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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.

**Pharmac's role:**

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

Pae Ora (Healthy Futures) Act 2022

To ensure our decisions are as fair and robust as possible we use a decision-making process that incorporates clinical, economic and commercial issues. We also seek the views of users and the wider community through consultation. The processes we generally use are outlined in our Operating Policies and Procedures.
Further information about Pharmac and the way we make funding decisions can be found on the Pharmac website at https://www.pharmac.govt.nz/about.

# Purpose of the Pharmaceutical Schedule

The purpose of the Schedule is to list:

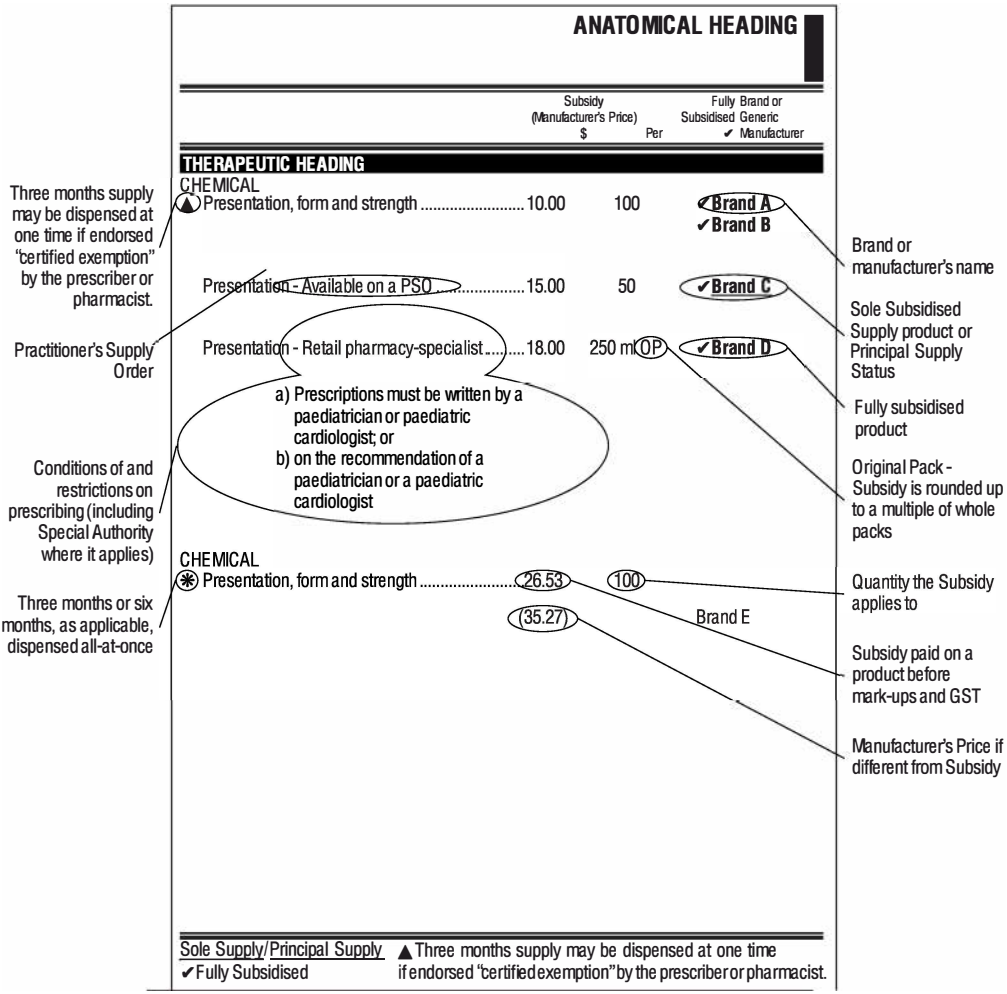
- the Community Pharmaceuticals that are subsidised by the Government and to show the amount of the subsidy paid to contractors, as well as the manufacturer's price and any access conditions that may apply;
- the Hospital Pharmaceuticals that may be used in Health NZ Hospitals, as well as any access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

The Schedule does not show the final cost to Government of subsidising each Community Pharmaceutical or to Health NZ Hospitals in purchasing each Pharmaceutical, since that will depend on any rebate and other arrangements Pharmac has with the supplier and, for Pharmaceuticals used in Health NZ Hospitals, on any logistics arrangements put in place.
This book contains sections A to D and Section I of the Pharmaceutical Schedule and lists the Pharmaceuticals funded for use in the community, including vaccines, as well as haemophilia and cancer treatments given in Health NZ hospitals. Section H lists the Pharmaceuticals that that can be used in Health NZ hospitals and is a separate publication.
The Pharmaceuticals in this book are listed by therapeutic group, which is based on the WHO Anatomical Therapeutic Chemical (ATC) system. The listings are displayed alphabetically under each heading.
The index lists both chemical entities and product brand names.

# Explaining pharmaceutical entries

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

**Example**



# Glossary

### Units of Measure

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

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

| | 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
(7.50) — 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 ..... 7.25 — 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 | 15 g OP | ✔ | **Cortifoam** S29 |
| | | 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 long-acting 500 mg | 56.10 | 100 | ✔ | **Pentasa** |
| Tab 800 mg | 85.50 | 90 | ✔ | **Asacol** |
| Modified release granules, 1 g | 118.10 | 100 OP | ✔ | **Pentasa** |
| Enema 1 g per 100 ml | 41.30 | 7 | ✔ | **Pentasa** |
| Suppos 500 mg | 22.80 | 20 | ✔ | **Asacol** |
| Suppos 1 g | 50.96 | 28 | ✔ | **Pentasa** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| OLSALAZINE | | | | |
| Tab 500 mg | 56.02 | 60 | ✔ | **Atnahs Olsalazine** S29 |
| | 93.37 | 100 | ✔ | **Dipentum** |
| Cap 250 mg | 53.00 | 100 | ✔ | **Dipentum** |
| PREDNISOLONE SODIUM | | | | |
| Rectal foam 20 mg per dose (14 applications) | 74.10 | 1 OP | ✔ | **Essential Prednisolone** S29 |
| SODIUM CROMOGLICATE | | | | |
| Cap 100 mg | 92.91 | 100 | ✔ | **Nalcrom** |
| | | | ✔ | **Ralicrom** |
| *(Nalcrom Cap 100 mg to be delisted 1 April 2023)* | | | | |
| 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 | 11.06 | 30 g OP | ✔ | **Ultraproct** |
| Suppos 630 mcg, with fluocortolone pivalate 610 mcg, and cinchocaine hydrochloride 1 mg | 7.30 | 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 | 65.45 | 10 | ✔ | **Max Health** |
| HYOSCINE BUTYLBROMIDE | | | | |
| ❋ Tab 10 mg | 6.35 | 100 | ✔ | **Buscopan** |
| ❋ Inj 20 mg, 1 ml – Up to 5 inj available on a PSO | 6.35 | 5 | ✔ | **Buscopan** |
| MEBEVERINE HYDROCHLORIDE | | | | |
| ❋ Tab 135 mg | 9.20 | 90 | ✔ | **Colofac** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

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

# Antiulcerants

## Antisecretory and Cytoprotective

MISOPROSTOL

| | | | | |
|---|---|---|---|---|
| ❋ | Tab 200 mcg – Up to 120 tab available on a PSO | 41.50 | 120 | ✔ **Cytotec** |

## Helicobacter Pylori Eradication

CLARITHROMYCIN

| | | | | |
|---|---|---|---|---|
| | Tab 500 mg – Subsidy by endorsement | 14.58 | 14 | ✔ **Klacid** |

a) Maximum of 28 tab per prescription

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

## H2 Antagonists

FAMOTIDINE – Only on a prescription

| | | | | |
|---|---|---|---|---|
| ❋ | Tab 20 mg | 4.91 | 100 | ✔ **Famotidine Hovid** S29 |
| ❋ | Tab 40 mg | 8.48 | 100 | ✔ **Famotidine Hovid** S29 |
| ❋ | Inj 10 mg per ml, 4 ml – Subsidy by endorsement | 57.02 | 10 | ✔ **Mylan** S29 |

Subsidy by endorsement – Subsidised for patients receiving treatment as part of palliative care.

## Proton Pump Inhibitors

LANSOPRAZOLE

| | | | | |
|---|---|---|---|---|
| ❋ | Cap 15 mg | 4.20 | 100 | ✔ **Lanzol Relief** |
| ❋ | Cap 30 mg | 5.26 | 100 | ✔ **Lanzol Relief** |

OMEPRAZOLE

For omeprazole suspension refer Standard Formulae, page 247

| | | | | |
|---|---|---|---|---|
| ❋ | Cap 10 mg | 1.94 | 90 | ✔ **Omeprazole actavis 10** |
| ❋ | Cap 20 mg | 1.86 | 90 | ✔ **Omeprazole actavis 20** |
| ❋ | Cap 40 mg | 3.11 | 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 | 37.38 | 5 | ✔ **Dr Reddy's Omeprazole** |

PANTOPRAZOLE

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

## Site Protective Agents

COLLOIDAL BISMUTH SUBCITRATE

| | | | | |
|---|---|---|---|---|
| | Tab 120 mg | 14.51 | 50 | ✔ **Gastrodenol** S29 |

| | 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 |
| | | | ✔ | **e5 Pharma** S29 |

**SA1320 Special Authority for Subsidy**

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

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

GLUCAGON HYDROCHLORIDE

| | | | | |
|---|---|---|---|---|
| Inj 1 mg syringe kit – Up to 5 kit available on a PSO | 32.00 | 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** |

| | 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**<br>**Mixtard 30** |
| ▲ Inj human with neutral insulin 100 u per ml, 3 ml | 42.66 | 5 | ✔ | **Humulin 30/70**<br>**PenMix 30**<br>**PenMix 40**<br>**PenMix 50** |
| *(PenMix 40 Inj human with neutral insulin 100 u per ml, 3 ml to be delisted 1 December 2022)* | | | | |
| 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 | 8.95 | 90 | ✔ | **Accarb** |
| ❋ Tab 100 mg | 15.29 | 90 | ✔ | **Accarb** |
| **Oral Hypoglycaemic Agents** | | | | |
| GLIBENCLAMIDE | | | | |
| ❋ Tab 5 mg | 7.50 | 100 | ✔ | **Daonil** |
| GLICLAZIDE | | | | |
| ❋ Tab 80 mg | 15.18 | 500 | ✔ | **Glizide** |
| GLIPIZIDE | | | | |
| ❋ Tab 5 mg | 4.58 | 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 | 14.74 | 1,000 | ✔ | **Metformin Mylan** |
| | | | ✔ | **Metformin Viatris** |
| ❋ Tab immediate-release 850 mg | 11.28 | 500 | ✔ | **Metformin Mylan** |
| PIOGLITAZONE | | | | |
| ❋ Tab 15 mg | 6.80 | 90 | ✔ | **Vexazone** |
| ❋ Tab 30 mg | 7.30 | 90 | ✔ | **Vexazone** |
| ❋ Tab 45 mg | 12.25 | 90 | ✔ | **Vexazone** |
| VILDAGLIPTIN | | | | |
| Tab 50 mg | 35.00 | 60 | ✔ | **Galvus** |
| VILDAGLIPTIN WITH METFORMIN HYDROCHLORIDE | | | | |
| Tab 50 mg with 1,000 mg metformin hydrochloride | 35.00 | 60 | ✔ | **Galvumet** |
| Tab 50 mg with 850 mg metformin hydrochloride | 35.00 | 60 | ✔ | **Galvumet** |

## GLP-1 Agonists

➽SA2065 **Special Authority for Subsidy**

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

Either:

1 Patient has previously received an initial approval for an SGLT-2 inhibitor; or

2 All of the following:

2.1 Patient has type 2 diabetes; and

2.2 Any of the following:

2.2.1 Patient is Māori or any Pacific ethnicity*; or

2.2.2 Patient has pre-existing cardiovascular disease or risk equivalent (see note a)*; or

2.2.3 Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator*; or

2.2.4 Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*; or

2.2.5 Patient has diabetic kidney disease (see note b)*; and

2.3 Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of at least one blood-glucose lowering agent (e.g. metformin, vildagliptin, or insulin) for at least 3 months.

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

a) Pre-existing cardiovascular disease or risk equivalent defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.

b) Diabetic kidney disease defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m2 in the presence of diabetes, without alternative cause.

DULAGLUTIDE – Special Authority see SA2065 above – Retail pharmacy

Note: Not to be given in combination with a funded SGLT-2 inhibitor.

| | | | | |
|---|---|---|---|---|
| ❋ Inj 1.5mg per 0.5 ml prefilled pen | 115.23 | 4 | ✔ | **Trulicity** |

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

## SGLT2 Inhibitors

➽SA2068 **Special Authority for Subsidy**

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

Either:

1 Patient has previously received an initial approval for a GLP-1 agonist; or

2 All of the following:

2.1 Patient has type 2 diabetes; and

2.2 Any of the following:

2.2.1 Patient is Māori or any Pacific ethnicity*; or

2.2.2 Patient has pre-existing cardiovascular disease or risk equivalent (see note a)*; or

2.2.3 Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator*; or

2.2.4 Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*; or

2.2.5 Patient has diabetic kidney disease (see note b)*; and

2.3 Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of at least one blood-glucose lowering agent (e.g. metformin, vildagliptin, or insulin) for at least 3 months.

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

a) Pre-existing cardiovascular disease or risk equivalent defined as: prior cardiovascular disease event (i.e. angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia.

b) Diabetic kidney disease defined as: persistent albuminuria (albumin:creatinine ratio greater than or equal to 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m2 in the presence of diabetes, without alternative cause.

EMPAGLIFLOZIN – Special Authority see SA2068 above – Retail pharmacy

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

| | | | | | |
|---|---|---|---|---|---|
| ✻ | Tab 10 mg | 58.56 | 30 | ✔ | **Jardiance** |
| ✻ | Tab 25 mg | 58.56 | 30 | ✔ | **Jardiance** |

EMPAGLIFLOZIN WITH METFORMIN HYDROCHLORIDE – Special Authority see SA2068 above – Retail pharmacy

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

| | | | | | |
|---|---|---|---|---|---|
| ✻ | Tab 5 mg with 1,000 mg metformin hydrochloride | 58.56 | 60 | ✔ | **Jardiamet** |
| ✻ | Tab 5 mg with 500 mg metformin hydrochloride | 58.56 | 60 | ✔ | **Jardiamet** |
| ✻ | Tab 12.5 mg with 1,000 mg metformin hydrochloride | 58.56 | 60 | ✔ | **Jardiamet** |
| ✻ | Tab 12.5 mg with 500 mg metformin hydrochloride | 58.56 | 60 | ✔ | **Jardiamet** |

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

## Diabetes Management

### Ketone Testing

BLOOD KETONE DIAGNOSTIC TEST STRIP – Subsidy by endorsement

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

The prescription must be endorsed accordingly.

| | | | | |
|---|---|---|---|---|
| Test strips | 15.50 | 10 strip | OP | ✔ **KetoSens** |

### Dual Blood Glucose and Blood Ketone Testing

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

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

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

| | | | | |
|---|---|---|---|---|
| Meter with 50 lancets, a lancing device and 10 blood glucose diagnostic test strips | 20.00 | 1 | OP | ✔ **CareSens Dual** |

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

## Blood Glucose Testing

BLOOD GLUCOSE DIAGNOSTIC TEST METER – Subsidy by endorsement

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

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

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

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

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

Note: Only 1 meter available per PSO

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

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

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

| | | | | |
|---|---|---|---|---|
| Test strips | 10.56 | 50 test OP | ✔ | **CareSens N** |
| | | | ✔ | **CareSens PRO** |

BLOOD GLUCOSE TEST STRIPS (VISUALLY IMPAIRED)

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

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

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

| | 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 x 12.7 mm | 10.95 | 100 | ✔ **B-D Micro-Fine** |
| ❋ | 31 g x 5 mm | 12.26 | 100 | ✔ **B-D Micro-Fine** |
| ❋ | 31 g x 6 mm | 9.50 | 100 | ✔ **Berpu** |
| ❋ | 31 g x 8 mm | 10.95 | 100 | ✔ **B-D Micro-Fine** |
| ❋ | 32 g x 4 mm | 10.95 | 100 | ✔ **B-D Micro-Fine** |

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

| | | | | |
|---|---|---|---|---|
| ❋ | Syringe 0.3 ml with 29 g x 12.7 mm needle | 13.56 | 100 | ✔ **B-D Ultra Fine** |
| | | 1.36 | 10 | |
| | | (1.99) | | B-D Ultra Fine |
| ❋ | Syringe 0.3 ml with 31 g x 8 mm needle | 13.56 | 100 | ✔ **B-D Ultra Fine II** |
| | | 1.30 | 10 | |
| | | (1.99) | | B-D Ultra Fine II |
| ❋ | Syringe 0.5 ml with 29 g x 12.7 mm needle | 13.56 | 100 | ✔ **B-D Ultra Fine** |
| | | 1.36 | 10 | |
| | | (1.99) | | B-D Ultra Fine |
| ❋ | Syringe 0.5 ml with 31 g x 8 mm needle | 13.56 | 100 | ✔ **B-D Ultra Fine II** |
| | | 1.36 | 10 | |
| | | (1.99) | | B-D Ultra Fine II |
| ❋ | Syringe 1 ml with 29 g x 12.7 mm needle | 13.56 | 100 | ✔ **B-D Ultra Fine** |
| | | 1.36 | 10 | |
| | | (1.99) | | B-D Ultra Fine |
| ❋ | Syringe 1 ml with 31 g x 8 mm needle | 13.56 | 100 | ✔ **B-D Ultra Fine II** |
| | | 1.36 | 10 | |
| | | (1.99) | | B-D Ultra Fine II |

## Insulin Pumps

INSULIN PUMP – 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 770G** |
| Min basal rate 0.1 U/h | 4,500.00 | 1 | ✔ **Tandem t:slim X2 with Basal-IQ** |

**➽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

continued…

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

continued…

education from an appropriate health professional); and

5 Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care; and

6 Either:

6.1 Applicant is a relevant specialist; or

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

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

All of the following:

1 Patient is continuing to derive benefit according to the treatment plan agreed at induction; and

2 Patient remains fully compliant and transition to MDI is considered inappropriate by the treating physician; and

3 It has been at least 4 years since the last insulin pump received by the patient or, in the case of patients qualifying under previous pump therapy for the initial application; the pump is due for replacement; and

4 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

➽SA1985 **Special Authority for Subsidy**

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

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

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

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

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

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

continued…

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

continued…

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

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

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

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

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

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

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

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

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

continued…

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

continued…

pump therapy; and

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

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

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

INSULIN PUMP CARTRIDGE – Special Authority see SA1985 on page 19 – 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** |

INSULIN PUMP INFUSION SET (STEEL CANNULA) – Special Authority see SA1985 on page 19 – 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** |
| 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** |
| 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** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| INSULIN PUMP INFUSION SET (STEEL CANNULA, STRAIGHT INSERTION) – Special Authority see SA1985 on page 19 – Retail pharmacy | | | | |
| a) Maximum of 3 sets per prescription<br>b) Only on a prescription<br>c) Maximum of 13 infusion sets will be funded per year. | | | | |
| 6 mm steel cannula; straight insertion; 80 cm line × 10 with 10 needles | 130.00 | 1 OP | ✔ | **TruSteel** |
| 8 mm steel cannula; straight insertion; 80 cm line × 10 with 10 needles | 130.00 | 1 OP | ✔ | **TruSteel** |
| 6 mm steel cannula; straight insertion; 60 cm line × 10 with 10 needles | 130.00 | 1 OP | ✔ | **TruSteel** |
| 8 mm steel cannula; straight insertion; 60 cm line × 10 with 10 needles | 130.00 | 1 OP | ✔ | **TruSteel** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| INSULIN PUMP INFUSION SET (TEFLON CANNULA) – Special Authority see SA1985 on page 19 – Retail pharmacy | | | | |
| a) Maximum of 3 set per prescription<br>b) Only on a prescription<br>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** |

▲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 PUMP INFUSION SET (TEFLON CANNULA, ANGLE INSERTION WITH INSERTION DEVICE) – Special Authority see SA1985 on page 19 – Retail pharmacy | | | | |
| a) Maximum of 3 sets per prescription | | | | |
| b) Only on a prescription | | | | |
| c) Maximum of 13 infusion sets will be funded per year. | | | | |
| 13 mm teflon cannula; angle insertion; insertion device; 110 cm line × 10 with 10 needles | 140.00 | 1 OP | ✔ | **AutoSoft 30** |
| 13 mm teflon cannula; angle insertion; insertion device; 60 cm line × 10 with 10 needles | 140.00 | 1 OP | ✔ | **AutoSoft 30** |
| INSULIN PUMP INFUSION SET (TEFLON CANNULA, ANGLE INSERTION) – Special Authority see SA1985 on page 19 – 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. | | | | |
| 17 mm teflon cannula; angle insertion; 60 cm line × 10 with 10 needles; luer lock | 130.00 | 1 OP | ✔ | **Silhouette MMT-373** |
| INSULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIGHT INSERTION WITH INSERTION DEVICE) – Special Authority see SA1985 on page 19 – 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; 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** |
| INSULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIGHT INSERTION) – Special Authority see SA1985 on page 19 – 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; 60 cm tubing × 10 with 10 needles; luer lock | 130.00 | 1 OP | ✔ | **Quick-Set MMT-393** |
| 9 mm teflon cannula; straight insertion; 60 cm tubing × 10 with 10 needles; luer lock | 130.00 | 1 OP | ✔ | **Quick-Set MMT-392** |
| INSULIN PUMP RESERVOIR – Special Authority see SA1985 on page 19 – 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 | ✔ | **MiniMed 1.8 Reservoir MMT-326A** |
| Cartridge for 7 series pump; 3.0 ml × 10 | 50.00 | 1 OP | ✔ | **MiniMed 3.0 Reservoir MMT-332A** |



✔ **fully subsidised**

**Principal Supply**

S29 Unapproved medicine supplied under Section 29

**Sole Subsidised Supply**

| | 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** |

*(Panzytrat Cap pancreatin (175 mg (25,000 U lipase, 22,500 U amylase, 1,250 U protease)) to be delisted 1 June 2023)*

URSODEOXYCHOLIC ACID – Special Authority see SA1739 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Cap 250 mg | 32.95 | 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.

continued…

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

continued…

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

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

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

## Laxatives

### Bulk-forming Agents

ISPAGHULA (PSYLLIUM) HUSK – Only on a prescription

| | | | | |
|---|---|---|---|---|
| ❋ | Powder for oral soln | 6.00 | 250 g OP | ✔ **Macro Organic Psyllium Husk** |
| | | 12.20 | 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 | 3.50 | 200 | ✔ **Laxsol** |

POLOXAMER – Only on a prescription

Not funded for use in the ear.

| | | | | |
|---|---|---|---|---|
| ❋ | Oral drops 10% | 3.98 | 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** |
| ❋ | Suppos 4 g – Only on a prescription | 10.39 | 20 | ✔ **Lax-suppositories Glycerol** |

*(PSM Suppos 3.6 g to be delisted 1 February 2023)*

LACTULOSE – Only on a prescription

| | | | | |
|---|---|---|---|---|
| ❋ | Oral liq 10 g per 15 ml | 3.61 | 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 | 6.70 | 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**<br>✔ **Micolette-S29** S29 |

## Stimulant Laxatives

BISACODYL – Only on a prescription

| | | | | |
|---|---|---|---|---|
| ❋ | Tab 5 mg | 5.80 | 200 | ✔ **Bisacodyl Viatris**<br>✔ **Pharmacy Health** |
| ❋ | Suppos 10 mg | 3.69 | 10 | ✔ **Lax-Suppositories** |

*(Pharmacy Health Tab 5 mg to be delisted 1 January 2023)*

SENNA – Only on a prescription

| | | | | |
|---|---|---|---|---|
| ❋ | Tab, standardised | 2.17 | 100 | |
| | | (8.21) | | Senokot |
| | | 0.43 | 20 | |
| | | (2.06) | | Senokot |

SODIUM PICOSULFATE – Special Authority see SA2053 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| | Oral soln 7.5 mg per ml | 7.40 | 30 ml OP | ✔ **Dulcolax SP Drop** |

➽**SA2053** **Special Authority for Subsidy**

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

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

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

## Metabolic Disorder Agents

ALGLUCOSIDASE ALFA – Special Authority see SA1986 on the next page – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| | Inj 50 mg vial | 1,142.60 | 1 | ✔ **Myozyme** |

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

**➽SA1986 Special Authority for Subsidy**

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

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

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

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

ARGININE – Special Authority see SA2042 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Tab 1,000 mg | CBS | 90 | ✔ | **Clinicians** |
| Cap 500 mg | CBS | 50 | ✔ | **Solgar** |
| Powder | CBS | 400 g | ✔ | **Biomed** |

**➽SA2042 Special Authority for Subsidy**

**Initial application** only from a metabolic physician. Approvals valid for 6 months where patient has a suspected inborn error of metabolism that may respond to arginine supplementation.
**Renewal** only from a metabolic physician. Approvals valid for 24 months for applications meeting the following criteria:
Both:

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

BETAINE – Special Authority see SA1987 on the next page – Retail pharmacy

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

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

**➽SA1987 Special Authority for Subsidy**

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

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

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

COENZYME Q10 – Special Authority see SA2039 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Cap 120 mg | CBS | 30 | ✔ | **Solgar** |
| Cap 160 mg | CBS | 60 | ✔ | **Go Healthy** |

**➽SA2039 Special Authority for Subsidy**

**Initial application** only from a metabolic physician. Approvals valid for 6 months where patient has a suspected inborn error of metabolism that may respond to coenzyme Q10 supplementation.
**Renewal** only from a metabolic physician. Approvals valid for 24 months for applications meeting the following criteria:
Both:

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

GALSULFASE – Special Authority see SA1988 below – Retail pharmacy

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

**➽SA1988 Special Authority for Subsidy**

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

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

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

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

IDURSULFASE – Special Authority see SA1623 on the next page – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Inj 2 mg per ml, 3 ml vial | 4,608.30 | 1 | ✔ | **Elaprase** |

▲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 |
|---|---|---|---|---|

**➽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.

LEVOCARNITINE – Special Authority see SA2040 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Tab 500 mg | CBS | | 30 | ✔ **Solgar** |
| Cap 250 mg | CBS | | 30 | ✔ **Solgar** |
| Cap 500 mg | CBS | | 60 | ✔ **Balance** |
| Oral liq 1 g per 10 ml | CBS | | 118 ml | ✔ **Carnitor** S29 |
| Oral liq 500 mg per 10 ml | CBS | | 300 ml | ✔ **Balance** |

**➽SA2040 Special Authority for Subsidy**

**Initial application** only from a metabolic physician. Approvals valid for 6 months where patient has a suspected inborn error of metabolism that may respond to carnitine supplementation.
**Renewal** only from a metabolic physician. Approvals valid for 24 months for applications meeting the following criteria:
Both:

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

RIBOFLAVIN – Special Authority see SA2041 on the next page – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Tab 100 mg | CBS | | 100 | ✔ **Country Life** |
| Cap 100 mg | CBS | | 100 | ✔ **Solgar** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

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

**➽SA2041 Special Authority for Subsidy**

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

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

Both:

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

SAPROPTERIN DIHYDROCHLORIDE – Special Authority see SA1989 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Tab soluble 100 mg | 1,452.70 | 30 OP | ✔ | **Kuvan** |

**➽SA1989 Special Authority for Subsidy**

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

All of the following:

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

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

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

All of the following:

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

SODIUM BENZOATE – Special Authority see SA1599 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Soln 100 mg per ml | CBS | 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 SA1990 on the next page – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Grans 483 mg per g | 2,016.00 | 174 g OP | ✔ | **Pheburane** |

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

➽SA1990 **Special Authority for Subsidy**

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

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

TAURINE – Special Authority see SA2043 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Cap 500 mg | CBS | 50 | ✔ | **Solgar** |
| Cap 1,000 mg | CBS | 90 | ✔ | **Life Extension** |
| Powder | CBS | 300 g | ✔ | **Life Extension** |

➽SA2043 **Special Authority for Subsidy**

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

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

Both:

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

## Gaucher's Disease

TALIGLUCERASE ALFA – Special Authority see SA2137 below – Retail pharmacy

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

➽SA2137 **Special Authority for Subsidy**

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

All of the following:

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

Note: Indication marked with * is an unapproved indication

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

All of the following:

1 Patient has demonstrated a symptomatic improvement and has maintained improvements in the main symptom or symptoms for which therapy was started; and
2 Patient has demonstrated a clinically objective improvement or no deterioration in haemoglobin levels, platelet counts and liver and spleen size; and

continued…

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

continued…

3 Radiological (MRI) signs of bone activity performed at two years since initiation of treatment, and five yearly thereafter, demonstrate no deterioration shown by the MRI, compared with MRI taken immediately prior to commencement of therapy or adjusted dose; and

4 Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT; and

5 Patient is adherent with regular treatment and taliglucerase alfa is to be administered at a dose no greater than 30 unit/kg every other week rounded to the nearest whole vial (200 units).

# Mouth and Throat

## Agents Used in Mouth Ulceration

| | | | | |
|---|---|---|---|---|
| BENZYDAMINE HYDROCHLORIDE | | | | |
| Soln 0.15% – Higher subsidy of $20.31 per 500 ml with Endorsement | 9.00 | 500 ml | | |
| | (20.31) | | | Difflam |
| Additional subsidy by endorsement for a patient who has oral mucositis as a result of treatment for cancer, and the prescription is endorsed accordingly. | | | | |
| CARMELLOSE SODIUM WITH GELATIN AND PECTIN | | | | |
| Paste | 17.20 | 56 g OP | ✔ | **Stomahesive** |
| | 4.55 | 15 g OP | | |
| | (7.90) | | | Orabase |
| | 1.52 | 5 g OP | | |
| | (3.60) | | | Orabase |
| Powder | 8.48 | 28 g OP | | |
| | (10.95) | | | Stomahesive |
| 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 | 1.76 | 24 ml OP | ✔ | **Nilstat** |

# Vitamins

## Vitamin B

| | | | | |
|---|---|---|---|---|
| HYDROXOCOBALAMIN | | | | |
| ✻ Inj 1 mg per ml, 1 ml ampoule – Up to 6 inj available on a PSO | 2.46 | 3 | ✔ | **Hydroxocobalamin Panpharma** |

▲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 | 23.45 | 500 | ✔ | **Pyridoxine multichem** |
| THIAMINE HYDROCHLORIDE – Only on a prescription | | | | |
| ❋ Tab 50 mg | 4.65 | 100 | ✔ | **Thiamine multichem** |
| | 7.09 | | ✔ | **Max Health** |
| *(Max Health Tab 50 mg to be delisted 1 April 2023)* | | | | |
| 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 | 12.50 | 500 | ✔ | **Cvite** |

## Vitamin D

| | | | | |
|---|---|---|---|---|
| ALFACALCIDOL | | | | |
| ❋ Cap 0.25 mcg | 26.32 | 100 | ✔ | **One-Alpha** |
| ❋ Cap 1 mcg | 87.98 | 100 | ✔ | **One-Alpha** |
| | | | ✔ | **One-Alpha S29** S29 |
| ❋ Oral drops 2 mcg per ml | 60.68 | 20 ml OP | ✔ | **One-Alpha** |
| CALCITRIOL | | | | |
| ❋ Cap 0.25 mcg | 7.89 | 100 | ✔ | **Calcitriol-AFT** |
| Calcitriol-AFT to be Principal Supply on 1 December 2022 | | | | |
| ❋ Cap 0.5 mcg | 13.68 | 100 | ✔ | **Calcitriol-AFT** |
| Calcitriol-AFT to be Principal Supply on 1 December 2022 | | | | |
| COLECALCIFEROL | | | | |
| ❋ Cap 1.25 mg (50,000 iu) – Maximum of 12 cap per prescription | 2.95 | 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 on the next page – Retail pharmacy | | | | |
| ❋ Powder | 72.00 | 200 g OP | ✔ | **Paediatric Seravit** |

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

**➽SA1036 Special Authority for Subsidy**
**Initial application** from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has inborn errors of metabolism.
**Renewal** from any relevant practitioner. Approvals valid without further renewal unless notified where patient has had a previous approval for multivitamins.

VITAMINS

| | | | | |
|---|---|---|---|---|
| ✱ | Tab (BPC cap strength) | 18.50 | 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 1.25 g (500 mg elemental) | 6.69 | 250 | ✔ **Calci-Tab 500** |
| ✱ | Tab eff 1.25 g (500 mg elemental) – Subsidy by endorsement | 260.00 | 100 | ✔ **Calcium 500 mg Hexal** S29 |

Subsidy by endorsement – Only when prescribed for paediatric patients (< 5 years) where calcium carbonate oral liquid is considered unsuitable.

CALCIUM GLUCONATE

| | | | | |
|---|---|---|---|---|
| ✱ | 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) | 8.64 | 100 | ✔ **PSM** |

*(PSM Tab 1.1 mg (0.5 mg elemental) to be delisted 1 March 2023)*

## Iodine

POTASSIUM IODATE

| | | | | |
|---|---|---|---|---|
| ✱ | Tab 253 mcg (150 mcg elemental iodine) | 4.58 | 90 | ✔ **NeuroTabs** |

## Iron

FERROUS FUMARATE

| | | | | |
|---|---|---|---|---|
| ✱ | Tab 200 mg (65 mg elemental) | 3.04 | 100 | ✔ **Ferro-tab** |

FERROUS FUMARATE WITH FOLIC ACID

| | | | | |
|---|---|---|---|---|
| ✱ | Tab 310 mg (100 mg elemental) with folic acid 350 mcg | 5.98 | 100 | ✔ **Ferro-F-Tabs** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| FERROUS SULFATE | | | | |
| ❋ Tab long-acting 325 mg (105 mg elemental) | 2.55 | 30 | ✔ | **Ferrograd** |
| ❋ Oral liq 30 mg (6 mg elemental) per 1 ml | 13.10 | 500 ml | ✔ | **Ferodan** |
| IRON (AS FERRIC CARBOXYMALTOSE) – Special Authority see SA1840 below – Retail pharmacy | | | | |
| Inj 50 mg per ml, 10 ml vial | 150.00 | 1 | ✔ | **Ferinject** |

➽**SA1840** **Special Authority for Subsidy**

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

Both:

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

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

Both:

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

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

Both:

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

| | | | | |
|---|---|---|---|---|
| IRON POLYMALTOSE | | | | |
| ❋ Inj 50 mg per ml, 2 ml ampoule | 34.50 | 5 | ✔ | **Ferrosig** |

## Magnesium

| | | | | |
|---|---|---|---|---|
| MAGNESIUM HYDROXIDE | | | | |
| Suspension 8% | 33.60 | 355 ml | ✔ | **Phillips Milk of Magnesia** S29 |
| MAGNESIUM SULPHATE | | | | |
| ❋ Inj 2 mmol per ml, 5 ml ampoule | 25.53 | 10 | ✔ | **Martindale** |

## Zinc

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



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

| | 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.

**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.

**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

EPOETIN ALFA – Special Authority see SA1775 above – Retail pharmacy

Wastage claimable

| | | | | |
|---|---|---|---|---|
| Inj 1,000 iu in 0.5 ml, syringe | 250.00 | 6 | ✔ | **Binocrit** |
| Inj 2,000 iu in 1 ml, syringe | 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** |

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

## Megaloblastic

FOLIC ACID

| | | | | |
|---|---|---|---|---|
| | Tab 0.8 mg | 26.60 | 1,000 | ✔ **Folic Acid multichem** |
| ❋ | Tab 5 mg | 5.82 | 100 | ✔ **Folic Acid Mylan** |
| | Oral liq 50 mcg per ml | 27.82 | 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** |
| Inj 4,000 iu vial | 9,800.00 | 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. 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

continued…

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

continued…

and significant mucocutaneous bleeding.

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

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

**Renewal — (idiopathic thrombocytopenic purpura - post-splenectomy)** only from a haematologist. Approvals valid for 12 months where the patient has obtained a response (see Note) from treatment during the initial approval or subsequent renewal periods and further treatment is required.
Note: Response to treatment is defined as a platelet count of > 30,000 platelets per microlitre.

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

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

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

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

EMICIZUMAB – [Xpharm] – Special Authority see SA1969 below

| | | | | |
|---|---|---|---|---|
| Inj 30 mg in 1 ml vial | 3,570.00 | 1 | ✔ | **Hemlibra** |
| Inj 60 mg in 0.4 ml vial | 7,138.00 | 1 | ✔ | **Hemlibra** |
| Inj 105 mg in 0.7 ml vial | 12,492.00 | 1 | ✔ | **Hemlibra** |
| Inj 150 mg in 1 ml vial | 17,846.00 | 1 | ✔ | **Hemlibra** |

➽SA1969 **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 severe congenital haemophilia A and history of bleeding and bypassing agent usage within the last six months; and
2 Either:
  2.1 Patient has had greater than or equal to 6 documented and treated spontaneous bleeds within the last 6 months if on an on-demand bypassing agent regimen; or
  2.2 Patient has had greater than or equal to 2 documented and treated spontaneous bleeds within the last 6 months if on a bypassing agent prophylaxis regimen; and
3 Patient has a high-titre inhibitor to Factor VIII (greater than or equal to 5 Bethesda units per ml) which has persisted for six months or more; and
4 There is no immediate plan for major surgery within the next 12 months; and
5 Either:
  5.1 Patient has failed immune tolerance induction (ITI) after an initial period of 12 months; or

continued…

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

continued…

5.2 The Haemophilia Treaters Group considers the patient is not a suitable candidate for ITI; and

6 Treatment is to be administered at a maximum dose of 3 mg/kg weekly for 4 weeks followed by the equivalent of 1.5 mg/kg weekly.

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

1 Patient has had no more than two spontaneous and clinically significant treated bleeds after the end of the loading dose period (i.e. after the first four weeks of treatment until the end of the 24-week treatment period); and

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

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** |

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** |

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

## 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** |
| TICAGRELOR – Special Authority see SA1955 below – Retail pharmacy | | | | |
| ✱ Tab 90 mg | 23.85 | 56 | ✔ | **Ticagrelor Sandoz** |
| | 90.00 | | ✔ | **Brilinta** |

*(Brilinta Tab 90 mg to be delisted 1 March 2023)*

➽SA1955 **Special Authority for Subsidy**

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

Both:

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

continued…

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

continued…

syndrome; and

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

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

Both:

1 Either:

1.1 Patient has had a neurological stenting procedure* in the last 60 days; or

1.2 Patient is about to have a neurological stenting procedure performed*; and

2 Either:

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

2.2 Either:

2.2.1 Clopidogrel resistance has been demonstrated by the occurrence of a new cerebral ischemic event; or

2.2.2 Clopidogrel resistance has been demonstrated by the occurrence of transient ischemic attack symptoms referable to the stent.

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

All of the following:

1 Patient has undergone percutaneous coronary intervention; and

2 Patient has had a stent deployed in the previous 4 weeks; and

3 Patient is clopidogrel-allergic**.

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

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

Both:

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

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

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

Both:

1 Patient is continuing to benefit from treatment; and

2 Treatment continues to be clinically appropriate.

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

All of the following:

1 Patient has undergone percutaneous coronary intervention; and

2 Patient has had a stent deployed in the previous 4 weeks; and

3 Patient is clopidogrel-allergic**.

Notes: indications marked with * are unapproved indications.

