| 4 . 11 0005 | | | | | | |
|---|-----------|---|---------|--|--|--|
| April 2025 Volume 32 Editors: Kaye Wilson, Doris Chong, Sophie Molloy | Section A | General Rules | 5 | | | |
| email: enquiry@pharmac.govt.nz Telephone +64 4 460 4990 Level 9, 40 Mercer Street PO Box 10 254 Wellington | Section B | Alimentary Tract & Metabolism Blood & Blood Forming Organs | 6 35 | | | |
| Freephone Information Line 0800 66 00 50 (9am – 5pm weekdays) | | Cardiovascular System | 44 | | | |
| Circulation | | Dermatologicals | 65 | | | |
| You can register to have an electronic version of the Pharmaceutical Schedule (link | | Genito Urinary System | 74 | | | |
| to PDF copy) emailed to your nominated | | Hormone Preparations – Systemic | 81 | | | |
| email address each month by subscribing at pharmac.govt.nz/subscribe. | | Infections – Agents For Systemic Use | 92 | | | |
| Production | | Musculoskeletal System | 114 | | | |
| Typeset automatically from XML and TEX. XML version of the Schedule available from <u>schedule.pharmac.govt.nz/pub/schedule</u> | | Nervous System | 120 | | | |
| | | Oncology Agents & Immunosuppressants | 150 | | | |
| Programmers Anrik Drenth | | Respiratory System & Allergies | 256 | | | |
| email: texschedule@pharmac.govt.nz ©Pharmaceutical Management Agency ISSN 1179-3686 This work is licensed under the Creative Commons Attribution 4.0 International licence. In essence, you are free to copy, distribute and adapt it, as long as you attribute the work to Pharmac and abide by the other licence terms. To view a copy of this licence, visit: creativecommons.org/licenses/by/4.0/. Attribution to Pharmac should be in written form and not by reproduction of the Pharmac logo. While care has been taken in compiling this Schedule, Pharmac takes no responsibility for any errors or omissions, and shall not be liable for any consequences arising there from. | | Sensory Organs | 267 | | | |
| | | Various | 272 | | | |
| | Section C | Extemporaneous Compounds (ECPs) | 274 | | | |
| | Section D | Special Foods | 276 | | | |
| | Section I | National Immunisation Schedule | 300 | | | |
| | | Index | 316 | | | |

Introducing Pharmac

2

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://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.

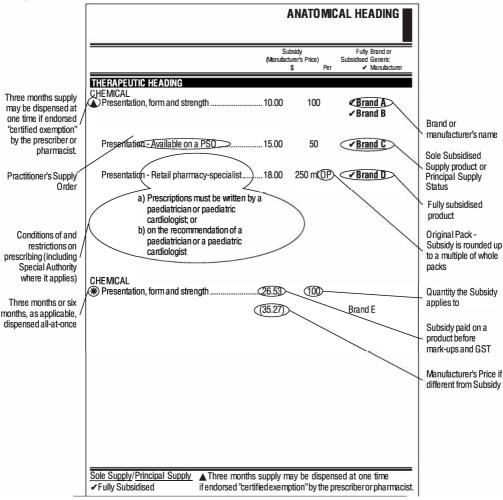
The Pharmaceuticals in this book are listed by therapeutic group, which is based on the WHO Anatomical Therapeutic Chemical (ATC) system. The listings are displayed alphabetically under each heading.

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 | |

Abbreviations

| Capsule Cream Device Dispersible Effervescent Emulsion | Amp Cap Crm Dev Disp Eff Emul EC |
|---|---|
| Enteric Coated | EC |
| | |

| microgram me | cg |
|--------------|----|
| milligramn | ng |
| millilitreı | ml |

| millimole | mmol |
|-----------|------|
| unit | u |

| Gelatinous | Gel | SolutionSoln |
|-------------|------|-----------------------|
| Granules | Gran | SuppositorySupp |
| Infusion | Inf | TabletTab |
| Injection | Inj | Tincture Tinc |
| Liquid | Liq | Trans Dermal Delivery |
| Long Acting | LA | SystemTDDS |
| Ointment | Oint | - |
| Sachet | Sach | |

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

SECTION B: ALIMENTARY TRACT AND METABOLISM

| | Subsidy | | Fully | Brand or |
|--|------------------------------|----------------|------------|---|
| | (Manufacturer's Price) \$ | Per | Subsidised | Generic Manufacturer |
| Antacids and Antiflatulents | | | | |
| Antacids and Reflux Barrier Agents | | | | |
| LGINIC ACID Sodium alginate 225 mg and magnesium alginate 87.5 mg pe sachet | | 30 | | Gaviscon Infant |
| ODIUM ALGINATE Tab 500 mg with sodium bicarbonate 267 mg and calcium | | 00 | - | |
| carbonate 160 mg - peppermint flavour | 1.80 (17.99) | 60 | | Gaviscon Extra Strength |
| Oral liq 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml | | 500 m | | Acidex |
| Phosphate Binding Agents | | | | |
| LUMINIUM HYDROXIDE ← Tab 600 mg | 12.56 | 100 | 1 | Alu-Tab |
| ALCIUM CARBONATE Oral liq 1,250 mg per 5 ml (500 mg elemental per 5 ml) – Subsidy by endorsement | 47.30 | 500 m 473 m | ✓ | Roxane Calcium carbonate PAI \$29 |
| Only when prescribed for patients unable to swallow calc inappropriate and the prescription is endorsed according | | IS OF W | mere calci | um carbonale labiels are |
| Antidiarrhoeals | | | | |
| Agents Which Reduce Motility | | | | |
| OPERAMIDE HYDROCHLORIDE – Up to 30 cap available on a ∉ Tab 2 mg ∉ Cap 2 mg | 10.75 | 400 400 | | Nodia Diamide Relief |
| Rectal and Colonic Anti-inflammatories | | | | |
| UDESONIDE Cap modified-release 3 mg – Special Authority see SA1886 below – Retail pharmacy | 87.60 | 90 | , | Budesonide Te Arai |
| SA1886 Special Authority for Subsidy itial application — (Crohn's disease) from any relevant pract e following criteria: oth: | | | | |
| Mild to moderate ileal, ileocaecal or proximal Crohn's disea Any of the following: | ase; and | | | |
| 2.1 Diabetes; or | | | | |

continued...

6

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

continued...

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

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

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

Note: Indication marked with * is an unapproved indication.

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

All of the following:

- 1 Patient has autoimmune hepatitis*; and
- 2 Patient does not have cirrhosis; and
- 3 Any of the following:

- 3.1 Diabetes; or
- 3.2 Cushingoid habitus; or
- 3.3 Osteoporosis where there is significant risk of fracture; or
- 3.4 Severe acne following treatment with conventional corticosteroid therapy; or
- 3.5 History of severe psychiatric problems associated with corticosteroid treatment; or
- 3.6 History of major mental illness (such as bipolar affective disorder) where the risk of conventional corticosteroid treatment causing relapse is considered to be high; or
- 3.7 Relapse during pregnancy (where conventional corticosteroids are considered to be contraindicated); or
- 3.8 Adolescents with poor linear growth (where conventional corticosteroid use may limit further growth).
- Note: Indication marked with * is an unapproved indication.

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

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

| HIDROCORTISONE ACETATE | | |
|--|---------|------------------------------------|
| Rectal foam 10%, CFC-Free (14 applications)57.09 | 15 g OP | Colifoam |
| HYDROCORTISONE ACETATE WITH PRAMOXINE HYDROCHLORIDE | | |
| Topical aerosol foam, 1% with pramoxine hydrochloride 1% | 10 g OP | Proctofoam S29 |
| MESALAZINE | | |
| Tab 400 mg | 100 | Asacol |
| Tab long-acting 500 mg56.10 | 100 | Pentasa |
| Tab 800 mg | 90 | Asacol |
| - | | Asacol S29 S29 |
| Modified release granules, 1 g118.10 | 100 OP | Pentasa |
| Enema 1 g per 100 ml | 7 | Pentasa |
| Suppos 500 mg | 20 | Asacol |
| Suppos 1 g | | Pentasa |
| (Asacol S29 S29 Tab 800 mg to be delisted 1 July 2025) | | |

(Asacol S29 S29 Tab 800 mg to be delisted 1 July 2025)

| | Subsidy | | Fully | Brand or |
|--|-----------------------|----------|------------|---------------------------|
| | (Manufacturer's Price |) Per | Subsidised | I Generic Manufacturer |
| | \$ | rei | • | Manufacturer |
| DLSALAZINE Tab 500 mg | 56.02 | 60 | 1 | Atnahs |
| Tab 500 mg | | 00 | • | Olsalazine S29 |
| | 02.27 | 100 | | Dipentum |
| Cap 250 mg | 93.37 53.00 | 100 | | Dipentum |
| | | 100 | • | Dipentum |
| ODIUM CROMOGLICATE | 110.05 | 400 | | Dellement |
| Cap 100 mg | | 100 | • | Ralicrom |
| ULFASALAZINE | | | | |
| Tab 500 mg | | 100 | | Salazopyrin |
| Tab EC 500 mg | 20.54 | 100 | <i>.</i> | Salazopyrin EN |
| Local preparations for Anal and Rectal Disorder | S | | | |
| Antihaemorrhoidal Preparations | | | | |
| LUOCORTOLONE CAPROATE WITH FLUOCORTOLONE PIV | ALATE AND CINCH | IOCAI | NE | |
| Oint 950 mcg, with fluocortolone pivalate 920 mcg, and | | | | |
| cinchocaine hydrochloride 5 mg per g | | 30 g O | P 🗸 | Ultraproct |
| Suppos 630 mcg, with fluocortolone pivalate 610 mcg, and | | • | | |
| cinchocaine hydrochloride 1 mg | 8.61 | 12 | ✓ | Ultraproct |
| YDROCORTISONE WITH CINCHOCAINE | | | | - |
| Oint 5 mg with cinchocaine hydrochloride 5 mg per g | | 30 g O | P 🗸 | Proctosedyl |
| Suppos 5 mg with cinchocaine hydrochloride 5 mg per g | | 12 | | Proctosedyl |
| Management of Anal Fissures | | | | |
| LYCERYL TRINITRATE – Special Authority see SA1329 below | | 30 g C | P 🗸 | Rectogesic |
| | | 00 g 0 | | licologicolo |
| SA1329 Special Authority for Subsidy nitial application from any relevant practitioner. Approvals valid | without further ren | ewal u | nless noti | ied where the patient has |
| hronic anal fissure that has persisted for longer than three weeks | 3. | | | |
| Antispasmodics and Other Agents Altering Gut | Motility | | | |
| Antiopuolito and other Agento Altering dat | motinty | | | |
| LYCOPYRRONIUM BROMIDE | | | | |
| Inj 200 mcg per ml, 1 ml ampoule - Up to 10 inj available on | а | | | |
| PSO | | 5 | ~ | Robinul |
| YOSCINE BUTYLBROMIDE | | | | |
| € Tab 10 mg | 2.25 | 20 | 1 | Hyoscine |
| 5 | | | | Butylbromide |
| | | | | (Adiramedica) |
| Inj 20 mg, 1 ml – Up to 5 inj available on a PSO | 1.91 | 5 | 1 | Spazmol |
| IEBEVERINE HYDROCHLORIDE | | | | |
| Tab 135 mg | 8.50 | 90 | 1 | Colofac |
| Antiulcerants | | | | |
| | | | | |
| Antisecretory and Cytoprotective | | | | |
| IISOPROSTOL – Wastage claimable | | | | |
| Tab 200 mcg – Up to 120 tab available on a PSO | 47.73 | 120 | 1 | Cytotec |
| fully such as discard | C00 11 | | | duradar Ocation CO |
| fully subsidised Principal Supply | Sole Subsidised | | | ed under Section 29 |
| | Sole Subsidised | - oapp | | |

| | Subsidy (Manufacturer's Price) | | Fully Subsidised | Brand or Generic |
|--|-----------------------------------|--------------------------|---------------------|---|
| | \$ | Per | | Manufacturer |
| Helicobacter Pylori Eradication | | | | |
| CLARITHROMYCIN Tab 500 mg - Subsidy by endorsement a) Maximum of 28 tab per prescription b) Subsidised only if prescribed for helicobacter pylori Note: the prescription is considered endorsed if cla inhibitor and either amoxicillin or metronidazole. | eradication and prescr | 14 ription ed in d | is endorse | Klacid d accordingly. with a proton pump |
| H2 Antagonists | | | | |
| FAMOTIDINE – Only on a prescription * Tab 20 mg | 4.91 | 100 | ✓ | Famotidine Hovid ©29 |
| * Tab 40 mg | 10.32 | 100 | ✓ | Famotidine Hovid S29 |
| * Inj 10 mg per ml, 4 ml - Subsidy by endorsement | | 10 | | Mylan S29 |
| Subsidy by endorsement – Subsidised for patients rece | eiving treatment as par | t of pa | alliative car | 9. |
| Proton Pump Inhibitors | | | | |
| LANSOPRAZOLE | | | | |
| * Cap 15 mg | | 100 | | Lanzol Relief |
| * Cap 30 mg | 5.43 | 100 | | Lanzol Relief |
| OMEPRAZOLE For omeprazole suspension refer Standard Formulae, page | 074 | | | |
| * Cap 10 mg | | 90 | | Omeprazole Teva <u>Omeprazole actavis</u> 10 |
| * Cap 20 mg | 2.02 | 90 | | Omeprazole Teva Omeprazole actavis 20 |
| * Cap 40 mg | 3.18 | 90 | | Omeprazole Teva <u>Omeprazole actavis</u> <u>40</u> |
| Powder – Only in combination Only in extemporaneously compounded omeprazole su | | 5 g | ✓ | Midwest |
| Inj 40 mg ampoule with diluent | 37.38 | 5 | - | <u>Dr Reddy's</u> <u>Omeprazole</u> Ocicure ©29 |
| PANTOPRAZOLE | | | | |
| * Tab EC 20 mg * Tab EC 40 mg | | 90 90 | | <u>Panzop Relief</u> Panzop Relief |
| Site Protective Agents | | | - | |
| • | | | | |
| COLLOIDAL BISMUTH SUBCITRATE Tab 120 mg | 14 51 | 50 | 1 | Gastrodenol S29 |
| SUCRALFATE | | 50 | • | |
| Tab 1 g | 35.50 (48.28) | 120 | (| Carafate |

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

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

| | Subsidy (Manufacturer's Pric | e) Subs | Fully Brand or sidised Generic |
|--|---------------------------------|------------------------------|---|
| | \$ | Per | Manufacturer |
| Bile and Liver Therapy | | | |
| RIFAXIMIN – Special Authority see SA1461 below – Retail phar Tab 550 mg | | 56 | ✓ Xifaxan |
| SA1461 Special Authority for Subsidy Initial application only from a gastroenterologist, hepatologist o hepatologist. Approvals valid for 6 months where the patient has tolerated doses of lactulose. Renewal only from a gastroenterologist, hepatologist or Practitic hepatologist. Approvals valid without further renewal unless not benefiting from treatment. | s hepatic encephalo | pathy despi endation of a | te an adequate trial of maximum a gastroenterologist or |
| Diabetes | | | |
| Hyperglycaemic Agents | | | |
| DIAZOXIDE – Special Authority see SA1320 below – Retail pha | armacy | | |
| Cap 25 mg | • | 100 | Proglicem S29 |
| Cap 100 mg | | 100 | Proglicem S29 |
| Oral liq 50 mg per ml | | 30 ml OP | e5 Pharma S29 |
| nitial application from any relevant practitioner. Approvals val hypoglycaemia caused by hyperinsulinism. Renewal from any relevant practitioner. Approvals valid without appropriate and the patient is benefiting from treatment. GLUCAGON HYDROCHLORIDE Inj 1 mg syringe kit – Up to 5 kit available on a PSO | t further renewal unl | | |
| Insulin - Short-acting Preparations | | | |
| NSULIN NEUTRAL ▲ Inj human 100 u per ml, 3 ml | 42.66 | 5 | ✓ Actrapid Penfill ✓ Humulin R |
| ▲ Inj human 100 u per ml, 10 ml vial | 25.26 | 1 OP | ✓ Actrapid ✓ Humulin R |
| Insulin - Intermediate-acting Preparations | | | |
| NSULIN ASPART WITH INSULIN ASPART PROTAMINE ▲ Inj 100 iu per ml, 3 ml prefilled pen NSULIN ISOPHANE | 52.15 | 5 | ✓ NovoMix 30 FlexPen |
| Inj human 100 u per ml, 3 ml | | 5 | ✓ Humulin NPH |
| ▲ Inj human 100 u per ml, 10 ml vial | 17.68 | 1 OP | Protaphane Penfill Humulin NPH Protaphane |

| | Subsidy | | Fully Brand or |
|--|--------------------|------------------|--|
| | (Manufacturer's Pr | rice) Sub Per | sidised Generic Manufacturer |
| | \$ | Per | Manufacturer |
| INSULIN ISOPHANE WITH INSULIN NEUTRAL | | | |
| Inj human with neutral insulin 100 u per ml, 3 ml | | 5 | Humulin 30/70 |
| | | | PenMix 30 |
| | | | PenMix 50 |
| ▲ Inj human with neutral insulin 100 u per ml, 10 ml vial | | 1 OP | Humulin 30/70 |
| ,,,,,,,,,,,,,,, | | | ✓ Mixtard 30 |
| (PenMix 50 Inj human with neutral insulin 100 u per ml, 3 ml to b (Mixtard 30 Inj human with neutral insulin 100 u per ml, 10 ml via INSULIN LISPRO WITH INSULIN LISPRO PROTAMINE ▲ Inj lispro 25% with insulin lispro protamine 75% 100 u per ml | I to be delisted 1 | | |
| | | F | Humalog Mix 25 |
| 3 ml | | 5 | |
| Inj lispro 50% with insulin lispro protamine 50% 100 u per ml | - | | |
| 3 ml | | 5 | Humalog Mix 50 |
| | | | |
| Insulin - Long-acting Preparations | | | |
| | | | |
| INSULIN GLARGINE | 00.00 | | |
| ▲ Inj 100 u per ml, 10 ml | | 1 | ✓ Lantus |
| ▲ Inj 100 u per ml, 3 ml | | 5 | Lantus |
| Inj 100 u per ml, 3 ml disposable pen | 94.50 | 5 | Lantus SoloStar |
| Inculin Denid Acting Drenerations | | | |
| Insulin - Rapid Acting Preparations | | | |
| INSULIN ASPART | | | |
| ▲ Inj 100 u per ml, 10 ml | 30.03 | 1 | NovoRapid |
| Inj 100 u per ml, 3 ml | | 5 | NovoRapid Penfill |
| | | 5 | NovoRapid FlexPen |
| | | 5 | |
| INSULIN GLULISINE | | | |
| Inj 100 u per ml, 10 ml | | 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, 3 ml | 50 52 | 5 | ✓ Humalog |
| Inj 100 u per ml, 10 ml vial | | 1 OP | ✓ Humalog ✓ Humalog |
| | | 101 | • Humalog |
| Alpha Glucosidase Inhibitors | | | |
| • | | | |
| ACARBOSE | | | |
| * Tab 50 mg | 11.20 | 90 | ✓ <u>Accarb</u> |
| * Tab 100 mg | 17.38 | 90 | ✓ <u>Accarb</u> |
| • ··· · · · · | | | |
| Oral Hypoglycaemic Agents | | | |
| GLIBENCLAMIDE | | | |
| | 7 50 | 100 | Deenil |
| * Tab 5 mg | | 100 | Daonil |
| GLICLAZIDE | | | _ |
| * Tab 80 mg | 20.10 | 500 | ✓ Glizide |
| GLIPIZIDE | | | |
| * Tab 5 mg | 6 86 | 100 | Minidiab |
| 5 | | | <u></u> |
| | 4474 | 4 000 | |
| * Tab immediate-release 500 mg | | 1,000 | Metformin Viatris |
| * Tab immediate-release 850 mg | 11.28 | 500 | Metformin Viatris |
| | | | |

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

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

| | | | | _ . |
|---|-------------------------|------------|------------|------------------------------|
| | Subsidy | | Fully | Brand or |
| | (Manufacturer's Price) | | bsidised | Generic |
| | \$ | Per | 1 | Manufacturer |
| PIOGLITAZONE | | | | |
| * Tab 15 mg | 6.15 | 90 | 1 | Vexazone |
| * Tab 30 mg | | 90 | | Vexazone |
| * Tab 45 mg | | 90 | | Vexazone |
| 5 | | 00 | - | T OKALONO |
| VILDAGLIPTIN | | | | • • |
| Tab 50 mg | | 60 | | Galvus |
| VILDAGLIPTIN WITH METFORMIN HYDROCHLORIDE | | | | |
| Tab 50 mg with 1,000 mg metformin hydrochloride | | 60 | 1 | Galvumet |
| Tab 50 mg with 850 mg metformin hydrochloride | | 60 | 1 | Galvumet |
| | | | | |
| GLP-1 Agonists | | | | |
| DUILACI LITIDE Crassial Authority and CA0000 holeyy Datail | nharmaay | | | |
| DULAGLUTIDE – Special Authority see SA2338 below – Retail | | | | 110 |
| Note: Not to be given in combination with another funded G | | | | |
| hydrochloride unless receiving empagliflozin / empagliflozin | | | | |
| Inj 1.5mg per 0.5 ml prefilled pen | | 4 | v | Trulicity |
| SA2338 Special Authority for Subsidy | | | | |
| Note: Subsidy for patients with existing approvals prior to 1 May | 2024. Approvals vali | d withou | t further | renewal unless notified. |
| No new patients will be granted from 1 May 2024 until further no | tice. | | | |
| LIRAGLUTIDE - Special Authority see SA2440 below - Retail p | | | | |
| | inalinacy | | | |
| a) Maximum of 9 inj per prescription | | | | |
| b) | | | | / |
| a) Note: Not to be given in combination with another | • | | • | |
| metformin hydrochloride unless receiving empaglifl | ozin / empagliflozin wi | th metto | rmin hyd | drochloride for the |
| treatment of heart failure. | | | | |
| b) Maximum of 1 pack of 3 (6 mg per ml, 3 ml) prefille | | • | | |
| Inj 6 mg per ml, 3 ml prefilled pen | | 3 | | Victoza |
| ► SA2440 Special Authority for Subsidy | | | | |
| Initial application from any relevant practitioner. Approvals vali | d without further renev | wal unles | ss notifie | ed for applications meeting |
| the following criteria: | | | | a ioi appiloaliono mooling |
| All of the following: | | | | |
| 5 | | | | |
| 1 Patient has type 2 diabetes; and | | | | ha fallaudaa fuusiaal blaad |
| 2 Target HbA1c (of 53 mmol/mol or less) has not been ach | | | | • |
| glucose lowering agents for a period of least 6 months, w | nere clinically appropr | late: en | ipagiino | zin, metformin, and |
| vildagliptin; and | | | | |
| 3 Any of the following: | | | | |
| 3.1 Patient is Māori or any Pacific ethnicity*; or | | | | |
| 3.2 Patient has pre-existing cardiovascular disease or | risk equivalent (see n | ote a)*; | or | |
| 3.3 Patient has an absolute 5-year cardiovascular dise | ease risk of 15% or gro | eater acc | cording | to a validated |
| cardiovascular risk assessment calculator*; or | | | | |
| 3.4 Patient has a high lifetime cardiovascular risk due | to being diagnosed w | ith type 2 | 2 diabet | es during childhood or as a |
| young adult*; or | | | | - |
| 3.5 Patient has diabetic kidney disease (see note b)*. | | | | |
| Notes: * Criteria intended to describe patients at high risk of car | diovascular or renal or | omplicati | ons of d | liabetes |
| a) Pre-existing cardiovascular disease or risk equivalent def | | • | | |
| myocardial infarction, percutaneous coronary interventior | | | | |
| | | | | |
| ischaemic stroke, peripheral vascular disease), congestiv | | | | |
| b) Diabetic kidney disease defined as: persistent albuminur | ia (aipumin:creatinine | ratio gre | eater tha | in or equal to 3 mg/mmol, in |
| | | | | |

continued...

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

continued...

at least two out of three samples over a 3-6 month period) and/or eGFR less than 60 mL/min/1.73m2 in the presence of diabetes, without alternative cause identified.

c) Funded GLP-1a treatment is not to be given in combination with (empagliflozin /empagliflozin with metformin hydrochloride) unless receiving (empagliflozin or empagliflozin in combination with metformin hydrochloride) for the treatment of heart failure.

SGLT2 Inhibitors

⇒SA2408 Special Authority for Subsidy

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

All of the following:

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

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

Either:

- 1 Patient has previously received an initial approval for a GLP-1 agonist; or
- 2 All of the following:
 - 2.1 Patient has type 2 diabetes; and
 - 2.2 Any of the following:
 - 2.2.1 Patient is Māori or any Pacific ethnicity*; or
 - 2.2.2 Patient has pre-existing cardiovascular disease or risk equivalent (see note a)*; or
 - 2.2.3 Patient has an absolute 5-year cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator*; or
 - 2.2.4 Patient has a high lifetime cardiovascular risk due to being diagnosed with type 2 diabetes during childhood or as a young adult*; or
 - 2.2.5 Patient has diabetic kidney disease (see note b)*; and
 - 2.3 Target HbA1c (of 53 mmol/mol or less) has not been achieved despite the regular use of at least one blood-glucose lowering agent (e.g. metformin, vildagliptin, or insulin) for at least 3 months.

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

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

| EIV | PAGLIFLOZIN – Special Authority see SA2408 above – Retail pharmacy | | |
|-----|--|----|-------------------------------|
| * | Tab 10 mg | 30 | Jardiance |
| * | Tab 25 mg | 30 | Jardiance |

▲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 \$ | e) Per | Fully Subsidised | |
|---|---|------------------------------------|--|---|
| EMPAGLIFLOZIN WITH METFORMIN HYDROCHLORIDE - S | pecial Authority see | SA240 | 8 on the pr | revious page – Retail |
| pharmacy Tab 5 mg with 1,000 mg metformin hydrochloride | | 60 | | Jardiamet |
| Tab 5 mg with 500 mg metformin hydrochloride Tab 12.5 mg with 1,000 mg metformin hydrochloride | | 60 60 | | Jardiamet Jardiamet |
| * Tab 12.5 mg with 1,000 mg metformin hydrochloride * Tab 12.5 mg with 500 mg metformin hydrochloride | | 60 | | Jardiamet |
| Diabetes Management | | | | |
| Ketone Testing | | | | |
| BLOOD KETONE DIAGNOSTIC TEST STRIP – Subsidy by end 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: type 1 diabetes; or permanent neonatal diabetes; or undergone a pancreatectomy; or cystic fibrosis-related diabetes; or metabolic disease or epilepsy under the care of a p The prescription must be endorsed accordingly. | paediatrician, neurolo | ogist or 0 strip | | specialist. KetoSens |
| Dual Blood Glucose and Blood Ketone Testing | | | | |
| DUAL BLOOD GLUCOSE AND BLOOD KETONE DIAGNOSTIC 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 m 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 p The prescription must be endorsed accordingly. Only 1 the avoidance of doubt patients who have previously rec funded CareSens meter. | neter is subsidised fo paediatrician, neurol meter per patient wi seived a funded mete | or a pati ogist or Il be sul | ent who ha metabolic bsidised (n | as: specialist. to repeat prescriptions). For |
| diagnostic test strips | | 1 OP | ✓ | CareSens Dual |

| sidy irer's Price) S | Fully Subsidised | Brand or Generic | |
|-------------------------|---------------------|---------------------|---|
| B Per | ✓ | Manufacturer | |
| | | | - |

Blood Glucose Testing

BLOOD GLUCOSE DIAGNOSTIC TEST METER - Subsidy by endorsement

- a) Maximum of 1 pack per prescription
- b) Up to 1 pack available on a PSO
- c) A diagnostic blood glucose test meter is subsidised for a patient who:
 - 1) is receiving insulin or sulphonylurea therapy; or
 - 2) is pregnant with diabetes: or
 - 3) is on home TPN at risk of hypoglycaemia or hyperglycaemia; or
 - 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) cvstic 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 avai | lable per F | SO | | | |

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
- 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 (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.

50 test OP SensoCard

50 test OP

CareSens N

CareSens PRO

| | Subsidy (Manufacturer's Price) \$ | Su Per | Fully bsidised | Brand or Generic Manufacturer |
|---|---|-----------|-------------------|-------------------------------------|
| Insulin Syringes and Needles | | | | |
| Subsidy is available for disposable insulin syringes, need the supply of insulin or liraglutide or when prescribed for annotate the prescription as endorsed where there exists | a patient and the prescription | is endo | rsed acco | ordingly. Pharmacists may |
| NSULIN PEN NEEDLES - Maximum of 200 dev per pre | escription | | | |
| ¥ 29 g × 12.7 mm | | 100 | 🗸 E | B-D Micro-Fine |
| 米 31 g × 5 mm | | 100 | 🖌 E | B-D Micro-Fine |
| ★ 31 g × 6 mm | 9.50 | 100 | 🗸 E | Berpu |
| ★ 31 g × 8 mm | | 100 | 🗸 E | B-D Micro-Fine |
| 米 32 g × 4 mm | | 100 | 🗸 E | B-D Micro-Fine |
| INSULIN SYRINGES, DISPOSABLE WITH ATTACHED | NEEDLE - Maximum of 200 | dev per | prescript | ion |
| * Syringe 0.3 ml with 29 g × 12.7 mm needle | | 100 | | B-D Ultra Fine |
| | 1.36 | 10 | | |
| | (1.99) | | E | B-D Ultra Fine |
| * Syringe 0.3 ml with 31 g × 8 mm needle | | 100 | 🖌 E | B-D Ultra Fine II |
| | 1.30 | 10 | | |
| | (1.99) | | E | B-D Ultra Fine II |
| Syringe 0.5 ml with 29 g × 12.7 mm needle | | 100 | 🗸 E | B-D Ultra Fine |
| | 1.36 | 10 | | |
| | (1.99) | | - | 3-D Ultra Fine |
| Syringe 0.5 ml with 31 g × 8 mm needle | | 100 | 🗸 E | B-D Ultra Fine II |
| | 1.36 | 10 | | |
| | (1.99) | | - | B-D Ultra Fine II |
| Syringe 1 ml with 29 g × 12.7 mm needle | | 100 | ✓ E | B-D Ultra Fine |
| | 1.36 | 10 | _ | |
| | (1.99) | | - | B-D Ultra Fine |
| Syringe 1 ml with 31 g × 8 mm needle | | 100 | ✓ E | B-D Ultra Fine II |
| | 1.36 | 10 | _ | |
| | (1.99) | | E | B-D Ultra Fine II |

Insulin Pumps

INSULIN PUMP WITH ALGORITHM – Special Authority see SA2367 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 pe | eriod. | | |
|--|----------|---|--|
| Min basal rate 0.02 U/h | 8,970.00 | 1 | mylife YpsoPump with CamAPS FX |
| Min basal rate 0.1 U/h | 7,653.00 | 1 | ✓ Tandem t:slim X2 with Basal-IQ ✓ Tandem t:slim X2 with Control-IQ |

► SA2367 Special Authority for Subsidy

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

All of the following:

16

1 Any of the following:

continued...

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

continued...

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

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

Insulin Pump Consumables

⇒SA2380 Special Authority for Subsidy

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

All of the following:

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

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

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

- a) Maximum of 50 cart per prescription
- b) Only on a prescription
- c) Maximum of 190 cartridges will be funded per year.

Tandem Cartridge

| | Subsidy (Manufacturer's P \$ | rice) Sut Per | Fully Brand or osidised Generic Manufacturer |
|--|------------------------------------|------------------|--|
| NSULIN PUMP INFUSION SET (STEEL CANNULA) – Specia a) Maximum of 5 set per prescription | I Authority see SA | 2380 on the p | previous page – Retail pharmacy |
| b) Only on a prescription | | | |
| c) Maximum of 19 infusion sets will be funded per year. | | | |
| * 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 |
| (MiniMed Sure-T MMT-876A 8 mm steel needle; 80 cm tubing > INSULIN PUMP INFUSION SET (STEEL CANNULA, STRAIGH page – Retail pharmacy a) Maximum of 5 sets per prescription | | | , |
| a) Maximum of 5 sets per prescription b) Only on a prescription c) Maximum of 19 infusion sets will be funded per year. | | | |
| 5.5 mm steel cannula; straight insertion; 45 cm line × 10 wir 10 needles | | 1 OP | ✓ mylife Orbit micro |
| 5.5 mm steel needle; straight insertion; 60 cm line × 10 with | | | |
| 10 needles | | 1 OP | mylife Orbit micro |
| 5.5 mm steel needle; straight insertion; 80 cm line × 10 with 10 needles | | | . mulife Orhit miere |
| 10 needles ★ 8.5 mm steel needle; straight insertion; 60 cm line × 10 with | | 1 OP | mylife Orbit micro |
| 10 needles | | 1 OP | mylife Orbit micro |
| 8.5 mm steel needle; straight insertion; 80 cm line × 10 with | | | |
| 10 needles | | 1 OP | mylife Orbit micro |
| * 6 mm steel cannula; straight insertion; 80 cm line × 10 with | | | , |
| 10 needles | | 1 OP | TruSteel |
| ₭ 8 mm steel cannula; straight insertion; 80 cm line × 10 with | | | |
| 10 needles | | 1 OP | TruSteel |
| * 6 mm steel cannula; straight insertion; 60 cm line × 10 with | | 4.00 | |
| 10 needles | | 1 OP | TruSteel |
| ✤ 8 mm steel cannula; straight insertion; 60 cm line × 10 with | | | |

| | | Subsidy (Manufacturer's Pric | e) Sub: | Fully Bran sidised Gene | |
|-----|---|---------------------------------|------------|--|----------------------|
| _ | | \$ | Per | | lfacturer |
| INS | SULIN PUMP INFUSION SET (TEFLON CANNULA) - Spec | cial Authority see SA2 | 380 on pag | e 17 – Retail p | harmacy |
| | a) Maximum of 5 set per prescription b) Only on a prescription | | | | |
| | c) Maximum of 19 infusion sets will be funded per year. | | | | |
| * | 13 mm teflon needle, 60 cm tubing × 10 | | 1 OP | MiniMe MMT· | d Silhouette 381A |
| * | 17 mm teflon needle, 110 cm tubing × 10 | | 1 OP | ✓ MiniMe MMT· | d Silhouette 377A |
| * | 17 mm teflon needle, 60 cm tubing × 10 | | 1 OP | ✓ MiniMe MMT· | d Silhouette 378A |
| * | 6 mm teflon needle, 110 cm tubing × 10 | | 1 OP | | d Quick-Set |
| * | 6 mm teflon needle, 45 cm blue tubing × 10 | | 1 OP | ✓ MiniMe MMT· | |
| * | 6 mm teflon needle, 45 cm pink tubing × 10 | | 1 OP | ✓ MiniMe MMT· | |
| * | 6 mm teflon needle, 60 cm blue tubing \times 10 | | 1 OP | ✓ MiniMe MMT· | |
| * | 6 mm teflon needle, 60 cm pink tubing × 10 | | 1 OP | ✓ MiniMe MMT | d Mio |
| * | 6 mm teflon needle, 60 cm tubing × 10 | | 1 OP | | d Quick-Set |
| * | 6 mm teflon needle, 80 cm blue tubing | | 1 OP | ✓ MiniMe MMT· | |
| * | 6 mm teflon needle, 80 cm clear tubing × 10 | | 1 OP | ✓ MiniMe MMT | d Mio |
| * | 6 mm teflon needle, 80 cm pink tubing × 10 | | 1 OP | ✓ MiniMe MMT | d Mio |
| * | 9 mm teflon needle, 110 cm tubing × 10 | | 1 OP | | d Quick-Set |
| * | 9 mm teflon needle, 60 cm tubing × 10 | | 1 OP | | d Quick-Set |
| * | 9 mm teflon needle, 80 cm clear tubing × 10 | | 1 OP | ✓ MiniMe MMT· | d Mio |
| | | | | | |

(MiniMed Silhouette MMT-381A 13 mm teflon needle, 60 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Silhouette MMT-377A 17 mm teflon needle, 110 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Silhouette MMT-378A 17 mm teflon needle, 60 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Quick-Set MMT-398A 6 mm teflon needle, 10 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-941A 6 mm teflon needle, 45 cm blue tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-921A 6 mm teflon needle, 45 cm pink tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-921A 6 mm teflon needle, 60 cm blue tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-923A 6 mm teflon needle, 60 cm blue tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-933A 6 mm teflon needle, 60 cm blue tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-943A 6 mm teflon needle, 60 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-945A 6 mm teflon needle, 80 cm clear tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-945A 6 mm teflon needle, 80 cm clear tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-945A 6 mm teflon needle, 80 cm pink tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-945A 6 mm teflon needle, 80 cm pink tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-945A 6 mm teflon needle, 80 cm pink tubing × 10 to be delisted 1 October 2026) (MiniMed Quick-Set MMT-396A 9 mm teflon needle, 60 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Quick-Set MMT-397A 9 mm teflon needle, 60 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Quick-Set MMT-397A 9 mm teflon needle, 60 cm tubing × 10 to be delisted 1 October 2026) (MiniMed Mio MMT-975A 9 mm teflon needle, 80 cm clear tubing × 10 to be delisted 1 October 2026)

| | Subsidy (Manufacturer's Pri | iaa) Cub | | rand or eneric |
|---|--------------------------------|---------------|---------------------------|--|
| | (Manulactuler's Fil | Per Sub | | anufacturer |
| INSULIN PUMP INFUSION SET (TEFLON CANNULA, ANGLI | E INSERTION WITH | INSERTION | DEVICE) | - Special Authority see |
| SA2380 on page 17 – Retail pharmacy | | | | |
| a) Maximum of 5 sets per prescription b) Only on a prescription | | | | |
| c) Maximum of 19 infusion sets will be funded per year. | | | | |
| * 13 mm teflon cannula; angle insertion; insertion device; 11 | 0 cm | | | |
| line × 10 with 10 needles | | 1 OP | 🗸 Auto | Soft 30 |
| * 13 mm teflon cannula; angle insertion; insertion device; 60 | | | | |
| line × 10 with 10 needles | | 1 OP | Auto | |
| INSULIN PUMP INFUSION SET (TEFLON CANNULA, FLEXI | BLE INSERTION WI | TH INSERTI | ON DEVICE | Special Authority |
| see SA2380 on page 17 – Retail pharmacy a) Maximum of 5 set per prescription | | | | |
| b) Only on a prescription | | | | |
| c) Maximum of 19 infusion sets will be funded per year. | | | | |
| * 6 mm teflon cannula; flexible insertion; insertion device; 4 | | | | |
| line × 10 with 10 needles | | 1 OP | 🗸 myli | fe Inset soft |
| * 6 mm teflon cannula; flexible insertion; insertion device; 60 line with integrated inserter × 10 with 10 needles | | 1 OP | 🖌 myli | fe Inset soft |
| 6 mm teflon cannula; flexible insertion; insertion device; 80 | | 101 | • myn | |
| line × 10 with 10 needles | | 1 OP | 🖌 myli | fe Inset soft |
| * 9 mm teflon cannula; flexible insertion; insertion device; 60 |) cm | | | |
| line × 10 with 10 needles | | 1 OP | 🖌 myli | fe Inset soft |
| 9 mm teflon cannula; flexible insertion; insertion device; 80 | | 1 OP | . muli | fo lucat caft |
| line × 10 with 10 needles | | - | • | fe Inset soft |
| INSULIN PUMP INFUSION SET (TEFLON CANNULA, STRAI see SA2380 on page 17 – Retail pharmacy | GHT INSERTION W | IIH INSERT | ION DEVIC | E) – Special Authority |
| a) Maximum of 5 sets per prescription | | | | |
| b) Only on a prescription | | | | |
| c) Maximum of 19 infusion sets will be funded per year. | | | | |
| * 6 mm teflon cannula; straight insertion; insertion device; | 100.00 | 1.00 | | 0.400 |
| 110 cm line × 10 with 10 needles | | 1 OP | ✓ Auto | Soft 90 |
| line × 10 with 10 needles | | 1 OP | 🗸 Auto | Soft 90 |
| * 9 mm teflon cannula; straight insertion; insertion device; | | - | | |
| 110 cm line × 10 with 10 needles | 182.00 | 1 OP | 🗸 Auto | Soft 90 |
| * 9 mm teflon cannula; straight insertion; insertion device; 6 | | 4.00 | | o <i>"</i> oo |
| line × 10 with 10 needles | | 1 OP | Auto | |
| INSULIN PUMP INFUSION SET (TEFLON CANNULA, VARIA | BLE INSERTION) - | - Special Aut | hority see S | A2380 on page 17 – |
| Retail pharmacy a) Maximum of 5 set per prescription | | | | |
| b) Only on a prescription | | | | |
| c) Maximum of 19 infusion sets will be funded per year. | | | | |
| * 13 mm teflon cannula; variable insertion; 60 cm line × 10 v | | 4.05 | • • • • | - <i>"</i> |
| 10 needles | | 1 OP | Varis | δοπ |

20

| | Subsidy (Manufacturer's Price) \$ | Sul Per | Fully bsidised | Brand or Generic Manufacturer |
|--|---|----------------|-------------------|---|
| INSULIN PUMP RESERVOIR – Special Authority see SA238 a) Maximum of 90 cart per prescription b) Only on a prescription c) Maximum of 360 reservoirs will be funded per year. | 0 on page 17 – Retail p | harmacy | | |
| * 10 × 1.6 ml glass reservoir for YpsoPump | | 10 OP | ✓ r | nylife YpsoPump Reservoir |
| * 10 × luer lock conversion cartridges 1.8 ml for paradigm p * Cartridge for 7 series pump; 3.0 ml × 10 | | 10 OP 10 OP | | ADR Cartridge 1.8 /iniMed 3.0 Reservoir MMT-332A |
| Continuous Glucose Monitor | | | | |
| CONTINUOUS GLUCOSE MONITOR (INTEROPERABLE) – Only on a prescription * Sensor (9) and transmitter (Dexcom G6) – Maximum of 1 | | SA2371 b | elow – F | letail pharmacy |
| per prescription Maximum of 5 dev will be funded per year. | | 1 OP | √ [| Dexcom G6 |
| Sensor (Dexcom G7) – Maximum of 9 dev per prescriptic Maximum of 40 dev will be funded per year. | n 110.00 | 1 | √ [| Dexcom G7 |
| Sensor (Freestyle Libre 3 Plus) – Maximum of 6 dev per prescription | | 1 | √ | Freestyle Libre 3 Plus |
| Maximum of 28 dev will be funded per year. | | | | 01100 |

Maximum of 28 dev will be funded per year.

