppression.

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch-up programmes.

Inj 80D antigen units in 0.5 ml syringe	0.00	1	✔	**IPOL**

ROTAVIRUS ORAL VACCINE – [Xpharm]

Maximum of two doses for patients meeting the following:

1) first dose to be administered in infants aged under 14 weeks of age; and
2) no vaccination being administered to children aged 24 weeks or over.

Oral susp live attenuated human rotavirus 1,000,000 CCID50 per dose, prefilled oral applicator	0.00	10	✔	**Rotarix**

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

VARICELLA VACCINE [CHICKENPOX VACCINE] – [Xpharm]

Either:

1) Maximum of one dose for primary vaccination for either:
   a) Any infant born on or after 1 April 2016; or
   b) For previously unvaccinated children turning 11 years old on or after 1 July 2017, who have not previously had a varicella infection (chickenpox), or
2) Maximum of two doses for any of the following:
   a) Any of the following for non-immune patients:
      i) with chronic liver disease who may in future be candidates for transplantation; or
      ii) with deteriorating renal function before transplantation; or
      iii) prior to solid organ transplant; or
      iv) prior to any elective immunosuppression*, or
      v) for post exposure prophylaxis who are immune competent inpatients.; or
   b) For patients at least 2 years after bone marrow transplantation, on advice of their specialist, or
   c) For patients at least 6 months after completion of chemotherapy, on advice of their specialist, or
   d) For HIV positive non immune to varicella with mild or moderate immunosuppression on advice of HIV specialist, or
   e) For patients with inborn errors of metabolism at risk of major metabolic decompensation, with no clinical history of varicella, or
   f) For household contacts of paediatric patients who are immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella, or
   g) For household contacts of adult patients who have no clinical history of varicella and who are severely immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella.

* immunosuppression due to steroid or other immunosuppressive therapy must be for a treatment period of greater than 28 days

Inj 2000 PFU prefilled syringe plus vial	0.00	1	✔	Varilrix
		10	✔	Varilrix

VARICELLA ZOSTER VIRUS (OKA STRAIN) LIVE ATTENUATED VACCINE [SHINGLES VACCINE] – [Xpharm]

Funded for patients meeting either of the following criteria:

1) One dose for all people aged 65 years; or
2) One dose for all people aged between 66 and 80 years inclusive from 1 April 2018 and 31 December 2020.

Inj 19,400 PFU prefilled syringe plus vial	0.00	1	✔	Zostavax
		10	✔	Zostavax

Diagnostic Agents

TUBERCULIN PPD [MANTOUX] TEST – [Xpharm]

Inj 5 TU per 0.1 ml, 1 ml vial	0.00	1	✔	Tubersol

- Q -

- R -