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

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

## Heparin and Antagonist Preparations

ENOXAPARIN SODIUM – Special Authority see SA2152 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Inj 20 mg in 0.2 ml syringe | 31.28 | 10 | ✔ | **Clexane** |
| Inj 40 mg in 0.4 ml syringe | 42.49 | 10 | ✔ | **Clexane** |
| Inj 60 mg in 0.6 ml syringe | 60.67 | 10 | ✔ | **Clexane** |
| Inj 80 mg in 0.8 ml syringe | 80.89 | 10 | ✔ | **Clexane** |
| Inj 100 mg in 1 ml syringe | 101.30 | 10 | ✔ | **Clexane** |
| Inj 120 mg in 0.8 ml syringe | 125.87 | 10 | ✔ | **Clexane Forte** |
| Inj 150 mg in 1 ml syringe | 143.86 | 10 | ✔ | **Clexane Forte** |

**➽SA2152 Special Authority for Subsidy**

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

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

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

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

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

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

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

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

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

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| HEPARIN SODIUM | | | | |
| Inj 1,000 iu per ml, 5 ml ampoule | 72.84 | 50 | ✔ | **Pfizer** |
| Inj 5,000 iu per ml, 1 ml | 32.66 | 5 | ✔ | **DBL Heparin Sodium** S29 |
| | 70.33 | | ✔ | **Hospira** |
| Inj 5,000 iu per ml, 5 ml ampoule | 289.05 | 50 | ✔ | **Pfizer** |
| Inj 25,000 iu per ml, 0.2 ml | 22.42 | 5 | ✔ | **Hospira** |
| | 42.40 | | ✔ | **Heparin DBL** S29 |
| | 482.20 | 50 | ✔ | **Heparin DBL** 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 below – Retail pharmacy | | | | |
| Inj 300 mcg per 0.5 ml prefilled syringe | 96.22 | 10 | ✔ | **Nivestim** |
| Inj 480 mcg per 0.5 ml prefilled syringe | 148.58 | 10 | ✔ | **Nivestim** |

**➽SA1259 Special Authority for Subsidy**

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

Any of the following:

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

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

| | | | | |
|---|---|---|---|---|
| PEGFILGRASTIM – Special Authority see SA1912 on the next page – Retail pharmacy | | | | |
| Inj 6 mg per 0.6 ml syringe | 1,080.00 | 1 | ✔ | **Neulastim** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

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

➽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 | 30.65 | 5 | ✔ **Biomed** |
| ✱ | Inj 50%, 90 ml bottle – Up to 5 inj available on a PSO | 15.00 | 1 | ✔ **Biomed** |

POTASSIUM CHLORIDE

| | | | | |
|---|---|---|---|---|
| ✱ | Inj 75 mg per ml, 10 ml | 65.00 | 50 | ✔ **Juno** |

SODIUM BICARBONATE

| | | | | |
|---|---|---|---|---|
| | Inj 8.4%, 50 ml | 21.40 | 1 | ✔ **Biomed** |
| | a) Up to 5 inj available on a PSO<br>b) Not in combination | | | |
| | Inj 8.4%, 100 ml | 21.95 | 1 | ✔ **Biomed** |
| | a) Up to 5 inj available on a PSO<br>b) Not in combination | | | |

SODIUM CHLORIDE

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

| | | | | |
|---|---|---|---|---|
| | Inj 0.9%, bag – Up to 2000 ml available on a PSO | 1.33 | 500 ml | ✔ **Baxter** |
| | | 1.36 | 1,000 ml | ✔ **Baxter** |
| | Only if prescribed on a prescription for renal dialysis, maternity or post-natal care in the home of the patient, or on a PSO for emergency use. (500 ml and 1,000 ml packs) | | | |
| | Inj 23.4% (4 mmol/ml), 20 ml ampoule | 35.50 | 5 | ✔ **Biomed** |
| | For Sodium chloride oral liquid formulation refer Standard Formulae, page 247 | | | |
| | Inj 0.9%, 5 ml ampoule – Up to 5 inj available on a PSO | 4.00 | 20 | ✔ **Fresenius Kabi** |
| | Inj 0.9%, 10 ml ampoule – Up to 5 inj available on a PSO | 5.25 | 50 | ✔ **Fresenius Kabi** |
| | Inj 0.9%, 20 ml ampoule | 5.00 | 20 | ✔ **Fresenius Kabi** |

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 10 ml ampoule – Up to 5 inj available on a PSO | 7.19 | 50 | ✔ **Pfizer** |
| | Inj 20 ml ampoule – Up to 5 inj available on a PSO | 5.00 | 20 | ✔ **Fresenius Kabi**<br>✔ **Multichem** |

*(Multichem Inj 20 ml ampoule to be delisted 1 January 2023)*

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| **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 | 9.53 | 50 | ✔ | **Electral** |
| Electral to be Principal Supply on 1 December 2022 | | | | |
| 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 (17.10) | 60 | | Chlorvescent |
| ❋ Tab long-acting 600 mg (8 mmol) | 15.35 | 200 | ✔ | **Span-K** |
| SODIUM BICARBONATE | | | | |
| Cap 840 mg | 8.52 | 100 | ✔ | **Sodibic** |
| | | | ✔ | **Sodibic** |
| SODIUM POLYSTYRENE SULPHONATE | | | | |
| Powder | 84.65 | 454 g OP | ✔ | **Resonium-A** |

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

## Alpha-Adrenoceptor Blockers

### Alpha Adrenoceptor Blockers

DOXAZOSIN

| | | | | |
|---|---|---|---|---|
| ❋ | Tab 2 mg | 17.35 | 500 | ✔ **Doxazosin Clinect** |
| ❋ | Tab 4 mg | 20.94 | 500 | ✔ **Doxazosin Clinect** |

PHENOXYBENZAMINE HYDROCHLORIDE

| | | | | |
|---|---|---|---|---|
| ❋ | Cap 10 mg | 65.00 | 30 | ✔ **BNM** S29 |
| | | 216.67 | 100 | ✔ **Dibenzyline** S29 |

PRAZOSIN

| | | | | |
|---|---|---|---|---|
| ❋ | Tab 1 mg | 5.53 | 100 | ✔ **Arrotex-Prazosin S29** S29 |
| ❋ | Tab 2 mg | 7.00 | 100 | ✔ **Arrotex-Prazosin S29** S29 |
| ❋ | Tab 5 mg | 11.70 | 100 | ✔ **Arrotex-Prazosin S29** S29 |

## 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 – Subsidy by endorsement

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

| | | | | |
|---|---|---|---|---|
| ❋ | Tab 0.5 mg | 2.09 | 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 | 11.07 | 90 | ✔ **Ethics Lisinopril**<br>✔ **Teva Lisinopril** |
| ❋ | Tab 10 mg | 11.67 | 90 | ✔ **Ethics Lisinopril**<br>✔ **Teva Lisinopril** |
| ❋ | Tab 20 mg | 14.69 | 90 | ✔ **Ethics Lisinopril**<br>✔ **Teva Lisinopril** |

PERINDOPRIL

| | | | | |
|---|---|---|---|---|
| ❋ | Tab 2 mg | 1.58 | 30 | ✔ **Coversyl** |
| ❋ | Tab 4 mg | 2.95 | 30 | ✔ **Coversyl** |
| ❋ | Tab 8 mg | 5.02 | 30 | ✔ **Coversyl** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| QUINAPRIL | | | | |
| Tab 5 mg | 5.97 | 90 | ✔ | **Arrow-Quinapril 5** |
| Tab 10 mg | 5.18 | 90 | ✔ | **Arrow-Quinapril 10** |
| Tab 20 mg | 7.95 | 90 | ✔ | **Arrow-Quinapril 20** |

## ACE Inhibitors with Diuretics

QUINAPRIL WITH HYDROCHLOROTHIAZIDE – Subsidy by endorsement

Subsidy by endorsement – Subsidised for patients who were taking quinapril with hydrochlorothiazide prior to 1 May 2022 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of quinapril with hydrochlorothiazide.

| | | | | |
|---|---|---|---|---|
| Tab 10 mg with hydrochlorothiazide 12.5 mg | 4.10 | 30 | ✔ | **Accuretic 10** |
| Tab 20 mg with hydrochlorothiazide 12.5 mg | 5.25 | 30 | ✔ | **Accuretic 20** |

## Angiotensin II Antagonists

| | | | | |
|---|---|---|---|---|
| CANDESARTAN CILEXETIL | | | | |
| ❋ Tab 4 mg | 2.00 | 90 | ✔ | **Candestar** |
| ❋ Tab 8 mg | 2.28 | 90 | ✔ | **Candestar** |
| ❋ Tab 16 mg | 3.31 | 90 | ✔ | **Candestar** |
| ❋ Tab 32 mg | 5.26 | 90 | ✔ | **Candestar** |
| LOSARTAN POTASSIUM | | | | |
| ❋ Tab 12.5 mg | 1.56 | 84 | ✔ | **Losartan Actavis** |
| ❋ Tab 25 mg | 1.84 | 84 | ✔ | **Losartan Actavis** |
| ❋ Tab 50 mg | 2.25 | 84 | ✔ | **Losartan Actavis** |
| ❋ Tab 100 mg | 3.50 | 84 | ✔ | **Losartan Actavis** |

## Angiotensin II Antagonists with Diuretics

| | | | | |
|---|---|---|---|---|
| LOSARTAN POTASSIUM WITH HYDROCHLOROTHIAZIDE | | | | |
| ❋ Tab 50 mg with hydrochlorothiazide 12.5 mg | 4.00 | 30 | ✔ | **Arrow-Losartan & Hydrochlorothiazide** |

## Angiotensin II Antagonists with Neprilysin Inhibitors

| | | | | |
|---|---|---|---|---|
| SACUBITRIL WITH VALSARTAN – Special Authority see SA1905 below – Retail pharmacy | | | | |
| Tab 24.3 mg with valsartan 25.7 mg | 190.00 | 56 | ✔ | **Entresto 24/26** |
| Tab 48.6 mg with valsartan 51.4 mg | 190.00 | 56 | ✔ | **Entresto 49/51** |
| Tab 97.2 mg with valsartan 102.8 mg | 190.00 | 56 | ✔ | **Entresto 97/103** |

➽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
  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

continued…

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

continued…

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 117

| | | | | |
|---|---|---|---|---|
| AMIODARONE HYDROCHLORIDE | | | | |
| ▲ | Tab 100 mg | 3.49 | 30 | ✔ **Aratac** |
| | Aratac to be Principal Supply on 1 December 2022 | | | |
| ▲ | Tab 200 mg | 4.49 | 30 | ✔ **Aratac** |
| | Aratac to be Principal Supply on 1 December 2022 | | | |
| | Inj 50 mg per ml, 3 ml ampoule – Up to 10 inj available on a PSO | 15.22 | 10 | ✔ **Max Health** |
| | Max Health to be Principal Supply on 1 December 2022 | | | |
| ATROPINE SULPHATE | | | | |
| ✱ | Inj 600 mcg per ml, 1 ml ampoule – Up to 5 inj available on a PSO | 15.09 | 10 | ✔ **Martindale** |
| DIGOXIN | | | | |
| ✱ | Tab 62.5 mcg – Up to 30 tab available on a PSO | 7.80 | 240 | ✔ **Lanoxin PG** |
| ✱ | Tab 250 mcg – Up to 30 tab available on a PSO | 16.90 | 240 | ✔ **Lanoxin** |
| ✱ | Oral liq 50 mcg per ml | 16.60 | 60 ml | ✔ **Lanoxin**<br>✔ **Lanoxin Paediatric Elixir** S29<br>✔ **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 | ✔ **Teva** S29 |
| ▲ | Cap 250 mg | 202.00 | 100 | ✔ **Teva** S29 |
| PROPAFENONE HYDROCHLORIDE | | | | |
| ▲ | Tab 150 mg | 40.90 | 50 | ✔ **Rytmonorm** |

## Antihypotensives

| | | | | |
|---|---|---|---|---|
| MIDODRINE – Special Authority see SA1474 on the next page – Retail pharmacy | | | | |
| | Tab 2.5 mg | 53.00 | 100 | ✔ **Gutron** |
| | Tab 5 mg | 79.00 | 100 | ✔ **Gutron** |

▲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 |
|---|---|---|---|---|

➽SA1474 **Special Authority for Subsidy**

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

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

## Beta-Adrenoceptor Blockers

### Beta Adrenoceptor Blockers

ATENOLOL

| | | | | |
|---|---|---|---|---|
| ❋ | Tab 50 mg | 9.33 | 500 | ✔ **Mylan Atenolol** |
| ❋ | Tab 100 mg | 14.20 | 500 | ✔ **Mylan Atenolol** |
| ❋ | Oral liq 25 mg per 5 ml | 21.25 | 300 ml OP | ✔ **Atenolol AFT** |
| | | | | **S29** S29 |
| | | 38.20 | | ✔ **Essential** |
| | | | | **Generics** S29 |
| | | 49.85 | | ✔ **Atenolol AFT** |

Restricted to children under 12 years of age.

BISOPROLOL FUMARATE

| | | | | |
|---|---|---|---|---|
| ❋ | Tab 2.5 mg | 1.84 | 90 | ✔ **Bisoprolol Mylan** |
| ❋ | Tab 5 mg | 2.55 | 90 | ✔ **Bisoprolol Mylan** |
| ❋ | Tab 10 mg | 3.62 | 90 | ✔ **Bisoprolol Mylan** |

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** |

LABETALOL

| | | | | |
|---|---|---|---|---|
| ❋ | Tab 100 mg | 14.50 | 100 | ✔ **Trandate** |
| ❋ | Tab 200 mg | 27.00 | 100 | ✔ **Trandate** |
| ❋ | Inj 5 mg per ml, 20 ml ampoule | 59.06 | 5 | |
| | | (88.60) | | Trandate |
| ❋ | inj 5 mg per ml, 20 ml vial | 42.29 | 1 | |
| | | (48.20) | | Alvogen S29 |

METOPROLOL SUCCINATE

| | | | | |
|---|---|---|---|---|
| ❋ | Tab long-acting 23.75 mg | 1.45 | 30 | ✔ **Betaloc CR** |
| ❋ | Tab long-acting 47.5 mg | 1.43 | 30 | ✔ **Betaloc CR** |
| ❋ | Tab long-acting 95 mg | 2.15 | 30 | ✔ **Betaloc CR** |
| ❋ | Tab long-acting 190 mg | 4.27 | 30 | ✔ **Betaloc CR** |

METOPROLOL TARTRATE

| | | | | |
|---|---|---|---|---|
| ❋ | Tab 50 mg | 5.66 | 100 | ✔ **IPCA-Metoprolol** |
| ❋ | Tab 100 mg | 7.55 | 60 | ✔ **IPCA-Metoprolol** |
| ❋ | Tab long-acting 200 mg | 23.40 | 28 | ✔ **Slow-Lopresor** |
| ❋ | Inj 1 mg per ml, 5 ml vial | 26.50 | 5 | ✔ **Metoprolol IV Mylan** |

NADOLOL

| | | | | |
|---|---|---|---|---|
| | Tab 40 mg | 19.19 | 100 | ✔ **Nadolol BNM** S29 |
| | Tab 80 mg | 30.39 | 100 | ✔ **Nadolol BNM** S29 |



✔ **fully subsidised**

**Principal Supply**

S29 Unapproved medicine supplied under Section 29

**Sole Subsidised Supply**

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| PROPRANOLOL | | | | |
| Tab 10 mg | 7.04 | 100 | ✔ | **Drofate** |
| ✻ Tab 40 mg | 8.75 | 100 | ✔ | **IPCA-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-Propranolol** S29 |

➸**SA1327** **Special Authority for Subsidy**

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

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

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

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

| | | | | |
|---|---|---|---|---|
| SOTALOL | | | | |
| ✻ Tab 80 mg | 37.50 | 500 | ✔ | **Mylan** |
| ✻ Tab 160 mg | 14.00 | 100 | ✔ | **Mylan** |

## Calcium Channel Blockers

### Dihydropyridine Calcium Channel Blockers

| | | | | |
|---|---|---|---|---|
| AMLODIPINE | | | | |
| ✻ Tab 2.5 mg | 1.08 | 90 | ✔ | **Vasorex** |
| ✻ Tab 5 mg | 0.96 | 90 | ✔ | **Vasorex** |
| ✻ Tab 10 mg | 1.19 | 90 | ✔ | **Vasorex** |
| FELODIPINE | | | | |
| ✻ Tab long-acting 2.5 mg | 1.45 | 30 | ✔ | **Plendil ER** |
| ✻ Tab long-acting 5 mg | 4.07 | 90 | ✔ | **Felo 5 ER** |
| ✻ Tab long-acting 10 mg | 4.32 | 90 | ✔ | **Felo 10 ER** |
| NIFEDIPINE | | | | |
| ✻ Tab long-acting 10 mg | 18.80 | 56 | ✔ | **Tensipine MR10** S29 |
| ✻ Tab long-acting 20 mg | 9.12 | 50 | ✔ | **Mylan (12 hr release)** S29 |
| | 17.72 | 100 | ✔ | **Nyefax Retard** |
| ✻ Tab long-acting 30 mg | 4.78 | 14 | ✔ | **Mylan Italy (24 hr release)** S29 |
| | 34.10 | 100 | ✔ | **Mylan (24 hr release)** S29 |
| ✻ Tab long-acting 60 mg | 52.81 | 100 | ✔ | **Mylan (24 hr release)** S29 |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| **Other Calcium Channel Blockers** | | | | |
| DILTIAZEM HYDROCHLORIDE | | | | |
| Cap extended-release 120 mg | 44.40 | 100 | ✔ | **Accord** S29 |
| ❋ Cap long-acting 120 mg | 33.42 | 500 | ✔ | **Apo-Diltiazem CD** |
| ❋ Cap long-acting 180 mg | 7.00 | 30 | ✔ | **Cardizem CD** |
| ❋ Cap long-acting 240 mg | 9.30 | 30 | ✔ | **Cardizem 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** |
| ❋ Inj 2.5 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO | 25.00 | 5 | ✔ | **Isoptin** |
| **Centrally-Acting Agents** | | | | |
| CLONIDINE | | | | |
| ❋ Patch 2.5 mg, 100 mcg per day – Only on a prescription | 10.34 | 4 | ✔ | **Mylan** |
| ❋ Patch 5 mg, 200 mcg per day – Only on a prescription | 13.18 | 4 | ✔ | **Mylan** |
| ❋ Patch 7.5 mg, 300 mcg per day – Only on a prescription | 16.93 | 4 | ✔ | **Mylan** |
| CLONIDINE HYDROCHLORIDE | | | | |
| ❋ Tab 25 mcg | 29.32 | 112 | ✔ | **Clonidine Teva** |
| ❋ Tab 150 mcg | 37.07 | 100 | ✔ | **Catapres** |
| ❋ Inj 150 mcg per ml, 1 ml ampoule | 29.68 | 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** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| FUROSEMIDE [FRUSEMIDE] | | | | |
| Tab 40 mg – Up to 30 tab available on a PSO | 8.00 | 1,000 | ✔ | **IPCA-Frusemide** |
| ✻ Tab 500 mg | 25.00 | 50 | ✔ | **Urex Forte** |
| | 89.48 | | ✔ | **Furosemid-Ratiopharm** S29 |
| | 169.96 | 100 | ✔ | **Furosemid-Ratiopharm** S29 |
| ✻ 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 | 2.40 | 5 | ✔ | **Furosemide-Baxter** |

## Potassium Sparing Diuretics

| | | | | |
|---|---|---|---|---|
| AMILORIDE HYDROCHLORIDE | | | | |
| Oral liq 1 mg per ml | 32.10 | 25 ml OP | ✔ | **Biomed** |
| EPLERENONE – Special Authority see SA1728 below – Retail pharmacy | | | | |
| Tab 25 mg | 18.50 | 30 | ✔ | **Inspra** |
| Tab 50 mg | 25.00 | 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 | 3.68 | 100 | ✔ | **Spiractin** |
| ✻ Tab 100 mg | 10.65 | 100 | ✔ | **Spiractin** |
| Oral liq 5 mg per ml | 30.60 | 25 ml OP | ✔ | **Biomed** |

## Potassium Sparing Combination Diuretics

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

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| **Thiazide and Related Diuretics** | | | | |
| BENDROFLUMETHIAZIDE [BENDROFLUAZIDE] | | | | |
| ❋ Tab 2.5 mg – Up to 150 tab available on a PSO | 20.00 | 500 | ✔ | **Arrow-Bendrofluazide** |
| May be supplied on a PSO for reasons other than emergency. | | | | |
| ❋ Tab 5 mg | 34.55 | 500 | ✔ | **Arrow-Bendrofluazide** |
| CHLOROTHIAZIDE | | | | |
| Oral liq 50 mg per ml | 27.82 | 25 ml OP | ✔ | **Biomed** |
| CHLORTALIDONE [CHLORTHALIDONE] | | | | |
| Tab 25 mg | 3.90 | 30 | ✔ | **Igroton** S29 |
| | 6.95 | 50 | ✔ | **Hygroton** |
| *(Igroton S29 Tab 25 mg to be delisted 1 April 2023)* | | | | |
| INDAPAMIDE | | | | |
| ❋ Tab 2.5 mg | 10.45 | 90 | ✔ | **Dapa-Tabs** |
| | 11.61 | 100 | ✔ | **Mylan Indapamide** S29 |
| **Lipid-Modifying Agents** | | | | |
| **Fibrates** | | | | |
| BEZAFIBRATE | | | | |
| ❋ Tab 200 mg | 19.46 | 90 | ✔ | **Bezalip** |
| ❋ Tab long-acting 400 mg | 21.21 | 30 | ✔ | **Bezalip Retard** |
| **Other Lipid-Modifying Agents** | | | | |
| ACIPIMOX | | | | |
| ❋ Cap 250 mg | 21.56 | 30 | ✔ | **Olbetam** |
| | | | ✔ | **Olbetam S29** S29 |
| **Resins** | | | | |
| COLESTIPOL HYDROCHLORIDE | | | | |
| Grans for oral liq 5 g | 32.89 | 30 | ✔ | **Colestid** |
| **HMG CoA Reductase Inhibitors (Statins)** | | | | |
| ATORVASTATIN | | | | |
| ❋ Tab 10 mg | 6.16 | 500 | ✔ | **Lorstat** |
| ❋ Tab 20 mg | 9.24 | 500 | ✔ | **Lorstat** |
| ❋ Tab 40 mg | 14.92 | 500 | ✔ | **Lorstat** |
| ❋ Tab 80 mg | 26.54 | 500 | ✔ | **Lorstat** |
| PRAVASTATIN | | | | |
| ❋ Tab 20 mg | 2.11 | 28 | ✔ | **Pravastatin Mylan** |
| ❋ Tab 40 mg | 3.61 | 28 | ✔ | **Pravastatin Mylan** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| ROSUVASTATIN – Special Authority see SA2093 below – Retail pharmacy | | | | |
| ✻ Tab 5 mg | 1.70 | 30 | ✔ | **Rosuvastatin Viatris** |
| ✻ Tab 10 mg | 2.42 | 30 | ✔ | **Rosuvastatin Viatris** |
| ✻ Tab 20 mg | 3.92 | 30 | ✔ | **Rosuvastatin Viatris** |
| ✻ Tab 40 mg | 5.28 | 30 | ✔ | **Rosuvastatin Viatris** |

**➽SA2093 Special Authority for Subsidy**

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

Either:

1 Both:
- 1.1 Patient is considered to be at risk of cardiovascular disease; and
- 1.2 Patient is Māori or any Pacific ethnicity; or

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

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

Both:

1 Patient has familial hypercholesterolemia (defined as a Dutch Lipid Criteria score greater than or equal to 6); and

2 LDL cholesterol has not reduced to less than 1.8 mmol/litre with treatment with the maximum tolerated dose of atorvastatin and/or simvastatin.

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

Both:

1 Any of the following:
- 1.1 Patient has proven coronary artery disease (CAD); or
- 1.2 Patient has proven peripheral artery disease (PAD); or
- 1.3 Patient has experienced an ischaemic stroke; and

2 LDL cholesterol has not reduced to less than 1.4 mmol/litre with treatment with the maximum tolerated dose of atorvastatin and/or simvastatin.

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

Both:

1 Patient has experienced a recurrent major cardiovascular event (defined as myocardial infarction, ischaemic stroke, coronary revascularisation, hospitalisation for unstable angina) in the last 2 years; and

2 LDL cholesterol has not reduced to less than 1.0 mmol/litre with treatment with the maximum tolerated dose of atorvastatin and/or simvastatin.

| | | | | |
|---|---|---|---|---|
| SIMVASTATIN | | | | |
| ✻ Tab 10 mg | 1.23 | 90 | ✔ | **Simvastatin Mylan** |
| ✻ Tab 20 mg | 2.03 | 90 | ✔ | **Simvastatin Mylan** |
| ✻ Tab 40 mg | 3.58 | 90 | ✔ | **Simvastatin Mylan** |
| ✻ Tab 80 mg | 7.12 | 90 | ✔ | **Simvastatin Mylan** |

## Selective Cholesterol Absorption Inhibitors

| | | | | |
|---|---|---|---|---|
| EZETIMIBE – Special Authority see SA1045 on the next page – Retail pharmacy | | | | |
| ✻ Tab 10 mg | 1.95 | 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.

**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.

**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 | 6.09 | | 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** |

ISOSORBIDE MONONITRATE

| | | | | |
|---|---|---|---|---|
| ✻ Tab 20 mg | 19.55 | | 100 | ✔ **Ismo 20** |
| ✻ Tab long-acting 40 mg | 8.20 | | 30 | ✔ **Ismo 40 Retard** |
| ✻ Tab long-acting 60 mg | 9.25 | | 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** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

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

## 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 ..... 257.12 — 5 — ✔ **Hospira**

PENTOXIFYLLINE [OXPENTIFYLLINE]

Tab 400 mg ..... 42.26 — 50 — ✔ **Trental 400**

## Endothelin Receptor Antagonists

AMBRISENTAN – Special Authority see SA1702 below – Retail pharmacy

| | | | |
|---|---|---|---|
| Tab 5 mg ..... 1,550.00 | 30 | ✔ | **Ambrisentan Mylan** |
| Tab 10 mg ..... 1,550.00 | 30 | ✔ | **Ambrisentan Mylan** |
| | | ✔ | **Mylan** |

*(Ambrisentan Mylan Tab 10 mg to be delisted 1 March 2023)*

**SA1702 Special Authority for Subsidy**

Special Authority approved by the Pulmonary Arterial Hypertension Panel

Notes: Application details may be obtained from Pharmac's website schedule.pharmac.govt.nz/SAForms 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 SA1991 on the next page – Retail pharmacy

| | | | |
|---|---|---|---|
| Tab 62.5 mg ..... 119.85 | 60 | ✔ | **Bosentan Dr Reddy's** |
| Tab 125 mg ..... 119.85 | 60 | ✔ | **Bosentan Dr Reddy's** |

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

➽SA1991 **Special Authority for Subsidy**

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

All of the following:

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

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

Any of the following:

1 Both:
  1.1 Bosentan is to be used as PAH monotherapy; and
  1.2 Patient is stable or has improved while on bosentan; or
2 Both:
  2.1 Bosentan is to be used as PAH dual therapy; and
  2.2 Patient has tried a PAH monotherapy for at least three months and either failed to respond or later deteriorated; or
3 Both:
  3.1 Bosentan is to be used as PAH triple therapy; and
  3.2 Any of the following:
    3.2.1 Patient is on the lung transplant list; or
    3.2.2 Patient is presenting acutely with idiopathic pulmonary arterial hypertension (IPAH) in New York Heart Association/World Health Organization (NYHA/WHO) Functional Class IV; or
    3.2.3 Patient is deteriorating rapidly to NYHA/WHO Functional Class IV who may be lung transplant recipients in the future, if their disease is stabilised; or
    3.2.4 Patient has PAH associated with the scleroderma spectrum of diseases (APAHSSD) who have no major morbidities and are deteriorating despite combination therapy.

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

## Phosphodiesterase Type 5 Inhibitors

SILDENAFIL – Special Authority see SA1992 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Tab 25 mg | 0.85 | 4 | ✔ | **Vedafil** |
| Tab 50 mg | 1.70 | 4 | ✔ | **Vedafil** |
| Tab 100 mg | 10.20 | 12 | ✔ | **Vedafil** |

➽**SA1992** **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
    4.1.3 Patient has a pulmonary vascular resistance (PVR) of at least 3 Wood Units or at least 240 International Units (dyn s cm-5); or
  4.2 Testing for PCWP, PAPm, or PVR cannot be performed due to the patient's young age.

Note: Indications marked with * are unapproved indications.

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

Both:

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

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

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

## 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 schedule.pharmac.govt.nz/SAForms 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 | 185.03 | 30 | ✔ | **Vebulis** |
| | 740.10 | | ✔ | **Ventavis** |

*(Ventavis Nebuliser soln 10 mcg per ml, 2 ml to be delisted 1 March 2023)*

**SA1705 Special Authority for Subsidy**

Special Authority approved by the Pulmonary Arterial Hypertension Panel

Notes: Application details may be obtained from Pharmac's website schedule.pharmac.govt.nz/SAForms or:
The Coordinator, PAH Panel
Pharmac, PO Box 10-254, WELLINGTON
Tel: (04) 916 7561, Fax: (04) 974 4858, Email: PAH@pharmac.govt.nz



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

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

## Antiacne Preparations

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 89

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 SA2023 below – Retail pharmacy

| | | | |
|---|---|---|---|
| Cap 5 mg | 11.26 | 60 | ✔ **Oratane** |
| Cap 10 mg | 18.75 | 120 | ✔ **Oratane** |
| Cap 20 mg | 26.73 | 120 | ✔ **Oratane** |

➽**SA2023** **Special Authority for Subsidy**

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

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

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

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

TRETINOIN

| | | | |
|---|---|---|---|
| Crm 0.5 mg per g – Maximum of 50 g per prescription | 15.57 | 50 g OP | ✔ **ReTrieve** |

## Antibacterials Topical

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 89

HYDROGEN PEROXIDE

| | | | |
|---|---|---|---|
| ✻ Crm 1% | 8.56 | 10 g OP | ✔ **Crystaderm** |
| | | 15 g OP | ✔ **Crystaderm** |

MUPIROCIN

| | | | |
|---|---|---|---|
| Oint 2% | 6.60 | 15 g OP | |
| | (11.50) | | Bactroban |

a) Only on a prescription
b) Not in combination

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

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

## Antifungals Topical

For systemic antifungals, refer to INFECTIONS, Antifungals, page 96

| | | | | |
|---|---|---|---|---|
| AMOROLFINE | | | | |
| a) Only on a prescription<br>b) Not in combination | | | | |
| Nail soln 5% | 14.93 | 5 ml OP | ✔ | **MycoNail** |
| CLOTRIMAZOLE | | | | |
| ❋ Crm 1% | 1.10 | 20 g OP | ✔ | **Clomazol** |
| a) Only on a prescription<br>b) Not in combination | | | | |
| ❋ Soln 1% | 4.36 | 20 ml OP | | |
| | (7.55) | | | Canesten |
| a) Only on a prescription<br>b) Not in combination | | | | |
| ECONAZOLE NITRATE | | | | |
| Crm 1% | 1.00 | 20 g OP | | |
| | (7.48) | | | Pevaryl |
| a) Only on a prescription<br>b) Not in combination | | | | |
| Foaming soln 1%, 10 ml sachets | 9.89 | 3 | | |
| | (17.23) | | | Pevaryl |
| a) Only on a prescription<br>b) Not in combination | | | | |
| MICONAZOLE NITRATE | | | | |
| ❋ Crm 2% | 0.81 | 15 g OP | ✔ | **Multichem** |
| a) Only on a prescription<br>b) Not in combination | | | | |
| ❋ Lotn 2% | 4.36 | 30 ml OP | | |
| | (10.03) | | | Daktarin |
| a) Only on a prescription<br>b) Not in combination | | | | |
| ❋ Tinct 2% | 4.36 | 30 ml OP | | |
| | (12.10) | | | Daktarin |
| a) Only on a prescription<br>b) Not in combination | | | | |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

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

## Antipruritic Preparations

CALAMINE

a) Only on a prescription
b) Not in combination

| | | | | |
|---|---|---|---|---|
| Crm, aqueous, BP | 1.08 | 100 g | ✔ | **Calamine-AFT** |

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 79

### Corticosteroids - Plain

BETAMETHASONE DIPROPIONATE

| | | | | |
|---|---|---|---|---|
| Crm 0.05% | 2.96 | 15 g OP | ✔ | **Diprosone** |
| | 36.00 | 50 g OP | ✔ | **Diprosone** |
| Oint 0.05% | 2.96 | 15 g OP | ✔ | **Diprosone** |
| | 36.00 | 50 g OP | ✔ | **Diprosone** |
| Oint 0.05% in propylene glycol base | 4.33 | 30 g OP | ✔ | **Diprosone OV** |

BETAMETHASONE VALERATE

| | | | | |
|---|---|---|---|---|
| ✻ Crm 0.1% | 4.53 | 50 g OP | ✔ | **Beta Cream** |
| ✻ Oint 0.1% | 5.84 | 50 g OP | ✔ | **Beta Ointment** |
| ✻ Lotn 0.1% | 25.00 | 50 ml OP | ✔ | **Betnovate** |

CLOBETASOL PROPIONATE

| | | | | |
|---|---|---|---|---|
| ✻ Crm 0.05% | 2.40 | 30 g OP | ✔ | **Dermol** |
| ✻ Oint 0.05% | 2.33 | 30 g OP | ✔ | **Dermol** |

CLOBETASONE BUTYRATE

| | | | | |
|---|---|---|---|---|
| Crm 0.05% | 5.38 | 30 g OP | | |
| | (10.00) | | | Eumovate |

HYDROCORTISONE

| | | | | |
|---|---|---|---|---|
| ✻ Crm 1% – Only on a prescription | 1.78 | 30 g OP | ✔ | **Ethics** |
| | 17.15 | 500 g | ✔ | **Hydrocortisone (PSM)** |
| ✻ Powder – Only in combination | 49.95 | 25 g | ✔ | **ABM** |

Up to 5% in a dermatological base (not proprietary Topical Corticosteriod – Plain) with or without other dermatological galenicals

HYDROCORTISONE AND PARAFFIN LIQUID AND LANOLIN

| | | | | |
|---|---|---|---|---|
| Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% – Only on a prescription | 10.57 | 250 ml | ✔ | **DP Lotn HC** |

▲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 |
|---|---|---|---|---|
| HYDROCORTISONE BUTYRATE | | | | |
| Lipocream 0.1% | 4.85 | 100 g OP | ✔ | **Locoid Lipocream** |
| Oint 0.1% | 10.28 | 100 g OP | ✔ | **Locoid** |
| Milky emul 0.1% | 12.33 | 100 ml OP | ✔ | **Locoid Crelo** |
| METHYLPREDNISOLONE ACEPONATE | | | | |
| Crm 0.1% | 4.46 | 15 g OP | ✔ | **Advantan** |
| Oint 0.1% | 4.46 | 15 g OP | ✔ | **Advantan** |
| MOMETASONE FUROATE | | | | |
| Crm 0.1% | 1.95 | 15 g OP | ✔ | **Elocon Alcohol Free** |
| | 3.10 | 50 g OP | ✔ | **Elocon Alcohol Free** |
| Oint 0.1% | 1.95 | 15 g OP | ✔ | **Elocon** |
| | 2.90 | 50 g OP | ✔ | **Elocon** |
| Lotn 0.1% | 4.50 | 30 ml OP | ✔ | **Elocon** |
| TRIAMCINOLONE ACETONIDE | | | | |
| Crm 0.02% | 6.30 | 100 g OP | ✔ | **Aristocort** |
| Oint 0.02% | 6.35 | 100 g OP | ✔ | **Aristocort** |

## Corticosteroids - Combination

| | | | | |
|---|---|---|---|---|
| BETAMETHASONE VALERATE WITH 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% | 1.89 | 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** |

*(Pimafucort Crm 1% with natamycin 1% and neomycin sulphate 0.5% to be delisted 1 April 2023)*

| | | | | |
|---|---|---|---|---|
| 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 | | |
| | (9.28) | | | Viaderm KC |

# Barrier Creams and Emollients

## Barrier Creams

| | | | | |
|---|---|---|---|---|
| DIMETHICONE | | | | |
| ❋ Crm 5% pump bottle | 4.30 | 500 ml OP | ✔ | **healthE Dimethicone 5%** |
| healthE Dimethicone 5% to be Principal Supply on 1 December 2022 | | | | |
| ❋ Crm 10% pump bottle | 4.52 | 500 ml OP | ✔ | **healthE Dimethicone 10%** |
| ZINC AND CASTOR OIL | | | | |
| ❋ Oint | 4.65 | 500 g | ✔ | **Boucher** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| **Emollients** | | | | |
| AQUEOUS CREAM | | | | |
| ❋ Crm | 1.73 | 500 g | ✔ | **GEM Aqueous Cream** |
| CETOMACROGOL | | | | |
| ❋ Crm BP | 1.99 | 500 g | ✔ | **Cetomacrogol-AFT** |
| CETOMACROGOL WITH GLYCEROL | | | | |
| Crm 90% with glycerol 10% | 2.35 | 500 ml OP | ✔ | **Boucher** |
| | | | ✔ | **Evara** |
| | | | ✔ | **Pharmacy Health Sorbolene with Glycerin** |
| | 3.10 | 1,000 ml OP | ✔ | **Boucher** |
| | | | ✔ | **Evara** |
| *(Boucher Crm 90% with glycerol 10% to be delisted 1 March 2023)* | | | | |
| *(Boucher Crm 90% with glycerol 10% to be delisted 1 March 2023)* | | | | |
| EMULSIFYING OINTMENT | | | | |
| ❋ Oint BP | 3.40 | 500 g | ✔ | **Emulsifying Ointment ADE** |
| OIL IN WATER EMULSION | | | | |
| ❋ Crm | 2.04 | 500 g | ✔ | **Fatty Cream AFT** |
| 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.

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

## Minor Skin Infections

POVIDONE IODINE

Oint 10% ..... 7.40 — 65 g OP — ✔ **Betadine**

a) Maximum of 130 g per prescription
b) Only on a prescription

Antiseptic Solution 10% ..... 4.15 — 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

## Parasiticidal Preparations

DIMETHICONE

❋ Lotn 4% ..... 4.25 — 200 ml OP — ✔ **healthE Dimethicone 4% Lotion**

healthE Dimethicone 4% Lotion to be Principal Supply on 1 December 2022

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:

continued…

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

continued…

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.

**Initial application — (Other parasitic infections)** only from an infectious disease specialist, clinical microbiologist or dermatologist. Approvals valid for 1 month for applications meeting the following criteria:
Any of the following:
1 Filaricides; or
2 Cutaneous larva migrans (creeping eruption); or
3 Strongyloidiasis.

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

**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% | 5.75 | 30 g | OP | ✔ **Lyderm** |
| Lotn 5% | 3.99 | 30 ml | OP | ✔ **A-Scabies** |

## Psoriasis and Eczema Preparations

ACITRETIN – Special Authority see SA2024 on the next page – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Cap 10 mg | 17.86 | 60 | | ✔ **Novatretin** |
| Cap 25 mg | 41.36 | 60 | | ✔ **Novatretin** |

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

**➽SA2024 Special Authority for Subsidy**

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

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

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

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

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 | 39.35 | 60 g | OP | ✔ **Daivobet** |
| Oint 500 mcg with calcipotriol 50 mcg per g | 15.90 | 30 g | OP | ✔ **Daivobet** |

CALCIPOTRIOL

| | | | | |
|---|---|---|---|---|
| Oint 50 mcg per g | 40.00 | 120 g | OP | ✔ **Daivonex** |

COAL TAR

| | | | | |
|---|---|---|---|---|
| Soln BP – Only in combination | 36.25 | 200 ml | | ✔ **Midwest** |

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

COAL TAR WITH ALLANTOIN, MENTHOL, PHENOL AND SULPHUR

| | | | | |
|---|---|---|---|---|
| Soln 5% with sulphur 0.5%, menthol 0.75%, phenol 0.5% and allantoin crm 2.5% | 6.59 | 75 g | OP | |
| | (8.00) | | | 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** |

PIMECROLIMUS – Special Authority see SA1970 on the next page – Retail pharmacy

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

| | | | | |
|---|---|---|---|---|
| Cream 1% | 28.50 | 15 g | OP | ✔ **Elidel** |

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

➽SA1970 **Special Authority for Subsidy**
**Initial application** only from a dermatologist, paediatrician, ophthalmologist or any relevant practitioner on the recommendation of a dermatologist, paediatrician or ophthalmologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:
Both:

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

PINE TAR WITH TROLAMINE LAURILSULFATE AND FLUORESCEIN – Only on a prescription
✻ Soln 2.3% with trolamine laurilsulfate and fluorescein sodium ..... 4.44 — 500 ml — ✔ **Pinetarsol**

SALICYLIC ACID
Powder – Only in combination ..... 18.88 — 250 g — ✔ **Midwest**
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.

TACROLIMUS
Oint 0.1% – Special Authority see SA2074 below – Retail pharmacy ..... 33.00 — 30 g OP — ✔ **Zematop**
a) Maximum of 30 g per prescription
b) Note: a maximum of 30 g per prescription and no more than one prescription per 12 weeks.