► SA2371 Special Authority for Subsidy

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

Both:

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

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

CONTINUOUS GLUCOSE MONITOR (STANDALONE) – Special Authority see SA2370 on the next page – Retail pharmacy Only on a prescription

| * | Sensor (Dexcom ONE+) - Maximum of 9 dev per prescription81.00 | 1 | Dexcom ONE+ |
|---|---|---|-------------------|
| | Maximum of 40 dev will be funded per year. | | |
| * | Sensor (Freestyle Libre 2) – Maximum of 7 dev per prescription92.83 | 1 | Freestyle Libre 2 |
| | Maximum of 29 dev will be funded per year. | | |

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

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

⇒SA2370 Special Authority for Subsidy

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

Any of the following:

- 1 The patient has type 1 diabetes; or
- 2 The patient has permanent neonatal diabetes or specific monogenic diabetes subtypes with insulin deficiency, considered by the treating endocrinologist or relevant secondary health care professional as practicable, as likely to benefit; or
- 3 The patient has Type 3c diabetes considered by the treating endocrinologist or relevant secondary health care professional as practicable, as likely to benefit (Type 3c diabetes includes insulin deficiency due to pancreatectomy, insulin deficiency secondary to cystic fibrosis or pancreatitis); or
- 4 The patient has atypical inherited forms of diabetes.

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

Digestives Including Enzymes

PANCREATIC ENZYME

| Cap pancreatin 150 mg (amylase 8,000 Ph Eur U, lipase 10,000 Ph Eur U, total protease 600 Ph Eur U) | | 100 | ✓ Creon 10000 |
|--|----------------|---------|---------------------------------|
| Cap pancreatin 300 mg (amylase 18,000 Ph Eur U, lipase 25,000 Ph Eur U, total protease 1,000 Ph Eur U) | 94.38 | 100 | Creon 25000 |
| Modified release granules pancreatin 60.12 mg (amylase 3,600 Ph Eur U, lipase 5,000 Ph Eur U, protease 200 Ph Eur U) | 34 93 | 20 g OP | ✓ Creon Micro |
| URSODEOXYCHOLIC ACID – Special Authority see SA2448 belo Cap 250 mg | w – Retail pha | U | ✓ Ursosan |

➡SA2448 Special Authority for Subsidy

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

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

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

All of the following:

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

22

- 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

continued...

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

continued...

meeting the following criteria:

Both:

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

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

Both:

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

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

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

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

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

Laxatives

Bulk-forming Agents

| ISPAGHULA (PSYLLIUM) HUSK – Only on a prescription * Powder for oral soln | 500 g OP | ✓ Konsyl-D |
|--|------------|--------------------------------------|
| Faecal Softeners | | |
| DOCUSATE SODIUM - Only on a prescription * Tab 50 mg * Tab 120 mg 4.98 | 100 100 | ✓ <u>Coloxyl</u> ✓ <u>Coloxyl</u> |
| DOCUSATE SODIUM WITH SENNOSIDES Tab 50 mg with sennosides 8 mg | 200 | ✓ Laxsol |
| POLOXAMER − Only on a prescription Not funded for use in the ear. ★ Oral drops 10% | 30 ml OP | ✓ <u>Coloxyl</u> |
| | | |

Opioid Receptor Antagonists - Peripheral

| METHYLNALTREXONE BROMIDE - Special Au | uthority see SA1691 below - Retail p | harmacy | 1 |
|---------------------------------------|--------------------------------------|---------|------------------------------|
| Inj 12 mg per 0.6 ml vial | | 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

continued...

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

| (| Subsidy Manufacturer's Price \$ |) : Per | Fully Subsidised | Brand or Generic Manufacturer |
|---|---------------------------------------|------------|---------------------|--|
| continued unless notified for applications meeting the following criteria: Both: | | | | |
| The patient is receiving palliative care; and Either: | | | | |
| 2.1 Oral and rectal treatments for opioid induced constip2.2 Oral and rectal treatments for opioid induced constip | | | erated. | |
| Osmotic Laxatives | | | | |
| GLYCEROL * Suppos 2.8/4.0 g – Only on a prescription | 10.39 | 20 | 1 | Lax-suppositories Glycerol |
| LACTULOSE – Only on a prescription Oral liq 10 g per 15 ml | 3.61 | 500 ml | 1 | Laevolac |
| ACROGOL 3350 WITH POTASSIUM CHLORIDE, SODIUM BIC/ Powder for oral soln 13.125 g with potassium chloride 46.6 mg | ARBONATE AND | SODIU | M CHLOF | RIDE |
| sodium bicarbonate 178.5 mg and sodium chloride 350.7 r | | 30 | | APO Health Macrogol S29 Molaxole |
| SODIUM ACID PHOSPHATE – Only on a prescription Enema 16% with sodium phosphate 8% | 2.50 | 1 | 1 | Fleet Phosphate Enema |
| SODIUM CITRATE WITH SODIUM LAURYL SULPHOACETATE - Enema 90 mg with sodium lauryl sulphoacetate 9 mg per ml, | Only on a prescr | iption | | |
| 5 ml | 35.89 | 50 | 1 | Micolette |
| Stimulant Laxatives | | | | |
| BISACODYL – Only on a prescription ₭ Tab 5 mg | 5.80 | 200 | 1 | Bisacodyl Viatris |
| Suppos 10 mg | | 10 | | Lax-Suppositories |
| SENNA – Only on a prescription ₭ Tab, standardised | | 100 | | 0 |
| | (9.38) 0.43 (2.06) | 20 | | Senokot Senokot |
| SODIUM PICOSULFATE – Special Authority see SA2053 below – Oral soln 7.5 mg per ml | Retail pharmacy | 30 ml O | P 🗸 | 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.

| (N | Subsidy lanufacturer's Price) \$ | Per | Fully Subsidised | Brand or Generic Manufacturer |
|--|--|---------------|---------------------|-------------------------------------|
| Metabolic Disorder Agents | | | | |
| ALGLUCOSIDASE ALFA – Special Authority see SA1986 below – Inj 50 mg vial | .1,142.60 | 1 r applic | | yozyme |
| All of the following: 1 The patient is aged up to 24 months at the time of initial appl and | cation and has be | een dia | gnosed with | n infantile Pompe disease; |
| 2 Any of the following: 2.1 Diagnosis confirmed by documented deficiency of aci villus biopsies and/or cultured amniotic cells; or | | | | |
| 2.2 Documented deficiency of acid alpha-glucosidase, an elevation of glucose tetrasaccharides; or | | | • | |
| 2.3 Documented deficiency of acid alpha-glucosidase, an disease-causing mutation in the acid alpha-glucosida2.4 Documented urinary tetrasaccharide testing indicating | se gene (GAA gei | ne); or | • | |
| molecular genetic testing indicating a disease-causing | g mutation in the (| GAA ge | ne; and | |
| 3 Patient has not required long-term invasive ventilation for res (ERT); and | piratory failure pr | ior to st | arting enzy | me replacement therapy |
| Patient does not have another life-threatening or severe dise or might be reasonably expected to compromise a response Alglucosidase alfa to be administered at doses no greater that | to ERT; and | - | - | to be influenced by ERT |
| Renewal only from a metabolic physician. Approvals valid for 12 m | | | | llowing criteria: |
| All of the following: | | | 0 | 0 |
| The treatment remains appropriate for the patient and the pa Alglucosidase alfa to be administered at doses no greater that Patient has not had severe infusion-related adverse reactions and/or adjustment of infusion rates; and | an 20 mg/kg ever | y 2 wee | ks; and | |
| 4 Patient has not developed another life threatening or severe influenced by ERT; and | | - | | - |
| 5 Patient has not developed another medical condition that mig ERT; and | | | | |
| 6 There is no evidence of life threatening progression of respirative ventilation; and7 There is no evidence of new or progressive cardiomyopathy. | | evidenc | ea by the n | eeded for > 14 days of |
| ARGININE - Special Authority see SA2042 below - Retail pharmac | y. | | | |
| Tab 1,000 mg | | 90 | - | linicians |
| Cap 500 mg Powder | | 50 400 q | | olgar iomed |
| ➡SA2042 Special Authority for Subsidy | | | | |
| Initial application only from a metabolic physician. Approvals valid | for 6 months whe | ere pati | ent has a s | uspected inborn error of |
| metabolism that may respond to arginine supplementation. Renewal only from a metabolic physician. Approvals valid for 24 m | onths for applicati | ions me | eting the fo | llowing criteria: |

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

180 g OP 🖌 Cystadane

| (Manufacturer's Price) Subsidised Generic Per | Subsidy | | Fully | Brand or | |
|--|------------------------|-----|----------|--------------|--|
| \$ Per ✓ Manufacturer | (Manufacturer's Price) | | bsidised | | |
| | \$ | Per | 1 | 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 | CBŚ | 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

⇒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

26

| | ALIMENTAR | IY TRACT | AND |) METABOLISM |
|--|---|--|-------------------|--|
| | Subsidy (Manufacturer's Price \$ | | Fully dised | Brand or Generic Manufacturer |
| SA1623 Special Authority for Subsidy Initial application only from a metabolic physician. Approvals of All of the following: 1 The patient has been diagnosed with Hunter Syndrome (| | | meet | ing the following criteria: |
| 2 Either: 2.1 Diagnosis confirmed by demonstration of iduronal assay in cultured skin fibroblasts; or 2.2 Detection of a disease causing mutation in the idu 3 Patient is going to proceed with a haematopoietic stem c idursulfase would be bridging treatment to transplant; and 4 Patient has not required long-term invasive ventilation for (ERT); and 5 Idursulfase to be administered for a total of 24 weeks (ecc | ironate 2-sulfatase g ell transplant (HSCT d r respiratory failure p | iene; and) within the n rior to startin | ext 3 r g Enzy | months and treatment with yme Replacement Therapy |
| greater than 0.5 mg/kg every week. LARONIDASE – Special Authority see SA1695 below – Retail p Inj 100 U per ml, 5 ml vial | harmacy | 1 | | Aldurazyme |
| SA1695 Special Authority for Subsidy Initial application only from a metabolic physician. Approvals of All of the following: The patient has been diagnosed with Hurler Syndrome (not specified on the specifi | | | meet | ing the following criteria: |
| 2 Either: 2.1 Diagnosis confirmed by demonstration of alpha-L- assay in cultured skin fibroblasts; or 2.2 Detection of two disease causing mutations in the to have Hurler syndrome; and | | • | | |
| 3 Patient is going to proceed with a haematopoietic stem c laronidase would be bridging treatment to transplant; and 4 Patient has not required long-term invasive ventilation for (ERT); and 5 Laronidase to be administered for a total of 24 weeks (ec than 100 units/kg every week. | l r respiratory failure p | rior to startin | g Enzy | yme Replacement Therapy |
| LEVOCARNITINE – Special Authority see SA2040 below – Ret Tab 500 mg Cap 250 mg Cap 500 mg | CBS CBS CBS | 30 30 60 300 | ✓ S ✓ B ✓ N | olgar olgar salance letabolics |
| Oral liq 1 g per 10 ml | CBS | 118 ml | | Carnitor S29 Iovitium Sugar Free S29 |

Oral liq 500 mg per 10 mlCBS 300 ml

► 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.

✓ Balance

| | Subsidy (Manufacturer's Price) \$ | Per | Fully Subsidised | Brand or Generic Manufacturer |
|--|---|-----|---------------------|---|
| RIBOFLAVIN – Special Authority see SA2041 below – Retail pha Tab 100 mg | | 100 | 1 | Country Life |
| Tau Tou nig | | 100 | | Puritan's Pride Vitamin B-2 100 mg \$29 |
| Cap 100 mg | CBS | 100 | √ 9 | Solgar |

⇒SA2041 Special Authority for Subsidy

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

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

Both:

1 The patient has a confirmed diagnosis of an inborn error of metabolism that responds to riboflavin supplementation; and

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

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 mlCBS

➡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.

| 28 | 🗸 fully subsidised |
|----|--------------------|
| 20 | Principal Supply |

✓ Amzoate S29

100 ml

| | Subsidy (Manufacturer's Pric \$ | ce) Subs Per | Fully Brand idised Gene Manu | |
|--|--|--------------------------------|--|-----------------------|
| SODIUM PHENYLBUTYRATE – Special Authority see SA199 Grans 483 mg per g | | rmacy 174 g OP | ✓ Phebur | ane |
| ►SA1990 Special Authority for Subsidy Initial application only from a metabolic physician. Approvals cycle disorder involving a deficiency of carbamylphosphate syn synthetase. Renewal only from a metabolic physician. Approvals valid for patient is benefiting from treatment. | nthetase, ornithine tra | anscarbamyla | ise or argininc | succinate |
| TAURINE – Special Authority see SA2043 below – Retail pha Cap 500 mg Cap 1,000 mg Powder | CBS CBS | 50 90 300 g | ✓ Solgar ✓ Life Ext ✓ Life Ext | |
| SA2043 Special Authority for Subsidy Initial application only from a metabolic physician. Approvals mitochondrial disorder that may respond taurine supplementat Renewal only from a metabolic physician. Approvals valid for Both: The patient has confirmed diagnosis of a specific mitoc The tractment remains appropriate and the patient is here. | ion. 24 months for applic hondrial disorder whi | ations meetir ch responds | ig the followin | g criteria: |
| 2 The treatment remains appropriate and the patient is be TRIENTINE – Special Authority see SA2324 below – Retail pl Cap 250 mg | harmacy 2,022.00 | 100 | | e Waymade |
| All of the following: Patient has confirmed Wilson disease; and Treatment with D-penicillamine has been trialled and dieffects or has not received sufficient benefit; and Treatment with zinc has been trailled and discontinued not received sufficient benefit, or zinc is considered clin and requires copper chelation. | because the person | has experien | ced intolerable | e side effects or has |
| Gaucher's Disease | | | | |
| TALIGLUCERASE ALFA – Special Authority see SA2137 bek Inj 200 unit vial | 1,072.00 | 1 | ✓ Elelyson ms meeting the | |
| All of the following: 1 The patient has a diagnosis of symptomatic type 1 or ty deficiency of glucocerebrosidase in leukocytes or culture 2 Patient does not have another life-threatening or severe enzyme replacement therapy (ERT) or the disease mig 3 Any of the following: | red skin fibroblasts, a e disease where the p ht be reasonably exp | nd genotypic prognosis is ι | analysis; and Inlikely to be i | nfluenced by |
| 3.1 Patient has haematological complications of Ga | | | | |

- 3.2 Patient has skeletal complications of Gaucher disease; or
- 3.3 Patient has significant liver dysfunction or hepatomegaly attributable to Gaucher disease; or

continued...

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

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

continued...

- 3.4 Patient has reduced vital capacity from clinically significant or progressive pulmonary disease due to Gaucher disease; or
- 3.5 Patient is a child and has experienced growth failure with significant decrease in percentile linear growth over a 6-12 month period; and
- 4 Taliglucerase alfa is to be administered at a dose no greater than 30 unit/kg every other week rounded to the nearest whole vial (200 units).

Note: Indication marked with * is an unapproved indication

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

All of the following:

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

Mouth and Throat

Agents Used in Mouth Ulceration

BENZYDAMINE HYDROCHLORIDE

| Soln 0.15% – Higher subsidy of \$22.60 per 500 ml with Endorsement | 9.00 (22.60) | 500 ml | Difflam |
|--|-----------------|--------------------|--|
| Additional subsidy by endorsement for a patient who has prescription is endorsed accordingly. | · · · · | as a result of tre | |
| CARMELLOSE SODIUM WITH GELATIN AND PECTIN | | | |
| Paste | 17.20 | 56.7 g OP | Stomahesive |
| | 4.55 | 15 g OP | |
| | (7.90) | | Orabase |
| | 1.52 | 5 g OP | |
| | (3.60) | - | Orabase |
| Powder | | 28 g OP | |
| | (10.95) | 5 | Stomahesive |
| TRIAMCINOLONE ACETONIDE | . , | | |
| Paste 0.1% | 5.49 | 5 g OP | Kenalog in Orabase |
| Oropharyngeal Anti-infectives | | | |
| | | | |
| AMPHOTERICIN B | = 00 | | / - |
| Lozenges 10 mg | 5.86 | 20 | Fungilin |
| MICONAZOLE | | | |
| Oral gel 20 mg per g | 5 19 | 40 g OP | Decozol |

30

| (Manu | Subsidy facturer's Price \$ |) Subsi Per | Fully idised | Brand or Generic Manufacturer |
|---|--|-------------------------|------------------|---|
| IYSTATIN Oral liq 100,000 u per ml | 2.22 2 | 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 | - | Cobal-B12 S29 Vita-B12 |
| | 3.95 | | | Hydroxocobalamin Panpharma |
| | 4.10 | 5 | - | Cobalin-H S29 Neo-Cytamen S29 S29 |
| | 8.20 | 10 | 1 | Vitarubin Depot |
| Cobal-B12 11 Inj 1 mg per ml, 1 ml ampoule to be delisted 1 July 20. Vita-B12 Inj 1 mg per ml, 1 ml ampoule to be delisted 1 July 2025) | 25) | | | |
| Cobalin-H \$29 Inj 1 mg per ml, 1 ml ampoule to be delisted 1 July 202 (Neo-Cytamen S29 \$29 Inj 1 mg per ml, 1 ml ampoule to be delisted 1 (Vitarubin Depot Injection \$29 Inj 1 mg per ml, 1 ml ampoule to be delisted 1 (Vitarubin Depot Injection \$29 Inj 1 mg per ml, 1 ml ampoule to be delisted 1 PYRIDOXINE HYDROCHLORIDE a) No more than 100 mg per dose b) Only on a prescription ★ Tab 25 mg - No patient co-payment payable | July 2025) isted 1 July 20 | 90 500 | | <u>Vitamin B6 25</u> Pyridoxine multichem |
| Neo-Cytamen S29 529 Inj 1 mg per ml, 1 ml ampoule to be delisted 1 Vitarubin Depot Injection 529 Inj 1 mg per ml, 1 ml ampoule to be delis PYRIDOXINE HYDROCHLORIDE a) No more than 100 mg per dose b) Only on a prescription ★ Tab 25 mg - No patient co-payment payable | July 2025) isted 1 July 20 3.43 23.45 | 90 | ~ | Pyridoxine |
| Neo-Cytamen S29 ≤29 Inj 1 mg per ml, 1 ml ampoule to be delisted 1 Vitarubin Depot Injection ≤29 Inj 1 mg per ml, 1 ml ampoule to be delis PYRIDOXINE HYDROCHLORIDE a) No more than 100 mg per dose b) Only on a prescription ★ Tab 25 mg – No patient co-payment payable | July 2025) isted 1 July 20 3.43 23.45 4.65 | 90 500 | ٠ ٠ | Pyridoxine multichem |
| Neo-Cytamen S29 ≤29 Inj 1 mg per ml, 1 ml ampoule to be delisted 1 Vitarubin Depot Injection ≤29 Inj 1 mg per ml, 1 ml ampoule to be delis PYRIDOXINE HYDROCHLORIDE a) No more than 100 mg per dose b) Only on a prescription ¥ Tab 25 mg – No patient co-payment payable ¥ Tab 50 mg | July 2025) isted 1 July 20 3.43 23.45 4.65 | 90 500 100 | ٠ ٠ | Pyridoxine multichem Thiamine multichem |
| Neo-Cytamen S29 \$29 Inj 1 mg per ml, 1 ml ampoule to be delisted 1 Vitarubin Depot Injection \$29 Inj 1 mg per ml, 1 ml ampoule to be delised 1 PYRIDOXINE HYDROCHLORIDE a) No more than 100 mg per dose b) Only on a prescription * Tab 25 mg - No patient co-payment payable * Tab 50 mg * Tab 50 mg * Tab 50 mg /ITAMIN B COMPLEX * Tab, strong, BPC Vitamin C ASCORBIC ACID a) No more than 100 mg per dose b) Only on a prescription | July 2025) isted 1 July 20 3.43 23.45 4.65 | 90 500 100 | ٠ ٠ | Pyridoxine multichem Thiamine multichem |
| (Neo-Cytamen S29 \$29 Inj 1 mg per ml, 1 ml ampoule to be delisted 1 (Vitarubin Depot Injection \$29 Inj 1 mg per ml, 1 ml ampoule to be delisted 1 PYRIDOXINE HYDROCHLORIDE a) No more than 100 mg per dose b) Only on a prescription * Tab 25 mg - No patient co-payment payable | July 2025) isted 1 July 20 3.43 23.45 4.65 11.25 | 90 500 100 500 | ٠ ٠ | Pyridoxine multichem <u>Thiamine multichem</u> Bplex |
| Neo-Cytamen S29 see Inj 1 mg per ml, 1 ml ampoule to be delisted 1 (Vitarubin Depot Injection see Inj 1 mg per ml, 1 ml ampoule to be delisted 1 PYRIDOXINE HYDROCHLORIDE a) No more than 100 mg per dose b) Only on a prescription * Tab 25 mg – No patient co-payment payable | July 2025) isted 1 July 20 3.43 23.45 4.65 11.25 12.50 | 90 500 100 500 | 5 5 5 5 | Pyridoxine multichem <u>Thiamine multichem</u> Bplex |

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

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

| | Subsidy | | Fully Brand or |
|---|-------------------------|-----------------|--|
| | (Manufacturer's Pri | | idised Generic |
| | \$ | Per | Manufacturer |
| CALCITRIOL | | | |
| * Cap 0.25 mcg | 7 80 | 100 | Calcitriol XL \$29 |
| * Oap 0.25 mcg | | 100 | ✓ Calcitriol-AFT |
| | | | |
| * Cap 0.5 mcg | 13.68 | 100 | Calcitriol XL \$29 |
| | | | <u>Calcitriol-AFT</u> |
| COLECALCIFEROL | | | |
| * Cap 1.25 mg (50,000 iu) - Maximum of 12 cap per prescri | ption3.65 | 12 | Vit.D3 |
| * Oral lig 188 mcg per ml (7,500 iu per ml) | | 5 ml OP | Clinicians |
| · · · · · · · · · · · · · · · · · · · | | | |
| Multivitamin Preparations | | | |
| inditivitarini i reparationo | | | |
| MULTIVITAMIN RENAL - Special Authority see SA1546 below | v – Retail pharmacv | | |
| * Cap | | 30 | Clinicians Renal Vit |
| ► SA1546 Special Authority for Subsidy | | | |
| | Patrick Contraction | | |
| Initial application from any relevant practitioner. Approvals va | alid without further re | enewai uniess | notified for applications meeting |
| the following criteria: | | | |
| Either: | | | |
| The patient has chronic kidney disease and is receiving | either peritoneal dia | lysis or haem | odialysis; or |
| 2 The patient has chronic kidney disease grade 5, defined | l as patient with an e | estimated glor | nerular filtration rate of < |
| 15 ml/min/1.73 m ² body surface area (BSA). | | | |
| | ail pharman | | |
| MULTIVITAMINS – Special Authority see SA1036 below – Ret | | 000 - 00 | / Descliptula Consult |
| * Powder | | 200 g OP | Paediatric Seravit |
| SA1036 Special Authority for Subsidy | | | |
| Initial application from any relevant practitioner. Approvals va | alid without further re | enewal unless | notified where the patient has |
| inborn errors of metabolism. | | | |
| Renewal from any relevant practitioner. Approvals valid without | ut further renewal ur | less notified v | where patient has had a previous |
| approval for multivitamins. | | | |
| VITAMINS | | | |
| * Tab (BPC cap strength) | 18 50 | 1,000 | Mvite |
| | | 1,000 | - MVIC |
| * Cap (fat soluble vitamins A, D, E, K) – Special Authority second se | | <u></u> | . Vitabalaala |
| SA1720 below – Retail pharmacy | 23.40 | 60 | Vitabdeck |
| SA1720 Special Authority for Subsidy | | | |
| Initial application from any relevant practitioner. Approvals va | alid without further re | enewal 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 gu | | | |
| 3 Patient has severe malabsorption syndrome. | ,, | | |
| | | | |
| Minerals | | | |
| WITHET AIS | | | |
| Coloium | | | |
| Calcium | | | |
| CALCIUM CARBONATE | | | |
| | 7.00 | 050 | Coloi Tob 500 |
| * Tab 1.25 g (500 mg elemental) | | 250 | <u>Calci-Tab 500</u> <u>Calcium 500</u> |
| * Tab eff 1.25 g (500 mg elemental) – Subsidy by endorsem | ieni260.00 | 100 | Calcium 500 mg |
| | | | Hexal S29 |
| Subsidy by endorsement – Only when prescribed for p | aediatric patients (< | 5 years) whe | re calcium carbonate oral liquid is |
| considered unsuitable. | | | |
| | | | |

| | Subsidy (Manufacturada Driad) | Cuba | Fully | Brand or |
|--|----------------------------------|------------------------|-------------|-----------------------------------|
| | (Manufacturer's Price) \$ | Per Subs | idised ✓ | Generic Manufacturer |
| CALCIUM GLUCONATE * Inj 10%, 10 ml ampoule | | 10 | ✓ N | lax Health - Hameln 529 |
| lodine | | | | |
| POTASSIUM IODATE * Tab 253 mcg (150 mcg elemental iodine) | 5.99 | 90 | ✓ <u>N</u> | leuroTabs |
| Iron | | | | |
| FERROUS FUMARATE * Tab 200 mg (65 mg elemental) FERROUS FUMARATE WITH FOLIC ACID | 3.49 | 100 | ✓ <u>F</u> | erro-tab |
| Tab 310 mg (100 mg elemental) with folic acid 350 mcg FERROUS SULFATE | 5.98 | 100 | ✓ <u>F</u> | erro-F-Tabs |
| * Tab long-acting 325 mg (105 mg elemental) * Oral liq 30 mg (6 mg elemental) per 1 ml | 9.25 | 30 250 ml 500 ml | ✓ F | errograd erro-Liquid erodan |
| IRON (AS FERRIC CARBOXYMALTOSE) – Special Authority se Inj 50 mg per ml, 10 ml vial | | Retail pharn 1 | | erinject |
| SA2394 Special Authority for Subsidy Initial application — (Anaemia) from any relevant practitioner. following criteria: | Approvals valid for | 3 months fo | r applie | cations meeting the |
| All of the following: 1 Patient has been diagnosed with anaemia; and | | | | |
| 2 Any of the following: | | | | |
| 2.1 Serum ferritin level is 20 mcg/L or less; or 2.2 Both: | | | | |
| 2.2.1 Serum ferritin is between 20 and 50 mcg/L; 2.2.2 C-Reactive Protein (CRP) is at least 5 mg/L | | | | |
| 2.3 Patient has chronic inflammatory disease with sym | nptoms of anaemia d | espite norm | al iron | levels; and |
| 3 Any of the following: 3.1 Oral iron treatment has proven ineffective; or 3.2 Oral iron treatment has resulted in dose-limiting inf 3.3 Rapid correction of anaemia is required. | tolerance; or | | | |
| Renewal — (Anaemia) from any relevant practitioner. Approva criteria: Both: | ls valid for 3 months | for applicat | ions m | eeting the following |
| Patient continues to have anaemia with a serum ferritin le at least 5 mg/L, or has chronic inflammatory disease with A trial (or re-trial) with oral iron is clinically inappropriate. | • | | | U U |
| Initial application — (iron deficiency anaemia) only from an ir anaesthetist or medical practitioner on the recommendation of a anaesthetist. Approvals valid for 3 months for applications meeti | internal medicine phy | ysician, obs | | |

Both:

- 1 Patient has been diagnosed with iron-deficiency anaemia; and
- 2 Any of the following:

continued...

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

| Subsidy (Manufacturer's Price) | 0 | Fully | Brand or |
|-----------------------------------|-----|-------|-------------------------|
| (Manufacturer's Price) \$ | Per | | Generic Manufacturer |

continued...

- 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 | 5 | ✓ Ferrosig |
|--|--------|---|
| Magnesium | | |
| MAGNESIUM HYDROXIDE | | |
| Suspension 8% | 355 ml | Phillips Milk of Magnesia S29 |
| MAGNESIUM SULPHATE | | |
| * Inj 2 mmol per ml, 5 ml ampoule | 10 | ✓ Martindale |
| * Inj 2 mmol per ml, 10 ml ampoule75.06 | 10 | Inresa S29 |
| Zinc | | |
| ZINC SULPHATE * Cap 137.4 mg (50 mg elemental)11.00 | 100 | ✓ Zincaps |

BLOOD AND BLOOD FORMING ORGANS

Subsidised

Per

Fully

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

Manufacturer

Antianaemics

Hypoplastic and Haemolytic

⇒SA2266 Special Authority for Subsidy

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

All of the following:

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

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

All of the following:

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

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

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

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

Note: Indication marked with * is an unapproved indication

EPOETIN ALFA - Special Authority see SA2266 above - Retail pharmacy

Wastage claimable

| Inj 1,000 iu in 0.5 ml, syringe | 6 | Binocrit |
|---------------------------------|-------|------------------------------|
| Inj 2,000 iu in 1 ml, syringe | 6 | Binocrit |
| Inj 3,000 iu in 0.3 ml, syringe | 6 | Binocrit |
| Inj 4,000 iu in 0.4 ml, syringe | 6 | Binocrit |
| Inj 5,000 iu in 0.5 ml, syringe | 6 | Binocrit |
| Inj 6,000 iu in 0.6 ml, syringe | 6 | Binocrit |
| Inj 8,000 iu in 0.8 ml, syringe | 6 | Binocrit |
| Inj 10,000 iu in 1 ml, syringe | 6 | Binocrit |
| Inj 40,000 iu in 1 ml, syringe | 1 | Binocrit |
| | | |

BLOOD AND BLOOD FORMING ORGANS

| | Subsidy (Manufacturer's Price) \$ | Subsi Per | Fully dised | Brand or Generic Manufacturer |
|---|---|----------------|----------------|-------------------------------------|
| Megaloblastic | | | | |
| FOLIC ACID * Tab 0.8 mg | | 1,000 | ✔ F | olic Acid multichem |
| * Tab 5 mg Oral liq 50 mcg per ml | | 100 5 ml OP | | olic Acid Viatris iomed |
| Antifibrinolytics, Haemostatics and Local Sci | erosants | | | |

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 | Alprolix |
| Inj 1,000 iu vial | 2,450.00 | 1 | Alprolix |
| Inj 2,000 iu vial | | 1 | Alprolix |
| Inj 3,000 iu vial | | 1 | Alprolix |
| Inj 4,000 iu vial | | 1 | Alprolix |
| ELTROMBOPAG – Special Authority see SA1743 Wastage claimable | below – Retail pharmacy | | |
| Tab 25 mg | 1 550 00 | 28 | Revolade |
| Tab 50 mg | - | 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 | F | ully | Brand or | |
|------------------------|---------|------|--------------|--|
| (Manufacturer's Price) | Subsidi | sed | Generic | |
| \$ | Per | ✓ | Manufacturer | |

continued...

and significant mucocutaneous bleeding.

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

Both:

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

- 2 Either:
 - 2.1 Patient has severe aplastic anaemia with a platelet count of less than or equal to 20,000 platelets per microliter; or
 - 2.2 Patient has severe aplastic anaemia with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding.

Renewal — (idiopathic thrombocytopenic purpura - post-splenectomy) only from a haematologist. Approvals valid for 12 months where the patient has obtained a response (see Note) from treatment during the initial approval or subsequent renewal periods and further treatment is required.

Note: Response to treatment is defined as a platelet count of > 30,000 platelets per microlitre.

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

All of the following:

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

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

Both:

- 1 The patient has obtained a response from treatment of at least 20.000 platelets per microlitre above baseline during the initial approval period; and
- 2 Platelet transfusion independence for a minimum of 8 weeks during the initial approval period.

EMICIZUMAB - [Xpharm] - Special Authority see SA2272 below

| Inj 30 mg in 1 ml vial | | 1 | Hemlibra |
|---------------------------|-----------|---|------------------------------|
| Inj 60 mg in 0.4 ml vial | 7,138.00 | 1 | Hemlibra |
| Inj 105 mg in 0.7 ml vial | | 1 | Hemlibra |
| Inj 150 mg in 1 ml vial | 17,846.00 | 1 | Hemlibra |

■SA2272 Special Authority for Subsidy

Initial application — (Severe Haemophilia A with or without FVIII inhibitors) only from a haematologist. Approvals valid without further renewal unless notified for applications meeting the following criteria: Both:

- - 1 Patient has severe congenital haemophilia A with a severe bleeding phenotype (endogenous factor VIII activity less than or equal to 2%); and
 - 2 Emicizumab is to be administered at a dose of no greater than 3 mg/kg weekly for 4 weeks followed by the equivalent of 1.5 mg/kg weekly.

EPTACOG ALFA [RECOMBINANT FACTOR VIIA] - [Xpharm]

For patients with haemophilia. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group. Rare Clinical Circumstances Brand of bypassing agent for > 14 days predicted use. Access to funded treatment for > 14 days predicted use is by named patient application to the Haemophilia Treaters Group, subject to access criteria.

| Inj 1 mg syringe1,178.30 | 1 | NovoSeven RT |
|--------------------------|---|--------------|
| Inj 2 mg syringe2,356.60 | 1 | NovoSeven RT |
| Inj 5 mg syringe | 1 | NovoSeven RT |
| Inj 8 mg syringe9,426.40 | 1 | NovoSeven RT |

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

| | Subsidy | | Fully | Brand or |
|---|------------------------|---------|-------------|-----------------------------|
| | (Manufacturer's Price) | _ | Subsidised | Generic |
| | \$ | Per | | Manufacturer |
| ACTOR EIGHT INHIBITOR BYPASSING FRACTION - [Xpha | | | | |
| For patients with haemophilia. Preferred Brand of bypassin | | | | |
| is managed by the Haemophilia Treaters Group in conjuncti | | | | |
| Inj 500 U | | 1 | | FEIBA NF |
| Inj 1,000 U | ' | 1 | | FEIBA NF |
| Inj 2,500 U | | 1 | • | FEIBA NF |
| IOROCTOCOG ALFA [RECOMBINANT FACTOR VIII] - [Xpha | | | | |
| For patients with haemophilia. Rare Clinical Circumstances | | | | |
| treatment is managed by the Haemophilia Treaters Group in | i conjunction with the | inatio | nai Haemo | opnilla Management Group, |
| subject to criteria. Inj 250 iu prefilled syringe | 007 E0 | 1 | | Xyntha |
| Inj 500 iu prefilled syringe | | 1 | | Xyntha |
| Inj 1,000 iu prefilled syringe | | 1 | | Xyntha |
| Inj 2,000 iu prefilled syringe | ' | 1 | | Xvntha |
| Inj 3,000 iu prefilled syringe | | 1 | | Xyntha |
| NONACOG GAMMA, [RECOMBINANT FACTOR IX] – [Xpharm | | | • | Aynana |
| For patients with haemophilia. Access to funded treatment | | omor | hilia Troat | ere Group in conjunction |
| with the National Haemophilia Management Group. | is managed by the ha | emop | | |
| Inj 1.000 iu vial | 870.00 | 1 | 1 | RIXUBIS |
| Inj 2,000 iu vial | | 1 | | RIXUBIS |
| Inj 3,000 iu vial | , | 1 | | RIXUBIS |
| • | | | | |
| CTOCOG ALFA [RECOMBINANT FACTOR VIII] (ADVATE) – For patients with haemophilia. Preferred Brand of short hall | | or VIII | Accesst | o funded treatment is |
| managed by the Haemophilia Treaters Group in conjunction | | | | |
| Inj 500 iu vial | | 1 1 | | Advate |
| Inj 1,000 iu vial | | 1 | | Advate |
| Inj 2,000 iu vial | | 1 | | Advate |
| Inj 3,000 iu vial | ' | 1 | | Advate |
| OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (KOGENATE | | | | |
| For patients with haemophilia. Rare Clinical Circumstances | | e reco | ombinant f | actor VIII Access to funder |
| treatment is managed by the Haemophilia Treaters Group in | | | | |
| subject to criteria. | | | | prima management en cap |
| Inj 250 iu vial | | 1 | 1 | Kogenate FS |
| Inį 500 iu vial | | 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 treatm | | d trea | atment is m | nanaged by the Haemophil |
| Treaters Group in conjunction with the National Haemophilia | | | | |
| Inj 1,000 iu vial | 1,200.00 | 1 | ✓ | Adynovate |
| Inj 2,000 iu vial | | 1 | ✓ | Adynovate |
| ODIUM TETRADECYL SULPHATE | | | | |
| k lnj 3% 2 ml | | 5 | | |
| , | (73.00) | - | | Fibro-vein |
| RANEXAMIC ACID | · · · / | | | |
| Tab 500 mg | 10.45 | 60 | 1 | Mercury Pharma |
| | 45.68 | 100 | | Cyklokapron |
| Cyklokapron Tab 500 mg to be delisted 1 November 2025) | 10.00 | | - | |
| | | | | |

| | Subsidy (Manufacturer's Price) \$ | Per | Fully Subsidised | |
|---|---|--------|---------------------|----------------------------|
| Vitamin K | | | | |
| PHYTOMENADIONE Inj 2 mg per 0.2 ml – Up to 5 inj available on a PSO Inj 10 mg per ml, 1 ml – Up to 5 inj available on a PSO | | 5 5 | | Konakion MM Konakion MM |
| Antithrombotic Agents | | | | |
| Antiplatelet Agents | | | | |
| ASPIRIN * Tab 100 mg CLOPIDOGREL | 12.65 | 990 | 1 | Ethics Aspirin EC |
| * Tab 75 mg | 5.07 | 84 | 1 | Arrow - Clopid |
| DIPYRIDAMOLE Tab long-acting 150 mg | 13.93 | 60 | 1 | Pytazen SR |
| TICAGRELOR – Special Authority see SA1955 below – Retail ph * Tab 90 mg | | 56 | 1 | Ticagrelor Sandoz |

⇒SA1955 Special Authority for Subsidy

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

Both:

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

▲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 | F | ully | Brand or |
|-------|--------------------|---------|------|--------------|
| (Manu | ufacturer's Price) | Subsidi | sed | Generic |
| | \$ | Per | ✓ | Manufacturer |

applications meeting the following criteria:

Both:

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

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

Both:

- 1 Patient is continuing to benefit from treatment; and
- 2 Treatment continues to be clinically appropriate.

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

All of the following:

- 1 Patient has undergone percutaneous coronary intervention; and
- 2 Patient has had a stent deployed in the previous 4 weeks; and
- 3 Patient is clopidogrel-allergic**.

Notes: indications marked with * are unapproved indications.

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

Heparin and Antagonist Preparations

ENOXAPARIN SODIUM - Special Authority see SA2152 below - Retail pharmacy

| Inj 20 mg in 0.2 ml syringe | | 10 | <u>Clexane</u> |
|------------------------------|--------|----|------------------------------------|
| Inj 40 mg in 0.4 ml syringe | | 10 | Clexane |
| Inj 60 mg in 0.6 ml syringe | | 10 | Clexane |
| Inj 80 mg in 0.8 ml syringe | | 10 | Clexane |
| Inj 100 mg in 1 ml syringe | | 10 | ✓ Clexane |
| Inj 120 mg in 0.8 ml syringe | | 10 | ✓ Clexane Forte |
| Inj 150 mg in 1 ml syringe | 100.70 | 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

continued...

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

continued...

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).

