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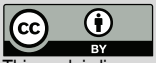

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Introducing PHARMAC

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:

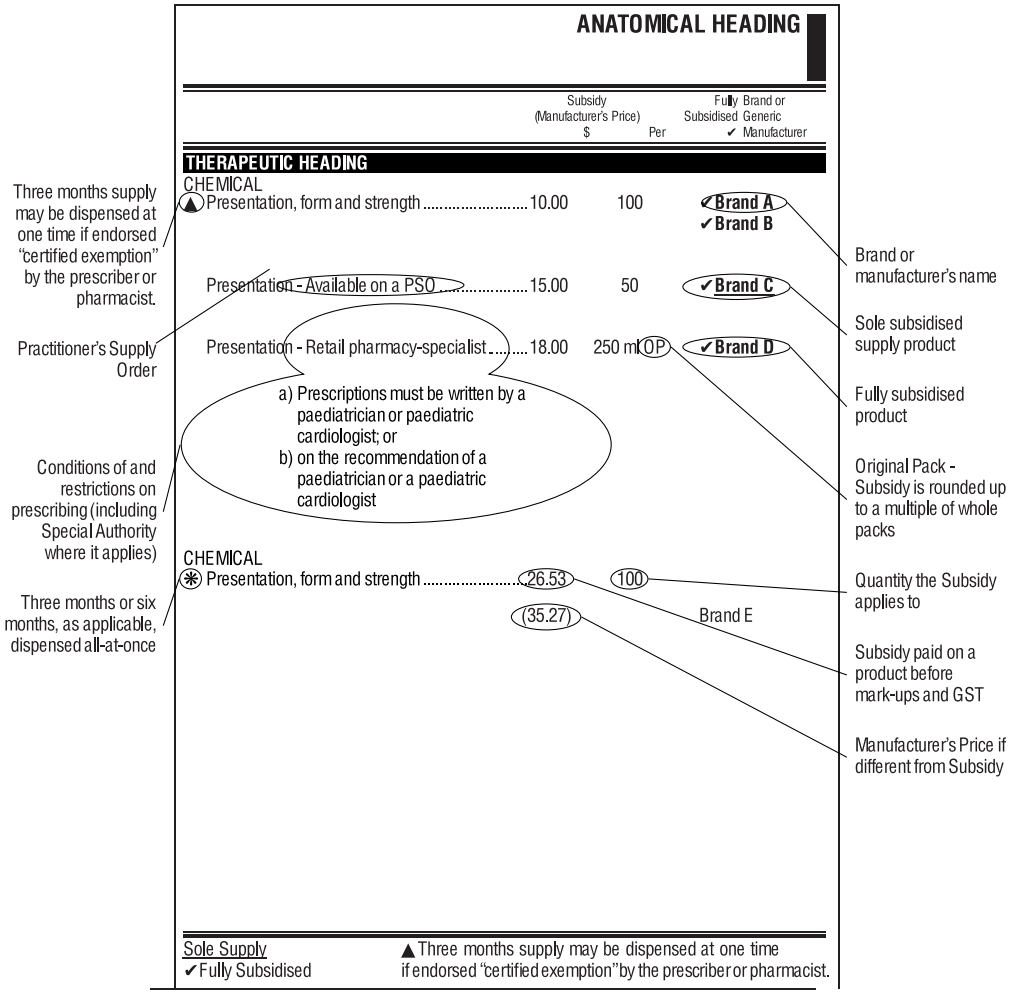
- the Community Pharmaceuticals that are subsidised by the Government and to show the amount of the subsidy paid to contractors, as well as the manufacturer's price and any access conditions that may apply;
- the Hospital Pharmaceuticals that may be used in DHB Hospitals, as well as any access conditions 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 — 60
(8.60) — Gaviscon Double Strength

Oral liq 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml — 1.50 — 500 ml
(4.95) — 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 SA1886 below – Retail pharmacy — 166.50 — 90 — ✔ **Entocort CIR**

➽**SA1886** **Special Authority for Subsidy**

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

Both:

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

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

All of the following:

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

Note: Indication marked with * is an unapproved indication.

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

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

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

HYDROCORTISONE ACETATE				
Rectal foam 10%, CFC-Free (14 applications)	26.55	21.1 g OP	✔	**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	56.10	100	✔	**Pentasa**
Pentasa to be Sole Supply on 1 July 2020				
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**

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

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**

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	6.35	5	✔	**Buscopan**
Buscopan to be Sole Supply on 1 July 2020				
MEBEVERINE HYDROCHLORIDE				
Tab 135 mg	9.20	90	✔	**Colofac**
Colofac to be Sole Supply on 1 July 2020				

Antiulcerants

Antisecretory and Cytoprotective

MISOPROSTOL				
Tab 200 mcg	41.50	120	✔	**Cytotec**

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

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 ..... 4.91 | 100 | ✔ **Famotidine Hovid** S29

Tab 40 mg ..... 8.48 | 100 | ✔ **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**

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 244

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**

✔ **Ocicure** S29

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

▲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
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 below – Retail pharmacy

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

SA1320 Special Authority for Subsidy

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

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

GLUCAGON HYDROCHLORIDE

Inj 1 mg syringe kit – Up to 5 kit available on a PSO Glucagen Hypokit to be Sole Supply on 1 July 2020	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**

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

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

▲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
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**

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**

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	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

29 g × 12.7 mm	10.50	100	✔	**B-D Micro-Fine**
31 g × 5 mm	11.75	100	✔	**B-D Micro-Fine**
31 g × 6 mm	9.50	100	✔	**Berpu**
31 g × 8 mm	10.50	100	✔	**B-D Micro-Fine**
32 g × 4 mm	10.50	100	✔	**B-D Micro-Fine**

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

Syringe 0.3 ml with 29 g × 12.7 mm needle	13.00	100	✔	**B-D Ultra Fine**
	1.30	10		
	(1.99)			B-D Ultra Fine
Syringe 0.3 ml with 31 g × 8 mm needle	13.00	100	✔	**B-D Ultra Fine II**
	1.30	10		
	(1.99)			B-D Ultra Fine II
Syringe 0.5 ml with 29 g × 12.7 mm needle	13.00	100	✔	**B-D Ultra Fine**
	1.30	10		
	(1.99)			B-D Ultra Fine
Syringe 0.5 ml with 31 g × 8 mm needle	13.00	100	✔	**B-D Ultra Fine II**
	1.30	10		
	(1.99)			B-D Ultra Fine II
Syringe 1 ml with 29 g × 12.7 mm needle	13.00	100	✔	**B-D Ultra Fine**
	1.30	10		
	(1.99)			B-D Ultra Fine
Syringe 1 ml with 31 g × 8 mm needle	13.00	100	✔	**B-D Ultra Fine II**
	1.30	10		
	(1.99)			B-D Ultra Fine II

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.

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

➠SA1906 **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) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Both:

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.

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
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

continued…

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

continued…

8.2 Applicant is a nurse practitioner working within their vocational scope.

Renewal — (severe unexplained hypoglycaemia) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Both:

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, according to the most recent result.

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

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, according to the most recent result; and
2 The number of severe unexplained recurrent hypoglycaemic episodes has not increased from baseline.

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 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) from any relevant practitioner. Approvals valid for 2 years 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 is continuing to derive benefit according to the treatment plan and has maintained a HbA1c of equal to or less than 80 mmol/mol according to a recent laboratory result; and

2 The patient's HbA1c has not deteriorated more than 5 mmol/mol from initial application, according to the most recent result; and

3 The patient has not had an increase in severe unexplained hypoglycaemic episodes from baseline.

INSULIN PUMP CARTRIDGE – Special Authority see SA1906 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 SA1906 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; 60 cm tubing × 10	130.00	1 OP	✔	**MiniMed Sure-T MMT-884A**
10 mm steel needle; 80 cm tubing × 10	130.00	1 OP	✔	**MiniMed Sure-T MMT-886A**
6 mm steel needle; 60 cm tubing × 10	130.00	1 OP	✔	**MiniMed Sure-T MMT-864A**
6 mm steel needle; 80 cm tubing × 10	130.00	1 OP	✔	**MiniMed Sure-T MMT-866A**
8 mm steel needle; 60 cm tubing × 10	130.00	1 OP	✔	**MiniMed Sure-T MMT-874A**
8 mm steel needle; 80 cm tubing × 10	130.00	1 OP	✔	**MiniMed Sure-T MMT-876A**
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**

✔ **fully subsidised**

Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
8 mm steel needle; 29 G; manual insertion; 80 cm tubing x 10 with 10 needles; luer lock	130.00	1 OP	✔	**Sure-T MMT-875**

(Sure-T MMT-883 10 mm steel needle; 29 G; manual insertion; 60 cm tubing x 10 with 10 needles; luer lock to be delisted 1 September 2020)
(Sure-T MMT-885 10 mm steel needle; 29 G; manual insertion; 80 cm tubing x 10 with 10 needles; luer lock to be delisted 1 September 2020)
(Sure-T MMT-865 6 mm steel needle; 29 G; manual insertion; 80 cm tubing x 10 with 10 needles; luer lock to be delisted 1 September 2020)
(Sure-T MMT-875 8 mm steel needle; 29 G; manual insertion; 80 cm tubing x 10 with 10 needles; luer lock to be delisted 1 September 2020)

INSULIN PUMP INFUSION SET (STEEL CANNULA, STRAIGHT INSERTION) – Special Authority see SA1906 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 x 10 with 10 needles	130.00	1 OP	✔	**TruSteel**
6 mm steel cannula; straight insertion; 81 cm line x 10 with 10 needles	130.00	1 OP	✔	**TruSteel**
8 mm steel cannula; straight insertion; 60 cm line x 10 with 10 needles	130.00	1 OP	✔	**TruSteel**
8 mm steel cannula; straight insertion; 81 cm line x 10 with 10 needles	130.00	1 OP	✔	**TruSteel**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
INSULIN PUMP INFUSION SET (TEFLON CANNULA) – Special Authority see SA1906 on page 17 – Retail pharmacy				
a) Maximum of 3 set per prescription b) Only on a prescription c) Maximum of 13 infusion sets will be funded per year.				
13 mm teflon needle, 110 cm tubing x 10	130.00	1 OP	✔	**MiniMed Silhouette MMT-382A**
13 mm teflon needle, 45 cm tubing x 10	130.00	1 OP	✔	**MiniMed Silhouette MMT-368A**
13 mm teflon needle, 60 cm tubing x 10	130.00	1 OP	✔	**MiniMed Silhouette MMT-381A**
13 mm teflon needle, 80 cm tubing x 10	130.00	1 OP	✔	**MiniMed Silhouette MMT-383A**
17 mm teflon needle, 110 cm tubing x 10	130.00	1 OP	✔	**MiniMed Silhouette MMT-377A**
17 mm teflon needle, 60 cm tubing x 10	130.00	1 OP	✔	**MiniMed Silhouette MMT-378A**
17 mm teflon needle, 80 cm tubing x 10	130.00	1 OP	✔	**MiniMed Silhouette MMT-384A**
6 mm teflon needle, 110 cm tubing x 10	130.00	1 OP	✔	**MiniMed Quick-Set MMT-398A**
6 mm teflon needle, 45 cm blue tubing x 10	130.00	1 OP	✔	**MiniMed Mio MMT-941A**
6 mm teflon needle, 45 cm pink tubing x 10	130.00	1 OP	✔	**MiniMed Mio MMT-921A**
6 mm teflon needle, 60 cm blue tubing x 10	130.00	1 OP	✔	**MiniMed Mio MMT-943A**
6 mm teflon needle, 60 cm pink tubing x 10	130.00	1 OP	✔	**MiniMed Mio MMT-923A**
6 mm teflon needle, 60 cm tubing x 10	130.00	1 OP	✔	**MiniMed Quick-Set MMT-399A**
6 mm teflon needle, 80 cm blue tubing	130.00	1 OP	✔	**MiniMed Mio MMT-945A**
6 mm teflon needle, 80 cm clear tubing x 10	130.00	1 OP	✔	**MiniMed Mio MMT-965A**
6 mm teflon needle, 80 cm pink tubing x 10	130.00	1 OP	✔	**MiniMed Mio MMT-925A**
6 mm teflon needle, 80 cm tubing x 10	130.00	1 OP	✔	**MiniMed Quick-Set MMT-387A**
9 mm teflon needle, 110 cm tubing x 10	130.00	1 OP	✔	**MiniMed Quick-Set MMT-396A**
9 mm teflon needle, 60 cm tubing x 10	130.00	1 OP	✔	**MiniMed Quick-Set MMT-397A**
9 mm teflon needle, 80 cm clear tubing x 10	130.00	1 OP	✔	**MiniMed Mio MMT-975A**
9 mm teflon needle, 80 cm tubing x 10	130.00	1 OP	✔	**MiniMed Quick-Set MMT-386A**

✔ **fully subsidised**

Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	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 SA1906 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 x 10 with 10 needles	140.00	1 OP	✔	**AutoSoft 30**
13 mm teflon cannula; angle insertion; insertion device; 60 cm line x 10 with 10 needles	140.00	1 OP	✔	**AutoSoft 30**
INSULIN PUMP INFUSION SET (TEFLON CANNULA, ANGLE INSERTION) – Special Authority see SA1906 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 x 10 with 10 needles	130.00	1 OP	✔	**Paradigm Silhouette MMT-382**
13 mm teflon cannula; angle insertion; 45 cm line x 10 with 10 needles	130.00	1 OP	✔	**Paradigm Silhouette MMT-368**
13 mm teflon cannula; angle insertion; 60 cm line x 10 with 10 needles	130.00	1 OP	✔	**Paradigm Silhouette MMT-381**
13 mm teflon cannula; angle insertion; 80 cm line x 10 with 10 needles	130.00	1 OP	✔	**Paradigm Silhouette MMT-383**
17 mm teflon cannula; angle insertion; 110 cm line x 10 with 10 needles	130.00	1 OP	✔	**Paradigm Silhouette MMT-377**
17 mm teflon cannula; angle insertion; 110 cm line x 10 with 10 needles; luer lock	130.00	1 OP	✔	**Silhouette MMT-371**
17 mm teflon cannula; angle insertion; 60 cm line x 10 with 10 needles	130.00	1 OP	✔	**Paradigm Silhouette MMT-378**
17 mm teflon cannula; angle insertion; 60 cm line x 10 with 10 needles; luer lock	130.00	1 OP	✔	**Silhouette MMT-373**
17 mm teflon cannula; angle insertion; 80 cm line x 10 with 10 needles	130.00	1 OP	✔	**Paradigm Silhouette MMT-384**

(Silhouette MMT-371 17 mm teflon cannula; angle insertion; 110 cm line x 10 with 10 needles; luer lock to be delisted 1 September 2020)

	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 SA1906 on page 17 – Retail pharmacy				
a) Maximum of 3 sets per prescription b) Only on a prescription c) Maximum of 13 infusion sets will be funded per year.				
6 mm teflon cannula; straight insertion; insertion device; 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**

✔ **fully subsidised**

Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

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

INSULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIGHT INSERTION) – Special Authority see SA1906 on page 17 – Retail pharmacy

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

6 mm teflon cannula; straight insertion; 110 cm tubing × 10 with 10 needles	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**

(Quick-Set MMT-391 6 mm teflon cannula; straight insertion; 110 cm tubing × 10 with 10 needles; luer lock to be delisted 1 September 2020)

(Quick-Set MMT-390 9 mm teflon cannula; straight insertion; 110 cm tubing × 10 with 10 needles; luer lock to be delisted 1 September 2020)

INSULIN PUMP RESERVOIR – Special Authority see SA1906 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.

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**

▲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

Digestives Including Enzymes

PANCREATIC ENZYME

Cap pancreatin 150 mg (amylase 8,000 Ph Eur U, lipase 10,000 Ph Eur U, total protease 600 Ph Eur U)	34.93	100	✔	**Creon 10000**
Cap pancreatin (175 mg (25,000 U lipase, 22,500 U amylase, 1,250 U protease))	94.40	100	✔	**Panzytrat**
Cap pancreatin 300 mg (amylase 18,000 Ph Eur U, lipase 25,000 Ph Eur U, total protease 1,000 Ph Eur U)	94.38	100	✔	**Creon 25000**
Modified release granules pancreatin 60.12 mg (amylase 3,600 Ph Eur U, lipase 5,000 Ph Eur U, protease 200 Ph Eur U)	34.93	20 g OP	✔	**Creon Micro**

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

continued…

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

continued…

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.

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	500 g OP		
	(17.32)			Normacol Plus
	2.41	200 g OP		
	(8.72)			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.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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**
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		
	(8.21)			Senokot
	0.43	20		
	(2.06)			Senokot
Metabolic Disorder Agents				
ALGLUCOSIDASE ALFA – Special Authority see SA1920 below – Retail pharmacy				
Inj 50 mg vial	1,142.60	1	✔	**Myozyme**

➸**SA1920** **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

continued…

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

continued…

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 from any relevant practitioner. 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.