➽SA2074 **Special Authority for Subsidy**
**Initial application** only from a dermatologist, paediatrician or any relevant practitioner on the recommendation of a dermatologist, paediatrician, . Approvals valid without further renewal unless notified for applications meeting the following criteria:
Both:

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

## Scalp Preparations

BETAMETHASONE VALERATE
✻ Scalp app 0.1% ..... 9.84 — 100 ml OP — ✔ **Beta Scalp**

CLOBETASOL PROPIONATE
✻ Scalp app 0.05% ..... 6.26 — 30 ml OP — ✔ **Dermol**

HYDROCORTISONE BUTYRATE
Scalp lotn 0.1% ..... 6.57 — 100 ml OP — ✔ **Locoid**

KETOCONAZOLE
Shampoo 2% ..... 3.23 — 100 ml OP — ✔ **Sebizole** ✔ **Sebizole**
a) Maximum of 100 ml per prescription
b) Only on a prescription

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

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

## Sunscreens

SUNSCREENS, PROPRIETARY – Subsidy by endorsement

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

| | | | | |
|---|---|---|---|---|
| Lotn | 6.50 | 200 g | OP | ✔ **Marine Blue Lotion SPF 50+** |

## Wart Preparations

For salicylic acid preparations refer to PSORIASIS AND ECZEMA PREPARATIONS, page 67

IMIQUIMOD

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

PODOPHYLLOTOXIN

| | | | | |
|---|---|---|---|---|
| Soln 0.5% | 33.60 | 3.5 ml | OP | ✔ **Condyline** |

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

## Other Skin Preparations

### Antineoplastics

FLUOROURACIL SODIUM

| | | | | |
|---|---|---|---|---|
| Crm 5% | 6.95 | 20 g | OP | ✔ **Efudix** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

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

▲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

## Contraceptives - Non-hormonal

### Condoms

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| 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<br>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<br>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<br>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<br>b) Maximum of 60 dev per prescription | | | | |
| ❋ 56 mm | 0.97 | 10 | ✔ | **Moments** |
| | 11.64 | 144 | ✔ | **Moments** |
| a) Maximum of 60 dev per prescription<br>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<br>b) Maximum of 60 dev per prescription | | | | |
| ❋ 56 mm, 0.05mm thickness (bulk pack) | 14.61 | 144 | ✔ | **Gold Knight** |
| a) Maximum of 60 dev per prescription<br>b) Up to 60 dev available on a PSO | | | | |
| ❋ 56 mm, 0.08 mm thickness | 0.97 | 10 | ✔ | **Moments** |
| | 11.64 | 144 | ✔ | **Moments** |
| a) Up to 60 dev available on a PSO<br>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<br>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<br>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<br>b) Maximum of 60 dev per prescription | | | | |
| ❋ 60 mm | 1.42 | 12 | ✔ | **Gold Knight XL** |
| | 14.87 | 144 | ✔ | **Shield XL** |
| | 17.02 | | ✔ | **Gold Knight XL** |
| a) Maximum of 60 dev per prescription<br>b) Up to 60 dev available on a PSO | | | | |



✔ Fully subsidised
Principal Supply

S29 Unapproved medicine supplied under Section 29
Sole Subsidised Supply

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| ✻ 60 mm (bulk pack) | 14.87 | 144 | ✔ | **Gold Knight XL** |
| a) Maximum of 60 dev per prescription<br>b) Up to 60 dev available on a PSO | | | | |

## Contraceptive Devices

INTRA-UTERINE DEVICE

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

| | | | | |
|---|---|---|---|---|
| ✻ IUD 29.1 mm length × 23.2 mm width | 29.80 | 1 | ✔ | **7 MED NSHA Silver/ Copper Short** |
| | | | ✔ | **Choice 380 7med Nsha Silver/ copper Short** |
| | | | ✔ | **Choice TT380 Short** |
| ✻ IUD 33.6 mm length × 29.9 mm width | 29.80 | 1 | ✔ | **Choice TT380 Standard** |
| ✻ IUD 35.5 mm length × 19.6 mm width | 33.00 | 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 – Up to 84 tab available on a PSO | 10.00 | 84 | ✔ | **Mercilon 28** |

| | 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 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<br>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 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 and 7 inert tab – Up to 84 tab available on a PSO | 21.99 | 84 | ✔ | **Norimin** |
| | 29.32 | 112 | ✔ | **Norimin** |

## Progestogen-only Contraceptives

**➽SA0500 Special Authority for Alternate Subsidy**

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

1 Either:
- 1.1 Patient is on a Social Welfare benefit; or
- 1.2 Patient has an income no greater than the benefit; and

2 Has tried at least one of the fully funded options and has been unable to tolerate it.

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

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

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

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

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

| | | | | |
|---|---|---|---|---|
| LEVONORGESTREL | | | | |
| ❋ Tab 30 mcg – Up to 84 tab available on a PSO | 16.50 | 84 | ✔ | **Microlut** |
| | 22.00 | 112 | ✔ | **Microlut** |
| ❋ Subdermal implant (2 × 75 mg rods) – Up to 3 pack available on a PSO | 106.92 | 1 | ✔ | **Jadelle** |
| MEDROXYPROGESTERONE ACETATE | | | | |
| Inj 150 mg per ml, 1 ml syringe – Up to 5 inj available on a PSO | 7.98 | 1 | ✔ | **Depo-Provera** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| NORETHISTERONE | | | | |
| Tab 350 mcg – Up to 84 tab available on a PSO | 12.25 | 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 | 4.98 | 168 | ✔ | **Ginet** |

## Gynaecological Anti-infectives

| | | | | |
|---|---|---|---|---|
| ACETIC ACID WITH HYDROXYQUINOLINE AND RICINOLEIC ACID | | | | |
| Jelly with glacial acetic acid 0.94%, hydroxyquinoline sulphate 0.025%, glycerol 5% and ricinoleic acid 0.75% with applicator | 8.43 (24.15) | 100 g OP | | Aci-Jel |
| CLOTRIMAZOLE | | | | |
| ✱ Vaginal crm 1% with applicators | 3.50 | 35 g OP | ✔ | **Clomazol** |
| ✱ Vaginal crm 2% with applicators | 3.85 | 20 g OP | ✔ | **Clomazol** |
| MICONAZOLE NITRATE | | | | |
| ✱ Vaginal crm 2% with applicator | 6.89 | 40 g OP | ✔ | **Micreme** |
| NYSTATIN | | | | |
| Vaginal crm 100,000 u per 5 g with applicator(s) | 4.00 | 75 g OP | ✔ | **Nilstat** |

## Myometrial and Vaginal Hormone Preparations

| | | | | |
|---|---|---|---|---|
| ERGOMETRINE MALEATE | | | | |
| Inj 500 mcg per ml, 1 ml ampoule – Up to 5 inj available on a PSO | 160.00 | 5 | ✔ | **DBL Ergometrine** |
| 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 ampoule | 32.40 | 5 | ✔ | **Syntometrine** |

Syntometrine to be Principal Supply on 1 December 2022

▲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 |
|---|---|---|---|---|

## 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** |
| | 16.00 | | ✔ | **David One Step Cassette Pregnancy Test** |

## Urinary Agents

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

### 5-Alpha Reductase Inhibitors

FINASTERIDE – Special Authority see SA0928 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| ✱ Tab 5 mg | 4.81 | 100 | ✔ | **Ricit** |

➽**SA0928** **Special Authority for Subsidy**

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

Both:

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

### Alpha-1A Adrenoreceptor Blockers

TAMSULOSIN HYDROCHLORIDE – Special Authority see SA1032 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| ✱ Cap 400 mcg | 22.31 | 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 | 5.42 | 100 | ✔ | **Alchemy Oxybutynin** S29 |

POTASSIUM CITRATE

| | | | | |
|---|---|---|---|---|
| Oral liq 3 mmol per ml – Special Authority see SA1083 on the next page – Retail pharmacy | 31.80 | 200 ml OP | ✔ | **Biomed** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

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

➽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 | 2.22 | 28 | ✔ | **Ural** |
| SOLIFENACIN SUCCINATE | | | | |
| Tab 5 mg | 2.05 | 30 | ✔ | **Solifenacin Mylan** |
| Tab 10 mg | 3.72 | 30 | ✔ | **Solifenacin Mylan** |

## Detection of Substances in Urine

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

## Obstetric Preparations

### Antiprogesterones

| | | | | |
|---|---|---|---|---|
| MIFEPRISTONE | | | | |
| Tab 200 mg – Up to 15 tab available on a PSO | 60.00 | 1 | ✔ | **Mifegyne** |
| | 180.00 | 3 | ✔ | **Mifegyne** |

▲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 |
|---|---|---|---|---|

## 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 ..... 42.06 | 28 | ✔ **Cinacalet Devatis**

Tab 60 mg – Wastage claimable ..... 84.12 | 28 | ✔ **Cinacalet Devatis**

**➽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 SA2109 below – Retail pharmacy ..... 18.00 | 1 | ✔ **Zoledronic acid Mylan**; ✔ **Zoledronic acid Viatris**

**➽SA2109 Special Authority for Subsidy**

**Initial application — (bone metastases)** from any relevant practitioner. 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*)** from any relevant practitioner. Approvals valid for 3 years for applications meeting

continued…

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

continued…
the following criteria:
All of the following:

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

Note: Indications marked with * are unapproved indications.

**Initial application — (symptomatic hypercalcaemia*)** from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has symptomatic hypercalcaemia .

Note: Indications marked with * are unapproved indications.

## 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<br>(36.96) | 5 | Celestone<br>Chronodose |
| DEXAMETHASONE | | | | |
| ❋ | Tab 0.5 mg – Up to 60 tab available on a PSO | 1.50 | 30 | ✔ **Dexmethsone** |
| ❋ | Tab 4 mg – Up to 30 tab available on a PSO | 2.65 | 30 | ✔ **Dexmethsone** |
| | Oral liq 1 mg per ml | 48.15 | 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 | 7.86<br>9.25 | 10 | ✔ **Hameln**<br>✔ **Dexamethasone Phosphate Panpharma** |
| ❋ | Inj 4 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO | 13.10<br>16.37 | 10 | ✔ **Hameln**<br>✔ **Dexamethasone Phosphate Panpharma** |

*(Dexamethasone Phosphate Panpharma Inj 4 mg per ml, 1 ml ampoule to be delisted 1 February 2023)*
*(Dexamethasone Phosphate Panpharma Inj 4 mg per ml, 2 ml ampoule to be delisted 1 February 2023)*

| | | | | |
|---|---|---|---|---|
| FLUDROCORTISONE ACETATE | | | | |
| ❋ | Tab 100 mcg<br>Florinef to be Principal Supply on 1 December 2022 | 11.46 | 100 | ✔ **Florinef** |
| HYDROCORTISONE | | | | |
| ❋ | Tab 5 mg | 8.10 | 100 | ✔ **Douglas** |
| ❋ | Tab 20 mg | 20.32 | 100 | ✔ **Douglas** |
| ❋ | Inj 100 mg vial | 4.38 | 1 | ✔ **Solu-Cortef** |
| | a) Up to 5 inj available on a PSO<br>b) Only on a PSO | | | |
| METHYLPREDNISOLONE | | | | |
| ❋ | Tab 4 mg | 112.00 | 100 | ✔ **Medrol** |
| ❋ | Tab 100 mg | 223.10 | 20 | ✔ **Medrol** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| METHYLPREDNISOLONE (AS SODIUM SUCCINATE) | | | | |
| Inj 40 mg vial | 22.30 | 1 | ✔ | **Solu-Medrol-Act-O-Vial** |
| Inj 125 mg vial | 34.10 | 1 | ✔ | **Solu-Medrol-Act-O-Vial** |
| Inj 500 mg vial | 26.88 | 1 | ✔ | **Solu-Medrol-Act-O-Vial** |
| Inj 1 g vial | 32.84 | 1 | ✔ | **Solu-Medrol** |
| METHYLPREDNISOLONE ACETATE | | | | |
| Inj 40 mg per ml, 1 ml vial | 47.06 | 5 | ✔ | **Depo-Medrol** |
| PREDNISOLONE | | | | |
| ❋ Oral liq 5 mg per ml – Up to 30 ml available on a PSO<br>Restricted to children under 12 years of age. | 6.00 | 30 ml OP | ✔ | **Redipred** |
| PREDNISONE | | | | |
| ❋ Tab 1 mg | 18.58 | 500 | ✔ | **Prednisone Clinect** |
| ❋ Tab 2.5 mg | 21.04 | 500 | ✔ | **Prednisone Clinect** |
| ❋ Tab 5 mg – Up to 30 tab available on a PSO | 19.30 | 500 | ✔ | **Prednisone Clinect** |
| ❋ Tab 20 mg – Up to 30 tab available on a PSO | 50.51 | 500 | ✔ | **Prednisone Clinect** |
| TETRACOSACTRIN | | | | |
| ❋ Inj 250 mcg per ml, 1 ml ampoule | 75.00 | 1 | ✔ | **AU Synacthen**<br>✔ **Synacthen**<br>✔ **UK Synacthen** |
| ❋ Inj 1 mg per ml, 1 ml ampoule | 690.00 | 1 | ✔ | **Synacthen Depot**<br>✔ **Synacthene Retard** S29 |
| *(AU Synacthen Inj 250 mcg per ml, 1 ml ampoule to be delisted 1 March 2023)* | | | | |
| TRIAMCINOLONE ACETONIDE | | | | |
| Inj 10 mg per ml, 1 ml ampoule | 20.80 | 5 | ✔ | **Kenacort-A 10** |
| Inj 40 mg per ml, 1 ml ampoule | 51.10 | 5 | ✔ | **Kenacort-A 40** |

## Sex Hormones Non Contraceptive

### Androgen Agonists and Antagonists

| | | | | |
|---|---|---|---|---|
| CYPROTERONE ACETATE | | | | |
| Tab 50 mg | 14.37 | 50 | ✔ | **Siterone** |
| Tab 100 mg | 28.03 | 50 | ✔ | **Siterone** |
| TESTOSTERONE | | | | |
| Patch 5 mg per day | 225.00 | 30 | ✔ | **Androderm** |
| TESTOSTERONE CIPIONATE | | | | |
| Inj 100 mg per ml, 10 ml vial | 85.00 | 1 | ✔ | **Depo-Testosterone** |
| | 393.00 | | ✔ | **Taro-Testosterone** S29 |
| TESTOSTERONE ESTERS | | | | |
| Inj 250 mg per ml, 1 ml | 12.98 | 1 | ✔ | **Sustanon Ampoules** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| TESTOSTERONE UNDECANOATE | | | | |
| Cap 40 mg – Subsidy by endorsement | 21.00 | 60 | ✔ | **Andriol Testocaps** |
| | 35.00 | 100 | ✔ | **Steril-Gene** S29 |
| Subsidy by endorsement – subsidised for patients who were taking testosterone undecanoate cap 40mg prior to 1 November 2021 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of testosterone undecanoate cap 40 mg in the preceding 12 months. | | | | |
| Inj 250 mg per ml, 4 ml vial | 86.00 | 1 | ✔ | **Reandron 1000** |

## Hormone Replacement Therapy - Systemic

### Oestrogens

| | | | | |
|---|---|---|---|---|
| OESTRADIOL | | | | |
| ✻ Tab 1 mg | 4.12 | 28 OP | | |
| | (11.10) | | | Estrofem |
| ✻ Tab 2 mg | 4.12 | 28 OP | | |
| | (11.10) | | | Estrofem |
| Patch 50 mcg per 24 hours | 7.04 | 4 | ✔ | **Climara** |
| a) No more than 1 patch per week<br>b) Only on a prescription | | | | |
| Patch 25 mcg per day | 6.12 | 8 | ✔ | **Estradot** |
| | 13.50 | | ✔ | **Estraderm MX** S29 |
| a) No more than 2 patch per week<br>b) Only on a prescription | | | | |
| Patch 50 mcg per day | 7.04 | 8 | ✔ | **Estradot 50 mcg** |
| | 9.22 | | ✔ | **Estradiol TDP Mylan** S29 |
| | 14.50 | | ✔ | **Estraderm MX** S29 |
| a) No more than 2 patch per week<br>b) Only on a prescription | | | | |
| Patch 75 mcg per day | 7.91 | 8 | ✔ | **Estradot** |
| | 10.60 | | ✔ | **Estradiol TDP Mylan** S29 |
| a) No more than 2 patch per week<br>b) Only on a prescription | | | | |
| Patch 100 mcg per day | 7.91 | 8 | ✔ | **Estradot** |
| | 15.50 | | ✔ | **Estraderm MX** S29 |
| a) No more than 2 patch per week<br>b) Only on a prescription | | | | |
| OESTRADIOL VALERATE | | | | |
| ✻ Tab 1 mg | 12.36 | 84 | ✔ | **Progynova** |
| ✻ Tab 2 mg | 12.36 | 84 | ✔ | **Progynova** |
| OESTROGENS | | | | |
| ✻ Conjugated, equine tab 300 mcg | 3.01 | 28 | | |
| | (17.50) | | | Premarin |
| ✻ Conjugated, equine tab 625 mcg | 4.12 | 28 | | |
| | (17.50) | | | Premarin |

▲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 |
|---|---|---|---|---|
| **Progestogens** | | | | |
| MEDROXYPROGESTERONE ACETATE | | | | |
| ❋ Tab 2.5 mg | 4.69 | 30 | ✔ | **Provera** |
| | 8.75 | 56 | ✔ | **Provera** |
| ❋ Tab 5 mg | 9.80 | 56 | ✔ | **Provera** |
| | 17.50 | 100 | ✔ | **Provera** |
| ❋ Tab 10 mg | 8.94 | 30 | ✔ | **Provera** |
| **Progestogen and Oestrogen Combined Preparations** | | | | |
| OESTRADIOL WITH NORETHISTERONE | | | | |
| ❋ Tab 1 mg with 0.5 mg norethisterone acetate | 5.40 | 28 OP | | |
| | (18.10) | | | Kliovance |
| ❋ Tab 2 mg with 1 mg norethisterone acetate | 5.40 | 28 OP | | |
| | (18.10) | | | Kliogest |
| ❋ Tab 2 mg with 1 mg norethisterone acetate (10), and 2 mg oestradiol tab (12) and 1 mg oestradiol tab (6) | 5.40 | 28 OP | | |
| | (18.10) | | | Trisequens |
| **Other Oestrogen Preparations** | | | | |
| ETHINYLOESTRADIOL – Subsidy by endorsement | | | | |
| Subsidy by endorsement – Subsidised for patients who were taking ethinyloestradiol prior to 1 March 2022 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of ethinyloestradiol. | | | | |
| Tab 10 mcg | 17.60 | 100 | ✔ | **NZ Medical and Scientific** |
| *(NZ Medical and Scientific Tab 10 mcg to be delisted 1 February 2023)* | | | | |
| OESTRIOL | | | | |
| ❋ Tab 2 mg | 7.00 | 30 | ✔ | **Ovestin** |
| **Other Progestogen Preparations** | | | | |
| LEVONORGESTREL | | | | |
| ❋ Intra-uterine device 52 mg | 269.50 | 1 | ✔ | **Mirena** |
| ❋ Intra-uterine device 13.5 mg | 215.60 | 1 | ✔ | **Jaydess** |
| MEDROXYPROGESTERONE ACETATE | | | | |
| Tab 100 mg | 116.15 | 100 | ✔ | **Provera HD** |
| NORETHISTERONE | | | | |
| ❋ Tab 5 mg – Up to 30 tab available on a PSO | 5.49 | 30 | ✔ | **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:

continued…

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

continued…

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

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

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

Note: Indications marked with * are unapproved indications.

## Thyroid and Antithyroid Agents

| | | | | |
|---|---|---|---|---|
| CARBIMAZOLE | | | | |
| ✻ Tab 5 mg | 7.56 | 100 | ✔ | **Neo-Mercazole** |
| LEVOTHYROXINE | | | | |
| ✻ Tab 25 mcg | 5.55 | 90 | ✔ | **Synthroid** |
| ✻ Tab 50 mcg | 1.71 | 28 | ✔ | **Mercury Pharma** |
| | 5.79 | 90 | ✔ | **Synthroid** |
| | 64.28 | 1,000 | ✔ | **Eltroxin** |
| ✻ Tab 100 mcg | 1.78 | 28 | ✔ | **Mercury Pharma** |
| | 6.01 | 90 | ✔ | **Synthroid** |
| | 66.78 | 1,000 | ✔ | **Eltroxin** |
| PROPYLTHIOURACIL – Special Authority see SA1199 below – Retail pharmacy | | | | |
| Tab 50 mg | 35.00 | 100 | ✔ | **PTU** S29 |

➽**SA1199** **Special Authority for Subsidy**

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

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

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

## Trophic Hormones

### Growth Hormones

| | | | | |
|---|---|---|---|---|
| SOMATROPIN (OMNITROPE) – Special Authority see SA2032 below – Retail pharmacy | | | | |
| ✻ Inj 5 mg cartridge | 69.75 | 1 | ✔ | **Omnitrope** |
| ✻ Inj 10 mg cartridge | 69.75 | 1 | ✔ | **Omnitrope** |
| ✻ Inj 15 mg cartridge | 139.50 | 1 | ✔ | **Omnitrope** |

➽**SA2032** **Special Authority for Subsidy**

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

continued…

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

continued…

Either:

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

2 All of the following:

2.1 Height velocity < 25th percentile for age adjusted for bone age/pubertal status if appropriate over 6 or 12 months using the standards of Tanner and Davies (1985); and

2.2 A current bone age is < 14 years (female patients) or < 16 years (male patients); and

2.3 Peak growth hormone value of < 5.0 mcg per litre in response to two different growth hormone stimulation tests. In children who are 5 years or older, GH testing with sex steroid priming is required; and

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

2.5 Appropriate imaging of the pituitary gland has been obtained.

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

All of the following:

1 A current bone age is 14 years or under (female patients) or 16 years or under (male patients); and

2 Height velocity is greater than or equal to 25th percentile for age (adjusted for bone age/pubertal status if appropriate) while on growth hormone treatment, as calculated over six months using the standards of Tanner and Davis (1985); and

3 Height velocity is greater than or equal to 2.0 cm per year, as calculated over 6 months; and

4 No serious adverse effect that the patients specialist considers is likely to be attributable to growth hormone treatment has occurred; and

5 No malignancy has developed since starting growth hormone.

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

All of the following:

1 The patient has a post-natal genotype confirming Turner Syndrome; and

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

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

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

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

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

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

**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:

continued…

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

continued…

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

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

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

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

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.

continued…

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

continued…

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

Any of the following:

1 All of the following:
- 1.1 The patient has been treated with somatropin for < 12 months; and
- 1.2 There has been an improvement in Quality of Life defined as a reduction of at least 8 points on the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA®) score from baseline; and
- 1.3 Serum IGF-I levels have been increased within ±1SD of the mean of the normal range for age and sex; and
- 1.4 The dose of somatropin has not exceeded 0.7 mg per day for male patients, or 1 mg per day for female patients; or

2 All of the following:
- 2.1 The patient has been treated with somatropin for more than 12 months; and
- 2.2 The patient has not had a deterioration in Quality of Life defined as a 6 point or greater increase from their lowest QoL-AGHDA® score on treatment (other than due to obvious external factors such as external stressors); and
- 2.3 Serum IGF-I levels have continued to be maintained within ±1SD of the mean of the normal range for age and sex (other than for obvious external factors); and
- 2.4 The dose of somatropin has not exceeded 0.7 mg per day for male patients or 1 mg per day for female patients; or

3 All of the following:
- 3.1 The patient has had a Special Authority approval for somatropin for childhood deficiency in children and no longer meets the renewal criteria under this indication; and
- 3.2 The patient has undergone appropriate treatment of other hormonal deficiencies and psychological illnesses; and
- 3.3 The patient has severe growth hormone deficiency (see notes); and
- 3.4 The patient's serum IGF-I is more than 1 standard deviation below the mean for age and sex; and
- 3.5 The patient has poor quality of life, as defined by a score of 16 or more using the disease-specific quality of life questionnaire for adult growth hormone deficiency (QoL-AGHDA®).

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

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

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

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

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

## GnRH Analogues

GOSERELIN

| | | | | |
|---|---|---|---|---|
| Implant 3.6 mg, syringe | 65.68 | 1 | ✔ | **Teva** |
| Implant 10.8 mg, syringe | 122.37 | 1 | ✔ | **Teva** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| 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 | | | | |
| Wafer 120 mcg | 47.00 | 30 | ✔ | **Minirin Melt** |
| DESMOPRESSIN ACETATE | | | | |
| Tab 100 mcg | 25.00 | 30 | ✔ | **Minirin** |
| Tab 200 mcg | 54.45 | 30 | ✔ | **Minirin** |
| ▲ Nasal spray 10 mcg per dose | 27.95 | 6 ml OP | ✔ | **Desmopressin-PH&T** |
| Inj 4 mcg per ml, 1 ml | 67.18 | 10 | ✔ | **Minirin** |

## Other Endocrine Agents

| | | | | |
|---|---|---|---|---|
| CABERGOLINE | | | | |
| Tab 0.5 mg – Maximum of 2 tab per prescription; can be waived by Special Authority see SA2070 below | 3.75 | 2 | ✔ | **Dostinex** |
| | 15.20 | 8 | ✔ | **Dostinex** |

**SA2070 Special Authority for Waiver of Rule**

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

Any of the following:

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

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

Note: Indication marked with * is an unapproved indication.

| | | | | |
|---|---|---|---|---|
| CLOMIFENE CITRATE | | | | |
| Tab 50 mg | 29.84 | 10 | ✔ | **Mylan Clomiphen** S29 |
| METYRAPONE | | | | |
| Cap 250 mg | 558.00 | 50 | ✔ | **Metopirone** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

| | 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 | 7.97 | 6 | ✔ | **Vermox** |
| Oral liq 100 mg per 5 ml | 2.18 | 15 ml | | |
| | (7.53) | | | Vermox |

PRAZIQUANTEL

| | | | | |
|---|---|---|---|---|
| Tab 600 mg | 68.00 | 8 | ✔ | **Biltricide** |

## Antibacterials

a) For topical antibacterials, refer to DERMATOLOGICALS, page 61
b) For anti-infective eye preparations, refer to SENSORY ORGANS, page 240

### Cephalosporins and Cephamycins

CEFACLOR MONOHYDRATE

| | | | | |
|---|---|---|---|---|
| Cap 250 mg | 24.70 | 100 | ✔ | **Ranbaxy-Cefaclor S29** S29 |
| | 25.85 | | ✔ | **Ranbaxy-Cefaclor** |
| Grans for oral liq 125 mg per 5 ml – Wastage claimable | 3.53 | 100 ml | ✔ | **Ranbaxy-Cefaclor S29** S29 |
| | 3.75 | | ✔ | **Ranbaxy-Cefaclor** |

*(Ranbaxy-Cefaclor S29* S29 *Cap 250 mg to be delisted 1 April 2023)*
*(Ranbaxy-Cefaclor S29* S29 *Grans for oral liq 125 mg per 5 ml to be delisted 1 April 2023)*

CEFALEXIN

| | | | | |
|---|---|---|---|---|
| Cap 250 mg | 3.85 | 20 | ✔ | **Cephalexin ABM** |
| Cap 500 mg | 5.85 | 20 | ✔ | **Cephalexin ABM** |
| Grans for oral liq 25 mg per ml – Wastage claimable | 7.88 | 100 ml | ✔ | **Flynn** |
| | 8.75 | | ✔ | **Cefalexin Sandoz** |
| Grans for oral liq 50 mg per ml – Wastage claimable | 10.38 | 100 ml | ✔ | **Flynn** |
| | 11.75 | | ✔ | **Cefalexin Sandoz** |

*(Cefalexin Sandoz Grans for oral liq 25 mg per ml to be delisted 1 January 2023)*
*(Cefalexin Sandoz Grans for oral liq 50 mg per ml to be delisted 1 January 2023)*

CEFAZOLIN – Subsidy by endorsement

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

| | | | | |
|---|---|---|---|---|
| Inj 500 mg vial | 3.39 | 5 | ✔ | **AFT** |
| Inj 1 g vial | 3.49 | 5 | ✔ | **AFT** |

▲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 |
|---|---|---|---|---|
| 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 | 0.79 | 1 | ✔ | **Ceftriaxone-AFT** |
| Inj 1 g vial | 3.59 | 5 | ✔ | **Ceftriaxone-AFT** |
| CEFUROXIME AXETIL – Subsidy by endorsement | | | | |
| Only if prescribed for prophylaxis of endocarditis and the prescription is endorsed accordingly. | | | | |
| Tab 250 mg | 45.93 | 50 | ✔ | **Zinnat** |
| *(Zinnat Tab 250 mg to be delisted 1 March 2024)* | | | | |

## Macrolides

| | | | | |
|---|---|---|---|---|
| AZITHROMYCIN – Maximum of 5 days treatment per prescription; can be waived by Special Authority see SA1683 below | | | | |
| A maximum of 24 months of azithromycin treatment for non-cystic fibrosis bronchiectasis will be subsidised on Special Authority. | | | | |
| Tab 250 mg | 8.19 | 30 | ✔ | **Apo-Azithromycin** |
| Tab 500 mg – Up to 8 tab available on a PSO | 2.57 | 2 | ✔ | **Zithromax** |
| Grans for oral liq 200 mg per 5 ml (40 mg per ml) – Wastage claimable | 16.97 | 15 ml | ✔ | **Zithromax** |

**SA1683 Special Authority for Waiver of Rule**

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

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

Note: Indications marked with * are unapproved indications.

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

1 For prophylaxis of exacerbations of non-cystic fibrosis bronchiectasis*; and
2 Patient is aged 18 and under; and
3 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

continued…

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

continued…

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 | 8.53 | 14 | ✔ | **Klacid** |
| 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:

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** |
| Erythrocin IV to be Principal Supply on 1 December 2022 | | | | |

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 | | | | |

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** |

*(Rulide D Tab disp 50 mg to be delisted 1 March 2023)*

| | 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<br>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<br>b) Up to 10 x the maximum PSO quantity for RFPP | | | | |
| Grans for oral liq 125 mg per 5 ml | 1.40 | 100 ml | ✔ | **Alphamox 125** |
| a) Up to 200 ml available on a PSO<br>b) Wastage claimable | | | | |
| Grans for oral liq 250 mg per 5 ml | 1.73 | 100 ml | ✔ | **Alphamox 250** |
| a) Up to 300 ml available on a PSO<br>b) Up to 10 x the maximum PSO quantity for RFPP<br>c) Wastage claimable | | | | |
| Inj 250 mg vial | 15.97 | 10 | ✔ | **Ibiamox** |
| Inj 500 mg vial | 17.43 | 10 | ✔ | **Ibiamox** |
| Inj 1 g vial – Up to 5 inj available on a PSO | 21.64 | 10 | ✔ | **Ibiamox** |
| AMOXICILLIN WITH CLAVULANIC ACID | | | | |
| Tab 500 mg with clavulanic acid 125 mg – Up to 30 tab available on a PSO | 0.89 | 10 | ✔ | **Curam Duo 500/125** |
| Grans for oral liq amoxicillin 25 mg with clavulanic acid 6.25 mg per ml | 6.50 | 100 ml | ✔ | **Augmentin** |
| a) Up to 200 ml available on a PSO<br>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 | 375.97 | 10 | ✔ | **Bicillin LA** |
| BENZYLPENICILLIN SODIUM [PENICILLIN G] | | | | |
| Inj 600 mg (1 million units) vial – Up to 5 inj available on a PSO | 11.09 | 10 | ✔ | **Sandoz** |
| FLUCLOXACILLIN | | | | |
| Cap 250 mg – Up to 30 cap available on a PSO | 15.79 | 250 | ✔ | **Flucloxacillin-AFT** |
| Cap 500 mg – Up to 30 cap available on a PSO | 52.99 | 500 | ✔ | **Flucloxacillin-AFT** |
| Grans for oral liq 25 mg per ml | 3.29 | 100 ml | ✔ | **AFT** |
| a) Up to 200 ml available on a PSO<br>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<br>b) Wastage claimable | | | | |
| Inj 250 mg vial | 17.56 | 10 | ✔ | **Flucloxin** |
| Inj 500 mg vial | 18.87 | 10 | ✔ | **Flucloxin** |
| Inj 1 g vial – Up to 5 inj available on a PSO | 5.70 | 5 | ✔ | **Flucil** |

| | 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 | 3.84 | 50 | ✔ | **Cilicaine VK** |
| Cap 500 mg | 6.86 | 50 | ✔ | **Cilicaine VK** |
| a) Up to 20 cap available on a PSO<br>b) Up to 2 x the maximum PSO quantity for RFPP | | | | |
| Grans for oral liq 125 mg per 5 ml | 3.40 | 100 ml | ✔ | **AFT** |
| a) Up to 200 ml available on a PSO<br>b) Wastage claimable | | | | |
| Grans for oral liq 250 mg per 5 ml | 4.24 | 100 ml | ✔ | **AFT** |
| a) Up to 300 ml available on a PSO<br>b) Up to 2 x the maximum PSO quantity for RFPP<br>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** |
| *(Cilicaine Inj 1.5 g in 3.4 ml syringe to be delisted 1 February 2023)* | | | | |

## 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 |

➽**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.

## Other Antibiotics

For topical antibiotics, refer to DERMATOLOGICALS, page 61

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 | 2.42 | 28 | ✔ | **Cipflox** |
| Tab 500 mg – Up to 5 tab available on a PSO | 3.40 | 28 | ✔ | **Cipflox** |
| Tab 750 mg | 5.95 | 28 | ✔ | **Cipflox** |

▲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 |
|---|---|---|---|---|
| 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 | 95.00 | 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 | 91.00 | 5 | ✔ | **Wockhardt** S29 |
| | 182.00 | 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 | 42.00 | 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

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

continued…

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

continued…

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 | 67.85 | 36 | ✔ | **Fucidin** |

SULFADIAZINE SODIUM – Special Authority see SA1331 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Tab 500 mg | 543.20 | 56 | ✔ | **Wockhardt** S29 |

➽**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<br>Only if prescribed for dialysis or cystic fibrosis patient and the prescription is endorsed accordingly. | 18.50 | 5 | ✔ | **Tobramycin Mylan** |
| Solution for inhalation 60 mg per ml, 5 ml – Subsidy by endorsement<br>a) Wastage claimable<br>b) Only if prescribed for a cystic fibrosis patient and the prescription is endorsed accordingly. | 395.00 | 56 dose | ✔ | **Tobramycin BNM** |

TRIMETHOPRIM

| | | | | |
|---|---|---|---|---|
| ✱ Tab 300 mg – Up to 30 tab available on a PSO | 18.55 | 50 | ✔ | **TMP** |

▲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 |
|---|---|---|---|---|
| TRIMETHOPRIM WITH SULPHAMETHOXAZOLE [CO-TRIMOXAZOLE] | | | | |
| ❋ Tab trimethoprim 80 mg and sulphamethoxazole 400 mg – Up to 30 tab available on a PSO | 64.80 | 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<br>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.<br>Inj 500 mg vial | 2.35 | 1 | ✔ | **Mylan** |

## Antifungals

a) For topical antifungals refer to DERMATOLOGICALS, page 62
b) For topical antifungals refer to GENITO URINARY, page 75

| | | | | |
|---|---|---|---|---|
| FLUCONAZOLE | | | | |
| Cap 50 mg | 2.75 | 28 | ✔ | **Dizole** |
| | | | ✔ | **Mylan** |
| Cap 150 mg | 0.65 | 1 | ✔ | **Mylan** |
| Cap 200 mg | 12.89 | 28 | ✔ | **Mylan** |
| Powder for oral suspension 10 mg per ml – Special Authority see SA1359 below – Retail pharmacy<br>Wastage claimable | 109.34 | 35 ml | ✔ | **Diflucan** |

**➽SA1359 Special Authority for Subsidy**

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

Both:

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

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

All of the following:

1 Patient is immunocompromised; and
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 on the next page – Retail pharmacy | 141.80 | 150 ml OP | ✔ | **Sporanox** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

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

**➽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 | 206.00 | 24 | ✔ | **Posaconazole Juno** |
| | 869.86 | | ✔ | **Noxafil** |
| Oral liq 40 mg per ml | 761.13 | 105 ml OP | ✔ | **Noxafil** |

*(Noxafil Tab modified-release 100 mg to be delisted 1 April 2023)*

**➽SA1285 Special Authority for Subsidy**

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

Either:

1 Patient has acute myeloid leukaemia and is to be treated with high dose remission induction, re-induction or consolidation chemotherapy; or

2 Patient has received a stem cell transplant and has graft versus host disease and is on significant immunosuppressive therapy*.

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

Either:

1 Patient has acute myeloid leukaemia and is to be treated with high dose remission induction, re-induction or consolidation therapy; or

2 Patient has received a stem cell transplant and has graft versus host disease and is on significant immunosuppression* and requires on going posaconazole treatment.

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

TERBINAFINE

| | | | | |
|---|---|---|---|---|
| ✱ Tab 250 mg | 8.15 | 84 | ✔ | **Deolate** |

VORICONAZOLE – Special Authority see SA1273 on the next page – 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 | 1,523.22 | 70 ml | ✔ | **Vfend** |

▲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 |
|---|---|---|---|---|

➽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 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Tab 15 mg | 400.00 | 100 | ✔ | **Sanofi Primaquine** S29 |

➽SA1684 **Special Authority for Subsidy**

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

Both:

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

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

Both:

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

## Antitrichomonal Agents

METRONIDAZOLE

| | | | | |
|---|---|---|---|---|
| Tab 200 mg – Up to 30 tab available on a PSO | 33.15 | 250 | ✔ | **Metrogyl** |
| Tab 400 mg – Up to 15 tab available on a PSO | 5.23 | 21 | ✔ | **Metrogyl** |
| Oral liq benzoate 200 mg per 5 ml | 25.00 | 100 ml | ✔ | **Flagyl-S** |
| Suppos 500 mg | 24.48 | 10 | ✔ | **Flagyl** |

ORNIDAZOLE

| | | | | |
|---|---|---|---|---|
| Tab 500 mg | 36.16 | 10 | ✔ | **Arrow-Ornidazole** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

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

## 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 |

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 | 23.00 | 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 | 89.82 | 100 | ✔ **Rifinah** |
| ❋ | Tab 150 mg with rifampicin 300 mg | 179.13 | 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 |

▲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 |
|---|---|---|---|---|
| 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 | 64.95 | 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** |
| 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 | 58.54 | 100 | ✔ | **Rifadin** |
| ❋ Cap 300 mg | 122.06 | 100 | ✔ | **Rifadin** |
| ❋ Oral liq 100 mg per 5 ml | 12.60 | 60 ml | ✔ | **Rifadin** |

## Antivirals

For eye preparations refer to Eye Preparations, Anti-Infective Preparations, page 240

### Hepatitis B Treatment

| | | | | |
|---|---|---|---|---|
| ENTECAVIR | | | | |
| ❋ Tab 0.5 mg | 52.00 | 30 | ✔ | **Entecavir Sandoz** |
| LAMIVUDINE – Special Authority see SA1685 below – Retail pharmacy | | | | |
| Tab 100 mg | 6.95 | 28 | ✔ | **Zetlam** |
| Oral liq 5 mg per ml | 270.00 | 240 ml OP | ✔ | **Zeffix** |

➽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 SA2139., page 103 | | | | |
| ❋ Tab 245 mg (300 mg as a maleate) | 15.00 | 30 | ✔ | **Tenofovir Disoproxil Mylan** |
| Tenofovir Disoproxil Mylan to be Principal Supply on 1 December 2022 | | | | |
| ❋ Tab 245 mg (300.6 mg as a succinate) | 38.10 | 30 | ✔ | **Tenofovir Disoproxil Teva** |

*(Tenofovir Disoproxil Teva Tab 245 mg (300.6 mg as a succinate) to be delisted 1 December 2022)*

### Herpesvirus Treatments

| | | | | |
|---|---|---|---|---|
| ACICLOVIR | | | | |
| ❋ Tab dispersible 200 mg | 1.78 | 25 | ✔ | **Lovir** |
| ❋ Tab dispersible 400 mg | 5.81 | 56 | ✔ | **Lovir** |
| ❋ Tab dispersible 800 mg | 6.46 | 35 | ✔ | **Lovir** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| VALACICLOVIR | | | | |
| Tab 500 mg | 6.50 | 30 | ✔ | Vaclovir |
| Tab 1,000 mg | 13.76 | 30 | ✔ | Vaclovir |
| VALGANCICLOVIR – Special Authority see SA1993 below – Retail pharmacy | | | | |
| Tab 450 mg | 132.00 | 60 | ✔ | Valganciclovir Mylan |

**➽SA1993 Special Authority for Subsidy**

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

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

Either:

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

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

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

Both:

1 Patient has undergone a solid organ transplant and received valganciclovir under Special Authority more than 2 years ago (27 months); and

2 Patient has received anti-thymocyte globulin and requires valganciclovir for CMV prophylaxis.

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

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

All of the following:

1 Patient has undergone a lung transplant; and

2 Either:
- 2.1 The donor was cytomegalovirus positive and the patient is cytomegalovirus negative; or
- 2.2 The recipient is cytomegalovirus positive; and

3 Patient has a high risk of CMV disease.

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

Both:

1 Patient is immunocompromised; and

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

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

Both:

continued…

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

continued…

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

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

## Hepatitis C Treatment

GLECAPREVIR WITH PIBRENTASVIR – [Xpharm]

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

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

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

No patient co-payment payable

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

➽**SA1605** **Special Authority for Subsidy**

Special Authority approved by the Hepatitis C Treatment Panel (HepCTP)
Notes: By application to the Hepatitis C Treatment Panel (HepCTP).
Applications will be considered by HepCTP and approved subject to confirmation of eligibility.
Application details may be obtained from Pharmac's website http://www.pharmac.govt.nz/maviret or:
The Coordinator, Hepatitis C Treatment Panel
Pharmac, PO Box 10-254, WELLINGTON Tel: (04) 460 4990,
Email: hepcpanel@pharmac.govt.nz

## HIV Prophylaxis and Treatment

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

a) Funding for emtricitabine with tenofovir disoproxil for use as PrEP, should be applied using Special Authority SA2138.
b) Endorsement for treatment of conditions approved via Special Authority SA2139 (antiretrovirals for confirmed HIV, prevention of maternal transmission, post-exposure prophylaxis following exposure to HIV and percutaneous exposure): Prescription is deemed to be endorsed if emtricitabine with tenofovir disoproxil is co-prescribed with another antiretroviral subsidised under Special Authority SA2139 and the prescription is annotated accordingly by the Pharmacist or endorsed by the prescriber.
Note: Emtricitabine with tenofovir disoproxil prescribed under endorsement, for treatment of conditions approved via Special Authority SA2139 (antiretrovirals for confirmed HIV, prevention of maternal transmission, post-exposure prophylaxis following exposure to HIV and percutaneous exposure), is included in the count of up to 4 subsidised antiretrovirals, and counts as two antiretroviral medications, for the purposes of Special Authority SA2139, page 103
There is an approval process to become a named specialist to prescribe antiretroviral therapy in New Zealand. Further information is available on the Pharmac website.