HEPARIN SODIUM

| Inj 1,000 iu per ml, 10 ml vial12 | 7.44 | 25 • | Pfizer S29 |
|---|------|-------|---|
| Inj 1,000 iu per ml, 5 ml ampoule2 | 5.49 | 10 • | Wockhardt S29 |
| | 3.70 | | Wockhardt PSF §29 |
| 12 | 7.44 | 50 • | Pfizer |
| Inj 5,000 iu per ml, 5 ml vial8 | 3.00 | 10 • | <u>Heparin Sodium</u> <u>Panpharma</u> |
| Inj 5,000 iu per ml, 1 ml70 | 0.33 | 5 • | Hospira |
| Inj 25,000 iu per ml, 0.2 ml | 5.78 | 5 • | Hospira |
| | 2.20 | 50 • | Heparin DBL \$29 |
| HEPARINISED SALINE | | | |
| Inj 10 iu per ml, 5 ml | 6.91 | 50 • | ✓ Pfizer |
| Oral Anticoagulants | | | |
| DABIGATRAN | | | |
| Cap 75 mg – No more than 2 cap per day2 | 7.99 | 60 • | Pradaxa |
| Cap 110 mg2 | | 60 • | Pradaxa |
| Cap 150 mg2 | 7.99 | 60 • | Pradaxa |
| RIVAROXABAN | | | |
| Tab 10 mg - No more than 1 tab per day1 | 5.60 | 30 | Xarelto |
| Tab 15 mg - Up to 14 tab available on a PSO14 | | 28 | ✓ Xarelto |
| Tab 20 mg | | 28 • | ✓ Xarelto |
| WARFARIN SODIUM | | | |
| Note: Marevan and Coumadin are not interchangeable. | | | |
| * Tab 1 mg | 3.46 | 50 • | Coumadin |
| | | 100 • | Marevan |
| * Tab 2 mg | 4.31 | 50 • | Coumadin |
| * Tab 3 mg12 | 2.00 | 100 • | Marevan |
| * Tab 5 mg | 5.93 | 50 • | Coumadin |
| 10 | 3.50 | 100 • | Marevan |
| | | | |

| | Subsidy | | Fully | Brand or |
|--|------------------------------|----------|--------------|-------------------------|
| | (Manufacturer's Price) \$ | Per | Subsidised | Generic Manufacturer |
| Blood Colony-stimulating Factors | | | | |
| FILGRASTIM – Special Authority see SA1259 below – Retail ph Inj 300 mcg per 0.5 ml prefilled syringe Inj 480 mcg per 0.5 ml prefilled syringe | | 10 10 | | livestim livestim |
| ▶SA1259 Special Authority for Subsidy Initial application only from a relevant specialist, vocationally re recommendation of a relevant specialist. Approvals valid withou following criteria: Any of the following: | | | | |
| Prevention of neutropenia in patients undergoing high risk or equal to 20%*); or Desire and the end stars and machine the stars and end of the stars an | | | ` | |
| Peripheral blood stem cell mobilisation in patients underg Peripheral blood stem cell mobilisation or bone marrow de Treatment of severe chronic neutropenia (ANC < 0.5 ×10 Treatment of drug-induced prolonged neutropenia (ANC | onation from healthy o | | , | |
| Note: *Febrile neutropenia risk greater than or equal to 20% afte European Organisation for Research and Treatment of Cancer (I | • | other | risk factors | as defined by the |
| PEGFILGRASTIM - Special Authority see SA1912 below - Retain | ail pharmacy | | | |

- ✓ <u>Ziextenzo</u>
 ✓ Ziextenzo AU

1

⇒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 * Inj 50%, 90 ml bottle – Up to 5 inj available on a PSO POTASSIUM CHLORIDE | | 5 1 | ✓ <u>Biomed</u> ✓ <u>Biomed</u> |
|---|-------|--------|--|
| ✤ Inj 75 mg per ml, 10 ml | 65.00 | 50 | ✓ Juno ✓ LumaCina ✓ Pfizer ^{\$29} |
| SODIUM BICARBONATE Inj 8.4%, 50 ml a) Up to 5 inj available on a PSO | 24.70 | 1 | Biomed |
| b) Not in combinationInj 8.4%, 100 mla) Up to 5 inj available on a PSO | 25.31 | 1 | Biomed |

b) Not in combination

| | Subsidy | 、 <u> </u> | Fully | Brand or |
|--|----------------------------|--------------------------------|---|--|
| | (Manufacturer's Pric \$ | ce) Sub: Per | sidised | Generic Manufacturer |
| SODIUM CHLORIDE | Ŷ | 1.01 | - | manufacturor |
| Not funded for use as a nasal drop. Not funded for nebulis | or uso excent when | used in coni | unction | with an antibiotic intende |
| for nebuliser use. | ei use except when | useu in conj | unction | |
| Inj 23.4% (4 mmol/ml), 20 ml ampoule | | 5 | ✓ В | liomed |
| For Sodium chloride oral liquid formulation refer Standa | | • | _ | |
| Inj 0.9%, 5 ml ampoule - Up to 5 inj available on a PSO | | 20 | ✓ F | resenius Kabi |
| Inj 0.9%, 10 ml ampoule - Up to 5 inj available on a PSO | | 50 | ✓ F | resenius Kabi |
| Inj 0.9%, 20 ml ampoule | 5.00 | 20 | ✓ <u>F</u> | resenius Kabi |
| Inj 0.9%, 1,000 ml bag – Up to 2 bag available on a PSO | | 1 | | axter |
| Only if prescribed on a prescription for renal dialysis, m | aternity or post-nata | al care in the | home of | of the patient, or on a PS |
| for emergency use. (500 ml and 1,000 ml packs) | | | | |
| Inj 0.9%, 500 ml bag – Up to 4 bag available on a PSO | | 1 | | axter |
| Only if prescribed on a prescription for renal dialysis, m | aternity or post-nata | al care in the | home c | of the patient, or on a PS |
| for emergency use. (500 ml and 1,000 ml packs) | | | | |
| TOTAL PARENTERAL NUTRITION (TPN) | 0.50 | | | |
| Infusion | CBS | 1 OP | ✓ T | PN |
| VATER | | | | |
| On a prescription or Practitioner's Supply Order only v Schedule requiring a solvent or diluent; or On a bulk supply order; or When used in the extemporaneous compounding of e When used for the dilution of sodium chloride soln 7% | eye drops; or | | ection li | sted in the Pharmaceuti |
| Inj 10 ml ampoule – Up to 5 inj available on a PSO | | 50 | | lultichem |
| Inj 20 ml ampoule – Up to 5 inj available on a PSO | 5.00 | 20 | v <u>r</u> | |
| Qual Administration | | | | resenius Kabi |
| Oral Administration | | | | resenius Kabi |
| | | | | resenius Kabi |
| | | 300 g OP | √ 0 | resenius Kabi alcium Resonium |
| CALCIUM POLYSTYRENE SULPHONATE Powder | | 300 g OP | √ 0 | |
| CALCIUM POLYSTYRENE SULPHONATE Powder | | Ū | - | alcium Resonium |
| CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO | 9.53 | 300 g OP 50 | - | |
| CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE | 9.53 :] | 50 | ✓ <u>E</u> | alcium Resonium |
| CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO | 9.53 :] | Ū | ✓ <u>E</u> | alcium Resonium Iectral Iydralyte - |
| CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE Soln with electrolytes | 9.53 :] | 50 | ✓ <u>E</u> | alcium Resonium |
| CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE Soln with electrolytes | 9.53 [] 6.53 | 50 1 OP | ✓ <u>E</u> | alcium Resonium <u>lectral</u> lydralyte - Lemonade |
| CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE Soln with electrolytes PHOSPHORUS Tab eff 500 mg (16 mmol) | 9.53 [] 6.53 | 50 | ✓ <u>E</u> | alcium Resonium Iectral Iydralyte - |
| CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE Soln with electrolytes PHOSPHORUS Tab eff 500 mg (16 mmol) POTASSIUM CHLORIDE | 9.53 [] 6.53 | 50 1 OP 100 | ✓ <u>E</u> | alcium Resonium <u>lectral</u> lydralyte - Lemonade |
| CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE Soln with electrolytes PHOSPHORUS Tab eff 500 mg (16 mmol) POTASSIUM CHLORIDE | 9.53 [] 6.53 | 50 1 OP | ✓ <u>E</u> ✓ <u>H</u> ✓ P | ealcium Resonium <u>lectral</u> lydralyte - Lemonade hosphate Phebra |
| CALCIUM POLYSTYRENE SULPHONATE Powder | | 50 1 OP 100 60 | ✓ ⊑ ✓ <u>H</u> ✓ P | calcium Resonium <u>lectral</u> lydralyte - Lemonade hosphate Phebra |
| CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE Soln with electrolytes PHOSPHORUS Tab eff 500 mg (16 mmol) POTASSIUM CHLORIDE ★ Tab eff 548 mg (14 m eq) with chloride 285 mg (8 m eq) ★ Tab long-acting 600 mg (8 mmol) | | 50 1 OP 100 | ✓ ⊑ ✓ <u>H</u> ✓ P | ealcium Resonium <u>lectral</u> lydralyte - Lemonade hosphate Phebra |
| CALCIUM POLYSTYRENE SULPHONATE Powder | | 50 1 OP 100 60 200 | ✓ <u>⊨</u> ✓ <u>H</u> ✓ P ✓ S | ealcium Resonium lectral lydralyte - Lemonade hosphate Phebra chlorvescent pan-K |
| CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE Soln with electrolytes PHOSPHORUS Tab eff 500 mg (16 mmol) POTASSIUM CHLORIDE ★ Tab eff 548 mg (14 m eq) with chloride 285 mg (8 m eq) ★ Tab long-acting 600 mg (8 mmol) | | 50 1 OP 100 60 | ✓ <u>E</u> ✓ <u>H</u> ✓ P ✓ S ✓ S | alcium Resonium lectral lydralyte - Lemonade hosphate Phebra chlorvescent pan-K |
| CALCIUM POLYSTYRENE SULPHONATE Powder | | 50 1 OP 100 60 200 | ✓ <u>E</u> ✓ <u>H</u> ✓ P ✓ S ✓ S | ealcium Resonium lectral lydralyte - Lemonade hosphate Phebra chlorvescent pan-K |
| CALCIUM POLYSTYRENE SULPHONATE Powder COMPOUND ELECTROLYTES Powder for oral soln – Up to 5 sach available on a PSO COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE Soln with electrolytes PHOSPHORUS Tab eff 500 mg (16 mmol) POTASSIUM CHLORIDE * Tab eff 548 mg (14 m eq) with chloride 285 mg (8 m eq) * Tab long-acting 600 mg (8 mmol) SODIUM BICARBONATE | | 50 1 OP 100 60 200 | ✓ ⊑ ✓ <u>H</u> ✓ P ✓ S ✓ S ✓ S | alcium Resonium lectral lydralyte - Lemonade hosphate Phebra chlorvescent pan-K |

| | Subsidy (Manufacturer's Price) \$ | Per | Fully Subsidised | Generic |
|--|---|-----|---------------------|-----------------------------|
| Alpha-Adrenoceptor Blockers | | | | |
| Alpha Adrenoceptor Blockers | | | | |
| DOXAZOSIN | | | | |
| * Tab 2 mg | | 500 | | Doxazosin Clinect |
| * Tab 4 mg | 20.94 | 500 | ~ | Doxazosin Clinect |
| PHENOXYBENZAMINE HYDROCHLORIDE | | | | |
| * Cap 10 mg | | 30 | | BNM S29 |
| | 216.67 | 100 | 1 | Dibenzyline S29 |
| (Dibenzyline ^{\$29} Cap 10 mg to be delisted 1 July 2025) | | | | |
| PRAZOSIN | | | | |
| * Tab 1 mg | 5.53 | 100 | ~ | Arrotex-Prazosin S29 S29 |
| | 9.98 | | 1 | Minipress S29 |
| * Tab 2 mg | 7.00 | 100 | ~ | Arrotex-Prazosin S29 S29 |
| | 13.29 | | 1 | Minipress S29 |
| * Tab 5 mg | 11.70 | 100 | ~ | Arrotex-Prazosin S29 S29 |
| | 22.00 | | 1 | Minipress S29 |
| * Cap 1 mg | | 100 | 1 | Prazosin Mylan S29 |
| * Cap 2 mg | | 100 | 1 | Prazosin Mylan S29 |
| * Cap 5 mg | | 100 | 1 | Prazosin Mylan S29 |

Agents Affecting the Renin-Angiotensin System

ACE Inhibitors

| CAPTOPRIL | | |
|---|-----------|---------------------------------------|
| * Oral liq 5 mg per ml | 100 ml OP | ✓ <u>DP-Captopril</u> |
| ENALAPRIL MALEATE | | |
| * Tab 5 mg1.75 | 90 | ✓ Acetec |
| * Tab 10 mg1.97 | 90 | ✓ Acetec |
| * Tab 20 mg2.35 | 90 | ✓ Acetec |
| LISINOPRIL | | |
| * Tab 5 mg | 90 | Ethics Lisinopril |
| | | Teva Lisinopril |
| * Tab 10 mg 11.67 | 90 | Ethics Lisinopril |
| 5 | | Teva Lisinopril |
| * Tab 20 mg14.69 | 90 | Ethics Lisinopril |
| , , , , , , , , , , , , , , , , , , , | | Teva Lisinopril |
| PERINDOPRIL | | |
| * Tab 2 mg | 30 | Coversyl |
| * Tab 4 mg | 30 | ✓ Coversvl |
| * Tab 8 mg | 30 | ✓ Coversvl |
| | 50 | <u></u> |

| | | Manufacturer |
|-------|----|---|
| | | |
| 10.24 | 90 | Arrow-Quinapril 5 |
| | 90 | Arrow-Quinapril 10 |
| 14.83 | 90 | Arrow-Quinapril 20 |
| | | |
| 17.25 | 90 | <u>Tryzan</u> |
| 16.50 | 90 | Tryzan |
| | | Tryzan |
| 17.63 | 90 | <u>Tryzan</u> |
| | | |
| | | |
| 2.68 | 90 | Candestar |
| 2.67 | 90 | Candestar |
| 4.22 | 90 | ✓ Candestar |
| 5.24 | 90 | ✓ Candestar |
| | | |
| 2.00 | 84 | Losartan Actavis |
| 2.29 | 84 | Losartan Actavis |
| 2.86 | 84 | Losartan Actavis |
| 4.57 | 84 | Losartan Actavis |
| | | |
| F | | |
| — | 30 | APO-Candesartan |
| | 50 | HCTZ 16/12.5 |
| | 30 | ✓ APO-Candesartan |
| | | HCTZ 32/12.5 |
| | | |
| 4.00 | 30 | ✓ <u>Arrow-Losartan &</u> <u>Hydrochlorothiazide</u> |
| | | 12.51 90 14.83 90 17.25 90 16.50 90 16.88 90 17.63 90 2.68 90 2.67 90 4.22 90 5.24 90 2.00 84 2.29 84 2.86 84 4.57 84 E 4.10 30 |

Angiotensin II Antagonists with Neprilysin Inhibitors

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

⇒SA2302 Special Authority for Subsidy

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

All of the following:

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

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

- 2.3 Patient is in NYHA/WHO functional class IV; and
- 3 Either:
 - 3.1 Patient has a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%; or
 - 3.2 An ECHO is not reasonably practical, and in the opinion of the treating practitioner the patient would benefit from treatment; and
- 4 Patient is receiving concomitant optimal standard chronic heart failure treatments.

Antiarrhythmics

| r lignocaine hydrochloride refer to NERVOUS SYSTEM, Anaesth /IODARONE HYDROCHLORIDE | ietics, Local, p | age 120 | |
|--|------------------|---------|-------------------------------------|
| Tab 100 mg | 3.49 | 30 | Aratac |
| Tab 200 mg | | 30 | Aratac |
| Inj 50 mg per ml, 3 ml ampoule - Up to 10 inj available on a PS | SO9.12 | 6 | Cordarone-X |
| | 15.22 | 10 | Max Health |
| ROPINE SULPHATE | | | |
| Inj 600 mcg per ml, 1 ml ampoule – Up to 5 inj available on a | | | |
| PSO | 16.10 | 10 | Hikma S29 |
| | | | Juno S29 |
| | | | ✓ Martindale |
| GOXIN | | | |
| 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 |
| | | | Lanoxin S29 S29 |
| SOPYRAMIDE PHOSPHATE | | | |
| Cap 100 mg | 23.87 | 100 | Rythmodan |
| | 55.90 | 84 | Rythmodan - |
| | | | Cheplafarm S29 |
| ythmodan Cap 100 mg to be delisted 1 November 2025) | | | |
| ECAINIDE ACETATE | | | |
| Tab 50 mg | 19.95 | 60 | Flecainide BNM |
| Cap long-acting 100 mg | | 90 | ✓ Flecainide |
| | | | Controlled |
| | | | Release Teva |
| Cap long-acting 200 mg | 54.28 | 90 | Flecainide |
| | | | Controlled |
| | | | Release Teva |
| Inj 10 mg per ml, 15 ml ampoule | 102.79 | 5 | Almarytm S29 |
| | 108.16 | | Tambocor |
| | | | Tambocor |
| | | | German S29 |
| EXILETINE HYDROCHLORIDE | | | |
| Cap 150 mg | 162.00 | 100 | Teva S29 |
| Cap 250 mg | | 100 | Teva S29 |
| ROPAFENONE HYDROCHLORIDE | | | |
| Tab 150 mg | 40 90 | 50 | Rytmonorm |
| | | 00 | - injunionomi |

46 fully subsidised Principal Supply

| (| Subsidy Manufacturer's Price) \$ | S Per | Fully ubsidised | Brand or Generic Manufacturer |
|---|--|----------|--------------------|--|
| Antihypotensives | | | | |
| MIDODRINE - Special Authority see SA1474 below - Retail pharm | nacy | | | |
| Tab 2.5 mg | | 100 | | IAR-Midodrine ^(S29) Iidodrine <u>Medsurge</u> |
| Tab 5 mg | 58.88 | 100 | | IAR-Midodrine S29 Iidodrine Medsurge |

► 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 |
|----------|
|----------|

| ATENOLOL | | | |
|--|---------|-----------|--|
| * Tab 50 mg | 11.00 | 500 | ✓ <u>Viatris</u> |
| * Tab 100 mg | | 500 | Atenolol Viatris |
| * Oral liq 25 mg per 5 ml | | 300 ml OP | ✓ Atenolol AFT |
| Restricted to children under 12 years of age. | | | |
| BISOPROLOL FUMARATE | | | |
| * Tab 2.5 mg | 1.36 | 90 | Ipca-Bisoprolol |
| * Tab 5 mg | | 90 | ✓ Ipca-Bisoprolol |
| * Tab 10 mg | | 90 | ✓ Ipca-Bisoprolol |
| • | | 00 | |
| | 0.04 | <u></u> | |
| * Tab 6.25 mg | | 60 | Carvedilol Sandoz Carvedilol Sandoz |
| * Tab 12.5 mg | | 60 | Carvedilol Sandoz |
| * Tab 25 mg | 2.95 | 60 | Carvedilol Sandoz |
| LABETALOL | | | |
| * Tab 100 mg | 14.50 | 100 | Trandate |
| * Tab 200 mg | 27.00 | 100 | Trandate |
| * Inj 5 mg per ml, 20 ml ampoule | | 5 | |
| | (88.60) | | Trandate |
| METOPROLOL SUCCINATE | | | |
| * Tab long-acting 23.75 mg | 4.20 | 90 | Myloc CR |
| * Tab long-acting 47.5 mg. | | 90 | ✓ Myloc CR |
| * Tab long-acting 95 mg | | 90 | ✓ Myloc CR |
| * Tab long-acting 190 mg | | 90 | ✓ Myloc CR |
| METOPROLOL TARTRATE | | | _ |
| * Tab 50 mg | 5.66 | 100 | ✓ IPCA-Metoprolol |
| * Tab 100 mg | | 60 | ✓ IPCA-Metoprolol |
| * Tab long-acting 200 mg | | 28 | ✓ Slow-Lopresor |
| * Inj 1 mg per ml, 5 ml vial | | 5 | Metoprolol IV Mylan |
| | | 5 | Metoprolol IV Mylan Metoprolol IV Viatris |
| | | | |

| | Subsidy (Manufacturer's Price) \$ | Per | Fully Subsidised | Brand or Generic Manufacturer |
|---|---|-------|---------------------|-------------------------------------|
| NADOLOL | | | | |
| * Tab 40 mg | | 100 | ✓ [| Nadolol BNM |
| * Tab 80 mg | | 100 | ✓ [| Nadolol BNM |
| PROPRANOLOL | | | | |
| * Tab 10 mg | 7.04 | 100 | ✓ | Drofate |
| * Tab 40 mg | | 100 | ✓] | IPCA-Propranolol |
| * Cap long-acting 160 mg | | 100 | 1 | Cardinol LA |
| * Oral liq 4 mg per ml - Special Authority see SA1327 below - | | | | |
| Retail pharmacy | CBS | 500 m | nl 🖌 l | 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.

| 00 | | | | |
|----|------------|-------|-----|---------------------------|
| * | Tab 80 mg | 37.50 | 500 | 🗸 Mylan |
| * | Tab 160 mg | 14.00 | 100 | Mylan |

Calcium Channel Blockers

Dihydropyridine Calcium Channel Blockers

SOTALO

| * Tab 2.5 mg | 1.45 | 90 | ✓ Vasorex |
|---|------|----|--------------------------------|
| * Tab 5 mg | | 90 | ✓ Vasorex |
| * Tab 10 mg | 1.31 | 90 | ✓ Vasorex |
| FELODIPINE | | | |
| * Tab long-acting 2.5 mg | 2.18 | 30 | Plendil ER |
| * Tab long-acting 5 mg | 6.57 | 90 | ✓ Felo 5 ER |
| * Tab long-acting 10 mg | | 90 | Felo 10 ER |
| NIFEDIPINE | | | |
| Tab long-acting 10 mg – Subsidy by endorsement. | | 56 | Tensipine MR10 S29 |
| | | | |

Subsidised for patients who were taking nifedipine tab long-acting 10 mg prior to 1 July 2023 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of nifedipine tab long-acting 10 mg.

| * | Tab long-acting 20 mg | 100 | Nyefax Retard |
|---|----------------------------|-----|--|
| * | Tab long-acting 30 mg4.78 | 14 | Mylan Italy (24 hr release) \$29 |
| | 34.10 | 100 | Mylan (24 hr release) S29 |
| * | Tab long-acting 60 mg52.81 | 100 | Mylan (24 hr release) \$29 |

| | Subsidy (Manufacturer's Price | 3 | Fully Subsidised | |
|--|----------------------------------|---------|---------------------|----------------------|
| | (Manulacturers Frice \$ | Per | | Manufacturer |
| Other Calcium Channel Blockers | | | | |
| DILTIAZEM HYDROCHLORIDE | | | | |
| * Cap long-acting 120 mg | 65.35 | 500 | 1 | Diltiazem CD Clinect |
| * Cap long-acting 180 mg | | 30 | | Cardizem CD |
| * Cap long-acting 240 mg | 9.30 | 30 | ~ | Cardizem CD |
| PERHEXILINE MALEATE | | | | |
| * Tab 100 mg | 62.90 | 100 | 1 | Pexsig |
| VERAPAMIL HYDROCHLORIDE | | | | |
| * Tab 40 mg | | 100 | | Isoptin |
| * Tab 80 mg | | 100 | ~ | Isoptin |
| * Tab long-acting 120 mg | | 100 | | Isoptin Retard S29 |
| No. Tables a stine 040 mm | 45.40 | ~~ | | Isoptin SR |
| * Tab long-acting 240 mg | | 30 | ~ | Isoptin SR |
| * Inj 2.5 mg per ml, 2 ml ampoule – Up to 5 inj available on a | | - | | leantin |
| PSO | 25.00 | 5 | • | Isoptin |
| Centrally-Acting Agents | | | | |
| CLONIDINE | | | | |
| * Patch 2.5 mg, 100 mcg per day – Only on a prescription | 11.70 | 4 | 1 | Mylan |
| * Patch 5 mg, 200 mcg per day - Only on a prescription | | 4 | - | Mylan |
| * Patch 7.5 mg, 300 mcg per day - Only on a prescription | 17.90 | 4 | 1 | Mylan |
| CLONIDINE HYDROCHLORIDE | | | | |
| * Tab 25 mcg | | 112 | 1 | Clonidine Teva |
| * Tab 150 mcg | | 100 | | Catapres |
| * Inj 150 mcg per ml, 1 ml ampoule | 14.10 | 5 | 1 | Catapres |
| METHYLDOPA | | | | |
| * Tab 250 mg | 15.10 | 100 | 1 | Methyldopa Viatris |
| Diuretics | | | | |
| Loop Diuretics | | | | |
| BUMETANIDE | | | | |
| * Tab 1 mg | | 100 | 1 | Burinex |
| * Inj 500 mcg per ml, 4 ml vial | | 5 | - | Burinex |
| FUROSEMIDE [FRUSEMIDE] | | | | |
| Tab 40 mg – Up to 30 tab available on a PSO | | 1,000 | | IPCA-Frusemide |
| * Tab 500 mg | | 50 | | Urex Forte |
| * Oral liq 10 mg per ml | | 30 ml C | DP 🗸 | Lasix |
| * Inj 10 mg per ml, 25 ml ampoule | | 6 | | Lasix |
| * Inj 10 mg per ml, 2 ml ampoule – Up to 5 inj available on a | PSO2.40 | 5 | 1 | Furosemide-Baxter |
| Potassium Sparing Diuretics | | | | |
| AMILORIDE HYDROCHLORIDE | | | | |
| Tab 5 mg | | 100 | 1 | Padagis S29 |
| · ···y | 171.41 | 28 | | Wockhardt S29 |
| Oral lig 1 mg per ml | | 25 ml C | | Biomed |
| | | -5 C | | |

▲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 \$ | e) Per | Fully Subsidised | |
|--|--|-----------------------|---------------------|--|
| EPLERENONE – Special Authority see SA1728 below – Retail p Tab 25 mg Tab 50 mg | | 30 30 | | Inspra Inspra |
| SA1728 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valit the following criteria: Both: 1 Patient has heart failure with ejection fraction less than 40 2 Either: 2.1 Patient is intolerant to optimal dosing of spironolad 2.2 Patient has experienced a clinically significant adv |)%; and stone; or | | | |
| SPIRONOLACTONE * Tab 25 mg * Tab 100 mg Oral liq 5 mg per ml | | 100 100 25 ml O | 1 | <u>Spiractin</u> <u>Spiractin</u> Biomed |
| Potassium Sparing Combination Diuretics | | | | |
| AMILORIDE HYDROCHLORIDE WITH FUROSEMIDE * Tab 5 mg with furosemide 40 mg AMILORIDE HYDROCHLORIDE WITH HYDROCHLOROTHIAZ | IDE | 28 | | Frumil |
| * Tab 5 mg with hydrochlorothiazide 50 mg | 5.00 | 50 | 1 | Moduretic |
| Thiazide and Related Diuretics | | | | |
| BENDROFLUMETHIAZIDE [BENDROFLUAZIDE] * Tab 2.5 mg – Up to 150 tab available on a PSO | 51.50 | 500 | 1 | Arrow- Bendrofluazide |
| May be supplied on a PSO for reasons other than emerget * Tab 5 mg | | 500 | 1 | Arrow- Bendrofluazide |
| CHLOROTHIAZIDE Oral liq 50 mg per ml CHLORTALIDONE [CHLORTHALIDONE] | | 25 ml O | P 🗸 | Biomed |
| * Tab 25 mg | 6.95 | 50 | 1 | Hygroton |
| INDAPAMIDE * Tab 2.5 mg METOLAZONE | | 90 | ~ | Dapa-Tabs |
| Tab 5 mg | CBS | 1 50 | | Metolazone S29 Zaroxolyn S29 |
| (Metolazone S29) Tab 5 mg to be delisted 1 July 2025) | | | | |

| | Subsidy (Manufacturer's Price) | | Fully lised | Brand or Generic |
|---|-----------------------------------|-------|----------------|---------------------|
| | (inditidated of a 1.000) \$ | Per | 1 | Manufacturer |
| Vasopressin receptor antagonists | | | | |
| TOLVAPTAN - Special Authority see SA2166 below - Retail pha | irmacy | | | |
| Tab 15 mg | | 28 OP | 🗸 J | inarc |
| Tab 30 mg | | 28 OP | 🗸 J | inarc |
| Tab 45 mg + 15 mg | 1,747.00 | 56 OP | 🗸 J | inarc |
| Tab 60 mg + 30 mg | 1,747.00 | 56 OP | 🗸 J | inarc |
| Tab 90 mg + 30 mg | 1,747.00 | 56 OP | 🗸 J | inarc |
| | | | | |

⇒SA2166 Special Authority for Subsidy

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

- 1 Patient has a confirmed diagnosis of autosomal dominant polycystic kidney disease; and
- 2 Patient has an estimated glomerular filtration rate (eGFR) of greater than or equal to 25 ml/min/1.73 m² at treatment initiation; and
- 3 Either:
 - 3.1 Patient's disease is rapidly progressing, with a decline in eGFR of greater than or equal to 5 mL/min/1.73 m² within one-year; or
 - 3.2 Patient's disease is rapidly progressing, with an average decline in eGFR of greater than or equal to 2.5 mL/min/1.73 m² per year over a five-year period.

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

- 1 Patient has not developed end-stage renal disease, defined as an eGFR of less than 15 mL/min/1.73 m²; and
- 2 Patient has not undergone a kidney transplant.

Lipid-Modifying Agents

Fibrates

| BEZAFIBRATE * Tab 200 mg | 90 30 | ✓ <u>Bezalip</u> ✓ <u>Bezalip</u> Retard |
|---|----------|---|
| Other Lipid-Modifying Agents | | |
| ACIPIMOX * Cap 250 mg | 30 | Olbetam |
| Resins | | |
| COLESTYRAMINE Powder for oral suspension 4 g sachet61.50 | 50 | Colestyramine - Mylan (\$29) Quantalan sugar free (\$29) |

| | Subsidy (Manufacturer's Price) \$ | Per | Fully Subsidised | |
|--|---|-----|---------------------|----------------------|
| HMG CoA Reductase Inhibitors (Statins) | | | | |
| ATORVASTATIN | | | | |
| * Tab 10 mg | 0.31 | 30 | ✓ | Lorstat |
| - | 5.16 | 500 | ✓ | Lorstat |
| * Tab 20 mg | 0.45 | 28 | ✓ | Lipitor |
| | 8.12 | 500 | ✓ | Lorstat |
| * Tab 40 mg | 13.79 | 500 | ✓ | Lorstat |
| * Tab 80 mg | 1.52 | 30 | ✓ | Lorstat |
| | 25.39 | 500 | ✓ | Lorstat |
| PRAVASTATIN | | | | |
| * Tab 20 mg | 7.16 | 100 | ✓ | Clinect |
| * Tab 40 mg | | 100 | ✓ | Clinect |
| ROSUVASTATIN – Special Authority see SA2093 below – Retail | | | | |
| * Tab 5 mg | | 30 | ✓ | Rosuvastatin Viatris |
| * Tab 10 mg | | 30 | ✓ | Rosuvastatin Viatris |
| * Tab 20 mg | 2.71 | 30 | ✓ | Rosuvastatin Viatris |
| * Tab 40 mg | | 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:

| | Subsidy (Manufacturer's Price \$ | | Fully Brand or dised Generic ✓ Manufacturer |
|--|--|-----------|---|
| continued | | | |
| Patient has experienced a recurrent major cardiovascular of coronary revascularisation, hospitalisation for unstable and 2 LDL cholesterol has not reduced to less than 1.0 mmol/litre and/or simvastatin. | jina) in the last 2 y | ears; and | |
| SIMVASTATIN | | | |
| * Tab 10 mg | 1.68 | 90 | ✓ <u>Simvastatin Mylan</u> ✓ Simvastatin Viatris |
| * Tab 20 mg | 2.54 | 90 | Simvastatin Viatris |
| * Tab 40 mg | | 90 | Simvastatin Viatris |
| * Tab 80 mg | | 90 | Simvastatin Viatris |
| Selective Cholesterol Absorption Inhibitors | | | |
| EZETIMIBE | | | _ |
| * Tab 10 mg | 1.76 | 30 | Ezemibe Viatris |
| (Examine Vietrie Teh 10 me to be delisted 1, July 2025) | | | Ezetimibe Sandoz |
| (Ezemibe Viatris Tab 10 mg to be delisted 1 July 2025) | | | |
| EZETIMIBE WITH SIMVASTATIN | E 1E | 30 | Zimybe |
| Tab 10 mg with simvastatin 10 mg Tab 10 mg with simvastatin 20 mg | | 30 | ✓ Zimybe |
| Tab 10 mg with simvastatin 40 mg | | 30 | ✓ Zimybe |
| Tab 10 mg with simvastatin 80 mg | | 30 | ✓ Zimybe |
| Nitrates | | | |
| | | | |
| GLYCERYL TRINITRATE | | | |
| Oral pump spray, 400 mcg per dose – Up to 250 dose available on a PSO | | 0 dose OP | Nitrolingual Pump Spray |
| * Patch 25 mg, 5 mg per day | | 30 | ✓ Nitroderm TTS |
| Patch 50 mg, 10 mg per day SOSORBIDE MONONITRATE | | 30 | Nitroderm TTS |
| * Tab 20 mg | | 100 | 🗸 Ismo 20 |
| * Tab long-acting 40 mg | | 30 | Ismo 40 Retard |
| * Tab long-acting 60 mg | | 90 | ✓ Duride |
| Sympathomimetics | | | |
| ADRENALINE | | | |
| Inj 1 in 1,000, 1 ml ampoule - Up to 5 inj available on a PSO | 4.98 | 5 | Aspen Adrenaline |
| | 13.27 | | DBL Adrenaline |
| | 25.30 | 10 | Hameln S29 |
| Inj 1 in 10,000, 10 ml ampoule – Up to 5 inj available on a PS | SO27.00 | 5 | Hospira |
| | 49.00 | 10 | Aspen Adrenaline |

▲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 | |
|--|---|------|---------------------|-----------------------|
| Vasodilators | | | | |
| HYDRALAZINE HYDROCHLORIDE | | | | |
| * Tab 25 mg - Special Authority see SA1321 below - Retail | | | | |
| pharmacy | CBS | 1 | | Hydralazine |
| | | 56 | | Onelink S29 |
| | | 84 | ~ | AMDIPHARM S29 |
| | | 100 | 1 | Camber S29 |
| Inj 20 mg ampoule | 25.90 | 5 | ~ | Apresoline |
| Initial application from any relevant practitioner. Approvals va the following criteria: Either: 1 For the treatment of refractory hypertension; or 2 For the treatment of heart failure in combination with a n inhibitors and/or angiotensin receptor blockers. | | | | |
| MINOXIDIL | | | | |
| ▲ Tab 10 mg | | 60 | 1 | Minoxidil Roma S29 |
| | 78.40 | 100 | 1 | Loniten |
| NICORANDIL | | | | |
| ▲ Tab 10 mg | 21.73 | 60 | 1 | Max Health |
| ▲ Tab 20 mg | 27.44 | 60 | ✓ | Max Health |
| PAPAVERINE HYDROCHLORIDE | | | | |
| Inj 12 mg per ml, 10 ml ampoule | 257.12 | 5 | 1 | Hospira |
| PENTOXIFYLLINE (OXPENTIFYLLINE) | | | | • |
| Tab 400 mg | | 50 | 1 | Trental 400 |
| · | | | | |
| Endothelin Receptor Antagonists | | | | |
| AMBRISENTAN – Special Authority see SA2253 below – Reta | il pharmacy | | | |
| Tab 5 mg | | 30 | ✓ | Ambrisentan Viatris |
| Tab 10 mg | 200.00 | 30 | 1 | Ambrisentan Viatris |
| SA2253 Special Authority for Subsidy Initial application — (PAH monotherapy) only from a respiration. | tony energialist cardiolo | aiet | rhoumatol | ogist or any relevant |

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

All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH); and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and

4 Any of the following:

- 4.1 All of the following:
 - 4.1.1 PAH has been confirmed by right heart catheterisation; and
 - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
 - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
 - 4.1.4 Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s

| Subsidy | | Fully | Brand or | |
|------------------------|------|-----------|--------------|--|
| (Manufacturer's Price) |) Si | ubsidised | Generic | |
| \$ | Per | 1 | Manufacturer | |

continued...

- cm⁻⁵); and
- 4.1.5 Any of the following:
 - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH 2022 (see note below for link to these guidelines) †; or
 - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**; or
 - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
- 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease; or
- 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
- 5 Both:
 - 5.1 Ambrisentan is to be used as PAH monotherapy; and
 - 5.2 Any of the following:
 - 5.2.1 Patient has experienced intolerable side effects with both sildenafil and bosentan; or
 - 5.2.2 Patient has an absolute contraindication to sildenafil and an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease); or
 - 5.2.3 Patient is a child with idiopathic PAH or PAH secondary to congenital heart disease.

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

All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH); and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
 - 4.1 All of the following:
 - 4.1.1 PAH has been confirmed by right heart catheterisation; and
 - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
 - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
 - 4.1.4 Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm⁵); and
 - 4.1.5 Any of the following:
 - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH 2022 (see note below for link to these guidelines) †; or
 - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**; or
 - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
 - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease; or
 - 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
- 5 All of the following:
 - 5.1 Ambrisentan is to be used as PAH dual therapy; and
 - 5.2 Either:

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

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

- 5.2.1 Patient has tried a PAH monotherapy (sildenafil or bosentan) for at least three months and has not experienced an acceptable response to treatment according to a validated risk stratification tool**; or
- 5.2.2 Patient has tried PAH dual therapy including bosentan and has experienced intolerable side effects on bosentan; and
- 5.3 Both:
 - 5.3.1 Patient is presenting in NYHA/WHO functional class III or IV, and in the opinion of the treating clinician would benefit from initial dual therapy; and
 - 5.3.2 Patient has an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease).

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

All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH); and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
 - 4.1 All of the following:
 - 4.1.1 PAH has been confirmed by right heart catheterisation; and
 - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
 - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
 - 4.1.4 Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm⁵); and
 - 4.1.5 Any of the following:
 - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH 2022 (see note below for link to these guidelines) †; or
 - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**; or
 - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
 - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease; or
 - 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
- 5 Both:
 - 5.1 Ambrisentan is to be used as PAH triple therapy; and
 - 5.2 Any of the following:
 - 5.2.1 Patient is on the lung transplant list; or
 - 5.2.2 Both:
 - 5.2.2.1 Patient is presenting in NYHA/WHO functional class IV; and
 - 5.2.2.2 Patient has an absolute or relative contraindication to bosentan (e.g. due to current use of a combined oral contraceptive or liver disease); or
 - 5.2.3 Both:
 - 5.2.3.1 Patient has tried PAH dual therapy for at least three months and remains in an unacceptable risk category according to a validated risk stratification tool**; and
 - 5.2.3.2 Patient does not have major life-threatening comorbidities and triple therapy is not being used in a palliative scenario.

continued...

| ce) | Fully Subsidised | Brand or Generic | |
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| \$ Per | 1 | Manufacturer | |

continued...

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

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

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

| BOSENTAN - Special Authorit | see SA2254 below - I | Retail pharmacy |
|-----------------------------|----------------------|-----------------|
|-----------------------------|----------------------|-----------------|

| Tab 62.5 mg | 60 | Bosentan Dr |
|-------------|--------|---------------------------------|
| - | | Reddy's |
| Tab 125 mg | 60 | Bosentan Dr |
| | | Reddy's |

⇒SA2254 Special Authority for Subsidy

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

All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH)*; and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
 - 4.1 All of the following:
 - 4.1.1 PAH has been confirmed by right heart catheterisation; and
 - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
 - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
 - 4.1.4 Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm⁵); and
 - 4.1.5 Any of the following:
 - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †; or
 - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**; or
 - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
 - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease; or
 - 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and

5 Both:

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

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

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

applications meeting the following criteria:

All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH)*; and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
 - 4.1 All of the following:
 - 4.1.1 PAH has been confirmed by right heart catheterisation; and
 - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
 - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
 - 4.1.4 Pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm⁵); and
 - 4.1.5 Any of the following:
 - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †; or
 - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**; or
 - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
 - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease; or
 - 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and
- 5 Bosentan is to be used as part of PAH dual therapy; and
- 6 Either:
 - 6.1 Patient has tried a PAH monotherapy (sildenafil) for at least three months and has experienced an inadequate therapeutic response to treatment according to a validated risk stratification tool**; or
 - 6.2 Patient is presenting in NYHA/WHO functional class III or IV, and in the opinion of the treating clinician would likely benefit from initial dual therapy.

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

All of the following:

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

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

continued...