BETAINE – Special Authority see SA1921 below – Retail pharmacy

Powder for oral soln	575.00	180 g	OP	✔ **Cystadane**

➽**SA1921** **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 from any relevant practitioner. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.

GALSULFASE – Special Authority see SA1922 below – Retail pharmacy

Inj 1 mg per ml, 5 ml vial	2,234.00	1		✔ **Naglazyme**

➽**SA1922** **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 from any relevant practitioner. 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.

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

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 SA1923 below – Retail pharmacy				
Tab soluble 100 mg	1,452.70	30 OP	✔	**Kuvan**

SA1923 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 from any relevant practitioner. Approvals valid for 12 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 Following the initial one-month approval, the patient has demonstrated an adequate response to a 2 to 4 week trial of sapropterin with a clinically appropriate reduction in phenylalanine levels to support management of PKU during pregnancy; or

1.2 On subsequent renewal applications, the patient has previously demonstrated response to treatment with sapropterin and maintained adequate phenylalanine levels to support management of PKU during pregnancy; and

2 Any of the following:

2.1 Patient continues to be pregnant and treatment with sapropterin will not continue after delivery; or

2.2 Patient is actively planning a pregnancy and this is the first renewal for treatment with sapropterin; or

2.3 Treatment with sapropterin is required for a second or subsequent pregnancy to support management of their PKU during pregnancy; and

3 Sapropterin to be administered at doses no greater than a total daily dose of 20 mg/kg; and

4 Sapropterin to be used alone or in combination with PKU dietary management; and

5 Total treatment duration with sapropterin will not exceed 22 months for each pregnancy (includes time for planning and becoming pregnant) and treatment will be stopped after delivery.

SODIUM BENZOATE – Special Authority see SA1599 below – Retail pharmacy

Soln 100 mg per ml	CBS	100 ml	✔	**Amzoate** S29

➠**SA1599** **Special Authority for Subsidy**

Initial application only from a metabolic physician. Approvals valid for 12 months where the patient has a diagnosis of a urea cycle 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 SA1924 below – Retail pharmacy

Grans 483 mg per g	1,920.00	174 g OP	✔	**Pheburane**

➠**SA1924** **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 from any relevant practitioner. 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 SA1880 below – Retail pharmacy

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

➠**SA1880** **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

continued…

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

continued…

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, 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
   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 two years since initiation of treatment, and 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) Patient has not had severe infusion-related adverse reactions which were not preventable by appropriate pre-medication and/or adjustment of infusion rates; and
5) Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT; and
6) 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
7) Supporting clinical information including test reports, MRI whole body STIR, haematological data, and other relevant investigations are submitted to the Gaucher Panel for assessment as required.

Mouth and Throat

Agents Used in Mouth Ulceration

BENZYDAMINE HYDROCHLORIDE

Soln 0.15% – Higher subsidy of $20.31 per 500 ml with Endorsement ..... 9.00 (20.31) 500 ml 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.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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**
(healthE Mouthwash 0.2% to be delisted 1 November 2020)				
CHOLINE SALICYLATE WITH CETALKONIUM CHLORIDE				
Adhesive gel 8.7% with cetalkonium chloride 0.01%	2.06	15 g OP		
	(6.00)			Bonjela
TRIAMCINOLONE ACETONIDE				
Paste 0.1%	5.33	5 g OP	✔	**Kenalog in Orabase**

Oropharyngeal Anti-infectives

AMPHOTERICIN B				
Lozenges 10 mg	5.86	20	✔	**Fungilin**
MICONAZOLE				
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 244

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

Note that funding of vitamin A oral liquid can be applied for through the Exceptional Circumstances process; the application form can be found on the PHARMAC website https://pharmac.govt.nz/assets/form-alphatocopherylacetate-and-vitaminA.pdf

Soln 1000 u with Vitamin D 400 u and ascorbic acid 30 mg per 10 drops	4.50	10 ml OP	✔	**Vitadol C**

(Vitadol C Soln 1000 u with Vitamin D 400 u and ascorbic acid 30 mg per 10 drops to be delisted 1 July 2020)

Vitamin B

HYDROXOCOBALAMIN				
Inj 1 mg per ml, 1 ml ampoule – Up to 6 inj available on a PSO	1.89	3	✔	**Neo-B12**

▲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
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**

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.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
VITAMINS				
Tab (BPC cap strength)	11.45	1,000	✔	**Mvite**
Cap (fat soluble vitamins A, D, E, K) – Special Authority see SA1720 below – Retail pharmacy	23.40	60	✔	**Vitabdeck**

SA1720 Special Authority for Subsidy

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

Any of the following:

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

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	32.00	10	✔	**Max Health - Hameln** S29
	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.

continued…

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

continued…

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 and a trial of oral iron is unlikely to be effective; or
  2.4 Rapid correction of anaemia is required.

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

Both:

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

FERROUS FUMARATE				
Tab 200 mg (65 mg elemental)	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	34.50	5	✔	**Ferrosig**

Magnesium

For magnesium hydroxide mixture refer Standard Formulae, page 244

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

ZINC SULPHATE				
Cap 137.4 mg (50 mg elemental)	11.00	100	✔	**Zincaps**

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	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**

▲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
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**

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	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**
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 thrombosis) 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 SA1887 below – Retail pharmacy				
Tab 90 mg	90.00	56	✔	**Brilinta**

➽**SA1887** **Special Authority for Subsidy**

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

Both:

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

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

Both:

1 Patient has had a neurological stenting procedure* in the last 60 days; and

continued…

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

continued…

2 Either:

2.1 Patient has demonstrated clopidogrel resistance using the P2Y12 (VerifyNow) assay and requires antiplatelet treatment with ticagrelor; or

2.2 Clopidogrel resistance has been demonstrated by the occurrence of a new cerebral ischemic event.

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

1 Patient has recently (within the last 60 days) been diagnosed with an ST-elevation or a non-ST-elevation acute coronary syndrome; and

2 Fibrinolytic therapy has not been given in the last 24 hours and is not planned.

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

1 Patient is continuing to benefit from treatment; and

2 Treatment continues to be clinically appropriate.

Note: indications marked with * are unapproved indications.

Heparin and Antagonist Preparations

ENOXAPARIN SODIUM – Special Authority see SA1646 below – 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** ✔ **Clexane Forte**
Inj 150 mg in 1 ml syringe	133.20	10	✔ **Clexane** ✔ **Clexane Forte**

(Clexane Inj 120 mg in 0.8 ml syringe to be delisted 1 January 2021)
(Clexane Inj 150 mg in 1 ml syringe to be delisted 1 January 2021)

➽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.

continued…

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

continued…

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	✔	**Pfizer**
	32.66		✔	**Hospira**
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	65.48	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**
WARFARIN SODIUM				
Note: Marevan and Coumadin are not interchangeable.				
Tab 1 mg	3.46	50	✔	**Coumadin**
	6.46	100	✔	**Marevan**
Tab 2 mg	4.31	50	✔	**Coumadin**
Tab 3 mg	10.03	100	✔	**Marevan**
Tab 5 mg	5.93	50	✔	**Coumadin**
	11.48	100	✔	**Marevan**

Blood Colony-stimulating Factors

FILGRASTIM – Special Authority see SA1259 on the next page – 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**

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

➽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 SA1912 below – Retail pharmacy

Inj 6 mg per 0.6 ml syringe	1,080.00	1	✔	**Neulastim**

➽SA1912 Special Authority for Subsidy

Initial application only from a relevant specialist, vocationally registered general practitioner or medical practitioner on the recommendation of a relevant specialist. Approvals valid without further renewal unless notified where used for prevention of neutropenia in patients undergoing high risk chemotherapy for cancer (febrile neutropenia risk greater than or equal to 5%*).

Note: *Febrile neutropenia risk greater than or equal to 5% after taking into account other risk factors as defined by the European Organisation for Research and Treatment of Cancer (EORTC) guidelines.

Fluids and Electrolytes

Intravenous Administration

GLUCOSE [DEXTROSE]

Inj 50%, 10 ml ampoule – Up to 5 inj available on a PSO	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

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				

✔ fully subsidised
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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 244				
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)				
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 5 sach available on a PSO	9.77	50	✔	**Electral**
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**
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**

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

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
Alpha-Adrenoceptor Blockers				
Alpha Adrenoceptor Blockers				
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**
Tab 5 mg	8.35	90	✔	**Zapril**
ENALAPRIL MALEATE				
Tab 5 mg	1.82	100	✔	**Acetec**
Tab 10 mg	2.02	100	✔	**Acetec**
Tab 20 mg	2.42	100	✔	**Acetec**
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**
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**

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

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

ACE Inhibitors with Diuretics

CILAZAPRIL WITH HYDROCHLOROTHIAZIDE – Subsidy by endorsement

Subsidy by endorsement – Subsidised for patients who were taking cilazapril with hydrochlorothiazide prior to 1 March 2020 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of cilazapril with hydrochlorothiazide.

Tab 5 mg with hydrochlorothiazide 12.5 mg	10.18	100	✔	**Apo-Cilazapril/ Hydrochlorothiazide**

(Apo-Cilazapril/ Hydrochlorothiazide Tab 5 mg with hydrochlorothiazide 12.5 mg to be delisted 1 December 2020)

QUINAPRIL WITH HYDROCHLOROTHIAZIDE

Tab 10 mg with hydrochlorothiazide 12.5 mg	3.57	28	✔	**Accuretic**
	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 SA1905 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**

➽**SA1905** **Special Authority for Subsidy**

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

1 Patient has heart failure; and

2 Any of the following:

2.1 Patient is in NYHA/WHO functional class II; or

continued…

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

continued…

2.2 Patient is in NYHA/WHO functional class III; or
2.3 Patient is in NYHA/WHO functional class IV; and

3 Either:
3.1 Patient has a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%; or
3.2 An ECHO is not reasonably practical, and in the opinion of the treating practitioner the patient would benefit from treatment; and

4 Patient is receiving concomitant optimal standard chronic heart failure treatments.

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 115

AMIODARONE HYDROCHLORIDE				
Tab 100 mg	3.80	30	✔	**Aratac**
Tab 200 mg	5.25	30	✔	**Aratac**
Inj 50 mg per ml, 3 ml ampoule – Up to 10 inj available on a PSO	16.37	10	✔	**Max Health**
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				
Tab 50 mg	19.95	60	✔	**Flecainide BNM**
Cap long-acting 100 mg	39.51	90	✔	**Flecainide Controlled Release Teva**
Cap long-acting 200 mg	61.06	90	✔	**Flecainide Controlled Release Teva**
Inj 10 mg per ml, 15 ml ampoule	100.00	5	✔	**Tambocor**
MEXILETINE HYDROCHLORIDE				
Cap 150 mg	162.00	100	✔	**Mexiletine Hydrochloride USP** S29
Cap 250 mg	202.00	100	✔	**Mexiletine Hydrochloride USP** S29
PROPAFENONE HYDROCHLORIDE				
Tab 150 mg	40.90	50	✔	**Rytmonorm**

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

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

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**
			✔	**Atenolol AFT**
				S29 S29

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
	14.50		✔	**Trandate**
Trandate to be Sole Supply on 1 September 2020				
Tab 200 mg	27.00	100	✔	**Trandate**
	29.74		✔	**Presolol** S29
Trandate to be Sole Supply on 1 September 2020				
Inj 5 mg per ml, 20 ml ampoule	59.06	5		
	(88.60)			Trandate

(Presolol S29 Tab 100 mg to be delisted 1 September 2020)

(Presolol S29 Tab 200 mg to be delisted 1 September 2020)

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**

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

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

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**
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**

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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**
Tab long-acting 60 mg	5.67	30	✔	**Adalat Oros**
			✔	**Adefin XL**

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	36.02	100	✔	**Isoptin Retard** S29
			✔	**Isoptin SR**
Tab long-acting 240 mg	15.12	30	✔	**Isoptin SR**
	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 240 mg to be delisted 1 September 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

Diuretics

Loop Diuretics

BUMETANIDE				
Tab 1 mg	4.91	30	✔	**Burinex S29** S29
	16.36	100	✔	**Burinex**
Inj 500 mcg per ml, 4 ml vial	7.95	5	✔	**Burinex**

▲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
FUROSEMIDE [FRUSEMIDE]				
Tab 40 mg – Up to 30 tab available on a PSO	7.24	1,000	✔	Apo-Furosemide
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

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

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

✔ fully subsidised

Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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	21.56	30	✔	**Olbetam**
			✔	**Olbetam S29** S29
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)

ATORVASTATIN				
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**
PRAVASTATIN				
Tab 20 mg	4.72	100	✔	**Apo-Pravastatin**
Tab 40 mg	8.06	100	✔	**Apo-Pravastatin**
SIMVASTATIN				
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 on the next page – Retail pharmacy				
Tab 10 mg	2.00	30	✔	**Ezetimibe Sandoz**

▲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

➽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 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

Oral pump spray, 400 mcg per dose – Up to 250 dose available on a PSO	4.45	250 dose OP	✔	**Nitrolingual Pump Spray**
Patch 25 mg, 5 mg per day	15.73	30	✔	**Nitroderm TTS**
Patch 50 mg, 10 mg per day	18.62	30	✔	**Nitroderm TTS**

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
ISOSORBIDE MONONITRATE				
Tab 20 mg	18.80	100	✔	**Ismo 20**
Tab long-acting 40 mg	8.20	30	✔	**Ismo 40 Retard**
Tab long-acting 60 mg	8.29	90	✔	**Duride**

Sympathomimetics

ADRENALINE				
Inj 1 in 1,000, 1 ml ampoule – Up to 5 inj available on a PSO	4.98	5	✔	**Aspen Adrenaline**
	10.76		✔	**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]				
Inj 200 mcg per ml, 1 ml ampoule	36.80	25		
	(164.20)			Isuprel

Vasodilators

HYDRALAZINE HYDROCHLORIDE				
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				
Tab 10 mg	70.00	100	✔	**Loniten**
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 on the next page – Retail pharmacy				
Tab 5 mg	4,585.00	30	✔	**Volibris**
Tab 10 mg	4,585.00	30	✔	**Volibris**

▲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

➽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 SA1908 below – Retail pharmacy

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

➽SA1908 Special Authority for Subsidy
Initial application only from a respiratory specialist, cardiologist or medical practitioner on the recommendation of a respiratory physician or cardiologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

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

Renewal from any relevant practitioner. 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

continued…

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

continued…

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 SA1909 below – Retail pharmacy

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

➽**SA1909** **Special Authority for Subsidy**

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

All of the following:

1 Patient has Raynaud's Phenomenon*; and

2 Patient has severe digital ischaemia (defined as severe pain requiring hospital admission or with a high likelihood of digital ulceration; digital ulcers; or gangrene); and

3 Patient is following lifestyle management (avoidance of cold exposure, sufficient protection, smoking cessation support, avoidance of sympathomimetic drugs); and

4 Patient is being treated with calcium channel blockers and nitrates (or these are contraindicated/not tolerated).

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

All of the following:

1 Patient has pulmonary arterial hypertension (PAH)*; and

2 Any of the following:

2.1 PAH is in Group 1 of the WHO (Venice) clinical classifications; or

2.2 PAH is in Group 4 of the WHO (Venice) clinical classifications; or

2.3 PAH is in Group 5 of the WHO (Venice) clinical classifications; and

3 Any of the following:

3.1 PAH is in NYHA/WHO functional class II; or

3.2 PAH is in NYHA/WHO functional class III; or

3.3 PAH is in NYHA/WHO functional class IV; and

4 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

continued…

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

continued…

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, or health system capacity constraints.