✻ Tab 200 mg with tenofovir disoproxil 245 mg (300 mg as a maleate)..... 15.45 30 ✔ **Tenofovir Disoproxil Emtricitabine Mylan**

Tenofovir Disoproxil Emtricitabine Mylan to be Principal Supply on 1 December 2022

✻ Tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a succinate) ..... 61.15 30 ✔ **Teva**

*(Teva Tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a succinate) to be delisted 1 December 2022)*

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

➽SA2138 **Special Authority for Subsidy**
**Initial application** from any relevant practitioner. Approvals valid for 24 months for applications meeting the following criteria:
Both:

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

Notes: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines:
https://ashm.org.au/HIV/PrEP/
**Renewal** from any relevant practitioner. Approvals valid for 24 months for applications meeting the following criteria:
Both:

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

Notes: Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines:
https://ashm.org.au/HIV/PrEP/

## COVID-19 Treatments

MOLNUPIRAVIR – [Xpharm] – Subsidy by endorsement

a) No patient co-payment payable
b) Treatment is funded only if patient meets access criteria for oral antiviral COVID-19 treatments (as on Pharmac's website) and has been endorsed accordingly by the prescriber. The supply of treatment is via Pharmac's approved distribution process. Refer to the Pharmac website for more information about this and stock availability.

| | | | | |
|---|---|---|---|---|
| Cap 200 mg | 0.00 | 40 | ✔ | **Lagevrio** |

NIRMATRELVIR WITH RITONAVIR – [Xpharm] – Subsidy by endorsement

a) No patient co-payment payable
b) Treatment is funded only if patient meets access criteria for oral antiviral COVID-19 treatments (as on Pharmac's website) and has been endorsed accordingly by the prescriber. The supply of treatment is via Pharmac's approved distribution process. Refer to the Pharmac website for more information about this and stock availability.

| | | | | |
|---|---|---|---|---|
| Tab 150 mg with ritonavir 100 mg | 0.00 | 30 | ✔ | **Paxlovid** |

## Antiretrovirals

➽SA2139 **Special Authority for Subsidy**
**Initial application — (Confirmed HIV)** only from a named specialist. Approvals valid without further renewal unless notified where the patient has confirmed HIV infection.
Notes: Tenofovir disoproxil prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals. Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.
**Renewal — (Confirmed HIV)** only from a named specialist. Approvals valid without further renewal unless notified where the treatment remains appropriate and the patient is benefiting from treatment.
**Initial application — (Prevention of maternal transmission)** only from a named specialist. Approvals valid for 1 year for applications meeting the following criteria:
Either:

continued…

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

continued…

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

Notes: Tenofovir disoproxil prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals. Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.
Some antiretrovirals are unapproved or contraindicated for this indication. Practitioners prescribing these medications should exercise their own skill, judgement, expertise and discretion, and make their own prescribing decisions with respect to the use of a Pharmaceutical for an indication for which it is not approved or contraindicated.
**Initial application — (post-exposure prophylaxis following exposure to HIV)** from any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria:
Both:

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

Notes: Tenofovir disoproxil prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals. Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.
Refer to local health pathways or the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine clinical guidelines for PEP (https://www.ashm.org.au/hiv/hiv-management/pep/).
**Renewal — (second or subsequent post-exposure prophylaxis)** from any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria:
Both:

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

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

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| **Non-nucleosides Reverse Transcriptase Inhibitors** | | | | |
| EFAVIRENZ – Special Authority see SA2139 on page 103 – Retail pharmacy | | | | |
| Tab 200 mg | 190.15 | 90 | ✔ | **Stocrin** |
| Tab 600 mg | 63.38 | 30 | ✔ | **Stocrin** |
| ETRAVIRINE – Special Authority see SA2139 on page 103 – Retail pharmacy | | | | |
| Tab 200 mg | 770.00 | 60 | ✔ | **Intelence** |
| NEVIRAPINE – Special Authority see SA2139 on page 103 – Retail pharmacy | | | | |
| Tab 200 mg | 84.00 | 60 | ✔ | **Nevirapine Alphapharm** |
| Oral suspension 10 mg per ml | 203.55 | 240 ml OP | ✔ | **Viramune Suspension** |
| **Nucleosides Reverse Transcriptase Inhibitors** | | | | |
| ABACAVIR SULPHATE – Special Authority see SA2139 on page 103 – 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 SA2139 on page 103 – 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 SA2139 on page 103 – 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 SA2139 on page 103 – Retail pharmacy | | | | |
| Cap 200 mg | 307.20 | 30 | ✔ | **Emtriva** |
| LAMIVUDINE – Special Authority see SA2139 on page 103 – Retail pharmacy | | | | |
| Tab 150 mg | 84.50 | 60 | ✔ | **Lamivudine Alphapharm** |
| Oral liq 10 mg per ml | 102.50 | 240 ml OP | ✔ | **3TC** |
| ZIDOVUDINE [AZT] – Special Authority see SA2139 on page 103 – 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 SA2139 on page 103 – Retail pharmacy | | | | |
| Note: zidovudine [AZT] with lamivudine (combination tablets) counts as two anti-retroviral medications for the purposes of the anti-retroviral Special Authority. | | | | |
| Tab 300 mg with lamivudine 150 mg | 33.00 | 60 | ✔ | **Alphapharm** |
| **Protease Inhibitors** | | | | |
| ATAZANAVIR SULPHATE – Special Authority see SA2139 on page 103 – Retail pharmacy | | | | |
| Cap 150 mg | 141.68 | 60 | ✔ | **Teva** |
| Cap 200 mg | 188.91 | 60 | ✔ | **Teva** |

▲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 |
|---|---|---|---|---|
| DARUNAVIR – Special Authority see SA2139 on page 103 – Retail pharmacy | | | | |
| Tab 400 mg | 132.00 | 60 | ✔ | **Darunavir Mylan** |
| Tab 600 mg | 196.65 | 60 | ✔ | **Darunavir Mylan** |
| | | | ✔ | **Darunavir Viatris** |
| LOPINAVIR WITH RITONAVIR – Special Authority see SA2139 on page 103 – Retail pharmacy | | | | |
| Tab 100 mg with ritonavir 25 mg | 150.00 | 60 | ✔ | **Lopinavir/Ritonavir Mylan** |
| Tab 200 mg with ritonavir 50 mg | 295.00 | 120 | ✔ | **Lopinavir/Ritonavir Mylan** |
| Oral liq 80 mg with ritonavir 20 mg per ml | 735.00 | 300 ml OP | ✔ | **Kaletra** |
| RITONAVIR – Special Authority see SA2139 on page 103 – Retail pharmacy | | | | |
| Tab 100 mg | 43.31 | 30 | ✔ | **Norvir** |

## Strand Transfer Inhibitors

| | | | | |
|---|---|---|---|---|
| DOLUTEGRAVIR – Special Authority see SA2139 on page 103 – Retail pharmacy | | | | |
| Tab 50 mg | 1,090.00 | 30 | ✔ | **Tivicay** |
| RALTEGRAVIR POTASSIUM – Special Authority see SA2139 on page 103 – Retail pharmacy | | | | |
| Tab 400 mg | 1,090.00 | 60 | ✔ | **Isentress** |
| Tab 600 mg | 1,090.00 | 60 | ✔ | **Isentress HD** |

## Immune Modulators

| | | | | |
|---|---|---|---|---|
| PEGYLATED INTERFERON ALFA-2A – Special Authority see SA2034 below – Retail pharmacy | | | | |
| Note: Pharmac will consider funding ribavirin for the small group of patients who have a clinical need for ribavirin and meet Special Authority criteria. Please contact the Hepatitis C Coordinator at Pharmac on 0800-023-588 option 4. | | | | |
| Inj 180 mcg prefilled syringe | 500.00 | 4 | ✔ | **Pegasys** |

**SA2034 Special Authority for Subsidy**

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

Both:

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

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

All of the following:

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

continued…

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

continued…
following criteria:
All of the following:

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

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

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

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

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

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

1 Patient has a cutaneous T cell lymphoma*; or
2 All of the following:
  2.1 Patient has a myeloproliferative disorder*; and
  2.2 Patient is intolerant of hydroxyurea; and
  2.3 Treatment with anagrelide and busulfan is not clinically appropriate; or
3 Both:
  3.1 Patient has a myeloproliferative disorder; and
  3.2 Patient is pregnant, planning pregnancy or lactating.

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

1 No evidence of disease progression; and

continued…

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

continued…

2 The treatment remains appropriate and patient is benefitting from treatment; and
3 Either:
3.1 Patient has a cutaneous T cell lymphoma*; or
3.2 Both:
3.2.1 Patient has a myeloproliferative disorder*; and
3.2.2 Either:
3.2.2.1 Remains intolerant of hydroxyurea and treatment with anagrelide and busulfan remains clinically inappropriate; or
3.2.2.2 Patient is pregnant, planning pregnancy or lactating.

Note: Indications marked with * are unapproved indications.

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

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

Note: Indications marked with * are unapproved indications.

## Urinary Tract Infections

METHENAMINE (HEXAMINE) HIPPURATE

❋ Tab 1 g ..... 19.95 100 ✔ **Hiprex**

NITROFURANTOIN

❋ Tab 50 mg – Up to 30 tab available on a PSO ..... 22.20 100 ✔ **Nifuran**
Nifuran to be Principal Supply on 1 December 2022

❋ Tab 100 mg ..... 37.50 100 ✔ **Nifuran**
Nifuran to be Principal Supply on 1 December 2022

❋ Cap modified-release 100 mg – Up to 15 cap available on a PSO ..... 86.40 100 ✔ **Macrobid**

NORFLOXACIN

Tab 400 mg – Subsidy by endorsement ..... 245.00 100 ✔ **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 | 33.81 | 10 | ✔ | **Max Health** |
| PYRIDOSTIGMINE BROMIDE | | | | |
| ▲ Tab 60 mg | 45.79 | 100 | ✔ | **Mestinon** |
| **Non-Steroidal Anti-Inflammatory Drugs** | | | | |
| DICLOFENAC SODIUM | | | | |
| ✻ Tab EC 25 mg | 1.99 | 50 | ✔ | **Diclofenac Sandoz** |
| ✻ Tab 50 mg dispersible | 1.50 | 20 | ✔ | **Voltaren D** |
| ✻ Tab EC 50 mg | 1.99 | 50 | ✔ | **Diclofenac Sandoz** |
| ✻ Tab long-acting 75 mg | 19.60 | 100 | ✔ | **Voltaren SR** |
| ✻ Inj 25 mg per ml, 3 ml ampoule – Up to 5 inj available on a 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 | 21.40 | 1,000 | ✔ | **Relieve** |
| ✻ Tab long-acting 800 mg | 3.05 | 30 | ✔ | **Brufen SR** |
| ✻ Oral liq 20 mg per ml | 2.25 | 200 ml | ✔ | **Ethics** |
| | 11.29 | | ✔ | **Fenpaed 100 mg per 5 ml** |
| 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 | | |
| | (7.50) | | | Ponstan |
| NAPROXEN | | | | |
| ✻ Tab 250 mg | 32.69 | 500 | ✔ | **Noflam 250** |
| ✻ Tab 500 mg | 28.71 | 250 | ✔ | **Noflam 500** |
| ✻ Tab long-acting 750 mg | 6.47 | 28 | ✔ | **Naprosyn SR 750** |
| ✻ Tab long-acting 1 g | 8.62 | 28 | ✔ | **Naprosyn SR 1000** |
| TENOXICAM | | | | |
| ✻ Tab 20 mg | 18.50 | 100 | ✔ | **Tilcotil** |
| ✻ Inj 20 mg vial | 9.95 | 1 | ✔ | **AFT** |
| **NSAIDs Other** | | | | |
| CELECOXIB | | | | |
| Cap 100 mg | 3.45 | 60 | ✔ | **Celebrex** |
| | | | ✔ | **Celecoxib Pfizer** |
| Cap 200 mg | 3.20 | 30 | ✔ | **Celebrex** |
| | | | ✔ | **Celecoxib Pfizer** |

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

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

## Topical Products for Joint and Muscular Pain

CAPSAICIN

Crm 0.025% – Special Authority see SA1289 below – Retail pharmacy ..... 9.75 — 45 g OP — ✔ **Zostrix**

**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

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)*, sarcoidosis (pulmonary and non-pulmonary)*, 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 ..... 8.78 — 100 — ✔ **Plaquenil**

LEFLUNOMIDE

Tab 10 mg ..... 6.00 — 30 — ✔ **Arava**

Tab 20 mg ..... 6.00 — 30 — ✔ **Arava**

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 below – Retail pharmacy

Inj 60 mg prefilled syringe ..... 326.00 — 1 — ✔ **Prolia**

**SA1777 Special Authority for Subsidy**

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

All of the following:

1 The patient has severe, established osteoporosis; and

2 Either:

2.1 The patient is female and postmenopausal; or

2.2 The patient is male or non-binary; and

3 Any of the following:

3.1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density

continued…

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

continued…

(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 | 27.53 | 1 | ✔ | **Pamisol** |
| Inj 6 mg per ml, 10 ml vial | 74.67 | 1 | ✔ | **Pamisol** |
| Inj 9 mg per ml, 10 ml vial | 79.95 | 1 | ✔ | **Pamisol** |

RALOXIFENE HYDROCHLORIDE – Special Authority see SA1779 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| ✻ Tab 60 mg | 53.76 | 28 | ✔ | **Evista** |

➽**SA1779** **Special Authority for Subsidy**

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

Any of the following:

1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) greater than or equal to 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -2.5) (see Notes); or

continued…

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

continued…

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 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.

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| ZOLEDRONIC ACID | | | | |
| Inj 0.05 mg per ml, 100 ml, vial – Special Authority see SA2110 below – Retail pharmacy | 60.00 | 100 ml OP | ✔ | **Aclasta** |

**➽SA2110 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

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:

continued…

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

continued…

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.

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

All of the following:

1 Patient has experienced an acute traumatic spinal cord injury in the last six months; and
2 Patient is being managed by a specialist spinal acute care and rehabilitation unit; and
3 The patient will not be prescribed more than 5 mg of zoledronic acid in a 12-month period.

Note: Indications marked with * are unapproved indications.

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

Both:

1 The patient will not be prescribed more than 5 mg of zoledronic acid in a 12-month period; and
2 The patient has not received more than two doses of zoledronic acid for this indication.

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

Notes: No further renewals will be subsidised. A maximum of 2 vials of zoledronic acid treatment for spinal cord injury will be subsidised. Indications marked with * are unapproved indications.

a) BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA).

continued…

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

continued…

Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.

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

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

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

## Hyperuricaemia and Antigout

| | | | | |
|---|---|---|---|---|
| ALLOPURINOL | | | | |
| ✻ Tab 100 mg | 11.47 | 500 | ✔ | **DP-Allopurinol** |
| ✻ Tab 300 mg | 28.57 | 500 | ✔ | **DP-Allopurinol** |
| BENZBROMARONE – Special Authority see SA1963 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 |

**➽SA1963 Special Authority for Subsidy**

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

Both:

1 The treatment remains appropriate and the patient is benefitting from the treatment; and

2 There is no evidence of liver toxicity and patient is continuing to receive regular (at least every three months) liver function tests.

| | | | | |
|---|---|---|---|---|
| COLCHICINE | | | | |
| ✻ Tab 500 mcg | 6.00 | 100 | ✔ | **Colgout** |
| FEBUXOSTAT – Special Authority see SA2054 below – Retail pharmacy | | | | |
| Tab 80 mg | 20.00 | 28 | ✔ | **Febuxostat multichem** |
| Tab 120 mg | 20.00 | 28 | ✔ | **Febuxostat multichem** |

**➽SA2054 Special Authority for Subsidy**

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

Both:

1 Patient has been diagnosed with gout; and

2 Any of the following:

2.1 The patient has a serum urate level greater than 0.36 mmol/l despite treatment with allopurinol at doses of at least 600 mg/day and addition of probenecid at doses of up to 2 g per day or maximum tolerated dose; or

2.2 The patient has experienced intolerable side effects from allopurinol such that treatment discontinuation is required

continued…

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

continued…

and serum urate remains greater than 0.36 mmol/l despite use of probenecid at doses of up to 2 g per day or maximum tolerated dose; or

2.3 The patient has renal impairment such that probenecid is contraindicated or likely to be ineffective and serum urate remains greater than 0.36 mmol/l despite optimal treatment with allopurinol (see Note); or

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

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

Both:

1 Patient is scheduled to receive cancer therapy carrying an intermediate or high risk of tumour lysis syndrome; and

2 Patient has a documented history of allopurinol intolerance.

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

**Renewal — (Tumour lysis syndrome)** only from a haematologist or oncologist. Approvals valid for 6 weeks where the treatment remains appropriate and the patient is benefitting from treatment.

PROBENECID

| | | | | |
|---|---|---|---|---|
| ❋ | Tab 500 mg ..... 66.95 | 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..... 306.82 | 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 ..... 20.76 | 100 | ✔ | **Norflex** |



✔ **fully subsidised**

**Principal Supply**

S29 Unapproved medicine supplied under Section 29

**Sole Subsidised Supply**

| | 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**
63.73 — 100 — ✔ **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**

ENTACAPONE

▲ Tab 200 mg ..... 18.04 — 100 — ✔ **Comtan**

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 ..... 21.11 — 100 — ✔ **Sinemet**
✻ Tab long-acting 200 mg with carbidopa 50 mg ..... 43.65 — 100 — ✔ **Sinemet CR**
✻ Tab 250 mg with carbidopa 25 mg ..... 38.39 — 100 — ✔ **Sinemet**

PRAMIPEXOLE HYDROCHLORIDE

▲ Tab 0.25 mg ..... 5.51 — 100 — ✔ **Ramipex**
Ramipex to be Principal Supply on 1 December 2022
▲ Tab 1 mg ..... 18.66 — 100 — ✔ **Ramipex**
Ramipex to be Principal Supply on 1 December 2022

RASAGILINE

✻ Tab 1 mg ..... 53.50 — 30 — ✔ **Azilect** S29

ROPINIROLE HYDROCHLORIDE

▲ Tab 0.25 mg ..... 3.39 — 100 — ✔ **Mylan** S29
4.05 — 84 — ✔ **Ropin**
▲ Tab 1 mg ..... 4.70 — 100 — ✔ **Mylan** S29
4.95 — 84 — ✔ **Ropin**
▲ Tab 2 mg ..... 6.48 — 84 — ✔ **Ropin**
▲ Tab 5 mg ..... 14.50 — 84 — ✔ **Ropin**

*(Mylan S29 Tab 0.25 mg to be delisted 1 January 2023)*
*(Mylan S29 Tab 1 mg to be delisted 1 December 2022)*

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

✻ Tab 5 mg ..... 48.00 — 100 — ✔ **Eldepryl** S29

TOLCAPONE

▲ Tab 100 mg ..... 152.38 — 100 — ✔ **Tasmar**

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

## Anticholinergics

BENZATROPINE MESYLATE

Tab 2 mg ..... 9.59 — 60 — ✔ **Benztrop**

Inj 1 mg per ml, 2 ml ..... 95.00 — 5 — ✔ **Phebra**

a) Up to 10 inj available on a PSO

b) Only on a PSO

PROCYCLIDINE HYDROCHLORIDE

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 ..... 106.59 — 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 ..... 59.50 — 10 — ✔ **Instillagel Lido**

a) Up to 5 each available on a PSO

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

| | 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 | 9.50 | 25 | ✔ | **Lidocaine-Baxter** |
| | 17.50 | 50 | | |
| | (35.00) | | | Xylocaine |
| Inj 2%, 5 ml ampoule – Up to 5 inj available on a PSO | 8.25 | 25 | ✔ | **Lidocaine-Baxter** |
| Inj 1%, 20 ml ampoule – Up to 5 inj available on a PSO | 12.00 | 5 | | |
| | (20.00) | | | Xylocaine |
| Inj 1%, 20 ml vial – Up to 5 inj available on a PSO | 6.20 | 5 | ✔ | **Lidocaine-Baxter** |
| | | | ✔ | **Lidocaine-Claris** |
| Inj 2%, 20 ml vial – Up to 5 inj available on a PSO | 6.45 | 5 | ✔ | **Lidocaine-Baxter** |
| LIDOCAINE [LIGNOCAINE] WITH CHLORHEXIDINE | | | | |
| Gel 2% with chlorhexidine 0.05%, 10 ml urethral syringes – Subsidy by endorsement | 103.32 | 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 109

## Non-opioid Analgesics

| | | | | |
|---|---|---|---|---|
| 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% | 11.95 | 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 | 19.75 | 1,000 | ✔ | **Pacimol** |

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 | 17.92 | 1,000 | ✔ | **Noumed Paracetamol** |

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 | 5.45 | 1,000 ml | ✔ | **Paracare** |
| | 10.50 | 200 ml OP | ✔ | **Avallon** |

a) Maximum of 600 ml per prescription; can be waived by endorsement
b) Up to 200 ml available on a PSO
c) Not in combination
d)
1) Maximum of 200 ml per dispensing for non-endorsed patients. If quantities prescribed exceed 200 ml (for non-endorsed patients), then dispense in repeat dispensing not exceeding 200 ml per dispensing.
2) 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 endorsed or annotated accordingly. Pharmacists may annotate the prescription as endorsed where dispensing history supports a long-term condition.

| | | | | |
|---|---|---|---|---|
| Oral liq 240 mg per 5 ml | 11.92 | 200 ml OP | ✔ | **Avallon** S29 |

a) Maximum of 600 ml per prescription; can be waived by endorsement
b) Up to 200 ml available on a PSO
c) Not in combination
d)
1) Maximum of 200 ml per dispensing for non-endorsed patients. If quantities prescribed exceed 200 ml (for non-endorsed patients), then dispense in repeat dispensing not exceeding 200 ml per dispensing.
2) 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 endorsed or annotated accordingly. Pharmacists may annotate the prescription as endorsed where dispensing history supports a long-term condition.

| | | | | |
|---|---|---|---|---|
| Oral liq 250 mg per 5 ml | 3.35 | 200 ml | ✔ | **Pamol** |
| | 6.25 | 1,000 ml | ✔ | **Paracare Double Strength** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

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

a) Maximum of 600 ml per prescription; can be waived by endorsement
b) Up to 100 ml available on a PSO
c) Not in combination
d)
1) Maximum of 200 ml per dispensing for non-endorsed patients. If quantities prescribed exceed 200 ml (for non-endorsed patients), then dispense in repeat dispensing not exceeding 200 ml per dispensing.
2) 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 endorsed or annotated accordingly. Pharmacists may annotate the prescription as endorsed where dispensing history supports a long-term condition.

| | | | | |
|---|---|---|---|---|
| ❋ | Suppos 125 mg | 3.59 | 10 | ✔ **Gacet** |
| ❋ | Suppos 250 mg | 4.18 | 10 | ✔ **Gacet** |
| ❋ | Suppos 500 mg | 12.40 | 50 | ✔ **Gacet** |

*(Paracare Double Strength Oral liq 250 mg per 5 ml to be delisted 1 April 2023)*

## Opioid Analgesics

CODEINE PHOSPHATE – Safety medicine; prescriber may determine dispensing frequency

| | | | |
|---|---|---|---|
| Tab 15 mg | 6.25 | 100 | ✔ **PSM** |
| Tab 30 mg | 6.98 | 100 | ✔ **Aspen** |
| | | | ✔ **Noumed** |
| | 7.45 | | ✔ **PSM** |
| Tab 60 mg | 13.89 | 100 | ✔ **Noumed** |
| | 14.25 | | ✔ **PSM** |

*(PSM Tab 30 mg to be delisted 1 April 2023)*
*(PSM Tab 60 mg to be delisted 1 April 2023)*

DIHYDROCODEINE TARTRATE

| | | | |
|---|---|---|---|
| Tab long-acting 60 mg | 8.60 | 60 | ✔ **DHC Continus** |

DHC Continus to be Principal Supply on 1 December 2022

FENTANYL

a) Only on a controlled drug form
b) No patient co-payment payable
c) Safety medicine; prescriber may determine dispensing frequency

| | | | |
|---|---|---|---|
| Inj 50 mcg per ml, 2 ml ampoule | 3.75 | 10 | ✔ **Boucher and Muir** |
| Inj 50 mcg per ml, 10 ml ampoule | 9.41 | 10 | ✔ **Boucher and Muir** |
| Patch 12.5 mcg per hour | 6.99 | 5 | ✔ **Fentanyl Sandoz** |
| Patch 25 mcg per hour | 7.99 | 5 | ✔ **Fentanyl Sandoz** |
| Patch 50 mcg per hour | 9.49 | 5 | ✔ **Fentanyl Sandoz** |
| Patch 75 mcg per hour | 17.99 | 5 | ✔ **Fentanyl Sandoz** |
| Patch 100 mcg per hour | 18.59 | 5 | ✔ **Fentanyl Sandoz** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| METHADONE HYDROCHLORIDE | | | | |
| a) Only on a controlled drug form | | | | |
| b) No patient co-payment payable | | | | |
| c) Safety medicine; prescriber may determine dispensing frequency | | | | |
| d) Extemporaneously compounded methadone will only be reimbursed at the rate of the cheapest form available (methadone powder, not methadone tablets). | | | | |
| e) For methadone hydrochloride oral liquid refer Standard Formulae, page 247 | | | | |
| Tab 5 mg | 1.40 | 10 | ✔ | **Methatabs** |
| | 1.45 | | ✔ | **Methadone BNM** |
| Oral liq 2 mg per ml | 6.40 | 200 ml | ✔ | **Biodone** |
| Oral liq 5 mg per ml | 6.40 | 200 ml | ✔ | **Biodone Forte** |
| Oral liq 10 mg per ml | 7.50 | 200 ml | ✔ | **Biodone Extra Forte** |
| Inj 10 mg per ml, 1 ml | 68.90 | 10 | ✔ | **AFT** |
| *(Methatabs Tab 5 mg to be delisted 1 February 2023)* | | | | |
| 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 | 11.98 | 200 ml | ✔ | **RA-Morph** |
| Oral liq 2 mg per ml | 16.24 | 200 ml | ✔ | **RA-Morph** |
| Oral liq 5 mg per ml | 19.44 | 200 ml | ✔ | **Ordine** S29 |
| | | | ✔ | **RA-Morph** |
| Oral liq 10 mg per ml | 27.74 | 200 ml | ✔ | **Ordine** S29 |
| | | | ✔ | **RA-Morph** |
| MORPHINE SULPHATE | | | | |
| a) Only on a controlled drug form | | | | |
| b) No patient co-payment payable | | | | |
| c) Safety medicine; prescriber may determine dispensing frequency | | | | |
| Tab immediate-release 10 mg | 2.80 | 10 | ✔ | **Sevredol** |
| Tab immediate-release 20 mg | 5.52 | 10 | ✔ | **Sevredol** |
| Cap long-acting 10 mg | 3.00 | 10 | ✔ | **m-Eslon** |
| Cap long-acting 30 mg | 4.30 | 10 | ✔ | **m-Eslon** |
| Cap long-acting 60 mg | 9.00 | 10 | ✔ | **m-Eslon** |
| Cap long-acting 100 mg | 10.50 | 10 | ✔ | **m-Eslon** |
| Inj 5 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO | 5.38 | 5 | ✔ | **Medsurge** |
| | 6.99 | | ✔ | **DBL Morphine Sulphate** |
| Inj 10 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO | 4.68 | 5 | ✔ | **Medsurge** |
| | 5.61 | | ✔ | **DBL Morphine Sulphate** |
| Inj 15 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO | 5.53 | 5 | ✔ | **Medsurge** |
| | 7.08 | | ✔ | **DBL Morphine Sulphate** |
| Inj 30 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO | 6.28 | 5 | ✔ | **Medsurge** |
| | 7.28 | | ✔ | **DBL Morphine Sulphate** |

*(DBL Morphine Sulphate Inj 5 mg per ml, 1 ml ampoule to be delisted 1 March 2023)*
*(DBL Morphine Sulphate Inj 10 mg per ml, 1 ml ampoule to be delisted 1 March 2023)*
*(DBL Morphine Sulphate Inj 15 mg per ml, 1 ml ampoule to be delisted 1 March 2023)*
*(DBL Morphine Sulphate Inj 30 mg per ml, 1 ml ampoule to be delisted 1 March 2023)*


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

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| OXYCODONE HYDROCHLORIDE | | | | |
| a) Only on a controlled drug form | | | | |
| b) No patient co-payment payable | | | | |
| c) Safety medicine; prescriber may determine dispensing frequency | | | | |
| Tab controlled-release 5 mg | 2.69 | 20 | ✔ | **Oxycodone Sandoz** |
| Tab controlled-release 10 mg | 2.69 | 20 | ✔ | **Oxycodone Sandoz** |
| Tab controlled-release 20 mg | 3.49 | 20 | ✔ | **Oxycodone Sandoz** |
| Tab controlled-release 40 mg | 5.49 | 20 | ✔ | **Oxycodone Sandoz** |
| Tab controlled-release 80 mg | 12.99 | 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 | 5.23 | 20 | ✔ | **OxyNorm** |
| Oral liq 5 mg per 5 ml | 11.20 | 250 ml | ✔ | **OxyNorm** |
| Inj 10 mg per ml, 1 ml ampoule | 5.82 | 5 | ✔ | **Hameln** |
| Inj 10 mg per ml, 2 ml ampoule | 11.49 | 5 | ✔ | **Hameln** |
| Inj 50 mg per ml, 1 ml ampoule | 22.92 | 5 | ✔ | **Hameln** |
| PARACETAMOL WITH CODEINE – Safety medicine; prescriber may determine dispensing frequency | | | | |
| ✻ Tab paracetamol 500 mg with codeine phosphate 8 mg | 27.50 | 1,000 | ✔ | **Paracetamol + Codeine (Relieve)** |
| PETHIDINE HYDROCHLORIDE | | | | |
| a) Only on a controlled drug form | | | | |
| b) No patient co-payment payable | | | | |
| c) Safety medicine; prescriber may determine dispensing frequency | | | | |
| Tab 50 mg | 4.70 | 10 | ✔ | **PSM** |
| Inj 50 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO | 29.88 | 5 | ✔ | **DBL Pethidine Hydrochloride** |
| Inj 50 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO | 30.72 | 5 | ✔ | **DBL Pethidine Hydrochloride** |
| TRAMADOL HYDROCHLORIDE | | | | |
| Tab sustained-release 100 mg | 1.52 | 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 | 2.80 | 100 | ✔ | **Arrow-Tramadol** |

## Antidepressants

### Cyclic and Related Agents

| | | | | |
|---|---|---|---|---|
| AMITRIPTYLINE – Safety medicine; prescriber may determine dispensing frequency | | | | |
| Tab 10 mg | 2.49 | 100 | ✔ | **Arrow-Amitriptyline** |
| Tab 25 mg | 1.51 | 100 | ✔ | **Arrow-Amitriptyline** |
| Tab 50 mg | 2.51 | 100 | ✔ | **Arrow-Amitriptyline** |
| CLOMIPRAMINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency | | | | |
| Tab 10 mg | 10.17 | 30 | ✔ | **Clomipramine Teva** |
| Tab 25 mg | 11.99 | 30 | ✔ | **Clomipramine Teva** |

▲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 |
|---|---|---|---|---|
| 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 | 3.85 | 30 | ✔ | **Dosulepin Mylan** |
| | | | ✔ | **Dosulepin Viatris** |
| Cap 25 mg | 7.83 | 50 | ✔ | **Dosulepin Mylan** S29 |
| 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** |
| NORTRIPTYLINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency | | | | |
| Tab 10 mg | 2.44 | 100 | ✔ | **Norpress** |
| Tab 25 mg | 5.98 | 180 | ✔ | **Norpress** |

## Monoamine-Oxidase Inhibitors (MAOIs) - Non Selective

| | | | | |
|---|---|---|---|---|
| TRANYLCYPROMINE SULPHATE | | | | |
| Tab 10 mg | 12.85 | 28 | ✔ | **Parnate S29** S29 |
| | 22.94 | 50 | ✔ | **Parnate** |
| | 45.88 | 100 | ✔ | **Parnate S29** S29 |
| | 96.00 | | ✔ | **Parnate S29** S29 |

## Monoamine-Oxidase Type A Inhibitors

| | | | | |
|---|---|---|---|---|
| MOCLOBEMIDE | | | | |
| ❋ Tab 150 mg | 11.80 | 60 | ✔ | **Aurorix** |
| ❋ Tab 300 mg | 19.25 | 60 | ✔ | **Aurorix** |

## Selective Serotonin Reuptake Inhibitors

| | | | | |
|---|---|---|---|---|
| CITALOPRAM HYDROBROMIDE | | | | |
| ❋ Tab 20 mg | 1.91 | 84 | ✔ | **PSM Citalopram** |
| | 2.86 | | ✔ | **Celapram** |
| *(PSM Citalopram Tab 20 mg to be delisted 1 March 2023)* | | | | |
| ESCITALOPRAM | | | | |
| ❋ Tab 10 mg | 1.07 | 28 | ✔ | **Escitalopram (Ethics)** |
| ❋ Tab 20 mg | 1.92 | 28 | ✔ | **Escitalopram (Ethics)** |
| FLUOXETINE HYDROCHLORIDE | | | | |
| ❋ Tab dispersible 20 mg, scored – Subsidy by endorsement | 2.50 | 28 | ✔ | **Fluox** |

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** |



✔ **fully subsidised**

**Principal Supply**

S29 Unapproved medicine supplied under Section 29

**Sole Subsidised Supply**

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| PAROXETINE | | | | |
| ❋ Tab 20 mg | 4.11 | 90 | ✔ | **Loxamine** |
| SERTRALINE | | | | |
| ❋ Tab 50 mg | 0.99 | 30 | ✔ | **Setrona** |
| | | | ✔ | **Setrona AU** |
| ❋ Tab 100 mg | 1.74 | 30 | ✔ | **Setrona** |
| | | | ✔ | **Setrona AU** |

*(Setrona AU Tab 50 mg to be delisted 1 April 2023)*
*(Setrona AU Tab 100 mg to be delisted 1 April 2023)*

## Other Antidepressants

| | | | | |
|---|---|---|---|---|
| MIRTAZAPINE | | | | |
| Tab 30 mg | 2.60 | 28 | ✔ | **Noumed** |
| Tab 45 mg | 3.45 | 28 | ✔ | **Noumed** |
| 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

| | | | | |
|---|---|---|---|---|
| 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<br>b) Only on a PSO<br>c) PSO must be endorsed "not for anaesthetic procedures". | | | | |
| Rectal tubes 5 mg – Up to 5 tube available on a PSO | 54.58 | 5 | ✔ | **Stesolid** |
| PHENYTOIN SODIUM | | | | |
| ❋ Inj 50 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO | 104.58 | 5 | ✔ | **Hospira** |
| ❋ Inj 50 mg per ml, 5 ml ampoule – Up to 5 inj available on a PSO | 154.01 | 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** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| ETHOSUXIMIDE | | | | |
| Cap 250 mg | 78.89 | 56 | ✔ | **Essential Ethosuximide** S29 |
| | 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 | 6.45 | 100 | ✔ | **Nupentin** |
| ❋ Cap 300 mg | 8.45 | 100 | ✔ | **Nupentin** |
| ❋ Cap 400 mg | 10.26 | 100 | ✔ | **Nupentin** |
| 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: Patients of childbearing potential are not required to have a trial of sodium valporate

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

| | | | | |
|---|---|---|---|---|
| LAMOTRIGINE | | | | |
| ▲ Tab dispersible 2 mg | 55.00 | 30 | ✔ | **Lamictal** |
| ▲ Tab dispersible 5 mg | 50.00 | 30 | ✔ | **Lamictal** |
| ❋ 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 247 | | | | |
| ❋ 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** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| PREGABALIN | | | | |
| Note: Not subsidised in combination with subsidised gabapentin | | | | |
| Cap 25 mg | 2.25 | 56 | ✔ | **Pregabalin Pfizer** |
| | 7.80 | | ✔ | **Milpharm** S29 |
| ✻ Cap 75 mg | 2.65 | 56 | ✔ | **Pregabalin Pfizer** |
| | 8.10 | | ✔ | **Milpharm** S29 |
| Cap 150 mg | 4.01 | 56 | ✔ | **Lyrica** |
| | | | ✔ | **Pregabalin Pfizer** |
| Cap 300 mg | 7.38 | 56 | ✔ | **Pregabalin Pfizer** |
| PRIMIDONE | | | | |
| ✻ Tab 250 mg | 37.35 | 100 | ✔ | **Apo-Primidone** |
| | | | ✔ | **Primidone Clinect** |
| *(Apo-Primidone Tab 250 mg to be delisted 1 January 2023)* | | | | |
| 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 SA2088 on the next page – Retail pharmacy | | | | |
| ▲ Tab 500 mg | 119.30 | 100 | ✔ | **Sabril** |

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

➽SA2088 **Special Authority for Subsidy**

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

Both:

1 Any of the following:
- 1.1 Patient has infantile spasms; or
- 1.2 Both:
  - 1.2.1 Patient has epilepsy; and
  - 1.2.2 Either:
    - 1.2.2.1 Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents; or
    - 1.2.2.2 Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents; or
- 1.3 Patient has tuberous sclerosis complex; and

2 Either:
- 2.1 Patient is, or will be, receiving regular automated visual field testing (ideally before starting therapy and on a 6-monthly basis thereafter); or
- 2.2 It is impractical or impossible (due to comorbid conditions) to monitor the patient's visual fields..

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

Both:

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

2 Either:
- 2.1 Patient is receiving regular automated visual field testing (ideally every 6 months) on an ongoing basis for duration of treatment with vigabatrin; or
- 2.2 It is impractical or impossible (due to comorbid conditions) to monitor the patient's visual fields..

## Antimigraine Preparations

For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, page 109

### Acute Migraine Treatment

| | | | | |
|---|---|---|---|---|
| RIZATRIPTAN | | | | |
| Tab orodispersible 10 mg | 3.65 | 30 | ✔ | **Rizamelt** |
| SUMATRIPTAN | | | | |
| Tab 50 mg | 14.41 | 90 | ✔ | **Sumagran** |
| Tab 100 mg | 22.68 | 90 | ✔ | **Sumagran** |
| Inj 12 mg per ml, 0.5 ml prefilled pen – Maximum of 10 inj per prescription | 34.00 | 2 OP | ✔ | **Imigran** |

### Prophylaxis of Migraine

For Beta Adrenoceptor Blockers refer to CARDIOVASCULAR SYSTEM, page 50

| | | | | |
|---|---|---|---|---|
| PIZOTIFEN | | | | |
| ✳ Tab 500 mcg | 23.21 | 100 | ✔ | **Sandomigran** |

## Antinausea and Vertigo Agents

For Antispasmodics refer to ALIMENTARY TRACT, page 8

| | | | | |
|---|---|---|---|---|
| APREPITANT – Special Authority see SA0987 on the next page – Retail pharmacy | | | | |
| Cap 2 × 80 mg and 1 × 125 mg | 30.00 | 3 OP | ✔ | **Emend Tri-Pack** |

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

**➽SA0987 Special Authority for Subsidy**

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

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

BETAHISTINE DIHYDROCHLORIDE

| | | | | |
|---|---|---|---|---|
| ✻ | Tab 16 mg | 4.62 | 100 | ✔ **Serc** |

CYCLIZINE HYDROCHLORIDE

| | | | | |
|---|---|---|---|---|
| | Tab 50 mg | 0.49 | 10 | ✔ **Nausicalm** |

CYCLIZINE LACTATE

| | | | | |
|---|---|---|---|---|
| | Inj 50 mg per ml, 1 ml ampoule | 16.36 | 10 | ✔ **Hameln** |
| | Hameln to be Principal Supply on 1 December 2022 | | | |

DOMPERIDONE

| | | | | |
|---|---|---|---|---|
| ✻ | Tab 10 mg | 2.85 | 100 | ✔ **Pharmacy Health** |

HYOSCINE HYDROBROMIDE

| | | | | |
|---|---|---|---|---|
| ✻ | Inj 400 mcg per ml, 1 ml ampoule | 93.00 | 10 | ✔ **Martindale** S29 |
| | Patch 1.5 mg – Special Authority see SA1998 below – Retail pharmacy | 14.11 | 2 | ✔ **Scopoderm TTS** |

**➽SA1998 Special Authority for Subsidy**

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

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

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

METOCLOPRAMIDE HYDROCHLORIDE

| | | | | |
|---|---|---|---|---|
| ✻ | Tab 10 mg – Up to 30 tab available on a PSO | 1.30 | 100 | ✔ **Metoclopramide Actavis 10** |
| ✻ | Inj 5 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO | 7.00 | 10 | ✔ **Baxter** |
| | | 9.50 | | ✔ **Pfizer** |
| | Baxter to be Principal Supply on 1 December 2022 | | | |
| | *(Pfizer Inj 5 mg per ml, 2 ml ampoule to be delisted 1 December 2022)* | | | |

ONDANSETRON

| | | | | |
|---|---|---|---|---|
| ✻ | Tab 4 mg | 2.68 | 50 | ✔ **Onrex** |
| | Tab disp 4 mg – Up to 10 tab available on a PSO | 0.76 | 10 | ✔ **Ondansetron ODT-DRLA** |
| ✻ | Tab 8 mg | 4.57 | 50 | ✔ **Onrex** |
| | Tab disp 8 mg – Up to 10 tab available on a PSO | 1.13 | 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 | 8.00 | 250 | ✔ **Nausafix** |
| ✻ | Inj 12.5 mg per ml, 1 ml – Up to 5 inj available on a PSO | 25.81 | 10 | ✔ **Stemetil** |

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

## Antipsychotics

### General

AMISULPRIDE – Safety medicine; prescriber may determine dispensing frequency

| | | | | |
|---|---|---|---|---|
| Tab 100 mg | 5.15 | 30 | ✔ | **Sulprix** |
| Tab 200 mg | 14.96 | 60 | ✔ | **Sulprix** |
| Tab 400 mg | 29.78 | 60 | ✔ | **Sulprix** |

ARIPIPRAZOLE – Safety medicine; prescriber may determine dispensing frequency

| | | | | |
|---|---|---|---|---|
| Tab 5 mg | 10.50 | 30 | ✔ | **Aripiprazole Sandoz** |
| Tab 10 mg | 10.50 | 30 | ✔ | **Aripiprazole Sandoz** |
| Tab 15 mg | 10.50 | 30 | ✔ | **Aripiprazole Sandoz** |
| Tab 20 mg | 10.50 | 30 | ✔ | **Aripiprazole Sandoz** |
| Tab 30 mg | 10.50 | 30 | ✔ | **Aripiprazole Sandoz** |

CHLORPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency

| | | | | |
|---|---|---|---|---|
| Tab 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 | 6.69 | 50 | ✔ | **Clopine** |
| | | | ✔ | **Clozaril** |
| | 13.37 | 100 | ✔ | **Clopine** |
| | | | ✔ | **Clozaril** |
| Tab 50 mg | 8.67 | 50 | ✔ | **Clopine** |
| | 17.33 | 100 | ✔ | **Clopine** |
| Tab 100 mg | 17.33 | 50 | ✔ | **Clopine** |
| | | | ✔ | **Clozaril** |
| | 34.65 | 100 | ✔ | **Clopine** |
| | | | ✔ | **Clozaril** |
| Tab 200 mg | 34.65 | 50 | ✔ | **Clopine** |
| | 69.30 | 100 | ✔ | **Clopine** |
| Suspension 50 mg per ml | 67.62 | 100 ml | ✔ | **Versacloz** |

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 | 14.86 | 50 | ✔ | **Serenace** |
| | 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** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| LEVOMEPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency | | | | |
| Inj 25 mg per ml, 1 ml ampoule | 16.75 | 5 | ✔ | **Neuraxpharm** S29 |
| | | | ✔ | **Nozinan S29** S29 |
| | 24.48 | 10 | ✔ | **Wockhardt** |
| | 33.50 | | ✔ | **Nozinan** |
| *(Nozinan Inj 25 mg per ml, 1 ml ampoule to be delisted 1 April 2023)* | | | | |
| LITHIUM CARBONATE – Safety medicine; prescriber may determine dispensing frequency | | | | |
| Tab long-acting 400 mg | 72.00 | 100 | ✔ | **Priadel** |
| Cap 250 mg | 9.42 | 100 | ✔ | **Douglas** |
| OLANZAPINE – Safety medicine; prescriber may determine dispensing frequency | | | | |
| Tab 2.5 mg | 1.35 | 28 | ✔ | **Zypine** |
| Tab 5 mg | 1.58 | 28 | ✔ | **Zypine** |
| Tab orodispersible 5 mg | 1.81 | 28 | ✔ | **Zypine ODT** |
| Tab 10 mg | 2.01 | 28 | ✔ | **Zypine** |
| Tab orodispersible 10 mg | 2.38 | 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 | 2.15 | 90 | ✔ | **Quetapel** |
| Tab 100 mg | 5.06 | 90 | ✔ | **Quetapel** |
| Tab 200 mg | 8.90 | 90 | ✔ | **Quetapel** |
| Tab 300 mg | 12.86 | 90 | ✔ | **Quetapel** |
| RISPERIDONE – Safety medicine; prescriber may determine dispensing frequency | | | | |
| Tab 0.5 mg | 1.86 | 60 | ✔ | **Risperidone (Teva)** |
| Tab 1 mg | 2.06 | 60 | ✔ | **Risperidone (Teva)** |
| Tab 2 mg | 2.29 | 60 | ✔ | **Risperidone (Teva)** |
| Tab 3 mg | 2.50 | 60 | ✔ | **Risperidone (Teva)** |
| Tab 4 mg | 3.42 | 60 | ✔ | **Risperidone (Teva)** |
| Oral liq 1 mg per ml | 8.90 | 30 ml | ✔ | **Risperon** |
| ZIPRASIDONE – Safety medicine; prescriber may determine dispensing frequency | | | | |
| Cap 20 mg | 17.90 | 60 | ✔ | **Zusdone** |
| Cap 40 mg | 27.41 | 60 | ✔ | **Zusdone** |
| Cap 60 mg | 38.39 | 60 | ✔ | **Zusdone** |
| Cap 80 mg | 46.55 | 60 | ✔ | **Zusdone** |
| ZUCLOPENTHIXOL HYDROCHLORIDE – Safety medicine; 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 |

▲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 |
|---|---|---|---|---|
| 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.

| | | | | |
|---|---|---|---|---|
| PALIPERIDONE – Special Authority see SA1429 below – Retail pharmacy | | | | |
| Safety medicine; prescriber may determine dispensing frequency | | | | |
| Inj 25 mg syringe | 194.25 | 1 | ✔ | **Invega Sustenna** |
| Inj 50 mg syringe | 271.95 | 1 | ✔ | **Invega Sustenna** |
| Inj 75 mg syringe | 357.42 | 1 | ✔ | **Invega Sustenna** |
| Inj 100 mg syringe | 435.12 | 1 | ✔ | **Invega Sustenna** |
| Inj 150 mg syringe | 435.12 | 1 | ✔ | **Invega Sustenna** |

**SA1429 Special Authority for Subsidy**

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

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

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

| | | | | |
|---|---|---|---|---|
| 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

continued…

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

continued…

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.