- 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**; or
- 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
- 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease; or
- 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and

5 Both:

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

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

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

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

Phosphodiesterase Type 5 Inhibitors

| SILDENAFIL - Special Authorit | y see SA2255 below – Retail pharmacy |
|-------------------------------|--------------------------------------|
|-------------------------------|--------------------------------------|

| Tab 25 mg0.72 | 4 | Vedafil |
|-----------------|----|-----------------------------|
| Tab 50 mg1.45 | 4 | ✓ Vedafil |
| Tab 100 mg11.22 | 12 | ✓ Vedafil |

► SA2255 Special Authority for Subsidy

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

All of the following:

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

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

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

continued...

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

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

- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
 - 4.1 All of the following:
 - 4.1.1 PAH is confirmed by right heart catheterisation; and
 - 4.1.2 A mean pulmonary artery pressure (PAPm) of greater than 20 mmHg; and
 - 4.1.3 A pulmonary capillary wedge pressure (PCWP) that is less than or equal to 15 mmHg; and
 - 4.1.4 Pulmonary vascular resistance (PVR) of at least 2 Wood Units or greater than 160 International Units (dyn s cm⁵); and
 - 4.1.5 Any of the following:
 - 4.1.5.1 PAH is non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †; or
 - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**; or
 - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
 - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including severe chronic neonatal lung disease; or
 - 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures.

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

Both:

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

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

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

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

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

Prostacyclin Analogues

| EPOPROSTENOL - Special Authority see SA2256 below - | Retail pharmacy | | |
|---|-----------------|---|-----------------------------|
| Inj 500 mcg vial | | 1 | Veletri |
| Inj 1.5 mg vial | 73.21 | 1 | 🗸 Veletri |

⇒SA2256 Special Authority for Subsidy

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

All of the following:

60

- 1 Patient has pulmonary arterial hypertension (PAH); and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class III or IV; and
- 4 Any of the following:

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

- 4.1 All of the following:
 - 4.1.1 PAH has been confirmed by right heart catheterisation; and
 - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
 - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
 - 4.1.4 A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm⁵); and
 - 4.1.5 Any of the following:
 - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †; or
 - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**; or
 - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
- 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease; or
- 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures ; and
- 5 All of the following:
 - 5.1 Epoprostenol is to be used as part of PAH dual therapy with either sildenafil or an endothelin receptor antagonist; and
 - 5.2 Patient is presenting in NYHA/WHO functional class IV; and
 - 5.3 Patient has tried a PAH monotherapy for at least three months and remains in an unacceptable risk category according to a validated risk stratification tool.

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

All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH); and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class III or IV; and
- 4 Any of the following:
 - 4.1 All of the following:
 - 4.1.1 PAH has been confirmed by right heart catheterisation; and
 - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
 - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
 - 4.1.4 A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm⁵); and
 - 4.1.5 Any of the following:
 - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †; or
 - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**; or
 - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
 - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease; or
 - 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major

▲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

| (Ma | Subsidy anufacturer's Price) | Fu Subsidis | | Brand or Generic |
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| | \$ | Per | / | Manufacturer |

complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures ; and

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

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

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

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

ILOPROST – Special Authority see SA2257 below – Retail pharmacy

⇒SA2257 Special Authority for Subsidy

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

All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH); and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
 - 4.1 All of the following:
 - 4.1.1 PAH has been confirmed by right heart catheterisation; and
 - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
 - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
 - 4.1.4 A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm⁵); and
 - 4.1.5 Any of the following:
 - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †; or
 - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**; or
 - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
 - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease; or
 - 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and

continued...

62

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| (Manufacturer's Price) | S | ubsidised | Generic | |
| \$ | Per | ✓ | Manufacturer | |

- 5 Both:
 - 5.1 Iloprost is to be used as PAH monotherapy; and
 - 5.2 Either:
 - 5.2.1 Patient has experienced intolerable side effects on sildenafil and both the funded endothelin receptor antagonists (i.e. both bosentan and ambrisentan); or
 - 5.2.2 Patient has an absolute contraindication to sildenafil and an absolute or relative contraindication to endothelin receptor antagonists.

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

All of the following:

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

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

All of the following:

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

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

- 1 Patient has pulmonary arterial hypertension (PAH); and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice 2003) clinical classifications; and
- 3 PAH is in New York Heart Association/World Health Organization (NYHA/WHO) functional class II, III or IV; and
- 4 Any of the following:
 - 4.1 All of the following:
 - 4.1.1 PAH has been confirmed by right heart catheterisation; and
 - 4.1.2 A mean pulmonary artery pressure (PAPm) greater than 20 mmHg (unless peri Fontan repair); and
 - 4.1.3 A pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
 - 4.1.4 A pulmonary vascular resistance greater than 2 Wood Units or greater than 160 International Units (dyn s cm⁵); and
 - 4.1.5 Any of the following:
 - 4.1.5.1 PAH has been demonstrated to be non-responsive in vasoreactivity assessment using iloprost or nitric oxide, as defined in the 2022 ECS/ERS Guidelines for PAH (see note below for link to these guidelines) †; or
 - 4.1.5.2 Patient has not experienced an acceptable response to calcium antagonist treatment, according to a validated risk stratification tool**; or
 - 4.1.5.3 Patient has PAH other than idiopathic / heritable or drug-associated type; or
 - 4.2 Patient is a child with PAH secondary to congenital heart disease or PAH due to idiopathic, congenital or developmental lung disorders including chronic neonatal lung disease; or
 - 4.3 Patient has palliated single ventricle congenital heart disease and elevated pulmonary pressures or a major complication of the Fontan circulation requiring the minimising of pulmonary/venous filling pressures; and

5 Both:

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

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

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

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

| | Subsidy (Manufacturer's Price) \$ | Subsi Per | Fully dised | Brand or Generic Manufacturer |
|--|---|------------------|----------------|-------------------------------------|
| Antiacne Preparations | | | | |
| For systemic antibacterials, refer to INFECTIONS, Antibacterials, ADAPALENE a) Maximum of 30 g per prescription b) Only on a prescription Gel 0.1% | | 0 g OP | ✓ D | ifferin |
| ISOTRETINOIN – Special Authority see SA2449 below – Retail p Cap 5 mg Cap 10 mg Cap 20 mg | bharmacy 11.26 18.75 | 60 120 120 | ✓ 0 | iratane iratane iratane |

➡SA2449 Special Authority for Subsidy

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

- 1 Applicant is a vocationally registered dermatologist, paediatrician, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice; and
- 2 Applicant has an up to date knowledge of the safety issues around isotretinoin and is competent to prescribe isotretinoin; and
- 3 Any of the following:

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

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

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

| Crm 0.5 mg per g – Maximum of 50 g per prescription | 16.82 | 50 g OP | ✓ <u>ReTrieve</u> |
|--|-----------------|---------|--------------------------------|
| Antibacterials Topical | | | |
| For systemic antibacterials, refer to INFECTIONS, Antibacterials, pa | ge 92 | | |
| HYDROGEN PEROXIDE | | | |
| * Crm 1% | 8.56 | 10 g OP | Crystaderm |
| MUPIROCIN | | | |
| Oint 2% | 6.60 (13.00) | 15 g OP | Bactroban |
| a) Only on a prescription | | | |
| b) Not in combination | | | |

| | Subsidy | | Fully Brand or |
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| | (Manufacturer's F \$ | Price) Subs Per | sidised Generic Manufacturer |
| SODIUM FUSIDATE [FUSIDIC ACID] | | | |
| Crm 2% | 1.69 | 5 g OP | Foban |
| a) Maximum of 5 g per prescription | | · | |
| b) Only on a prescription | | | |
| c) Not in combination | | | |
| Oint 2% | 1.69 | 5 g OP | Foban |
| a) Maximum of 5 g per prescription | | | |
| b) Only on a prescription | | | |
| c) Not in combination | | | |
| SULFADIAZINE SILVER | 40.00 | 50 . 00 | |
| Crm 1% | | 50 g OP | ✓ Flamazine |
| | 15.44 | | Ascend S29 |
| a) Up to 250 g available on a PSO | | | |
| b) Not in combination | | | |
| (Ascend S29) Crm 1% to be delisted 1 July 2025) | | | |
| Antifungals Topical | | | |
| Antinungais Topicai | | | |
| For systemic antifungals, refer to INFECTIONS, Antifungals, pa | ige 99 | | |
| AMOROLFINE | 0 | | |
| a) Only on a prescription | | | |
| b) Not in combination | | | |
| Nail soln 5% | 21.87 | 5 ml OP | MycoNail |
| CLOTRIMAZOLE | | | _ |
| * Cm 1% | | 20 g OP | Clomazol |
| a) Only on a prescription | | _0 g 0. | |
| b) Not in combination | | | |
| * Soln 1% | 4.36 | 20 ml OP | |
| | (7.55) | | Canesten |
| a) Only on a prescription | | | |
| b) Not in combination | | | |
| ECONAZOLE NITRATE | | | |
| Crm 1% | 8.04 | 20 g OP | Pevaryl |
| a) Only on a prescription | | ũ | • |
| b) Not in combination | | | |
| | | | |
| c) Pevaryl to be Principal Supply on 1 June 2025 | | | |
| , | 9.89 | 3 | |
| c) Pevaryl to be Principal Supply on 1 June 2025 | 9.89 (18.64) | 3 | Pevaryl |
| c) Pevaryl to be Principal Supply on 1 June 2025 | | 3 | Pevaryl |

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| | (Manufacturer's F | | sidised Generic |
| | \$ | Per | Manufacturer |
| | | | |
| * Crm 2% | 0.90 | 15 g OP | <u>Multichem</u> |
| a) Only on a prescription | | | |
| b) Not in combination | 4.00 | | |
| ₭ Lotn 2% | (10.03) | 30 ml OP | Daktarin |
| a) Only on a prescription | (10.03) | | Daklann |
| b) Not in combination | | | |
| * Tinct 2% | 4.36 | 30 ml OP | |
| | (12.10) | | Daktarin |
| a) Only on a prescription | · · · · | | |
| b) Not in combination | | | |
| | | | |
| Antipruritic Preparations | | | |
| CALAMINE | | | |
| a) Only on a prescription | | | |
| b) Not in combination | | | |
| Crm, aqueous, BP | 3.45 | 100 g | ✓ healthE Calamine |
| | | - 3 | Aqueous |
| CROTAMITON | | | |
| a) Only on a prescription | | | |
| b) Not in combination | | | |
| | | | |
| Crm 10% | 3.49 | 20 g OP | Itch-Soothe |
| | 3.49 | 20 g OP | ✓ <u>Itch-Soothe</u> |
| IENTHOL – Only in combination | | Ū | |
| | | Ū | |
| IENTHOL – Only in combination 1) Only in combination with a dermatological base or pi 2) With or without other dermatological galenicals. | roprietary Topical C | Ū | |
| IENTHOL – Only in combination 1) Only in combination with a dermatological base or p | roprietary Topical C | Corticosteriod – 25 g | Plain ✓ MidWest |
| IENTHOL – Only in combination 1) Only in combination with a dermatological base or pi 2) With or without other dermatological galenicals. | roprietary Topical C | Corticosteriod – | Plain |
| IENTHOL – Only in combination 1) Only in combination with a dermatological base or pi 2) With or without other dermatological galenicals. Crystals | roprietary Topical C | Corticosteriod – 25 g | Plain ✓ MidWest |
| IENTHOL – Only in combination 1) Only in combination with a dermatological base or pi 2) With or without other dermatological galenicals. Crystals | roprietary Topical C | Corticosteriod – 25 g | Plain ✓ MidWest |
| IENTHOL – Only in combination 1) Only in combination with a dermatological base or pi 2) With or without other dermatological galenicals. Crystals Crystals | roprietary Topical C 6.92 29.60 | Corticosteriod – 25 g 100 g | Plain ✓ MidWest |
| IENTHOL – Only in combination 1) Only in combination with a dermatological base or pr 2) With or without other dermatological galenicals. Crystals Corticosteroids Topical For systemic corticosteroids, refer to CORTICOSTEROIDS AND | roprietary Topical C 6.92 29.60 | Corticosteriod – 25 g 100 g | Plain ✓ MidWest |
| IENTHOL – Only in combination 1) Only in combination with a dermatological base or pr 2) With or without other dermatological galenicals. Crystals Corticosteroids Topical For systemic corticosteroids, refer to CORTICOSTEROIDS AND | roprietary Topical C 6.92 29.60 | Corticosteriod – 25 g 100 g | Plain ✓ MidWest |
| MENTHOL – Only in combination 1) Only in combination with a dermatological base or pr 2) With or without other dermatological galenicals. Crystals Corticosteroids Topical For systemic corticosteroids, refer to CORTICOSTEROIDS AN Corticosteroids - Plain ETAMETHASONE DIPROPIONATE | roprietary Topical C 6.92 29.60 ND RELATED AGE | Corticosteriod – 25 g 100 g | Plain ✓ MidWest |
| IENTHOL – Only in combination 1) Only in combination with a dermatological base or pi 2) With or without other dermatological galenicals. Crystals Corticosteroids Topical For systemic corticosteroids, refer to CORTICOSTEROIDS AN Corticosteroids - Plain | roprietary Topical C 6.92 29.60 ND RELATED AGE | Corticosteriod – 25 g 100 g NTS, page 82 15 g OP | Plain ✓ MidWest ✓ MidWest ✓ Diprosone |
| MENTHOL – Only in combination 1) Only in combination with a dermatological base or pr 2) With or without other dermatological galenicals. Crystals Corticosteroids Topical For systemic corticosteroids, refer to CORTICOSTEROIDS AN Corticosteroids - Plain BETAMETHASONE DIPROPIONATE Crm 0.05% | roprietary Topical C 6.92 29.60 ND RELATED AGE 2.96 36.00 | Corticosteriod – 25 g 100 g NTS, page 82 15 g OP 50 g OP | Plain ✓ MidWest ✓ MidWest ✓ Diprosone ✓ Diprosone |
| MENTHOL – Only in combination 1) Only in combination with a dermatological base or pr 2) With or without other dermatological galenicals. Crystals Corticosteroids Topical For systemic corticosteroids, refer to CORTICOSTEROIDS AN Corticosteroids - Plain BETAMETHASONE DIPROPIONATE | roprietary Topical C 6.92 29.60 ND RELATED AGE 2.96 36.00 2.96 | Corticosteriod – 25 g 100 g NTS, page 82 15 g OP 50 g OP 15 g OP | Plain ✓ MidWest ✓ MidWest ✓ Diprosone ✓ Diprosone ✓ Diprosone |
| MENTHOL – Only in combination 1) Only in combination with a dermatological base or pr 2) With or without other dermatological galenicals. Crystals Corticosteroids Topical For systemic corticosteroids, refer to CORTICOSTEROIDS AN Corticosteroids - Plain BETAMETHASONE DIPROPIONATE Crm 0.05% | roprietary Topical C 6.92 29.60 ND RELATED AGE 2.96 36.00 2.96 36.00 | Corticosteriod – 25 g 100 g NTS, page 82 15 g OP 50 g OP 15 g OP 50 g OP | Plain MidWest MidWest MidWest Diprosone Diprosone Diprosone Diprosone Diprosone Diprosone |
| MENTHOL – Only in combination 1) Only in combination with a dermatological base or pr 2) With or without other dermatological galenicals. Crystals Corticosteroids Topical For systemic corticosteroids, refer to CORTICOSTEROIDS AN Corticosteroids - Plain SETAMETHASONE DIPROPIONATE Crm 0.05% Oint 0.05% in propylene glycol base | roprietary Topical C 6.92 29.60 ND RELATED AGE 2.96 36.00 2.96 36.00 | Corticosteriod – 25 g 100 g NTS, page 82 15 g OP 50 g OP 15 g OP | Plain ✓ MidWest ✓ MidWest ✓ Diprosone ✓ Diprosone ✓ Diprosone |
| MENTHOL – Only in combination 1) Only in combination with a dermatological base or pr 2) With or without other dermatological galenicals. Crystals Corticosteroids Topical For systemic corticosteroids, refer to CORTICOSTEROIDS AN Corticosteroids - Plain SETAMETHASONE DIPROPIONATE Crm 0.05% Oint 0.05% in propylene glycol base SETAMETHASONE VALERATE | Coprietary Topical C | Corticosteriod – 25 g 100 g NTS, page 82 15 g OP 50 g OP 15 g OP 50 g OP 30 g OP | Plain MidWest MidWest Diprosone D |
| MENTHOL – Only in combination 1) Only in combination with a dermatological base or pr 2) With or without other dermatological galenicals. Crystals Corticosteroids Topical For systemic corticosteroids, refer to CORTICOSTEROIDS AN Corticosteroids - Plain DETAMETHASONE DIPROPIONATE Crm 0.05% Oint 0.05% in propylene glycol base Dint 0.05% in propylene glycol base ETAMETHASONE VALERATE € Crm 0.1% | roprietary Topical C 6.92 29.60 ND RELATED AGE 2.96 36.00 2.96 36.00 4.33 5.85 | Corticosteriod – 25 g 100 g NTS, page 82 15 g OP 50 g OP 15 g OP 50 g OP 30 g OP 50 g OP | Plain MidWest MidWest MidWest Diprosone Di |
| MENTHOL – Only in combination 1) Only in combination with a dermatological base or pr 2) With or without other dermatological galenicals. Crystals Corticosteroids Topical For systemic corticosteroids, refer to CORTICOSTEROIDS AN Corticosteroids - Plain SETAMETHASONE DIPROPIONATE Crm 0.05% Oint 0.05% in propylene glycol base BETAMETHASONE VALERATE & Crm 0.1% | roprietary Topical C 6.92 29.60 ND RELATED AGE 2.96 36.00 2.96 36.00 4.33 5.85 7.90 | Corticosteriod – 25 g 100 g NTS, page 82 15 g OP 50 g OP 15 g OP 30 g OP 50 g OP 50 g OP 50 g OP | Plain MidWest MidWest MidWest Diprosone Di |
| MENTHOL – Only in combination 1) Only in combination with a dermatological base or pr 2) With or without other dermatological galenicals. Crystals Corticosteroids Topical Gorticosteroids Topical Gorticosteroids Topical Gorticosteroids Topical Gorticosteroids - Plain SETAMETHASONE DIPROPIONATE Crm 0.05% Oint 0.05% Oint 0.05% Oint 0.05% GETAMETHASONE VALERATE Crm 0.1% Cont 0.1% Lotn 0.1% | roprietary Topical C 6.92 29.60 ND RELATED AGE 2.96 36.00 2.96 36.00 4.33 5.85 7.90 | Corticosteriod – 25 g 100 g NTS, page 82 15 g OP 50 g OP 15 g OP 50 g OP 30 g OP 50 g OP | Plain MidWest MidWest MidWest Diprosone Di |
| MENTHOL – Only in combination 1) Only in combination with a dermatological base or pr 2) With or without other dermatological galenicals. Crystals | roprietary Topical C 6.92 29.60 ND RELATED AGE 2.96 36.00 2.96 36.00 4.33 5.85 7.90 | Corticosteriod – 25 g 100 g NTS, page 82 15 g OP 50 g OP 15 g OP 30 g OP 50 g OP 50 g OP 50 g OP | Plain MidWest MidWest MidWest Diprosone Di |
| MENTHOL – Only in combination 1) Only in combination with a dermatological base or pr 2) With or without other dermatological galenicals. Crystals | roprietary Topical C 6.92 29.60 ND RELATED AGE 2.96 36.00 2.96 36.00 4.33 5.85 7.90 30.00 | Corticosteriod – 25 g 100 g NTS, page 82 15 g OP 50 g OP 30 g OP 50 g OP | Plain MidWest MidWest MidWest Diprosone Diprosone Diprosone Diprosone Diprosone Diprosone Diprosone Diprosone Diprosone OV Beta Cream Beta Ointment Betnovate |
| MENTHOL – Only in combination 1) Only in combination with a dermatological base or pr 2) With or without other dermatological galenicals. Crystals Corticosteroids Topical For systemic corticosteroids, refer to CORTICOSTEROIDS AN Corticosteroids - Plain SETAMETHASONE DIPROPIONATE Crm 0.05% Oint 0.05% in propylene glycol base BETAMETHASONE VALERATE * Crm 0.1% * Oint 0.1% | roprietary Topical C 6.92 29.60 ND RELATED AGE 2.96 36.00 2.96 36.00 4.33 5.85 7.90 30.00 | Corticosteriod – 25 g 100 g NTS, page 82 15 g OP 50 g OP 15 g OP 30 g OP 50 g OP 50 g OP 50 g OP | Plain MidWest MidWest MidWest Diprosone Di |

▲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 Pr | | Fully Brand or sidised Generic |
|---|-------------------------------|----------------------|--------------------------------------|
| | (Manufacturer's Pr \$ | Per Subs | Manufacturer |
| CLOBETASONE BUTYRATE | | | |
| Crm 0.05% | 5.38 | 30 g OP | |
| | (10.00) | 00 9 01 | Eumovate |
| HYDROCORTISONE | (/ | | |
| * Crm 1% – Only on a prescription | 1 78 | 30 g OP | Ethics |
| | 20.40 | 500 g | ✓ Noumed |
| Powder – Only in combination | | 25 g | ✓ ABM |
| Up to 5% in a dermatological base (not proprietary To galenicals | | | |
| HYDROCORTISONE AND PARAFFIN LIQUID AND LANOLI | N | | |
| Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% - On | | | |
| a prescription | | 250 ml | DP Lotn HC |
| HYDROCORTISONE BUTYRATE | | | |
| Lipocream 0.1% | 1 05 | 100 g OP | Locoid Lipocream |
| Oint 0.1% | | 100 g OP 100 g OP | |
| Oint 0.1% Milky emul 0.1% | | 100 g OP | ✓ Locoid Crelo |
| | 12.00 | 100 III OF | |
| METHYLPREDNISOLONE ACEPONATE | | | . |
| Crm 0.1% | | 15 g OP | Advantan |
| Oint 0.1% | 4.95 | 15 g OP | Advantan |
| MOMETASONE FUROATE | | | |
| Crm 0.1% | 2.25 | 15 g OP | Elocon Alcohol Free |
| | 3.50 | 50 g OP | Elocon Alcohol Free |
| Oint 0.1% | 2.25 | 15 g OP | ✓ Elocon |
| | 3.50 | 50 g OP | ✓ Elocon |
| Lotn 0.1% | 4.99 | 30 ml OP | Elocon |
| FRIAMCINOLONE ACETONIDE | | | |
| Crm 0.02% | 6.49 | 100 g OP | Aristocort |
| Oint 0.02% | 6.54 | 100 g OP | ✓ Aristocort |
| Corticosteroids - Combination | | | |
| BETAMETHASONE VALERATE WITH SODIUM FUSIDATE [| | | |
| Crm 0.1% with sodium fusidate (fusidic acid) 2% | | 15 g OP | |
| | (10.45) | 15 9 01 | Fucicort |
| a) Maximum of 15 a par proceription | (10.43) | | |
| a) Maximum of 15 g per prescriptionb) Only on a prescription | | | |
| HYDROCORTISONE WITH MICONAZOLE - Only on a pres | cription | | |
| * Crm 1% with miconazole nitrate 2% | | 15 g OP | ✓ Micreme H |
| HYDROCORTISONE WITH NATAMYCIN AND NEOMYCIN | - Only on a prescript | ion | |
| Oint 1% with natamycin 1% and neomycin sulphate 0.5% | , , , | 15 g OP | Pimafucort |
| FRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOM | | U U | |
| | | IN . | |
| Crm 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 | 0 | 15 a OP | |
| and gramicidin 250 mcg per g – Only on a prescription | | 15 g OP | Viaderm KC |
| | (9.28) | | viauerni KC |

| | Subsidy (Manufacturer's F | Price) Sub | Fully Brand or sidised Generic |
|--|------------------------------|-----------------|--|
| | \$ | Per | Manufacturer |
| Barrier Creams and Emollients | | | |
| Barrier Creams | | | |
| IMETHICONE | | | |
| ₭ Crm 5% pump bottle | 4.30 | 460 g OP | ✓ <u>healthE</u> <u>Dimethicone 5%</u> |
| ₭ Crm 10% pump bottle | 4.52 | 460 g OP | healthE Dimethicone 10% |
| ZINC AND CASTOR OIL | 4.05 | 500 | <u> </u> |
| * Oint | 4.25 | 500 g | ✓ <u>Evara</u> |
| Emollients | | | |
| AQUEOUS CREAM | | | _ |
| * Crm | 1.65 | 500 g | ✓ Evara |
| CETOMACROGOL * Crm BP | 0.00 | 500 g | ✓ Cetomacrogol-AFT |
| CETOMACROGOL WITH GLYCEROL | 2.29 | 500 g | Cetomacrogol-AFT |
| Crm 90% with glycerol 10% | 2 13 | 460 g OP | ✓ Evara |
| | 3.50 | 920 g OP | ✓ Evara |
| EMULSIFYING OINTMENT | | Ū | |
| ₭ Oint BP | 3.13 | 500 g | <u>Emulsifying</u> <u>Ointment ADE</u> |
| DIL IN WATER EMULSION | | | |
| ₭ Crm | 2.10 | 500 g | Fatty Emulsion <u>Cream (Evara)</u> |
| PARAFFIN | | | • · · · · · · · · · · · · · · · · · · · |
| Oint liquid paraffin 50% with white soft paraffin 50% | 4.94 | 500 g OP | ✓ White Soft Liquid Paraffin AFT |
| | 4.07 | 400 - 00 | |
| ₭ Crm 10% | 1.37 | 100 g OP | healthE Urea Cream |
| VOOL FAT WITH MINERAL OIL − Only on a prescription ★ Lotn hydrous 3% with mineral oil | 5.60 | 1,000 ml | |
| | (14.96) | 1,000 111 | DP Lotion |
| | (20.53) | | Alpha-Keri Lotion |
| | 1.40 | 250 ml OP | |
| | (5.87) | | DP Lotion |
| | 5.60 | 1,000 ml | RK Lation |
| | (23.91) 1.40 | 250 ml OP | BK Lotion |
| | (7.73) | 200 111 01 | BK Lotion |
| Other Dermatological Bases | | | |
| PARAFFIN | | | |
| White soft – Only in combination | 4.74 | 450 g | <u>EVARA White Soft</u> <u>Paraffin</u> |
| | 19.00 | 2,500 g | ✓ EVARA White Soft Paraffin |
| Only in combination with a dermatological galenical or a | s a diluent for a | proprietary Top | |

| | Subsidy | | Fully | Brand or |
|--|--------------------------|------------------|-------------|--------------------------|
| | (Manufacturer's Pr \$ | Per | idised ✓ | Generic Manufacturer |
| Minor Skin Infections | | | | |
| POVIDONE IODINE | | | | |
| Oint 10% | 7.40 | 65 g OP | 🗸 E | Betadine |
| a) Maximum of 130 g per prescription | | | | |
| b) Only on a prescription | | | | |
| Antiseptic Solution 10% | 4.99 | 100 ml | ✓ F | liodine |
| Antiseptic soln 10% | 3.83 | 15 ml | ✓ F | liodine |
| | 6.99 | 500 ml | ✓ F | liodine |
| Skin preparation, povidone iodine 10% with 30% alcohol | 1.63 | 100 ml | | |
| | (3.48) | | E | etadine Skin Prep |
| Parasiticidal Preparations | | | | |
| DIMETHICONE | | | | |
| ¥ Lotn 4% | 4.25 | 200 ml OP | ✓ <u>h</u> | ealthE Dimethicone 4% |
| | | | | Lotion |
| VERMECTIN – Special Authority see SA2294 below – Retail p | | | | |
| Tab 3 mg – Up to 100 tab available on a PSO | 17.20 | 4 | ✓ S | stromectol |
| PSO for institutional use only. Must be endorsed | with the name of the | he institution f | or whic | h the PSO is required an |

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

⇒SA2294 Special Authority for Subsidy

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

Either:

- 1 The person has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
- 2 Both:
 - 2.1 The person has a confirmed diagnosis of scabies or is a close contact of a scabies case; and
 - 2.2 Either:
 - 2.2.1 The person is unable to complete topical therapy; or
 - 2.2.2 Previous treatment with topical therapy has been tried and not cleared the infestation.

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

Any of the following:

- 1 filariasis; or
- 2 cutaneous larva migrans (creeping eruption); or
- 3 strongyloidiasis.

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

- 1 The person has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
- 2 Both:

70

- 2.1 The person has a confirmed diagnosis of scabies or is a close contact of a scabies case; and
- 2.2 Either:

| | Subsidy (Manufacturer's Pr \$ | ice) Subs Per | Fully sidised | Brand or Generic Manufacturer |
|---|---|----------------------------------|------------------------|--|
| ontinued 2.2.1 The person is unable to complete topical th 2.2.2 Previous treatment with topical therapy has enewal — (Other parasitic infections) from any relevant prac Illowing criteria: ny of the following: | been tried and no | | | |
| filariasis; or cutaneous larva migrans (creeping eruption); or strongyloidiasis. | | | | |
| ERMETHRIN Lotn 5% | 4.28 | 30 ml OP | ✓ <u>A</u> | -Scabies |
| Psoriasis and Eczema Preparations | | | | |
| CITRETIN – Special Authority see SA2024 below – Retail phar Cap 10 mg Cap 25 mg | 26.20 | 60 60 | | <u>ovatretin</u> ovatretin |
| SA2024 Special Authority for Subsidy itial application from any relevant practitioner. Approvals vali- Il of the following: | | plications me | _ | |
| working in a relevant scope of practice; and Applicant has an up to date knowledge of the safety issue Either: 3.1 Patient is of child bearing potential and the possibit treatment and patient has been counselled and un pregnancy and that they must not become pregnation of treatment; or 3.2 Patient is not of child bearing potential. | lity of pregnancy I derstands the risk | nas been excl a of teratogeni | uded pr icity if ac | ior to commencement o citretin is used during |
| enewal from any relevant practitioner. Approvals valid for 1 ye ther: | ar for applications | meeting the | following | g criteria: |
| Patient is of child bearing potential and the possibility of p treatment and patient has been counselled and understar and that they must not become pregnant during treatment or Patient is not of child bearing potential. | nds the risk of tera | togenicity if a | citretin i | s used during pregnand |
| ETAMETHASONE DIPROPIONATE WITH CALCIPOTRIOL Foam spray 500 mcg with calcipotriol 50 mcg per g Gel 500 mcg with calcipotriol 50 mcg per g Oint 500 mcg with calcipotriol 50 mcg per g | 40.92 | 60 g OP 60 g OP 30 g OP | ✓ <u>D</u> | nstilar <u>aivobet</u> aivobet |
| ALCIPOTRIOL Oint 50 mcg per g | 40.00 | 120 g OP | ✓ D | aivonex |
| OAL TAR Soln BP – Only in combination | | 200 ml | 🗸 N | lidwest |
| - | | | | |

| | Subsidy | | Fully Brand or |
|---|--------------------------|-----------------|-----------------------------------|
| (M) | anufacturer's P \$ | Per Sub | sidised Generic Manufacturer |
| COAL TAR WITH ALLANTOIN, MENTHOL, PHENOL AND SULPHU | | | |
| Soln 5% with sulphur 0.5%, menthol 0.75%, phenol 0.5% and | 'n | | |
| allantoin crm 2.5% | 6 59 | 75 g OP | |
| | (8.00) | 7590 | Egopsoryl TA |
| | 3.43 | 30 g OP | |
| | (4.35) | 5 5 - | 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 |
| <i>,</i> , , , , , , , , , , , , , , , , , , | 7.95 | 40 g OP | Coco-Scalp |
| PIMECROLIMUS - Special Authority see SA1970 below - Retail ph | armacy | • | |
| a) Maximum of 15 g per prescription | | | |
| b) Note: a maximum of 15 g per prescription and no more than | one prescrip | tion per 12 we | eks. |
| Cream 1% | | 15 g OP | ✓ Elidel |
| ► SA1970 Special Authority for Subsidy | | • | |
| Initial application only from a dermatologist, paediatrician, ophthaln | nologist or an | v relevant pra | ctitioner on the recommendation |
| of a dermatologist, paediatrician or ophthalmologist. Approvals valid | | | |
| 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 te | | | |
| documented epidermal atrophy, documented allergy to topica | l corticostero | ids, cataracts, | glaucoma, or raised intraocular |
| pressure. | | | |
| PINE TAR WITH TROLAMINE LAURILSULFATE AND FLUORESCE | EIN – Only or | n a prescriptio | n |
| Soln 2.3% with trolamine laurilsulfate and fluorescein sodium | 5.41 | 500 ml | Pinetarsol |
| SALICYLIC ACID | | | |
| Powder – Only in combination | 18.88 | 250 g | Midwest |
| 1) Only in combination with a dermatological base or pro | | al Corticoster | oid – 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 pro | | - | pid – 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 | | 0 | t |
| b) Note: a maximum of 30 g per prescription and no more | than one pres | scription per 1 | 2 weeks. |
| ➡SA2074 Special Authority for Subsidy | | | |
| Initial application only from a dermatologist, paediatrician or any re | levant practiti | oner on the re | commendation of a dermatologis |
| paediatrician, Approvals valid without further renewal unless notifie | | | |
| Both: | | 5 | 0 |
| 1 Patient has atopic dermatitis on the face; and | | | |

- 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.

DERMATOLOGICALS

| | Subsidy (Manufacturer's \$ | Price) Subs Per | Fully Brand or idised Generic ✓ Manufacturer | |
|---|----------------------------------|--------------------|--|----|
| Scalp Preparations | | | | |
| BETAMETHASONE VALERATE | | | | |
| * Scalp app 0.1% | | 100 ml OP | Beta Scalp | |
| CLOBETASOL PROPIONATE * Scalp app 0.05% | 6.26 | 30 ml OP | ✓ Dermol | |
| HYDROCORTISONE BUTYRATE | 0.20 | 50 111 01 | • <u>Dermor</u> | |
| Scalp lotn 0.1% | | 100 ml OP | ✓ Locoid | |
| KETOCONAZOLE | | | | |
| Shampoo 2% | 3.23 | 100 ml OP | ✓ Sebizole | |
| | 4.09 | | Sebizole | |
| a) Maximum of 100 ml per prescription b) Only on a prescription | | | | |
| b) Only on a prescription | | | | |
| Sunscreens | | | | |
| | | | | |
| SUNSCREENS, PROPRIETARY – Subsidy by endorsemer Only if prescribed for a patient with severe photosensitiv | | efined clinical co | ondition and the prescription | is |
| endorsed accordingly. | | | ····· | |
| Lotn, | 6.50 | 200 g OP | ✓ Marine Blue Lotion | |
| | | | SPF 50+ | |
| Wart Preparations | | | | |
| indiri ropulationo | | | | |
| For salicylic acid preparations refer to PSORIASIS AND EC2 | ZEMA PREPARATIO | NS, page 71 | | |
| PODOPHYLLOTOXIN | | | | |
| Soln 0.5% | | 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% | 5 56 | 20 g OP | ✓ Efudix | |
| IMIQUIMOD | | 20 y 01 | | |
| Crm 5%, 250 mg sachet | 21.72 | 24 | ✓ Perrigo | |
| | | | | |

| | Subsidy | Fully | Brand or |
|--------|---------|------------|--------------|
| (Manuf | | Subsidised | Generic |
| | \$ Per | 1 | Manufacturer |

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic \$ Per Manufacturer **Contraceptives - Non-hormonal** Condoms CONDOMS * 49 mm - Up to 144 dev available on a PSO 14.25 ✓ Moments 144 Moments 10 Moments 14 25 144 a) Maximum of 60 dev per prescription b) Up to 60 dev available on a PSO 10 ✓ Moments * ✓ Moments 14.25 144 a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription ✓ Moments 10 Moments 14.25 144 a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription 53 mm, strawberry, red.....1.15 ✓ Moments * 10 14.25 144 ✓ Moments a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription Moments 10 14.50 144 ✓ Moments a) Maximum of 60 dev per prescription b) Up to 60 dev available on a PSO * 56 mm. 0.05 mm thickness......2.00 Gold Knight 12 Gold Knight 24.10 144 a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription 144 Gold Knight a) Maximum of 60 dev per prescription b) Up to 60 dev available on a PSO ✓ Moments 10 * ✓ Moments 14.25 144 a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription ✓ Moments 10 14.25 144 Moments a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription Gold Knight 12 Gold Knight 21.45 144 a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription Gold Knight 12 21.45 144 Gold Knight a) Up to 60 dev available on a PSO b) Maximum of 60 dev per prescription 12 Gold Knight XL 21.89 144 Gold Knight XL a) Maximum of 60 dev per prescription

XL

75

GENITO-URINARY SYSTEM

GENITO-URINARY SYSTEM

| | Subsidy (Manufacturer's Price) \$ | Su Per | Fully bsidised | Brand or Generic Manufacturer |
|--|---|-----------|-------------------|--|
| a) Maximum of 60 dev per prescriptionb) 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 | | | | |
| ✤ IÚD 29.1 mm length × 23.2 mm width | 29.80 | 1 | _ | hoice 380 7med Nsha Silver/ copper Short |
| * IUD 33.6 mm length × 29.9 mm width | | 1 | _ | <u>Cu 380 Plus</u> Normal |
| * IUD 35.5 mm length × 19.6 mm width | | 1 | ✓ <u>c</u> | u 375 Standard |

Contraceptives - Hormonal

Combined Oral Contraceptives

⇒SA0500 Special Authority for Alternate Subsidy

Initial application from any medical practitioner. Approvals valid for 2 years for applications meeting the following criteria: 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 - U | lp to | | |
|---|---|-------|----|---------------------------------|
| | 84 tab available on a PSO | | 84 | Mercilon 28 |

GENITO-URINARY SYSTEM

| | Subsidy (Manufacturer's Price) \$ | S Per | Fully ubsidised | Brand or Generic Manufacturer |
|---|---|----------|--------------------|-------------------------------------|
| ETHINYLOESTRADIOL WITH LEVONORGESTREL | | | | |
| * Tab 20 mcg with levonorgestrel 100 mcg and 7 inert tablets | - | | | |
| Up to 84 tab available on a PSO | 1.50 | 84 | ✓ L | o-Oralcon 20 ED |
| * Tab 30 mcg with levonorgestrel 150 mcg | 6.62 | 63 | | |
| | (16.50) | | Ν | licrogynon 30 |
| a) Higher subsidy of \$15.00 per 63 tab with Special Aut b) Up to 63 tab available on a PSO * Tab 30 mcg with levonorgestrel 150 mcg and 7 inert tablets Up to 84 tab available on a PSO | - | the pr | | _{je} Dralcon 30 ED |
| ETHINYLOESTRADIOL WITH NORETHISTERONE | | | | |
| Tab 35 mcg with norethisterone 1 mg and 7 inert tab – Up to 84 tab available on a PSO | | 84 | | lyacen Brevinor 1/28 |
| Tab 35 mcg with norethisterone 500 mcg and 7 inert tab – L to 84 tab available on a PSO | • | 84 | 🗸 N | lorimin |
| 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

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. .

| DE | SOG | _0 | | | |
|----|-----|----|-----|---|--|
| * | Tah | 75 | mca | _ | |

| * Tab 75 mcg – Up to 84 tab available on a PSO24.50 | 84 | Cerazette |
|--|------|-------------------------------|
| LEVONORGESTREL | | |
| * Tab 30 mcg – Up to 112 tab available on a PSO | 112 | Microlut |
| ✤ Subdermal implant (2 × 75 mg rods) - Up to 3 impl available | | |
| on a PSO106.92 | 2 OP | ✓ Jadelle |
| MEDROXYPROGESTERONE ACETATE | | |
| Inj 150 mg per ml, 1 ml syringe - Up to 5 inj available on a PSO 10.56 | 1 | Depo-Provera |
| | | • |

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

| | 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 | ✓ | Norethinderone - CDC Noriday Noriday 28 |
| Emergency Contraceptives | | | | |
| LEVONORGESTREL ★ Tab 1.5 mg a) Maximum of 2 tab per prescription b) Up to 5 tab available on a PSO c) Note: Direct Provision by a pharmacist permitted ur | | 1 Part I | | Levonorgestrel BNM A. |
| Antiandrogen Oral Contraceptives | | | | |
| Prescribers may code prescriptions "contraceptive" (code "O") w and prescription charge will be as per other contraceptives, as fo • A maximum \$5.00 prescription charge (patient co-payment • prescription may be written for up to six months supply. Prescriptions coded in any other way are subject to any non con non-contraceptive period of supply. ie. Prescriptions may be w CYPROTERONE ACETATE WITH ETHINYLOESTRADIOL * Tab 2 mg with ethinyloestradiol 35 mcg and 7 inert tabs – L | bllows: t) may apply. traceptive prescription ritten for up to three m | char | ges that ap | |

| to 168 tab available on a PSO5.08 | 168 | ✓ Ginet |
|--|----------|-------------------------------------|
| Gynaecological Anti-infectives | | |
| ACETIC ACID WITH HYDROXYQUINOLINE AND RICINOLEIC ACID | | |
| Jelly with glacial acetic acid 0.94%, hydroxyquinoline sulphate | | |
| 0.025%, glycerol 5% and ricinoleic acid 0.75% with applicator 8.43 | 100 g OP | |
| (24.87) | | Aci-Jel |
| CLOTRIMAZOLE | | |
| * Vaginal crm 1% with applicators | 35 g OP | ✓ Clomazol |
| Vaginal crm 2% with applicators | 20 g OP | <u>Clomazol</u> |
| MICONAZOLE NITRATE | | |
| ✤ Vaginal crm 2% with applicator6.89 | 40 g OP | ✓ Micreme |
| NYSTATIN | | |
| Vaginal crm 100,000 u per 5 g with applicator(s)5.70 | 75 g OP | ✓ <u>Nilstat</u> |
| | | |
| Myometrial and Vaginal Hormone Preparations | | |
| ERGOMETRINE MALEATE | | |
| Inj 500 mcg per ml, 1 ml ampoule – Up to 5 inj available on a | | |

| PSO | | 5 | DBL Ergometrine |
|----------------------------------|------|---------|-------------------------------------|
| OESTRIOL | | | - |
| * Crm 1 mg per g with applicator | 6.95 | 15 g OP | Ovestin |
| * Pessaries 500 mcg | 7.55 | 15 | ✓ Ovestin |