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

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

Antiacne Preparations

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 86

ADAPALENE

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

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

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

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 86

HYDROGEN PEROXIDE

Crm 1%	8.56	10 g	OP	✔ **Crystaderm**
		15 g	OP	✔ **Crystaderm**

▲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
MUPIROCIN				
Oint 2%	6.60	15 g OP		
	(9.26)			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 93

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	20 ml OP		
	(7.55)			Canesten
a) Only on a prescription b) Not in combination				
ECONAZOLE NITRATE				
Crm 1%	1.00	20 g OP		
	(7.48)			Pevaryl
a) Only on a prescription b) Not in combination				
Foaming soln 1%, 10 ml sachets	9.89	3		
	(17.23)			Pevaryl
a) Only on a prescription b) Not in combination				

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
MICONAZOLE NITRATE				
Crm 2%.....	0.74	15 g OP	✔	**Multichem**
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				
(Mycostatin Crm 100,000 u per g to be delisted 1 August 2020)				

Antipruritic Preparations

CALAMINE				
a) Only on a prescription b) Not in combination				
Crm, aqueous, BP	1.26	100 g	✔	**healthE Calamine Aqueous Cream BP**
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	✔	**Itch-Soothe**
MENTHOL – Only in combination				
1) Only in combination with a dermatological base or proprietary Topical Corticosteriod – Plain 2) With or without other dermatological galenicals.				
Crystals.....	6.92	25 g	✔	**MidWest**
	29.60	100 g	✔	**MidWest**

Corticosteroids Topical

For systemic corticosteroids, refer to CORTICOSTEROIDS AND RELATED AGENTS, page 76

Corticosteroids - Plain

BETAMETHASONE DIPROPIONATE				
Crm 0.05%.....	2.96	15 g OP	✔	**Diprosone**
	8.97	50 g OP	✔	**Diprosone**
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**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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
(Nerisone Crm 0.1% to be delisted 1 December 2020)				
(Nerisone Fatty oint 0.1% to be delisted 1 August 2021)				
HYDROCORTISONE				
Crm 1% – Only on a prescription	3.42	30 g OP	✔	**DermAssist**
	3.70	100 g OP	✔	**Hydrocortisone (PSM)**
	17.15	500 g	✔	**Pharmacy Health**
Hydrocortisone (PSM) to be Sole Supply on 1 September 2020				
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				
(DermAssist Crm 1% to be delisted 1 September 2020)				
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**
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**

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

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

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**

(healthE Handrub 1% with ethanol 70% to be delisted 1 November 2020)
(healthE Soln 4% wash to be delisted 1 November 2020)

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**

(healthE Soln 1% to be delisted 1 November 2020)

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**

▲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
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	✔	**ADE**
			✔	**Boucher**
	3.10	1,000 ml OP	✔	**ADE**
			✔	**Boucher**
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
Other Dermatological Bases				
PARAFFIN				
White soft – Only in combination	4.99	450 g	✔	**healthE**
	19.99	2,500 g	✔	**healthE**
Only in combination with a dermatological galenical or as a diluent for a proprietary Topical Corticosteroid – Plain.				
Minor Skin Infections				
POVIDONE IODINE				
Oint 10%	7.40	65 g OP	✔	**Betadine**
a) Maximum of 130 g per prescription b) Only on a prescription				
Antiseptic Solution 10%	2.55	100 ml	✔	**Riodine**
Antiseptic soln 10%	3.83	15 ml	✔	**Riodine**
	5.40	500 ml	✔	**Riodine**
Skin preparation, povidone iodine 10% with 30% alcohol	1.63	100 ml		
	(3.48)			Betadine Skin Prep
Skin preparation, povidone iodine 10% with 70% alcohol	1.63	100 ml		
	(7.78)			Pfizer

✔ **fully subsidised**

Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

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

Parasiticidal Preparations

DIMETHICONE

Lotn 4% ..... 4.98 — 200 ml OP — ✔ **healthE Dimethicone 4% Lotion**

IVERMECTIN – Special Authority see SA1225 below – Retail pharmacy

Tab 3 mg – Up to 100 tab available on a PSO ..... 17.20 — 4 — ✔ **Stromectol**

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

➽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

continued…

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

continued…

microbiologist; and

2 Either:

2.1 Both:

2.1.1 The patient is in the community; and

2.1.2 Any of the following:

2.1.2.1 Patient has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or

2.1.2.2 The community patient is physically or mentally unable to comply with the application instructions of topical therapy; or

2.1.2.3 The patient has previously tried and failed to clear infestation using topical therapy; or

2.2 All of the following:

2.2.1 The Patient is a resident in an institution; and

2.2.2 All residents of the institution with scabies or at risk of carriage are to be treated for scabies concurrently; and

2.2.3 Any of the following:

2.2.3.1 Patient has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or

2.2.3.2 The patient is physically or mentally unable to comply with the application instructions of topical therapy; or

2.2.3.3 Previous topical therapy has been tried and failed to clear the infestation.

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

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

Any of the following:

1 Filaricides; or

2 Cutaneous larva migrans (creeping eruption); or

3 Strongyloidiasis.

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

continued…

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

continued…

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

Foam spray 500 mcg with calcipotriol 50 mcg per g	59.95	60 g OP	✔	**Enstilar**
Gel 500 mcg with calcipotriol 50 mcg per g	52.24	60 g OP	✔	**Daivobet**
Oint 500 mcg with calcipotriol 50 mcg per g	19.95	30 g OP	✔	**Daivobet**

CALCIPOTRIOL

Oint 50 mcg per g	45.00	100 g OP	✔	**Daivonex**

COAL TAR

Soln BP – Only in combination	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**

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

Sunscreens

SUNSCREENS, PROPRIETARY – Subsidy by endorsement

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

Lotn,	5.10	200 g OP	✔	**Marine Blue Lotion SPF 50+**

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

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

Contraceptives - Non-hormonal

Condoms

CONDOMS

49 mm – Up to 144 dev available on a PSO	11.42	144	✔	**Moments**
53 mm	0.95	10	✔	**Moments**
	11.64	144	✔	**Moments**
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				
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				
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				
56 mm	0.97	10	✔	**Moments**
	11.64	144	✔	**Moments**
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				
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				
56 mm, 0.08 mm thickness, red	0.97	10	✔	**Moments**
	11.64	144	✔	**Moments**
a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription				
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				
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				
60 mm – Up to 144 dev available on a PSO	14.87	144	✔	**Shield XL**

▲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

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.

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

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

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

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

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

ETHINYLOESTRADIOL WITH DESOGESTREL

Tab 20 mcg with desogestrel 150 mcg and 7 inert tab	6.62	84		
	(19.80)			Mercilon 28

a) Higher subsidy of $13.80 per 84 tab with Special Authority see SA0500 above
b) Up to 84 tab available on a PSO

Tab 30 mcg with desogestrel 150 mcg and 7 inert tab	6.62	84		
	(19.80)			Marvelon 28

a) Higher subsidy of $13.80 per 84 tab with Special Authority see SA0500 above
b) Up to 84 tab available on a PSO

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
ETHINYLOESTRADIOL WITH LEVONORGESTREL				
Tab 20 mcg with levonorgestrel 100 mcg and 7 inert tablets – Up to 112 tab available on a PSO	2.18	84	✔	**Microgynon 20 ED**
	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	63		
	(16.50)			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				
Tab 30 mcg with levonorgestrel 150 mcg and 7 inert tablets – Up to 112 tab available on a PSO	1.77	84	✔	**Levlen ED**
	6.45	112	✔	**Femme-Tab ED**
ETHINYLOESTRADIOL WITH NORETHISTERONE				
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	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	✔	**Necon** S29
			✔	**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)

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 (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
LEVONORGESTREL				
Tab 30 mcg – Up to 84 tab available on a PSO	16.50	84	✔	**Microlut**
	22.00	112	✔	**Microlut SCT**
				S29 S29
Subdermal implant (2 x 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

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.

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	100 g OP		
	(24.00)			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**

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

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

Urinary Agents

For urinary tract Infections refer to INFECTIONS, Antibacterials, page 104

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**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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**
TOLTERODINE – Special Authority see SA1272 below – Retail pharmacy				
Tab 2 mg	14.56	56	✔	**Arrow-Tolterodine**

(Arrow-Tolterodine Tab 2 mg to be delisted 1 July 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

ORTHO-TOLIDINE			
Compound diagnostic sticks	7.50	50 test OP	
	(8.25)		Hemastix
TETRABROMOPHENOL			
Blue diagnostic strips	7.02	100 test OP	
	(13.92)		Albustix

✔ **fully subsidised**

Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	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

BETAMETHASONE SODIUM PHOSPHATE WITH BETAMETHASONE ACETATE				
Inj 3.9 mg with betamethasone acetate 3 mg per ml, 1 ml	19.20	5		
	(36.96)			Celestone Chronodose
DEXAMETHASONE				
Tab 0.5 mg – Up to 60 tab available on a PSO	0.99	30	✔	**Dexmethsone**
Tab 4 mg – Up to 30 tab available on a PSO	1.90	30	✔	**Dexmethsone**
Oral liq 1 mg per ml	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	9.25	10	✔	**Dexamethasone Phosphate Panpharma**
	14.19		✔	**Max Health**
Dexamethasone Phosphate Panpharma to be Sole Supply on 1 July 2020				
Inj 4 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	16.37	10	✔	**Dexamethasone Phosphate Panpharma**
	25.18		✔	**Max Health**
Dexamethasone Phosphate Panpharma to be Sole Supply on 1 July 2020				
(Max Health Inj 4 mg per ml, 1 ml ampoule to be delisted 1 July 2020)				
(Max Health Inj 4 mg per ml, 2 ml ampoule to be delisted 1 July 2020)				
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	5.30	1	✔	**Solu-Cortef**
a) Up to 5 inj available on a PSO				
b) Only on a PSO				
METHYLPREDNISOLONE				
Tab 4 mg	112.00	100	✔	**Medrol**
Tab 100 mg	194.00	20	✔	**Medrol**

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Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
METHYLPREDNISOLONE (AS SODIUM SUCCINATE)				
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**
PREDNISOLONE				
Oral liq 5 mg per ml – Up to 30 ml available on a PSO Restricted to children under 12 years of age.	6.00	30 ml OP	✔	**Redipred**
PREDNISONE				
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 – Up to 30 tab available on a PSO	29.03	500	✔	**Apo-Prednisone**
TETRACOSACTRIN				
Inj 250 mcg per ml, 1 ml ampoule	75.00	1	✔	**UK Synacthen** S29
			✔	**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**
	26.62		✔	**Adcortyl** S29
Inj 40 mg per ml, 1 ml ampoule	11.30	1	✔	**Triaver** S29
	51.10	5	✔	**Kenacort-A 40**
	70.62		✔	**Kenalog** S29

Sex Hormones Non Contraceptive

Androgen Agonists and Antagonists

CYPROTERONE ACETATE				
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				
Inj 100 mg per ml, 10 ml vial	76.50	1	✔	**Depo-Testosterone**
TESTOSTERONE ESTERS				
Inj 250 mg per ml, 1 ml	12.98	1	✔	**Sustanon Ampoules**

▲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
TESTOSTERONE UNDECANOATE				
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".

Oestrogens

OESTRADIOL – See prescribing guideline above				
Tab 1 mg	4.12	28 OP		
	(11.10)			Estrofem
Tab 2 mg	4.12	28 OP		
	(11.10)			Estrofem
Patch 25 mcg per day	6.12	8	✔	**Estradot**
a) No more than 2 patch per week b) Only on a prescription				
Patch 50 mcg per day	7.04	8	✔	**Estradot 50 mcg**
a) No more than 2 patch per week b) Only on a prescription				
Patch 75 mcg per day	7.91	8	✔	**Estradot**
a) No more than 2 patch per week b) Only on a prescription				
Patch 100 mcg per day	7.91	8	✔	**Estradot**
a) No more than 2 patch per week b) Only on a prescription				
OESTRADIOL VALERATE – See prescribing guideline above				
Tab 1 mg	12.36	84	✔	**Progynova**
Tab 2 mg	12.36	84	✔	**Progynova**
OESTROGENS – See prescribing guideline above				
Conjugated, equine tab 300 mcg	3.01	28		
	(13.50)			Premarin
Conjugated, equine tab 625 mcg	4.12	28		
	(13.50)			Premarin

Progestogens

MEDROXYPROGESTERONE ACETATE – See prescribing guideline above				
Tab 2.5 mg	3.75	30	✔	**Provera**
Tab 5 mg	14.00	100	✔	**Provera**
Tab 10 mg	7.15	30	✔	**Provera**

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S29 Unapproved medicine supplied under Section 29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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**
OESTRIOL				
Tab 2 mg	7.00	30	✔	**Ovestin**
Ovestin to be Sole Supply on 1 July 2020				
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	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.

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

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 below – 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

➽**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

continued…

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S29 Unapproved medicine supplied under Section 29

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

continued…

children who are 5 years or older, GH testing with sex steroid priming is required; and

2.4 If the patient has been treated for a malignancy, they should be disease free for at least one year based upon follow-up laboratory and radiological imaging appropriate for the malignancy, unless there are strong medical reasons why this is either not necessary or appropriate; and

2.5 Appropriate imaging of the pituitary gland has been obtained.

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

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

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

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

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

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

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

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

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

1 Height velocity is greater than or equal to 50th percentile (adjusted for bone age/pubertal status if appropriate) as calculated over 6 to 12 months using the standards of Tanner and Davies (1985); and
2 Height velocity is greater than or equal to 2 cm per year as calculated over six months; and

continued…

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

continued…

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..

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:

continued…

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

continued…

5.1.1 The patient is aged two years or older; and

5.1.2 There is no evidence of type II diabetes or uncontrolled obesity defined by BMI that has increased by greater than or equal to 0.5 standard deviations in the preceding 12 months; or

5.2 The patient is aged between six months and two years and a thorough upper airway assessment is planned to be undertaken prior to treatment commencement and at six to 12 weeks following treatment initiation.

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

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

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

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

Notes: For the purposes of adults and adolescents, severe growth hormone deficiency is defined as a peak serum growth hormone level of less than or equal to 3 mcg per litre during an adequately performed insulin tolerance test (ITT) or glucagon stimulation test.
Patients with one or more additional anterior pituitary hormone deficiencies and a known structural pituitary lesion only require one test. Patients with isolated growth hormone deficiency require two growth hormone stimulation tests, of which, one should be ITT unless otherwise contraindicated. Where an additional test is required, an arginine provocation test can be used with a peak serum growth hormone level of less than or equal to 0.4 mcg per litre.
The dose of somatropin should be started at 0.2 mg daily and be titrated by 0.1 mg monthly until the serum IGF-I is within 1 standard deviation of the mean normal value for age and sex; and
Dose of somatropin not to exceed 0.7 mg per day for male patients, or 1 mg per day for female patients.
At the commencement of treatment for hypopituitarism, patients must be monitored for any required adjustment in replacement doses of corticosteroid and levothyroxine.
Renewal — (adults and adolescents) only from a paediatric endocrinologist or endocrinologist. Approvals valid for 12 months for applications meeting the following criteria:
Either:

1 All of the following:
1.1 The patient has been treated with somatropin for < 12 months; and
1.2 There has been an improvement in Quality of Life defined as a reduction of at least 8 points on the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA®) score from baseline; and
1.3 Serum IGF-I levels have been increased within ±1SD of the mean of the normal range for age and sex; and

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

continued…

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

Vasopressin Agonists

DESMOPRESSIN ACETATE

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	39.03	2.5 ml OP	✔	**Minirin**
Nasal spray 10 mcg per dose	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:

continued…

✔ fully subsidised
Sole Subsidised Supply

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

continued…

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

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

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

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

Other Endocrine Agents

CABERGOLINE

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

Tab 50 mg	29.84	10	✔	**Mylan Clomiphen** S29

DANAZOL

Cap 100 mg	19.13	28	✔	**Mylan** S29
Cap 200 mg	97.83	100	✔	**Azol**

METYRAPONE

Cap 250 mg	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	15 ml		
	(7.17)			Vermox

PRAZIQUANTEL

Tab 600 mg	68.00	8	✔	**Biltricide**

Antibacterials

a) For topical antibacterials, refer to DERMATOLOGICALS, page 59
b) For anti-infective eye preparations, refer to SENSORY ORGANS, page 237

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**
			✔	**Ibilex** S29
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**

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	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.

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	100		
	(22.29)			ERA
Tab 500 mg	29.90	100		
	(44.58)			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**

✔ **fully subsidised**

Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
Penicillins				
AMOXICILLIN				
Cap 250 mg	22.50	500	✔	**Alphamox**
a) Up to 30 cap available on a PSO b) Up to 10 x the maximum PSO quantity for RFPP				
Cap 500 mg	36.98	500	✔	**Alphamox**
a) Up to 30 cap available on a PSO b) Up to 10 x the maximum PSO quantity for RFPP				
Grans for oral liq 125 mg per 5 ml	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**
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
FLUCLOXACILLIN				
Cap 250 mg – Up to 30 cap available on a PSO	16.83	250	✔	**Staphlex**
Cap 500 mg – Up to 30 cap available on a PSO	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**

▲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
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

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

➽SA1355 Special Authority for Manufacturers Price

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

TETRACYCLINE – Special Authority see SA1332 below – Retail pharmacy				
Tab 250 mg	21.42	28	✔	**Accord** S29
Cap 500 mg	46.00	30	✔	**Tetracyclin Wolff** S29

(Tetracyclin Wolff S29 *Cap 500 mg to be delisted 1 December 2020)*

➽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.

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

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

Other Antibiotics

For topical antibiotics, refer to DERMATOLOGICALS, page 59

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	4.61	24	✔	**Dalacin C**
Inj phosphate 150 mg per ml, 4 ml ampoule	39.00	10	✔	**Dalacin C**

COLISTIN SULPHOMETHATE – Retail pharmacy-Specialist – Subsidy by endorsement

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

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 10 mg per ml, 2 ml ampoule – Subsidy by endorsement	144.00	10	✔	**Teligent** S29
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**
	87.50	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
  - 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

continued…

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

continued…

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	34.50	12	✔	**Fucidin**

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

Inj 40 mg per ml, 2 ml vial – Subsidy by endorsement Only if prescribed for dialysis or cystic fibrosis patient and the prescription is endorsed accordingly.	15.00	5	✔	**Tobramycin Mylan**
Solution for inhalation 60 mg per ml, 5 ml – Subsidy by endorsement a) Wastage claimable b) Only if prescribed for a cystic fibrosis patient and the prescription is endorsed accordingly.	2,200.00	56 dose	✔	**TOBI**

TRIMETHOPRIM

Tab 300 mg – Up to 30 tab available on a PSO	16.50	50	✔	**TMP**

TRIMETHOPRIM WITH SULPHAMETHOXAZOLE [CO-TRIMOXAZOLE]

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.