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 | 18.50 | | 100 | ✔ **Buspirone Viatris** |
| ✻ Tab 10 mg | 12.50 | | 100 | ✔ **Buspirone Viatris** |

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 | 61.07 | | 500 | ✔ **Arrow-Diazepam** |
| Tab 5 mg | 73.60 | | 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** |

## Multiple Sclerosis Treatments

➽SA2140 **Special Authority for Subsidy**
**Initial application — (Multiple sclerosis)** only from a neurologist or general physician. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:

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

continued…

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

continued…

4.5.1 Each significant attack is severe enough to change either the EDSS or at least one of the Kurtze Functional System scores by at least 1 point; or

4.5.2 Each significant attack is a recurrent paroxysmal symptom of multiple sclerosis (tonic seizures/spasms, trigeminal neuralgia, Lhermitte's symptom); and

5 Evidence of new inflammatory activity on an MRI scan within the past 24 months; and

6 Any of the following:

6.1 A sign of that new inflammatory activity on MRI scanning (in criterion 5 immediately above) is a gadolinium enhancing lesion; or

6.2 A sign of that new inflammatory activity is a lesion showing diffusion restriction; or

6.3 A sign of that new inflammatory is a T2 lesion with associated local swelling; or

6.4 A sign of that new inflammatory activity is a prominent T2 lesion that clearly is responsible for the clinical features of a recent attack that occurred within the last 2 years; or

6.5 A sign of that new inflammatory activity is new T2 lesions compared with a previous MRI scan.

Note: Natalizumab can only be dispensed from a pharmacy registered in the Tysabri Australasian Prescribing Programme operated by the supplier. Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

**Renewal — (Multiple sclerosis)** only from a neurologist or general physician. Approvals valid for 12 months where patient has had an EDSS score of 0 to 6.0 (inclusive) with or without the use of unilateral or bilateral aids at any time in the last six months (i.e. the patient has walked 100 metres or more with or without aids in the last six months).

Note: Natalizumab can only be dispensed from a pharmacy registered in the Tysabri Australasian Prescribing Programme operated by the supplier. Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted.

DIMETHYL FUMARATE – Special Authority see SA2140 on the previous page – Retail pharmacy

a) Wastage claimable

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

| | | | | |
|---|---|---|---|---|
| Cap 120 mg | 520.00 | 14 | ✔ | **Tecfidera** |
| Cap 240 mg | 2,000.00 | 56 | ✔ | **Tecfidera** |

FINGOLIMOD – Special Authority see SA2140 on the previous page – Retail pharmacy

a) Wastage claimable

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

| | | | | |
|---|---|---|---|---|
| Cap 0.5 mg | 2,200.00 | 28 | ✔ | **Gilenya** |

GLATIRAMER ACETATE – Special Authority see SA2140 on the previous page – Retail pharmacy

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

| | | | | |
|---|---|---|---|---|
| Inj 40 mg prefilled syringe | 1,137.48 | 12 | ✔ | **Copaxone** |

INTERFERON BETA-1-ALPHA – Special Authority see SA2140 on the previous page – Retail pharmacy

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

| | | | | |
|---|---|---|---|---|
| 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** |

INTERFERON BETA-1-BETA – Special Authority see SA2140 on the previous page – Retail pharmacy

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

| | | | | |
|---|---|---|---|---|
| Inj 8 million iu per 1 ml | 1,322.89 | 15 | ✔ | **Betaferon** |

NATALIZUMAB – Special Authority see SA2140 on the previous page – Retail pharmacy

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

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

OCRELIZUMAB – Special Authority see SA2140 on the previous page – Retail pharmacy

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

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

TERIFLUNOMIDE – Special Authority see SA2140 on the previous page – Retail pharmacy

a) Wastage claimable

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

| | | | | |
|---|---|---|---|---|
| Tab 14 mg | 659.90 | 28 | ✔ | **Aubagio** |

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

## Sedatives and Hypnotics

MELATONIN – Special Authority see SA1666 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Tab modified-release 2 mg – No more than 5 tab per day | 11.50 | 30 | ✔ | **Vigisom** |

➽**SA1666** **Special Authority for Subsidy**

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

All of the following:

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

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

All of the following:

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

Note: Indications marked with * are unapproved indications.

MIDAZOLAM – Safety medicine; prescriber may determine dispensing frequency

| | | | | |
|---|---|---|---|---|
| Inj 1 mg per ml, 5 ml ampoule | 6.10 | 10 | ✔ | **Midazolam-Baxter** |
| Inj 1 mg per ml, 5 ml plastic ampoule – Up to 10 inj available on a PSO | 17.28 | 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 | 5.00 | 5 | ✔ | **Midazolam-Baxter** |
| Inj 5 mg per ml, 3 ml plastic ampoule – Up to 5 inj available on a PSO | 13.09 | 5 | ✔ | **Pfizer** |
| On a PSO for status epilepticus use only. PSO must be endorsed for status epilepticus use only. | | | | |

PHENOBARBITONE SODIUM – Special Authority see SA1386 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Inj 200 mg per ml, 1 ml ampoule | 103.30 | 10 | ✔ | **Max Health** S29 |

➽**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 | 1.33 | 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 |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| ZOPICLONE – Safety medicine; prescriber may determine dispensing frequency | | | | |
| Tab 7.5 mg | 10.80 | 500 | ✔ | **Zopiclone Actavis** |

## Stimulants/ADHD Treatments

| | | | | |
|---|---|---|---|---|
| ATOMOXETINE | | | | |
| Cap 10 mg | 18.41 | 28 | ✔ | **APO-Atomoxetine** |
| | | | ✔ | **APO-Atomoxetine S29** S29 |
| | | | ✔ | **Generic Partners** |
| | 107.03 | | ✔ | **Strattera** |
| Cap 18 mg | 27.06 | 28 | ✔ | **APO-Atomoxetine** |
| | | | ✔ | **Generic Partners** |
| | 107.03 | | ✔ | **Strattera** |
| Cap 25 mg | 29.22 | 28 | ✔ | **APO-Atomoxetine** |
| | | | ✔ | **Generic Partners** |
| Cap 40 mg | 29.22 | 28 | ✔ | **APO-Atomoxetine** |
| | | | ✔ | **Generic Partners** |
| | 107.03 | | ✔ | **Strattera** |
| Cap 60 mg | 46.51 | 28 | ✔ | **APO-Atomoxetine** |
| | | | ✔ | **APO-Atomoxetine S29** S29 |
| | | | ✔ | **Generic Partners** |
| Cap 80 mg | 56.45 | 28 | ✔ | **APO-Atomoxetine** |
| | | | ✔ | **APO-Atomoxetine S29** S29 |
| | | | ✔ | **Generic Partners** |
| Cap 100 mg | 58.48 | 28 | ✔ | **APO-Atomoxetine** |
| | | | ✔ | **APO-Atomoxetine S29** S29 |
| | | | ✔ | **Generic Partners** |
| 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 | 21.00 | 100 | ✔ | **PSM** |
| | 28.50 | | ✔ | **Aspen** |

**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

continued…

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

continued…

applications meeting the following criteria:
Both:

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

**Initial application — (Narcolepsy)** only from a neurologist or respiratory specialist. Approvals valid for 24 months where the patient suffers from narcolepsy.
**Renewal — (ADHD in patients 5 or over)** only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:
Both:

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

**Renewal — (ADHD in patients under 5)** only from a paediatrician or psychiatrist. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.
**Renewal — (Narcolepsy)** only from a neurologist or respiratory specialist. Approvals valid for 24 months where the treatment remains appropriate and the patient is benefiting from treatment.

METHYLPHENIDATE HYDROCHLORIDE – Special Authority see SA1964 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**<br>✔ **Rubifen** |
| Tab extended-release 18 mg | 7.75 | | 30 | ✔ **Methylphenidate ER - Teva** |
| Tab immediate-release 20 mg | 7.85 | | 30 | ✔ **Rubifen** |
| Tab sustained-release 20 mg | 10.95 | | 30 | ✔ **Rubifen SR** |
| Tab extended-release 27 mg | 11.45 | | 30 | ✔ **Methylphenidate ER - Teva** |
| Tab extended-release 36 mg | 15.50 | | 30 | ✔ **Methylphenidate ER - Teva** |
| Tab extended-release 54 mg | 22.25 | | 30 | ✔ **Methylphenidate ER - Teva** |

**➽SA1964 Special Authority for Subsidy**
**Initial application — (ADHD in patients 5 or over)** only from a paediatrician, psychiatrist, medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:
All of the following:

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

**Initial application — (ADHD in patients under 5)** only from a paediatrician or psychiatrist. Approvals valid for 12 months for

continued…

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

continued…

applications meeting the following criteria:
Both:

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

**Initial application — (Narcolepsy*)** only from a neurologist or respiratory specialist. Approvals valid for 24 months where the patient suffers from narcolepsy.
Note: *narcolepsy is not a registered indication for Methylphenidate ER – Teva.
**Renewal — (ADHD in patients 5 or over)** only from a paediatrician, psychiatrist, medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:
Both:

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

**Renewal — (ADHD in patients under 5)** only from a paediatrician or psychiatrist. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.
**Renewal — (Narcolepsy*)** only from a neurologist or respiratory specialist. Approvals valid for 24 months where the treatment remains appropriate and the patient is benefiting from treatment.
Note: *narcolepsy is not a registered indication for Methylphenidate ER – Teva.

METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE – Special Authority see SA1965 below – Retail pharmacy

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

| | | | | |
|---|---|---|---|---|
| Tab extended-release 18 mg | 58.96 | | 30 | ✔ **Concerta** |
| Tab extended-release 27 mg | 65.44 | | 30 | ✔ **Concerta** |
| Tab extended-release 36 mg | 71.93 | | 30 | ✔ **Concerta** |
| Tab extended-release 54 mg | 86.24 | | 30 | ✔ **Concerta** |
| Cap modified-release 10 mg | 15.60 | | 30 | ✔ **Ritalin LA** |
| Cap modified-release 20 mg | 20.40 | | 30 | ✔ **Ritalin LA** |
| Cap modified-release 30 mg | 25.52 | | 30 | ✔ **Ritalin LA** |
| Cap modified-release 40 mg | 30.60 | | 30 | ✔ **Ritalin LA** |

➽SA1965 **Special Authority for Subsidy**
**Initial application** only from a paediatrician, psychiatrist, medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:
All of the following:

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

continued…

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

continued…

hydrochloride.

**Renewal** only from a paediatrician, psychiatrist, medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing) or nurse practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:
Both:

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

MODAFINIL – Special Authority see SA1999 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Tab 100 mg | 29.13 | 60 | ✔ | **Modavigil** |

➽**SA1999** **Special Authority for Subsidy**
**Initial application** only from a neurologist or respiratory specialist. Approvals valid for 24 months for applications meeting the following criteria:
All of the following:

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

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

## Treatments for Dementia

DONEPEZIL HYDROCHLORIDE

| | | | | |
|---|---|---|---|---|
| ✱ Tab 5 mg | 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 | 38.00 | 30 | ✔ | **Rivastigmine Patch BNM 5** |
| Patch 9.5 mg per 24 hour | 38.00 | 30 | ✔ | **Rivastigmine Patch BNM 10** |

➽**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.

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

## Treatments for Substance Dependence

BUPRENORPHINE WITH NALOXONE – Special Authority see SA1203 below – Retail pharmacy

a) No patient co-payment payable
b) Safety medicine; prescriber may determine dispensing frequency

| | | | | |
|---|---|---|---|---|
| Tab sublingual 2 mg with naloxone 0.5 mg | 11.76 | 28 | ✔ | **Buprenorphine Naloxone BNM** |
| Buprenorphine Naloxone BNM to be Principal Supply on 1 December 2022 | | | | |
| Tab sublingual 8 mg with naloxone 2 mg | 34.00 | 28 | ✔ | **Buprenorphine Naloxone BNM** |
| Buprenorphine Naloxone BNM to be Principal Supply on 1 December 2022 | | | | |

**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.

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| BUPROPION HYDROCHLORIDE | | | | |
| Tab modified-release 150 mg | 11.00 | 30 | ✔ | **Zyban** |
| DISULFIRAM | | | | |
| Tab 200 mg | 236.40 | 100 | ✔ | **Antabuse** S29 |
| NALTREXONE HYDROCHLORIDE – Special Authority see SA1408 below – Retail pharmacy | | | | |
| Tab 50 mg | 133.33 | 30 | ✔ | **Naltraccord** |

➽**SA1408** **Special Authority for Subsidy**

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

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

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

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

| | | | | |
|---|---|---|---|---|
| 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 | 18.14 | 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 | 19.95 | 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 | 22.86 | 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 | 19.18 | 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 | 21.02 | 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 | 38.21 | 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 | 38.21 | 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 | 44.17 | 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 | 44.17 | 384 | ✔ | **Habitrol** |
| Gum 4 mg (Mint) for direct distribution only – [Xpharm] | 10.01 | 96 | ✔ | **Habitrol** |
| VARENICLINE TARTRATE – Special Authority see SA1845 on the next page – Retail pharmacy | | | | |
| a) A maximum of 12 weeks' varenicline will be subsidised on each Special Authority approval, including the starter pack | | | | |
| b) Varenicline will not be funded in amounts less than 4 weeks of treatment. | | | | |
| c) The 6-month time period in which a patient can receive a funded 12-week course of varenicline tartrate starts from the date the Special Authority is approved. | | | | |
| Tab 0.5 mg × 11 and 1 mg × 42 | 16.67 | 53 OP | ✔ | **Varenicline Pfizer** |
| Tab 1 mg | 17.62 | 56 | ✔ | **Varenicline Pfizer** |

▲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 |
|---|---|---|---|---|

➽SA1845 **Special Authority for Subsidy**

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

1 Short-term therapy as an aid to achieving abstinence in a patient who has indicated that they are ready to cease smoking; and
2 The patient is part of, or is about to enrol in, a comprehensive support and counselling smoking cessation programme, which includes prescriber or nurse monitoring; and
3 Either:
  3.1 The patient has tried but failed to quit smoking after at least two separate trials of nicotine replacement therapy, at least one of which included the patient receiving comprehensive advice on the optimal use of nicotine replacement therapy; or
  3.2 The patient has tried but failed to quit smoking using bupropion or nortriptyline; and
4 The patient has not had a Special Authority for varenicline approved in the last 6 months; and
5 Varenicline is not to be used in combination with other pharmacological smoking cessation treatments and the patient has agreed to this; and
6 The patient is not pregnant; and
7 The patient will not be prescribed more than 12 weeks' funded varenicline (see note).

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

1 Short-term therapy as an aid to achieving abstinence in a patient who has indicated that they are ready to cease smoking; 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 SA2153 below

| | | | | |
|---|---|---|---|---|
| Inj 25 mg vial | 77.00 | 1 | ✔ | **Ribomustin** |
| Inj 100 mg vial | 308.00 | 1 | ✔ | **Ribomustin** |
| Inj 1 mg for ECP | 3.23 | 1 mg | ✔ | **Baxter** |

➽**SA2153** **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 Any of the following:
  3.1 Both:
    3.1.1 Patient is treatment naive; and
    3.1.2 Bendamustine is to be administered for a maximum of 6 cycles (in combination with rituximab when CD20+); or
  3.2 Both:
    3.2.1 Patient is refractory to or has relapsed within 12 months of a rituximab containing combined chemo-immunotherapy regimen; and
    3.2.2 Bendamustine is to be administered in combination with obinutuzumab for a maximum of 6 cycles; or
  3.3 All of the following:
    3.3.1 The patient has not received prior bendamustine therapy; and
    3.3.2 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and
    3.3.3 Patient has had a rituximab treatment-free interval of 12 months or more; or
  3.4 Bendamustine is to be administered as monotherapy for a maximum of 6 cycles in rituximab refractory patients.

**Renewal — (Indolent, Low-grade lymphomas)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria:
Either:

1 Both:
  1.1 Patient is refractory to or has relapsed within 12 months of rituximab in combination with bendamustine; and
  1.2 Bendamustine is to be administered in combination with obinutuzumab for a maximum of 6 cycles; or

continued…

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

continued…

2 Both:

2.1 Patients have not received a bendamustine regimen within the last 12 months; and

2.2 Either:

2.2.1 Both:

2.2.1.1 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and

2.2.1.2 Patient has had a rituximab treatment-free interval of 12 months or more; or

2.2.2 Bendamustine is to be administered as a monotherapy for a maximum of 6 cycles in rituximab refractory patients.

Note: 'indolent, low-grade lymphomas' includes follicular, mantle cell, marginal zone and lymphoplasmacytic/ Waldenstrom's macroglobulinaemia.

**Initial application — (Hodgkin's lymphoma*)** only from a relevant specialist or 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 Hodgkin's lymphoma requiring treatment; and

2 Patient has a ECOG performance status of 0-2; and

3 Patient has received one prior line of chemotherapy; and

4 Patient's disease relapsed or was refractory following prior chemotherapy; and

5 Bendamustine is to be administered in combination with gemcitabine and vinorelbine (BeGeV) at a maximum dose of no greater than 90 mg/m2 twice per cycle, for a maximum of four cycles.

Note: Indications marked with * are unapproved indications.

| | | | | |
|---|---|---|---|---|
| BUSULFAN – PCT – Retail pharmacy-Specialist | | | | |
| 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 | 710.00 | 1 | ✔ | **BiCNU** |
| Inj 100 mg for ECP | 710.00 | 100 mg OP | ✔ | **Baxter** |
| CHLORAMBUCIL – PCT – Retail pharmacy-Specialist | | | | |
| Tab 2 mg | 29.06 | 25 | ✔ | **Leukeran FC** |
| CISPLATIN – PCT only – Specialist | | | | |
| Inj 1 mg per ml, 50 ml vial | 15.00 | 1 | ✔ | **Cisplatin Ebewe** |
| Inj 1 mg per ml, 100 ml vial | 21.00 | 1 | ✔ | **Cisplatin Ebewe** |
| | 29.66 | | ✔ | **DBL Cisplatin** |
| Inj 1 mg for ECP | 0.31 | 1 mg | ✔ | **Baxter** |
| CYCLOPHOSPHAMIDE | | | | |
| Tab 50 mg – PCT – Retail pharmacy-Specialist | 145.00 | 50 | ✔ | **Cyclonex** |
| 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** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| 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** |
| | | | ✔ | **Alkeran S29** S29 |
| 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 |
| | | | ✔ | **Max Health** S29 |
| | | | ✔ | **THIO-TEPA** S29 |
| | | | ✔ | **Tepadina** S29 |
| Inj 100 mg vial | CBS | 1 | ✔ | **Max Health** S29 |
| | | | ✔ | **Tepadina** S29 |

## Antimetabolites

| | | | | |
|---|---|---|---|---|
| AZACITIDINE – PCT only – Specialist – Special Authority see SA2141 below | | | | |
| Inj 100 mg vial | 75.06 | 1 | ✔ | **Azacitidine Dr Reddy's** |
| Inj 1 mg for ECP | 0.83 | 1 mg | ✔ | **Baxter** |

➽**SA2141** **Special Authority for Subsidy**

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

All of the following:

1 Any of the following:

1.1 The patient has International Prognostic Scoring System (IPSS) intermediate-2 or high risk myelodysplastic syndrome; or

1.2 The patient has chronic myelomonocytic leukaemia (10%-29% marrow blasts without myeloproliferative disorder); or

1.3 The patient has acute myeloid leukaemia with 20-30% blasts and multi-lineage dysplasia, according to World Health Organisation Classification (WHO); and

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

3 The patient has an estimated life expectancy of at least 3 months.

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

Both:

1 No evidence of disease progression; and

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

| | Subsidy (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** |
| | | | ✔ | **Calcium Folinate Sandoz S29** S29 |
| Inj 50 mg – PCT – Retail pharmacy-Specialist | 72.80 | 10 | ✔ | **Leucovorin Pharmacia** S29 |
| Inj 10 mg per ml, 10 ml vial – PCT only – Specialist | 9.49 | 1 | ✔ | **Calcium Folinate Sandoz** |
| Inj 100 mg – PCT only – Specialist | 7.33 | 1 | ✔ | **Calcium Folinate Ebewe** |
| | 94.90 | 10 | ✔ | **Leucovorin Pharmacia** S29 |
| Inj 300 mg – PCT only – Specialist | 22.51 | 1 | ✔ | **Calcium Folinate Ebewe** |
| | 25.14 | | ✔ | **Leucovorin DBL** S29 |
| Inj 10 mg per ml, 35 ml vial – PCT only – Specialist | 25.14 | 1 | ✔ | **Calcium Folinate Sandoz** |
| | | | ✔ | **Calcium Folinate Sandoz S29** S29 |
| Inj 1 g – PCT only – Specialist | 67.51 | 1 | ✔ | **Calcium Folinate Ebewe** |
| Inj 10 mg per ml, 100 ml vial – PCT only – Specialist | 72.00 | 1 | ✔ | **Calcium Folinate Sandoz** |
| Inj 1 mg for ECP – PCT only – Specialist | 0.06 | 1 mg | ✔ | **Baxter** |
| CAPECITABINE – Retail pharmacy-Specialist | | | | |
| Tab 150 mg | 10.00 | 60 | ✔ | **Capercit** |
| Tab 500 mg | 49.00 | 120 | ✔ | **Capercit** |
| CLADRIBINE – PCT only – Specialist | | | | |
| Inj 2 mg per ml, 5 ml | 749.96 | 1 | ✔ | **Litak** S29 |
| Inj 1 mg per ml, 10 ml | 749.96 | 1 | ✔ | **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 | 634.00 | 5 | ✔ | **Fludarabine Ebewe** |
| Inj 50 mg for ECP – PCT only – Specialist | 126.80 | 50 mg OP | ✔ | **Baxter** |



✔ **fully subsidised**

**Principal Supply**

S29 Unapproved medicine supplied under Section 29

**Sole Subsidised Supply**

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| FLUOROURACIL | | | | |
| Inj 50 mg per ml, 20 ml vial – PCT only – Specialist | 10.51 | 1 | ✔ | **Fluorouracil Accord** |
| Inj 50 mg per ml, 100 ml vial – PCT only – Specialist | 29.44 | 1 | ✔ | **Fluorouracil Accord** |
| Inj 1 mg for ECP – PCT only – Specialist | 0.62 | 100 mg | ✔ | **Baxter** |
| GEMCITABINE HYDROCHLORIDE – PCT only – Specialist | | | | |
| Inj 1 g, 26.3 ml vial | 62.50 | 1 | ✔ | **DBL Gemcitabine** |
| Inj 1 g | 15.89 | 1 | ✔ | **Gemcitabine Ebewe** |
| Inj 1 mg for ECP | 0.02 | 1 mg | ✔ | **Baxter** |
| IRINOTECAN HYDROCHLORIDE – PCT only – Specialist | | | | |
| Inj 20 mg per ml, 5 ml vial | 52.57 | 1 | ✔ | **Accord** |
| | 71.44 | | ✔ | **Irinotecan Actavis 100** |
| | 100.00 | | ✔ | **Irinotecan-Rex** |
| Inj 1 mg for ECP | 0.54 | 1 mg | ✔ | **Baxter** |
| MERCAPTOPURINE | | | | |
| Tab 50 mg – PCT – Retail pharmacy-Specialist | 25.90 | 25 | ✔ | **Puri-nethol** |
| Puri-nethol to be Principal Supply on 1 December 2022 | | | | |
| 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 | 9.98 | 90 | ✔ | **Trexate** |
| ✻ | Tab 10 mg – PCT – Retail pharmacy-Specialist | 33.71 | 90 | ✔ | **Trexate** |
| ✻ | Inj 2.5 mg per ml, 2 ml – PCT – Retail pharmacy-Specialist | 47.50 | 5 | ✔ | **Methotrexate DBL** |
| ✻ | 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 | ✔ | **Methotrexate DBL 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** |

▲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 |
|---|---|---|---|---|
| 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 | 1,175.87 | 100 | ✔ | **Agrylin** |
| 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** |


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

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| BLEOMYCIN SULPHATE – PCT only – Specialist | | | | |
| Inj 15,000 iu, vial | 185.16 | 1 | ✔ | **DBL Bleomycin Sulfate** |
| Inj 1,000 iu for ECP | 14.32 | 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** |
| Inj 1 mg for ECP | 31.20 | 1 mg | ✔ | **Baxter** |

➽**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.

| | | | | |
|---|---|---|---|---|
| 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 vial | 1,495.00 | 10 | ✔ | **Daunorubicin Zentiva** S29 |
| Inj 20 mg for ECP | 149.50 | 20 mg OP | ✔ | **Baxter** |
| DOCETAXEL – PCT only – Specialist | | | | |
| Inj 20 mg | 48.75 | 1 | ✔ | **Docetaxel Sandoz** |
| Inj 10 mg per ml, 8 ml vial | 46.89 | 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 | 0.65 | 1 mg | ✔ | **Baxter** |
| DOXORUBICIN HYDROCHLORIDE – PCT only – Specialist | | | | |
| Inj 2 mg per ml, 5 ml vial | 10.00 | 1 | ✔ | **Doxorubicin Ebewe** |
| Inj 2 mg per ml, 25 ml vial | 11.50 | 1 | ✔ | **Doxorubicin Ebewe** |
| | 17.00 | | ✔ | **Arrow-Doxorubicin** |
| Inj 2 mg per ml, 50 ml vial | 23.00 | 1 | ✔ | **Doxorubicin Ebewe** |
| Inj 2 mg per ml, 100 ml vial | 65.00 | 1 | ✔ | **Arrow-Doxorubicin** |
| | 69.99 | | ✔ | **Doxorubicin Ebewe** |
| Inj 1 mg for ECP | 0.35 | 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 | 99.99 | 1 | ✔ | **Epirubicin Ebewe** |
| Inj 1 mg for ECP | 0.50 | 1 mg | ✔ | **Baxter** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| 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 [HYDROXYCARBAMIDE] – PCT – Retail pharmacy-Specialist | | | | |
| Cap 500 mg | 23.82 | 100 | ✔ | **Devatis** |
| IDARUBICIN HYDROCHLORIDE | | | | |
| Inj 5 mg vial – PCT only – Specialist | 109.74 | 1 | ✔ | **Zavedos** |
| Inj 10 mg vial – PCT only – Specialist | 233.64 | 1 | ✔ | **Zavedos** |
| Inj 1 mg for ECP – PCT only – Specialist | 25.77 | 1 mg | ✔ | **Baxter** |
| LENALIDOMIDE – Retail pharmacy-Specialist – Special Authority see SA2047 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** |

**SA2047 Special Authority for Subsidy**

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

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

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

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

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

continued…

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

continued…

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 | 641.70 | 1 | ✔ | **Accord** S29 |
| Inj 20 mg vial | 1,250.00 | 1 | ✔ | **Teva** |
| Inj 1 mg for ECP | 269.85 | 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 SA2163 below | | | | |
| Tab 100 mg | 3,701.00 | 56 | ✔ | **Lynparza** |
| Tab 150 mg | 3,701.00 | 56 | ✔ | **Lynparza** |

**SA2163 Special Authority for Subsidy**

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

1 Patient has a high-grade serous* epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
2 There is documentation confirming pathogenic germline BRCA1 or BRCA2 gene mutation; and
3 Either:
  3.1 All of the following:
    3.1.1 Patient has newly diagnosed, advanced disease; and
    3.1.2 Patient has received one line** of previous treatment with platinum-based chemotherapy; and
    3.1.3 Patient's disease must have experienced a partial or complete response to the first-line platinum-based regimen; or
  3.2 All of the following:
    3.2.1 Patient has received at least two lines** of previous treatment with platinum-based chemotherapy; and
    3.2.2 Patient has platinum sensitive disease defined as disease progression occurring at least 6 months after the last dose of the penultimate line** of platinum-based chemotherapy; and
    3.2.3 Patient's disease must have experienced a partial or complete response to treatment with the immediately preceding platinum-based regimen; and
    3.2.4 Patient has not previously received funded olaparib treatment; and

continued…

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

continued…

4 Treatment will be commenced within 12 weeks of the patient's last dose of the immediately preceding platinum-based regimen; and
5 Treatment to be administered as maintenance treatment; and
6 Treatment not to be administered in combination with other chemotherapy.

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

1 Treatment remains clinically appropriate and patient is benefitting from treatment; and
2 Either:
  2.1 No evidence of progressive disease; or
  2.2 Evidence of residual (not progressive) disease and the patient would continue to benefit from treatment in the clinician's opinion; and
3 Treatment to be administered as maintenance treatment; and
4 Treatment not to be administered in combination with other chemotherapy; and
5 Either:
  5.1 Both:
    5.1.1 Patient has received one line** of previous treatment with platinum-based chemotherapy; and
    5.1.2 Documentation confirming that the patient has been informed and acknowledges that the funded treatment period of olaparib will not be continued beyond 2 years if the patient experiences a complete response to treatment and there is no radiological evidence of disease at 2 years; or
  5.2 Patient has received at least two lines** of previous treatment with platinum-based chemotherapy.

Notes: *Note "high-grade serous" includes tumours with high-grade serous features or a high-grade serous component.
**A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

PACLITAXEL – PCT only – Specialist

| | | | | |
|---|---|---|---|---|
| Inj 30 mg | 47.30 | 5 | ✔ | **Paclitaxel Ebewe** |
| Inj 100 mg | 24.00 | 1 | ✔ | **Paclitaxel Ebewe** |
| | 91.67 | | ✔ | **Paclitaxel Actavis** |
| Inj 150 mg | 26.69 | 1 | ✔ | **Paclitaxel Ebewe** |
| | 137.50 | | ✔ | **Anzatax** |
| | | | ✔ | **Paclitaxel Actavis** |
| Inj 300 mg | 44.00 | 1 | ✔ | **Paclitaxel Ebewe** |
| | 275.00 | | ✔ | **Anzatax** |
| | | | ✔ | **Paclitaxel Actavis** |
| Inj 1 mg for ECP | 0.20 | 1 mg | ✔ | **Baxter** |

PEGASPARGASE – PCT only – Special Authority see SA1979 below

| | | | | |
|---|---|---|---|---|
| Inj 750 iu per ml, 5 ml vial | 3,455.00 | 1 | ✔ | **Oncaspar LYO** S29 |

**SA1979 Special Authority for Subsidy**

**Initial application — (Acute lymphoblastic leukaemia)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:
Both:

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

**Initial application — (Lymphoma)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months where the patient has lymphoma requiring L-asparaginase containing protocols (e.g. SMILE).

continued…

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

continued…

**Renewal — (Acute lymphoblastic leukaemia)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:
Both:

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

| | | | | |
|---|---|---|---|---|
| PENTOSTATIN [DEOXYCOFORMYCIN] – PCT only – Specialist | | | | |
| Inj 10 mg | CBS | 1 | ✔ | **Nipent** S29 |
| 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 |

*(Accord S29 Cap 20 mg to be delisted 1 December 2022)*
*(Accord S29 Cap 100 mg to be delisted 1 December 2022)*
*(Amneal S29 Cap 140 mg to be delisted 1 December 2022)*
*(Amneal S29 Cap 250 mg to be delisted 1 December 2022)*

➽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

continued…

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

continued…

relapsed/refractory Ewing's sarcoma.

**Renewal — (high grade gliomas)** only from a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Either:

1 Both:
- 1.1 Patient has glioblastoma multiforme; and
- 1.2 The treatment remains appropriate and the patient is benefitting from treatment; or

2 All of the following:
- 2.1 Patient has anaplastic astrocytoma*; and
- 2.2 The treatment remains appropriate and the patient is benefitting from treatment; and
- 2.3 Adjuvant temozolomide is to be used for a maximum of 24 months.

**Renewal — (neuroendocrine tumours)** only from a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 No evidence of disease progression; and

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

**Renewal — (ewing's sarcoma)** only from a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 No evidence of disease progression; and

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

Note: Indication marked with a * is an unapproved indication. Temozolomide is not subsidised for the treatment of relapsed high grade glioma.

THALIDOMIDE – Retail pharmacy-Specialist – Special Authority see SA1124 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 on the next page

| | | | | |
|---|---|---|---|---|
| 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** |

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

➽SA1868 **Special Authority for Subsidy**

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

All of the following:

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

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

Both:

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

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

All of the following:

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

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

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

| | | | | |
|---|---|---|---|---|
| VINBLASTINE SULPHATE | | | | |
| Inj 1 mg per ml, 10 ml vial – PCT – Retail pharmacy-Specialist | 270.37 | | 5 | ✔ **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** |
| | 328.65 | | | ✔ **Sagent** S29 |
| Inj 1 mg for ECP | 1.25 | | 1 mg | ✔ **Baxter** |
| Inj 50 mg for ECP | 328.65 | | 50 mg OP | ✔ **Baxter (Sagent)** |

▲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 |
|---|---|---|---|---|

## 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
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/

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| ERLOTINIB – Retail pharmacy-Specialist – Special Authority see SA2115 below | | | | |
| Tab 100 mg | 329.70 | 30 | ✔ | **Alchemy** |
| | 764.00 | | ✔ | **Tarceva** |
| Tab 150 mg | 569.70 | 30 | ✔ | **Alchemy** |
| | 1,146.00 | | ✔ | **Tarceva** |

*(Tarceva Tab 100 mg to be delisted 1 February 2023)*
*(Tarceva Tab 150 mg to be delisted 1 February 2023)*

**➽SA2115 Special Authority for Subsidy**
**Initial application** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:

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

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

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

| | | | | |
|---|---|---|---|---|
| GEFITINIB – Retail pharmacy-Specialist – Special Authority see SA2116 below | | | | |
| Tab 250 mg | 918.00 | 30 | ✔ | **Iressa** |

**➽SA2116 Special Authority for Subsidy**
**Initial application** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:

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

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

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

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| IMATINIB MESILATE | | | | |
| Note: The Glivec brand of imatinib mesilate (supplied by Novartis) remains fully subsidised under Special Authority for patients with unresectable and/or metastatic malignant GIST only, see SA1460 in Section B of the Pharmaceutical Schedule. | | | | |
| Tab 100 mg – [Xpharm] – Special Authority see SA1460 below | 2,400.00 | 60 | ✔ | **Glivec** |
| ❋ Cap 100 mg | 58.23 | 60 | ✔ | **Imatinib-Rex** |
| ❋ Cap 400 mg | 84.79 | 30 | ✔ | **Imatinib-Rex** |

**➽SA1460 Special Authority for Subsidy**

Special Authority approved by the CML/GIST Co-ordinator

Notes: Application details may be obtained from Pharmac's website schedule.pharmac.govt.nz/SAForms, 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 SA2035 below – Retail pharmacy | | | | |
| Note – no new patients to be initiated on lapatinib ditosylate. | | | | |
| Tab 250 mg | 1,899.00 | 70 | ✔ | **Tykerb** |

**➽SA2035 Special Authority for Subsidy**

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

All of the following:

1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
2 The cancer has not progressed at any time point during the previous 12 months whilst on lapatinib; and
3 Lapatinib not to be given in combination with trastuzumab; and
4 Lapatinib to be discontinued at disease progression.

| | | | | |
|---|---|---|---|---|
| NILOTINIB – Special Authority see SA1489 below – Retail pharmacy | | | | |
| Wastage claimable | | | | |
| Cap 150 mg | 4,680.00 | 120 | ✔ | **Tasigna** |
| Cap 200 mg | 6,532.00 | 120 | ✔ | **Tasigna** |

**➽SA1489 Special Authority for Subsidy**

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

All of the following:

1 Patient has a diagnosis of chronic myeloid leukaemia (CML) in blast crisis, accelerated phase, or in chronic phase; and
2 Either:
  2.1 Patient has documented CML treatment failure* with imatinib; or

continued…

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

continued…

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

| | | | | |
|---|---|---|---|---|
| Tab 75 mg | 4,000.00 | 21 | ✔ | **Ibrance** |
| Tab 100 mg | 4,000.00 | 21 | ✔ | **Ibrance** |
| Tab 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.

PAZOPANIB – Special Authority see SA1190 on the next page – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Tab 200 mg | 1,334.70 | 30 | ✔ | **Votrient** |
| Tab 400 mg | 2,669.40 | 30 | ✔ | **Votrient** |

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

**➽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 10mg | 5,000.00 | | 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:

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

continued…

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

continued…

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 SA2117 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Cap 12.5 mg | 208.38 | 28 | ✔ | **Sunitinib Pfizer** |
| Cap 25 mg | 416.77 | 28 | ✔ | **Sunitinib Pfizer** |
| Cap 50 mg | 694.62 | 28 | ✔ | **Sunitinib Pfizer** |

➽**SA2117** **Special Authority for Subsidy**

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

All of the following:

1 The patient has metastatic renal cell carcinoma; and

2 Any of the following:

2.1 The patient is treatment naive; or

2.2 The patient has only received prior cytokine treatment; or

2.3 The patient has only received prior treatment with an investigational agent within the confines of a bona fide clinical trial which has Ethics Committee approval; or

2.4 Both:

2.4.1 The patient has discontinued pazopanib within 3 months of starting treatment due to intolerance; and

2.4.2 The cancer did not progress whilst on pazopanib; and

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

4 The disease is of predominant clear cell histology; and
The patient has intermediate or poor prognosis defined as:

5 Any of the following:

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

5.2 Haemoglobin level < lower limit of normal; or

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

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

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

5.6 2 or more sites of organ metastasis; and

6 Sunitinib to be used for a maximum of 2 cycles.

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

Both:

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

2 Either:

2.1 The patient's disease has progressed following treatment with imatinib; or

2.2 The patient has documented treatment-limiting intolerance, or toxicity to, imatinib.

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

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 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 83

ABIRATERONE ACETATE – Retail pharmacy-Specialist – Special Authority see SA2118 below

| | | | | |
|---|---|---|---|---|
| Wastage claimable | | | | |
| Tab 250 mg | 4,276.19 | 120 | ✔ | **Zytiga** |

**➽SA2118 Special Authority for Subsidy**

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

1 Patient has prostate cancer; and
2 Patient has metastases; and
3 Patient's disease is castration resistant; and
4 Either:

  4.1 All of the following:

continued…

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

continued…

4.1.1 Patient is symptomatic; and
4.1.2 Patient has disease progression (rising serum PSA) after second line anti-androgen therapy; and
4.1.3 Patient has ECOG performance score of 0-1; and
4.1.4 Patient has not had prior treatment with taxane chemotherapy; or

4.2 All of the following:
4.2.1 Patient's disease has progressed following prior chemotherapy containing a taxane; and
4.2.2 Patient has ECOG performance score of 0-2; and
4.2.3 Patient has not had prior treatment with abiraterone.

**Renewal — (abiraterone acetate)** only from a medical oncologist, radiation oncologist, urologist or medical practitioner on the recommendation of a medical oncologist, radiation oncologist or urologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1 Significant decrease in serum PSA from baseline; and
2 No evidence of clinical disease progression; and
3 No initiation of taxane chemotherapy with abiraterone; and
4 The treatment remains appropriate and the patient is benefiting from treatment.

**Renewal — (pandemic circumstances)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1 The patient is clinically benefiting from treatment and continued treatment remains appropriate; and
2 Abiraterone acetate to be discontinued at progression; and
3 No initiation of taxane chemotherapy with abiraterone; and
4 The regular Special Authority renewal requirements cannot be met due to COVID-19 constraints on the health sector.