GENITO-URINARY SYSTEM

| | Subsidy | | Fully | Brand or |
|--|----------------------|-----------|--------------|------------------------------|
| | (Manufacturer's Pric | ce) (| Subsidised | |
| | \$ | Per | / Jabolalooc | Manufacturer |
| | Ψ | 1.01 | - | Manalaotaroi |
| OXYTOCIN – Up to 5 inj available on a PSO | | | | |
| Inj 5 iu per ml, 1 ml ampoule | 4.98 | 5 | 1 | Oxytocin BNM |
| Inj 10 iu per ml, 1 ml ampoule | | 5 | | Oxytocin BNM |
| | | | | |
| | 11.96 | 10 | ~ | Oxytocin |
| | | | | Panpharma |
| OXYTOCIN WITH ERGOMETRINE MALEATE - Up to 5 inj avai | ilabla an a PSO | | | |
| | | - | | Cumbo motivino |
| Inj 5 iu with ergometrine maleate 500 mcg per ml, 1 ml ampo | oule32.40 | 5 | • | Syntometrine |
| | | | | |
| Pregnancy Tests - hCG Urine | | | | |
| | | | | |
| BETA-HCG LOW SENSITIVITY URINE TEST KIT - Up to 15 test | st available on a PS | SO | | |
| Note: For use in abortion services only. | | | | |
| Midstream | 16.28 | 1 test O | - J | CheckTop |
| | 10.20 | 1 1631 0 | • | Спесктор |
| PREGNANCY TESTS - HCG URINE | | | | |
| a) Up to 200 test available on a PSO | | | | |
| b) Only on a PSO | | | | |
| | 10.00 | 40.1 | - <i>1</i> | Devid One Oten |
| Cassette | | 40 test C | P V | David One Step |
| | | | | Cassette |
| | | | | Pregnancy Test |
| | | | | |
| Urinary Agents | | | | |
| offinally Agents | | | | |
| | | | | |
| For urinary tract Infections refer to INFECTIONS, Antibacterials, | page 111 | | | |
| 5 Alpha Doductoco Inhibitoro | | | | |
| 5-Alpha Reductase Inhibitors | | | | |
| FINA OTEDIDE - Or with Authority and OA00000 holes. Detailed | h | | | |
| FINASTERIDE - Special Authority see SA0928 below - Retail p | | | | |
| * Tab 5 mg | 4.79 | 100 | ~ | Ricit |
| ► SA0928 Special Authority for Subsidy | | | | |
| Initial application from any relevant practitioner. Approvals value | d without further re | nowolun | looo notif | ind for applications mosting |
| | | inewai un | | led for applications meeting |
| the following criteria: | | | | |
| Both: | | | | |
| 1 Patient has symptomatic benign prostatic hyperplasia; and | d | | | |
| 2 Either: | - | | | |
| | | | | |
| 2.1 The patient is intolerant of non-selective alpha bloc | | | icated; oi | ſ |
| 2.2 Symptoms are not adequately controlled with non- | selective alpha blo | ockers. | | |
| | | | | |
| Alpha-1A Adrenoreceptor Blockers | | | | |
| TAMSULOSIN HYDROCHLORIDE - Special Authority see SA1 | 032 below - Retail | nharmar | AV. | |
| | | | | Temeuleein Deu |
| * Cap 400 mcg | | 100 | • | Tamsulosin-Rex |
| ➡SA1032 Special Authority for Subsidy | | | | |
| Initial application from any relevant practitioner. Approvals value | d without further re | newalun | less notif | ied for applications meeting |
| | | nowar ur | 1000 11001 | ica ici applications meeting |
| the following criteria: | | | | |
| | | | | |

Both:

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

GENITO-URINARY SYSTEM

| | Subsidy (Manufacturer's P \$ | Price) Subs Per | Fully Brand or sidised Generic Manufacturer |
|--|------------------------------------|--------------------|--|
| Other Urinary Agents | | | |
| OXYBUTYNIN * Tab 5 mg | 5.42 | 100 | Alchemy Oxybutynin |
| POTASSIUM CITRATE | | | |
| Oral liq 3 mmol per ml – Special Authority see SA1083 belo Retail pharmacy | | 200 ml OP | ✓ Biomed |
| ➡SA1083 Special Authority for Subsidy | | for analisations | and the following outputs |
| Initial application from any relevant practitioner. Approvals val Both: | lid for 12 months i | or applications | meeting the following criteria: |
| 1 The patient has recurrent calcium oxalate urolithiasis; an 2 The patient has had more than two renal calculi in the tw | | - application | |
| Renewal from any relevant practitioner. Approvals valid for 2 ye benefitting from the treatment. | | | is appropriate and the patient is |
| SODIUM CITRO-TARTRATE | 0.50 | | 4 · · · · · |
| * Grans eff 4 g sachets | 3.50 | 28 | ✓ <u>Ural</u> |
| SOLIFENACIN SUCCINATE Tab 5 mg | 1.95 | 30 | Solifenacin succinate Max Health |
| O 17 Contraction of the Marcella shifts have Detected Operations | 2.05 | | ✓ Solifenacin Viatris |
| Solifenacin succinate Max Health to be Principal Supply Tab 10 mg | | 30 | Solifenacin succinate Max Health |
| Solifenacin succinate Max Health to be Principal Supply (Solifenacin Viatris Tab 5 mg to be delisted 1 June 2025) (Solifenacin Viatris Tab 10 mg to be delisted 1 June 2025) | 3.72 y on 1 June 2025 | | ✓ Solifenacin Viatris |
| Detection of Substances in Urine | | | |
| | | 50 to st OD | |
| ORTHO-TOLIDINE * Compound diagnostic sticks | 7.50 (8.25) | 50 test OP | Hemastix |

Antiprogesterones

| MIFEPRISTONE | | | |
|--|--------|---|------------------------------|
| Tab 200 mg – Up to 15 tab available on a PSO | 83.90 | 1 | Mifegyne |
| | 180.00 | 3 | Mifegyne |

| | Subsidy (Manufacturer's Price) \$ | Sub Per | Fully sidised | Brand or Generic Manufacturer |
|---|---|------------|------------------|--------------------------------------|
| Calcium Homeostasis | | | | |
| CALCITONIN * Inj 100 iu per ml, 1 ml ampoule | | 5 | ✓ M | liacalcic |
| CINACALCET – Special Authority see SA2170 below – Retail ph Tab 30 mg – Wastage claimable Tab 60 mg – Wastage claimable | | 28 28 | - | inacalet Devatis inacalet Devatis |
| ■SA2170 Special Authority for Subsidy | | 20 | - | |

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

- 1 The patient's serum calcium level has fallen to < 3mmol/L; and
- 2 The patient has experienced clinically significant symptom improvement.
- Note: This does not include parathyroid adenomas unless these have become malignant.

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

All of the following:

- 1 Patient has primary hyperparathyroidism; and
- 2 Either:
 - 2.1 Patient has hypercalcaemia of more than 3 mmol/L with or without symptoms; or
 - 2.2 Patient has hypercalcaemia of more than 2.85 mmol/L with symptoms; and
- 3 Surgery is not feasible or has failed; and
- 4 Patient has other comorbidities, severe bone pain, or calciphylaxis.

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

All of the following:

1 Either:

- 1.1 Patient has tertiary hyperparathyroidism and markedly elevated parathyroid hormone (PTH) with hypercalcaemia; or
- 1.2 Patient has symptomatic secondary hyperparathyroidism and elevated PTH; and
- 2 Patient is on renal replacement therapy; and
- 3 Any of the following:
 - 3.1 Residual parathyroid tissue has not been localised despite repeat unsuccessful parathyroid explorations; or

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

| | Subsidy | | Fully | Brand or |
|---|---------------------------|-----------|------------|----------------------------|
| (Ma | anufacturer's Price \$ | e) Per | Subsidised | Generic Manufacturer |
| ontinued | | | | |
| 3.2 Parathyroid tissue is surgically inaccessible; or 3.3 Parathyroid surgery is not feasible. | | | | |
| Renewal — (secondary or tertiary hyperparathyroidism) from an applications meeting the following criteria: Either: | y relevant pract | itioner. | Approvals | s valid for 12 months for |
| The patient has had a kidney transplant, and following a treating parathyroid hormone (PTH) level to support ongoing cessation The patient has not received a kidney transplant and trial of w | n of treatment h | as not l | been reach | ned; or |
| OLEDRONIC ACID | | | | |
| Inj 4 mg per 5 ml, vial | 15.65 | 1 | 1 | Zoledronic acid Viatris |
| Corticosteroids and Related Agents for Systemic I | Jse | | | |
| | | | | |
| BETAMETHASONE SODIUM PHOSPHATE WITH BETAMETHASO | | F | | |
| Inj 3.9 mg with betamethasone acetate 3 mg per ml, 1 ml | (36.96) | 5 | | Celestone |
| | (00.00) | | | Chronodose |
| DEXAMETHASONE | | | | |
| ₭ Tab 0.5 mg – Up to 60 tab available on a PSO | 1.80 | 30 | ✓ | Dexmethsone |
| K Tab 4 mg – Up to 30 tab available on a PSO | 3.18 | 30 | | <u>Dexmethsone</u> |
| Oral liq 1 mg per ml | 53.86 | 25 ml C | DP 🗸 | Biomed |
| DEXAMETHASONE PHOSPHATE | | | | |
| Dexamethasone phosphate injection will not be funded for oral u | | 10 | | Hemela |
| Inj 4 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO. Inj 4 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO. | | 10 10 | | <u>Hameln</u> Hameln |
| LUDROCORTISONE ACETATE | 10.10 | 10 | • | namem |
| * Tab 100 mcg | 11.46 | 100 | 1 | Florinef |
| HYDROCORTISONE | | 100 | - | |
| * Tab 5 mg | 8.10 | 100 | 1 | Douglas |
| k Tab 20 mg | | 100 | | Douglas |
| 🖌 Inj 100 mg vial | | 1 | | Solu-Cortef |
| a) Not on a BSO | | | | |
| b) Up to 5 inj available on a PSO | | | | |
| /ETHYLPREDNISOLONE | | | | |
| ₭ Tab 4 mg | | 100 | - | Medrol |
| ₭ Tab 100 mg | 223.10 | 20 | ~ | Medrol |
| METHYLPREDNISOLONE (AS SODIUM SUCCINATE) | | | - | |
| Inj 40 mg vial | 22.30 | 1 | 1 | Solu-Medrol-Act- |
| | | | | O-Vial |
| Inj 125 mg vial | 34.10 | 1 | 1 | Solu-Medrol-Act- O-Vial |
| Inj 500 mg vial | 43.01 | 1 | 1 | Solu-Medrol-Act- O-Vial |
| | | | | |

| | Subsidy (Manufacturer's Price | | Fully Subsidised | |
|---|----------------------------------|----------------------------|---------------------------|---|
| | (Manulactule) S Frice | Per | | Manufacturer |
| METHYLPREDNISOLONE ACETATE | | | | |
| Inj 40 mg per ml, 1 ml vial | | 5 | 1 | Depo-Medrol |
| PREDNISOLONE | | • | | |
| * Oral liq 5 mg per ml – Up to 30 ml available on a PSO Restricted to children under 12 years of age. | 6.00 | 30 ml O | Р 🗸 | Redipred |
| , . | | | | |
| PREDNISONE | 10.50 | 500 | | Duaduia ana Olivaat |
| * Tab 1 mg * Tab 2.5 mg | | 500 500 | | Prednisone Clinect Prednisone Clinect |
| Tab 2.5 mg – Up to 30 tab available on a PSO | | 500 | | Prednisone Clinect |
| Tab 20 mg – Up to 30 tab available on a PSO | | 500 | | Prednisone Clinect |
| | | 000 | • | |
| TETRACOSACTRIN Inj 250 mcg per ml, 1 ml ampoule | 96.25 | 1 | 1 | Synacthen |
| | | I | | UK Synacthen |
| * Inj 1 mg per ml, 1 ml ampoule | 690.00 | 1 | | Synacthen Depot |
| ······································ | | • | | Synacthene |
| | | | | Retard S29 |
| TRIAMCINOLONE ACETONIDE | | | | |
| Inj 10 mg per ml, 1 ml ampoule | 21 42 | 5 | 1 | Kenacort-A 10 |
| Inj 40 mg per ml, 1 ml ampoule | | 5 | | Kenacort-A 40 |
| Sex Hormones Non Contraceptive | | | | |
| Androgen Agonists and Antagonists | | | | |
| CYPROTERONE ACETATE | | | | |
| Tab 50 mg | | 50 | 1 | Siterone |
| Siterone to be Principal Supply on 1 July 2025 | | | | |
| Tab 100 mg | 31.00 | 50 | 1 | Siterone |
| Siterone to be Principal Supply on 1 July 2025 | | | | |
| TESTOSTERONE | | | | |
| Gel (transdermal) 16.2 mg per g, 88 g | | 60 OP | ✓ | Testogel |
| TESTOSTERONE CIPIONATE | | | | |
| Inj 100 mg per ml, 10 ml vial | | 1 | 1 | Depo-Testosterone |
| TESTOSTERONE ESTERS | | | | • |
| | | | | |
| Ini 250 ma per ml. 1 ml | | 1 | 1 | Sustanon Ampoules |
| Inj 250 mg per ml, 1 ml | 12.98 | 1 | 1 | Sustanon Ampoules |
| TESTOSTERONE UNDECANOATE | | | | |
| TESTOSTERONE UNDECANOATE Cap 40 mg – Subsidy by endorsement | | 100 | 1 | Steril-Gene S29 |
| TESTOSTERONE UNDECANOATE Cap 40 mg – Subsidy by endorsement Subsidy by endorsement – subsidised for patients who | | 100 rone un | ✓ decanoat | Steril-Gene S29 e cap 40mg prior to |
| TESTOSTERONE UNDECANOATE Cap 40 mg – Subsidy by endorsement | | 100 rone un ts may a | ✓ decanoat annotate | Steril-Gene 529 e cap 40mg prior to the prescription as endorse |

| | Subsidy | | Fully Brand or |
|---|-------------------|---------|---|
| | (Manufacturer's P | | sidised Generic |
| | \$ | Per | Manufacturer |
| Hormone Replacement Therapy - S | Systemic | | |
| Oestrogens | | | |
| DESTRADIOL | | | |
| * Tab 1 mg | 4.12 | 28 OP | |
| | (11.10) | | Estrofem |
| * Tab 2 mg | | 28 OP | Estudion |
| K Gel (transdermal) 0.06% (750 mcg/actuatio | (11.10) | 80 g OP | Estrofem ✓ Estrogel |
| Patch 25 mcg per day | | 80 y OF | Estroger Estradiol TDP Mylan |
| | 13.50 | 0 | Estraderm MX \$29 |
| | 14.50 | | Estradetin MA 323 Estradot |
| | 21.35 | | ✓ Lyllana |
| a) No more than 2 patch per week | 21.00 | | -, |
| b) Only on a prescription | | | |
| Patch 50 mcg per day | | 8 | Estradiol TDP Mylan |
| | | | Estradiol Viatris |
| | 14.50 | | Estraderm MX S29 |
| | | | Estradiol Sandoz |
| | | | Estradot |
| | 21.55 | | 🗸 Lyllana |
| a) No more than 2 patch per week | | | |
| b) Only on a prescription | | | |
| Patch 75 mcg per day | | 8 | Estradiol TDP Mylan |
| | 11.50 | | Estradiol Viatris |
| | 14.50 | | Estradiol Sandoz Estradot |
| | 22.37 | | ✓ Lyllana |
| a) No more than 2 patch per week | 22.01 | | • Lynana |
| b) Only on a prescription | | | |
| Patch 100 mcg per day | | 8 | Estradiol TDP Mylan |
| | | | Estradiol Viatris |
| | 14.50 | | Estradiol Sandoz |
| | | | Estradot |
| | 15.50 | | Estraderm MX S29 |
| | 22.77 | | 🗸 Lyllana |
| a) No more than 2 patch per week | | | |
| b) Only on a prescription | | | |
| ESTRADIOL VALERATE | | | |
| 🖌 Tab 1 mg | | 84 | Progynova |
| Tab 2 mg | | 84 | Progynova |
| DESTROGENS | | | |
| Conjugated, equine tab 300 mcg | | 28 | |
| | (19.25) | _ | Premarin |
| Conjugated, equine tab 625 mcg | | 28 | D . |
| | (19.25) | | Premarin |

| | Subsidy (Manufacturer's Price) | | Fully Brand or ubsidised Generic |
|---|-----------------------------------|-----------|--|
| | (Manulacturer's Flice) \$ | Per | Manufacturer |
| Progestogens | | | |
| EDROXYPROGESTERONE ACETATE | | | |
| € Tab 2.5 mg | 6.56 | 30 | Provera |
| | 8.75 | 56 | Provera |
| Tab 5 mg | | 56 | Provera Provera |
| € Tab 10 mg | 20.13 | 100 30 | Provera Provera |
| • | | 00 | • Hovera |
| Progestogen and Oestrogen Combined Prepara | tions | | |
| ESTRADIOL WITH NORETHISTERONE | | | |
| Tab 1 mg with 0.5 mg norethisterone acetate | | 28 OP | |
| | (18.10) | | Kliovance |
| Tab 2 mg with 1 mg norethisterone acetate | | 28 OP | Klippost |
| Tab 2 mg with 1 mg porethistoropo apotato (10) and 2 mg | (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) | 20 01 | Trisequens |
| | (| | |
| Other Oestrogen Preparations | | | |
| ESTRIOL | | | |
| ► Tab 2 mg | 7 70 | 30 | Ovestin |
| | | 00 | <u>orodan</u> |
| Other Progestogen Preparations | | | |
| EVONORGESTREL | | | |
| Intra-uterine device 52 mg | 269.50 | 1 | Mirena |
| Intra-uterine device 13.5 mg | | 1 | ✓ Jaydess |
| | | | |
| Tab 100 mg | 133.57 | 100 | Provera HD |
| ORETHISTERONE | | | |
| Tab 5 mg – Up to 30 tab available on a PSO | | 30 | Primolut N |
| ROGESTERONE | | | |
| Cap 100 mg | | 30 | Utrogestan |
| | | | <u>j</u> |
| Thyroid and Antithyroid Agents | | | |
| ARBIMAZOLE | | | |
| AnDIMAZOLL ★ Tab 5 mg | | 100 | ✓ Neo-Mercazole |
| EVOTHYBOXINE | | | |
| Tab 25 mcg | | 90 | Synthroid |
| Tab 50 mcg | | 28 | ✓ Mercury Pharma |
| 0 | 5.79 | 90 | ✓ Synthroid |
| | 64.28 | 1,000 | Eltroxin |
| F Tablet 50 mcg | 12.86 | 200 | Eltroxin |
| • Tab 100 mcg | | 28 | Mercury Pharma |
| | 6.01 | 90 | Synthroid |
| | 66.78 | 1,000 | Eltroxin |
| Tablet 100 mcg | 13 36 | 200 | Eltroxin |

▲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) \$ | Subs Per | Fully sidised | Brand or Generic Manufacturer |
|---|---|-------------|------------------|-------------------------------------|
| PROPYLTHIOURACIL – Special Authority see SA1199 below – | Retail pharmacy | | | |
| Tab 50 mg | | 100 | 🖌 P | TU \$29 |

➡SA1199 Special Authority for Subsidy

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

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

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

Trophic Hormones

Growth Hormones

| SC | MATROPIN (OMNITROPE) – Special Authority see SA2032 | below – Retail pha | irmacy | |
|----|---|--------------------|--------|-------------------------------|
| * | Inj 5 mg cartridge | | i | Omnitrope |
| | Inj 10 mg cartridge | | 1 | Omnitrope |
| | Inj 15 mg cartridge | | 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: Fither:

- 1 Growth hormone deficiency causing symptomatic hypoglycaemia, or with other significant growth hormone deficient sequelae (e.g. cardiomyopathy, hepatic dysfunction) and diagnosed with GH < 5 mcg/l on at least two random blood samples in the first 2 weeks of life, or from samples during established hypoglycaemia (whole blood glucose < 2 mmol/l using a laboratory device); or
- 2 All of the following:
 - Height velocity < 25th percentile for age adjusted for bone age/pubertal status if appropriate over 6 or 12 months using the standards of Tanner and Davies (1985); and
 - 2.2 A current bone age is < 14 years (female patients) or < 16 years (male patients); and
 - 2.3 Peak growth hormone value of < 5.0 mcg per litre in response to two different growth hormone stimulation tests. In children who are 5 years or older, GH testing with sex steroid priming is required; and</p>
 - 2.4 If the patient has been treated for a malignancy, they should be disease free for at least one year based upon follow-up laboratory and radiological imaging appropriate for the malignancy, unless there are strong medical reasons why this is either not necessary or appropriate; and
 - 2.5 Appropriate imaging of the pituitary gland has been obtained.

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

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

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

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

continued...

All of the following:

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

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

All of the following:

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

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

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

Renewal — (short stature without growth hormone deficiency) only from a paediatric endocrinologist or endocrinologist.

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

All of the following:

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

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

All of the following:

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

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6.2 The patient has received a renal transplant and has received < 5mg/ m²/day of prednisone or equivalent for at least 6 months..

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

All of the following:

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

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

All of the following:

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

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months for applications meeting the following criteria:

All of the following:

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

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

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

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

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

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

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

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.

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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 | 1 |
|-----------|---|
|-----------|---|

| Implant 3.6 mg, syringe | 1 | ✓ <u>Zoladex</u> |
|--------------------------|---|------------------|
| Implant 10.8 mg, syringe | 1 | ✓ <u>Zoladex</u> |
| 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 |

| Vaen | pressin | A a o | niete |
|------|----------|--------------|--------|
| 1030 | pressili | Age | 111919 |

| DESMOPRESSIN | 47.00 | 30 | ✓ Minirin Melt |
|-------------------------------------|-------|-------|-----------------------------------|
| Wafer 120 mcg | | 30 | |
| DESMOPRESSIN ACETATE | | | |
| Tab 100 mcg | | 30 | Minirin |
| Tab 200 mcg | | 30 | Minirin |
| Inj 4 mcg per ml, 1 ml | 67.18 | 10 | 🖌 Minirin |
| ▲ Nasal spray 10 mcg per dose, 6 ml | | 60 OP | Desmopressin- |
| | | | PH&T |

| Other Endocrine Agents | | | |
|--|-------|---|------------------------------|
| CABERGOLINE | | | |
| Tab 0.5 mg – Maximum of 2 tab per prescription; can be | | | |
| waived by Special Authority see SA2070 below | 4.43 | 2 | Dostinex |
| | 17.94 | 8 | Dostinex |

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

Any of the following:

90

1 Hyperprolactinemia; or

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| continued | | | | |
| 2 Acromegaly*; or | | | | |
| 3 Inhibition of lactation. | | | | |
| Renewal — (for patients who have previously been funded upractitioner. Approvals valid without further renewal unless notif which has expired and the treatment remains appropriate and the Note: Indication marked with * is an unapproved indication. | ied where the patient I | nas pr | eviously he | |
| CLOMIFENE CITRATE | | | | |
| Tab 50 mg | 29.84 | 10 | 🗸 N | lylan |
| | | | | Clomiphen S29 |
| METYRAPONE | | | | |
| Cap 250 mg | 558.00 | 50 | 🗸 N | letopirone |

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| | ð | rei | • | Manufacturer |
| Anthelmintics | | | | |
| ALBENDAZOLE - Special Authority see SA1318 below - Reta | il pharmacy | | | |
| Tab 400 mg | | 60 | ✓ E | skazole S29 |
| ➡SA1318 Special Authority for Subsidy | | | | |
| Initial application only from an infectious disease specialist or | clinical microbiologist | . Approva | ls valid f | or 6 months where the |
| patient has hydatids. | involution Approx | ala valid fa | . C mont | ha whare the treatment |
| Renewal only from an infectious disease specialist or clinical m remains appropriate and the patient is benefitting from the treat | | ais valiu lu | | ins where the treatment |
| MEBENDAZOLE – Only on a prescription | | | | |
| Tab 100 mg | | 6 | 🗸 V | ermox |
| Oral liq 100 mg per 5 ml | | 15 ml | _ | <u> </u> |
| | (7.83) | | V | ermox |
| PRAZIQUANTEL | | | | |
| Tab 600 mg | 68.00 | 8 | ✓ B | liltricide |
| Authoritation | | | | |
| Antibacterials | | | | |
| a) For topical antibacterials, refer to DERMATOLOGICALS, pa | ge 65 | | | |
| b) For anti-infective eye preparations, refer to SENSORY ORG | ANS, page 267 | | | |
| Cephalosporins and Cephamycins | | | | |
| | | | | |
| CEFACLOR MONOHYDRATE Cap 250 mg | 25.85 | 100 | . | anbaxy-Cefaclor |
| Grans for oral lig 125 mg per 5 ml – Wastage claimable | | 100 ml | | anbaxy-Cefaclor |
| CEFALEXIN | | 100 11 | • • | andaxy octation |
| Cap 250 mg | 3.85 | 20 | √ 0 | ephalexin ABM |
| Cap 500 mg | | 20 | | ephalexin ABM |
| Grans for oral liq 25 mg per ml - Wastage claimable | 7.88 | 100 ml | 🖌 F | lynn |
| Grans for oral liq 50 mg per ml – Wastage claimable | 10.38 | 100 ml | | lynn |
| | 11.75 | | ✓ C | efalexin Sandoz |
| CEFAZOLIN – Subsidy by endorsement | | | | |
| Only if prescribed for dialysis or cellulitis in accordance with | a Health NZ Hospita | approved | l protoco | I and the prescription is |
| endorsed accordingly. Inj 500 mg vial | 3 30 | 5 | 10 | efazolin-AFT |
| Inj 1 g vial | | 5 | | cefazolin-AFT |
| lnj 2 g vial | | 5 | | efazolin-AFT |
| CEFTRIAXONE – Subsidy by endorsement | | | _ | |
| a) Up to 10 inj available on a PSO | | | | |
| b) Subsidised only if prescribed for a dialysis or cystic fibro | sis patient, or the trea | atment of g | gonorrho | ea, or the treatment of |
| pelvic inflammatory disease, or the treatment of suspect | ed meningococcal dis | sease, and | the pre | scription or PSO is |
| endorsed accordingly. | | | | |
| Inj 500 mg vial | | 1 5 | | eftriaxone-AFT eftriaxone-AFT |
| | | 5 | • [| |
| CEFUROXIME AXETIL – Subsidy by endorsement Only if prescribed for prophylaxis of endocarditis and the pr | escription is endorsed | laccordin | alv | |
| Tab 250 mg | | 20 | | scend- |
| = v mg | | 20 | | Cefuroxime S29 |
| | | | | |
| | | | | |

| | Subsidy (Manufacturer's Price) \$ | F Subsidi Per | Fully ised | Brand or Generic Manufacturer |
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| 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 | 30 | Apo-Azithromycin |
| Tab 500 mg - Up to 8 tab available on a PSO2.57 | 2 | Zithromax |
| Grans for oral liq 200 mg per 5 ml (40 mg per ml) – Wastage | | |
| claimable | 15 ml | Zithromax |
| | | |

⇒SA1683 Special Authority for Waiver of Rule

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

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

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

All of the following:

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

Note: Indications marked with * are unapproved indications.

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

All of the following:

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

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

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

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

| Tab 250 mg7.31 | 12 | Klaricid S29 |
|--|-------|----------------------------------|
| 8.53 | 14 | Klacid |
| Grans for oral liq 250 mg per 5 ml – Wastage claimable | 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:

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|------------------------|------------|--------------|
| (Manufacturer's Price) | Subsidised | Generic |
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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 | | 1 | Erythrocin IV |
|--|-------|--------|---|
| ERYTHROMYCIN ETHYL SUCCINATE | | | - |
| Tab 400 mg | | 100 | E-Mycin |
| a) Up to 20 tab available on a PSOb) Up to 2 x the maximum PSO quantity for RFPP | | | |
| Grans for oral liq 200 mg per 5 ml | 6.53 | 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 | 9.41 | 100 ml | ✓ E-Mycin |
| a) Up to 200 ml available on a PSOb) Wastage claimable | | | |
| ROXITHROMYCIN | | | |
| Tab 150 mg | 13.19 | 50 | ✓ <u>Arrow-</u> <u>Roxithromycin</u> |
| Tab 300 mg | 25.00 | 50 | ✓ <u>Arrow-</u> <u>Roxithromycin</u> |

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|---|------------------------------|---------------|-----------------|---------------------------|
| Penicillins | \$ | Per | <u> </u> | Manufacturer |
| AMOXICILLIN | | | | |
| Cap 250 mg | 27.50 | 500 | 🗸 <u>Mi</u> | ro-Amoxicillin |
| a) Up to 30 cap available on a PSO | | | | |
| b) Up to 10 x the maximum PSO quantity for RFPP Cap 500 mg | 41 00 | 500 | 🖌 Mi | ro-Amoxicillin |
| a) Up to 30 cap available on a PSO | | 500 | • <u>IVII</u> | IO AMOXICIIIII |
| b) Up to 10 x the maximum PSO quantity for RFPP | | | | |
| Grans for oral liq 125 mg per 5 ml | 2.22 | 100 ml | 🗸 🗸 | phamox 125 |
| a) Up to 200 ml available on a PSO | | | | |
| b) Wastage claimable | 0.01 | 100 | | |
| Grans for oral liq 250 mg per 5 ml | 2.81 | 100 ml | ✓ <u>AI</u> | phamox 250 |
| a) Up to 300 ml available on a PSO b) Up to 10 x the maximum PSO guantity for RFPP | | | | |
| c) Wastage claimable | | | | |
| Inj 250 mg vial | | 10 | 🖌 Ibi | amox |
| Inj 500 mg vial | 17.43 | 10 | | amox |
| Inj 1 g vial – Up to 5 inj available on a PSO | 21.64 | 10 | 🗸 Ibi | amox |
| AMOXICILLIN WITH CLAVULANIC ACID | | | | |
| Tab 500 mg with clavulanic acid 125 mg – Up to 30 tab | | | | // |
| available on a PSO | | 10 | ✓ <u>Cu</u> | iram Duo 500/125 |
| Grans for oral liq amoxicillin 25 mg with clavulanic acid 6.2 per ml | - | 100 ml | ۸. | Igmentin |
| a) Up to 200 ml available on a PSO | 0.50 | 100 111 | • A | iginentin |
| b) Wastage claimable | | | | |
| c) Augmentin to be Principal Supply on 1 May 2025 | | | | |
| Grans for oral liq amoxicillin 50 mg with clavulanic acid 12. | | | | |
| per ml – Up to 200 ml available on a PSO | | 100 ml OP | 🗸 Cu | |
| | 5.61 | | | noxiclav Devatis Forte |
| Amoxiclav Devatis Forte to be Principal Supply on 1 Ju | ine 2025 | | I | Fonte |
| (Curam Grans for oral lig amoxicillin 50 mg with clavulanic acid | | be delisted 1 | lune 202 | 5) |
| BENZATHINE BENZYLPENICILLIN | 01 | | | , |
| Inj 900 mg (1.2 million units) in 2.3 ml syringe – Up to 5 inj | | | | |
| available on a PSO | | 10 | 🗸 Bi | cillin LA |
| BENZYLPENICILLIN SODIUM [PENICILLIN G] | | | | |
| Inj 600 mg (1 million units) vial – Up to 5 inj available on a | PSO 16.50 | 10 | ✓ <u>Sa</u> | ndoz |

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| | (International Contraction of the second sec | Per | | Manufacturer |
| LUCLOXACILLIN | | | | |
| Cap 250 mg – Up to 30 cap available on a PSO | | 250 | 1 | Flucloxacillin-AFT |
| | 22.58 | 200 | | Staphlex |
| Cap 500 mg – Up to 30 cap available on a PSO | | 500 | | Flucloxacillin-AFT |
| | 72.71 | 000 | | Staphlex |
| Grans for oral liq 25 mg per ml | | 100 m | - | AFT |
| a) Up to 200 ml available on a PSO | | 100 111 | | |
| b) Wastage claimable | | | | |
| Grans for oral liq 50 mg per ml | E 00 | 100 m | | AET |
| | | 100 m | | <u>AFT</u> |
| a) Up to 200 ml available on a PSO | | | | |
| b) Wastage claimable | | | | |
| Inj 250 mg vial | | 10 | | Flucloxin |
| Inj 500 mg vial | 45.63 | 10 | | Flucloxin |
| Inj 1 g vial – Up to 5 inj available on a PSO | 6.00 | 5 | 1 | Flucil |
| Flucloxacillin-AFT Cap 250 mg to be delisted 1 August 2025) | | | | |
| Flucloxacillin-AFT Cap 500 mg to be delisted 1 August 2025) | | | | |
| HENOXYMETHYLPENICILLIN (PENICILLIN V) | | | | |
| Cap 250 mg – Up to 30 cap available on a PSO | 7 68 | 50 | 1 | Cilicaine VK |
| Cap 500 mg | | 50 | | Cilicaine VK |
| a) Up to 20 cap available on a PSO | | 50 | • | <u>onicanic vit</u> |
| b) Up to 2 x the maximum PSO quantity for RFPP | | | | |
| Grans for oral liq 125 mg per 5 ml | 2.40 | 100 m | | AET |
| | | 100 11 | . • | <u>AFT</u> |
| a) Up to 200 ml available on a PSO | | | | |
| b) Wastage claimable | | | | |
| Grans for oral liq 250 mg per 5 ml | 4.24 | 100 m | | <u>AFT</u> |
| a) Up to 300 ml available on a PSO | | | | |
| b) Up to 2 x the maximum PSO quantity for RFPP | | | | |
| c) Wastage claimable | | | | |
| Tetracyclines | | | | |
| OXYCYCLINE | | | | |
| Tab 100 mg – Up to 30 tab available on a PSO | | 500 | 1 | Doxine |
| | | | - | |
| | | | | |
| Tab 50 mg – Additional subsidy by Special Authority see | - - - | ~~ | | |
| SA1355 below – Retail pharmacy | | 60 | | |
| | (12.05) | | | Mino-tabs |
| ← Cap 100 mg | | 100 | | |
| | (52.04) | | | Minomycin |
| SA1355 Special Authority for Manufacturers Price | | | | |
| nitial application from any relevant practitioner. Approvals va | alid without further ren | ewal u | nless notif | ied where the patient ha |
| osacea. | | | | |
| ETRACYCLINE – Special Authority see SA1332 below – Ret | ail pharmacy | | | |
| Tab 250 mg | | 28 | 1 | Accord S29 |
| | | | | |

Both: 1 For the eradication of helicobacter pylori following unsuccessful treatment with appropriate first-line therapy; and

2 For use only in combination with bismuth as part of a quadruple therapy regimen.

| | Subsidy (Manufacturer's Price) \$ | Sub Per | Fully sidised | Brand or Generic Manufacturer |
|---|---|------------|------------------|-------------------------------------|
| Other Antibiotics | Ŷ | | | manufactoron |
| For topical antibiotics, refer to DERMATOLOGICALS, page 65 | | | | |
| CIPROFLOXACIN | | | | |
| Recommended for patients with any of the following: | | | | |
| i) microbiologically confirmed and clinically significant pse | udomonas infection: | or | | |
| ii) prostatitis; or | , | | | |
| iii) pyelonephritis; or | | | | |
| iv) gonorrhoea. | | | | |
| Tab 250 mg – Up to 5 tab available on a PSO | | 28 | ~ 1 | pca-Ciprofloxacin |
| Tab 500 mg – Up to 5 tab available on a PSO | | 28 | | pca-Ciprofloxacin |
| Tab 750 mg | 4.80 | 28 | ✓ 1 | pca-Ciprofloxacin |
| LINDAMYCIN | | | | |
| Cap hydrochloride 150 mg | | 24 | | Dalacin C |
| Inj 150 mg per ml, 4 ml ampoule | 35.10 | 10 | ✓ 1 | lameln |
| COLISTIN SULPHOMETHATE – Retail pharmacy-Specialist – S | | | | |
| Only if prescribed for dialysis or cystic fibrosis patient and the | | | | |
| Inj 150 mg | | 1 | | Colistin-Link |
| Inj 2 million iu, 10 ml vial Colistin-Link Inj 150 mg to be delisted 1 June 2025) | | 10 | v (| Colomycin S29 |
| ENTAMICIN SULPHATE | | | | |
| Inj 40 mg per ml, 2 ml vial – Subsidy by endorsement | | 5 | ✓ (| Cidomycin P/Free S29 |
| Only if prescribed for a dialysis or cystic fibrosis patient c endorsed accordingly. | or complicated urinary | rract inf | ection a | nd the prescription is |
| Inj 10 mg per ml, 1 ml ampoule – Subsidy by endorsement | | 5 | √ [| DBL Gentamicin |
| Only if prescribed for a dialysis or cystic fibrosis patient of endorsed accordingly. | | ract info | | |
| Inj 10 mg per ml, 2 ml ampoule - Subsidy by endorsement | 91.00 | 5 | ۷ ۷ | Nockhardt S29 |
| Only if prescribed for a dialysis or cystic fibrosis patient or endorsed accordingly. | or complicated urinary | rract inf | ection a | nd the prescription is |
| Inj 40 mg per ml, 2 ml ampoule - Subsidy by endorsement | | 10 | ✓ (| Gentamicin |
| | | | | Amdipharm S29 |
| | | | - | Pfizer |
| | 91.90 | 50 | ✓ (| Gentamicin |
| | | | | Noridem S29 |
| Only if prescribed for a dialysis or cystic fibrosis patient of endorsed accordingly. | or complicated urinary | rract info | ection a | nd the prescription is |
| IOXIFLOXACIN – Special Authority see SA1740 below – Retail No patient co-payment payable | pharmacy | | | |
| Tab 400 mg | | 5 | 1 | Avelox |
| •SA1740 Special Authority for Subsidy | | - | | |
| itial application — (Tuberculosis) only from a respiratory speed or applications meeting the following criteria: | ecialist or infectious d | isease sp | pecialist | . Approvals valid for 1 ye |
| ny of the following: | | | | |

continued...

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

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

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

continued...

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; ٥r
- 2 Mycobacterium avium-intracellulare complex not responding to other therapy or where such therapy is contraindicated.*; or
- 3 Patient is under five years of age and has had close contact with a confirmed multi-drug resistant tuberculosis case.

Note: Indications marked with * are unapproved indications.

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

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

1 Has nucleic acid amplification test (NAAT) confirmed Mycoplasma genitalium* and is symptomatic; and

- 2 Either:
 - 2.1 Has tried and failed to clear infection using azithromycin; or
 - 2.2 Has laboratory confirmed azithromycin resistance; and
- 3 Treatment is only for 7 days.

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

Note: Indications marked with * are unapproved indications.