Inj 500 mg vial	2.37	1	✔	**Mylan**

Antifungals

a) For topical antifungals refer to DERMATOLOGICALS, page 60
b) For topical antifungals refer to GENITO URINARY, page 72

FLUCONAZOLE

Cap 50 mg	2.09	28	✔	**Mylan**
Cap 150 mg	0.33	1	✔	**Mylan**
Cap 200 mg	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:

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:

continued…

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

continued…

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	4.27	15	✔	**Itrazole**
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	CBS	30	✔	**Link Healthcare** S29
			✔	**Nizoral** S29
		100	✔	**Strides Shasun** S29
NYSTATIN				
Tab 500,000 u	14.16	50		
	(17.09)			Nilstat
Cap 500,000 u	12.81	50		
	(15.47)			Nilstat
POSACONAZOLE – Special Authority see SA1285 below – Retail pharmacy				
Tab modified-release 100 mg	869.86	24	✔	**Noxafil**
Oral liq 40 mg per ml	761.13	105 ml OP	✔	**Noxafil**

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*.

continued…

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

continued…

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.

Antimalarials

PRIMAQUINE – Special Authority see SA1684 on the next page – Retail pharmacy				
Tab 7.5 mg	117.00	56	✔	**Primacin** S29

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

➽SA1684 Special Authority for Subsidy

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

Both:

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

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

Both:

1 The patient has relapsed vivax or ovale malaria; and
2 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**
	36.35	250	✔	**Metrogyl**
Tab 400 mg – Up to 15 tab available on a PSO	5.55	21	✔	**Metrogyl**
	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**

(Trichozole Tab 200 mg to be delisted 1 September 2020)
(Trichozole Tab 400 mg to be delisted 1 September 2020)

ORNIDAZOLE

Tab 500 mg	32.95	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

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	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	299.75	30	✔	**Mycobutin**

	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.

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 237

Hepatitis B Treatment

ADEFOVIR DIPIVOXIL – Special Authority see SA0829 below – Retail pharmacy

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

Tab 0.5 mg	52.00	30	✔	**Entecavir Sandoz**

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

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 102

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 SA1904 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 102 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 — ✔ **Teva**

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

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

➽SA1904 **Special Authority for Subsidy**

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 and Hep B if not immune 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 and Hep B if not immune 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 HIV positive.

Non-nucleosides Reverse Transcriptase Inhibitors

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

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 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**

ZIDOVUDINE [AZT] WITH LAMIVUDINE – Special Authority see SA1651 on the previous page – 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**

▲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
Protease Inhibitors				
ATAZANAVIR SULPHATE – Special Authority see SA1651 on page 102 – Retail pharmacy				
Cap 150 mg	141.68	60	✔	**Teva**
Cap 200 mg	188.91	60	✔	**Teva**
DARUNAVIR – Special Authority see SA1651 on page 102 – 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 102 – 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 102 – Retail pharmacy				
Tab 100 mg	43.31	30	✔	**Norvir**
Strand Transfer Inhibitors				
DOLUTEGRAVIR – Special Authority see SA1651 on page 102 – Retail pharmacy				
Tab 50 mg	1,090.00	30	✔	**Tivicay**
RALTEGRAVIR POTASSIUM – Special Authority see SA1651 on page 102 – 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 ($< 2.0 \times 10^9$) and/or thrombocytopenia.
4) Continuing alcohol abuse and/or continuing intravenous drug users.

Dosage

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

Exit Criteria

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

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
INTERFERON ALFA-2A – PCT				
See prescribing guideline on the previous page				
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:
  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:

continued…

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

continued…

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

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 — 5.99 — 30 — ✔ **Ibuprofen SR BNM**
- 7.99 — ✔ **Brufen SR**

Ibuprofen SR BNM to be Sole Supply on 1 December 2020
- Oral liq 20 mg per ml — 1.88 — 200 ml — ✔ **Ethics**

(Brufen SR Tab long-acting 800 mg to be delisted 1 December 2020)

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**
- 9.57 — 56 — ✔ **Mylan** S29
- Tab 200 mg — 15.10 — 50 — ✔ **Aclin**
- 16.91 — 56 — ✔ **Sulindac Mylan** S29

(Aclin Tab 100 mg to be delisted 1 September 2020)

TENOXICAM
- Tab 20 mg — 9.15 — 100 — ✔ **Tilcotil**
- Inj 20 mg vial — 9.95 — 1 — ✔ **AFT**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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)				
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 – Subsidy by endorsement				
Subsidy by endorsement - Subsidised only if prescribed for rheumatoid arthritis, systemic or discoid lupus erythematosus, malaria treatment or suppression, relevant dermatological conditions (cutaneous forms of lupus and lichen planus, cutaneous vasculitides and mucosal ulceration)* and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of hydroxychloroquine. Note: Indication marked with a * is an unapproved indication.				
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**
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 on the next page – Retail pharmacy				
Inj 60 mg prefilled syringe	326.00	1	✔	**Prolia**

✔ **fully subsidised**

Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

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

➽SA1777 Special Authority for Subsidy

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

All of the following:

1 The patient has severe, established osteoporosis; and

2 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

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

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; zoledronic acid 5 mg per year. If an intolerance of a severity necessitating permanent treatment withdrawal develops

continued…

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

continued…

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

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

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

ZOLEDRONIC ACID

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

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 50 mg	22.50	100	✔ **Narcaricin mite** S29
Tab 100 mg	13.50	30	✔ **Desuric** S29
			✔ **Urinorm** S29
	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

continued…

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

continued…

allopurinol to 600 mg or the maximum tolerated dose.

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

COLCHICINE

Tab 500 mcg	9.58	100	✔	**Colgout**

FEBUXOSTAT – Special Authority see SA1931 below – Retail pharmacy

Tab 80 mg	39.50	28	✔	**Adenuric**
Tab 120 mg	39.50	28	✔	**Adenuric**

➽**SA1931** **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); or

2.4 The patient has previously had an initial Special Authority approval for benzbromarone for treatment of gout..

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	97.50	100	✔	**Dantrium**
			✔	**Dantrium** S29
Cap 50 mg	77.00	100	✔	**Dantrium**

ORPHENADRINE CITRATE

Tab 100 mg	18.54	100	✔	**Norflex**

	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**
Inj 10 mg per ml, 5 ml ampoule	121.84	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	2.85	84	✔	**Ropin**
	3.39	100	✔	**Mylan** S29
Tab 1 mg	3.95	84	✔	**Ropin**
	4.70	100	✔	**Mylan** S29
Tab 2 mg	5.48	84	✔	**Ropin**
Tab 5 mg	12.50	84	✔	**Ropin**
SELEGILINE HYDROCHLORIDE				
Tab 5 mg	22.00	100	✔	**Apo-Selegiline**
				S29 S29
TOLCAPONE				
Tab 100 mg	152.38	100	✔	**Tasmar**

▲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

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**

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%, 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.

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

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

Analgesics

For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, page 107

Non-opioid Analgesics

For aspirin & chloroform application refer Standard Formulae, page 244

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**
	15.83	57 g OP	✔	**Rugby Capsaicin Topical Cream** S29
NEFOPAM HYDROCHLORIDE				
Tab 30 mg	23.40	90	✔	**Acupan**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
PARACETAMOL				
Tab 500 mg - blister pack	7.12	1,000	✔	**Paracetamol Pharmacare**
			✔	**Pharmacare**

a) Maximum of 300 tab per prescription; can be waived by endorsement
b) Up to 30 tab available on a PSO
c)
1) Subsidy by endorsement for higher quantities is available for patients with long term conditions who require regular daily dosing for one month or greater, and the prescription is annotated accordingly. Pharmacists may annotate the prescription as endorsed where dispensing history supports a long-term condition.
2) Maximum of 100 tab per dispensing for non-endorsed patients. If quantities prescribed for more than 100 tabs (for non-endorsed patients), then dispense in repeat dispensings not exceeding 100 tab per dispensing.

Tab 500 mg - bottle pack – Maximum of 300 tab per prescription; can be waived by endorsement	6.32	1,000	✔	**Pharmacare**

1) Subsidy by endorsement for higher quantities is available for patients with long term conditions who require regular daily dosing for one month or greater, and the prescription is annotated accordingly. Pharmacists may annotate the prescription as endorsed where dispensing history supports a long-term condition.
2) Maximum of 100 tab per dispensing for non-endorsed patients. If quantities prescribed for more than 100 tabs (for non-endorsed patients), then dispense in repeat dispensings not exceeding 100 tab per dispensing.

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

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**

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

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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	1.78	5	✔	**Fentanyl GH** S29
	3.56	10	✔	**Boucher and Muir**
			✔	**Fentanyl IE** S29
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**
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 244				
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**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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**
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 10 mg to be delisted 1 October 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**
(DBL Morphine Tartrate Inj 80 mg per ml, 1.5 ml ampoule to be delisted 1 September 2020)				
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)**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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**
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	4.93	30	✔	**Dosulepin Mylan**
	11.19	100	✔	**Dopress**
Cap 25 mg	7.83	50	✔	**Dosulepin Mylan** S29

(Dopress Tab 75 mg to be delisted 1 August 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**

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

Monoamine-Oxidase Inhibitors (MAOIs) - Non Selective

PHENELZINE SULPHATE – Subsidy by endorsement

Subsidy by endorsement – Subsidised for patients who were taking phenelzine sulphate prior to 1 April 2020 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of phenelzine sulphate.

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

(Lupin S29 Tab 15 mg to be delisted 1 October 2020)
(Nardil S29 S29 Tab 15 mg to be delisted 1 October 2020)
(Nardil Tab 15 mg to be delisted 1 October 2020)

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**

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	1.98	30	✔ **Fluox**
	9.93		✔ **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	2.91	84	✔ **Fluox**
	7.49	90	✔ **Arrow-Fluoxetine**

PAROXETINE

Tab 20 mg	3.61	90	✔ **Loxamine**

SERTRALINE

Tab 50 mg	0.92	30	✔ **Setrona**
Tab 100 mg	1.61	30	✔ **Setrona**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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**
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	23.66	5	✔	**Hospira**
a) Up to 5 inj available on a PSO b) Only on a PSO c) PSO must be endorsed "not for anaesthetic procedures".				
Rectal tubes 5 mg – Up to 5 tube available on a PSO	43.50	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**

▲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
LACOSAMIDE – Special Authority see SA1125 below – 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**

➽**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.

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 244				
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**

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
PRIMIDONE				
Tab 250 mg	17.25	100	✔	**Apo-Primidone**
	62.00	200	✔	**Mysoline** S29
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.

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 SA1907 below – Retail pharmacy				
Tab 500 mg	119.30	100	✔	**Sabril**

➽**SA1907** **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:

continued…

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

continued…

1.2.2.1 Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents; or
1.2.2.2 Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents; and

2 Either:
2.1 Patient is, or will be, receiving regular automated visual field testing (ideally before starting therapy and on a 6-monthly basis thereafter); or
2.2 It is impractical or impossible (due to comorbid conditions, or health system capacity constraints) 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, or health system capacity constraints) 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 107

Acute Migraine Treatment

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	34.00	2 OP	✔	**Imigran**
	42.67		✔	**Sun Pharma** S29
	81.15		✔	**Clustran**

Imigran to be Sole Supply on 1 September 2020

(Sun Pharma S29 Inj 12 mg per ml, 0.5 ml prefilled pen to be delisted 1 September 2020)
(Clustran Inj 12 mg per ml, 0.5 ml prefilled pen to be delisted 1 September 2020)

Prophylaxis of Migraine

For Beta Adrenoceptor Blockers refer to CARDIOVASCULAR SYSTEM, page 49

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

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

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

Antinausea and Vertigo Agents

For Antispasmodics refer to ALIMENTARY TRACT, page 8

APREPITANT – Special Authority see SA0987 below – Retail pharmacy

Cap 2 × 80 mg and 1 × 125 mg	84.00	3 OP	✔	**Emend Tri-Pack**

➽SA0987 Special Authority for Subsidy

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

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

BETAHISTINE DIHYDROCHLORIDE

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 SA1927 below – Retail pharmacy	14.11	2	✔	**Scopoderm TTS**

(Hospira Inj 400 mcg per ml, 1 ml ampoule to be delisted 1 September 2020)

➽SA1927 Special Authority for Subsidy

Initial application — (control of intractable nausea, vomiting or inability to swallow saliva or clozapine induced hypersalivation) 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.

Initial application — (pandemic circumstances- symptomatic relief of respiratory secretions in palliative care) from any relevant practitioner. Approvals valid for 1 month for applications meeting the following criteria:
All of the following:

1 Requires palliative care in the community setting; and
2 Requires symptomatic relief of respiratory secretions that is not possible with 'as required subcutaneous hyoscine injections' due to COVID-19 constraints on the health sector; and
3 Access to a syringe driver for administration of injectable hyoscine is not possible due to COVID-19 constraints on the health sector.

Renewal — (control of intractable nausea, vomiting or inability to swallow saliva or clozapine induced hypersalivation) from any relevant practitioner. Approvals valid for 1 year where the treatment remains appropriate and the patient is benefiting from treatment.

METOCLOPRAMIDE HYDROCHLORIDE

Tab 10 mg – Up to 30 tab available on a PSO	1.30	100	✔	**Metoclopramide Actavis 10**
Inj 5 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	9.50	10	✔	**Pfizer**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
ONDANSETRON				
Tab 4 mg	2.68	50	✔	**Onrex**
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**
Tab disp 8 mg – Up to 10 tab available on a PSO	1.43	10	✔	**Ondansetron ODT-DRLA**
PROCHLORPERAZINE				
Tab 3 mg buccal	5.97	50		
	(30.00)			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**

Antipsychotics

General

AMISULPRIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 100 mg	5.15	30	✔	**Sulprix**
	17.16	100	✔	**Amisulpride Mylan** S29
Tab 200 mg	14.96	60	✔	**Sulprix**
Tab 400 mg	29.78	60	✔	**Sulprix**
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**

✔ **fully subsidised**

Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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 – Safety medicine; prescriber may determine dispensing frequency				
Tab 25 mg (33.8 mg as a maleate)	16.10	100	✔	**Nozinan (Swiss)**
Tab 25 mg as a maleate	16.10	100	✔	**Nozinan**
Tab 100 mg (135 mg as a maleate)	41.75	100	✔	**Nozinan (Swiss)**
Tab 100 mg as a maleate	41.75	100	✔	**Nozinan**
LEVOMEPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Inj 25 mg per ml, 1 ml ampoule	33.50	10	✔	**Nozinan**
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**

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

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.

continued…

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

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

continued…

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.

RISPERIDONE – Special Authority see SA1427 below – 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**

➽**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**

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

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).

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

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

continued…

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

continued…

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 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

continued…

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

continued…

- 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 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 on the next page – Retail pharmacy

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

✔ **fully subsidised**

Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

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

➠SA1563 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

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

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

The coordinator	Phone: 04 460 4990
Multiple Sclerosis Treatment Assessment Committee	Facsimile: 04 916 7571
PHARMAC PO Box 10 254	Email: mstaccoordinator@pharmac.govt.nz
Wellington	

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

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

Entry Criteria

1) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
2) patients must have Clinically Definite Relapsing Remitting MS with or without underlying progression; and
3) patients must have:
    a) EDSS score 0 - 4.0 and:
        - Experienced at least 1 significant relapse of MS in the previous 12 months or 2 significant relapses in the past 24 months; and
        - Evidence of new inflammatory activity on an MR scan within the past 24 months, any of the following:
            i) a gadolinium enhancing lesion; or
            ii) a Diffusion Weighted Imaging positive lesion; or
            iii) a T2 lesion with associated local swelling; or
            iv) a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse; or
            v) new T2 lesions compared with a previous MR scan; and
4) A significant relapse must:
    a) be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
    b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);
    c) last at least one week;
    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

continued…

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

continued…

10) patient must not be co-prescribed beta interferon or glatiramer acetate.

Stopping Criteria

Any of the following:

1) Confirmed progression of disability that is sustained for six months. Progression of disability is defined as progress by any of the following EDDSS points:
   a) from starting at EDSS 0 increasing to (i.e. stopping on reaching) EDSS 3.0; or
   b) 1.0 to 3.0; or
   c) 1.5 to 3.5; or
   d) 2.0 to 4.0; or
   e) 2.5 to 4.5; or
   f) 3.0 to 4.5; or
   g) 3.5 to 4.5; or
   h) 4.0 to 4.5.
2) increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment)(see note); or
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).