BICALUTAMIDE
Tab 50 mg ..... 4.21 — 28 — ✔ **Binarex**

FLUTAMIDE
Tab 250 mg ..... 107.55 — 90 — ✔ **Prostacur** S29
119.50 — 100 — ✔ **Flutamin**

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

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

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

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| MEGESTROL ACETATE – Subsidy by endorsement | | | | |
| Subsidy by endorsement – Subsidised for patients who were taking megestrol acetate prior to 1 August 2021 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of megestrol acetate. | | | | |
| Tab 160 mg | 48.80 | 30 | ✔ | **Megace** S29 |
| *(Megace S29 Tab 160 mg to be delisted 1 February 2023)* | | | | |
| OCTREOTIDE | | | | |
| Inj 50 mcg per ml, 1 ml ampoule | 27.58 | 5 | ✔ | **Max Health** |
| | | | ✔ | **Octreotide GH** S29 |
| Inj 100 mcg per ml, 1 ml ampoule | 32.71 | 5 | ✔ | **Max Health** |
| Inj 500 mcg per ml, 1 ml ampoule | 113.10 | 5 | ✔ | **Max Health** |
| OCTREOTIDE LONG-ACTING – Special Authority see SA2119 below – Retail pharmacy | | | | |
| Inj depot 10 mg prefilled syringe | 439.97 | 1 | ✔ | **Octreotide Depot Teva** |
| Inj depot 20 mg prefilled syringe | 647.03 | 1 | ✔ | **Octreotide Depot Teva** |
| Inj depot 30 mg prefilled syringe | 718.55 | 1 | ✔ | **Octreotide Depot Teva** |

**SA2119 Special Authority for Subsidy**

**Initial application — (Malignant Bowel Obstruction)** from any relevant practitioner. Approvals valid for 2 months for applications meeting the following criteria:
All of the following:

1 The patient has nausea* and vomiting* due to malignant bowel obstruction*; and
2 Treatment with antiemetics, rehydration, antimuscarinic agents, corticosteroids and analgesics for at least 48 hours has failed; and
3 Octreotide to be given at a maximum dose 1500 mcg daily for up to 4 weeks.

Note: Indications marked with * are unapproved indications.

**Renewal — (Malignant Bowel Obstruction)** from any relevant practitioner. Approvals valid for 3 months where the treatment remains appropriate and the patient is benefiting from treatment.

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

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

continued…

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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**Renewal — (Acromegaly - pandemic circumstances)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

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

**Initial application — (Other Indications)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

1 VIPomas and Glucagonomas - for patients who are seriously ill in order to improve their clinical state prior to definitive surgery; or
2 Both:
  2.1 Gastrinoma; and
  2.2 Either:
    2.2.1 Patient has failed surgery; or
    2.2.2 Patient in metastatic disease after H2 antagonists (or proton pump inhibitors) have failed; or
3 Both:
  3.1 Insulinomas; and
  3.2 Surgery is contraindicated or has failed; or
4 For pre-operative control of hypoglycaemia and for maintenance therapy; or
5 Both:
  5.1 Carcinoid syndrome (diagnosed by tissue pathology and/or urinary 5HIAA analysis); and
  5.2 Disabling symptoms not controlled by maximal medical therapy.

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

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

**Initial application — (pre-operative acromegaly)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 Patient has acromegaly; and
2 Patient has a large pituitary tumour, greater than 10 mm at its widest; and
3 Patient is scheduled to undergo pituitary surgery in the next six months.

TAMOXIFEN CITRATE

| | | | | |
|---|---|---|---|---|
| ✱ | Tab 10 mg | 15.00 | 60 | ✔ **Tamoxifen Sandoz** |
| ✱ | Tab 20 mg | 6.65 | 60 | ✔ **Tamoxifen Sandoz** |

## Aromatase Inhibitors

ANASTROZOLE

| | | | | |
|---|---|---|---|---|
| ✱ | Tab 1 mg | 4.55 | 30 | ✔ **Anatrole** |

EXEMESTANE

| | | | | |
|---|---|---|---|---|
| ✱ | Tab 25 mg | 14.50 | 30 | ✔ **Pfizer Exemestane** |

LETROZOLE

| | | | | |
|---|---|---|---|---|
| ✱ | Tab 2.5 mg | 5.84 | 30 | ✔ **Letrole** |

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

### Cytotoxic Immunosuppressants

AZATHIOPRINE

| | | | | |
|---|---|---|---|---|
| ❋ Tab 25 mg | 7.36 | 60 | ✔ | **Azamun** |
| ❋ Tab 50 mg | 8.10 | 100 | ✔ | **Azamun** |
| ❋ Inj 50 mg vial | 199.00 | 1 | ✔ | **Imuran** |

*(Imuran Inj 50 mg vial to be delisted 1 January 2023)*

MYCOPHENOLATE MOFETIL

| | | | | |
|---|---|---|---|---|
| Tab 500 mg | 35.90 | 50 | ✔ | **Cellcept** |
| Cap 250 mg | 35.90 | 100 | ✔ | **Cellcept** |
| Powder for oral liq 1 g per 5 ml – Subsidy by endorsement | 187.25 | 165 ml OP | ✔ | **Cellcept** |

Mycophenolate powder for oral liquid is subsidised only for patients unable to swallow tablets and capsules, and when the prescription is endorsed accordingly.

### Fusion Proteins

ETANERCEPT – Special Authority see SA2103 below – Retail pharmacy

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

**SA2103 Special Authority for Subsidy**

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

Either:

1 Both:
- 1.1 Either:
  - 1.1.1 The patient has had an initial Special Authority approval for adalimumab for adult-onset Still's disease (AOSD); or
  - 1.1.2 The patient has been started on tocilizumab for AOSD in a Health NZ Hospital; and
- 1.2 Either:
  - 1.2.1 The patient has experienced intolerable side effects from adalimumab and/or tocilizumab; or
  - 1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or tocilizumab such that they do not meet the renewal criteria for AOSD; or

2 All of the following:
- 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and
- 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal anti-inflammatory drugs (NSAIDs) and methotrexate; and
- 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

**Renewal — (adult-onset Still's disease)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 Either:
- 1.1 Applicant is a rheumatologist; or
- 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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2 The patient has a sustained improvement in inflammatory markers and functional status.

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

Either:

1 Both:
- 1.1 The patient has had an initial Special Authority approval for adalimumab for ankylosing spondylitis; and
- 1.2 Either:
  - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
  - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for ankylosing spondylitis; or

2 All of the following:
- 2.1 Patient has a confirmed diagnosis of ankylosing spondylitis present for more than six months; and
- 2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
- 2.3 Patient has bilateral sacroiliitis demonstrated by plain radiographs, CT or MRI scan; and
- 2.4 Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and
- 2.5 Either:
  - 2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following Bath Ankylosing Spondylitis Metrology Index (BASMI) measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or
  - 2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender (see Notes); and
- 2.6 A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 6 on a 0-10 scale.

Notes: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure must be no more than 1 month old at the time of initial application.

Average normal chest expansion corrected for age and gender:

18-24 years - Male: 7.0 cm; Female: 5.5 cm
25-34 years - Male: 7.5 cm; Female: 5.5 cm
35-44 years - Male: 6.5 cm; Female: 4.5 cm
45-54 years - Male: 6.0 cm; Female: 5.0 cm
55-64 years - Male: 5.5 cm; Female: 4.0 cm
65-74 years - Male: 4.0 cm; Female: 4.0 cm
75+ years - Male: 3.0 cm; Female: 2.5 cm

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

All of the following:

1 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.

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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**Initial application — (polyarticular course juvenile idiopathic arthritis)** only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Either:

1 Both:
- 1.1 The patient has had an initial Special Authority approval for adalimumab for polyarticular course juvenile idiopathic arthritis (JIA); and
- 1.2 Either:
  - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
  - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for polyarticular course JIA; or

2 All of the following:
- 2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2.2 Patient has had polyarticular course JIA for 6 months duration or longer; and
- 2.3 Any of the following:
  - 2.3.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
  - 2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or
  - 2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

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

1 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2 Either:
- 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
- 2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

**Initial application — (oligoarticular course juvenile idiopathic arthritis)** only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Either:

1 Both:
- 1.1 The patient has had an initial Special Authority approval for adalimumab for oligoarticular course juvenile idiopathic arthritis (JIA); and
- 1.2 Either:
  - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
  - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for oligoarticular course JIA; or

2 All of the following:
- 2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2.2 Patient has had oligoarticular course JIA for 6 months duration or longer; and
- 2.3 Any of the following:

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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2.3.1 At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
2.3.2 Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose); or
2.3.3 High disease activity (cJADAS10 score greater than 4) after a 6-month trial of methotrexate.

**Renewal — (oligoarticular course juvenile idiopathic arthritis)** only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:
1 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2 Either:
2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

**Initial application — (psoriatic arthritis)** only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Either:
1 Both:
1.1 The patient has had an initial Special Authority approval for adalimumab or secukinumab for psoriatic arthritis; and
1.2 Either:
1.2.1 The patient has experienced intolerable side effects from adalimumab or secukinumab; or
1.2.2 The patient has received insufficient benefit from adalimumab or secukinumab to meet the renewal criteria for adalimumab or secukinumab for psoriatic arthritis; or
2 All of the following:
2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and
2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
2.3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and
2.4 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

continued…

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and

2 Either:

2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or

2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior etanercept treatment in the opinion of the treating physician; and

3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

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

1 Patient has pyoderma gangrenosum*; and

2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate) and not received an adequate response; and

3 A maximum of 8 doses.

Note: Indications marked with * are unapproved indications.

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

1 Patient has shown clinical improvement; and

2 Patient continues to require treatment; and

3 A maximum of 8 doses.

**Initial application — (Arthritis - rheumatoid )** only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Either:

1 Both:

1.1 The patient has had an initial Special Authority approval for adalimumab for rheumatoid arthritis; and

1.2 Either:

1.2.1 The patient has experienced intolerable side effects; or

1.2.2 The patient has received insufficient benefit to meet the renewal criteria for rheumatoid arthritis; or

2 All of the following:

2.1 Patient has had rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and

2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

2.3 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and

2.4 Patient has tried and not responded to at least three months of methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses unless contraindicated); and

2.5 Either:

2.5.1 Patient has tried and not responded to at least three months of methotrexate in combination with the maximum tolerated dose of ciclosporin; or

2.5.2 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with methotrexate; and

2.6 Either:

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

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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2.6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip.

**Renewal — (Arthritis - rheumatoid)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
All of the following:

1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2 Either:
2.1 Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

**Initial application — (severe chronic plaque psoriasis)** only from a dermatologist. 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.
**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 |
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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

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

All of the following:

1 Patient has undifferentiated peripheral spondyloarthritis* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and

2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and

3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day (or maximum tolerated dose); and

4 Patient has tried and not responded to at least three months of leflunomide at a dose of up to 20 mg daily (or maximum tolerated dose); and

5 Any of the following:

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

5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour measured no more than one month prior to the date of this application; or

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

Note: Indications marked with * are unapproved indications.

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

All of the following:

1 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

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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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 | 2,774.48 | 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 |

## Monoclonal Antibodies

| | | | | |
|---|---|---|---|---|
| ADALIMUMAB (AMGEVITA) – Special Authority see SA2142 below – Retail pharmacy | | | | |
| Brand switch fee payable (Pharmacode 2645165) - see page 245 for details | | | | |
| Inj 20 mg per 0.4 ml prefilled syringe | 190.00 | 1 | ✔ | **Amgevita** |
| Inj 40 mg per 0.8 ml prefilled pen | 375.00 | 2 | ✔ | **Amgevita** |
| Inj 40 mg per 0.8 ml prefilled syringe | 375.00 | 2 | ✔ | **Amgevita** |

➽SA2142 **Special Authority for Subsidy**

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

Either:

1 The patient has previously had an approval for Humira; or

2 Both:

2.1 The patient has severe Behcet's disease* that is significantly impacting the patient's quality of life; and

2.2 Either:

2.2.1 The patient has severe ocular, neurological, and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s); or

2.2.2 The patient has severe gastrointestinal, rheumatological, and/or mucocutaneous symptoms and has not responded adequately to two or more treatments appropriate for the particular symptom(s).

Note: Indications marked with * are unapproved indications.

**Initial application — (Hidradenitis suppurativa)** only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

1 The patient has previously had an approval for Humira; or

2 All of the following:

2.1 Patient has hidradenitis suppurativa Hurley Stage II or Hurley Stage III lesions in distinct anatomic areas; and

2.2 Patient has tried, but had an inadequate response to at least a 90 day trial of systemic antibiotics or has demonstrated intolerance to or has contraindications for systemic antibiotics; and

2.3 Patient has 3 or more active lesions; and

2.4 The patient has a DLQI of 10 or more and the assessment is no more than 1 month old at time of application.

**Renewal — (Hidradenitis suppurativa)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the

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following criteria:
Both:

1 The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline; and
2 The patient has a DLQI improvement of 4 or more from baseline.

**Initial application — (Plaque psoriasis - severe chronic)** only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:
Either:

1 The patient has previously had an approval for Humira; or
2 Either:
  2.1 Both:
    2.1.1 Patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and
    2.1.2 Either:
      2.1.2.1 Patient has experienced intolerable side effects; or
      2.1.2.2 Patient has received insufficient benefit to meet the renewal criteria for etanercept for severe chronic plaque psoriasis; or
  2.2 All of the following:
    2.2.1 Either:
      2.2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a PASI score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
      2.2.1.2 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
    2.2.2 Patient has tried, but had an inadequate response to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
    2.2.3 A PASI assessment or DLQI assessment has been completed for at least the most recent prior treatment course but no longer than 1 month following cessation of each prior treatment course and is no more than 1 month old at the time of application.

**Renewal — (Plaque psoriasis - severe chronic)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Either:

1 Both:
  1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
  1.2 Either:
    1.2.1 The patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre treatment baseline value; or
    1.2.2 The patient has a DLQI improvement of 5 or more, when compared with the pre-treatment baseline value; or
2 Both:
  2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
  2.2 Either:
    2.2.1 The patient has 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 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.

**Initial application — (pyoderma gangrenosum)** only from a dermatologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

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Either:

1 The patient has previously had an approval for Humira; or
2 Both:
  2.1 Patient has pyoderma gangrenosum*; and
  2.2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate) and has not received an adequate response.

Note: Indications marked with * are unapproved indications.

**Initial application — (Crohn's disease - adults)** only from a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

Either:

1 The patient has previously had an approval for Humira; or
2 All of the following:
  2.1 Patient has severe active Crohn's disease; and
  2.2 Any of the following:
    2.2.1 Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10; or
    2.2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
    2.2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
    2.2.4 Patient has an ileostomy or colostomy and has intestinal inflammation; and
  2.3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids; and
  2.4 Surgery (or further surgery) is considered to be clinically inappropriate.

**Renewal — (Crohn's disease - adults)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

1 CDAI score has reduced by 100 points from the CDAI score, or HBI score has reduced by 3 points, from when the patient was initiated on adalimumab; or
2 CDAI score is 150 or less, or HBI is 4 or less; or
3 The patient has demonstrated an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed.

**Initial application — (Crohn's disease - children)** only from a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

Either:

1 The patient has previously had an approval for Humira; or
2 All of the following:
  2.1 Paediatric patient has active Crohn's disease; and
  2.2 Either:
    2.2.1 Patient has a PCDAI score of greater than or equal to 30; or
    2.2.2 Patient has extensive small intestine disease; and
  2.3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids; and
  2.4 Surgery (or further surgery) is considered to be clinically inappropriate.

**Renewal — (Crohn's disease - children)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab; or
2 PCDAI score is 15 or less; or
3 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed.

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**Initial application — (Crohn's disease - fistulising)** only from a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:
Either:

1 The patient has previously had an approval for Humira; or
2 All of the following:
  2.1 Patient has confirmed Crohn's disease; and
  2.2 Any of the following:
    2.2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
    2.2.2 Patient has one or more rectovaginal fistula(e); or
    2.2.3 Patient has complex peri-anal fistula; and
  2.3 A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application.

**Renewal — (Crohn's disease - fistulising)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Either:

1 The number of open draining fistulae have decreased from baseline by at least 50%; or
2 There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain.

**Initial application — (Ocular inflammation - chronic)** from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:
Either:

1 The patient has previously had an approval for Humira; or
2 Either:
  2.1 The patient has had an initial Special Authority approval for infliximab for chronic ocular inflammation; or
  2.2 Both:
    2.2.1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and
    2.2.2 Any of the following:
      2.2.2.1 Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective; or
      2.2.2.2 Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or
      2.2.2.3 Patient is under 8 years and treatment with steroids or methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or disease requires control to prevent irreversible vision loss prior to achieving a therapeutic dose of methotrexate.

**Renewal — (Ocular inflammation - chronic)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Any of the following:

1 The patient has had a good clinical response following 12 weeks' initial treatment; or
2 Following each 2 year treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
3 Following each 2 year treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.

**Initial application — (Ocular inflammation - severe)** from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:
Either:

1 The patient has previously had an approval for Humira; or

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2 Either:

2.1 Patient has had an initial Special Authority approval for infliximab for severe ocular inflammation; or

2.2 Both:

2.2.1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and

2.2.2 Any of the following:

2.2.2.1 Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms; or

2.2.2.2 Patient developed new inflammatory symptoms while receiving high dose steroids; or

2.2.2.3 Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms.

**Renewal — (Ocular inflammation - severe)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

1 The patient has had a good clinical response following 3 initial doses; or

2 Following each 2 year treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or

3 Following each 2 year treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.

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

Either:

1 The patient has previously had an approval for Humira; or

2 Either:

2.1 Both:

2.1.1 Patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; and

2.1.2 Either:

2.1.2.1 The patient has experienced intolerable side effects; or

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

2.2 All of the following:

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

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

2.2.3 Patient has bilateral sacroiliitis demonstrated by radiology imaging; and

2.2.4 Patient has not responded adequately to treatment with two or more NSAIDs, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and

2.2.5 Either:

2.2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following BASMI measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or

2.2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender; and

2.2.6 A BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment and is no more than 1 month old at the time of application.

**Renewal — (ankylosing spondylitis)** from any relevant practitioner. Approvals valid for 2 years where treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less.

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**Initial application — (Arthritis - oligoarticular course juvenile idiopathic)** only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Either:

1 The patient has previously had an approval for Humira; or
2 Either:
  2.1 Both:
    2.1.1 The patient has had an initial Special Authority approval for etanercept for oligoarticular course juvenile idiopathic arthritis (JIA); and
    2.1.2 Either:
      2.1.2.1 Patient has experienced intolerable side effects; or
      2.1.2.2 Patient has received insufficient benefit to meet the renewal criteria for oligoarticular course JIA; or
  2.2 All of the following:
    2.2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
    2.2.2 Patient has had oligoarticular course JIA for 6 months duration or longer; and
    2.2.3 Either:
      2.2.3.1 At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
      2.2.3.2 Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose).

**Renewal — (Arthritis - oligoarticular course juvenile idiopathic)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Either:

1 Following initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

**Initial application — (Arthritis - polyarticular course juvenile idiopathic)** only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Either:

1 The patient has previously had an approval for Humira; or
2 Either:
  2.1 Both:
    2.1.1 Patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA); and
    2.1.2 Either:
      2.1.2.1 Patient has experienced intolerable side effects; or
      2.1.2.2 Patient has received insufficient benefit to meet the renewal criteria for polyarticular course JIA; or
  2.2 All of the following:
    2.2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
    2.2.2 Patient has had polyarticular course JIA for 6 months duration or longer; and
    2.2.3 Any of the following:
      2.2.3.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
      2.2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or

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2.2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

**Renewal — (Arthritis - polyarticular course juvenile idiopathic)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

1 Following initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or

2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

**Initial application — (Arthritis - psoriatic)** only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 The patient has previously had an approval for Humira; or

2 Either:

2.1 Both:

2.1.1 Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis; and

2.1.2 Either:

2.1.2.1 The patient has experienced intolerable side effects; or

2.1.2.2 The patient has received insufficient benefit from to meet the renewal criteria for psoriatic arthritis; or

2.2 All of the following:

2.2.1 Patient has had active psoriatic arthritis for six months duration or longer; and

2.2.2 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and

2.2.3 Patient has tried and not responded to at least three months of sulfasalazine or leflunomide at maximum tolerated doses (unless contraindicated); and

2.2.4 Either:

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

2.2.4.2 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

2.2.5 Any of the following:

2.2.5.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or

2.2.5.2 Patient has an ESR greater than 25 mm per hour; or

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

**Renewal — (Arthritis - psoriatic)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

1 Following initial treatment, the patient has at least a 50% decrease in swollen joint count from baseline and a clinically significant response in the opinion of the physician; or

2 Patient demonstrates at least a continuing 30% improvement in swollen joint count from baseline and a clinically significant response in the opinion of the treating physician.

**Initial application — (Arthritis - rheumatoid)** only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 The patient has previously had an approval for Humira; or

2 Either:

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2.1 Both:
2.1.1 The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis; and
2.1.2 Either:
2.1.2.1 The patient has experienced intolerable side effects; or
2.1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for rheumatoid arthritis; or

2.2 All of the following:
2.2.1 Patient has had rheumatoid arthritis (either confirmed by radiology imaging, or the patient is CCP antibody positive) for six months duration or longer; and
2.2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2.2.3 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
2.2.4 Patient has tried and not responded to at least three months of methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate at maximum tolerated doses (unless contraindicated); and
2.2.5 Either:
2.2.5.1 Patient has tried and not responded to at least three months of methotrexate in combination with the maximum tolerated dose of ciclosporin; or
2.2.5.2 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with methotrexate; and
2.2.6 Either:
2.2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
2.2.6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip.

**Renewal — (Arthritis - rheumatoid)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Either:
1 Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician.

**Initial application — (Still's disease - adult-onset (AOSD))** only from a rheumatologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:
Either:
1 The patient has previously had an approval for Humira; or
2 Either:
2.1 Both:
2.1.1 The patient has had an initial Special Authority approval for etanercept and/or tocilizumab for AOSD; and
2.1.2 Either:
2.1.2.1 Patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
2.1.2.2 Patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab; or

2.2 All of the following:
2.2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria; and
2.2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, NSAIDs and methotrexate; and

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2.2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

**Initial application — (ulcerative colitis)** only from a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

Either:

1 The patient has previously had an approval for Humira; or

2 All of the following:

2.1 Patient has histologically confirmed ulcerative colitis; and

2.2 Either:

2.2.1 Patient's SCCAI score is greater than or equal to 4; or

2.2.2 Patient's PUCAI score is greater than or equal to 65; and

2.3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from prior therapy with immunomodulators and systemic corticosteroids; and

2.4 Surgery (or further surgery) is considered to be clinically inappropriate.

**Renewal — (ulcerative colitis)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

1 The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on adalimumab; or

2 The PUCAI score has reduced by 30 points or more from the PUCAI score since initiation on adalimumab.

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

Either:

1 The patient has previously had an approval for Humira; or

2 All of the following:

2.1 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

2.2 Patient has tried and not responded to at least three months of each of methotrexate, sulfasalazine and leflunomide, at maximum tolerated doses (unless contraindicated); and

2.3 Any of the following:

2.3.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or

2.3.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; or

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

Note: Indications marked with * are unapproved indications

**Renewal — (undifferentiated spondyloarthritis)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

1 Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or

2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response in the opinion of the treating physician.

**Initial application — (inflammatory bowel arthritis – axial)** only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 The patient has previously had an approval for Humira; or

2 All of the following:

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2.1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
2.2 Patient has axial inflammatory pain for six months or more; and
2.3 Patient is unable to take NSAIDs; and
2.4 Patient has bilateral sacroiliitis demonstrated by radiological imaging; and
2.5 Patient has not responded adequately to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist; and
2.6 A BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment.

**Renewal — (inflammatory bowel arthritis – axial)** from any relevant practitioner. Approvals valid for 2 years where treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less.

**Initial application — (inflammatory bowel arthritis – peripheral)** only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 The patient has previously had an approval for Humira; or
2 All of the following:
2.1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
2.2 Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular; and
2.3 Patient has tried and not responded to at least three months of methotrexate, or azathioprine at a maximum tolerated dose; and
2.4 Patient has tried and not responded to at least three months of sulfasalazine at a maximum tolerated dose; and
2.5 Any of the following:
2.5.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
2.5.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; 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 — (inflammatory bowel arthritis – peripheral)** from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

1 Following initial treatment, patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
2 Patient demonstrates at least a continuing 30% improvement in active joint count from baseline in the opinion of the treating physician.

ADALIMUMAB (HUMIRA - ALTERNATIVE BRAND) – Special Authority see SA2157 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Inj 20 mg per 0.2 ml prefilled syringe | 1,599.96 | 2 | ✔ | **Humira** |
| 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** |

*(Humira Inj 20 mg per 0.4 ml prefilled syringe to be delisted 1 December 2022)*

**➽SA2157 Special Authority for Subsidy**

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

All of the following:

1 Either:

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and

2 Patient has received a maximum of 6 months treatment with Amgevita; and

3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and

4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Renewal — (Behcet's disease – severe)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 The patient has had a good clinical response to treatment with measurably improved quality of life; and

2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Initial application — (Hidradenitis suppurativa)** only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 Either:

1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and

2 Patient has received a maximum of 6 months treatment with Amgevita; and

3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and

4 Adalimumab to be administered at doses no greater than 40 mg every 7 days. Fortnightly dosing has been considered.

**Renewal — (Hidradenitis suppurativa)** only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline; and

2 The patient has a Dermatology Quality of Life Index improvement of 4 or more from baseline; and

3 Adalimumab is to be administered at doses no greater than 40mg every 7 days. Fortnightly dosing has been considered.

**Initial application — (Psoriasis - severe chronic plaque)** only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 Either:

1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and

2 Patient has received a maximum of 6 months treatment with Amgevita; and

3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and

4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

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

Both:

1 Either:

1.1 Both:

1.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and

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

1.1.2.1 Following each prior adalimumab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-adalimumab treatment baseline value; or

1.1.2.2 Following each prior adalimumab treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value; or

1.2 Both:

1.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and

1.2.2 Either:

1.2.2.1 Following each prior adalimumab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or

1.2.2.2 Following each prior adalimumab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-adalimumab treatment baseline value; and

2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Initial application — (Pyoderma gangrenosum)** only from a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Either:

1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and

2 Patient has received a maximum of 6 months treatment with Amgevita; and

3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and

4 A maximum of 8 doses.

**Renewal — (Pyoderma gangrenosum)** only from a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:

1 The patient has demonstrated clinical improvement and continues to require treatment; and

2 A maximum of 8 doses.

**Initial application — (Crohn's disease - adult)** only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Any of the following:

1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevitat; or

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or

1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and

2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and

3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

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**Renewal — (Crohn's disease - adult)** only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:

1 Any of the following:
  1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab; or
  1.2 CDAI score is 150 or less; or
  1.3 The patient has demonstrated an adequate response to treatment, but CDAI score cannot be assessed; and
2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Initial application — (Crohn's disease - children)** only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Any of the following:
  1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
  1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
  1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and
2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Renewal — (Crohn's disease - children)** only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:

1 Any of the following:
  1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab; or
  1.2 PCDAI score is 15 or less; or
  1.3 The patient has demonstrated an adequate response to treatment, but PCDAI score cannot be assessed; and
2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Initial application — (Crohn's disease - fistulising)** only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Any of the following:
  1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
  1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
  1.3 Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment; and
2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Renewal — (Crohn's disease - fistulising)** only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:

1 Either:
  1.1 The number of open draining fistulae have decreased from baseline by at least 50%; or

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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1.2 There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain; and

2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Initial application — (Ocular inflammation – chronic)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:

1 Any of the following:

1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with Amgevita, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or

1.3 Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment; and

2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and

3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Renewal — (Ocular inflammation – chronic)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Both:

1 Any of the following:

1.1 The patient has had a good clinical response following 12 weeks' initial treatment; or

1.2 Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or

1.3 Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old; and

2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Initial application — (Ocular inflammation – severe)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
All of the following:

1 Any of the following:

1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or

1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with Amgevita, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or

1.3 Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment; and

2 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and

3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Renewal — (Ocular inflammation – severe)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Both:

1 Any of the following:

1.1 The patient has had a good clinical response following 3 initial doses; or

1.2 Following each 12-month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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1.3 Following each 12-month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old; and

2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Initial application — (ankylosing spondylitis)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Either:
- 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
- 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita); and

2 Patient has received a maximum of 6 months treatment with Amgevita; and
3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

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

1 Treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less; and
2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Initial application — (Arthritis – oligoarticular course juvenile idiopathic)** only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Either:
- 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
- 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and

2 Patient has received a maximum of 6 months treatment with Amgevita; and
3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

**Renewal — (Arthritis – oligoarticular course juvenile idiopathic)** only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months where the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

**Initial application — (Arthritis - polyarticular course juvenile idiopathic)** only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Either:
- 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
- 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and

2 Patient has received a maximum of 6 months treatment with Amgevita; and
3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

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**Renewal — (Arthritis - polyarticular course juvenile idiopathic)** only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months where the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

**Initial application — (Arthritis - psoriatic)** only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Either:
  1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
  1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2 Patient has received a maximum of 6 months treatment with Amgevita; and
3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Renewal — (Arthritis - psoriatic)** only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:

1 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician; and
2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

**Initial application — (Arthritis – rheumatoid)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Either:
  1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
  1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2 Patient has received a maximum of 6 months treatment with Amgevita; and
3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4 Either:
  4.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
  4.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

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

1 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician; and
2 Either:
  2.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
  2.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

**Initial application — (Still's disease – adult-onset (AOSD))** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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1 Either:
- 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
- 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and

2 Patient has received a maximum of 6 months treatment with Amgevita; and
3 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

**Renewal — (Still's disease – adult-onset (AOSD))** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months where the patient has demonstrated a sustained improvement in inflammatory markers and functional status.

AFLIBERCEPT – Special Authority see SA1772 below – Retail pharmacy

| | | | | |
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| 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

2 Either:
- 2.1 Patient has current approval to use ranibizumab for treatment of wAMD and was found to be intolerant to ranibizumab within 3 months; or
- 2.2 Patient has previously* (*before June 2018) received treatment with ranibizumab for wAMD and disease was stable while on treatment.

**Initial application — (diabetic macular oedema)** only from an ophthalmologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

1 Patient has centre involving diabetic macular oedema (DMO); and
2 Patient's disease is non responsive to 4 doses of intravitreal bevacizumab when administered 4-6 weekly; and
3 Patient has reduced visual acuity between 6/9 – 6/36 with functional awareness of reduction in vision; and
4 Patient has DMO within central OCT (ocular coherence tomography) subfield > 350 micrometers; and
5 There is no centre-involving sub-retinal fibrosis or foveal atrophy.

**Renewal — (wet age related macular degeneration)** only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 Documented benefit must be demonstrated to continue; and
2 Patient's vision is 6/36 or better on the Snellen visual acuity score; and

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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3 There is no structural damage to the central fovea of the treated eye.

**Renewal — (diabetic macular oedema)** only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 There is stability or two lines of Snellen visual acuity gain; and
2 There is structural improvement on OCT scan (with reduction in intra-retinal cysts, central retinal thickness, and sub-retinal fluid); and
3 Patient's vision is 6/36 or better on the Snellen visual acuity score; and
4 There is no centre-involving sub-retinal fibrosis or foveal atrophy; and
5 After each consecutive 12 months treatment with (2nd line anti-VEGF agent), patient has retrialled with at least one injection of bevacizumab and had no response.

BENRALIZUMAB – Special Authority see SA2151 on the next page – Retail pharmacy

| | | | | |
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| Inj 30 mg per ml, 1 ml prefilled pen | 3,539.00 | 1 | ✔ | **Fasenra** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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➽SA2151 **Special Authority for Subsidy**

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

All of the following:

1 Patient must be aged 12 years or older; and
2 Patient must have a diagnosis of severe eosinophilic asthma documented by a respiratory physician or clinical immunologist; and
3 Conditions that mimic asthma eg. vocal cord dysfunction, central airway obstruction, bronchiolitis etc. have been excluded; and
4 Patient has a blood eosinophil count of greater than 0.5 × 10^9 cells/L in the last 12 months; and
5 Patient must be adherent to optimised asthma therapy including inhaled corticosteroids (equivalent to at least 1000 mcg per day of fluticasone propionate) plus long-acting beta-2 agonist, or budesonide/formoterol as part of the anti-inflammatory reliever therapy plus maintenance regimen, unless contraindicated or not tolerated; and
6 Either:
  6.1 Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral corticosteroids; or
  6.2 Patient has received continuous oral corticosteroids of at least the equivalent of 10 mg per day over the previous 3 months; and
7 Treatment is not to be used in combination with subsidised mepolizumab; and
8 Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment; and
9 Either:
  9.1 Patient has not previously received an anti-IL5 biological therapy for their severe eosinophilic asthma; or
  9.2 Both:
    9.2.1 Patient was refractory or intolerant to previous anti-IL5 biological therapy; and
    9.2.2 Patient was not eligible to continue treatment with previous anti-IL5 biological therapy and discontinued within 12 months of commencing treatment.

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

Both:

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

CASIRIVIMAB AND IMDEVIMAB – [Xpharm] – Special Authority see SA2096 below

Inj 120 mg per ml casirivimab, 11.1 ml vial (1) and inj 120 mg per ml imdevimab, 11.1 ml vial (1)..... 0.00 — 1 OP — ✔ **Ronapreve**

➽SA2096 **Special Authority for Subsidy**

**Initial application — (Treatment of profoundly immunocompromised patients)** from any relevant practitioner. Approvals valid for 2 weeks for applications meeting the following criteria:

All of the following:

1 Patient has confirmed (or probable) COVID-19; and
2 The patient is in the community with mild to moderate disease severity*; and
3 Patient is profoundly immunocompromised** and is at risk of not having mounted an adequate response to vaccination against COVID-19 or is unvaccinated; and

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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4 Patient's symptoms started within the last 10 days; and
5 Patient is not receiving high flow oxygen or assisted/mechanical ventilation; and
6 Casirivimab and imdevimab is to be administered at a maximum dose of no greater than 2,400 mg.

Notes: * Mild to moderate disease severity as described on the Ministry of Health Website
** Examples include B-cell depletive illnesses or patients receiving treatment that is B-Cell depleting.

CETUXIMAB – PCT only – Specialist – Special Authority see 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.

GEMTUZUMAB OZOGAMICIN – PCT only – Specialist – Special Authority see SA2158 below

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| Inj 5 mg vial | 12,973.00 | 1 | ✔ | **Mylotarg** |

**SA2158 Special Authority for Subsidy**
**Initial application** only from a haematologist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1 Patient has not received prior chemotherapy for this condition; and
2 Patient has de novo CD33-positive acute myeloid leukaemia; and
3 Patient does not have acute promyelocytic leukaemia; and
4 Gemtuzumab ozogamicin will be used in combination with standard anthracycline and cytarabine (AraC); and
5 Patient is being treated with curative intent; and
6 Patient's disease risk has been assessed by cytogenetic testing to be good or intermediate; and
7 Patient must be considered eligible for standard intensive remission induction chemotherapy with standard anthracycline and cytarabine (AraC); and
8 Gemtuzumab ozogamicin to be funded for one course only (one dose at 3 mg per $m^2$ body surface area or up to 2 vials of 5 mg as separate doses).

Note: Acute myeloid leukaemia excludes acute promyelocytic leukaemia and acute myeloid leukaemia that is secondary to another haematological disorder (eg myelodysplasia or myeloproliferative disorder).

INFLIXIMAB – PCT only – Special Authority see SA2082 below

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

**SA2082 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

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

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

**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.

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| | Subsidy (Manufacturer's Price) $ | | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if infliximab is withdrawn.

**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:
    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, etanercept or secukinumab for severe chronic plaque psoriasis; and
  1.2 Either:

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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1.2.1 Patient has experienced intolerable side effects from adalimumab, etanercept or secukinumab; or
1.2.2 Patient has received insufficient benefit from adalimumab, etanercept or secukinumab to meet the renewal criteria for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis; or

2 All of the following:
2.1 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 has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
2.4 The most recent PASI assessment is no more than 1 month old at the time of initiation.

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand 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
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

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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2.2 Ankylosing spondylitis; or
2.3 Psoriatic arthritis; or
2.4 Severe ocular inflammation; or
2.5 Chronic ocular inflammation; or
2.6 Crohn's disease (adults); or
2.7 Crohn's disease (children); or
2.8 Fistulising Crohn's disease; or
2.9 Severe fulminant ulcerative colitis; or
2.10 Severe ulcerative colitis; or
2.11 Plaque psoriasis; or
2.12 Neurosarcoidosis; or
2.13 Severe Behcet's disease.

**Initial application — (psoriatic arthritis)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:
Both:

1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept and/or secukinumab for psoriatic arthritis; and
2 Either:
2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept and/or secukinumab; or
2.2 Following 3-4 months' initial treatment with adalimumab and/or etanercept and/or secukinumab, the patient did not meet the renewal criteria for adalimumab and/or etanercept and/or secukinumab for psoriatic arthritis.

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

1 Either:
1.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
1.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior infliximab treatment in the opinion of the treating physician; and
2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

**Initial application — (rheumatoid arthritis)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:

1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
2 Either:
2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept; and
3 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance.

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

1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2 Either:

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or

2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to 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:

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

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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 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 — (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 — (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 used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

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

1 Patient has pyoderma gangrenosum*; and

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate) and not received an adequate response; and
3 A maximum of 8 doses.

Note: Note: Indications marked with * are unapproved indications.

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

1 Patient has shown clinical improvement; and
2 Patient continues to require treatment; and
3 A maximum of 8 doses.

MEPOLIZUMAB – Special Authority see SA2154 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Inj 100 mg prefilled pen | 1,638.00 | 1 | ✔ | **Nucala** |
| Inj 100 mg vial | 1,638.00 | 1 | ✔ | **Nucala** |

➽**SA2154** **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 Treatment is not to be used in combination with subsidised benralizumab; and
8 Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment; and
9 Either:
  9.1 Patient has not previously received an anti-IL5 biological therapy for their severe eosinophilic asthma; or
  9.2 Both:
    9.2.1 Patient was refractory or intolerant to previous anti-IL5 biological therapy; and
    9.2.2 Patient was not eligible to continue treatment with previous anti-IL5 biological therapy and discontinued within 12 months of commencing treatment.

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

1 An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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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 SA2155 below

| | | | | |
|---|---|---|---|---|
| Inj 25 mg per ml, 40 ml vial | 5,910.00 | 1 | ✔ | **Gazyva** |
| Inj 1 mg for ECP | 6.21 | 1 mg | ✔ | **Baxter** |

➽**SA2155** **Special Authority for Subsidy**

**Initial application — (chronic lymphocytic leukaemia)** only from a haematologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 The patient has progressive Binet stage A, B or C CD20+ chronic lymphocytic leukaemia requiring treatment; and

2 The patient is obinutuzumab treatment naive; and

3 The patient is not eligible for full dose FCR due to comorbidities with a score > 6 on the Cumulative Illness Rating Scale (CIRS) or reduced renal function (creatinine clearance < 70mL/min); and

4 Patient has adequate neutrophil and platelet counts* unless the cytopenias are a consequence of marrow infiltration by CLL; and

5 Patient has good performance status; and

6 Obinutuzumab to be administered at a maximum cumulative dose of 8,000 mg and in combination with chlorambucil for a maximum of 6 cycles.

Notes: Chronic lymphocytic leukaemia includes small lymphocytic lymphoma. Comorbidity refers only to illness/impairment other than CLL induced illness/impairment in the patient. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with obinutuzumab is expected to improve symptoms and improve ECOG score to < 2.

* Neutrophil greater than or equal to $1.5 \times 10^9$/L and platelets greater than or equal to $75 \times 10^9$/L.

**Initial application — (follicular / marginal zone lymphoma)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

1 Either:

1.1 Patient has follicular lymphoma; or

1.2 Patient has marginal zone lymphoma; and

2 Patient is refractory to or has relapsed within 12 months of a rituximab containing combined chemo-immunotherapy regimen*; and

3 Patient has an ECOG performance status of 0-2; and

4 Patient has been previously treated with no more than four chemotherapy regimens; and

5 Obinutuzumab to be administered at a maximum dose of 1000 mg for a maximum of 6 cycles in combination with chemotherapy*.

Note: * includes unapproved indications

**Renewal — (follicular / marginal zone lymphoma)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 24 months for applications meeting the following criteria:

All of the following:

1 Patient has no evidence of disease progression following obinutuzumab induction therapy; and

2 Obinutuzumab to be administered at a maximum of 1000 mg every 2 months for a maximum of 2 years; and

3 Obinutuzumab to be discontinued at disease progression.

OMALIZUMAB – Special Authority see SA1744 on the next page – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Inj 150 mg prefilled syringe | 450.00 | 1 | ✔ | **Xolair** |
| Inj 150 mg vial | 450.00 | 1 | ✔ | **Xolair** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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➽SA1744 **Special Authority for Subsidy**

**Initial application — (severe asthma)** only from a respiratory specialist or clinical immunologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 Patient must be aged 6 years or older; and
2 Patient has a diagnosis of severe asthma; and
3 Past or current evidence of atopy, documented by skin prick testing or RAST; and
4 Total serum human immunoglobulin E (IgE) between 76 IU/mL and 1300 IU/ml at baseline; and
5 Proven adherence with optimal inhaled therapy including high dose inhaled corticosteroid (budesonide 1,600 mcg per day or fluticasone propionate 1,000 mcg per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 mcg bd or eformoterol 12 mcg bd) for at least 12 months, unless contraindicated or not tolerated; and
6 Either:
  6.1 Patient has received courses of systemic corticosteroids equivalent to at least 28 days treatment in the past 12 months, unless contraindicated or not tolerated; or
  6.2 Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral steroids; and
7 Patient has an Asthma Control Test (ACT) score of 10 or less; and
8 Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 26 weeks after the first dose to assess response to treatment.

**Initial application — (severe chronic spontaneous urticaria)** only from a clinical immunologist or dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 Patient must be aged 12 years or older; and
2 Either:
  2.1 Both:
    2.1.1 Patient is symptomatic with Urticaria Activity Score 7 (UAS7) of 20 or above; and
    2.1.2 Patient has a Dermatology life quality index (DLQI) of 10 or greater; or
  2.2 Patient has a Urticaria Control Test (UCT) of 8 or less; and
3 Any of the following:
  3.1 Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and ciclosporin (> 3 mg/kg day) for at least 6 weeks; or
  3.2 Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and at least 3 courses of systemic corticosteroids (> 20 mg prednisone per day for at least 5 days) in the previous 6 months; or
  3.3 Patient has developed significant adverse effects whilst on corticosteroids or ciclosporin; and
4 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

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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.