PAROMOMYCIN – Special Authority see SA1689 below – Retail pharmacy

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: Fither:

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

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

Either:

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

PYRIMETHAMINE - Special Authority see SA1328 below - Retail pharmacy

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.

| | Subsidy (Manufacturer's Price) \$ | Per | Fully Subsidised | |
|---|---|--------|---------------------|------------------------------|
| SODIUM FUSIDATE [FUSIDIC ACID] | | | | |
| Tab 250 mg | 135.70 | 36 | 1 | Fucidin |
| SULFADIAZINE SODIUM - Special Authority see SA1331 below | – Retail pharmacy | | | |
| Tab 500 mg | 150.70 | 100 | 1 | Sulfadiazin-Heyl S29 |
| | E 40.00 | 56 | | We alsh and ton |
| | 543.20 | 56 | • | Wockhardt S29 |
| SA1331 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid the following criteria: Any of the following: For the treatment of toxoplasmosis in patients with HIV for 2 For pregnant patients for the term of the pregnancy; or | | | nless notif | ied for applications meeting |
| 3 For infants with congenital toxoplasmosis until 12 months | of age. | | | |
| TOBRAMYCIN | | | | |
| Inj 40 mg per ml, 2 ml vial – Subsidy by endorsement | | 5 | | Tobramycin (Viatris) |
| Only if prescribed for dialysis or cystic fibrosis patient and | the prescription is e | endor | sed accord | lingly. |
| Solution for inhalation 60 mg per ml, 5 ml – Subsidy by endorsement | 395.00 | 56 dos | | Tobramycin BNM |
| a) Wastage claimable | | | | <u>Tobraniyoni Brini</u> |
| b) Only if prescribed for a cystic fibrosis patient and the | prescription is endor | sed a | ccordingly | |
| TRIMETHOPRIM | | | | |
| * Tab 300 mg – Up to 30 tab available on a PSO | 27.83 | 50 | 1 | TMP |
| TRIMETHOPRIM WITH SULPHAMETHOXAZOLE [CO-TRIMOX/ | AZOLE] | | | |
| * Tab trimethoprim 80 mg and sulphamethoxazole 400 mg - L | | | | |
| to 30 tab available on a PSO | | 500 | ~ | Trisul |
| * Oral liq 8 mg sulphamethoxazole 40 mg per ml – Up to 200 r available on a PSO | | 100 m | n 🖌 | Deprim |
| VANCOMYCIN – Subsidy by endorsement | 4.00 | 100 11 | | Deprim |
| Only if prescribed for a dialysis or cystic fibrosis patient or for | prophylaxis of endo | cardit | is or for tre | atment of Clostridium |
| difficile following metronidazole failure and the prescription is | | | | |
| Inj 500 mg vial | 3.38 | 1 | 1 | <u>Mylan</u> |
| Antifungolo | | | | |
| Antifungals | | | | |
| a) For topical antifungals refer to DERMATOLOGICALS, page 66b) For topical antifungals refer to GENITO URINARY, page 78 | 3 | | | |
| FLUCONAZOLE | | | | |
| Cap 50 mg | | 28 | | Mylan |
| Cap 150 mg | | 1 | | <u>Mylan</u> Mulan |
| Cap 200 mg Powder for oral suspension 10 mg per ml – Special Authority | | 28 | • | <u>Mylan</u> |
| see SA1359 below – Retail pharmacy Wastage claimable | | 35 m | ✓ | Diflucan |
| ► SA1359 Special Authority for Subsidy | | | | |
| Initial application — (Systemic candidiasis) from any relevant meeting the following criteria: | practitioner. Approv | als v | alid for 6 w | eeks for applications |

| (M | Subsidy anufacturer's Pric | e) Subs | Fully sidised | Brand or Generic |
|--|-------------------------------|---------------|------------------|--------------------------|
| ι, | \$ | Per | 1 | Manufacturer |
| ontinued | | | | |
| Both: | | | | |
| Patient requires prophylaxis for, or treatment of systemic cand Patient is unable to swallow capsules. | didiasis; and | | | |
| nitial application — (Immunocompromised) from any relevant pr neeting the following criteria: Il of the following: | actitioner. App | orovals valid | for 6 m | onths for applications |
| Patient is immunocompromised; and Patient is at moderate to high risk of invasive fungal infection; Patient is unable to swallow capsules. | ; and | | | |
| Renewal — (Systemic candidiasis) from any relevant practitioner. billowing criteria: Both: | Approvals val | id for 6 week | s for ap | plications meeting the |
| 1 Patient requires prophylaxis for, or treatment of systemic can 2 Patient is unable to swallow capsules. | didiasis; and | | | |
| Renewal — (Immunocompromised) from any relevant practitioner bllowing criteria: | | lid for 6 mon | ths for a | applications meeting the |
| TRACONAZOLE | | | | |
| Cap 100 mg | 6.83 | 15 | 🗸 lt | razole |
| | 27.32 | 60 | 🗸 lt | racap S29 |
| Oral lig 10 mg per ml – Special Authority see SA1322 below – | | | ✓ It | |

⇒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 | 30 100 | Burel \$29 Strides Shasun \$29 Taro \$29 Teva- Ketoconazole \$29 |
|---|------------------|-----------|---|
| NYSTATIN | | | |
| Tab 500,000 u | 14.16 | 50 | |
| | (17.09) | | Nilstat |
| Cap 500,000 u | 12.81 | 50 | |
| | (15.47) | | Nilstat |
| POSACONAZOLE - Special Authority see SA2383 on the next | page - Retail ph | armacy | |
| Tab modified-release 100 mg | | 24 | Posaconazole Juno |
| Oral liq 40 mg per ml | | 105 ml OP | ✓ Devatis |

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

⇒SA2383 Special Authority for Subsidy

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

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.

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

Both:

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

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

Both:

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

TERBINAFINE

| * Tab 250 mg | 8.97 | 84 | Deolate |
|--|---------------|-------|-----------------------------|
| VORICONAZOLE - Special Authority see SA2384 on the next page | – Retail phar | macy | |
| Tab 50 mg | 71.00 | 56 | Vttack |
| Tab 200 mg | 263.00 | 56 | Vttack |
| Powder for oral suspension 40 mg per ml - Wastage | | | |
| claimable | ,523.22 | 70 ml | Vfend |

▲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 | Ful | lly Brand or | |
|------------------------|-----------|----------------------------------|--|
| (Manufacturer's Price) | Subsidise | ed Generic | |
| \$ | Per • | Manufacturer | |

⇒SA2384 Special Authority for Subsidy

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

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

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

All of the following:

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

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

Both:

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

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

Both:

1 The patient is at risk of invasive fungal infection; and

2 Either:

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

Antimalarials

| PRIMAQUINE - Special Authority see SA1684 on the next page - F | Retail pharmacy | | | |
|--|-----------------|-----|---|--------|
| Tab 15 mg | 400.00 | 100 | ✓ | Sanofi |

Primaguine S29

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

➡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:

.. .. _ . .

| I he patient has relapsed vivax or ovale mail Primaquine is to be given for a maximum of | | | |
|--|------------------------------------|---------------------------------|---|
| Antitrichomonal Agents | | | |
| METRONIDAZOLE Tab 200 mg – Up to 30 tab available on a PS0 Tab 400 mg – Up to 15 tab available on a PS0 Oral liq benzoate 200 mg per 5 ml Suppos 500 mg ORNIDAZOLE Tab 500 mg | D4.29 25.00 24.48 | 250 21 100 ml 10 10 | <u>Metronidamed</u> <u>Metronidamed</u> Flagyl-S Flagyl <u>Arrow-Ornidazole</u> |
| Antituberculotics and Antileprotics | | | |
| Note: There is no co-payment charge for all pharm immigration status. | naceuticals listed in the Antitube | rculotics and | Antileprotics group regardless of |
| BEDAQUILINE – Special Authority see SA2244 be No patient co-payment payable Tab 100mg | . , | 24 OP | ✓ Sirturo |
| Initial application — (multi-drug resistant tuberd applications meeting the following criteria: Both: | culosis) from any relevant prac | titioner. App | rovals valid for 6 months for |
| The person has multi-drug resistant tubercu Ministry of Health's Tuberculosis Clinical Ne of the treatment regimen. | (); | al case and r | recommends bedaquiline as part |
| CLOFAZIMINE – Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the dermatologist. * Cap 50 mg | | is disease ph 100 | ysician, clinical microbiologist or |
| CYCLOSERINE – Retail pharmacy-Specialist | | | |
| a) No patient co-payment payable b) Prescriptions must be written by, or on the respiratory physician. | recommendation of, an infectiou | is disease ph | ysician, clinical microbiologist or |
| Cap 250 mg | | 60 | Cyclorin S29 |

| | Subsidy (Manufacturer's Price \$ |) (Per | Fully Subsidised | |
|--|--|---|--|---|
| APSONE – Retail pharmacy-Specialist | | | | |
| a) No patient co-payment payable | | | | |
| b) Prescriptions must be written by, or on the recommendermatologist | | disease | e physiciai | n, clinical microbiologist c |
| Tab 25 mg | | 100 | | Dapsone |
| Tab 100 mg | | 100 | <i>✓</i> | Dapsone |
| THAMBUTOL HYDROCHLORIDE – Retail pharmacy-Speci | ialist | | | |
| a) No patient co-payment payable b) Prescriptions must be written by, or on the recomment respiratory physician | dation of, an infectious | disease | physicia | n, clinical microbiologist c |
| Tab 100 mg | 85 73 | 100 | 1 | EMB Fatol S29 |
| Tab 400 mg | | 56 | - | Myambutol \$29 |
| 5 | | 50 | • | wyambator |
| ONIAZID – Retail pharmacy-Specialist | | | | |
| a) No patient co-payment payable b) Prescriptions must be written by, or on the recommen- microbiologist, dermatologist or public health physicial | | edicine | physician | , paediatrician, clinical |
| Tab 100 mg | | 100 | 1 | PSM |
| ů – | 94.50 | | ✓ | Isoniazid Teva S29 |
| | 327.41 | | ✓ | Noumed Isoniazid |
| Noumed Isoniazid to be Principal Supply on 1 May 20 SM Tab 100 mg to be delisted 1 May 2025) SONIAZID WITH RIFAMPICIN – Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommender (Commender) | | edicine | nhysician | . paediatrician. clinical |
| s, i recomptione much be written by, or on the recommen | ualion oi, an interna m | cultille | priyololuli | |
| microbiologist, dermatologist or public health physicial | n | | | |
| microbiologist, dermatologist or public health physicial Tab 100 mg with rifampicin 150 mg | n 89.82 | 100 | ✓ | Rifinah |
| microbiologist, dermatologist or public health physicial Tab 100 mg with rifampicin 150 mg Tab 150 mg with rifampicin 300 mg | n 89.82 179.13 | | ✓ | |
| microbiologist, dermatologist or public health physician Tab 100 mg with rifampicin 150 mg Tab 150 mg with rifampicin 300 mg NEZOLID – Special Authority see SA2234 below – Retail p | n 89.82 179.13 | 100 | ✓ | Rifinah |
| microbiologist, dermatologist or public health physician Tab 100 mg with rifampicin 150 mg Tab 150 mg with rifampicin 300 mg NEZOLID – Special Authority see SA2234 below – Retail p No patient co-payment payable | n | 100 100 | 1 | <u>Rifinah</u> Rifinah |
| microbiologist, dermatologist or public health physician Tab 100 mg with rifampicin 150 mg Tab 150 mg with rifampicin 300 mg NEZOLID – Special Authority see SA2234 below – Retail p No patient co-payment payable Tab 600 mg | n | 100 100 10 | 5 5 5 | <u>Rifinah</u> Rifinah Zyvox |
| microbiologist, dermatologist or public health physician Tab 100 mg with rifampicin 150 mg Tab 150 mg with rifampicin 300 mg NEZOLID – Special Authority see SA2234 below – Retail p No patient co-payment payable Tab 600 mg Oral liq 20 mg per ml | n | 100 100 | 5 5 5 | <u>Rifinah</u> Rifinah |
| microbiologist, dermatologist or public health physician Tab 100 mg with rifampicin 150 mg Tab 150 mg with rifampicin 300 mg NEZOLID – Special Authority see SA2234 below – Retail p No patient co-payment payable Tab 600 mg | n | 100 100 150 ml ioner. <i>A</i> | 4 Approvals | <u>Rifinah</u> <u>Rifinah</u> <u>Zyvox</u> Zyvox valid for 18 months for |
| microbiologist, dermatologist or public health physician Tab 100 mg with rifampicin 150 mg Tab 150 mg with rifampicin 300 mg NEZOLID – Special Authority see SA2234 below – Retail p No patient co-payment payable Tab 600 mg Oral liq 20 mg per ml SA2234 Special Authority for Subsidy itial application — (multi-drug resistant tuberculosis) fr oplications meeting the following criteria: oth: 1 The person has multi-drug resistant tuberculosis (MDF 2 Ministry of Health's Tuberculosis Clinical Network has the treatment regimen. | n | 100 100 150 ml ioner. <i>A</i> | 4 Approvals | Rifinah Rifinah Zyvox Zyvox valid for 18 months for |
| microbiologist, dermatologist or public health physician Tab 100 mg with rifampicin 150 mg Tab 150 mg with rifampicin 300 mg NEZOLID – Special Authority see SA2234 below – Retail p No patient co-payment payable Tab 600 mg Oral liq 20 mg per ml SA2234 Special Authority for Subsidy itial application — (multi-drug resistant tuberculosis) fr oplications meeting the following criteria: oth: 1 The person has multi-drug resistant tuberculosis (MDF 2 Ministry of Health's Tuberculosis Clinical Network has the treatment regimen. ARA-AMINO SALICYLIC ACID – Retail pharmacy-Specialis | n | 100 100 150 ml ioner. <i>A</i> | 4 Approvals | Rifinah Rifinah Zyvox Zyvox valid for 18 months for |
| microbiologist, dermatologist or public health physician Tab 100 mg with rifampicin 150 mg Tab 150 mg with rifampicin 300 mg NEZOLID – Special Authority see SA2234 below – Retail p No patient co-payment payable Tab 600 mg Oral liq 20 mg per ml SA2234 Special Authority for Subsidy itial application — (multi-drug resistant tuberculosis) fr oplications meeting the following criteria: oth: 1 The person has multi-drug resistant tuberculosis (MDF 2 Ministry of Health's Tuberculosis Clinical Network has the treatment regimen. ARA-AMINO SALICYLIC ACID – Retail pharmacy-Specialis a) No patient co-payment payable b) Prescriptions must be written by, or on the recommend | n | 100 100 150 ml ioner. <i>A</i> case ar | Approvals | Rifinah Rifinah Zyvox Zyvox valid for 18 months for nends linezolid as part o |
| microbiologist, dermatologist or public health physician Tab 100 mg with rifampicin 150 mg Tab 150 mg with rifampicin 300 mg NEZOLID – Special Authority see SA2234 below – Retail p No patient co-payment payable Tab 600 mg Oral liq 20 mg per ml SA2234 Special Authority for Subsidy itial application — (multi-drug resistant tuberculosis) fr oplications meeting the following criteria: oth: 1 The person has multi-drug resistant tuberculosis (MDF 2 Ministry of Health's Tuberculosis Clinical Network has the treatment regimen. ARA-AMINO SALICYLIC ACID – Retail pharmacy-Specialis a) No patient co-payment payable | n | 100 100 150 ml ioner. <i>A</i> case ar | Approvals nd recomm | Rifinah Rifinah Zyvox Zyvox valid for 18 months for nends linezolid as part o |
| microbiologist, dermatologist or public health physician Tab 100 mg with rifampicin 150 mg Tab 150 mg with rifampicin 300 mg NEZOLID – Special Authority see SA2234 below – Retail p No patient co-payment payable Tab 600 mg Oral liq 20 mg per ml SA2234 Special Authority for Subsidy itial application — (multi-drug resistant tuberculosis) fr oplications meeting the following criteria: oth: 1 The person has multi-drug resistant tuberculosis (MDF 2 Ministry of Health's Tuberculosis Clinical Network has the treatment regimen. ARA-AMINO SALICYLIC ACID – Retail pharmacy-Specialis a) No patient co-payment payable b) Prescriptions must be written by, or on the recommen- respiratory physician Grans for oral liq 4 g sachet | n | 100 100 150 ml ioner. <i>A</i> case ar disease | Approvals nd recomm | Rifinah Rifinah Zyvox Zyvox valid for 18 months for nends linezolid as part o t, clinical microbiologist o |
| microbiologist, dermatologist or public health physician Tab 100 mg with rifampicin 150 mg Tab 150 mg with rifampicin 300 mg NEZOLID – Special Authority see SA2234 below – Retail p No patient co-payment payable Tab 600 mg Oral liq 20 mg per ml *SA2234 Special Authority for Subsidy itial application — (multi-drug resistant tuberculosis) fr oplications meeting the following criteria: oth: 1 The person has multi-drug resistant tuberculosis (MDF 2 Ministry of Health's Tuberculosis Clinical Network has the treatment regimen. ARA-AMINO SALICYLIC ACID – Retail pharmacy-Specialis a) No patient co-payment payable b) Prescriptions must be written by, or on the recommen- respiratory physician Grans for oral liq 4 g sachet | n | 100 100 150 ml ioner. <i>A</i> case ar disease | Approvals nd recomm | Rifinah Rifinah Zyvox Zyvox valid for 18 months for nends linezolid as part o t, clinical microbiologist o |
| microbiologist, dermatologist or public health physician Tab 100 mg with rifampicin 150 mg. Tab 150 mg with rifampicin 300 mg. NEZOLID – Special Authority see SA2234 below – Retail p No patient co-payment payable Tab 600 mg. Oral liq 20 mg per ml. SA2234 Special Authority for Subsidy itial application — (multi-drug resistant tuberculosis) fr poplications meeting the following criteria: the person has multi-drug resistant tuberculosis (MDF Ministry of Health's Tuberculosis Clinical Network has the treatment regimen. ARA-AMINO SALICYLIC ACID – Retail pharmacy-Specialis a) No patient co-payment payable b) Prescriptions must be written by, or on the recomment respiratory physician | n | 100 100 150 ml ioner. <i>A</i> case ar disease 30 | Approvals and recommon specialis | Rifinah Rifinah Zyvox Zyvox valid for 18 months for nends linezolid as part o t, clinical microbiologist o Paser 529 |

| | Subsidy | | Fully | Brand or |
|---|-------------------------|---------------|--------------|---------------------------|
| | (Manufacturer's Price | | sidised | Generic |
| | \$ | Per | 1 | Manufacturer |
| PYRAZINAMIDE – Retail pharmacy-Specialist | | | | |
| a) No patient co-payment payable | | | | |
| b) Prescriptions must be written by, or on the recommend respiratory physician | ation of, an infectious | disease ph | ysician, c | linical microbiologist or |
| * Tab 500 mg | 64.95 | 100 | 🗸 AF | T-Pyrazinamide |
| RIFABUTIN – Retail pharmacy-Specialist | | | | |
| a) No patient co-payment payable | | | | |
| b) Prescriptions must be written by, or on the recommend | ation of, an infectious | disease ph | ysician, re | espiratory physician or |
| gastroenterologist | | | | |
| * Cap 150 mg | 353.71 | 30 | 🗸 My | cobutin |
| RIFAMPICIN – Subsidy by endorsement | | | | |
| a) No patient co-payment payable | | | | |
| b) For confirmed recurrent Staphylococcus aureus infection | on in combination with | other effect | tive anti-s | taphylococcal |
| antimicrobial based on susceptibilities and the prescrip | tion is endorsed accor | dingly; can | be waive | d by endorsement - |
| Retail pharmacy - Specialist. Specialist must be an int | ernal medicine physic | ian, clinical | microbiol | ogist, dermatologist, |
| paediatrician, or public health physician. | | | | |
| * Cap 150 mg | | 100 | ✓ <u>Rif</u> | |
| * Cap 300 mg | | 100 | ✓ <u>Rif</u> | |
| W Over lie 100 mer mer E mi | 10.00 | 00 ml | | adin Sanofi |
| * Oral liq 100 mg per 5 ml | 12.60 | 60 ml | ✓ <u>Rif</u> | adin |
| Antivirals | | | | |
| For eye preparations refer to Eye Preparations, Anti-Infective F | Preparations, page 26 | 7 | | |
| Hepatitis B Treatment | | | | |
| ENTECAVIR | | | | |
| * Tab 0.5 mg | | 30 | 🖌 En | tecavir (Rex) |
| LAMIVUDINE - Special Authority see SA1685 below - Retail | | | | ····· |
| Tab 100 mg | | 28 | 🗸 Zei | lam |
| Oral lig 5 mg per ml | | 40 ml OP | ✓ Zet | |
| ■SA1685 Special Authority for Subsidy | | | | |
| Initial application only from a relevant specialist or medical pr | actitioner on the recor | nmendatio | of a rolo | vant specialist |
| Approvals valid for 1 year where used for the treatment or prev | | mondation | | vant specialist. |
| Renewal from any relevant practitioner. Approvals valid for 2 v | | the treatme | nt or prev | ention of hepatitis B. |
| TENOFOVIR DISOPROXIL | , | | | |
| Tenofovir disoproxil prescribed under endorsement for the | treatment of HIV is in | cluded in th | e count o | f up to 4 subsidised |
| antiretrovirals for the purposes of Special Authority SA213 | | | | |
| * Tab 245 mg (300 mg as a maleate) | | 30 | 🗸 Tei | nofovir Disoproxil |
| 5 (5 , | | | | /iatris |
| * Tab 245 mg (300 mg as a fumarate) | | 30 | 🗸 Ric | ovir S29 |
| | | | | |
| Herpesvirus Treatments | | | | |
| ACICLOVIR | | | | |
| * Tab dispersible 200 mg | | 25 | ✓ <u>Lo</u> | |
| * Tab dispersible 400 mg | | 56 | ✓ Lo | |
| * Tab dispersible 800 mg | 6.46 | 35 | ✓ <u>Lo</u> | vir |
| | | | | |

▲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 | |
|--|---|-----|---------------------|---------------------------|
| VALACICLOVIR | | | | |
| Tab 500 mg | 9.64 | 30 | ✓ | Vaclovir |
| Tab 1,000 mg | 17.78 | 30 | 1 | Vaclovir |
| VALGANCICLOVIR - Special Authority see SA1993 below - Re | tail pharmacy | | | |
| Tab 450 mg | | 60 | 1 | Valganciclovir Viatris |

⇒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: Fither

1 Both:

- 1.1 Patient has undergone a solid organ transplant and received anti-thymocyte globulin and requires valganciclovir therapy for CMV prophylaxis; and
- 1.2 Patient is to receive a maximum of 90 days of valganciclovir prophylaxis following anti-thymocyte globulin; or
- 2 Both:
 - 2.1 Patient has received pulse methylprednisolone for acute rejection and requires further valganciclovir therapy for CMV prophylaxis; and
 - 2.2 Patient is to receive a maximum of 90 days of valganciclovir prophylaxis following pulse methylprednisolone.

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

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

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

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

All of the following:

1 Patient has undergone a lung transplant; and

2 Either:

- 2.1 The donor was cytomegalovirus positive and the patient is cytomegalovirus negative; or
- 2.2 The recipient is cytomegalovirus positive; and
- 3 Patient has a high risk of CMV disease.

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:

| | Subsidy | | Fully | Brand or |
|--|------------------------|---------|----------------|--------------------------|
| | (Manufacturer's Price) | | Subsidised | Generic |
| | \$ | Per | | Manufacturer |
| continued | | | | |
| 1 Patient is immunocompromised; and | | | | |
| 2 Any of the following: | | | | |
| 2.1 Patient has cytomegalovirus syndrome or tissue inv | asive disease; or | | | |
| 2.2 Patient has rapidly rising plasma CMV DNA in abse | ence of disease; or | | | |
| 2.3 Patient has cytomegalovirus retinitis. | | | | |
| Note: for the purpose of this Special Authority "immunocompromi | sed" includes transp | olant | recipients, pa | atients with |
| immunosuppressive diseases (e.g. HIV) or those receiving immu | nosuppressive treat | ment | for other cor | nditions. |
| Hepatitis C Treatment | | | | |
| GLECAPREVIR WITH PIBRENTASVIR – [Xpharm] | | | | |
| Note the supply of treatment is via Pharmac's approved direc website https://pharmac.govt.nz/maviret | t distribution supply. | Fur | ther details c | an be found on Pharmac's |
| Tab 100 mg with pibrentasvir 40 mg | 24,750.00 | 84 O | P 🖌 N | laviret |
| LEDIPASVIR WITH SOFOSBUVIR - [Xpharm] - Special Authorit | y see SA1605 belo | w | | |
| No patient co-payment payable | - | | | |
| Tab 90 mg with sofosbuvir 400 mg | 24,363.46 | 28 | | larvoni |
| ➡SA1605 Special Authority for Subsidy | | | | |
| Special Authority approved by the Hepatitis C Treatment Panel (H | epCTP) | | | |
| Notes: By application to the Hepatitis C Treatment Panel (HepCT | P). | | | |
| Applications will be considered by HepCTP and approved subject | to confirmation of e | ligibil | ity. | |
| Application dataile may be obtained from Dharman's website http: | lluuuu phormoo gov | + n-1 | onvirat or: | |

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: <u>hepcpanel@pharmac.govt.nz</u>

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 108 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 | ✓ <u>Tenofovir Dis</u> <u>Emtricitabi</u> | - |
|-----|---|----------------|-----------------|--|---|
| * | Tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a | | | | |
| | succinate) | 15.45 | 30 | 🗸 Teva | |
| (Te | eva Tab 200 mg with tenofovir disoproxil 245 mg (300.6 mg as a si | uccinate) to b | be delisted 1 A | lugust 2025) | |

| Subsidy (Manufacturer's Price) | S | Fully ubsidised | Brand or Generic |
|-----------------------------------|-----|--------------------|---------------------|
| \$ | Per | 1 | 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

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 <u>Pharmac's website</u>) 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
 30
 Image: 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:

- 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.

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

continued...

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.

Non-nucleosides Reverse Transcriptase Inhibitors

| EFAVIRENZ - Special Authority see SA2139 on the previous pa | ge – Retail pharm | acy | |
|--|--------------------|------|-------------------------------|
| Tab 600 mg | | 30 | Efavirenz |
| | | | Milpharm S29 |
| ETRAVIRINE - Special Authority see SA2139 on the previous pa | age – Retail pharr | nacy | |
| Tab 200 mg | 770.00 | 60 | Intelence |

| | Subsidy (Manufacturer's P \$ | | Fully Brand or dised Generic ✓ Manufacturer |
|--|------------------------------------|-----------------------|--|
| NEVIRAPINE – Special Authority see SA2139 on page 108 – Re Tab 200 mg Oral suspension 10 mg per ml | | 60 240 ml OP | ✓ <u>Nevirapine Viatris</u> ✓ Viramune Suspension |
| Nucleosides Reverse Transcriptase Inhibitors | | | |
| ABACAVIR SULPHATE – Special Authority see SA2139 on pag Tab 300 mg | | narmacy 60 | ✓ Ziagen |
| ABACAVIR SULPHATE WITH LAMIVUDINE – Special Authority Note: abacavir with lamivudine (combination tablets) counts anti-retroviral Special Authority. | | | tail pharmacy |
| Tab 600 mg with lamivudine 300 mg | 29.50 | 30 | ✓ <u>Abacavir/</u> <u>Lamivudine</u> <u>Viatris</u> |
| EFAVIRENZ WITH EMTRICITABINE AND TENOFOVIR DISOPI pharmacy | ROXIL – Special | Authority see S | SA2139 on page 108 – Retail |
| Note: Efavirenz with emtricitabine and tenofovir disoproxil co anti-retroviral Special Authority | | nti-retroviral med | dications for the purposes of the |
| Tab 600 mg with emtricitabine 200 mg and tenofovir disoprot 245 mg (300 mg as a fumarate) | 106.88 | 30 | Triovir S29 |
| Tab 600 mg with emtricitabine 200 mg and tenofovir disopro: 245 mg (300 mg as a maleate) | | 30 | ✓ Viatris |
| EMTRICITABINE – Special Authority see SA2139 on page 108 - Cap 200 mg | | зу 30 | ✓ Emtriva |
| LAMIVUDINE – Special Authority see SA2139 on page 108 – Re Tab 150 mg Oral liq 10 mg per ml | | 60 240 ml OP | ✓ Lamivudine Viatris ✓ 3TC |
| ZIDOVUDINE [AZT] - Special Authority see SA2139 on page 10 | 8 – Retail pharm | | |
| Cap 100 mg Oral lig 10 mg per ml | | 100 200 ml OP | ✓ Retrovir ✓ Retrovir |
| ZIDOVUDINE [AZT] WITH LAMIVUDINE – Special Authority see Note: zidovudine [AZT] with lamivudine (combination tablets | e SA2139 on pag | | |
| the anti-retroviral Special Authority. Tab 300 mg with lamivudine 150 mg | 92.40 | 60 | Lamivudine/ Zidovudine Viatris |
| Protease Inhibitors | | | |
| ATAZANAVIR SULPHATE – Special Authority see SA2139 on p Cap 150 mg | | pharmacy 60 | ✓ <u>Atazanavir Mylan</u> |
| Cap 200 mg | | 60 | Atazanavir Viatris Atazanavir Viatris |
| DARUNAVIR – Special Authority see SA2139 on page 108 – Re Tab 400 mg Tab 600 mg | | 60 60 | ✓ <u>Darunavir Viatris</u> ✓ <u>Darunavir Viatris</u> |
| LOPINAVIR WITH RITONAVIR – Special Authority see SA2139 Tab 100 mg with ritonavir 25 mg | | Retail pharmacy 60 | Lopinavir/Ritonavir |
| Tab 200 mg with ritonavir 50 mg | 875.00 | 120 | Mylan ✔ <u>Lopinavir/Ritonavir</u> <u>Mylan</u> |
| | | | |

| | Subsidy (Manufacturer's Price) \$ | Sub Per | Fully osidised | Brand or Generic Manufacturer |
|--|---|---------------------|-------------------|-------------------------------------|
| RITONAVIR – Special Authority see SA2139 on page 108 – Reta Tab 100 mg | | 30 | ✓ N | orvir |
| Strand Transfer Inhibitors | | | | |
| DOLUTEGRAVIR – Special Authority see SA2139 on page 108 - Tab 50 mg | | 30 | ✓ т | ivicay |
| DOLUTEGRAVIR WITH LAMIVUDINE – Special Authority see S Tab 50 mg with lamivudine 300 mg | 1.0 | - Retail p 30 | | ovato |
| RALTEGRAVIR POTASSIUM – Special Authority see SA2139 of Tab 400 mg Tab 600 mg | 1,090.00 | harmacy 60 60 | 🗸 ls | entress entress HD |

Immune Modulators

| PEGYLATED INTERFERON ALFA-2A - Special Authority see S | SA2034 below - Re | etail pharma | acy |
|---|------------------------|--------------|-------------------------------------|
| Note: Pharmac will consider funding ribavirin for the small g | group of patients with | ho have a c | linical need for ribavirin and meet |
| Special Authority criteria. Please contact the Hepatitis C Co | ordinator at Pharm | nac on 0800 |)-023-588 option 4. |
| Inj 180 mcg prefilled syringe | 748.50 | 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 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

continued...

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

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

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

continued...

- 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
- 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

| | Subsidy (Manufacturer's Price) | , | | Brand or Generic | |
|-----------|-----------------------------------|-----|---|---------------------|--|
| | \$ | Per | 1 | Manufacturer | |
| continued | | | | | |

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

FOSFOMYCIN - Special Authority see SA2406 below - Retail pharmacy

⇒SA2406 Special Authority for Subsidy

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

- 1 Patient has an acute, symptomatic, bacteriologically-proven uncomplicated urinary tract infection (UTI)/cystitis with Escherichia Coli; and
- 2 Either:
 - 2.1 Microbiological testing confirms the pathogen is resistant to all of: trimethoprim, nitrofurantoin, amoxicillin, cefaclor, cefalexin, amoxicillin with clavulanic acid, and norfloxacin; or
 - 2.2 The patient has a contraindication or intolerance to all of: trimethoprim, nitrofurantoin, amoxicillin, cefaclor, cefalexin, amoxicillin with clavulanic acid, and norfloxacin that the pathogen is susceptible to.

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

- 1 Patient has an acute, symptomatic, bacteriologically-proven uncomplicated urinary tract infection (UTI)/cystitis with Escherichia Coli; and
- 2 Either:
 - 2.1 Microbiological testing confirms the pathogen is resistant to all of: trimethoprim, nitrofurantoin, amoxicillin, cefaclor, cefalexin, amoxicillin with clavulanic acid, and norfloxacin; or
 - 2.2 The patient has a contraindication or intolerance to all of: trimethoprim, nitrofurantoin, amoxicillin, cefaclor, cefalexin, amoxicillin with clavulanic acid, and norfloxacin that the pathogen is susceptible to.

METHENAMINE (HEXAMINE) HIPPURATE

| * Tab 1 g 19.95 | 100 | ✓ Hiprex |
|---|-----|------------------------------------|
| NITROFURANTOIN | | |
| * Tab 50 mg – Up to 30 tab available on a PSO22.20 | 100 | <u>Nifuran</u> |
| * Tab 100 mg | 100 | Nifuran |
| * Cap modified-release 100 mg - Up to 15 cap available on a | | |
| PSO | 100 | Macrobid |
| NORFLOXACIN | | |
| Tab 400 mg – Subsidy by endorsement | 100 | Arrow-Norfloxacin |

MUSCULOSKELETAL SYSTEM

| | Subsidy |) Out | Fully | Brand or |
|--|------------------------------|---------|--------------------------------|-------------------------|
| | (Manufacturer's Price) \$ | Per Sub | sidised ✓ | Generic Manufacturer |
| Anticholinesterases | | | | |
| EOSTIGMINE METILSULFATE | | | | |
| Inj 2.5 mg per ml, 1 ml ampoule | | 10 | M | lax Health |
| YRIDOSTIGMINE BROMIDE | | | - | |
| Tab 60 mg | 50.28 | 100 | 🗸 N | lestinon |
| Non-Steroidal Anti-Inflammatory Drugs | | | | |
| ICLOFENAC SODIUM | | | | |
| Tab EC 25 mg | 2.19 | 50 | √ [| Diclofenac Sandoz |
| Tab 50 mg dispersible | | 20 | | oltaren D |
| Tab EC 50 mg | | 50 | I | Diclofenac Sandoz |
| Tab long-acting 75 mg | | 100 | _ | oltaren SR |
| Inj 25 mg per ml, 3 ml ampoule – Up to 5 inj available on a PS | | 5 | | /oltaren |
| Suppos 12.5 mg | | 10 | | /oltaren |
| Suppos 25 mg | | 10 | | /oltaren |
| Suppos 50 mg – Up to 10 supp available on a PSO | | 10 | | /oltaren |
| Suppos 100 mg | | 10 | | /oltaren |
| UPROFEN | | | | |
| - Tab 200 mg | 21 40 | 1,000 | V F | Relieve |
| Tab long-acting 800 mg | | 30 | _ | buprofen SR BNM |
| • Oral lig 20 mg per ml | | 200 ml | | Ethics |
| ETOPROFEN | 2.00 | 200 | = | |
| | 10.07 | 28 | | Druvail SR |
| | 12.07 | 20 | • (| Jiuvali Sh |
| EFENAMIC ACID | | | | |
| Cap 250 mg | | 50 | | |
| | (10.82) | | F | onstan |
| | 0.50 | 20 | _ | |
| | (7.50) | | F | Ponstan |
| APROXEN | | | | |
| • Tab 250 mg | | 500 | - | loflam 250 |
| Tab 500 mg | | 250 | - | loflam 500 |
| Tab long-acting 750 mg | | 28 | _ | laprosyn SR 750 |
| Tab long-acting 1 g | 11.50 | 28 | ✓ № | laprosyn SR 1000 |
| ENOXICAM | | | | |
| F Tab 20 mg | | 100 | ✓ 1 | ilcotil |
| Inj 20 mg vial | 9.95 | 1 | ✓ F | \FT |
| NSAIDs Other | | | | |
| ELECOXIB | | | | |
| Cap 100 mg | 3.45 | 60 | 10 | Celebrex |
| | | 00 | | celecoxib Pfizer |
| Cap 200 mg | 3 20 | 30 | _ | celebrex |
| 0ap 200 mg | | 50 | | |
| | | | ✓ | elecoxib Pfizer |

MUSCULOSKELETAL SYSTEM

| | Subsidy (Manufacturer's Pr \$ | ice) Subs Per | Fully Brand or idised Generic ✔ Manufacturer |
|--|--|------------------|--|
| Topical Products for Joint and Muscular Pain | | | |
| APSAICIN | | | |
| Crm 0.025% - Special Authority see SA1289 below - Reta | | | |
| pharmacy | 9.75 | 45 g OP | ✓ Zo-Rub Osteo S29 ✓ Zostrix |
| | 13.00 | 60 g OP | Rugby Capsaicin Topical Cream \$29 |
| Rugby Capsaicin Topical Cream 529 Crm 0.025% to be delist | ted 1 July 2025) | | oreani es |
| SA1289 Special Authority for Subsidy | | | |
| nitial application from any relevant practitioner. Approvals va | | | |
| steoarthritis that is not responsive to paracetamol and oral non | -steroidar anti-inna | mmatories are | |
| Antirheumatoid Agents | | | |
| IYDROXYCHLOROQUINE SULPHATE | | | |
| K Tab 200 mg | 7.80 | 100 | Ipca- Hydroxychloroquine |
| | 8.78 | | Plaquenil |
| Ipca-Hydroxychloroquine to be Principal Supply on 1 M | ay 2025 | | |
| Plaquenil Tab 200 mg to be delisted 1 May 2025) EFLUNOMIDE | | | |
| € Tab 10 mg | 6.00 | 30 | ✓ Arava |
| * Tab 20 mg | 6.00 | 30 | ✓ <u>Arava</u> |
| ENICILLAMINE | 67.00 | 100 | ✓ D-Penamine |
| Tab 125 mg Tab 250 mg | | 100 100 | ✓ D-Penamine ✓ D-Penamine |
| Drugs Affecting Bone Metabolism | | | |
| | | | |
| Alendronate for Osteoporosis | | | |
| LENDRONATE SODIUM | 0.10 | 4 | / F |
| ✓ Tab 70 mg LENDRONATE SODIUM WITH COLECALCIFEROL | 3.10 | 4 | ✓ Fosamax |
| Tab 70 mg with colecalciferol 5,600 iu | 1.99 | 4 | ✓ Fosamax Plus |
| Other Treatments | | | |
| ENOSUMAB – Special Authority see SA2441 on the next pag Note: Denosumab inj 60 mg per 1 ml pre-filled syringe is M per 1.7 ml vial is Medsafe approved for use in hypercalcaer Inj 120 mg per 1.7 ml vial | ledsafe approved finite nia of malignancy. | | oporosis. Denosumab inj 120 m |
| Inj 60 mg per 1 ml prefilled syringe | | 1 | ✓ Prolia |

| | Subsidy | Fu | Illy Brand or |
|-----|----------------------|-----------|---------------|
| (Ma | anufacturer's Price) | Subsidise | |
| | \$ | Per | Manufacturer |

⇒SA2441 Special Authority for Subsidy

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

All of the following:

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

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

Both:

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

PAMIDRONATE DISODIUM

| Inj 3 mg per ml, 10 ml vial | 32.49 | 1 | Pamisol |
|---|-------------------|---------|-----------------------------|
| Inj 6 mg per ml, 10 ml vial | 88.11 | 1 | Pamisol |
| Inj 9 mg per ml, 10 ml vial | 94.34 | 1 | Pamisol |
| RALOXIFENE HYDROCHLORIDE - Special Authority see SA1779 | below - Retail ph | narmacy | |
| * Tab 60 mg | | 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
- 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

MUSCULOSKELETAL SYSTEM

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

continued...

- 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:
 - 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 mg2.50 | 4 | Risedronate Sandoz |
|---|---|--|
| TERIPARATIDE – Special Authority see SA1139 below – Retail pharmacy | | |
| Inj 250 mcg per ml, 2.4 ml | 1 | Teriparatide - Teva |

➡SA1139 Special Authority for Subsidy

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

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

Notes:

- a) The bone mineral density (BMD) measurement used to derive the T-score must be made using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable
- b) Antiresorptive agents and their adequate doses for the purposes of this Special Authority are defined as: alendronate sodium tab 70 mg or tab 70 mg with colecalciferol 5,600 iu once weekly; raloxifene hydrochloride tab 60 mg once daily; zoledronic acid 5 mg per year. If an intolerance of a severity necessitating permanent treatment withdrawal develops during the use of one antiresorptive agent, an alternate antiresorptive agent must be trialled so that the patient achieves the minimum requirement of 12 months' continuous therapy.
- c) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.
- d) A maximum of 18 months of treatment (18 cartridges) will be subsidised.

ZOLEDRONIC ACID

| Inj 0.05 mg per ml, 100 ml, bag | 1 | Zoledronic Acid |
|---------------------------------|-------|-----------------|
| | | Viatris |

Hyperuricaemia and Antigout

| ALI | OPURINOL | | |
|-----|------------------|-------|--------------------------------------|
| * | Tab 100 mg 17.99 | 1,000 | Ipca-Allopurinol |
| * | Tab 300 mg22.50 | 500 | Ipca-Allopurinol |

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

| | Subsidy | | Fully | Brand or |
|---|--------------------------|----------|---------------|-----------------------------|
| | (Manufacturer's Price) | | Subsidised | Generic |
| | ð | Per | • | Manufacturer |
| BENZBROMARONE - Special Authority see SA1963 below - F | Retail pharmacy | | | |
| Tab 50 mg | | 100 | 🗸 N | larcaricin mite S29 |
| ➡SA1963 Special Authority for Subsidy | | | | |
| Renewal from any relevant practitioner. Approvals valid for 2 ye Both: | ears for applications m | neetin | g the followi | ng criteria: |
| 1 The treatment remains appropriate and the patient is ber | efitting from the treatr | nent; | and | |
| There is no evidence of liver toxicity and patient is contin tests. | uing to receive regular | r (at le | east every th | ree months) liver function |
| COLCHICINE | | | | |
| * Tab 500 mcg | 6.00 | 100 | ✓ <u>C</u> | olgout |
| FEBUXOSTAT - Special Authority see SA2054 below - Retail | | | | |
| Tab 80 mg | | 28 | 🖌 F | ebuxostat (Teva) |
| Tab 120 mg | 11.78 | 28 | ✓ F | ebuxostat (Teva) |
| ► SA2054 Special Authority for Subsidy | | | | |
| Initial application - (Gout) from any relevant practitioner. Ap | provals valid for 6 mo | nths f | or applicatio | ins meeting the following |
| criteria: | | | | |
| Both: | | | | |
| 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 tre | eatme | nt with allop | urinol at doses of at least |

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

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

Both:

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

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 mg66.95 100

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.