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

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

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

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

Entry Criteria

a) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
b) patients must have Clinically Definite Relapsing Remitting MS with or without underlying progression; and
c) patients must have:
   a) EDSS score 0 - 4.0 and:
      - Experienced at least 1 significant relapse of MS in the previous 12 months or 2 significant relapses in the past 24 months; and

continued…

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

continued…

- 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 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 on the next page – Retail pharmacy

Wastage claimable				
Tab 14 mg	1,582.62	28	✔	**Aubagio**

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

➽SA1560 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

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

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

The coordinator	Phone: 04 460 4990
Multiple Sclerosis Treatment Assessment Committee	Facsimile: 04 916 7571
PHARMAC PO Box 10 254	Email: mstaccoordinator@pharmac.govt.nz
Wellington	

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

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

Entry Criteria

1) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
2) patients must have Clinically Definite Relapsing Remitting MS with or without underlying progression; and
3) patients must have:
    a) EDSS score 0 - 4.0 and:
        - Experienced at least 1 significant relapse of MS in the previous 12 months or 2 significant relapses in the past 24 months; and
        - Evidence of new inflammatory activity on an MR scan within the past 24 months, any of the following:
            i) a gadolinium enhancing lesion; or
            ii) a Diffusion Weighted Imaging positive lesion; or
            iii) a T2 lesion with associated local swelling; or
            iv) a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse; or
            v) new T2 lesions compared with a previous MR scan; and
4) A significant relapse must:
    a) be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
    b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);
    c) last at least one week;
    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:

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 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 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

continued…

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

continued…

- 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 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

continued…

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

continued…

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:

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;
    e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least

continued…

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

continued…

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-BETA – Special Authority see SA1810 below – Retail pharmacy

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:

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.

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.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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 below – Retail pharmacy				
Inj 200 mg per ml, 1 ml ampoule	30.00	5	✔	**Aspen** S29
	68.00	10	✔	**Max Health** S29
(Aspen S29 Inj 200 mg per ml, 1 ml ampoule to be delisted 1 September 2020)				
➽SA1386 **Special Authority for Subsidy**				
Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:				
Both:				
1 For the treatment of terminal agitation that is unresponsive to other agents; and				
2 The applicant is part of a multidisciplinary team working in palliative care.				
TEMAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
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

ATOMOXETINE – Special Authority see SA1416 on the next page – 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**

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

➽SA1416 **Special Authority for Subsidy**

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

1 Patient has ADHD (Attention Deficit and Hyperactivity Disorder) diagnosed according to DSM-IV or ICD 10 criteria; and
2 Once-daily dosing; and
3 Any of the following:
  3.1 Treatment with a subsidised formulation of a stimulant has resulted in the development or worsening of serious adverse reactions or where the combination of subsidised stimulant treatment with another agent would pose an unacceptable medical risk; or
  3.2 Treatment with a subsidised formulation of a stimulant has resulted in worsening of co-morbid substance abuse or there is a significant risk of diversion with subsidised stimulant therapy; or
  3.3 An effective dose of a subsidised formulation of a stimulant has been trialled and has been discontinued because of inadequate clinical response; or
  3.4 Treatment with a subsidised formulation of a stimulant is considered inappropriate because the patient has a history of psychoses or has a first-degree relative with schizophrenia; and
4 The patient will not be receiving treatment with atomoxetine in combination with a subsidised formulation of a stimulant, except for the purposes of transitioning from subsidised stimulant therapy to atomoxetine.

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

Note: A "subsidised formulation of a stimulant" refers to currently subsidised methylphenidate hydrochloride tablet formulations (immediate-release, sustained-release and extended-release) or dexamfetamine sulphate tablets.

DEXAMFETAMINE SULFATE – Special Authority see SA1149 below – Retail pharmacy

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

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

continued…

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

continued…

2 Either:

2.1 Applicant is a paediatrician or psychiatrist; or

2.2 Applicant is a medical practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing.

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

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

METHYLPHENIDATE HYDROCHLORIDE – Special Authority see SA1150 below – Retail pharmacy

a) Only on a controlled drug form

b) Safety medicine; prescriber may determine dispensing frequency

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:

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 (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE – Special Authority see SA1151 below – Retail pharmacy				
a) Only on a controlled drug form				
b) Safety medicine; prescriber may determine dispensing frequency				
Tab extended-release 18 mg	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**

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 SA1932 below – Retail pharmacy				
Tab 100 mg	64.00	60	✔	**Modavigil**

SA1932 Special Authority for Subsidy

Initial application only from a neurologist or respiratory specialist. 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 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 Any of the following:

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 A multiple sleep latency test is not possible due to COVID-19 constraints on the health sectors; or

2.3 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**

RIVASTIGMINE – Special Authority see SA1488 below – Retail pharmacy

Patch 4.6 mg per 24 hour	48.75	30	✔	**Generic Partners**
	(90.00)			Exelon
Generic Partners to be Sole Supply on 1 July 2020				
Patch 9.5 mg per 24 hour	48.75	30	✔	**Generic Partners**
	(90.00)			Exelon
Generic Partners to be Sole Supply on 1 July 2020				

(Exelon Patch 4.6 mg per 24 hour to be delisted 1 July 2020)

(Exelon Patch 9.5 mg per 24 hour to be delisted 1 July 2020)

➽SA1488 **Special Authority for Subsidy**

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

1 The patient has been diagnosed with dementia; and

2 The patient has experienced intolerable nausea and/or vomiting from donepezil tablets.

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

1 The treatment remains appropriate; and

2 The patient has demonstrated a significant and sustained benefit from treatment.

Treatments for Substance Dependence

BUPRENORPHINE WITH NALOXONE – Special Authority see SA1203 on the next page – Retail pharmacy

a) Brand switch fee payable (Pharmacode 2586258) - see page 242 for details

b) No patient co-payment payable

c) Safety medicine; prescriber may determine dispensing frequency

Tab sublingual 2 mg with naloxone 0.5 mg	18.37	28	✔	**Buprenorphine Naloxone BNM**
Tab sublingual 8 mg with naloxone 2 mg	53.12	28	✔	**Buprenorphine Naloxone BNM**

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

➽SA1203 Special Authority for Subsidy

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

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

All of the following:

1 Patient is or has been receiving maintenance therapy with buprenorphine with naloxone (and is not receiving methadone); 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 on the next page – Retail pharmacy

Tab 50 mg	112.55	30	✔	**Naltraccord**

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

➽SA1408 Special Authority for Subsidy

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

1 Patient is currently enrolled in a recognised comprehensive treatment programme for alcohol dependence; and
2 Applicant works in or with a community Alcohol and Drug Service contracted to 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.

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 × 11 and 1 mg × 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

continued…

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

continued…

2 The patient is part of, or is about to enrol in, a comprehensive support and counselling smoking cessation programme, which includes prescriber or nurse monitoring; and
3 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; 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.

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**
	213.00		✔	**Alkeran s29** S29
	420.00		✔	**Tillomed** S29

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S29 Unapproved medicine supplied under Section 29

	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	✔	**Oxaliplatin Accord**
Inj 1 mg for ECP	0.48	1 mg	✔	**Baxter**
THIOTEPA – PCT only – Specialist				
Inj 15 mg vial	CBS	1	✔	**Bedford** S29
			✔	**THIO-TEPA** S29
			✔	**Tepadina** S29
Inj 100 mg vial	CBS	1	✔	**Tepadina** S29

Antimetabolites

AZACITIDINE – PCT only – Specialist – Special Authority see 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	114.69	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**
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**
Inj 1 mg for ECP – PCT only – Specialist	0.06	1 mg	✔	**Baxter**
CAPECITABINE – Retail pharmacy-Specialist				
Tab 150 mg	10.00	60	✔	**Capercit**
	11.15		✔	**Brinov**
Capercit to be Sole Supply on 1 July 2020				
Tab 500 mg	49.00	120	✔	**Capercit**
	62.28		✔	**Brinov**
Capercit to be Sole Supply on 1 July 2020				
(Brinov Tab 150 mg to be delisted 1 July 2020)				
(Brinov Tab 500 mg to be delisted 1 July 2020)				
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**

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Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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**
Gemcitabine Ebewe to be Sole Supply on 1 July 2020				
Inj 1 mg for ECP	0.02	1 mg	✔	**Baxter**
(Gemzar Inj 1 g to be delisted 1 September 2020)				
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.

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**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
PEMETREXED – PCT only – Specialist – Special Authority see SA1679 below				
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**

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.

THIOGUANINE – PCT – Retail pharmacy-Specialist				
Tab 40 mg	126.31	25	✔	**Lanvis**

Other Cytotoxic Agents

AMSACRINE – PCT only – Specialist				
Inj 50 mg per ml, 1.5 ml ampoule	1,500.00	6	✔	**Amsidine** S29
	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** S29
			✔	**Teva** S29
	1,175.87		✔	**Agrylin**

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S29 Unapproved medicine supplied under Section 29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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**
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 SA1889 below				
Inj 3.5 mg vial	105.00	1	✔	**Bortezomib Dr-Reddy's**
	1,892.50		✔	**Velcade**
Inj 1 mg for ECP	31.20	1 mg	✔	**Baxter**
	562.34		✔	**Baxter (Velcade)**

(Velcade Inj 3.5 mg vial to be delisted 1 August 2020)
(Baxter (Velcade) Inj 1 mg for ECP to be delisted 1 August 2020)

➽**SA1889** **Special Authority for Subsidy**

Initial application — (multiple myeloma/amyloidosis) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

1 The patient has symptomatic multiple myeloma; or
2 The patient has symptomatic systemic AL amyloidosis *.

Note: Indications marked with * are unapproved indications.

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	62.70	1	✔	**DBL Dacarbazine**
	580.60	10	✔	**Dacarbazine APP** S29
Inj 200 mg for ECP	62.70	200 mg OP	✔	**Baxter**
DACTINOMYCIN [ACTINOMYCIN D] – PCT only – Specialist				
Inj 0.5 mg vial	255.00	1	✔	**Cosmegen**
Inj 0.5 mg for ECP	255.00	0.5 mg OP	✔	**Baxter**
DAUNORUBICIN – PCT only – Specialist				
Inj 2 mg per ml, 10 ml	149.50	1	✔	**Pfizer**
Inj 20 mg for ECP	149.50	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**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
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	✔	**Vepesid**
Cap 100 mg – PCT – Retail pharmacy-Specialist	340.73	10	✔	**Vepesid**
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 SA1897 below				
Wastage claimable				
Cap 5 mg	5,122.76	28	✔	**Revlimid**
Cap 10 mg	4,655.25	21	✔	**Revlimid**
	6,207.00	28	✔	**Revlimid**
Cap 15 mg	5,429.39	21	✔	**Revlimid**
	7,239.18	28	✔	**Revlimid**
Cap 25 mg	7,627.00	21	✔	**Revlimid**

SA1897 Special Authority for Subsidy

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

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

continued…

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

continued…

4 Lenalidomide to be administered at a maximum dose of 25 mg/day in combination with dexamethasone.

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

1 Patient has newly diagnosed symptomatic multiple myeloma and has undergone first-line treatment that included an autologous stem cell transplantation; and
2 Patient has at least a stable disease response in the first 100 days after transplantation; and
3 Lenalidomide maintenance is to be commenced within 6 months of transplantation; and
4 The patient has ECOG performance score of 0-1; and
5 Lenalidomide to be administered at a maximum dose of 15 mg/day.

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

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

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

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

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

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	851.37	1	✔	**Teva**
Inj 20 mg vial	816.32	1	✔	**Omegapharm** S29
Inj 1 mg for ECP	175.38	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**
OLAPARIB – Retail pharmacy-Specialist – Special Authority see SA1883 below				
Tab 100 mg	3,701.00	56	✔	**Lynparza**
Tab 150 mg	3,701.00	56	✔	**Lynparza**
Cap 50 mg – Wastage claimable	7,402.00	448	✔	**Lynparza**

➽SA1883 Special Authority for Subsidy
Initial application only from a medical oncologist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:

continued…

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

continued…

1 Patient has a high-grade serous* epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
2 There is documentation confirming pathogenic germline BRCA1 or BRCA2 gene mutation; and
3 Patient has received at least two lines of previous treatment with platinum-based chemotherapy; and
4 Patient has platinum sensitive disease defined as disease progression occurring at least 6 months after the last dose of the penultimate line of platinum-based chemotherapy; and
5 Patient's disease must have achieved partial or complete response to treatment with the immediately preceding platinum-based regimen; and
6 Patient's disease has not progressed following prior treatment with olaparib; and
7 Treatment will be commenced within 8 weeks of the patient's last dose of the immediately preceding platinum-based regimen; and
8 Treatment to be administered as maintenance treatment; and
9 Treatment not to be administered in combination with other chemotherapy.

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

1 Treatment remains clinically appropriate and patient is benefitting from treatment; and
2 No evidence of progressive disease; and
3 Treatment to be administered as maintenance treatment; and
4 Treatment not to be administered in combination with other chemotherapy.

Note: *Note "high-grade serous" includes tumours with high-grade serous features or a high-grade serous component.

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 below

Inj 750 iu per ml, 5 ml vial	3,005.00	1	✔	**Oncaspar LYO** S29

SA1325 Special Authority for Subsidy

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

1 The patient has newly diagnosed acute lymphoblastic leukaemia; and
2 Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol; and
3 Treatment is with curative intent.

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

1 The patient has relapsed acute lymphoblastic leukaemia; and
2 Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol; and
3 Treatment is with curative intent.

PENTOSTATIN [DEOXYCOFORMYCIN] – PCT only – Specialist

Inj 10 mg	CBS	1	✔	**Nipent** S29

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
PROCARBAZINE HYDROCHLORIDE – PCT – Retail pharmacy-Specialist				
Cap 50 mg	980.00	50	✔	**Natulan** S29
TEMOZOLOMIDE – Special Authority see SA1741 below – Retail pharmacy				
Cap 5 mg	9.13	5	✔	**Temaccord**
Cap 20 mg	16.38	5	✔	**Temaccord**
	18.30		✔	**Apo-Temozolomide**
	136.00	14	✔	**Accord** S29
Cap 100 mg	35.98	5	✔	**Temaccord**
	40.20		✔	**Apo-Temozolomide**
	532.00	14	✔	**Accord** S29
Cap 140 mg	50.12	5	✔	**Temaccord**
	400.00		✔	**Amneal** S29
Cap 180 mg	620.00	14	✔	**Accord** S29
Cap 250 mg	86.34	5	✔	**Temaccord**
	688.00		✔	**Amneal** S29

➽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:

continued…

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

continued…

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 below

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

➽SA1124 **Special Authority for Subsidy**

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

Either:

1 The patient has multiple myeloma; or
2 The patient has systemic AL amyloidosis*.

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid without further renewal unless notified where the patient has obtained a response from treatment during the initial approval period.

Notes: Prescription must be written by a registered prescriber in the thalidomide risk management programme operated by the supplier.

Maximum dose of 400 mg daily as monotherapy or in a combination therapy regimen.

Indication marked with * is an unapproved indication.

TRETINOIN

Cap 10 mg – PCT – Retail pharmacy-Specialist	479.50	100	✔	**Vesanoid**

VENETOCLAX – Retail pharmacy-Specialist – Special Authority see SA1868 below

Tab 14 × 10 mg, 7 × 50 mg, 21 × 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

continued…

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

continued…

recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:
Both:

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

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

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

Renewal — (previously untreated chronic lymphocytic leukaemia with 17p deletion or TP53 mutation*) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where the treatment remains clinically appropriate and the patient is benefitting from and tolerating treatment.
Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL)* and B-cell prolymphocytic leukaemia (B-PLL)*. Indications marked with * are Unapproved indications.

VINBLASTINE SULPHATE				
Inj 1 mg per ml, 10 ml vial – PCT – Retail pharmacy-Specialist	270.37	5	✔	**DBL Vinblastine** S29
			✔	**Hospira**
Inj 1 mg for ECP – PCT only – Specialist	6.00	1 mg	✔	**Baxter**
VINCRISTINE SULPHATE				
Inj 1 mg per ml, 1 ml vial – PCT – Retail pharmacy-Specialist	74.52	5	✔	**DBL Vincristine Sulfate**
Inj 1 mg per ml, 2 ml vial – PCT – Retail pharmacy-Specialist	102.73	5	✔	**DBL Vincristine Sulfate**
Inj 1 mg for ECP – PCT only – Specialist	12.60	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				
Wastage claimable				
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

continued…

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

continued…

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
  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 SA1915 below

Tab 100 mg	764.00	30	✔	**Tarceva**
Tab 150 mg	1,146.00	30	✔	**Tarceva**

➽**SA1915** **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:

continued…

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

continued…

1 Patient has locally advanced or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
2 There is documentation confirming that the disease expresses activating mutations of EGFR tyrosine kinase; and
3 Either:
  3.1 Patient is treatment naive; or
  3.2 Both:
    3.2.1 The patient has discontinued gefitinib due to intolerance; and
    3.2.2 The cancer did not progress while on gefitinib; and
4 Erlotinib is to be given for a maximum of 3 months.