PALIVIZUMAB – PCT only – Specialist – Special Authority see SA2143 below

| | | | | |
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| Inj 100 mg per ml, 1 ml vial | 1,700.00 | 1 | ✔ | **Synagis** |

*(Synagis Inj 100 mg per ml, 1 ml vial to be delisted 1 January 2024)*

**SA2143 Special Authority for Subsidy**

**Initial application — (RSV prophylaxis for the 2022/2023 RSV seasons, in the context of COVID-19)** only from a paediatrician. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 Infant was born in the last 2 years and has severe lung, airway, neurological or neuromuscular disease that requires ongoing, life-sustaining community ventilation; or

2 Both:

2.1 Infant was born in the last 12 months; and

2.2 Any of the following:

2.2.1 Patient was born at less than 28 weeks gestation; or

2.2.2 Both:

2.2.2.1 Patient was born at less than 32 weeks gestation; and

2.2.2.2 Either:

2.2.2.2.1 Patient has chronic lung disease; or

2.2.2.2.2 Patient is Māori or any Pacific ethnicity; or

2.2.3 Both:

2.2.3.1 Patient has haemodynamically significant heart disease; and

2.2.3.2 Any of the following:

2.2.3.2.1 Patient has unoperated simple congenital heart disease with significant left to right shunt (see note a); or

2.2.3.2.2 Patient has unoperated or surgically palliated complex congenital heart disease; or

2.2.3.2.3 Patient has severe pulmonary hypertension (see note b); or

2.2.3.2.4 Patient has moderate or severe LV failure (see note c).

Notes:

a) Patient requires/will require heart failure medication, and/or patient has significant pulmonary hypertension, and/or patient will require surgical palliation/definitive repair within the next 3 months.

b) Mean pulmonary artery pressure more than 25 mmHg.

c) LV Ejection Fraction less than 40%.

**Renewal — (RSV prophylaxis for the 2022/2023 RSV seasons, in the context of COVID-19)** only from a paediatrician. Approvals valid for 6 months where patient still meets initial criteria.

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

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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 SA1976 below

| | | | | |
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| Inj 100 mg per 10 ml vial | 1,075.50 | 2 | ✔ | **Mabthera** |
| Inj 500 mg per 50 ml vial | 2,688.30 | 1 | ✔ | **Mabthera** |
| Inj 1 mg for ECP | 5.64 | 1 mg | ✔ | **Baxter (Mabthera)** |

➽**SA1976** **Special Authority for Subsidy**
**Initial application — (rheumatoid arthritis - TNF inhibitors contraindicated)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:

1 Treatment with a Tumour Necrosis Factor alpha inhibitor is contraindicated; and
2 Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses); and
5 Any of the following:
  5.1 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of ciclosporin; or
  5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or
  5.3 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate; and
6 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

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this application; or

7.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months; and

8 Either:

8.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or

8.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and

9 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

**Initial application — (rheumatoid arthritis - prior TNF inhibitor use)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:
All of the following:

1 Both:

1.1 The patient has had an initial community Special Authority approval for at least one of etanercept and/or adalimumab for rheumatoid arthritis; and

1.2 Either:

1.2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or

1.2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept for rheumatoid arthritis; and

2 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

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in the opinion of the physician; and

2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and

3 Either:

3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or

3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and

4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

RITUXIMAB (RIXIMYO) – PCT only – Specialist – Special Authority see SA2114 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)** |

➽SA2114 **Special Authority for Subsidy**

**Initial application — (ABO-incompatible organ transplant)** from any relevant practitioner. Approvals valid without further renewal unless notified where patient is to undergo an ABO-incompatible solid organ transplant*.

Note: Indications marked with * are unapproved indications.

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

All of the following:

1 Patient has been diagnosed with ANCA associated vasculitis*; and

2 The total rituximab dose would not exceed the equivalent of 375 mg/m$^2$ 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

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2.2 Either:

2.2.1 The patient is chemotherapy treatment naive; or

2.2.2 Both:

2.2.2.1 The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment; and

2.2.2.2 The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy; or

2.3 The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; and

3 The patient has good performance status; and

4 Either:

4.1 The patient does not have chromosome 17p deletion CLL; or

4.2 Rituximab treatment is to be used in combination with funded venetoclax for relapsed/refractory chronic lymphocytic leukaemia; and

5 Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles; and

6 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration), bendamustine or venetoclax.

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with rituximab is expected to improve symptoms and improve ECOG score to < 2.

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

Both:

1 Either:

1.1 The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; or

1.2 All of the following:

1.2.1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and

1.2.2 The patient has had an interval of 36 months or more since commencement of initial rituximab treatment; 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:

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2.1 The patient has experienced a severe episode or attack of NMOSD (rapidly progressing symptoms and clinical investigations supportive of a severe attack of NMOSD); or

2.2 All of the following:

2.2.1 The patient has experienced a breakthrough attack of NMOSD; and

2.2.2 The patient is receiving treatment with mycophenolate; and

2.2.3 The patients is receiving treatment with corticosteroids.

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

1 One of the following dose regimens is to be used: 2 doses of 1,000 mg rituximab administered fortnightly, or 4 doses of 375 mg/m2 administered weekly for four weeks; and

2 The patients has responded to the most recent course of rituximab; and

3 The patient has not received rituximab in the previous 6 months.

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

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

2 To be used for a maximum of 8 treatment cycles.

Note: Indications marked with * are unapproved indications.

**Renewal — (Post-transplant)** from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:
All of the following:

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

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

3 To be used for no more than 6 treatment cycles.

Note: Indications marked with * are unapproved indications.

**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

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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.

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.

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

Either:

1 All of the following:
  1.1 The patient has treatment naive aggressive CD20 positive NHL; and
  1.2 To be used with a multi-agent chemotherapy regimen given with curative intent; and
  1.3 To be used for a maximum of 8 treatment cycles; or
2 Both:
  2.1 The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy; and
  2.2 To be used for a maximum of 6 treatment cycles.

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

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

All of the following:

1 The patient has had a rituximab treatment-free interval of 12 months or more; and
2 The patient has relapsed refractory/aggressive CD20 positive NHL; and
3 To be used with a multi-agent chemotherapy regimen given with curative intent; and
4 To be used for a maximum of 4 treatment cycles.

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

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

Any of the following:

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

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

All of the following:

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

**Initial application — (immune thrombocytopenic purpura (ITP))** only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 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.

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**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

2 Both:

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

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

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

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

All of the following:

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

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

3 To be used for no more than 6 treatment cycles.

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

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

Note: Indications marked with * are unapproved indications.

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

Note: Indications marked with * are unapproved indications.

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

All of the following:

1 Patient has cold haemagglutinin disease*; and

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

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

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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 — (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.

**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.

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Note: Indications marked with * are unapproved indications.

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

1 Patient has warm autoimmune haemolytic anaemia*; and
2 One of the following treatments has been ineffective: steroids (including if patient requires ongoing steroids at doses equivalent to > 5 mg prednisone daily), cytotoxic agents (e.g. cyclophosphamide monotherapy or in combination), intravenous immunoglobulin; and
3 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks.

Note: Indications marked with * are unapproved indications.

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

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

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practitioner on the recommendation of a neurologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

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

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

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

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

1 Patient has severe anti-NMDA receptor autoimmune encephalitis; and
2 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.

**Initial application — (CD20+ low grade or follicular B-cell NHL)** from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:
Either:

1 Both:
  1.1 The patient has CD20+ low grade or follicular B-cell NHL with relapsed disease following prior chemotherapy; and

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1.2 To be used for a maximum of 6 treatment cycles; or

2 Both:

2.1 The patient has CD20+ low grade or follicular B-cell NHL requiring first-line systemic chemotherapy; and

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

**Renewal — (CD20+ low grade or follicular B-cell NHL)** from any relevant practitioner. Approvals valid for 24 months for applications meeting the following criteria:

Both:

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

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

**Initial application — (Membranous nephropathy)** only from a nephrologist or any relevant practitioner on the recommendation of a nephrologist. Approvals valid for 6 weeks for applications meeting the following criteria:

All of the following:

1 Either:

1.1 Patient has biopsy-proven primary/idiopathic membranous nephropathy*; or

1.2 Patient has PLA2 antibodies with no evidence of secondary cause, and an eGFR of > 60ml/min/1.73m2; and

2 Patient remains at high risk of progression to end-stage kidney disease despite more than 3 months of treatment with conservative measures (see Note); and

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

**Renewal — (Membranous nephropathy)** only from a nephrologist or any relevant practitioner on the recommendation of a nephrologist. Approvals valid for 6 weeks for applications meeting the following criteria:

All of the following:

1 Patient was previously treated with rituximab for membranous nephropathy*; and

2 Either:

2.1 Treatment with rituximab was previously successful, but the condition has relapsed, and the patient now requires repeat treatment; or

2.2 Patient achieved partial response to treatment and requires repeat treatment (see Note); and

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

Notes:

a) Indications marked with * are unapproved indications.

b) High risk of progression to end-stage kidney disease defined as > 5g/day proteinuria.

c) Conservative measures include renin-angiotensin system blockade, blood-pressure management, dietary sodium and protein restriction, treatment of dyslipidaemia, and anticoagulation agents unless contraindicated or the patient has experienced intolerable side effects.

d) Partial response defined as a reduction of proteinuria of at least 50% from baseline, and between 0.3 grams and 3.5 grams per 24 hours.

**Initial application — (B-cell acute lymphoblastic leukaemia/lymphoma*)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

1 Patient has newly diagnosed B-cell acute lymphoblastic leukaemia/lymphoma*; and

2 Treatment must be in combination with an intensive chemotherapy protocol with curative intent; and

3 The total rituximab dose would not exceed the equivalent of 375 mg/m$^2$ per dose for a maximum of 18 doses.

Note: Indications marked with * are unapproved indications.

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**Initial application — (desensisation prior to transplant)** from any relevant practitioner. Approvals valid for 6 weeks for applications meeting the following criteria:

Both:

1 Patient requires desensitisation prior to mismatched allogenic stem cell transplant*; and

2 Patient would receive no more than two doses at 375 mg/m2 of body-surface area.

Note: Indications marked with * are unapproved indications.

**Initial application — (pemiphigus*)** only from a dermatologist or relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 All of the following:

1.1 Patient has severe rapidly progressive pemphigus; and

1.2 Is used in combination with systemic corticosteroids (20 mg/day); and

1.3 Any of the following:

1.3.1 Skin involvement is at least 5% body surface area; or

1.3.2 Significant mucosal involvement (10 or more mucosal erosions) or diffuse gingivitis or confluent large erosions; or

1.3.3 Involvement of two or more mucosal sites; or

2 Both:

2.1 Patient has pemphigus; and

2.2 Patient has not experienced adequate clinical benefit from systemic corticosteroids (20 mg/day) in combination with a steroid sparing agent, unless contraindicated.

Note: Indications marked with * are unapproved indications.

**Renewal — (pemiphigus*)** only from a dermatologist or relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 Patient has experienced adequate clinical benefit from rituximab treatment, with improvement in symptoms and healing of skin ulceration and reduction in corticosteroid requirement; and

2 Patient has not received rituximab in the previous 6 months.

Note: Indications marked with * are unapproved indications.

SECUKINUMAB – Special Authority see SA2084 below – Retail pharmacy

| | | | | |
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| Inj 150 mg per ml, 1 ml prefilled syringe | 799.50 | 1 | ✔ | **Cosentyx** |
| | 1,599.00 | 2 | ✔ | **Cosentyx** |

**SA2084 Special Authority for Subsidy**

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

All of the following:

1 The patient has had an initial Special Authority approval for adalimumab or etanercept, or has trialled infliximab in a Health NZ Hospital, for severe chronic plaque psoriasis; and

2 Either:

2.1 The patient has experienced intolerable side effects from adalimumab, etanercept or infliximab; or

2.2 The patient has received insufficient benefit from adalimumab, etanercept or infliximab; and

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

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

**Initial application — (severe chronic plaque psoriasis – first-line biologic)** only from a dermatologist. Approvals valid for 4

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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.

**Initial application — (ankylosing spondylitis – second-line biologic)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 3 months for applications meeting the following criteria:
Both:

1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis; and
2 Either:
  2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
  2.2 Following 12 weeks of adalimumab and/or etanercept treatment, the patient did not meet the renewal criteria for adalimumab and/or etanercept for ankylosing spondylitis.

**Renewal — (ankylosing spondylitis – second-line biologic)** only from a rheumatologist or medical practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Following 12 weeks initial treatment of secukinumab treatment, BASDAI has improved by 4 or more points from pre-secukinumab baseline on a 10 point scale, or by 50%, whichever is less; and
2 Physician considers that the patient has benefitted from treatment and that continued treatment is appropriate; and
3 Secukinumab to be administered at doses no greater than 150 mg monthly.

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

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Either:

1 Both:

1.1 Patient has had an initial Special Authority approval for adalimumab, etanercept or infliximab for psoriatic arthritis; and

1.2 Either:

1.2.1 Patient has experienced intolerable side effects from adalimumab, etanercept or infliximab; or

1.2.2 Patient has received insufficient benefit from adalimumab, etanercept or infliximab to meet the renewal criteria for adalimumab, etanercept or infliximab for psoriatic arthritis; or

2 All of the following:

2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and

2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and

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

2.4 Either:

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

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

2.5 Any of the following:

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

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

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

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

Both:

1 Either:

1.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or

1.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior secukinumab treatment in the opinion of the treating physician; and

2 Secukinumab to be administered at doses no greater than 300 mg monthly.

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.

| | | | | |
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| 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.

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| TIXAGEVIMAB WITH CILGAVIMAB – [Xpharm] – Subsidy by endorsement | | | | |
| a) No patient co-payment payable | | | | |
| b) Treatment is funded only if patient meets access criteria for tixagevimab with cilgavimab (as per https://pharmac.govt.nz/Evusheld) and has been endorsed accordingly by the prescriber. The supply of treatment is via Pharmac's approved distribution process. Refer to the Pharmac website for more information about this and stock availability. | | | | |
| Inj 100 mg per ml, 1.5 ml vial with cilgavimab 100 mg per ml,1.5 ml vial | 0.00 | 1 | ✔ | **Evusheld** |
| TOCILIZUMAB – PCT only – Special Authority see SA2159 below | | | | |
| Inj 20 mg per ml, 4 ml vial | 220.00 | 1 | ✔ | **Actemra** |
| | | | ✔ | **Actemra S29** S29 |
| | | | ✔ | **RoActemra S29** S29 |
| | 880.00 | 4 | ✔ | **RoActemra S29** S29 |
| Inj 20 mg per ml, 10 ml vial | 550.00 | 1 | ✔ | **Actemra** |
| | | | ✔ | **Actemra S29** S29 |
| | | | ✔ | **RoActemra S29** S29 |
| Inj 20 mg per ml, 20 ml vial | 1,100.00 | 1 | ✔ | **Actemra** |
| | | | ✔ | **Actemra S29** S29 |
| | | | ✔ | **RoActemra S29** S29 |
| | 4,400.00 | 4 | ✔ | **RoActemra S29** S29 |
| Inj 1 mg for ECP | 2.85 | 1 mg | ✔ | **Baxter** |

➽SA2159 **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.

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**Initial application — (Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept))** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
2 Either:
  2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
  2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis; and
3 Either:
  3.1 The patient is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor; or
  3.2 Both:
    3.2.1 The patient has been started on rituximab for rheumatoid arthritis in a Health NZ Hospital; and
    3.2.2 Either:
      3.2.2.1 The patient has experienced intolerable side effects from rituximab; or
      3.2.2.2 At four months following the initial course of rituximab the patient has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis.

**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.

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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**Initial application — (adult-onset Still's disease)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Either:

1 Both:
  1.1 Either:
    1.1.1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for adult-onset Still's disease (AOSD); or
    1.1.2 The patient has been started on tocilizumab for AOSD in a Health NZ Hospital; and
  1.2 Either:
    1.2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
    1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for AOSD; or
2 All of the following:
  2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and
  2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal antiinflammatory drugs (NSAIDs) and methotrexate; and
  2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

**Initial application — (polyarticular juvenile idiopathic arthritis)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:
Either:

1 Both:
  1.1 The patient has had an initial Special Authority approval for both etanercept and adalimumab for polyarticular course juvenile idiopathic arthritis (JIA); and
  1.2 The patient has experienced intolerable side effects, or has received insufficient benefit from, both etanercept and adalimumab; or
2 All of the following:
  2.1 Treatment with a tumour necrosis factor alpha inhibitor is contraindicated; and
  2.2 Patient has had polyarticular course JIA for 6 months duration or longer; and
  2.3 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
  2.4 Any of the following:
    2.4.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
    2.4.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or
    2.4.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

**Initial application — (idiopathic multicentric Castleman's disease)** only from a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Patient has severe HHV-8 negative idiopathic multicentric Castleman's disease; and
2 Treatment with an adequate trial of corticosteroids has proven ineffective; and
3 Tocilizumab to be administered at doses no greater than 8 mg/kg IV every 3-4 weeks.

**Initial application — (moderate to severe COVID-19)** from any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria:
All of the following:

1 Patient has confirmed (or probable) COVID-19; and

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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2 Oxygen saturation of < 92% on room air, or requiring supplemental oxygen; and
3 Patient is receiving adjunct systemic corticosteroids, or systemic corticosteroids are contraindicated; and
4 Tocilizumab is to be administered at doses no greater than 8mg/kg IV for a maximum of one dose; and
5 Tocilizumab is not to be administered in combination with barcitinib.

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

1 Following 6 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician.

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

1 Following up to 6 months' initial treatment, the patient has achieved at least an American College of Rheumatology paediatric 30% improvement criteria (ACR Pedi 30) response from baseline; or
2 On subsequent reapplications, the patient demonstrates at least a continuing ACR Pedi 30 response from baseline.

**Renewal — (adult-onset Still's disease)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months where the patient has a sustained improvement in inflammatory markers and functional status.
**Renewal — (polyarticular juvenile idiopathic arthritis)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:

1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
2 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

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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3 months of starting treatment due to intolerance; and

2.2.2 The cancer did not progress whilst on lapatinib; and

3 Either:

3.1 Trastuzumab will not be given in combination with pertuzumab; or

3.2 All of the following:

3.2.1 Trastuzumab to be administered in combination with pertuzumab; and

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

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

4 Trastuzumab not to be given in combination with lapatinib; and

5 Trastuzumab to be discontinued at disease progression.

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

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

2 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and

3 Trastuzumab not to be given in combination with lapatinib; and

4 Trastuzumab to be discontinued at disease progression.

**Initial application — (early breast cancer)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 15 months for applications meeting the following criteria:
All of the following:

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

2 Maximum cumulative dose of 106 mg/kg (12 months' treatment); and

3 Any of the following:

3.1 9 weeks' concurrent treatment with adjuvant chemotherapy is planned; or

3.2 12 months' concurrent treatment with adjuvant chemotherapy is planned; or

3.3 12 months' sequential treatment following adjuvant chemotherapy is planned; or

3.4 12 months' treatment with neoadjuvant and adjuvant chemotherapy is planned; or

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:

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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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 SA2144 below

| | | | | |
|---|---|---|---|---|
| Inj 100 mg vial | 2,320.00 | 1 | ✔ | **Kadcyla** |
| Inj 160 mg vial | 3,712.00 | 1 | ✔ | **Kadcyla** |
| Inj 1 mg for ECP | 24.52 | 1 mg | ✔ | **Baxter** |

**SA2144 Special Authority for Subsidy**

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

1 Patient has early breast cancer expressing HER2 IHC3+ or ISH+; and
2 Documentation of pathological invasive residual disease in the breast and/or auxiliary lymph nodes following completion of surgery; and
3 Patient has completed systemic neoadjuvant therapy with trastuzumab and chemotherapy prior to surgery; and
4 Disease has not progressed during neoadjuvant therapy; and
5 Patient has left ventricular ejection fraction of 45% or greater; and
6 Adjuvant treatment with trastuzumab emtansine to be commenced within 12 weeks of surgery; and
7 Trastuzumab emtansine to be discontinued at disease progression; and
8 Total adjuvant treatment duration must not exceed 42 weeks (14 cycles).

**Initial application — (metastatic breast cancer)** only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
2 Patient has previously received trastuzumab and chemotherapy, separately or in combination; and
3 Either:
3.1 The patient has received prior therapy for metastatic disease*; or
3.2 The patient developed disease recurrence during, or within six months of completing adjuvant therapy*; and
4 Patient has a good performance status (ECOG 0-1); and
5 Either:
5.1 Patient does not have symptomatic brain metastases; or
5.2 Patient has brain metastases and has received prior local CNS therapy; and
6 Patient has not received prior funded trastuzumab emtansine treatment; and
7 Treatment to be discontinued at disease progression.

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

1 The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab emtansine; and
2 Treatment to be discontinued at disease progression.

Note: *Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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## Programmed Cell Death-1 (PD-1) Inhibitors

DURVALUMAB – PCT only – Specialist – Special Authority see SA2164 below

| | | | |
|---|---|---|---|
| Inj 50 mg per ml, 10 ml vial | 4,700.00 | 1 | ✔ **Imfinzi** |
| Inj 50 mg per ml, 2.4 ml vial | 1,128.00 | 1 | ✔ **Imfinzi** |
| Inj 1 mg for ECP | 9.59 | 1 mg | ✔ **Baxter** |

➽**SA2164** **Special Authority for Subsidy**

**Initial application — (Non-small cell lung cancer)** only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1 Patient has histologically or cytologically documented stage III, locally advanced, unresectable non-small cell lung cancer (NSCLC); and
2 Patient has received two or more cycles of platinum-based chemotherapy concurrently with definitive radiation therapy; and
3 Patient has no disease progression following the second or subsequent cycle of platinum-based chemotherapy with definitive radiation therapy treatment; and
4 Patient has a ECOG performance status of 0 or 1; and
5 Patient has completed last radiation dose within 8 weeks of starting treatment with durvalumab; and
6 Patient must not have received prior PD-1 or PD-L1 inhibitor therapy for this condition; and
7 Either:
  7.1 Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks; or
  7.2 Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks; and
8 Treatment with durvalumab to cease upon signs of disease progression.

**Renewal — (Non-small cell lung cancer)** only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1 The treatment remains clinically appropriate and the patient is benefitting from treatment; and
2 Either:
  2.1 Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks; or
  2.2 Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks; and
3 Treatment with durvalumab to cease upon signs of disease progression; and
4 Total continuous treatment duration must not exceed 12 months.

NIVOLUMAB – PCT only – Specialist – Special Authority see SA2120 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** |

➽**SA2120** **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

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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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 or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

1 All of the following:

1.1 Any of the following:

1.1.1 Patient's disease has had a complete response to treatment according to RECIST criteria (see Note); or

1.1.2 Patient's disease has had a partial response to treatment according to RECIST criteria (see Note); or

1.1.3 Patient has stable disease according to RECIST criteria (see Note); and

1.2 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 SA2121 below

| | | | | |
|---|---|---|---|---|
| Inj 25 mg per ml, 4 ml vial | 4,680.00 | 1 | ✔ | **Keytruda** |
| Inj 1 mg for ECP | 49.14 | 1 mg | ✔ | **Baxter** |

➽**SA2121** **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:

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

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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## 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 SA2008 below – Retail pharmacy

Wastage claimable

| | | | | |
|---|---|---|---|---|
| Tab 10 mg | 6,512.29 | 30 | ✔ | **Afinitor** |
| Tab 5 mg | 4,555.76 | 30 | ✔ | **Afinitor** |

➽**SA2008** **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.

SIROLIMUS – Special Authority see SA2005 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** |

➽**SA2005** **Special Authority for Subsidy**

**Initial application** from any medical practitioner. Approvals valid without further renewal unless notified where the drug is to be used for rescue therapy for an organ transplant recipient.

Notes: Rescue therapy defined as unresponsive to calcineurin inhibitor treatment as defined by refractory rejection; or intolerant to calcineurin inhibitor treatment due to any of the following:

- GFR< 30 ml/min; or
- Rapidly progressive transplant vasculopathy; or
- Rapidly progressive obstructive bronchiolitis; or
- HUS or TTP; or
- Leukoencepthalopathy; or
- Significant malignant disease

**Initial application — (severe non-malignant lymphovascular malformations*)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 Patient has severe non-malignant lymphovascular malformation*; and
2 Any of the following:
  2.1 Malformations are not adequately controlled by sclerotherapy and surgery; or
  2.2 Malformations are widespread/extensive and sclerotherapy and surgery are not considered clinically appropriate; or
  2.3 Sirolimus is to be used to reduce malformation prior to consideration of surgery; and
3 Patient is being treated by a specialist lymphovascular malformation multi-disciplinary team; and
4 Patient has measurable disease as defined by RECIST version 1.1 (see Note).

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| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
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**Renewal — (severe non-malignant lymphovascular malformations*)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 Either:
  1.1 Patient's disease has had either a complete response or a partial response to treatment, or patient has stable disease according to RECIST version 1.1 (see Note); or
  1.2 Patient's disease has stabilised or responded clinically and disease response to treatment has been clearly documents in patient notes; and
2 No evidence of progressive disease; and
3 The treatment remains clinically appropriate and the patient is benefitting from the treatment.

Notes: Baseline assessment and disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer et al. Eur J Cancer 2009;45:228-47)

Indications marked with * are unapproved indications

**Initial application — (renal angiomyolipoma(s) associated with tuberous sclerosis complex*)** only from a nephrologist or urologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 Patient has tuberous sclerosis complex*; and
2 Evidence of renal angiomyolipoma(s) measuring 3 cm or greater and that have shown interval growth.

**Renewal — (renal angiomyolipoma(s) associated with tuberous sclerosis complex*)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 Documented evidence of renal angiomyolipoma reduction or stability by magnetic resonance imaging (MRI) or ultrasound; and
2 Demonstrated stabilisation or improvement in renal function; and
3 The patient has not experienced angiomyolipoma haemorrhage or significant adverse effects to sirolimus treatment; and
4 The treatment remains appropriate and the patient is benefitting from treatment.

Note: Indications marked with * are unapproved indications

**Initial application — (refractory seizures associated with tuberous sclerosis complex*)** only from a neurologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 Patient has epilepsy with a background of documented tuberous sclerosis complex; and
2 Either:
  2.1 Both:
    2.1.1 Vigabatrin has been trialled and has not adequately controlled seizures; and
    2.1.2 Seizures are not adequately controlled by, or the patient has experienced unacceptable side effects from, optimal treatment with at least two of the following: sodium valproate, topiramate, levetiracetam, carbamazepine, lamotrigine, phenytoin sodium, and lacosamide (see Note); or
  2.2 Both:
    2.2.1 Vigabatrin is contraindicated; and
    2.2.2 Seizures are not adequately controlled by, or the patient has experienced unacceptable side effects from, optimal treatment with at least three of the following: sodium valproate, topiramate, levetiracetam, carbamazepine, lamotrigine, phenytoin sodium, and lacosamide (see Note); and
3 Seizures have a significant impact on quality of life; and
4 Patient has been assessed and surgery is considered inappropriate for this patient, or the patient has been assessed and would benefit from mTOR inhibitor treatment prior to surgery.

Note: Patients of childbearing potential are not required to have a trial of sodium valporate

**Renewal — (refractory seizures associated with tuberous sclerosis complex*)** only from a neurologist. Approvals valid for

continued…

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

continued…

12 months where demonstrated significant and sustained improvement in seizure rate (e.g. 50% reduction in seizure frequency) or severity and/or patient quality of life compared with baseline prior to starting sirolimus treatment.

Note: Indications marked with * are unapproved indications

TACROLIMUS – Special Authority see SA1745 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Cap 0.5 mg | 49.60 | 100 | ✔ | **Tacrolimus Sandoz** |
| Cap 0.75 mg | 99.30 | 100 | ✔ | **Tacrolimus Sandoz** |
| Cap 1 mg | 84.30 | 100 | ✔ | **Tacrolimus Sandoz** |
| Cap 5 mg | 248.20 | 50 | ✔ | **Tacrolimus Sandoz** |

**➽SA1745 Special Authority for Subsidy**

**Initial application — (organ transplant)** only from a relevant specialist. Approvals valid without further renewal unless notified where the patient is an organ transplant recipient.

Note: Subsidy applies for either primary or rescue therapy.

**Initial application — (non-transplant indications*)** only from a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

1 Patient requires long-term systemic immunosuppression; and
2 Ciclosporin has been trialled and discontinued treatment because of unacceptable side effects or inadequate clinical response.

Note: Indications marked with * are unapproved indications

## JAK inhibitors

UPADACITINIB – Special Authority see SA2079 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Tab 15 mg | 1,271.00 | 28 | ✔ | **RINVOQ** |

**➽SA2079 Special Authority for Subsidy**

**Initial application — (Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept))** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
2 Either:
  2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
  2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis; and
3 Either:
  3.1 The patient is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor; or
  3.2 Both:
    3.2.1 The patient has been started on rituximab for rheumatoid arthritis in a Health NZ Hospital; and
    3.2.2 Either:
      3.2.2.1 The patient has experienced intolerable side effects from rituximab; or
      3.2.2.2 At four months following the initial course of rituximab the patient has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis.

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

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.

| | 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

| | | | | |
|---|---|---|---|---|
| Initiation kit - 5 vials freeze dried venom with diluent | 305.00 | 1 OP | ✔ | **VENOX** S29 |
| Maintenance kit - 1 vial freeze dried venom with diluent | 305.00 | 1 OP | ✔ | **VENOX** S29 |
| Maintenance kit - 6 vials 120 mcg freeze dried venom, with 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 | 2.84 | 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 | 1.78 | 100 | ✔ **Lorafix** |
| ❋ | Oral liq 1 mg per ml | 1.43 | 100 ml | ✔ **Haylor syrup** |

PROMETHAZINE HYDROCHLORIDE

| | | | | |
|---|---|---|---|---|
| ❋ | Tab 10 mg | 1.39 | 50 | ✔ **Allersoothe** |
| ❋ | Tab 25 mg | 1.58 | 50 | ✔ **Allersoothe** |
| ❋ | Oral liq 1 mg per 1 ml | 3.39 | 100 ml | ✔ **Allersoothe** |
| ❋ | Inj 25 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO | 17.87 | 5 | ✔ **Hospira** |

## Inhaled Corticosteroids

BECLOMETHASONE DIPROPIONATE

| | | | |
|---|---|---|---|
| Aerosol inhaler, 50 mcg per dose | 14.01 | 200 dose OP | ✔ **Qvar** |
| Aerosol inhaler, 50 mcg per dose CFC-free | 8.54 | 200 dose OP | ✔ **Beclazone 50** |
| Aerosol inhaler, 100 mcg per dose | 17.52 | 200 dose OP | ✔ **Qvar** |
| Aerosol inhaler, 100 mcg per dose CFC-free | 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** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| FLUTICASONE | | | | |
| Aerosol inhaler, 50 mcg per dose | 7.19 | 120 dose OP | ✔ | **Flixotide** |
| Powder for inhalation, 50 mcg per dose | 7.50 | 60 dose OP | ✔ | **Flixotide Accuhaler** |
| Powder for inhalation, 100 mcg per dose | 7.50 | 60 dose OP | ✔ | **Flixotide Accuhaler** |
| Aerosol inhaler, 125 mcg per dose | 13.60 | 120 dose OP | ✔ | **Flixotide** |
| Aerosol inhaler, 250 mcg per dose | 24.62 | 120 dose OP | ✔ | **Flixotide** |
| Powder for inhalation, 250 mcg per dose | 13.60 | 60 dose OP | ✔ | **Flixotide Accuhaler** |

## Inhaled Long-acting Beta-adrenoceptor Agonists

| | | | | |
|---|---|---|---|---|
| EFORMOTEROL FUMARATE | | | | |
| Powder for inhalation, 12 mcg per dose, and monodose device | 20.64 (35.80) | 60 dose | | Foradil |
| *(Foradil Powder for inhalation, 12 mcg per dose, and monodose device to be delisted 1 July 2023)* | | | | |
| EFORMOTEROL FUMARATE DIHYDRATE | | | | |
| Powder for inhalation 4.5 mcg per dose, breath activated (equivalent to eformoterol fumarate 6 mcg metered dose) | 10.32 (16.90) | 60 dose OP | | Oxis Turbuhaler |
| INDACATEROL | | | | |
| Powder for inhalation 150 mcg | 61.00 | 30 dose OP | ✔ | **Onbrez Breezhaler** |
| Powder for inhalation 300 mcg | 61.00 | 30 dose OP | ✔ | **Onbrez Breezhaler** |
| SALMETEROL | | | | |
| Aerosol inhaler CFC-free, 25 mcg per dose | 26.25 | 120 dose OP | ✔ | **Serevent** |
| Powder for inhalation, 50 mcg per dose, breath activated | 26.25 | 60 dose OP | ✔ | **Serevent Accuhaler** |

## Inhaled Corticosteroids with Long-Acting Beta-Adrenoceptor Agonists

| | | | | |
|---|---|---|---|---|
| BUDESONIDE WITH EFORMOTEROL | | | | |
| Powder for inhalation 160 mcg with 4.5 mcg eformoterol fumarate per dose (equivalent to 200 mcg budesonide with 6 mcg eformoterol fumarate metered dose) | 41.50 | 120 dose OP | ✔ | **DuoResp Spiromax** |
| Powder for inhalation 320 mcg with 9 mcg eformoterol fumarate per dose (equivalent to 400 mcg budesonide with 12 mcg eformoterol fumarate metered dose) – No more than 2 dose per day | 82.50 | 120 dose OP | ✔ | **DuoResp Spiromax** |
| 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 | 33.74 | 120 dose OP | ✔ | **Symbicort Turbuhaler 200/6** |
| Powder for inhalation 400 mcg with eformoterol fumarate 12 mcg – No more than 2 dose per day | 33.74 | 60 dose OP | ✔ | **Symbicort Turbuhaler 400/12** |
| 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 | 25.79 | 120 dose OP | ✔ | **Seretide** |
| Aerosol inhaler 125 mcg with salmeterol 25 mcg | 32.60 | 120 dose OP | ✔ | **Seretide** |
| Powder for inhalation 100 mcg with salmeterol 50 mcg – No more than 2 dose per day | 33.74 | 60 dose OP | ✔ | **Seretide Accuhaler** |
| Powder for inhalation 250 mcg with salmeterol 50 mcg – No more than 2 dose per day | 44.08 | 60 dose OP | ✔ | **Seretide Accuhaler** |

## Beta-Adrenoceptor Agonists

| | | | | |
|---|---|---|---|---|
| SALBUTAMOL | | | | |
| Oral liq 400 mcg per ml | 40.00 | 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** |
| | (6.20) | | | Ventolin |
| Nebuliser soln, 1 mg per ml, 2.5 ml ampoule – Up to 30 neb available on a PSO | 8.96 | 20 | ✔ | **Asthalin** |
| Nebuliser soln, 2 mg per ml, 2.5 ml ampoule – Up to 30 neb available on a PSO | 9.43 | 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** |

## 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, 2 ml ampoule – Up to 40 neb available on a PSO | 11.73 | 20 | ✔ | **Univent** |
| | 28.20 | | ✔ | **Accord** S29 |

### 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 | 11.04 | 20 | ✔ | **Duolin** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

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

## Long-Acting Muscarinic Antagonists

GLYCOPYRRONIUM – Subsidy by endorsement

a) Inhaled glycopyrronium treatment will not be subsidised if patient is also receiving treatment with subsidised tiotropium or umeclidinium.

b) Glycopyrronium powder for inhalation 50 mcg per dose is subsidised only for patients who have been diagnosed as having COPD using spirometry if spirometry is possible, 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 using spirometry if spirometry is possible, and the prescription is endorsed accordingly. Patients who had tiotropium dispensed before 1 October 2018 with a valid Special Authority are deemed endorsed.

| | | | | |
|---|---|---|---|---|
| Powder for inhalation, 18 mcg per dose | 50.37 | 30 dose | | ✔ **Spiriva** |
| Soln for inhalation 2.5 mcg per dose | 50.37 | 60 dose | OP | ✔ **Spiriva Respimat** |

UMECLIDINIUM – Subsidy by endorsement

a) Umeclidinium will not be subsidised if patient is also receiving treatment with subsidised inhaled glycopyrronium or tiotropium bromide.

b) Umeclidinium powder for inhalation 62.5 mcg per dose is subsidised only for patients who have been diagnosed as having COPD using spirometry if spirometry is possible, and the prescription is endorsed accordingly.

| | | | | |
|---|---|---|---|---|
| Powder for inhalation 62.5 mcg per dose | 61.50 | 30 dose | OP | ✔ **Incruse Ellipta** |

## Long-Acting Muscarinic Antagonists with Long-Acting Beta-Adrenoceptor Agonists

Combination long acting muscarinic antagonist and long acting beta-2 agonist will not be subsidised if patient is also receiving treatment with a combination inhaled corticosteroid and long acting beta-2 agonist.

➸SA1584 **Special Authority for Subsidy**

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

1 Patient has been stabilised on a long acting muscarinic antagonist; and
2 The prescriber considers that the patient would receive additional benefit from switching to a combination product.

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

1 Patient is compliant with the medication; and
2 Patient has experienced improved COPD symptom control (prescriber determined).

GLYCOPYRRONIUM WITH INDACATEROL – Special Authority see SA1584 above – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Powder for Inhalation 50 mcg with indacaterol 110 mcg | 81.00 | 30 dose | OP | ✔ **Ultibro Breezhaler** |

TIOTROPIUM BROMIDE WITH OLODATEROL – Special Authority see SA1584 above – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Soln for inhalation 2.5 mcg with olodaterol 2.5 mcg | 81.00 | 60 dose | OP | ✔ **Spiolto Respimat** |

UMECLIDINIUM WITH VILANTEROL – Special Authority see SA1584 above – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Powder for inhalation 62.5 mcg with vilanterol 25 mcg | 77.00 | 30 dose | OP | ✔ **Anoro Ellipta** |

## Antifibrotics

NINTEDANIB – Special Authority see SA2012 on the next page – 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** |

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

**➽SA2012 Special Authority for Subsidy**

**Initial application — (idiopathic pulmonary fibrosis)** only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist; and
2 Forced vital capacity is between 50% and 90% predicted; and
3 Nintedanib is to be discontinued at disease progression (See Note); and
4 Nintedanib is not to be used in combination with subsidised pirfenidone; and
5 Any of the following:
  5.1 The patient has not previously received treatment with pirfenidone; or
  5.2 Patient has previously received pirfenidone, but discontinued pirfenidone within 12 weeks due to intolerance; or
  5.3 Patient has previously received pirfenidone, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with pirfenidone).

**Renewal — (idiopathic pulmonary fibrosis)** only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and
2 Nintedanib is not to be used in combination with subsidised pirfenidone; and
3 Nintedanib is to be discontinued at disease progression (See Note).

Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

PIRFENIDONE – Retail pharmacy-Specialist – Special Authority see SA2013 below

Note: Pirfenidone is not subsidised in combination with subsidised nintedanib.

| | | | | |
|---|---|---|---|---|
| Tab 801 mg | 3,645.00 | 90 | ✔ | **Esbriet** |
| Tab 267 mg | 1,215.00 | 90 | ✔ | **Esbriet** |

**➽SA2013 Special Authority for Subsidy**

**Initial application — (idiopathic pulmonary fibrosis)** only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist; and
2 Forced vital capacity is between 50% and 90% predicted; and
3 Pirfenidone is to be discontinued at disease progression (See Note); and
4 Pirfenidone is not to be used in combination with subsidised nintedanib; and
5 Any of the following:
  5.1 The patient has not previously received treatment with nintedanib; or
  5.2 Patient has previously received nintedanib, but discontinued nintedanib within 12 weeks due to intolerance; or
  5.3 Patient has previously received nintedanib, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with nintedanib).

**Renewal — (idiopathic pulmonary fibrosis)** only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and
2 Pirfenidone is not to be used in combination with subsidised nintedanib; and
3 Pirfenidone is to be discontinued at disease progression (See Note).

Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

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

## Leukotriene Receptor Antagonists

MONTELUKAST

| | | | | |
|---|---|---|---|---|
| ❋ | Tab 4 mg | 3.10 | 28 | ✔ **Montelukast Mylan** |
| | Montelukast Mylan to be Principal Supply on 1 December 2022 | | | |
| ❋ | Tab 5 mg | 3.10 | 28 | ✔ **Montelukast Mylan** |
| | Montelukast Mylan to be Principal Supply on 1 December 2022 | | | |
| ❋ | Tab 10 mg | 2.90 | 28 | ✔ **Montelukast Mylan** |
| | Montelukast Mylan to be Principal Supply on 1 December 2022 | | | |

## Methylxanthines

AMINOPHYLLINE

| | | | | |
|---|---|---|---|---|
| ❋ | Inj 25 mg per ml, 10 ml ampoule – Up to 5 inj available on a PSO | 180.00 | 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 SA1978 below – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| | Nebuliser soln, 2.5 mg per 2.5 ml ampoule | 250.00 | 6 | ✔ **Pulmozyme** |

➽**SA1978** **Special Authority for Subsidy**

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

All of the following:

1 Patient has a confirmed diagnosis of cystic fibrosis; and
2 Patient has previously undergone a trial with, or is currently being treated with, hypertonic saline; and
3 Any of the following:
- 3.1 Patient has required one or more hospital inpatient respiratory admissions in the previous 12 month period; or
- 3.2 Patient has had 3 exacerbations due to CF, requiring oral or intravenous (IV) antibiotics in the previous 12 month period; or
- 3.3 Patient has had 1 exacerbation due to CF, requiring oral or IV antibiotics in the previous 12 month period and a Brasfield score of < 22/25; or
- 3.4 Patient has a diagnosis of allergic bronchopulmonary aspergillosis (ABPA).

**Renewal — (cystic fibrosis)** only from a respiratory physician or paediatrician. Approvals valid without further renewal unless notified where the treatment remains appropriate and the patient continues to benefit from treatment.