Probenecid-AFT

MUSCULOSKELETAL SYSTEM

| | (| Per | Fully Subsidised | Brand or Generic Manufacturer |
|------------------------------------|-------|-----|---------------------|-------------------------------------|
| DANTROLENE | | | | |
| Cap 25 mg | | 100 | ✓ | Dantrium S29 S29 |
| Cap 50 mg | 77.00 | 100 | ✓ | Dantrium |
| ORPHENADRINE CITRATE Tab 100 mg | 23.25 | 100 | √ <u>i</u> | Norflex |

| | Subsidy (Manufacturer's Price) \$ | Subsidi Per | iully sed | Brand or Generic Manufacturer |
|--|---|----------------|--|-------------------------------------|
| Agents for Parkinsonism and Related Disorders | 3 | | | |
| Dopamine Agonists and Related Agents | | | | |
| AMANTADINE HYDROCHLORIDE | | | | |
| ▲ Cap 100 mg | | 60 | | Symmetrel |
| | 63.73 | 100 | ✓ S | Symmetrel |
| APOMORPHINE HYDROCHLORIDE | | _ | | - |
| ▲ Inj 10 mg per ml, 2 ml ampoule | | 5 | | Movapo |
| Inj 10 mg per ml, 5 ml ampoule | | 5 | ✓ N | Movapo |
| ENTACAPONE | | | | |
| ▲ Tab 200 mg | | 100 | | Entacapone Viatris |
| Enternana Mintria ta ha Drinainal Ourahu en 1 July 0001 | - 18.04 | | v (| Comtan |
| Entacapone Viatris to be Principal Supply on 1 July 2025 (Comtan Tab 200 mg to be delisted 1 July 2025) | 0 | | | |
| | | | | |
| LEVODOPA WITH BENSERAZIDE | 10.05 | 100 | | Jadanar Danid |
| * Tab dispersible 50 mg with benserazide 12.5 mg | | 100 100 | | Madopar Rapid |
| Cap 50 mg with benserazide 12.5 mg Cap 100 mg with benserazide 25 mg | | 100 | | Madopar 62.5 Madopar 125 |
| Cap for fig with benserazide 25 mg | | 100 | | Madopar HBS |
| Cap 200 mg with benserazide 50 mg. | | 100 | | Madopar 250 |
| LEVODOPA WITH CARBIDOPA | 20.20 | | | |
| * Tab 100 mg with carbidopa 25 mg | 26.49 | 100 | | Sinemet |
| Tab long-acting 200 mg with carbidopa 50 mg | | 100 | - | Sinemet CR |
| * Tab 250 mg with carbidopa 25 mg | | 100 | _ | Sinemet |
| LEVODOPA WITH CARBIDOPA AND ENTACAPONE | | | _ | |
| * Tab 50 mg with carbidopa 12.5 mg and entacapone 200 mg | 27.01 | 100 | √ s | Stalevo |
| Stalevo to be Principal Supply on 1 July 2025 * Tab 100 mg with carbidopa 25 mg and entacapone 200 mg. | 34 18 | 100 | 19 | Stalevo |
| Stalevo to be Principal Supply on 1 July 2025 | | 100 | | Alloro |
| * Tab 150 mg with carbidopa 37.5 mg and entacapone 200 mg Stalevo to be Principal Supply on 1 July 2025 | g44.96 | 100 | √ s | Stalevo |
| * Tab 200 mg with carbidopa 50 mg and entacapone 200 mg. | | 100 | √ s | Stalevo |
| Stalevo to be Principal Supply on 1 July 2025 | | | | |
| PRAMIPEXOLE HYDROCHLORIDE | | | | |
| ▲ Tab 0.25 mg | 5.51 | 100 | ✓ F | Ramipex |
| ▲ Tab 1 mg | | 100 | ✓ F | Ramipex |
| RASAGILINE | | | | |
| * Tab 1 mg | | 30 | A A | Azilect S29 |
| ROPINIROLE HYDROCHLORIDE | | | | |
| ▲ Tab 0.25 mg | 4.05 | 84 | / F | Ropin |
| ▲ Tab 1 mg | | 84 | _ | Ropin |
| ▲ Tab 2 mg | | 84 | | Ropin |
| ▲ Tab 5 mg | | 84 | _ | Ropin |
| TOLCAPONE | | | - | |
| ▲ Tab 100 mg | | 100 | ✓ T | Tasmar |

| NERVOUS S | SYSTEM |
|-----------|--------|
|-----------|--------|

| (Manufa Anticholinergics BENZATROPINE MESYLATE Tab 2 mg Inj 1 mg per ml, 2 ml | ubsidy cturer's Price) \$ | Subsidi Per | ully Brand o sed Generic ✓ Manufac | |
|--|---------------------------------|-----------------|---|---------------|
| BENZATROPINE MESYLATE Tab 2 mg Inj 1 mg per ml, 2 ml9 a) Up to 10 inj available on a PSO | \$ | Per | | cturer |
| BENZATROPINE MESYLATE Tab 2 mg Inj 1 mg per ml, 2 ml9 a) Up to 10 inj available on a PSO | | | | |
| Tab 2 mg Inj 1 mg per ml, 2 ml9 a) Up to 10 inj available on a PSO | | | | |
| Inj 1 mg per ml, 2 ml9. a) Up to 10 inj available on a PSO | | | | |
| a) Up to 10 inj available on a PSO | | 60 5 | ✓ Benztrop✓ Phebra | |
| | 5.00 | 5 | • Phebra | |
| b) Only on a PSO | | | | |
| PROCYCLIDINE HYDROCHLORIDE Tab 5 mg | 7.40 | 100 | ✓ Kemadrin | |
| - | | | | |
| Agents for Essential Tremor, Chorea and Related Disc | Juers | | | |
| RILUZOLE – Special Authority see SA1403 below – Retail pharmacy Wastage claimable | | | | |
| Tab 50 mg | 7.00 | 56 | ✓ <u>Rilutek</u> | |
| ⇒SA1403 Special Authority for Subsidy | | C | | |
| nitial application only from a neurologist or respiratory specialist. Appro ollowing criteria: | ivals valid for | 6 months to | or applications | meeting the |
| All of the following: | | | | |
| 1 The patient has amyotrophic lateral sclerosis with disease duration | | | the initial and | lication, and |
| 2 The patient has at least 60 percent of predicted forced vital capaci3 The patient has not undergone a tracheostomy; and | iy wiinin ≥ mo | ontris prior to | o me miliai app | dication; 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 fo III of the following: | r applications | s meeting the | e following crit | eria: |
| 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. | | | | |
| ETRABENAZINE | | | | |
| Tab 25 mg10 | 6.59 | 112 | ✓ Motetis | |
| Anaesthetics | | | | |
| Local | | | | |
| | | | | |
| IDOCAINE [LIGNOCAINE] Gel 2%, tube – Subsidy by endorsement1 | 150 ' | 30 ml | ✓ Xylocaine | 2% Jelly |
| a) Up to 150 ml available on a PSO | 1.00 | | - Aylocallie | Z /0 UCITY |
| b) Subsidised only if prescribed for urethral or cervical administr | ation and the | prescription | is endorsed a | accordinaly |
| Gel 2%, 11 ml urethral syringe – Subsidy by endorsement | 9.50 | 10 | ✓ Instillagel | |
| a) Up to 5 each available on a PSO | | | <u></u> | |
| b) Subsidised only if prescribed for urethral, cervical or rectal ad | ministration a | and the prese | cription is end | orsed |
| accordingly. | | | | |
| | | | | |

| | Subsidy | | Fully | Brand or |
|---|-----------------------|-------------|--|-------------------------|
| | (Manufacturer's Price |) Su Per | ubsidised | Generic Manufacturer |
| | Ψ | 1.01 | • | Mandiaetarer |
| LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE | | | | |
| Oral (gel) soln 2% | | 200 ml | Image: A second s | Mucosoothe |
| Inj 1%, 5 ml ampoule - Up to 25 inj available on a PSO | | 25 | ✓ | Lidocaine-Baxter |
| | 17.50 | 50 | | |
| | (35.00) | | 2 | Xylocaine |
| Inj 2%, 5 ml ampoule – Up to 5 inj available on a PSO | | 25 | ✓ | Lidocaine-Baxter |
| Inj 1%, 20 ml ampoule - Up to 5 inj available on a PSO | | 5 | | |
| | (20.00) | | 2 | Xylocaine |
| Inj 1%, 20 ml vial – Up to 5 inj available on a PSO | | 5 | Image: A second s | Lidocaine-Baxter |
| Inj 2%, 20 ml vial – Up to 5 inj available on a PSO | 14.00 | 5 | ✓ | Lidocaine-Baxter |
| Inj 10%, 5 ml ampoule - Subsidy by endorsement | CBS | 10 | Image: A start of the start of | Xylocard 500 S29 |
| Subsidised only for people receiving palliative care serv | vices where other and | alnesir ar | ients hav | en't heen effective |

Subsidised only for people receiving palliative care services where other analgesic agents haven't been effective.

Topical Local Anaesthetics

► SA0906 Special Authority for Subsidy

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

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

| LIDOCAINE [LIGNOCAINE] – Special Authority see SA0906 above – Retail pha | rmacy | |
|--|-----------------------------|-------------|
| Crm 4%5.40 | 5 g OP | 🖌 LMX4 |
| 27.00 | 30 g OP | 🖌 LMX4 |
| LIDOCAINE [LIGNOCAINE] WITH PRILOCAINE - Special Authority see SA090 | <mark>6 above</mark> – Reta | il pharmacy |
| Crm 2.5% with prilocaine 2.5%45.00 | 30 g OP | 🖌 EMLA |
| Crm 2.5% with prilocaine 2.5% (5 g tubes)45.00 | 5 | 🖌 EMLA |

Analgesics

For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, page 114

Non-opioid Analgesics

| ASPIRIN * Tab dispersible 300 mg – Up to 30 tab available on a PSO | 5.65 | 100 | Ethics Aspirin |
|---|-----------------|----------------|---|
| CAPSAICIN – Subsidy by endorsement | | | |
| Subsidised only if prescribed for post-herpetic neuralgia or dial accordingly. | petic periphera | I neuropathy a | nd the prescription is endorsed |
| Crm 0.075% | 11.95 | 45 g OP | ✓ Zo-Rub HP \$29 ✓ Zostrix HP |
| | 15.14 | 57 g OP | Rugby Capsaicin Topical Cream ^{\$29} |
| (Rugby Capsaicin Topical Cream \$29) Crm 0.075% to be delisted | 1 July 2025) | | |
| NEFOPAM HYDROCHLORIDE Tab 30 mg | 23.40 | 90 | Acupan |

| | | | NERVOUS | SYSTEM |
|--|---|---|--|--|
| | Subsidy (Manufacturer's Price \$ | e) Sub Per | Fully Brand c sidised Generic ✓ Manufa | 2 |
| PARACETAMOL | | | | |
| Tab 500 mg - blister pack | | 1,000 | Pacimol | |
| a) Maximum of 300 tab per prescription; can be waive b) Up to 30 tab available on a PSO c) | | | | |
| Subsidy by endorsement for higher quantities regular daily dosing for one month or greater annotate the prescription as endorsed where Maximum of 100 tab per dispensing for non- (for non-endorsed patients), then dispense in Tab 500 mg - bottle pack – Maximum of 300 tab per | , and the prescription dispensing history su endorsed patients. If o | is annotate pports a lor quantities p | d accordingly. P ng-term conditior rescribed for mo | harmacists may n. re than 100 tabs |
| prescription; can be waived by endorsement | | 1,000 | ✓ <u>Noumed</u> Parace | tamol |
| Subsidy by endorsement for higher quantities is daily dosing for one month or greater, and the pr prescription as endorsed where dispensing histo Maximum of 100 tab per dispensing for non-end non-endorsed patients), then dispense in repeat | rescription is annotate by supports a long-ter orsed patients. If qua | d according m condition ntities prese | ly. Pharmacists cribed for more th | may annotate the han 100 tabs (for |
| Oral liq 120 mg per 5 ml | | 200 ml | ✓ Paracetar (Ethics) | |
| a) Maximum of 600 ml per prescription; can be waive b) Up to 200 ml available on a PSO c) Not in combination d) | d by endorsement | | Lanos | I |
| Maximum of 200 ml per dispensing for non-e non-endorsed patients), then dispense in rep Subsidy by endorsement for higher quantities regular daily dosing for one month or greater Pharmacists may annotate the prescription a condition. | eat dispensing not exists available for patien and the prescription is | ceeding 200 nts with long s endorsed | 0 ml per dispensi g term conditions or annotated act | ing. s who require cordingly. |
| Note: 200 ml presentations of paracetamol of Pharmacist) under the provisions in Part I of | | olied on BS | O to a Vaccinato | r (other than a |
| Note: Direct Provision by a pharmacist of up conjunction with immunisation of a child under | er 2 years of age with | meningoco | ccal B multicomp | |
| Oral liq 250 mg per 5 ml a) Maximum of 600 ml per prescription; can be waive b) Up to 200 ml available on a PSO c) Not in combination | | 200 ml | ✓ <u>Pamol</u> | |
| d) | underwood and the stands. If a | | | 000 ml (far |
| Maximum of 200 ml per dispensing for non-e non-endorsed patients), then dispense in rep Subsidy by endorsement for higher quantities regular daily design for one month or groups | eat dispensing not ex s is available for patier | ceeding 200 nts with long | 0 ml per dispensi g term conditions | ing. s who require |
| regular daily dosing for one month or greater Pharmacists may annotate the prescription a condition. | s endorsed where dis | pensing his | tory supports a l | ong-term |
| Note: 200 ml presentations of paracetamol of Pharmacist) under the provisions in Part I of | Section A | | | |
| 4) Note: Direct Provision by a pharmacist of up conjunction with immunisation of a child under Suppos 125 mg | er 2 years of age with | | | |
| | | | | |

| _ | Subsidy (Manufacturer's Price) \$ | Per | | |
|--|---|----------------|--------------------------------------|----|
| Suppos 250 mg Suppos 500 mg | | 10 50 | ✓ <u>Gacet</u> ✓ <u>Gacet</u> | |
| Dpioid Analgesics | | | | |
| DDEINE PHOSPHATE - Safety medicine; prescriber may de | etermine dispensing fre | quen | | |
| Tab 15 mg | | 100 | | |
| Tab 30 mg | | 100 | | |
| Tab 60 mg | 13.89 | 100 | ✓ <u>Noumed</u> | |
| HYDROCODEINE TARTRATE | | | | |
| Tab long-acting 60 mg | 8.60 | 60 | DHC Continus | |
| NTANYL | | | | |
| a) Only on a controlled drug form | | | | |
| b) No patient co-payment payable | | | | |
| c) Safety medicine; prescriber may determine dispensing | | | * - · · · · · · | |
| Inj 50 mcg per ml, 2 ml ampoule | | 10 | Boucher and Muir | |
| Boucher and Muir to be Principal Supply on 1 May 202 Inj 50 mcg per ml, 10 ml ampoule | | 10 | Boucher and Muir | |
| Boucher and Muir to be Principal Supply on 1 May 202 | | 10 | | |
| Patch 12.5 mcg per hour | | 5 | Fentanyl Sandoz | |
| Patch 25 mcg per hour | | 5 | ✓ Fentanyl Sandoz | |
| Patch 50 mcg per hour | | 5 | ✓ Fentanyl Sandoz | |
| Patch 75 mcg per hour | | 5 | Fentanyl Sandoz | |
| Patch 100 mcg per hour | 16.37 | 5 | Fentanyl Sandoz | |
| ETHADONE HYDROCHLORIDE | | | | |
| a) Only on a controlled drug form | | | | |
| b) No patient co-payment payable | | | | |
| c) Safety medicine; prescriber may determine dispensing | frequency | | | |
| Tab 5 mg | 1.45 | 10 | Methadone BNM | |
| Oral liq 2 mg per ml | | 200 n | | |
| Oral liq 5 mg per ml | | 200 n | | |
| Oral liq 10 mg per ml | | 200 n | | te |
| Inj 10 mg per ml, 1 ml | | 10 | ✓ AFT | |
| ORPHINE HYDROCHLORIDE | | | | |
| a) Only on a controlled drug form | | | | |
| b) No patient co-payment payable | fraguanau | | | |
| c) Safety medicine; prescriber may determine dispensing Oral lig 1 mg per ml | | 200 n | | |
| Oral lig 2 mg per ml | | 200 n 200 n | | |
| Oral lig 5 mg per ml | | 200 n 200 n | | |
| Oral lig 10 mg per ml | | 200 n 200 n | | |
| | | | | |

| | Qubaidu | | Eully | Brand or |
|---|-----------------------------------|--------------|------------------|----------------------|
| | Subsidy (Manufacturer's Price) | Sub | Fully sidised | Generic |
| | (Manulacturer 5 Thee) \$ | Per | siuiseu V | Manufacturer |
| DRPHINE SULPHATE | | | | |
| a) Only on a controlled drug form | | | | |
| b) No patient co-payment payable | | | | |
| c) Safety medicine; prescriber may determine dispensing fre | equency | | | |
| Tab immediate-release 10 mg | | 10 | 19 | Sevredol |
| Tab immediate-release 20 mg | | 10 | 19 | Sevredol |
| Cap long-acting 10 mg | | 10 | 🗸 r | n-Eslon |
| Cap long-acting 30 mg | 4.30 | 10 | ✓ r | n-Eslon |
| Cap long-acting 60 mg | 9.00 | 10 | ✓ r | n-Eslon |
| Cap long-acting 100 mg | | 10 | ✓ r | n-Eslon |
| Oral lig 2 mg per ml | 16.31 | 100 ml | 1 | Vockhardt S29 |
| •····································· | 29.80 | | | Dramorph |
| | 20100 | | | Dramorph CDC |
| | | | | S29 S29 |
| Inj 5 mg per ml, 1 ml ampoule – Up to 5 inj available on a PS | C 5 29 | 5 | | Medsurge |
| Inj 10 mg per ml, 1 ml ampoule – Up to 5 inj available on a P | | 5 | | Medsurge |
| Inj 15 mg per ml, 1 ml ampoule – Up to 5 inj available on a P | SO4.00 | 5 | | Medsurge |
| Inj 30 mg per ml, 1 ml ampoule – Up to 5 inj available on a P | SO | 5 5 | | Medsurge Medsurge |
| | 30 0.20 | 5 | • ! | <u>weusuige</u> |
| (YCODONE HYDROCHLORIDE | | | | |
| a) Only on a controlled drug form | | | | |
| b) No patient co-payment payable | | | | |
| c) Safety medicine; prescriber may determine dispensing fre | equency | | | |
| Tab controlled-release 5 mg | 2.49 | 20 | ✓ (| Oxycodone Sandoz |
| | 3.77 | 28 | ✓ (| Oxycodone Sandoz |
| | | | | S29 S29 |
| | 4.04 | 30 | ✓ (| DxyContin S29 |
| Tab immediate-release 5 mg | | 100 | | Dxycodone Amneal |
| Tab controlled-release 10 mg | | 20 | | Oxycodone Sandoz |
| · · · · · · · · · · · · · · · · · · · | 3.77 | 28 | | Oxycodone Sandoz |
| | | | | S29 S29 |
| Tab immediate-release 10 mg | 18 77 | 100 | 1 | Dxycodone Amneal |
| Tab controlled-release 20 mg | | 20 | | Dxycodone Sandoz |
| Tab immediate-release 20 mg | | 100 | | Dxycodone Amneal |
| Tab controlled-release 40 mg | | 20 | | Dxycodone Sandoz |
| Tab controlled-release 80 mg | | 20 | - | Dxycodone Sandoz |
| Oral lig 1 mg per ml | | 20 250 ml | - | Dxycodone Lucis |
| Inj 10 mg per ml, 1 ml ampoule | | 250 mi 5 | | lameln |
| Inj 10 mg per ml, 2 ml ampoule | | 5 5 | - | lamein |
| Inj 50 mg per ml, 1 ml ampoule | | 5 5 | - | lamein |
| | | • | • [| |
| xycodone Sandoz S29 S29 Tab controlled-release 5 mg to be | |)) | | |
| xyContin 👓 Tab controlled-release 5 mg to be delisted 1 Ju | | | | |
| xycodone Sandoz S29 S29 Tab controlled-release 10 mg to b | e delisted 1 July 202 | 25) | | |
| RACETAMOL WITH CODEINE - Safety medicine; prescriber | may determine disp | ensina frea | quencv | |
| Tab paracetamol 500 mg with codeine phosphate 8 mg | | 1.000 | | Paracetamol + |
| | | , | - | Codeine (Believe) |

Codeine (Relieve)

| | Subsidy | | Fully | |
|---|------------------------------|-------------|-------------|--------------------------------|
| | (Manufacturer's Price) \$ | Per | Subsidised | Generic Manufacturer |
| THIDINE HYDROCHLORIDE | | | | |
| a) Only on a controlled drug form | | | | |
| b) No patient co-payment payable | | | | |
| c) Safety medicine; prescriber may determine dispensing fr | equency | | | |
| Tab 50 mg | | 10 | ✓ | Noumed Pethidine |
| Inj 50 mg per ml, 1 ml ampoule – Up to 5 inj available on a l | PSO29.88 | 5 | ~ | DBL Pethidine |
| | | | | Hydrochloride |
| Inj 50 mg per ml, 2 ml ampoule – Up to 5 inj available on a l | PSO 30.72 | 5 | ~ | DBL Pethidine Hydrochloride |
| RAMADOL HYDROCHLORIDE | | | | - |
| Tab sustained-release 100 mg | 1.95 | 20 | 1 | Tramal SR 100 |
| Tab sustained-release 150 mg | | 20 | 1 | Tramal SR 150 |
| Tab sustained-release 200 mg | 3.80 | 20 | ✓ | Tramal SR 200 |
| Cap 50 mg | 3.33 | 100 | 1 | Arrow-Tramadol |
| Antidepressants | | | | |
| Cyclic and Related Agents | | | | |
| /ITRIPTYLINE – Safety medicine; prescriber may determine of | dispensing frequency | | | |
| Tab 10 mg | | 100 | 1 | Arrow-Amitriptyline |
| Tab 25 mg | | 100 | | Arrow-Amitriptyline |
| Tab 50 mg | | 100 | | Arrow-Amitriptyline |
| OMIPRAMINE HYDROCHLORIDE - Safety medicine; presci | riber mav determine d | lisper | nsina freau | encv |
| Tab 10 mg | | 30 | | Clomipramine Teva |
| Tab 25 mg | | 30 | | Clomipramine Teva |
| 0 | 16.99 | 50 | | APO Clomipramine |
| | 39.97 | 100 | 1 | Anafranil S29 |
| APO Clomipramine to be Principal Supply on 1 July 202 | 25 | | | |
| Cap 10 mg | 35.50 | 28 | 1 | Clomipramine Teva |
| Cap 25 mg | 35.50 | 28 | ✓ | Clomipramine Teva |
| lomipramine Teva Tab 10 mg to be delisted 1 July 2025) | | | | |
| lomipramine Teva Tab 25 mg to be delisted 1 July 2025) | | | | |
| nafranil S29 Tab 25 mg to be delisted 1 July 2025) | | | | |
| lomipramine Teva Cap 10 mg to be delisted 1 July 2025) | | | | |
| lomipramine Teva Cap 25 mg to be delisted 1 July 2025) | | | | |
| DSULEPIN [DOTHIEPIN] HYDROCHLORIDE – Subsidy by er | ndorsement | | | |
| a) Safety medicine; prescriber may determine dispensing fra | equency | | | |
| b) Subsidy by endorsement - Subsidised for patients who w | vere taking dosulepin | [doth | iepin] hydi | ochloride prior to 1 June |
| 2019 and the prescription is endorsed accordingly. Phar | | e the | prescriptio | n as endorsed where the |
| exists a record of prior dispensing of dosulepin [dothiepin | | | | |
| Tab 75 mg | | 30 | | Dosulepin Viatris |
| Cap 25 mg | 7.83 | 50 | 1 | Dosulepin Viatris S29 |
| | may datarmina diana | noin | n froquere | |
| IPRAMINE HYDROCHLORIDE – Safety medicine; prescriber Tab 10 mg | | nsing 50 | | / Tofranil |
| 1 au 10 1119 | | 50 100 | | Tofranil |
| Tab 25 mg | | 28 | | Imipramine |
| | | 20 | • | Crescent S29 |
| Tab 23 mg | | | | |
| Tau 20 mg | 8.80 | 50 | | Tofranil |

| | Subsidy (Manufacturer's Price) | Subsi | Fully Brand or dised Generic |
|---|-----------------------------------|-------------|--|
| | (Manulacturer 3 1 1100) \$ | Per | ✓ Manufacturer |
| NORTRIPTYLINE HYDROCHLORIDE – Safety medicine; prescril | ber may determine | dispensina | frequency |
| Tab 10 mg | | 100 | ✓ Norpress |
| Tab 25 mg | 6.29 | 180 | Norpress |
| Monoamine-Oxidase Inhibitors (MAOIs) - Non Se | lective | | |
| TRANYLCYPROMINE SULPHATE | | | |
| * Tab 10 mg | 22.94 | 50 | Parnate |
| Monoamine-Oxidase Type A Inhibitors | | | |
| MOCLOBEMIDE | | | |
| * Tab 150 mg | | 60 | Aurorix |
| * Tab 300 mg | | 60 | ✓ Aurorix |
| Selective Serotonin Reuptake Inhibitors | | | |
| CITALOPRAM HYDROBROMIDE | | | |
| * Tab 20 mg | 2.86 | 84 | Celapram |
| ESCITALOPRAM | | | |
| * Tab 10 mg | 0.79 | 28 | Ipca-Escitalopram |
| | 1.07 | | Escitalopram |
| Y T-b 00 mm | 1.40 | 00 | (Ethics) |
| * Tab 20 mg | 1.49 | 28 | Ipca-Escitalopram |
| FLUOXETINE HYDROCHLORIDE | 0.50 | 00 | |
| Tab dispersible 20 mg, scored – Subsidy by endorsement Subsidised by endorsement | 2.50 | 28 | ✓ <u>Fluox</u> |
| When prescribed for a patient who cannot swallow v | whole tablets or can | sules and t | he prescription is endorsed |
| accordingly; or | | | |
| 2) When prescribed in a daily dose that is not a multiple | e of 20 mg in which | case the p | rescription is deemed to be |
| endorsed. Note: Tablets should be combined with | capsules to facilitat | e increment | tal 10 mg doses. |
| * Cap 20 mg | 2 1 2 | 90 | ✓ Arrow-Fluoxetine |
| | 0.10 | 30 | |
| PAROXETINE ₩ Tab 20 mg | 4 11 | 90 | ✓ Loxamine |
| - | | 50 | |
| SERTRALINE * Tab 50 mg | 0.99 | 30 | ✓ <u>Setrona</u> |
| ★ Tab 30 mg | | 30 | ✓ <u>Setrona</u> |
| , , , , , , , , , , , , , , , , , , , | | ~~ | |
| Other Antidepressants | | | |
| MIRTAZAPINE | | | _ |
| Tab 30 mg | | 30 | Noumed |
| Tab 45 mg | 3.45 | 30 | Noumed |
| VENLAFAXINE | | | |
| Cap 37.5 mg | | 84 | Enlafax XR |
| Cap 75 mg | | 28 | Enlafax XR |
| 0 450 | 10.32 | 84 | Enlafax XR |
| Cap 150 mg | | 28 | Enlafax XR Enlafax XR |
| | 13.95 | 84 | Enlafax XR |

▲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

| | 0.1.11 | | | |
|--|----------------------------------|------------|---------------------|-------------------------|
| | Subsidy (Manufacturer's Price |) | Fully Subsidised | Brand or Generic |
| | (Manulacturer's Flice | Per | | Manufacturer |
| | | | | |
| Antiepilepsy Drugs | | | | |
| Agents for Control of Status Epilepticus | | | | |
| DIAZEPAM – Safety medicine; prescriber may determine dispension | sing frequency | | | |
| Inj 5 mg per ml, 2 ml ampoule - Subsidy by endorsement | | 5 | ✓ | Hospira |
| a) Up to 5 inj available on a PSO | | | | |
| b) Only on a PSO | | | | |
| c) PSO must be endorsed "not for anaesthetic procedur | | | - | |
| Rectal tubes 5 mg – Up to 5 tube available on a PSO | 54.58 | 5 | 1 | Stesolid |
| PHENYTOIN SODIUM | | | | |
| * Inj 50 mg per ml, 2 ml ampoule – Up to 5 inj available on a | | | | |
| PSO | 104.58 | 5 | 1 | 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 | 44.50 | 400 | | T |
| * Tab 200 mg | 14.53 | 100 | | Tegretol |
| * Tab long acting 200 mg | 16.00 | 100 | - | Tegretol AU |
| * Tab long-acting 200 mg | | 100 200 | | Tegretol CR |
| * Tab 400 mg | | 200 100 | | Tegretol CR Tegretol |
| * Tab long-acting 400 mg | | 100 | | Tegretol CR |
| * Oral lig 20 mg per ml | | 250 m | | Tegretol |
| CLOBAZAM – Safety medicine; prescriber may determine disper | | 200 11 | | |
| Tab 10 mg | 0 1 2 | 50 | 1 | Frisium |
| 5 | | 50 | • | i norum |
| CLONAZEPAM – Safety medicine; prescriber may determine dis Oral drops 2.5 mg per ml | | 10 ml C | | Rivotril |
| | | | /r' ▼ | |
| ETHOSUXIMIDE | 70.00 | F ^ | , | F |
| Cap 250 mg | | 56 | | Essential |
| | | | | Ethosuximide S29 |
| | 140.88 | 100 | | Zarontin |
| Oral liq 250 mg per 5 ml | | 200 m | i 🗸 | Zarontin |
| GABAPENTIN | | | | |
| Note: Not subsidised in combination with subsidised pregaba | | | - | |
| * Cap 100 mg | | 100 | | Nupentin |
| * Cap 300 mg | | 100 | | Nupentin |
| * Cap 400 mg | | 100 | ~ | Nupentin |
| LACOSAMIDE – Special Authority see SA2267 on the next page | | ,. | | |
| ▲ Tab 50 mg | | 14 | | Vimpat |
| ▲ Tab 100 mg | | 14 | | Vimpat |
| Tab 150 mg | 200.24 | 56 | | Vimpat Vimpat |
| ▲ Tab 150 mg | | 14 56 | | Vimpat Vimpat |
| ▲ Tab 200 mg | | 56 | | Vimpat |
| | | 50 | • | Timpat |

| Su | ubsidy | Fully | Brand or |
|----------|--------------------|----------|--------------|
| (Manufac | cturer's Price) Su | bsidised | Generic |
| | \$ Per | ✓ | Manufacturer |

➡SA2267 Special Authority for Subsidy

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

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

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

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

| LA | MOTRIGINE | | | | |
|-----|--|---------|-----------|---|---------------------|
| ▲ | Tab dispersible 2 mg | | 30 | - | Lamictal |
| ▲ | Tab dispersible 5 mg | | 30 | - | Lamictal |
| * | Tab dispersible 25 mg | 4.20 | 56 | - | Logem |
| * | Tab dispersible 50 mg | 5.11 | 56 | - | Logem |
| * | Tab dispersible 100 mg | 6.75 | 56 | 1 | Logem |
| LE | VETIRACETAM | | | | |
| | Tab 250 mg | | 60 | 1 | Everet |
| | Tab 500 mg | | 60 | - | Everet |
| | Tab 750 mg | | 60 | - | Everet |
| | Tab 1,000 mg | | 60 | - | Everet |
| | Oral lig 100 mg per ml | | 300 ml OP | - | Levetiracetam-AFT |
| | Inj 100 mg per ml, 5 ml vial | | 10 | | Levetiracetam-AFT |
| PH | ENOBARBITONE | | | | |
| ••• | For phenobarbitone oral liquid refer Standard Formulae, p | age 274 | | | |
| | Tab 15 mg | | 500 | 1 | Noumed |
| | | | | | Phenobarbitone |
| | Tab 30 mg | 398.50 | 500 | 1 | Noumed |
| | | | | | Phenobarbitone |
| DН | IENYTOIN SODIUM | | | | <u></u> |
| | Tab 50 mg | 75.00 | 200 | 1 | Dilantin Infatab |
| * | Cap 30 mg | | 200 | | Dilantin |
| | Cap 100 mg | | 200 | | Dilantin |
| * | Oral liq 30 mg per 5 ml | | 500 ml | | Dilantin Paediatric |
| | | | 000 111 | • | Bhantin i dediatrio |
| PH | EGABALIN Note: Not subsidised in combination with subsidised gaba | opontin | | | |
| * | 8 | | 56 | 1 | Pregabalin Pfizer |
| 不 | Cap 25 mg | | 50 | | |
| | 0 | 7.80 | 50 | | Milpharm S29 |
| * | Cap 75 mg | | 56 | | Pregabalin Pfizer |
| | | 8.10 | | | Milpharm S29 |
| * | Cap 150 mg | 4.01 | 56 | | Lyrica |
| | a | | | | Pregabalin Pfizer |
| * | Cap 300 mg | 7.38 | 56 | ~ | Pregabalin Pfizer |
| PR | IMIDONE | | | | |
| * | Tab 250 mg | | 100 | 1 | Primidone Clinect |
| | | | | | |

| Subsidy | | Fully | |
|----------------------------|--------|---|---|
| anufacturer's Price) \$ | Per | ubsidised ✓ | Generic Manufacturer |
| | | | |
| 13.65 | 100 | ✓ | Epilim Crushable |
| 27.44 | 100 | ✓ | Epilim |
| 52.24 | 100 | ✓ | Epilim |
| 20.48 | 300 ml | ✓ | Epilim S/F Liquid |
| | | ✓ | Epilim Syrup |
| 41.50 | 1 | ✓ | Epilim IV |
| nacv | | | |
| , | 60 | ✓ | Diacomit |
| | 60 | ✓ | Diacomit |
| | 52.24 | 52.24 100 20.48 300 ml 41.50 1 nacy 509.29 60 | 52.24 100 • 20.48 300 ml • 41.50 1 • nacy 509.29 60 • |

⇒SA2268 Special Authority for Subsidy

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

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

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

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

| TOPIF | AMATE |
|-------|-------|
|-------|-------|

| ▲ Tab 25 mg | | 60 | Arrow-Topiramate |
|---|-----------------|-----|--|
| - | | | Topiramate Actavis |
| | 26.04 | | Topamax |
| ▲ Tab 50 mg | | 60 | Arrow-Topiramate |
| - | | | Topiramate Actavis |
| | 44.26 | | Topamax |
| ▲ Tab 100 mg | | 60 | Arrow-Topiramate |
| J. J | | | Topiramate Actavis |
| | 75.25 | | Topamax |
| ▲ Tab 200 mg | 55.19 | 60 | Arrow-Topiramate |
| J. J | | | Topiramate Actavis |
| | 129.85 | | Topamax |
| Sprinkle cap 15 mg | 20.84 | 60 | Topamax |
| Sprinkle cap 25 mg | | 60 | Topamax |
| VIGABATRIN - Special Authority see SA2088 below - F | letail pharmacy | | |
| ▲ Tab 500 mg | | 100 | Sabril |
| ▲ Powder for oral soln 500 mg per sachet | | 60 | ✓ Sabril |
| | | | |

➡SA2088 Special Authority for Subsidy

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

- 1 Any of the following:
 - 1.1 Patient has infantile spasms; or
 - 1.2 Both:
 - 1.2.1 Patient has epilepsy; and
 - 1.2.2 Either:

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

continued...