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.
Renewal — (pandemic circumstances) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and
2 Erlotinib to be discontinued at progression; and
3 The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector.

GEFITINIB – Retail pharmacy-Specialist – Special Authority see SA1916 below

Tab 250 mg	1,700.00	30	✔	**Iressa**

➽**SA1916** **Special Authority for Subsidy**
Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:

1 Patient has locally advanced, or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
2 Either:
  2.1 Patient is treatment naive; or
  2.2 Both:
    2.2.1 The patient has discontinued erlotinib due to intolerance; and
    2.2.2 The cancer did not progress whilst on erlotinib; and
3 There is documentation confirming that disease expresses activating mutations of EGFR tyrosine kinase; and
4 Gefitinib is to be given for a maximum of 3 months.

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.
Renewal — (pandemic circumstances) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and
2 Gefitinib to be discontinued at progression; and
3 The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector.

IMATINIB MESILATE

Note: Imatinib-AFT is not a registered for the treatment of Gastro Intestinal Stromal Tumours (GIST). The Glivec brand of imatinib mesilate (supplied by Novartis) remains fully subsidised under Special Authority for patients with unresectable and/or metastatic malignant GIST, see SA1460 in Section B of the Pharmaceutical Schedule.

Tab 100 mg – [Xpharm] – Special Authority see SA1460 on the next page	2,400.00	60	✔	**Glivec**
Cap 100 mg	98.00	60	✔	**Imatinib-AFT**
Cap 400 mg	197.50	30	✔	**Imatinib-AFT**

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

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

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
  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 on the next page – Retail pharmacy
Wastage claimable

Cap 150 mg	4,680.00		120	✔ **Tasigna**
Cap 200 mg	6,532.00		120	✔ **Tasigna**

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

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

➽SA1489 Special Authority for Subsidy

Initial application only from a haematologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Patient has a diagnosis of chronic myeloid leukaemia (CML) in blast crisis, accelerated phase, or in chronic phase; and
2 Either:
  2.1 Patient has documented CML treatment failure* with imatinib; or
  2.2 Patient has experienced treatment limiting toxicity with imatinib precluding further treatment with imatinib; and
3 Maximum nilotinib dose of 800 mg/day; and
4 Subsidised for use as monotherapy only.

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

Renewal only from a haematologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Lack of treatment failure while on nilotinib as defined by Leukaemia Net Guidelines; and
2 Nilotinib treatment remains appropriate and the patient is benefiting from treatment; and
3 Maximum nilotinib dose of 800 mg/day; and
4 Subsidised for use as monotherapy only.

PALBOCICLIB – Retail pharmacy-Specialist – Special Authority see SA1894 below

Wastage claimable

Cap 75 mg	4,000.00		21	✔ **Ibrance**
Cap 100 mg	4,000.00		21	✔ **Ibrance**
Cap 125 mg	4,000.00		21	✔ **Ibrance**

➽SA1894 Special Authority for Subsidy

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

1 Patient has unresectable locally advanced or metastatic breast cancer; and
2 There is documentation confirming disease is hormone-receptor positive and HER2-negative; and
3 Patient has an ECOG performance score of 0-2; and
4 Either:
  second or subsequent line setting
  4.1 Disease has relapsed or progressed during prior endocrine therapy; or
  4.2 Both:
    first line setting
    4.2.1 Patient is amenorrhoeic, either naturally or induced, with endocrine levels consistent with a postmenopausal state; and
    4.2.2 Either:
      4.2.2.1 Patient has not received prior systemic treatment for metastatic disease; or
      4.2.2.2 All of the following:
        4.2.2.2.1 Patient commenced treatment with palbociclib in combination with an endocrine agent prior to 1 April 2020; and
        4.2.2.2.2 Patient has not received prior systemic endocrine treatment for metastatic disease; and
        4.2.2.2.3 There is no evidence of progressive disease; and
5 Treatment must be used in combination with an endocrine partner.

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

1 Treatment must be used in combination with an endocrine partner; and
2 No evidence of progressive disease; and
3 The treatment remains appropriate and the patient is benefitting from treatment.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
PAZOPANIB – Special Authority see SA1190 below – Retail pharmacy				
Tab 200 mg	1,334.70	30	✔	**Votrient**
Tab 400 mg	2,669.40	30	✔	**Votrient**

➽SA1190 Special Authority for Subsidy

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

All of the following:

1 The patient has metastatic renal cell carcinoma; and

2 Any of the following:

2.1 The patient is treatment naive; or

2.2 The patient has only received prior cytokine treatment; or

2.3 Both:

2.3.1 The patient has discontinued sunitinib within 3 months of starting treatment due to intolerance; and

2.3.2 The cancer did not progress whilst on sunitinib; and

3 The patient has good performance status (WHO/ECOG grade 0-2); and

4 The disease is of predominant clear cell histology; and

The patient has intermediate or poor prognosis defined as:

5 Any of the following:

5.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or

5.2 Haemoglobin level < lower limit of normal; or

5.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or

5.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or

5.5 Karnofsky performance score of less than or equal to 70; or

5.6 2 or more sites of organ metastasis; and

6 Pazopanib to be used for a maximum of 3 months.

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

Both:

1 No evidence of disease progression; and

2 The treatment remains appropriate and the patient is benefiting from treatment.

Notes: Pazopanib treatment should be stopped if disease progresses.

Poor prognosis patients are defined as having at least 3 of criteria 5.1-5.6. Intermediate prognosis patients are defined as having 1 or 2 of criteria 5.1-5.6.

RUXOLITINIB – Special Authority see SA1890 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**

➽SA1890 Special Authority for Subsidy

Initial application only from a haematologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 The patient has primary myelofibrosis or post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis; and

2 Either:

2.1 A classification of risk of intermediate-2 or high-risk myelofibrosis according to either the International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or the Age-Adjusted DIPSS; or

2.2 Both:

continued…

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

continued…

2.2.1 A classification of risk of intermediate-1 myelofibrosis according to either the International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or the Age-Adjusted DIPSS; and

2.2.2 Patient has severe disease-related symptoms that are resistant, refractory or intolerant to available therapy; 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 SA1917 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**

➽**SA1917** **Special Authority for Subsidy**

Initial application — (RCC) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1 The patient has metastatic renal cell carcinoma; and
2 Any of the following:
2.1 The patient is treatment naive; or
2.2 The patient has only received prior cytokine treatment; or
2.3 The patient has only received prior treatment with an investigational agent within the confines of a bona fide clinical trial which has Ethics Committee approval; or
2.4 Both:
2.4.1 The patient has discontinued pazopanib within 3 months of starting treatment due to intolerance; and
2.4.2 The cancer did not progress whilst on pazopanib; and
3 The patient has good performance status (WHO/ECOG grade 0-2); and
4 The disease is of predominant clear cell histology; and
The patient has intermediate or poor prognosis defined as:
5 Any of the following:
5.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or
5.2 Haemoglobin level < lower limit of normal; or
5.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or
5.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or
5.5 Karnofsky performance score of less than or equal to 70; or
5.6 2 or more sites of organ metastasis; and
6 Sunitinib to be used for a maximum of 2 cycles.

Initial application — (GIST) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:
Both:

1 The patient has unresectable or metastatic malignant gastrointestinal stromal tumour (GIST); and
2 Either:
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.

continued…

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

continued…

Renewal — (RCC) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months for applications meeting the following criteria:
Both:

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

Notes: Sunitinib treatment should be stopped if disease progresses.
Poor prognosis patients are defined as having at least 3 of criteria 5.1-5.6. Intermediate prognosis patients are defined as having 1 or 2 of criteria 5.1-5.6

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

The patient has responded to treatment or has stable disease as determined by Choi's modified CT response evaluation criteria as follows:

1 Any of the following:
  1.1 The patient has had a complete response (disappearance of all lesions and no new lesions); or
  1.2 The patient has had a partial response (a decrease in size of 10% or more or decrease in tumour density in Hounsfield Units (HU) of 15% or more on CT and no new lesions and no obvious progression of non measurable disease); or
  1.3 The patient has stable disease (does not meet criteria the two above) and does not have progressive disease and no symptomatic deterioration attributed to tumour progression; and
2 The treatment remains appropriate and the patient is benefiting from treatment.

Note: It is recommended that response to treatment be assessed using Choi's modified CT response evaluation criteria (J Clin Oncol, 2007, 25:1753-1759). Progressive disease is defined as either: an increase in tumour size of 10% or more and not meeting criteria of partial response (PR) by tumour density (HU) on CT; or: new lesions, or new intratumoral nodules, or increase in the size of the existing intratumoral nodules.

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

1 The patient has unresectable or metastatic malignant gastrointestinal stromal (GIST); and
2 The patient is clinically benifiting from treatment and continued treatment remains appropriate; and
3 Sunitinib is to be discontinued at progression; and
4 The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector.

Endocrine Therapy

For GnRH ANALOGUES – refer to HORMONE PREPARATIONS, Trophic Hormones, page 80

ABIRATERONE ACETATE – Retail pharmacy-Specialist – Special Authority see SA1914 below
Wastage claimable
Tab 250 mg ..... 4,276.19 120 ✔ **Zytiga**

➽**SA1914** **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:

continued…

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

continued…

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 No evidence of clinical disease progression; and
2 No initiation of taxane chemotherapy with abiraterone; and
3 The treatment remains appropriate and the patient is benefiting from treatment.

BICALUTAMIDE				
Tab 50 mg	3.80	28	✔	**Binarex**
FLUTAMIDE				
Tab 250 mg	100.38	84	✔	**Flutamide Mylan** S29
	119.50	100	✔	**Flutamin**

(Flutamide Mylan S29 *Tab 250 mg to be delisted 1 July 2020)*

FULVESTRANT – Retail pharmacy-Specialist – Special Authority see SA1895 below				
Inj 50 mg per ml, 5 ml prefilled syringe	1,068.00	2	✔	**Faslodex** S29

➽**SA1895** **Special Authority for Subsidy**
Initial application only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1 Patient has oestrogen-receptor positive locally advanced or metastatic breast cancer; and
2 Patient has disease progression following prior treatment with an aromatase inhibitor or tamoxifen for their locally advanced or metastatic disease; and
3 Treatment to be given at a dose of 500 mg monthly following loading doses; and
4 Treatment to be discontinued at disease progression.

Renewal only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1 Treatment remains appropriate and patient is benefitting from treatment; and
2 Treatment to be given at a dose of 500 mg monthly; and
3 There is no evidence of disease progression.

MEGESTROL ACETATE				
Tab 160 mg	63.53	30	✔	**Apo-Megestrol**

	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**
	222.00		✔	**Octreotide (Sun)** S29
OCTREOTIDE LAR (SOMATOSTATIN ANALOGUE) – Special Authority see SA1918 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**

➽**SA1918** **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

continued…

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

continued…

2.2 Either:

2.2.1 Patient has failed surgery; or

2.2.2 Patient in metastatic disease after H2 antagonists (or proton pump inhibitors) have failed; or

3 Both:

3.1 Insulinomas; and

3.2 Surgery is contraindicated or has failed; or

4 For pre-operative control of hypoglycaemia and for maintenance therapy; or

5 Both:

5.1 Carcinoid syndrome (diagnosed by tissue pathology and/or urinary 5HIAA analysis); and

5.2 Disabling symptoms not controlled by maximal medical therapy.

Note: The use of octreotide in patients with fistulae, oesophageal varices, miscellaneous diarrhoea and hypotension will not be funded as a Special Authority item

Renewal — (Other Indications) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

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

All of the following:

1 Patient has acromegaly; and

2 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and

3 The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector.

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				
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.

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

Fusion Proteins

ETANERCEPT – Special Authority see SA1891 below – Retail pharmacy

Inj 25 mg	690.00	4	✔	**Enbrel**
Inj 50 mg autoinjector	1,050.00	4	✔	**Enbrel**
Inj 50 mg prefilled syringe	1,050.00	4	✔	**Enbrel**

➽**SA1891** **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

continued…

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

continued…

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.

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.

continued…

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

continued…

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

Either:

1 Both:

1.1 The patient has had an initial Special Authority approval for adalimumab for ankylosing spondylitis; and

1.2 Either:

1.2.1 The patient has experienced intolerable side effects from adalimumab; or

1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for ankylosing spondylitis; or

2 All of the following:

2.1 Patient has a confirmed diagnosis of ankylosing spondylitis present for more than six months; and

2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and

2.3 Patient has bilateral sacroiliitis demonstrated by plain radiographs, CT or MRI scan; and

2.4 Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and

2.5 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

continued…

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

continued…

2.3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and

2.4 Either:

2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints; or

2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and

2.5 Any of the following:

2.5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or

2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or

2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

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

1 Patient has pyoderma gangrenosum*; and
2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate) and not received an adequate response; and
3 A maximum of 4 doses.

Note: Indications marked with * are unapproved indications.

Initial application — (adult-onset Still's disease) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Either:

1 Both:

1.1 Either:

1.1.1 The patient has had an initial Special Authority approval for adalimumab for adult-onset Still's disease (AOSD); or

1.1.2 The patient has been started on tocilizumab for AOSD in a DHB hospital in accordance with the HML rules; and

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.

Initial application — (undifferentiated spondyloarthritis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Patient has undifferentiated peripheral spondyloarthritis* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and

continued…

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

continued…

3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day (or maximum tolerated dose); and
4 Patient has tried and not responded to at least three months of leflunomide at a dose of up to 20 mg daily (or maximum tolerated dose); and
5 Any of the following:
  5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
  5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour measured no more than one month prior to the date of this application; or
  5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Note: Indications marked with * are unapproved indications.

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

1 Either:
  1.1 Applicant is a named specialist or rheumatologist; or
  1.2 Applicant is a Practitioner and confirms that a named specialist or rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
2 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
3 Either:
  3.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
  3.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

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

1 Either:
  1.1 Applicant is a rheumatologist; or
  1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
3 Either:
  3.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  3.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
4 Etanercept to be administered at doses no greater than 50 mg every 7 days.

Renewal — (severe chronic plaque psoriasis) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Either:
  1.1 Applicant is a dermatologist; or

continued…

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

continued…

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:

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.

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

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

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

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

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

Immune Modulators

ANTITHYMOCYTE GLOBULIN (EQUINE) – PCT only – 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)

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

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

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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.

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:

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

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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:

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

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

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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:
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

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

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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

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:

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

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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
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

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

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2.3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and

2.4 Either:

2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints; or

2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and

2.5 Any of the following:

2.5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or

2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or

2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

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

All of the following:

1 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

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

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

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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:

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.

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

continued…

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

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.

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

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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:
- 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:

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

continued…

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
    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

continued…

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

continued…

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:

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 on the next page

Inj 100 mg	806.00	1	✔	**Remicade**
Inj 1 mg for ECP	8.29	1 mg	✔	**Baxter**

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

➽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:

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

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

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considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

Initial application — (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:
    2.2.1 Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective; or
    2.2.2 Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or
    2.2.3 Patient is under 8 years and treatment with steroids or methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or disease requires control to prevent irreversible vision loss prior to achieving a therapeutic dose of methotrexate.

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

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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 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:

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

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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:
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

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

continued…

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:
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

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

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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 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:

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	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 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
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

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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.

MEPOLIZUMAB – Special Authority see SA1896 below – Retail pharmacy

Inj 100 mg vial	1,638.00	1	✔	**Nucala**

➽**SA1896** **Special Authority for Subsidy**

Initial application — (Severe eosinophilic asthma) only from a respiratory physician or clinical immunologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 Patient must be aged 12 years or older; and
2 Patient must have a diagnosis of severe eosinophilic asthma documented by a respiratory physician or clinical immunologist; and
3 Conditions that mimic asthma eg. vocal cord dysfunction, central airway obstruction, bronchiolitis etc. have been excluded; and
4 Patient has a blood eosinophil count of greater than 0.5 × 10^9 cells/L in the last 12 months; and
5 Patient must be adherent to optimised asthma therapy including inhaled corticosteroids (equivalent to at least 1000 mcg per day of fluticasone propionate) plus long acting beta-2 agonist, or budesonide/formoterol as part of the single maintenance and reliever therapy regimen, unless contraindicated or not tolerated; and
6 Either:
  6.1 Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral corticosteroids; or
  6.2 Patient has received continuous oral corticosteroids of at least the equivalent of 10 mg per day over the previous 3 months; and
7 Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment.

Renewal — (Severe eosinophilic asthma) only from a respiratory physician or clinical immunologist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

1 An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and
2 Either:
  2.1 Exacerbations have been reduced from baseline by 50% as a result of treatment with mepolizumab; or
  2.2 Reduction in continuous oral corticosteroid use by 50% or by 10 mg/day while maintaining or improving asthma control.