IVACAFTOR – PCT only – Specialist – Special Authority see SA2017 below

| | | | | |
|---|---|---|---|---|
| | Tab 150 mg | 29,386.00 | 56 | ✔ **Kalydeco** |
| | Oral granules 50 mg, sachet | 29,386.00 | 56 | ✔ **Kalydeco** |
| | Oral granules 75 mg, sachet | 29,386.00 | 56 | ✔ **Kalydeco** |

➽**SA2017** **Special Authority for Subsidy**

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

All of the following:

1 Patient has been diagnosed with cystic fibrosis; and
2 Either:

continued…

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

continued…

2.1 Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; or

2.2 Patient must have other gating (class III) mutation (G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N and S549R) in the CFTR gene on at least 1 allele; and

3 Patients must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis or by Macroduct sweat collection system; and

4 Treatment with ivacaftor must be given concomitantly with standard therapy for this condition; and

5 Patient must not have an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing treatment with ivacaftor; and

6 The dose of ivacaftor will not exceed one tablet or one sachet twice daily; and

7 Applicant has experience and expertise in the management of cystic fibrosis.

SODIUM CHLORIDE

Not funded for use as a nasal drop.

| | | | | |
|---|---|---|---|---|
| Soln 7% | 24.50 | 90 ml | OP | ✔ **Biomed** |

## Nasal Preparations

### Allergy Prophylactics

BUDESONIDE

| | | | | |
|---|---|---|---|---|
| Metered aqueous nasal spray, 50 mcg per dose | 2.54 | 200 dose | OP | ✔ **SteroClear** |
| Metered aqueous nasal spray, 100 mcg per dose | 2.84 | 200 dose | OP | ✔ **SteroClear** |

FLUTICASONE PROPIONATE

| | | | | |
|---|---|---|---|---|
| Metered aqueous nasal spray, 50 mcg per dose | 1.98 | 120 dose | OP | ✔ **Flixonase Hayfever & Allergy** |

IPRATROPIUM BROMIDE

| | | | | |
|---|---|---|---|---|
| Aqueous nasal spray, 0.03% | 5.23 | 15 ml | OP | ✔ **Univent** |

## Respiratory Devices

MASK FOR SPACER DEVICE

a) Up to 50 dev available on a PSO
b) Only on a PSO
c) Only for children aged six years and under

| | | | | |
|---|---|---|---|---|
| Small | 2.20 | 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** |



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

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

## Respiratory Stimulants

CAFFEINE CITRATE

| | | | | |
|---|---|---|---|---|
| Oral liq 20 mg per ml (10 mg base per ml) | 15.10 | 25 ml | OP | ✔ **Biomed** |

▲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 |
|---|---|---|---|---|

## Ear Preparations

FLUMETASONE PIVALATE

Ear drops 0.02% with clioquinol 1% ..... 4.46 — 7.5 ml OP — ✔ **Locacorten-Viaform ED's**; ✔ **Locorten-Vioform**

TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCIN AND NYSTATIN

Ear drops 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 mcg per g ..... 5.16 — 7.5 ml OP — ✔ **Kenacomb**

## Ear/Eye Preparations

DEXAMETHASONE WITH FRAMYCETIN AND GRAMICIDIN

Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml ..... 4.50 — 8 ml OP

(9.27) — Sofradex

FRAMYCETIN SULPHATE

Ear/Eye drops 0.5% ..... 4.13 — 8 ml OP

(8.65) — Soframycin

## Eye Preparations

Eye preparations are only funded for use in the eye, unless explicitly stated otherwise.

### Anti-Infective Preparations

ACICLOVIR

✻ Eye oint 3% ..... 14.88 — 4.5 g OP — ✔ **ViruPOS**

CHLORAMPHENICOL

Eye oint 1% ..... 1.09 — 5 g OP — ✔ **Devatis**

Devatis to be Principal Supply on 1 December 2022

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 ..... 9.73 — 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**

*(Genoptic Eye drops 0.3% to be delisted 1 August 2023)*

PROPAMIDINE ISETHIONATE

✻ Eye drops 0.1% ..... 2.97 — 10 ml OP

(14.55) — Brolene

SODIUM FUSIDATE [FUSIDIC ACID]

Eye drops 1% ..... 5.29 — 5 g OP — ✔ **Fucithalmic**

TOBRAMYCIN

Eye oint 0.3% ..... 10.45 — 3.5 g OP — ✔ **Tobrex**

Eye drops 0.3% ..... 11.48 — 5 ml OP — ✔ **Tobrex**



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

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

## Corticosteroids and Other Anti-Inflammatory Preparations

DEXAMETHASONE

| | | | | |
|---|---|---|---|---|
| ✱ | Eye oint 0.1% | 5.86 | 3.5 g OP | ✔ **Maxidex** |
| ✱ | Eye drops 0.1% | 4.50 | 5 ml OP | ✔ **Maxidex** |
| | Ocular implant 700 mcg – Special Authority see SA1680 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% | 8.80 | 5 ml OP | ✔ **Voltaren Ophtha** |

FLUOROMETHOLONE

| | | | | |
|---|---|---|---|---|
| ✱ | Eye drops 0.1% | 3.09 | 5 ml OP | ✔ **FML** |
| | | 5.20 | | ✔ **Flucon** |

▲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 |
|---|---|---|---|---|
| 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% | 6.92 | 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** |
| | 2.62 | 10 ml OP | ✔ | **Allerfix** |

*(Rexacrom Eye drops 2% to be delisted 1 March 2023)*

## 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% | 1.81 | 5 ml OP | ✔ | **Arrow-Timolol** |
| ❋ Eye drops 0.5% | 2.04 | 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% | 7.30 | 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% | 2.73 | 5 ml OP | ✔ | **Dortimopt** |

## Glaucoma Preparations - Prostaglandin Analogues

| | | | | |
|---|---|---|---|---|
| BIMATOPROST | | | | |
| ❋ Eye drops 0.03% | 5.95 | 3 ml OP | ✔ | **Bimatoprost Multichem** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| LATANOPROST | | | | |
| ✻ Eye drops 0.005% | 1.82 | 2.5 ml OP | ✔ | **Teva** |
| TRAVOPROST | | | | |
| ✻ Eye drops 0.004% | 9.75 | 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** |
| LATANOPROST WITH TIMOLOL | | | | |
| Eye drops 0.005% with timolol 0.5% | 2.49 | 2.5 ml OP | ✔ | **Arrow - Lattim** |
| 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 247

| | | | | |
|---|---|---|---|---|
| HYPROMELLOSE | | | | |
| ✻ Eye drops 0.5% | 19.50 | 15 ml OP | ✔ | **Methopt** |
| HYPROMELLOSE WITH DEXTRAN | | | | |
| ✻ Eye drops 0.3% with dextran 0.1% | 2.30 | 15 ml OP | ✔ | **Poly-Tears** |

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

## Preservative Free Ocular Lubricants

➽SA2134 **Special Authority for Subsidy**

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

1 Confirmed diagnosis by slit lamp or Schirmer test of severe secretory dry eye; and
2 Either:
  2.1 Patient is using eye drops more than four times daily on a regular basis; or
  2.2 Patient has had a confirmed allergic reaction to preservative in eye drop.

**Renewal** from any relevant practitioner. Approvals valid for 24 months where the patient continues to require lubricating eye drops and has benefited from treatment.

CARBOMER – Special Authority see SA2134 above – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Ophthalmic gel 0.3%, 0.5 g | 8.25 | 30 | ✔ | **Poly-Gel** |

MACROGOL 400 AND PROPYLENE GLYCOL – Special Authority see SA2134 above – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Eye drops 0.4% and propylene glycol 0.3%, 0.4 ml | 4.30 | 24 | ✔ | **Systane Unit Dose** |
| Eye drops 0.4% and propylene glycol 0.3%, 0.8 ml | 10.78 | 30 | ✔ | **Systane Unit Dose** |

*(Systane Unit Dose Eye drops 0.4% and propylene glycol 0.3%, 0.4 ml to be delisted 1 June 2023)*

SODIUM HYALURONATE [HYALURONIC ACID] – Special Authority see SA2134 above – Retail pharmacy

| | | | | |
|---|---|---|---|---|
| Eye drops 1 mg per ml | 13.85 | 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** |

*(Naphcon Forte Eye drops 0.1% to be delisted 1 September 2023)*

OLOPATADINE

| | | | | |
|---|---|---|---|---|
| Eye drops 0.1% | 2.17 | 5 ml OP | ✔ | **Olopatadine Teva** |

Olopatadine Teva to be Principal Supply on 1 December 2022

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** |



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

| | 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 Amgevita**
The Pharmacode for BSF Amgevita is 2645165 - see also page 173
*(BSF Amgevita Brand switch fee to be delisted 1 January 2023)*

## Agents Used in the Treatment of Poisonings

### Antidotes

ACETYLCYSTEINE
Inj 200 mg per ml, 10 ml ampoule ..... 52.88 — 10 — ✔ **Martindale Pharma**
58.76 — ✔ **DBL Acetylcysteine**
✔ **Martindale Pharma S29** S29
Martindale Pharma to be Principal Supply on 1 December 2022
*(DBL Acetylcysteine Inj 200 mg per ml, 10 ml ampoule to be delisted 1 December 2022)*
*(Martindale Pharma S29 S29 Inj 200 mg per ml, 10 ml ampoule to be delisted 1 December 2022)*

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**
35.26 — 10 — ✔ **Hameln**
*(DBL Naloxone Hydrochloride Inj 400 mcg per ml, 1 ml ampoule to be delisted 1 February 2023)*

### 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

continued…

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

continued…

3.3 Treatment with deferiprone has resulted in arthritis; or

3.4 Treatment with deferiprone is contraindicated due to a history of agranulocytosis (defined as an absolute neutrophil count (ANC) of < 0.5 cells per µL) or recurrent episodes (greater than 2 episodes) of moderate neutropenia (ANC 0.5 - 1.0 cells per µL).

**Renewal** only from a haematologist. Approvals valid for 2 years for applications meeting the following criteria:
Either:

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 | 151.31 | 10 | ✔ | **DBL Desferrioxamine Mesylate for Inj BP** |
| | | | ✔ | **Deferoxamine Pfizer S29** S29 |

SODIUM CALCIUM EDETATE

| | | | | |
|---|---|---|---|---|
| ❋ Inj 200 mg per ml, 5 ml | 53.31 (156.71) | 6 | | Calcium Disodium Versenate |

## Standard Formulae

ACETYLCYSTEINE EYE DROPS

| | |
|---|---|
| Acetylcysteine inj 200 mg per ml, 10 ml | qs |
| Suitable eye drop base | qs |

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.)

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 capsules 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)

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

## Extemporaneously Compounded Preparations and Galenicals

CODEINE PHOSPHATE – Safety medicine; prescriber may determine dispensing frequency

| | | | | |
|---|---|---|---|---|
| Powder – Only in combination | 63.09 | 25 g | | |
| | (90.09) | | | Douglas |

Only in extemporaneously compounded codeine linctus.

COLLODION FLEXIBLE

Note: This product is no longer being manufactured by the supplier and will be delisted from the Schedule at a date to be determined.

| | | | | |
|---|---|---|---|---|
| Collodion flexible | 19.30 | 100 ml | ✔ | **PSM** |

COMPOUND HYDROXYBENZOATE – Only in combination

Only in extemporaneously compounded oral mixtures.

| | | | | |
|---|---|---|---|---|
| Soln | 30.00 | 100 ml | ✔ | **Midwest** |

GLYCERIN WITH SODIUM SACCHARIN – Only in combination

Only in combination with Ora-Plus.

| | | | | |
|---|---|---|---|---|
| Suspension | 30.95 | 473 ml | ✔ | **Ora-Sweet SF** |

GLYCERIN WITH SUCROSE – Only in combination

Only in combination with Ora-Plus.

| | | | | |
|---|---|---|---|---|
| Suspension | 30.95 | 473 ml | ✔ | **Ora-Sweet** |

GLYCEROL

| | | | | | |
|---|---|---|---|---|---|
| ✻ | Liquid – Only in combination | 3.23 | 500 ml | ✔ | **healthE Glycerol BP** |

Only in extemporaneously compounded oral liquid preparations.

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** |

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.

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

▲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 |
|---|---|---|---|---|

## 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 and Enteral Feeds

## Diabetic Products

**➽SA1095 Special Authority for Subsidy**
**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient is a type I or and II diabetic who is suffering weight loss and malnutrition that requires nutritional support.
**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:
Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

DIABETIC ENTERAL FEED 1KCAL/ML – Special Authority see SA1095 above – Hospital pharmacy [HP3]

| | | | | |
|---|---|---|---|---|
| Liquid | 3.75 | 500 ml | OP | ✔ **Glucerna Select** |
| | 7.50 | 1,000 ml | OP | ✔ **Diason RTH** |
| | | | | ✔ **Nutrison Advanced Diason** |

*(Diason RTH Liquid to be delisted 1 December 2022)*

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** |
| | 2.10 | | | ✔ **Nutren Diabetes** |

## 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** |

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

## Paediatric Products For Children Awaiting Liver Transplant

**➽SA1098 Special Authority for Subsidy**
**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient is a child (up to 18 years) who requires a liver transplant.
**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:
Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL FEED 1KCAL/ML – Special Authority see SA1098 above – Hospital pharmacy [HP3]

| | | | | |
|---|---|---|---|---|
| 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.

ENTERAL/ORAL FEED 1KCAL/ML – Special Authority see SA1099 above – Hospital pharmacy [HP3]

| | | | | |
|---|---|---|---|---|
| Powder | 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

continued…

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

continued…
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 on the previous page – Hospital pharmacy [HP3]

| | | | | |
|---|---|---|---|---|
| Liquid | 6.00 | 500 ml | OP | ✔ **Nutrini Energy RTH** |

PAEDIATRIC ENTERAL FEED 1KCAL/ML – Special Authority see SA1379 on the previous page – 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 on the previous page – Hospital pharmacy [HP3]

| | | | | |
|---|---|---|---|---|
| Liquid | 6.00 | 500 ml | OP | ✔ **Nutrini Energy Multi Fibre** |

PAEDIATRIC ORAL FEED 1.5KCAL/ML – Special Authority see SA1379 on the previous page – Hospital pharmacy [HP3]

| | | | | |
|---|---|---|---|---|
| Liquid (strawberry) | 1.60 | 200 ml | OP | ✔ **Fortini** |
| Liquid (vanilla) | 1.60 | 200 ml | OP | ✔ **Fortini** |
| | 6.99 | 500 ml | OP | ✔ **Pediasure Plus** |

PAEDIATRIC ORAL FEED 1KCAL/ML – Special Authority see SA1379 on the previous page – 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 on the previous page – 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 on the previous page – Hospital pharmacy [HP3]

| | | | | |
|---|---|---|---|---|
| Powder | 43.60 | 400 g | OP | ✔ **Peptamen Junior** |

## Renal Products

**➽SA1101 Special Authority for Subsidy**
**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient has acute or chronic kidney disease.
**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:
Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

RENAL ENTERAL FEED 1.8 KCAL/ML – Special Authority see SA1101 above – Hospital pharmacy [HP3]

| | | | | |
|---|---|---|---|---|
| Liquid | 6.08 | 500 ml | OP | ✔ **Nepro HP RTH** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| RENAL ORAL FEED 1.8 KCAL/ML – Special Authority see SA1101 on the previous page – 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 on the previous page – Hospital pharmacy [HP3] | | | | |
| Liquid, 200 ml bottle | 11.52 (13.24) | 4 OP | | NovaSource Renal |
| Liquid (apricot) 125 ml | 11.52 | 4 OP | ✔ | **Renilon 7.5** |
| Liquid (caramel) 125 ml | 11.52 | 4 OP | ✔ | **Renilon 7.5** |

## Specialised And Elemental Products

**SA1377 Special Authority for Subsidy**

**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

1 malabsorption; or
2 short bowel syndrome; or
3 enterocutaneous fistulas; or
4 eosinophilic oesophagitis; or
5 inflammatory bowel disease; or
6 patients with multiple food allergies requiring enteral feeding.

Notes: Each of these products is highly specialised and would be prescribed only by an expert for a specific disorder. The alternative is hospitalisation.

Elemental 028 Extra is more expensive than other products listed in this section and should only be used where the alternatives have been tried first and/or are unsuitable.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

| | | | | |
|---|---|---|---|---|
| ENTERAL/ORAL SEMI-ELEMENTAL FEED 1.5KCAL/ML – Special Authority see SA1377 above – Hospital pharmacy [HP3] | | | | |
| Liquid | 18.06 | 1,000 ml OP | ✔ | **Vital** |
| ORAL ELEMENTAL FEED 0.8KCAL/ML – Special Authority see SA1377 above – 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 above – Hospital pharmacy [HP3] | | | | |
| Powder (unflavoured) | 4.50 | 80 g OP | ✔ | **Vivonex TEN** |
| SEMI-ELEMENTAL ENTERAL FEED 1KCAL/ML – Special Authority see SA1377 above – Hospital pharmacy [HP3] | | | | |
| Liquid | 12.04 | 1,000 ml OP | ✔ | **Nutrison Advanced Peptisorb** |
| | | | ✔ | **Peptisorb** |

*(Peptisorb Liquid to be delisted 1 June 2023)*

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

## 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:

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:

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 It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease; and
3 General Practitioners and dietitians must include the name of the gastroenterologist recommending treatment and the date the gastroenterologist was contacted.

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

All of the following:

1 Any of the following:

Patient is Malnourished

1.1 Patient has a body mass index (BMI) of less than 18.5 kg/$m^2$; or
1.2 Patient has unintentional weight loss greater than 10% within the last 3-6 months; or
1.3 Patient has a BMI of less than 20 kg/$m^2$ and unintentional weight loss greater than 5% within the last 3-6 months; and

2 Any of the following:

Patient has not responded to first-line dietary measures over a 4 week period by:

2.1 Increasing their food intake frequency (eg snacks between meals); or
2.2 Using high-energy foods (e.g. milkshakes, full fat milk, butter, cream, cheese, sugar etc); or
2.3 Using over the counter supplements (e.g. Complan); and

3 A nutrition goal has been set (e.g. to reach a specific weight or BMI).

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

Both:

1 A nutrition goal has been set (eg reach a specific weight or BMI); and
2 Any of the following:

Patient is Malnourished

2.1 Patient has a body mass index (BMI) of less than 18.5 kg/$m^2$; or
2.2 Patient has unintentional weight loss greater than 10% within the last 3-6 months; or
2.3 Patient has a BMI of less than 20 kg/$m^2$ and unintentional weight loss greater than 5% within the last 3-6 months.

**Initial application — (Short-term medical condition)** from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

1 Is being fed via a nasogastric tube or a nasogastric tube is to be inserted for feeding; or
2 Malignancy and is considered likely to develop malnutrition as a result; or
3 Is undergoing a bone marrow transplant; or
4 Tempomandibular surgery or glossectomy; or
5 Both:

5.1 Pregnant; and
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.

continued…

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

continued…

**Renewal — (Short-term medical condition)** from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

1 Is being fed via a nasogastric tube; or
2 Malignancy and is considered likely to develop malnutrition as a result; or
3 Has undergone a bone marrow transplant; or
4 Tempomandibular surgery or glossectomy; or
5 Both:
  5.1 Pregnant; and
  5.2 Any of the following:
    5.2.1 Patient is in early pregnancy (< 13 weeks) and has severe clinical hyperemesis gravidarum requiring admission to hospital and is unlikely to meet her nutritional requirements due to continuing hyperemesis gravidarum; or
    5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or
    5.2.3 Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met.

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

Any of the following:

1 Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube - refer to specific medical condition criteria); or
2 Cystic Fibrosis; or
3 Liver disease; or
4 Chronic Renal failure; or
5 Inflammatory bowel disease; or
6 Chronic obstructive pulmonary disease with hypercapnia; or
7 Short bowel syndrome; or
8 Bowel fistula; or
9 Severe chronic neurological conditions; or
10 Epidermolysis bullosa; or
11 AIDS (CD4 count < 200 cells/$mm^3$); or
12 Chronic pancreatitis.

**Renewal — (Chronic disease OR tube feeding for patients who have previously been funded under Special Authority forms SA0702 or SA0583)** from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

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.

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| ENTERAL FEED 1.5KCAL/ML – Special Authority see SA1859 on page 257 – Hospital pharmacy [HP3] | | | | |
| Liquid | 1.75 | 250 ml OP | ✔ | **Ensure Plus HN** |
| | 7.00 | 1,000 ml OP | ✔ | **Ensure Plus RTH** |
| | | | ✔ | **Nutrison Energy** |
| ENTERAL FEED 1KCAL/ML – Special Authority see SA1859 on page 257 – 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 257 – 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 257 – Hospital pharmacy [HP3] | | | | |
| Liquid | 5.29 | 1,000 ml OP | ✔ | **Jevity RTH** |
| | | | ✔ | **Nutrison Multi Fibre** |
| ENTERAL FEED WITH FIBRE 1.2KCAL/ML – Special Authority see SA1859 on page 257 – Hospital pharmacy [HP3] | | | | |
| Liquid | 6.35 | 1,000 ml OP | ✔ | **Jevity Plus** |
| ENTERAL FEED WITH FIBRE 1.5KCAL/ML – Special Authority see SA1859 on page 257 – Hospital pharmacy [HP3] | | | | |
| Liquid | 7.00 | 1,000 ml OP | ✔ | **Jevity HiCal RTH** |
| | | | ✔ | **Nutrison Energy Multi Fibre** |
| ORAL FEED (POWDER) – Special Authority see SA1859 on page 257 – Hospital pharmacy [HP3] | | | | |
| Powder (chocolate) | 14.00 | 840 g OP | ✔ | **Sustagen Hospital Formula** |
| | 26.00 | 850 g OP | ✔ | **Ensure** |
| Powder (vanilla) | 14.00 | 840 g OP | ✔ | **Sustagen Hospital Formula Active** |
| | 26.00 | 850 g OP | ✔ | **Ensure** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| ORAL FEED 1.5KCAL/ML – Special Authority see SA1859 on page 257 – 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) | | | Fortisip |
| Liquid (vanilla) – Higher subsidy of up to $1.33 per 237 ml with Endorsement | 0.85 | 237 ml | OP | |
| | (1.33) | | | Ensure Plus |
| | 0.72 | 200 ml | OP | |
| | (1.26) | | | Ensure Plus |
| | (1.26) | | | Fortisip |
| ORAL FEED WITH FIBRE 1.5 KCAL/ML – Special Authority see SA1859 on page 257 – Hospital pharmacy [HP3] | | | | |
| Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, or who have severe epidermolysis bullosa. The prescription must be endorsed accordingly. | | | | |
| Liquid (chocolate) – Higher subsidy of $1.26 per 200 ml with Endorsement | 0.72 | 200 ml | OP | |
| | (1.26) | | | Fortisip Multi Fibre |
| Liquid (strawberry) – Higher subsidy of $1.26 per 200 ml with Endorsement | 0.72 | 200 ml | OP | |
| | (1.26) | | | Fortisip Multi Fibre |
| Liquid (vanilla) – Higher subsidy of $1.26 per 200 ml with Endorsement | 0.72 | 200 ml | OP | |
| | (1.26) | | | Fortisip Multi Fibre |

## High Calorie Products

➽SA1195 **Special Authority for Subsidy**

**Initial application — (Cystic fibrosis)** only from a dietitian, relevant specialist or vocationally registered general practitioner.
Approvals valid for 3 years for applications meeting the following criteria:
All of the following:

1 Cystic fibrosis; and
2 other lower calorie products have been tried; and
3 patient has substantially increased metabolic requirements.

continued…

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

continued…

**Initial application — (Indications other than cystic fibrosis)** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:
All of the following:

1 Any of the following:
  1.1 any condition causing malabsorption; or
  1.2 faltering growth in an infant/child; or
  1.3 increased nutritional requirements; or
  1.4 fluid restricted; and
2 other lower calorie products have been tried; and
3 patient has substantially increased metabolic requirements or is fluid restricted.

**Renewal — (Cystic fibrosis)** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:
Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

**Renewal — (Indications other than cystic fibrosis)** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:
Both:

1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL FEED 2 KCAL/ML – Special Authority see SA1195 on the previous page – Hospital pharmacy [HP3]

| | | | | |
|---|---|---|---|---|
| Liquid | 5.50 | 500 ml | OP | ✔ **Nutrison Concentrated** |
| | 11.00 | 1,000 ml | OP | ✔ **Ensure Two Cal HN RTH** |

ORAL FEED 2 KCAL/ML – Special Authority see SA1195 on the previous page – Hospital pharmacy [HP3]
Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, or who have severe epidermolysis bullosa. The prescription must be endorsed accordingly.

| | | | | |
|---|---|---|---|---|
| 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.

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| FOOD THICKENER – Special Authority see SA1106 on the previous page – Hospital pharmacy [HP3] | | | | |
| Powder | 6.53 | 300 g OP | ✔ | **Nutilis** |
| | 7.25 | 380 g OP | ✔ | **Feed Thickener Karicare Aptamil** |

## Gluten Free Foods

The funding of gluten free foods is no longer being actively managed by Pharmac from 1 April 2011. This means that we are no longer considering the listing of new products, or making subsidy, or other changes to the existing listings. As a result we anticipate that the range of funded items will reduce over time. Management of Coeliac disease with a gluten free diet is necessary for good outcomes. A range of gluten free options are available through retail outlets.

**SA1729 Special Authority for Subsidy**

**Initial application — (all patients)** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:
Either:

1 Gluten enteropathy has been diagnosed by biopsy; or
2 Patient suffers from dermatitis herpetiformis.

**Initial application — (paediatric patients diagnosed by ESPGHAN criteria)** only from a paediatric gastroenterologist. Approvals valid without further renewal unless notified where the paediatric patient fulfils ESPGHAN criteria for biopsy free diagnosis of coeliac disease.

| | | | | |
|---|---|---|---|---|
| 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 |
| GLUTEN FREE FLOUR – Special Authority see SA1729 above – Hospital pharmacy [HP3] | | | | |
| Powder | 5.62 | 2,000 g OP | | |
| | (18.10) | | | Horleys Flour |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| GLUTEN FREE PASTA – Special Authority see SA1729 on the previous page – Hospital pharmacy [HP3] | | | | |
| Buckwheat Spirals | 2.00 | 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 (berry) 28 g sachets | 936.00 | 30 | ✔ | **PKU Lophlex Powder** |
| Powder (chocolate) 36 g sachet | 393.00 | 30 | ✔ | **PKU Anamix Junior Chocolate** |
| Powder (neutral) 28 g sachets | 936.00 | 30 | ✔ | **PKU Lophlex Powder** |
| Powder (neutral) 36 g sachets | 393.00 | 30 | ✔ | **PKU Anamix Junior** |
| Powder (orange) 28 g sachets | 936.00 | 30 | ✔ | **PKU Lophlex Powder** |
| Powder (orange) 36 g sachet | 393.00 | 30 | ✔ | **PKU Anamix Junior Orange** |
| Powder (unflavoured) 28 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** |

*(PKU Lophlex Powder Powder (unflavoured) 28 g sachets to be delisted 1 December 2022)*
*(PKU Anamix Junior Powder (unflavoured) 36 g sachets to be delisted 1 December 2022)*

## Foods

LOW PROTEIN BAKING MIX – Special Authority see SA1108 on the previous page – Hospital pharmacy [HP3]

| | | | | |
|---|---|---|---|---|
| Powder | 8.22 | 500 g OP | ✔ | **Loprofin Mix** |

| | Subsidy (Manufacturer's Price) $ | Per | Fully Subsidised ✔ | Brand or Generic Manufacturer |
|---|---|---|---|---|
| LOW PROTEIN PASTA – Special Authority see SA1108 on page 264 – 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** |

## 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 SA2092 below – Hospital pharmacy [HP3] | | | | |
| Powder | 43.60 | 400 g OP | ✔ | **Alfamino** |
| | | | ✔ | **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** |

**SA2092 Special Authority for Subsidy**

**Initial application — (Infants under 12 months of age)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Any of the following:

1 History of anaphylaxis to cow's milk protein formula or dairy products; or
2 Eosinophilic oesophagitis; or
3 Ultra-short gut; or
4 Severe Immune deficiency; or

continued…

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

continued…

5 Extensively hydrolysed formula has been trialled in an inpatient setting and is clinically inappropriate; or
6 Both:
6.1 Extensively hydrolysed formula has been reasonably trialled for 2-4 weeks and is inappropriate due to documented severe intolerance or allergy or malabsorption; and
6.2 Either:
6.2.1 The patient has a valid Special Authority approval for extensively hydrolysed formula: approval number; or
6.2.2 Patient has IgE mediated allergy.

**Initial application — (Children 12 months of age and over)** only from a paediatrician, paediatric gastroenterologist, paediatric immunologist or dietitian on the recommendation of a paediatrician, paediatric gastroenterologist or paediatric immunologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:

1 Either:
1.1 Applicant is a paediatrician, paediatric gastroenterologist or paediatric immunologist; or
1.2 Applicant is a dietitian and confirms that a paediatrician, paediatric gastroenterologist or paediatric immunologist has been consulted within the last 12 months and has recommended treatment for the patient; and
2 Any of the following:
2.1 History of anaphylaxis to cow's milk protein formula or dairy products; or
2.2 Eosinophilic oesophagitis; or
2.3 Ultra-short gut; or
2.4 Severe Immune deficiency; or
2.5 Extensively hydrolysed formula has been trialled in an inpatient setting and is clinically inappropriate; or
2.6 Both:
2.6.1 Extensively hydrolysed formula has been reasonably trialled for 2-4 weeks and is inappropriate due to documented severe intolerance or allergy or malabsorption; and
2.6.2 Either:
2.6.2.1 The patient has a valid Special Authority approval for extensively hydrolysed formula: approval number; or
2.6.2.2 Patient has IgE mediated allergy.

**Renewal — (Infants up to 12 months of age)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
Either:

1 Both:
1.1 Patient has IgE mediated allergy; and
1.2 All of the following:
1.2.1 Patient remains allergic to cow's milk; and
1.2.2 An assessment as to whether the infant can be transitioned to a cow's milk protein, soy or extensively hydrolysed infant formula has been undertaken; and
1.2.3 The outcome of the assessment is that the infant continues to require an amino acid infant formula; and
1.2.4 Amino acid formula is required for a nutritional deficit; and
1.2.5 It has been more than three months from the previous approval; or
2 Both:
2.1 Patient has non IgE mediated severe gastrointestinal intolerance (including eosinophilic oesophagitis, ultra-short gut and severe immune deficiency); and
2.2 All of the following:
2.2.1 An assessment as to whether the infant can be transitioned to a cow's milk protein, soy, or extensively hydrolysed infant formula has been undertaken; and
2.2.2 The outcome of the assessment is that the infant continues to require an amino acid infant formula; and

continued…

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

continued…

2.2.3 Amino acid formula is required for a nutritional deficit; and
2.2.4 It has been more than three months from the previous approval.

**Renewal — (Children 12 months of age and over)** only from a paediatrician, paediatric gastroenterologist, paediatric immunologist or dietitian on the recommendation of a paediatrician, paediatric gastroenterologist or paediatric immunologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:

1 Either:
1.1 Applicant is a paediatrician, paediatric gastroenterologist or paediatric immunologist; or
1.2 Applicant is a dietitian and confirms that a paediatrician, paediatric gastroenterologist or paediatric immunologist has been consulted within the last 12 months and has recommended treatment for the patient; and
2 Any of the following:
2.1 History of anaphylaxis to cow's milk protein formula or dairy products; or
2.2 Eosinophilic oesophagitis; or
2.3 Ultra-short gut; or
2.4 Severe Immune deficiency; or
2.5 Extensively hydrolysed formula has been trialled in an inpatient setting and is clinically inappropriate; or
2.6 Both:
2.6.1 Extensively hydrolysed formula has been reasonably trialled for 2-4 weeks and is inappropriate due to documented severe intolerance or allergy or malabsorption; and
2.6.2 Either:
2.6.2.1 The patient has a valid Special Authority approval for extensively hydrolysed formula: approval number; or
2.6.2.2 Patient has IgE mediated allergy.

**Initial application — (for patients who have a current funding under Special Authority form SA1557)** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1 Patient has a valid Special Authority approval for extensively hydrolysed formula (SA1557); and
2 Extensively hydrolysed formula (Aptamil Gold+ Pepti Junior, AllerPro SYNEO 1 and 2) is unable to be supplied at this time; and
3 The approval only applies to funded dispensings of Neocate Gold and Neocate Syneo.

Note: This criteria is short term funding to cover an out-of-stock situation on some extensively hydrolysed formula powder funded under Special Authority form SA1557. There is no renewal criteria under this restriction.

ENTERAL LIQUID PEPTIDE FORMULA – Special Authority see SA1953 below – Hospital pharmacy [HP3]

| | | | | |
|---|---|---|---|---|
| Liquid 1 kcal/ml | 10.45 | 500 ml | OP | ✔ **Nutrini Peptisorb** |
| Liquid 1.5 kcal/ml | 15.68 | 500 ml | OP | ✔ **Nutrini Peptisorb Energy** |

**➽SA1953 Special Authority for Subsidy**
**Initial application** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1 Patient has impaired gastrointestinal function and either cannot tolerate polymeric feeds, or polymeric feeds are unsuitable; and
2 Any of the following:
2.1 Severe malabsorption; or
2.2 Short bowel syndrome; or

continued…

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

continued…

2.3 Intractable diarrhoea; or
2.4 Biliary atresia; or
2.5 Cholestatic liver diseases causing malabsorption; or
2.6 Cystic fibrosis; or
2.7 Proven fat malabsorption; or
2.8 Severe intestinal motility disorders causing significant malabsorption; or
2.9 Intestinal failure; or
2.10 Both:
2.10.1 The patient is currently receiving funded amino acid formula; and
2.10.2 The patient is to be trialled on, or transitioned to, an enteral liquid peptide formula; and

3 Either:
3.1 A semi-elemental or partially hydrolysed powdered feed has been reasonably trialled and considered unsuitable; or
3.2 For step down from intravenous nutrition.

Note: A reasonable trial is defined as a 2-4 week trial.

**Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 An assessment as to whether the patient can be transitioned to a cows milk protein or soy infant formula or extensively hydrolysed formula has been undertaken; and
2 The outcome of the assessment is that the patient continues to require an enteral liquid peptide formula; and
3 General practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.

EXTENSIVELY HYDROLYSED FORMULA – Special Authority see SA1557 below – Hospital pharmacy [HP3]

| | | | | |
|---|---|---|---|---|
| Powder | 15.21 | 450 g | OP | ✔ **Pepti-Junior** |
| | 30.42 | 900 g | OP | ✔ **Allerpro Syneo 1** |
| | | | | ✔ **Allerpro Syneo 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:

continued…

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

continued…

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:

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.

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

## 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

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

a) Only on a prescription
b) No patient co-payment payable
c)

A) Funded for any of the following criteria:
   1) A single dose for pregnant women in the second or third trimester of each pregnancy; or
   2) A single dose for parents or primary caregivers of infants admitted to a Neonatal Intensive Care Unit or Specialist Care Baby Unit for more than 3 days, who had not been exposed to maternal vaccination at least 14 days prior to birth; or
   3) A course of up to four doses is funded for children from age 7 up to the age of 18 years inclusive to complete full primary immunisation; or
   4) An additional four doses (as appropriate) are funded for (re-)immunisation for patients post haematopoietic stem cell transplantation or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens; or
   5) A single dose for vaccination of patients aged from 65 years old; or
   6) A single dose for vaccination of patients aged from 45 years old who have not had 4 previous tetanus doses; or
   7) For vaccination of previously unimmunised or partially immunised patients; or
   8) For revaccination following immunosuppression; or
   9) For boosting of patients with tetanus-prone wounds.

   Notes: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

B) Contractors will be entitled to claim payment from the Funder for the supply of diphtheria, tetanus and pertussis vaccine to patients eligible under the above criteria pursuant to their contract with Te Whatu Ora Health New Zealand for subsidised immunisation, and they may only do so in respect of the diphtheria, tetanus and pertussis vaccine listed in the Pharmaceutical Schedule.

C) Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraphs 1 – 9 above.

| | | | | |
|---|---|---|---|---|
| Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg pertussis toxoid, 8 mcg pertussis filamentous haemagglutinin and 2.5 mcg pertactin in 0.5 ml 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 haemagglutinin, 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 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin, 8 mcg pertactin, 80 D-Ag U polio virus, 10 mcg hepatitis B surface antigen in 0.5 ml 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** |

▲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 |
|---|---|---|---|---|

HEPATITIS B RECOMBINANT VACCINE – [Xpharm]

Inj 10 mcg per 0.5 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.

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.

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] | 11.00 | 1 | ✔ | **Afluria Quad Junior (2022 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 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) | 110.00 | 10 | ✔ | **Afluria Quad (2022 formulation)** |

▲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 |
|---|---|---|---|---|

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 55 to 64 years of age (inclusive) and is Māori or any Pacific ethnicity; or
c) 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
d) children 3 and 4 years of age (inclusive) who have been hospitalised for respiratory illness or have a history of significant respiratory illness; or
e) people under 65 years of age who:
i) have any of the following serious mental health conditions:
a) schizophrenia, or
b) major depressive disorder, or
c) bipolar disorder, or
d) schizoaffective disorder, or
ii) are currently accessing secondary or tertiary mental health and addiction services; or
f) children 3 to 12 years of age (inclusive), from 1 July 2022 to 31 December 2022;

Unless meeting the criteria set out above, the following conditions are excluded from funding:
a) asthma not requiring regular preventative therapy,
b) hypertension and/or dyslipidaemia without evidence of end-organ disease.

B) Contractors will be entitled to claim payment for the supply of influenza vaccine to patients eligible under the above criteria pursuant to their contract with Health NZ for subsidised immunisation, and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.
C) Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

| | Subsidy (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 for the supply of measles, mumps and rubella vaccine to patients eligible under the above criteria pursuant to their contract with Health NZ for subsidised immunisation, and they may only do so in respect of the measles, mumps and rubella vaccine listed in the Pharmaceutical Schedule.

C) Contractors can only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

| | | | | |
|---|---|---|---|---|
| Inj, measles virus 1,000 CCID50, mumps virus 5,012 CCID50, Rubella virus 1,000 CCID50; prefilled syringe/ampoule of diluent 0.5 ml | 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 of any group; or
3) One dose for person who has previously had meningococcal disease of any group; or
4) A maximum of two doses for bone marrow transplant patients; or
5) A maximum of two doses for person pre- and post-immunosuppression*; or

B) Both:

1) Person is aged between 13 and 25 years, inclusive; and
2) Either:
   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 2021.

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** |

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

MENINGOCOCCAL B MULTICOMPONENT VACCINE – [Xpharm]

Either:

A) Both:
1) Child is under one year of age; and
2) Any of the following:
i) 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
ii) up to three doses for close contacts of meningococcal cases of any group; or
iii) up to three doses for child who has previously had meningococcal disease of any group; or
iv) up to three doses for bone marrow transplant patients; or
v) up to three doses for child pre- and post-immunosuppression*; or

B) Both:
1) Person is one year of age or over; and
2) Any of the following:
i) up to two doses and a booster every five years for patients pre- and post-splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre- or post-solid organ transplant; or
ii) up to two doses for close contacts of meningococcal cases of any group; or
iii) up to two doses for person who has previously had meningococcal disease of any group; or
iv) up to two doses for bone marrow transplant patients; or
v) up to two doses for person pre- and post-immunosuppression*.

*Immunosuppression due to corticosteroid or other immunosuppressive therapy must be for a period of greater than 28 days.

Inj 175 mcg per 0.5 ml prefilled syringe ..... 0.00 — 1 — ✔ **Bexsero**

MENINGOCOCCAL C CONJUGATE VACCINE – [Xpharm]

Both:
1) The child is under 9 months of age; and
2) Any of the following:
1) Up to three doses for patients pre- and post splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre or post solid organ transplant; or
2) Two doses for close contacts of meningococcal cases of any group; or
3) Two doses for child who has previously had meningococcal disease of any group; or
4) A maximum of two doses for bone marrow transplant patients; or
5) A maximum of two doses for child pre- and post-immunosuppression*.

Note: children under nine months of age require two doses 8 weeks apart. Refer to the Immunisation Handbook for booster schedules with meningococcal ACWY vaccine.

*Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.

Inj 10 mcg in 0.5 ml syringe ..... 0.00 — 1 — ✔ **Neisvac-C**

PNEUMOCOCCAL (PCV10) CONJUGATE VACCINE – [Xpharm]

1) A primary course of three doses for previously unvaccinated individuals up to the age of 59 months inclusive

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**



✔ **fully subsidised**
**Principal Supply**

S29 Unapproved medicine supplied under Section 29
**Sole Subsidised Supply**

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

PNEUMOCOCCAL (PCV13) CONJUGATE VACCINE – [Xpharm]

Any of the following:

1) Two doses are funded for high risk children (over the age of 12 months and under 18 years) who have previously received two doses of the primary course 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, intracranial shunts, cerebrospinal fluid leaks 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

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|---|---|---|---|---|
| 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.

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|---|---|---|---|---|
| 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.

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| 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.

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| 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

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|---|---|---|---|---|
| Inj 1350 PFU prefilled syringe | 0.00 | 1 | ✔ | **Varivax** |
| | | 10 | ✔ | **Varivax** |

VARICELLA ZOSTER VACCINE [SHINGLES VACCINE] – [Xpharm]

Funded for patients meeting the following criteria:

1) Two doses for all people aged 65 years

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|---|---|---|---|---|
| Inj 50 mcg per 0.5 ml vial plus vial | 0.00 | 1 | ✔ | **Shingrix** |

VARICELLA ZOSTER VIRUS (OKA STRAIN) LIVE ATTENUATED VACCINE [SHINGLES VACCINE] – [Xpharm]

Funded for patients meeting the following criteria:

1) One dose for all people aged 65 years

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| Inj 19,400 PFU prefilled syringe plus vial | 0.00 | 1 | ✔ | **Zostavax** |
| | | 10 | ✔ | **Zostavax** |

## Diagnostic Agents

TUBERCULIN PPD [MANTOUX] TEST – [Xpharm]

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|---|---|---|---|---|
| Inj 5 TU per 0.1 ml, 1 ml vial | 0.00 | 1 | ✔ | **Tubersol** |