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

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

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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 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

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

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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 below

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

➽**SA1606** **Special Authority for Subsidy**

Initial application — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and

2 Either:

2.1 Patient is chemotherapy treatment naïve; or

2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and

3 The patient has good performance status (ECOG grade 0-1); and

4 Pertuzumab to be administered in combination with trastuzumab; and

5 Pertuzumab maximum first dose of 840 mg, followed by maximum of 420 mg every 3 weeks; and

6 Pertuzumab to be discontinued at disease progression.

Renewal — (metastatic breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a 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 (MABTHERA) – PCT only – Specialist – Special Authority see SA1901 on the next page

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 (Mabthera)**

▲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

➽SA1901 **Special Authority for Subsidy**

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

All of the following:

1 Patient has been diagnosed with ANCA associated vasculitis*; and
2 Patient has previously responded to treatment with rituximab but is now experiencing an acute flare of vasculitis; and
3 The total rituximab dose would not exceed the equivalent of 375 mg/m^2 of body-surface area per week for a total of 4 weeks.

Note: Indications marked with * are unapproved indications.

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; 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.

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.

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

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

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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.

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

All of the following:

1 Patient who was previously treated with rituximab for nephrotic syndrome*; and

2 Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment; and

3 The total rituximab dose used would not exceed the equivalent of 375 mg/m^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 8 weeks for applications meeting the following criteria:

All of the following:

1 Patient who was previously treated with rituximab for nephrotic syndrome*; and

2 Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment; and

3 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.

Note: Indications marked with * are unapproved indications.

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

All of the following:

1 The patient has had a rituximab treatment-free interval of 12 months or more; and

2 The patient has relapsed refractory/aggressive CD20 positive NHL; and

3 To be used with a multi-agent chemotherapy regimen given with curative intent; and

4 To be used for a maximum of 4 treatment cycles.

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia

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

All of the following:

1 Patient was previously treated with rituximab for haemophilia with inhibitors; and

2 An initial response lasting at least 12 months was demonstrated; and

3 Patient now requires repeat treatment.

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

Either:

1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^2 weekly for 4 weeks) is now planned; or

2 All of the following:

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

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2.1 Patient was previously treated with rituximab for immune thrombocytopenic purpura*; and
2.2 An initial response lasting at least 12 months was demonstrated; and
2.3 Patient now requires repeat treatment.

Note: Indications marked with * are unapproved indications.

Renewal — (indolent, low-grade lymphomas or hairy cell leukaemia*) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:
All of the following:

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

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

Renewal — (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:
  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.

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

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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
  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.

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

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

1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^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.

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

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

Note: Indications marked with * are unapproved indications.

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

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

Note: Indications marked with * are unapproved indications.

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

1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^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.

RITUXIMAB (RIXIMYO) – PCT only – Specialist – Special Authority see SA1902 below

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

➽**SA1902** **Special Authority for Subsidy**
Initial application — (ABO-incompatible organ transplant) from any relevant practitioner. Approvals valid without further renewal unless notified where patient is to undergo an ABO-incompatible solid organ transplant*.
Note: Indications marked with * are unapproved indications.
Initial application — (ANCA associated vasculitis) from any relevant practitioner. Approvals valid for 8 weeks for applications meeting the following criteria:

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

continued…

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 8 weeks for applications meeting the following criteria:

All of the following:

1 Patient has been diagnosed with ANCA associated vasculitis*; and
2 Patient has previously responded to treatment with rituximab but is now experiencing an acute flare of vasculitis; and
3 The total rituximab dose would not exceed the equivalent of 375 mg/m^2 of body-surface area per week for a total of 4 weeks.

Note: Indications marked with * are unapproved indications.

Initial application — (Antibody-mediated organ transplant rejection) from any relevant practitioner. Approvals valid without further renewal unless notified where patient has been diagnosed with antibody-mediated organ transplant rejection*.

Note: Indications marked with * are unapproved indications.

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

All of the following:

1 The patient has progressive Binet stage A, B or C chronic lymphocytic leukaemia (CLL) requiring treatment; and
2 Any of the following:
  2.1 The patient is rituximab treatment naive; or
  2.2 Either:
    2.2.1 The patient is chemotherapy treatment naive; or
    2.2.2 Both:
      2.2.2.1 The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment; and
      2.2.2.2 The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy; or
  2.3 The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; and
3 The patient has good performance status; and
4 Either:
  4.1 The patient does not have chromosome 17p deletion CLL; or
  4.2 Rituximab treatment is to be used in combination with funded venetoclax for relapsed/refractory chronic lymphocytic leukaemia; and
5 Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles; and
6 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous

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

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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; and
    1.2.3 The patient does not have chromosome 17p deletion CLL; and
    1.2.4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustine; and
2 Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles.

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

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

Both:

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

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

All of the following:

1 One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m2 administered weekly for four weeks; and
2 The patients has responded to the most recent course of rituximab; and
3 The patient has not received rituximab in the previous 6 months.

Initial application — (Post-transplant) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

1 The patient has B-cell post-transplant lymphoproliferative disorder*; and

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

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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:
  2.1 Treatment with corticosteroids and at least one other immunosuppressant for at least a period of 12 months has been ineffective; or
  2.2 Both:
    2.2.1 Treatment with at least one other immunosuppressant for a period of at least 12 months; and
    2.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.

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

All of the following:

1 One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart; and
2 An initial response lasting at least 12 months was demonstrated; and
3 Either:
  3.1 The patient has relapsed despite treatment with corticosteroids and at least one other immunosuppressant for a period of at least 12 months; or
  3.2 Both:
    3.2.1 The patient's myasthenia gravis has relapsed despite treatment with at least one immunosuppressant for a period of at least 12 months; and
    3.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.

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

All of the following:

1 Patient is a child with SDNS* or FRNS*; and
2 Treatment with steroids for at least a period of 3 months has been ineffective or associated with evidence of steroid toxicity; and
3 Treatment with ciclosporin for at least a period of 3 months has been ineffective and/or discontinued due to unacceptable side effects; and
4 Treatment with mycophenolate for at least a period of 3 months with no reduction in disease relapses; and
5 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.

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

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Note: Indications marked with * are unapproved indications.

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

All of the following:

1 Patient who was previously treated with rituximab for nephrotic syndrome*; and
2 Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
3 The total rituximab dose used would not exceed the equivalent of 375 mg/m^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 8 weeks for applications meeting the following criteria:

All of the following:

1 Patient is a child with SRNS* where treatment with steroids and ciclosporin for at least 3 months have been ineffective; and
2 Treatment with tacrolimus for at least 3 months has been ineffective; and
3 Genetic causes of nephrotic syndrome have been excluded; and
4 The total rituximab dose used would not exceed the equivalent of 375 mg/m^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 8 weeks for applications meeting the following criteria:

All of the following:

1 Patient who was previously treated with rituximab for nephrotic syndrome*; and
2 Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
3 The total rituximab dose used would not exceed the equivalent of 375 mg/m^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

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

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4 To be used for a maximum of 4 treatment cycles.

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia

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

Any of the following:

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

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

All of the following:

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

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

All of the following:

1 Either:
  1.1 Patient has immune thrombocytopenic purpura* with a platelet count of less than or equal to 20,000 platelets per microlitre; or
  1.2 Patient has immune thrombocytopenic purpura* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding; and
2 Any of the following:
  2.1 Treatment with steroids and splenectomy have been ineffective; or
  2.2 Treatment with steroids has been ineffective and splenectomy is an absolute contraindication; or
  2.3 Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy); and
3 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks.

Note: Indications marked with * are unapproved indications.

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

Either:

1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/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

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

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2 Both:

2.1 The patient has indolent, low grade lymphoma or hairy cell leukaemia* requiring first-line systemic chemotherapy; and

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

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

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

Either:

1 All of the following:

1.1 The patient has had a rituximab treatment-free interval of 12 months or more; and

1.2 The patient has indolent, low-grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy; and

1.3 To be used for no more than 6 treatment cycles; or

2 Both:

2.1 Rituximab is to be used for maintenance in CD20+ low grade or follicular B-cell NHL following induction with first-line systemic chemotherapy; and

2.2 Patient is intended to receive rituximab maintenance therapy for 2 years at a dose of 375 mg/m2 every 8 weeks (maximum of 12 cycles).

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

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

Note: Indications marked with * are unapproved indications.

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

Note: Indications marked with * are unapproved indications.

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

All of the following:

1 Patient has cold haemagglutinin disease*; and

2 Patient has severe disease which is characterized by symptomatic anaemia, transfusion dependence or disabling circulatory symptoms; and

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

Note: Indications marked with * are unapproved indications.

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

Either:

1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m^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

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

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2.3 Patient now requires repeat treatment.

Note: Indications marked with * are unapproved indications.

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

Both:

1 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks; and

2 Either:

2.1 Patient has thrombotic thrombocytopenic purpura* and has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange; or

2.2 Patient has acute idiopathic thrombotic thrombocytopenic purpura* with neurological or cardiovascular pathology.

Note: Indications marked with * are unapproved indications.

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

All of the following:

1 Patient was previously treated with rituximab for thrombotic thrombocytopenic purpura*; and

2 An initial response lasting at least 12 months was demonstrated; and

3 Patient now requires repeat treatment; and

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

Note: Indications marked with * are unapproved indications.

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

All of the following:

1 The patient has severe, immediately life- or organ-threatening SLE*; and

2 The disease has proved refractory to treatment with steroids at a dose of at least 1 mg/kg; and

3 The disease has relapsed following prior treatment for at least 6 months with maximal tolerated doses of azathioprine, mycophenolate mofetil and high dose cyclophosphamide, or cyclophosphamide is contraindicated; and

4 Maximum of four 1000 mg infusions of rituximab.

Note: Indications marked with * are unapproved indications.

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

All of the following:

1 Patient's SLE* achieved at least a partial response to the previous round of prior rituximab treatment; and

2 The disease has subsequently relapsed; and

3 Maximum of two 1000 mg infusions of rituximab.

Note: Indications marked with * are unapproved indications.

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

All of the following:

1 Patient has warm autoimmune haemolytic anaemia*; and

2 One of the following treatments has been ineffective: steroids (including if patient requires ongoing steroids at doses equivalent to > 5 mg prednisone daily), cytotoxic agents (e.g. cyclophosphamide monotherapy or in combination), intravenous immunoglobulin; and

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

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

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Note: Indications marked with * are unapproved indications.

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

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.

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

All of the following:

1 Patient has confirmed antisynthetase syndrome; and

2 Patient has severe, immediately life or organ threatening disease, including interstitial lung disease; and

3 Either:

3.1 Treatment with at least 3 immunosuppressants (oral steroids, cyclophosphamide, methotrexate, mycophenolate, ciclosporin, azathioprine) has not be effective at controlling active disease; or

3.2 Rapid treatment is required due to life threatening complications; and

4 Maximum of four 1,000mg infusions of rituximab.

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

All of the following:

1 Patient's disease has responded to the previous rituximab treatment with demonstrated improvement in inflammatory markers, muscle strength and pulmonary function; and

2 The patient has not received rituximab in the previous 6 months; and

3 Maximum of two cycles of 2 × 1,000mg infusions of rituximab given two weeks apart.

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

All of the following:

1 Patient has refractory graft versus host disease following transplant; and

2 Treatment with at least 3 immunosuppressants (oral steroids, ciclosporin, tacrolimus, mycophenolate, sirolimus) has not be effective at controlling active disease; and

3 The total rituximab dose used would not exceed the equivalent of 375 mg/m^2 of body surface area per week for a total of 4 weeks.

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

All of the following:

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

2 Either:

2.1 Both:

2.1.1 Treatment with steroids and intravenous immunoglobulin and/or plasma exchange has not been effective at controlling active disease; and

2.1.2 At least one other immunosuppressant (cyclophosphamide, ciclosporin, tacrolimus, mycophenolate) has not been effective at controlling active disease; or

2.2 Rapid treatment is required due to life threatening complications; and

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

continued…

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

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

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

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

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

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

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

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

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

continued…

4 The most recent PASI or DQLI assessment is no more than 1 month old at the time of application.

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

All of the following:

1 Either:
- 1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
- 1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and

3 A PASI assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and

4 The most recent PASI or DQLI assessment is no more than 1 month old at the time of application.

Note: A treatment course is defined as a minimum of 12 weeks of treatment. "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom sub scores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

Renewal — (severe chronic plaque psoriasis – first and second-line biologic) only from a dermatologist or medical practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 Either:
- 1.1 Patient's PASI score has reduced by 75% or more (PASI 75) as compared to baseline PASI prior to commencing secukinumab; or
- 1.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing secukinumab; and

2 Secukinumab to be administered at a maximum dose of 300 mg monthly.

SILTUXIMAB – Special Authority see SA1596 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.

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

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

continued…

3.2.2.2 At four months following the initial course of rituximab the patient has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis.

Initial application — (Rheumatoid Arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
2 Tocilizumab is to be used as monotherapy; and
3 Either:
  3.1 Treatment with methotrexate is contraindicated; or
  3.2 Patient has tried and did not tolerate oral and/or parenteral methotrexate; and
4 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

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

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2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, 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

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.

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

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Renewal — (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months where the patient has a sustained improvement in inflammatory markers and functional status.

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

Both:

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

2 Either:

2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or

2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Renewal — (idiopathic multicentric Castleman's disease) only from a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist. Approvals valid for 12 months where the treatment remains appropriate and the patient has a sustained improvement in inflammatory markers and functional status.

TRASTUZUMAB – PCT only – Specialist – Special Authority see SA1632 below

Inj 150 mg vial	1,350.00	1	✔	**Herceptin**
Inj 440 mg vial	3,875.00	1	✔	**Herceptin**
Inj 1 mg for ECP	9.36	1 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

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

continued…

2 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
3 Trastuzumab not to be given in combination with lapatinib; and
4 Trastuzumab to be discontinued at disease progression.

Initial application — (early breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 15 months for applications meeting the following criteria:
All of the following:

1 The patient has early breast cancer expressing HER 2 IHC 3+ or ISH + (including FISH or other current technology); and
2 Maximum cumulative dose of 106 mg/kg (12 months' treatment); and
3 Any of the following:
  3.1 9 weeks' concurrent treatment with adjuvant chemotherapy is planned; or
  3.2 12 months' concurrent treatment with adjuvant chemotherapy is planned; or
  3.3 12 months' sequential treatment following adjuvant chemotherapy is planned; or
  3.4 12 months' treatment with neoadjuvant and adjuvant chemotherapy is planned; or
  3.5 Other treatment regimen, in association with adjuvant chemotherapy, is planned.

Renewal — (early breast cancer*) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:

1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); 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

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:

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

continued…

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:
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 SA1911 below

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**

➽**SA1911** **Special Authority for Subsidy**

Initial application only from a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:

1 Patient has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
2 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 Baseline measurement of overall tumour burden is documented (see Note); and
6 Documentation confirming that the patient has been informed and acknowledges that funded treatment with nivolumab will not be continued if their disease progresses.

Renewal only from 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

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

continued…

1.2 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; or

2 All of the following:
2.1 Patient has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression; and
2.2 Patient has signs of disease progression; and
2.3 Disease has not progressed during previous treatment with nivolumab.

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 SA1910 below

Inj 25 mg per ml, 4 ml vial	4,680.00	1	✔ **Keytruda**
Inj 1 mg for ECP	49.14	1 mg	✔ **Baxter**

➽**SA1910** **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 Baseline measurement of overall tumour burden is documented (see Note); and
6 Documentation confirming that the patient has been informed and acknowledges that funded treatment with pembrolizumab will not be continued if their disease progresses.

Renewal — (unresectable or metastatic melanoma) only from a medical oncologist or medical practitioner on the

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

continued…

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 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; 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.

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**
EVEROLIMUS – Special Authority see SA1913 on the next page – Retail pharmacy				
Wastage claimable				
Tab 10 mg	6,512.29	30	✔	**Afinitor**
Tab 5 mg	4,555.76	30	✔	**Afinitor**

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

➽SA1913 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.

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

All of the following:

1 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and

2 Everolimus to be discontinued at progression of SEGAs; and

3 The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector.

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

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

continued…

unless notified for applications meeting the following criteria:

Both:

1 Patient requires long-term systemic immunosuppression; and

2 Ciclosporin has been trialled and discontinued treatment because of unacceptable side effects or inadequate clinical response.

Note: Indications marked with * are unapproved indications

	Subsidy (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**
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	17.87	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**

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
FLUTICASONE				
Aerosol inhaler, 50 mcg per dose	4.68	120 dose OP	✔	**Floair**
	7.19		✔	**Flixotide**
Flixotide to be Sole Supply on 1 September 2020				
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**
	13.60		✔	**Flixotide**
Flixotide to be Sole Supply on 1 September 2020				
Aerosol inhaler, 250 mcg per dose	10.18	120 dose OP	✔	**Floair**
	24.62		✔	**Flixotide**
Flixotide to be Sole Supply on 1 September 2020				
Powder for inhalation, 250 mcg per dose	13.60	60 dose OP	✔	**Flixotide Accuhaler**
(Floair Aerosol inhaler, 50 mcg per dose to be delisted 1 September 2020)				
(Floair Aerosol inhaler, 125 mcg per dose to be delisted 1 September 2020)				
(Floair Aerosol inhaler, 250 mcg per dose to be delisted 1 September 2020)				

Inhaled Long-acting Beta-adrenoceptor Agonists

EFORMOTEROL FUMARATE				
Powder for inhalation, 12 mcg per dose, and monodose device	20.64	60 dose		
	(35.80)			Foradil
EFORMOTEROL FUMARATE DIHYDRATE				
Powder for inhalation 4.5 mcg per dose, breath activated				
(equivalent to eformoterol fumarate 6 mcg metered dose)	10.32	60 dose OP		
	(16.90)			Oxis Turbuhaler
INDACATEROL				
Powder for inhalation 150 mcg	61.00	30 dose OP	✔	**Onbrez Breezhaler**
Powder for inhalation 300 mcg	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

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**

▲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 WITH SALMETEROL				
Aerosol inhaler 50 mcg with salmeterol 25 mcg	14.58	120 dose OP	✔	**RexAir**
	25.79		✔	**Seretide**
Seretide to be Sole Supply on 1 September 2020				
Aerosol inhaler 125 mcg with salmeterol 25 mcg	16.83	120 dose OP	✔	**RexAir**
	32.60		✔	**Seretide**
Seretide to be Sole Supply on 1 September 2020				
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**

(RexAir Aerosol inhaler 50 mcg with salmeterol 25 mcg to be delisted 1 September 2020)
(RexAir Aerosol inhaler 125 mcg with salmeterol 25 mcg to be delisted 1 September 2020)

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, 200 mcg per dose (equivalent to 250 mcg metered dose), breath activated	22.20	120 dose OP	✔	**Bricanyl Turbuhaler**
Powder for inhalation, 250 mcg per dose, breath activated	27.30	200 dose OP	✔	**Bricanyl Turbuhaler**

(Bricanyl Turbuhaler Powder for inhalation, 250 mcg per dose, breath activated to be delisted 1 October 2020)

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**

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

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

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, and the prescription is endorsed accordingly.

Powder for inhalation 50 mcg per dose	61.00	30 dose OP	✔	**Seebri Breezhaler**

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, 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, 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**

▲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
UMECLIDINIUM WITH VILANTEROL – Special Authority see SA1584 on the previous page – Retail pharmacy				
Powder for inhalation 62.5 mcg with vilanterol 25 mcg	77.00	30 dose OP	✔	**Anoro Ellipta**

Antifibrotics

NINTEDANIB – Special Authority see SA1928 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**

SA1928 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; and
2 Forced vital capacity is between 50% and 90% predicted; and
3 Nintedanib is to be discontinued at disease progression (See Note); and
4 Nintedanib is not to be used in combination with subsidised pirfenidone; and
5 Any of the following:
  5.1 The patient has not previously received treatment with pirfenidone; or
  5.2 Patient has previously received pirfenidone, but discontinued pirfenidone within 12 weeks due to intolerance; or
  5.3 Patient has previously received pirfenidone, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with pirfenidone).

Renewal — (idiopathic pulmonary fibrosis) from any relevant practitioner. 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 SA1929 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**

SA1929 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; 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).

continued…

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

continued…

Renewal — (idiopathic pulmonary fibrosis) from any relevant practitioner. 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**

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
PHARMAC, PO Box 10 254
Wellington

Phone: (04) 460 4990
Facsimile: (04) 916 7571
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**

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

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	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 244

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 (9.27) — 8 ml OP — Sofradex

FRAMYCETIN SULPHATE

Ear/Eye drops 0.5% — 4.13 (8.65) — 8 ml OP — 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**

Eye drops 0.5% — 1.54 — 10 ml OP — ✔ **Chlorafast**

Funded for use in the ear*. Indications marked with * are unapproved indications.

CIPROFLOXACIN

Eye drops 0.3% – Subsidy by endorsement — 9.99 — 5 ml OP — ✔ **Ciprofloxacin Teva**

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 (14.55) — 10 ml OP — 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**

	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%	5.93	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	✔	**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 244

HYPROMELLOSE
- Eye drops 0.5% ..... 2.00 — 15 ml OP
- (3.92) — Methopt

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	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**

Preservative Free Ocular Lubricants

➽SA1388 **Special Authority for Subsidy**

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

1 Confirmed diagnosis by slit lamp of severe secretory dry eye; and
2 Either:
  2.1 Patient is using eye drops more than four times daily on a regular basis; or
  2.2 Patient has had a confirmed allergic reaction to preservative in eye drop.

Renewal from any relevant practitioner. Approvals valid for 24 months where the patient continues to require lubricating eye drops and has benefited from treatment.

CARBOMER – Special Authority see SA1388 above – Retail 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

NAPHAZOLINE HYDROCHLORIDE				
Eye drops 0.1%	4.15	15 ml OP	✔	**Naphcon Forte**
OLOPATADINE				
Eye drops 0.1%	2.20	5 ml OP	✔	**Olopatadine Teva**
	10.00		✔	**Patanol**

(Patanol Eye drops 0.1% to be delisted 1 October 2020)

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 Buprenorphine Naloxone BNM**

The Pharmacode for BSF Buprenorphine Naloxone BNM is 2586258 - see also page 149

(BSF Buprenorphine Naloxone BNM Brand switch fee to be delisted 1 July 2020)

Agents Used in the Treatment of Poisonings

Antidotes

ACETYLCYSTEINE

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:

continued…

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

continued…

Either:

1 For the first renewal following 2 years of therapy, the treatment has been tolerated and has resulted in clinical improvement in all three parameters namely serum ferritin, cardiac MRI T2* and liver MRI T2* levels; or

2 For subsequent renewals, the treatment has been tolerated and has resulted in clinical stability or continued improvement in all three parameters namely serum ferritin, cardiac MRI T2* and liver MRI T2* levels.

DEFERIPRONE – Special Authority see SA1480 below – 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

▲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

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

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**

(PSM Chloroform BP to be delisted 1 November 2020)

CODEINE PHOSPHATE – Safety medicine; prescriber may determine dispensing frequency

Powder – Only in combination ..... 63.09 (90.09) 25 g 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**

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**

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

➽SA1930 **Special Authority for Subsidy**
Initial application — (Cystic fibrosis or kidney disease) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:
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 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula.
Initial application — (Inborn errors of metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified where the patient has inborn errors of metabolism.
Renewal — (Cystic fibrosis or renal failure) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian,relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:
Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis or renal failure) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:
Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

CARBOHYDRATE SUPPLEMENT – Special Authority see SA1930 above – Hospital pharmacy [HP3]
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]

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]

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 CO_2 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**

(Pulmocare Liquid to be delisted 1 October 2020)

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.

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	237 ml	OP	
	(3.31)			NovaSource Renal
Liquid (apricot) 125 ml	11.52	4	OP	✔ **Renilon 7.5**
Liquid (caramel) 125 ml	11.52	4	OP	✔ **Renilon 7.5**

Specialised And Elemental Products

➽SA1377 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

1 malabsorption; or
2 short bowel syndrome; or
3 enterocutaneous fistulas; or
4 eosinophilic oesophagitis; or
5 inflammatory bowel disease; or
6 patients with multiple food allergies requiring enteral feeding.

Notes: Each of these products is highly specialised and would be prescribed only by an expert for a specific disorder. The alternative is hospitalisation.

Elemental 028 Extra is more expensive than other products listed in this section and should only be used where the alternatives have been tried first and/or are unsuitable.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
ENTERAL/ORAL SEMI-ELEMENTAL FEED 1.5KCAL/ML – Special Authority see SA1377 on the previous page – Hospital pharmacy [HP3]				
Liquid	18.06	1,000 ml OP	✔	**Vital**
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.

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:

continued…

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

continued…

All of the following:

1 The patient is under 18 years of age; and
2 The treatment remains appropriate and the patient is benefiting from treatment; and
3 A nutrition goal has been set (eg reach a specific weight or BMI).

Initial application — (Children - exclusive enteral nutrition for Crohn's disease) only from a gastroenterologist or dietitian on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1 The patient is under 18 years of age; and
2 It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease; and
3 Dietitians must include the name of the gastroenterologist recommending treatment and the date the gastroenterologist was contacted.

Renewal — (Children - exclusive enteral nutrition for Crohn's disease) from any relevant practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1 The patient is under 18 years of age; and
2 It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease; and
3 General Practitioners and dietitians must include the name of the gastroenterologist recommending treatment and the date the gastroenterologist was contacted.

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

continued…

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

continued…

4 Tempomandibular surgery or glossectomy; or
5 Both:
  5.1 Pregnant; and
  5.2 Any of the following:
    5.2.1 Patient is in early pregnancy (< 13 weeks) and has severe clinical hyperemesis gravidarum requiring admission to hospital and is unlikely to meet her nutritional requirements due to continuing hyperemesis gravidarum; or
    5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or
    5.2.3 Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met.

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

continued…

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

continued…

meeting the following criteria:

Any of the following:

1 Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube - refer to specific medical condition criteria); or
2 Cystic Fibrosis; or
3 Liver disease; or
4 Chronic Renal failure; or
5 Inflammatory bowel disease; or
6 Chronic obstructive pulmonary disease with hypercapnia; or
7 Short bowel syndrome; or
8 Bowel fistula; or
9 Severe chronic neurological conditions.

ENTERAL FEED 1.5KCAL/ML – Special Authority see SA1859 on page 254 – Hospital pharmacy [HP3]

Liquid	7.00	1,000 ml	OP	✔ **Nutrison Energy**

ENTERAL FEED 1KCAL/ML – Special Authority see SA1859 on page 254 – 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 254 – 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 254 – 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 254 – 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**

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

ORAL FEED (POWDER) – Special Authority see SA1859 on page 254 – Hospital pharmacy [HP3]

Note: Higher subsidy for Sustagen Hospital Formula will only be reimbursed for patients with both a valid Special Authority number and an appropriately endorsed prescription.

Powder (chocolate) – Higher subsidy of up to $26.00 per 850 g

with Endorsement	26.00	850 g OP	✔ **Ensure**
	9.54	840 g OP	
	(26.00)		Sustagen Hospital Formula Active

Additional subsidy by endorsement is available for patients with fat malabsorption, fat intolerance or chyle leak. The prescription must be endorsed accordingly.

Powder (vanilla) – Higher subsidy of up to $26.00 per 850 g

with Endorsement	8.54	857 g OP	✔ **Fortisip**
	26.00	850 g OP	✔ **Ensure**
	9.54	840 g OP	
	(26.00)		Sustagen Hospital Formula Active

Additional subsidy by endorsement is available for patients with fat malabsorption, fat intolerance or chyle leak. The prescription must be endorsed accordingly.

ORAL FEED 1.5KCAL/ML – Special Authority see SA1859 on page 254 – Hospital pharmacy [HP3]

Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, who have severe epidermolysis bullosa, or as exclusive enteral nutrition in children under the age of 18 years for the treatment of Crohn's disease, or for patients with COPD and hypercapnia, defined as CO2 value exceeding 55mmHg. The prescription must be endorsed accordingly.

Liquid (banana) – Higher subsidy of $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

(Ensure Plus Liquid (strawberry) to be delisted 1 July 2020)

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

ORAL FEED WITH FIBRE 1.5 KCAL/ML – Special Authority see SA1859 on page 254 – 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.

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

1 Any of the following:
  1.1 any condition causing malabsorption; or
  1.2 faltering growth in an infant/child; or
  1.3 increased nutritional requirements; or
  1.4 fluid restricted; and
2 other lower calorie products have been tried; and
3 patient has substantially increased metabolic requirements or is fluid restricted.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL FEED 2 KCAL/ML – Special Authority see SA1195 above – Hospital pharmacy [HP3]

Liquid	5.50	500 ml	OP	✔ **Nutrison Concentrated**
	11.00	1,000 ml	OP	✔ **Two Cal HN RTH**

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

ORAL FEED 2 KCAL/ML – Special Authority see SA1195 on the previous page – Hospital pharmacy [HP3]

Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, or who have severe epidermolysis bullosa. The prescription must be endorsed accordingly.

Liquid (vanilla) – Higher subsidy of $1.90 per 200 ml with Endorsement

	0.96	200 ml OP	
	(1.90)		Two Cal HN

Food Thickeners

SA1106 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient has motor neurone disease with swallowing disorder.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

FOOD THICKENER – Special Authority see SA1106 above – 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.

GLUTEN FREE BAKING MIX – Special Authority see SA1729 above – Hospital pharmacy [HP3]

Powder

2.81	1,000 g OP	
(5.15)		Healtheries Simple Baking Mix

GLUTEN FREE BREAD MIX – Special Authority see SA1729 above – Hospital pharmacy [HP3]

Powder

3.93	1,000 g OP	
(7.32)		NZB Low Gluten Bread Mix
3.51		
(10.87)		Horleys Bread Mix

	Subsidy (Manufacturer's Price) $	Per	Fully Subsidised ✔	Brand or Generic Manufacturer
GLUTEN FREE FLOUR – Special Authority see SA1729 on the previous page – Hospital pharmacy [HP3]				
Powder	5.62	2,000 g OP		
	(18.10)			Horleys Flour
GLUTEN FREE PASTA – Special Authority see SA1729 on the previous page – Hospital pharmacy [HP3]				
Buckwheat Spirals	2.00	250 g OP		
	(3.11)			Orgran
Corn and Vegetable Shells	2.00	250 g OP		
	(2.92)			Orgran
Corn and Vegetable Spirals	2.00	250 g OP		
	(2.92)			Orgran
Rice and Corn Lasagne Sheets	1.60	200 g OP		
	(3.82)			Orgran
Rice and Corn Macaroni	2.00	250 g OP		
	(2.92)			Orgran
Rice and Corn Penne	2.00	250 g OP		
	(2.92)			Orgran
Rice and Maize Pasta Spirals	2.00	250 g OP		
	(2.92)			Orgran
Rice and Millet Spirals	2.00	250 g OP		
	(3.11)			Orgran
Rice and corn spaghetti noodles	2.00	375 g OP		
	(2.92)			Orgran
Vegetable and Rice Spirals	2.00	250 g OP		
	(2.92)			Orgran
Italian long style spaghetti	2.00	220 g OP		
	(3.11)			Orgran

Foods And Supplements For Inborn Errors Of Metabolism

➽SA1108 Special Authority for Subsidy

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

Any of the following:

1 Dietary management of homocystinuria; or
2 Dietary management of maple syrup urine disease; or
3 Dietary management of phenylketonuria (PKU); or
4 For use as a supplement to the Ketogenic diet in patients diagnosed with epilepsy.

Supplements For Homocystinuria

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]

Powder	44.40	400 g	OP	✔ **Locasol**

Gastrointestinal and Other Malabsorptive Problems

AMINO ACID FORMULA – Special Authority see SA1219 below – Hospital pharmacy [HP3]

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.

(ADT Booster Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid in 0.5 ml to be delisted 1 October 2020)

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**

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

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

Funded for any of the following criteria:

1) for dialysis patients; or
2) for liver or kidney transplant patient.

(HBvaxPRO Inj 5 mcg per 0.5 ml vial to be delisted 1 October 2020)
(HBvaxPRO Inj 10 mcg per 1 ml vial to be delisted 1 October 2020)
(HBvaxPRO Inj 40 mcg per 1 ml vial to be delisted 1 October 2020)

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

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 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine)				
– [Xpharm]	9.00	1	✔	**Afluria Quad Junior (2020 Formulation)**

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) Doctors are the only Contractors entitled to claim payment from the Funder for the supply of influenza vaccine inj 30 mcg in 0.25 ml syringe (paediatric quadrivalent vaccine) to patients eligible under the above criteria for subsidised immunisation and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.

Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine)	9.00	1	✔	**Influvac Tetra (2020 formulation)**
	90.00	10	✔	**Afluria Quad (2020 Formulation)**

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

	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) Only on a prescription
b) No patient co-payment payable
c)

A) **Measles, mumps and rubella vaccine**

A maximum of two doses for any patient meeting the following criteria:

1) For primary vaccination in children; or
2) For revaccination following immunosuppression; or
3) For any individual susceptible to measles, mumps or rubella; or
4) A maximum of three doses for children who have had their first dose prior to 12 months.

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes. Although a price is listed for the vaccine, doctors can still order measles mumps and rubella vaccine free of charge, as with other Schedule vaccines.

B) Contractors will be entitled to claim payment 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.

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.

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**

✔ **fully subsidised**
Sole Subsidised Supply

S29 Unapproved medicine supplied under Section 29

	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**

- B -

- C -

- E -

- Q -