- 1.2.2.1 Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents; or
- 1.2.2.2 Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents; 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 114

Acute Migraine Treatment

| RIZATRIPTAN Tab orodispersible 10 mg4.84 | 30 | ✓ <u>Rizamelt</u> | | | | |
|---|----------|--|--|--|--|--|
| SUMATRIPTAN Tab 50 mg14.41 Tab 100 mg22.68 | 90 90 | ✓ <u>Sumagran</u> ✓ <u>Sumagran</u> | | | | |
| Inj 12 mg per ml, 0.5 ml prefilled pen – Maximum of 10 inj per prescription | 2 OP | ✓ <u>Clustran</u> | | | | |
| Prophylaxis of Migraine | | | | | | |
| For Beta Adrenoceptor Blockers refer to CARDIOVASCULAR SYSTEM, page 47 | | | | | | |
| PIZOTIFEN * Tab 500 mcg23.21 | 100 | Sandomigran | | | | |
| Antinausea and Vertigo Agents | | | | | | |
| For Antispasmodics refer to ALIMENTARY TRACT, page 8 | | | | | | |
| APREPITANT – Special Authority see SA0987 below – Retail pharmacy Cap 2 × 80 mg and 1 × 125 mg21.90 | 3 OP | Emend Tri-Pack | | | | |
| ■ SA0987 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid for 12 months where the patient is undergoing highly emetogenic chemotherapy and/or anthracycline-based chemotherapy for the treatment of malignancy. Renewal from any relevant practitioner. Approvals valid for 12 months where the patient is undergoing highly emetogenic chemotherapy and/or anthracycline-based chemotherapy for the treatment of malignancy. BETAHISTINE DIHYDROCHLORIDE | | | | | | |
| * Tab 16 mg3.70 | 100 | ✓ <u>Serc</u> | | | | |

▲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 |
|--|---|-----|---------------------|--------------------------------------|
| CYCLIZINE HYDROCHLORIDE Tab 50 mg CYCLIZINE LACTATE | 0.66 | 10 | ✓ <u>N</u> | lausicalm |
| Inj 50 mg per ml, 1 ml ampoule – Up to 10 inj available on a PSO | | 10 | ✓ <u>⊦</u> | lameln |
| DOMPERIDONE * Tab 10 mg | 4.00 | 100 | ✓ [| <u>Domperidone</u> <u>Viatris</u> |
| HYOSCINE HYDROBROMIDE | | | | |
| Inj 400 mcg per ml, 1 ml ampoule Patch 1 mg per 72 hours – Special Authority see SA1998 | 93.00 | 10 | 🗸 N | lartindale S29 |
| below – Retail pharmacy | | 10 | ✓ S | Scopolamine - Mylan |

➡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 | 1.57 | 100 | ✓ <u>Metoclopramide</u> Actavis 10 |
| * Inj 5 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO | 7.00 | 10 | ✓ Baxter |
| ONDANSETRON | | | |
| * Tab 4 mg | 2.27 | 50 | Periset |
| Tab disp 4 mg - Up to 10 tab available on a PSO | | 10 | Periset ODT |
| * Tab 8 mg | | 50 | ✓ Periset |
| Tab disp 8 mg - Up to 10 tab available on a PSO | 0.90 | 10 | Periset ODT |
| PROCHLORPERAZINE | | | |
| * Tab 3 mg buccal | 5.97 | 50 | |
| | (30.00) | | Buccastem |
| | (30.00) | | Max Health S29 |
| | (30.00) | | Prochlorperazine |
| | , , | | Brown & Burk S29 |
| | (30.00) | | Prochlorperazine Max Health |
| * Tab 5 mg – Up to 30 tab available on a PSO | .25.00 | 250 | Nausafix |
| Inj 12.5 mg per ml, 1 ml – Up to 5 inj available on a PSO (Buccastem Tab 3 mg buccal to be delisted 1 July 2025) (Max Health \$29 Tab 3 mg buccal to be delisted 1 July 2025) | | 10 | ✓ Stemetil |
| | | | |

(Prochlorperazine Brown & Burk S29 Tab 3 mg buccal to be delisted 1 July 2025)

| | Subsidy | | Fully Brand or |
|--|-----------------------|-----------|--|
| | (Manufacturer's Price | | Subsidised Generic |
| | \$ | Per | Manufacturer |
| Antipsychotics | | | |
| General | | | |
| MISULPRIDE - Safety medicine; prescriber may determine d | ispensing frequency | | |
| Tab 100 mg | | 30 | Sulprix |
| Tab 200 mg | | 60 | ✓ Sulprix |
| Tab 400 mg | | 60 | ✓ Sulprix |
| IPIPRAZOLE – Safety medicine; prescriber may determine | | | <u> </u> |
| Tab 5 mg | | 30 | Aripiprazole Sandoz |
| Tab 5 mg | | 30 | ✓ Anpiprazole Sandoz |
| | | | |
| T 10 | 40.55 | | Aripiprazole S29 |
| Tab 10 mg | | 30 | Aripiprazole Sandoz |
| Tab 15 mg | | 30 | Aripiprazole Sandoz |
| Tab 20 mg | | 30 | Aripiprazole Sandoz |
| Tab 30 mg | | 30 | Aripiprazole Sandoz |
| scend Aripiprazole S29 Tab 5 mg to be delisted 1 July 2025 |) | | |
| LORPROMAZINE HYDROCHLORIDE - Safety medicine; p | rescriber may determ | ine dis | spensing frequency |
| Tab 25 mg - Up to 30 tab available on a PSO | | 100 | ✓ Largactil |
| Tab 100 mg – Up to 30 tab available on a PSO | | 100 | ✓ Largactil |
| Inj 25 mg per ml, 2 ml – Up to 5 inj available on a PSO | | 10 | ✓ Largactil |
| OZAPINE – Hospital pharmacy [HP4] | | | |
| | 10001 | | |
| Safety medicine; prescriber may determine dispensing freq | | 50 | Claning |
| Tab 25 mg | 0.09 | 50 | Clopine Clozaril |
| | 10.07 | 100 | ✓ Clopine |
| | 13.37 | 100 | ✓ Clozaril |
| | 0.07 | 50 | |
| Tab 50 mg | | 50 | Clopine |
| T-1 400 mm | 17.33 | 100 | Clopine |
| Tab 100 mg | 17.33 | 50 | Clopine |
| | | | Clozaril |
| | 34.65 | 100 | Clopine |
| | | | Clozaril |
| Tab 200 mg | | 50 | Clopine |
| | 69.30 | 100 | Clopine |
| Suspension 50 mg per ml | 147.30 | 100 m | Versacloz |
| LOPERIDOL - 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 | | 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 m | Serenace |
| Inj 5 mg per ml, 1 ml ampoule – Up to 5 inj available on a l | | 10 | ✓ Serenace |
| VOMEPROMAZINE – Safety medicine; prescriber may dete | | uonov | |
| · · · · · | | 100 uency | |
| Tab 25 mg (33.8 mg as a maleate) | | 100 | ✓ Nozinan (Swiss) ✓ Nozinan |
| Tab 25 mg as a maleate | | | |
| Tab 100 mg (135 mg as a maleate) | | 100 | Nozinan (Swiss) |
| Tab 100 mg as a maleate | 41./5 | 100 | Nozinan |

▲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) | | Fully Subsidised | |
|---|-----------------------------------|--------|---------------------|------------------------------|
| | (Manulacturer 3 1 1106) \$ | Per | | Manufacturer |
| EVOMEPROMAZINE HYDROCHLORIDE - Safety medicin | e; prescriber may deterr | nine d | ispensing | frequency |
| Inj 25 mg per ml, 1 ml ampoule | | 10 | | Nozinan S29 S29 Wockhardt |
| lozinan S29 S29 Inj 25 mg per ml, 1 ml ampoule to be deli | sted 1 July 2025) | | | |
| THIUM CARBONATE - Safety medicine; prescriber may d | etermine dispensing free | quency | / | |
| Tab long-acting 400 mg | | 100 | ✓ | Priadel |
| Cap 250 mg | 22.36 | 100 | ~ | Douglas |
| LANZAPINE - Safety medicine; prescriber may determine | dispensina frequency | | | |
| Tab 2.5 mg | | 30 | 1 | Zypine |
| Tab 5 mg | | 30 | | Zypine |
| Tab orodispersible 5 mg | | 28 | | Zypine ODT |
| Tab 10 mg | | 30 | | Zypine |
| Tab orodispersible 10 mg | | 28 | | Zypine ODT |
| | | 20 | • | Elburg on L |
| ERICYAZINE – Safety medicine; prescriber may determine | | | | |
| Tab 2.5 mg | | 100 | | Neulactil |
| Tab 10 mg | | 100 | ~ | Neulactil |
| UETIAPINE - Safety medicine; prescriber may determine of | lispensing frequency | | | |
| Tab 25 mg | | 30 | ✓ | Quetiapine |
| C C | | | | Viatris S29 |
| | 2.36 | 90 | 1 | Quetapel |
| | 13.11 | 500 | - | Quetiapine |
| | 10.11 | 500 | • | Viatris S29 |
| Tab 100 mm | C 40 | 00 | | |
| Tab 100 mg | | 90 | | Quetapel |
| Tab 200 mg | | 90 | | Quetapel |
| Tab 300 mg | 15.83 | 90 | • | Quetapel |
| ISPERIDONE – Safety medicine; prescriber may determine | e dispensing frequency | | | |
| Tab 0.5 mg | 0.72 | 20 | ✓ | Risperdal |
| | 2.17 | 60 | 1 | Risperidone (Teva) |
| | 4.01 | | ✓ | Risperidone |
| | | | | Sandoz S29 |
| Tab 1 mg | | 60 | 1 | Risperdal |
| · | | | | Risperidone (Teva) |
| | 3.68 | | | Risperidone |
| | 0.00 | | | Sandoz S29 |
| Tab 0 mg | 0.70 | 60 | | Risperdal |
| Tab 2 mg | | 00 | | • |
| | F 00 | | | Risperidone (Teva) |
| | 5.38 | | • | Risperidone |
| | | | | Sandoz S29 |
| Tab 3 mg | 4.50 | 60 | | Risperdal |
| | | | | Risperidone (Teva) |
| | 8.57 | | 1 | Risperidone |
| | | | | Sandoz S29 |
| Tab 4 mg | 6.25 | 60 | 1 | Risperdal |
| 5 | | | | Risperidone (Teva) |
| Oral lig 1 mg per ml | | 30 m | | Risperon |
| | | | - | |

NERVOUS SYSTEM

| | Subsidy (Manufacturer's Price) \$ | Subsi Per | Fully dised | Brand or Generic Manufacturer |
|---|---|--------------|----------------|---|
| ZIPRASIDONE – Safety medicine; prescriber may determine dis | pensing frequency | | | |
| Cap 20 mg | | 60 | 1 | Zusdone |
| Cap 40 mg | 27.41 | 60 | 1 | Zusdone |
| Cap 60 mg | | 60 | 1 | Zusdone |
| Cap 80 mg | | 60 | 1 | Zusdone |
| ZUCLOPENTHIXOL HYDROCHLORIDE - Safety medicine; pres | scriber may determine | e dispensir | ng fre | quency |
| Tab 10 mg | | 100 | | Clopixol |
| Depot Injections | | | | |
| ARIPIPRAZOLE – Special Authority see SA2395 below – Retail Safety medicine; prescriber may determine dispensing freque | , | | | |
| Inj 300 mg vial | | 1 | | Abilify Maintena Abilify Maintena S29 S29 |
| Inj 400 mg vial | | 1 | | Abilify Maintena Abilify Maintena S29 S29 |

⇒SA2395 Special Authority for Subsidy

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

Either:

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

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

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

FLUPENTHIXOL DECANOATE - Safety medicine; prescriber may 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 dispe | ensing freque | ency |
| 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 SA2313 below - Retail pl | narmacy | | | |
| a) Safety medicine; prescriber may determine dispensing fr | equency | | | |
| b) Note – no new patients to be initiated on olanzapine. | | | | |
| Inj 210 mg vial | | 1 | ✓ Z | yprexa Relprevv |
| Inj 300 mg vial | | 1 | ✓ Z | yprexa Relprevv |
| Inj 405 mg vial | 504.00 | 1 | | yprexa Relprevv |
| | | | | |

⇒SA2313 Special Authority for Subsidy

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

PALIPERIDONE - Special Authority see SA2396 below - Retail pharmacy

Safety medicine; prescriber may determine dispensing frequency

| Inj 25 mg syringe | 1 | Invega Sustenna |
|--------------------|-------|-------------------------------------|
| Inj 50 mg syringe | 1 | Invega Sustenna |
| Inj 75 mg syringe | 1 | Invega Sustenna |
| Inj 100 mg syringe | 1 | Invega Sustenna |
| Inj 150 mg syringe | 1 | Invega Sustenna |
| | | Invega oustenna |

⇒SA2396 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 been unable to adhere to treatment using oral atypical antipsychotic agents; and
 - 2.3 Has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in last 12 months.

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

| PALIPERIDONE PALMITATE - 5 | pecial Authority see SA2167 below – Retail pharm | iacy | |
|----------------------------|--|------|-----------------|
| Inj 175 mg syringe | | 1 | 🗸 Invega Trinza |
| Inj 263 mg syringe | | 1 | 🗸 Invega Trinza |
| Inj 350 mg syringe | | 1 | 🗸 Invega Trinza |
| | | 1 | 🗸 Invega Trinza |
| | | | |

➡SA2167 Special Authority for Subsidy

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

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

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

RISPERIDONE - Special Authority see SA2397 on the next page - Retail pharmacy

| Safety medicine; prescriber may determine dispens | sing frequency | | |
|---|----------------|---|--------------------------------------|
| Inj 25 mg vial | | 1 | Risperdal Consta |
| Inj 37.5 mg vial | | 1 | Risperdal Consta |
| Inj 50 mg vial | | 1 | Risperdal Consta |
| , 0 | | | |

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

⇒SA2397 Special Authority for Subsidy

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

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

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

ZUCLOPENTHIXOL DECANOATE – Safety medicine; prescriber may determine dispensing frequency 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 | | 00 | Buspirone Viatris |
| * Tab 10 mg | | 00 | Buspirone Viatris |
| CLONAZEPAM - Safety medicine; prescriber may de | etermine dispensing frequency | | |
| Tab 500 mcg | | 00 | 🗸 Paxam |
| Tab 2 mg | | 00 | 🗸 Paxam |
| DIAZEPAM – Safety medicine; prescriber may deterr | mine dispensing frequency | | |
| Tab 2 mg | | 00 | Arrow-Diazepam |
| Tab 5 mg | | 00 | Arrow-Diazepam |
| LORAZEPAM - Safety medicine; prescriber may dete | ermine dispensing frequency | | |
| Tab 1 mg | | 50 | Ativan |
| Tab 2.5 mg | | 00 | ✓ Ativan |
| | | | |

Multiple Sclerosis Treatments

➡SA2274 Special Authority for Subsidy

Initial application — (Multiple Sclerosis - dimethyl fumarate, fingolimod, glatiramer acetate, interferon beta-1-alpha, interferon beta-1-beta, natalizumab and teriflunomide) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Either:

- 1 All of the following:
 - 1.1 Diagnosis of multiple sclerosis (MS) meets the McDonald 2017 diagnostic criteria for MS and has been confirmed by a neurologist; and
 - 1.2 Patient has an EDSS score between 0 6.0; and
 - 1.3 Patient has had at least one significant attack of MS in the previous 12 months or two significant attacks in the past 24 months; and
 - 1.4 All of the following:
 - 1.4.1 Each significant attack must be confirmed by the applying neurologist or general physician (the patient may

| | Subsidy | Ful | ly | Brand or |
|--------|------------------|-----------|----|--------------|
| (Manuf | acturer's Price) | Subsidise | ed | Generic |
| | \$ | Per • | / | Manufacturer |

continued...

not necessarily have been seen by them during the attack, but the neurologist/physician must be satisfied that the clinical features were characteristic); and

- 1.4.2 Each significant attack is associated with characteristic new symptom(s)/sign(s) or substantially worsening of previously experienced symptoms(s)/sign(s); and
- 1.4.3 Each significant attack has lasted at least one week and has started at least one month after the onset of a previous attack (where relevant); and
- 1.4.4 Each significant attack can be distinguished from the effects of general fatigue; and is not associated with a fever (T> 37.5°C); and
- 1.4.5 Either:
 - 1.4.5.1 Each significant attack is severe enough to change either the EDSS or at least one of the Kurtze Functional System scores by at least 1 point; or
 - 1.4.5.2 Each significant attack is a recurrent paroxysmal symptom of multiple sclerosis (tonic seizures/spasms, trigeminal neuralgia, Lhermitte's symptom); and
- 1.5 Evidence of new inflammatory activity on an MRI scan within the past 24 months; and
- 1.6 Any of the following:
 - 1.6.1 A sign of that new inflammatory activity on MRI scanning (in criterion 5 immediately above) is a gadolinium enhancing lesion; or
 - 1.6.2 A sign of that new inflammatory activity is a lesion showing diffusion restriction; or
 - 1.6.3 A sign of that new inflammatory is a T2 lesion with associated local swelling; or
 - 1.6.4 A sign of that new inflammatory activity is a prominent T2 lesion that clearly is responsible for the clinical features of a recent attack that occurred within the last 2 years; or
 - 1.6.5 A sign of that new inflammatory activity is new T2 lesions compared with a previous MRI scan; or
- 2 Patient has an active approval for ocrelizumab and does not have primary progressive MS.

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

Renewal — (Multiple Sclerosis - dimethyl fumarate, fingolimod, glatiramer acetate, interferon beta-1-alpha, interferon beta-1-beta, natalizumab and teriflunomide) from any relevant practitioner. Approvals valid for 12 months where patient has had an EDSS score of 0 to 6.0 (inclusive) with or without the use of unilateral or bilateral aids at any time in the last six months (ie the patient has walked 100 metres or more with or without aids in the last six months).

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

DIMETHYL FUMARATE – Special Authority see SA2274 on the previous page – Retail pharmacy

| | i on the providuo page 1 | iotan priarin | aby |
|--|----------------------------|---------------|--------------------------------|
| a) Wastage claimable | | | |
| b) Note: Treatment on two or more funded multiple | sclerosis treatments simu | taneously is | s not permitted. |
| Cap 120 mg | | 14 | ✓ Tecfidera |
| | | | |
| Cap 240 mg | 2,000.00 | 56 | Tecfidera |
| FINGOLIMOD - Special Authority see SA2274 on the pr | revious page - Retail phar | macy | |
| a) Wastage claimable | | | |
| b) Note: Treatment on two or more funded multiple | sclarosis treatments simu | tanoously is | not permitted |
| , | | | |
| Cap 0.5 mg | 2,200.00 | 28 | Gilenya |
| GLATIRAMER ACETATE - Special Authority see SA22 | 74 on the previous page - | Retail pharr | nacv |
| Note: Treatment on two or more funded multiple scl | | | |
| • | | | Copaxone |
| Inj 40 mg prefilled syringe | 1,137.46 | 12 | Copaxone |
| INTERFERON BETA-1-ALPHA – Special Authority see | SA2274 on the previous pa | age – Retail | pharmacy |
| Note: Treatment on two or more funded multiple scl | | | |
| Inj 6 million iu prefilled syringe | | 4 | Avonex |
| | | | ✓ Avonex Pen |
| Injection 6 million iu per 0.5 ml pen injector | | 4 | Avonex Pen |
| (Avonex Pen Injection 6 million iu per 0.5 ml pen injector | to be delisted 1 Septembe | er 2025) | |
| INTERFERON BETA-1-BETA - Special Authority see S | A2274 on the previous page | ne – Retail r | harmacy |
| Note: Treatment on two or more funded multiple sch | | | |
| • | | | |
| | 4 000 00 | | |
| Inj 8 million iu per 1 ml | 1,322.89 | 15 | Betaferon |

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per Manufacturer \$ NATALIZUMAB - Special Authority see SA2274 on page 137 - Retail pharmacy Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted. Tysabri 1 TERIFLUNOMIDE - Special Authority see SA2274 on page 137 - Retail pharmacy a) Brand switch fee payable (Pharmacode 2701847) - see page 272 for details b) Wastage claimable c) Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted. Teriflunomide 28 Sandoz Multiple Sclerosis Treatments - Other OCRELIZUMAB – Special Authority see SA2273 below – Retail pharmacy Note: Treatment on two or more funded multiple sclerosis treatments simultaneously is not permitted. Inj 30 mg per ml, 10 ml vial......9,346.00 1 ✓ Ocrevus SA2273 Special Authority for Subsidy Initial application — (Multiple Sclerosis - ocrelizumab) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria: Either: 1 All of the following: 1.1 Diagnosis of multiple sclerosis (MS) meets the McDonald 2017 diagnostic criteria for MS and has been confirmed by a neurologist; and 1.2 Patient has an EDSS score between 0 - 6.0; and 1.3 Patient has had at least one significant attack of MS in the previous 12 months or two significant attacks in the past 24 months: and 1.4 All of the following: 1.4.1 Each significant attack must be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the attack, but the neurologist/physician must be satisfied that the clinical features were characteristic); and 1.4.2 Each significant attack is associated with characteristic new symptom(s)/sign(s) or substantially worsening of previously experienced symptoms(s)/sign(s); and 1.4.3 Each significant attack has lasted at least one week and has started at least one month after the onset of a previous attack (where relevant); and 1.4.4 Each significant attack can be distinguished from the effects of general fatigue; and is not associated with a fever (T> 37.5°C); and 1.4.5 Fither: 1.4.5.1 Each significant attack is severe enough to change either the EDSS or at least one of the Kurtze Functional System scores by at least 1 point; or 1.4.5.2 Each significant attack is a recurrent paroxysmal symptom of multiple sclerosis (tonic seizures/spasms, trigeminal neuralgia, Lhermitte's symptom); and 1.5 Evidence of new inflammatory activity on an MRI scan within the past 24 months; and 1.6 Any of the following: 1.6.1 A sign of that new inflammatory activity on MRI scanning (in criterion 5 immediately above) is a gadolinium enhancing lesion: or 1.6.2 A sign of that new inflammatory activity is a lesion showing diffusion restriction; or 1.6.3 A sign of that new inflammatory is a T2 lesion with associated local swelling; or 1.6.4 A sign of that new inflammatory activity is a prominent T2 lesion that clearly is responsible for the clinical features of a recent attack that occurred within the last 2 years: or

continued...

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

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

continued...

- 1.6.5 A sign of that new inflammatory activity is new T2 lesions compared with a previous MRI scan; or
- 2 Patient has an active Special Authority approval for either dimethyl fumarate, fingolimod, glatiramer acetate, interferon beta-1-alpha, interferon beta-1-beta, natalizumab or teriflunomide.

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

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

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

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

All of the following:

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

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

Sedatives and Hypnotics

MELATONIN - Special Authority see SA1666 below - Retail pharmacy

Restricted to patients aged 18 years or under.

► 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.

Vigisom

NERVOUS SYSTEM

| | Subsidy | | Fully | |
|--|------------------------------|---------|--------------|---------------------------------------|
| | (Manufacturer's Price) \$ | Per | Subsidised | |
| | * | rei | • | Manulaclurer |
| MIDAZOLAM – Safety medicine; prescriber may determine dispe | • • • | 10 | | Midanalam Davtar |
| Inj 1 mg per ml, 5 ml ampoule | | 10 | | Midazolam-Baxter Midazolam Viatris |
| Inj 1 mg per ml, 5 ml plastic ampoule – Up to 10 inj available | | | • | |
| on a PSO | | 10 | 1 | Pfizer |
| On a PSO for status epilepticus use only. PSO must be | | | | |
| Inj 5 mg per ml, 1 ml plastic ampoule - Up to 10 inj available | | • • | | , |
| on a PSO | | 10 | 1 | Midazolam-Pfizer |
| On a PSO for status epilepticus use only. PSO must be | | | | |
| Inj 5 mg per ml, 3 ml ampoule | | 5 | | Midazolam-Baxter |
| | 5.50 | | ~ | Midazolam Viatris |
| Inj 5 mg per ml, 3 ml plastic ampoule – Up to 5 inj available | | 5 | | Pfizer |
| a PSO On a PSO for status epilepticus use only. PSO must be | | | | |
| (Midazolam Viatris Inj 1 mg per ml, 5 ml ampoule to be delisted 1 | | spiicp | | only. |
| Midazolam Viatris Inj 5 mg per ml, 3 ml ampoule to be delisted 1 | | | | |
| PHENOBARBITONE SODIUM – Special Authority see SA1386 b | • • | acv | | |
| Inj 200 mg per ml, 1 ml ampoule | | 10 | 1 | Max Health S29 |
| ⇒SA1386 Special Authority for Subsidy | | 10 | - | |
| nitial application from any relevant practitioner. Approvals valid he following criteria: Both: | i without further rene | waru | niess notii | ned for applications meetin |
| For the treatment of terminal agitation that is unresponsive The applicant is part of a multidisciplinary team working in | • | ł | | |
| TEMAZEPAM – Safety medicine; prescriber may determine dispe | | | | |
| Tab 10 mg | 0 1 2 | 25 | 1 | Normison |
| ZOPICLONE – Safety medicine; prescriber may determine disper | | | | |
| Tab 7.5 mg | • • • | 500 | 1 | Zopiclone Actavis |
| Spinal Muscular Atrophy | | | | |
| | | | | |
| NUSINERSEN - PCT only - Special Authority see SA2174 below | | | | |
| Inj 12 mg per 5 ml vial | .120,000.00 | 1 | 1 | Spinraza |
| SA2174 Special Authority for Subsidy | | | | |
| nitial application — (spinal muscular atrophy (SMA)) from an | y relevant practition | er. A | pprovals v | alid for 12 months for |
| pplications meeting the following criteria: III of the following: | | | | |
| C C | anno dolotion homo | - | CMNI1 | a sint mutation or compour |
| Patient has genetic documentation of homozygous SMN1 heterozygous mutation; and | gene deletion, nomo | zygoi | us Siviivi j | solut mutation, or compour |
| 2 Patient is 18 years of age or under; and | | | | |
| 3 Either: | | | | |
| 3.1 Patient has experienced the defined signs and sym3.2 Both: | ptoms of SMA type | , II or | IIIa prior 1 | to three years of age; or |
| 3.2.1 Patient is pre-symptomatic; and | | | | |
| 3.2.2 Patient has three or less copies of SMN2. | | | | |

3.2.2 Patient has three or less copies of SMN2.

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

▲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 | | / Brand or | |
|------------------------|-----------|--------------|--|
| (Manufacturer's Price) | Subsidise | d Generic | |
| \$ | Per 🗸 | Manufacturer | |

continued...

All of the following:

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

RISDIPLAM - [Xpharm] - Special Authority see SA2203 below

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

Powder for oral soln 750 mcg per ml, 60 mg per bottle.....14,100.00 80 ml OP 🖌 Evrysdi

⇒SA2203 Special Authority for Subsidy

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

All of the following:

- 1 Patient has genetic documentation of homozygous SMN1 gene deletion, homozygous SMN1 point mutation, or compound heterozygous mutation; and
- 2 Patient is 18 years of age or under; and
- 3 Either:
 - 3.1 Patient has experienced the defined signs and symptoms of SMA type I, II or IIIa prior to three years of age; or
 - 3.2 Both:
 - 3.2.1 Patient is pre-symptomatic; and
 - 3.2.2 Patient has three or less copies of SMN2.

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

All of the following:

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

Stimulants/ADHD Treatments

ATOMOXETINE 28 ✓ APO-Atomoxetine ✓ APO-Atomoxetine 28 ✓ APO-Atomoxetine 28 ✓ APO-Atomoxetine 28 28 ✓ APO-Atomoxetine 28 ✓ APO-Atomoxetine Cap 100 mg......65.71 28 APO-Atomoxetine DEXAMFETAMINE SULFATE - Special Authority see SA2410 on the next page - Retail pharmacy

a) Only on a controlled drug form

| b) | Safety medicine | ; prescriber may determine disp | ensing frequency | |
|----|-----------------|---------------------------------|------------------|-----|
| Та | b 5 mg | | | 100 |

<u>Noumed</u>
 <u>Dexamfetamine</u>

Vyvanse

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

⇒SA2410 Special Authority for Subsidy

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

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

3 Either:

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

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

Both:

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

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

LISDEXAMFETAMINE DIMESILATE - Special Authority see SA2415 below - Retail pharmacy

a) Only on a controlled drug form

| b) Safety medicine; prescriber may determine dispensing frequency | | |
|---|----|---|
| Cap 30 mg - No more than 1 cap per day60.00 | 30 | \ \ |
| Cap 50 mg | 30 | \ \ |

| Cap 50 mg | 50.00 | 30 | vyvanse |
|-----------|-------|----|-----------------------------|
| Cap 70 mg | 60.00 | 30 | Vyvanse |

► SA2415 Special Authority for Subsidy

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

Either:

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

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

continued...

adherence difficulties; or

2.4.5 There is significant concern regarding the risk of diversion or abuse of immediate release methylphenidate hydrochloride; or

2.4.6 Both:

- 2.4.6.1 Patient would have been prescribed a subsidised formulation of methylphenidate hydrochloride (extended-release) but has been unable to access due to supply issues with methylphenidate hydrochloride (extended-release); and
- 2.4.6.2 Other alternative stimulant presentations (methylphenidate or dexamfetamine) are not appropriate; and
- 2.5 Lisdexamfetamine dimesilate is not to be used in combination with another funded methylphenidate presentation.

METHYLPHENIDATE HYDROCHLORIDE - Special Authority see SA2411 below - Retail pharmacy

a) Only on a controlled drug form

| Ł |)) | S | Saf | ety | m | ed | licin | e; | prescri | ber | may | det | erm | ine | di | sper | nsir | ٦g | frec | quei | ncy | |
|---|----|---|-----|-----|---|----|-------|----|---------|-----|-----|-----|-----|-----|----|------|------|----|------|------|-----|--|
| | | | | | | | | | | | | | | | | | | | | | | |

| Tab immediate-release 5 mg | | 30 | Rubifen |
|-----------------------------|-------|----|--|
| Tab immediate-release 10 mg | | 30 | Rubifen |
| · | 4.00 | | Ritalin |
| 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 |

⇒SA2411 Special Authority for Subsidy

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

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

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

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

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

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

| | Subsidy (Manufacturer's Price) \$ | Per | Fully Subsidised | |
|--|---|-------|---------------------|------------------------|
| METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEAS | SE – Special Authorit | / see | SA2450 b | elow – Retail pharmacy |
| a) Only on a controlled drug form | | | | |
| b) Safety medicine; prescriber may determine dispensing fr | equency | | | |
| Tab extended-release 18 mg | | 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 | | 30 | ✓ | Concerta |
| Cap modified-release 10 mg | | 30 | ✓ | Ritalin LA |
| Cap modified-release 20 mg | 27.72 | 30 | ✓ | Ritalin LA |
| Cap modified-release 30 mg | | 30 | ✓ | Ritalin LA |
| Cap modified-release 40 mg | | 30 | 1 | Ritalin LA |

➡SA2450 Special Authority for Subsidy

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

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

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

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

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

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

| MODAFINIL - Special Authorit | y see SA2451 below – Retail pharmacy |
|------------------------------|--------------------------------------|
| | |

| Tab 100 mg | 14.27 | 30 | Modafinil Max Health |
|---|-------|----|--|
| | 29.13 | 60 | Modavigil |
| Modafinil Max Health to be Principal Supply on 1 May 2025 | | | - |

(Modavigil Tab 100 mg to be delisted 1 May 2025)

⇒SA2451 Special Authority for Subsidy

Initial application only from a neurologist or respiratory specialist. Approvals valid without further renewal unless notified for

continued...

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

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

| Subsidy | F | ully | Brand or |
|------------------------|---------|------|--------------|
| (Manufacturer's Price) | Subsidi | sed | Generic |
| \$ | Per | ✓ | Manufacturer |

continued...

applications meeting the following criteria:

Either:

- 1 All of the following:
 - 1.1 The patient has a diagnosis of narcolepsy and has excessive daytime sleepiness associated with narcolepsy occurring almost daily for three months or more; and
 - 1.2 Either:
 - 1.2.1 The patient has a multiple sleep latency test with a mean sleep latency of less than or equal to 10 minutes and 2 or more sleep onset rapid eye movement periods; or
 - 1.2.2 The patient has at least one of: cataplexy, sleep paralysis or hypnagogic hallucinations; and
 - 1.3 Either:
 - 1.3.1 An effective dose of a subsidised formulation of methylphenidate or dexamfetamine has been trialled and discontinued because of intolerable side effects; or
 - 1.3.2 Methylphenidate and dexamfetamine are contraindicated; or

2 Both:

- 2.1 Patient meets the Special Authority criteria for methylphenidate hydrochloride or methylphenidate hydrochloride extended-release for narcolepsy; and
- 2.2 Patient is unable to access methylphenidate hydrochloride presentations due to an out of stock (see note).

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

Treatments for Dementia

DONEPEZIL HYDROCHLORIDE

| * Tab 5 mg | | 84 | Ipca-Donepezil |
|---|-----------------|----|--|
| * Tab 10 mg | | 84 | Ipca-Donepezil |
| RIVASTIGMINE - Special Authority see SA1488 below - F | letail pharmacy | | |
| Patch 4.6 mg per 24 hour | | 30 | <u>Rivastigmine Patch</u> <u>BNM 5</u> |
| | 90.00 | | Exelon Patch 5 |
| Patch 9.5 mg per 24 hour | | 30 | <u>Rivastigmine Patch</u> <u>BNM 10</u> |
| | 90.00 | | Exelon Patch 10 |
| (Evalor Datch & Datch & C manax 04 hours to be delicted 1 | luna 0005) | | |

(Exelon Patch 5 Patch 4.6 mg per 24 hour to be delisted 1 June 2025) (Exelon Patch 10 Patch 9.5 mg per 24 hour to be delisted 1 June 2025)

⇒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) \$ | F Subsidi Per | ully Brand or sed Generic Manufacturer |
|--|---|---------------------|---|
| Treatments for Substance Dependence | | | |
| BUPRENORPHINE WITH NALOXONE – Special Authority see 5 a) No patient co-payment payable b) Safety medicine; prescriber may determine dispensing fre | | il pharmacy | |
| Tab sublingual 2 mg with naloxone 0.5 mg | 11.76 | 28 | <u>Buprenorphine</u> Naloxone BNM |
| Tab sublingual 8 mg with naloxone 2 mg | 34.00 | 28 | ✓ <u>Buprenorphine</u> Naloxone BNM |

⇒SA1203 Special Authority for Subsidy

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

BUPROPION HYDROCHLORIDE

| Tab modified-release | 150 mg | 15.00 | 30 | 🗸 Zyban |
|----------------------|--------|-------|----|---------|
|----------------------|--------|-------|----|---------|

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

| | Subsidy (Manufacturer's Price) | | Fully Brand or Subsidised Generic |
|---|-----------------------------------|------|--|
| | (Manulacturer's Flice) \$ | Per | |
| DISULFIRAM | | | |
| Tab 200 mg | 236.40 | 100 |) 🖌 Antabuse |
| NALTREXONE HYDROCHLORIDE - Special Authority see SA14 | 08 below – Retail p | harm | nacy |
| Tab 50 mg | 77.77 | 28 | Naltrexone AOP S29 |
| | 83.33 | 30 | ✓ Naltraccord |
| | 102.60 | | Naltrexone Max Health \$29 |
| | 138.88 | 50 | Revia S29 |
| (Revia \$29) Tab 50 mg to be delicted 1 July 2025) | | | |

(Revia S29) Tab 50 mg to be delisted 1 July 2025)

⇒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 19.62 | 28 🖌 | Habitrol |
|---|-------|----------|
| Patch 14 mg – Up to 28 patch available on a PSO | 28 🖌 | Habitrol |
| Patch 14 mg for direct distribution only - [Xpharm]12.49 | 7 🖌 | Habitrol |
| Patch 21 mg – Up to 28 patch available on a PSO | 28 🖌 | Habitrol |
| Patch 21 mg for direct distribution only - [Xpharm]13.19 | 7 🖌 | Habitrol |
| Lozenge 1 mg - Up to 216 loz available on a PSO22.53 | 216 🖌 | Habitrol |
| Lozenge 1 mg for direct distribution only - [Xpharm] 12.89 | 36 🖌 | Habitrol |
| Lozenge 2 mg - Up to 216 loz available on a PSO24.68 | 216 🖌 | Habitrol |
| Lozenge 2 mg for direct distribution only - [Xpharm] 13.25 | 36 🖌 | Habitrol |
| Gum 2 mg (Fruit) – Up to 204 piece available on a PSO | 204 🖌 | Habitrol |
| Gum 2 mg (Fruit) for direct distribution only - [Xpharm]17.57 | 96 🖌 | Habitrol |
| Gum 2 mg (Mint) – Up to 204 piece available on a PSO23.02 | 204 🖌 | Habitrol |
| Gum 2 mg (Mint) for direct distribution only - [Xpharm]17.57 | 96 🖌 | Habitrol |
| Gum 4 mg (Fruit) – Up to 204 piece available on a PSO25.98 | 204 🖌 | Habitrol |
| Gum 4 mg (Fruit) for direct distribution only - [Xpharm]23.87 | 96 🖌 | Habitrol |
| Gum 4 mg (Mint) – Up to 204 piece available on a PSO25.98 | 204 🗸 | Habitrol |
| Gum 4 mg (Mint) for direct distribution only - [Xpharm]23.87 | 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 | Champix |
|-------------------------------|-------|-------|-----------------------------|
| Tab 1 mg | 17.62 | 56 | Champix |

| (I | Subsidy Ianufacturer's Price) | | Fully Subsidised | Brand or Generic |
|----|----------------------------------|-----|---------------------|---------------------|
| | \$ | Per | 1 | 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 - S | Special Authority see | SA23 | 398 below | |
| Inj 25 mg vial | | 1 | ✓ I | Bendamustine Sandoz |
| | 77.00 | | 🗸 I | Ribomustin |
| Inj 100 mg vial | 200.20 | 1 | ✓ I | Bendamustine Sandoz |
| | 308.00 | | 🗸 I | Ribomustin |
| Inj 1 mg for ECP | 2.11 | 1 mg | 🗸 I | Baxter |

⇒SA2398 Special Authority for Subsidy

Initial application — (CLL*) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria: All of the following:

- 1 The patient has chronic lymphocytic leukaemia requiring treatment; and
- 2 Patient has ECOG performance status of 0-2; and
- 3 Bendamustine is to be administered at a maximum dose of 100 mg/m² on days 1 and 2 every 4 weeks for a maximum of 6 cycles.

Note: Indication marked with a * includes indications that are unapproved. 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma (SLL).

Initial application — (Indolent, Low-grade lymphomas) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria: All of the following:

- 1 The patient has indolent low grade NHL requiring treatment; and
- 2 The patient has ECOG performance status of 0-2; and
- 3 Any of the following:
 - 3.1 Both:
 - 3.1.1 Patient is treatment naive; and
 - 3.1.2 Bendamustine is to be administered for a maximum of 6 cycles (in combination with rituximab when CD20+); or
 - 3.2 Both:
 - 3.2.1 Patient is refractory to or has relapsed within 12 months of a rituximab containing combined chemo-immunotherapy regimen; and
 - 3.2.2 Bendamustine is to be administered in combination with obinutuzumab for a maximum of 6 cycles; or
 - 3.3 All of the following:
 - 3.3.1 The patient has not received prior bendamustine therapy; and
 - 3.3.2 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and
 - 3.3.3 Patient has had a rituximab treatment-free interval of 12 months or more; or
 - 3.4 Bendamustine is to be administered as monotherapy for a maximum of 6 cycles in rituximab refractory patients.

Renewal — (Indolent, Low-grade lymphomas) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria: Either:

1 Both:

1.1 Patient is refractory to or has relapsed within 12 months of rituximab in combination with bendamustine; and

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

continued...

- 1.2 Bendamustine is to be administered in combination with obinutuzumab for a maximum of 6 cycles; or
- 2 Both:

DOT

- 2.1 Patients have not received a bendamustine regimen within the last 12 months; and
- 2.2 Either:
 - 2.2.1 Both:
 - 2.2.1.1 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and
 - 2.2.1.2 Patient has had a rituximab treatment-free interval of 12 months or more; or
 - 2.2.2 Bendamustine is to be administered as a monotherapy for a maximum of 6 cycles in rituximab refractory patients.

Note: 'indolent, low-grade lymphomas' includes follicular, mantle cell, marginal zone and lymphoplasmacytic/ Waldenstrom's macroglobulinaemia.

Initial application — (Hodgkin's lymphoma*) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Patient has Hodgkin's lymphoma requiring treatment; and
- 2 Patient has a ECOG performance status of 0-2; and
- 3 Patient has received one prior line of chemotherapy; and
- 4 Patient's disease relapsed or was refractory following prior chemotherapy; and

~

5 Bendamustine is to be administered in combination with gemcitabine and vinorelbine (BeGeV) at a maximum dose of no greater than 90 mg/m2 twice per cycle, for a maximum of four cycles.

Note: Indications marked with * are unapproved indications.

D · · · ·

| BUSULFAN – PCT – Retail pharmacy-Specialist | | | |
|---|--------|------------|--|
| Tab 2 mg | | 100 | Myleran |
| CARBOPLATIN – PCT only – Specialist | | | |
| Inj 10 mg per ml, 45 ml vial | 25.73 | 1 | Carboplatin Accord |
| | | | DBL Carboplatin S29 S29 |
| | 32.59 | | DBL Carboplatin |
| | 48.50 | | ✓ Carbaccord |
| Inj 1 mg for ECP | 0.06 | 1 mg | ✓ Baxter |
| CARMUSTINE – PCT only – Specialist | | - | |
| Inj 100 mg vial | 710.00 | 1 | BiCNU |
| | | | BiCNU S29 S29 |
| | | | ✓ Novadoz S29 |
| Inj 100 mg for ECP | 710.00 | 100 mg OP | ✓ Baxter |
| (BiCNU S29 \$29 Inj 100 mg vial to be delisted 1 July 2025) | | loo nig ol | Buildi |
| | | | |
| (Novadoz \$29 Inj 100 mg vial to be delisted 1 July 2025) | | | |
| 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 | 9.45 | 1 | Cisplatin Accord |
| | 15.00 | | Cisplatin Ebewe |
| Inj 1 mg per ml, 100 ml vial | | 1 | Cisplatin Accord |
| | 21.00 | | Cisplatin Ebewe |
| | 29.66 | | DBL Cisplatin |
| Inj 1 mg for ECP | 0.19 | 1 mg | ✓ 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 | | Fully | |
|--|------------------------------|------|------------|------------------------------|
| (1 | /lanufacturer's Price) \$ | Per | Subsidised | Generic Manufacturer |
| YCLOPHOSPHAMIDE | * | | | |
| Tab 50 mg - PCT - Retail pharmacy-Specialist | 145.00 | 50 | 1 | Cyclonex |
| Inj 1 g vial – PCT – Retail pharmacy-Specialist | | 1 | | Endoxan |
| ······································ | 127.80 | 6 | | Cytoxan |
| Inj 2 g vial – PCT only – Specialist | 95.06 | 1 | | Endoxan |
| Inj 1 mg for ECP - PCT only - Specialist | | 1 mg | 1 | Baxter |
| FOSFAMIDE – PCT only – Specialist | | - | | |
| lnj 1 g | 96.00 | 1 | 1 | Holoxan |
| lnį 2 g | | 1 | 1 | Holoxan |
| Inj 1 mg for ECP | | 1 mg | 1 | Baxter |
| OMUSTINE – PCT – Retail pharmacy-Specialist | | • | | |
| Cap 40 mg | 880.00 | 20 | 1 | Medac S29 |
| /ELPHALAN | | 20 | • | incuto 😅 |
| Tab 2 mg – PCT – Retail pharmacy-Specialist | 40 70 | 25 | 1 | Alkeran |
| | | 1 | | Megval \$29 |
| Inj 50 mg – PCT only – Specialist | 48.20 | I | | Melpha |
| | 67.80 | | | Alkeran |
| Megval 🚥 Inj 50 mg to be delisted 1 July 2025) | 07.00 | | • | Aikelali |
| | | | | |
| DXALIPLATIN – PCT only – Specialist | | | | |
| Inj 100 mg vial | 25.01 | 1 | ~ | Oxaliplatin Actavis |
| | | | | 100 |
| hi Farmana da Obartaist | 110.00 | | | Oxaliplatin Ebewe |
| Inj 5 mg per ml, 20 ml vial | | 1 | | Alchemy Oxaliplatin |
| Ini 1 ma fax ECD | 46.32 | 1 | | Oxaliplatin Accord Baxter |
| Inj 1 mg for ECP | 0.35 | 1 mg | • | Baxter |
| HIOTEPA – PCT only – Specialist | | | | |
| Inj 15 mg vial | CBS | 1 | 1 | Bedford S29 |
| | | | 1 | Max Health S29 |
| | | | 1 | THIO-TEPA S29 |
| | 398.00 | | 1 | Tepadina |
| Inj 100 mg vial | CBS | 1 | 1 | Max Health S29 |
| | 1,800.00 | | ~ | Tepadina |
| Antimetabolites | | | | |
| ZACITIDINE – PCT only – Specialist – Special Authority see SA2 | 141 bolow | | | |
| Inj 100 mg vial | | 1 | 1 | Azacitidine Dr |
| IIIJ 100 IIIY viai | | I. | • | Reddy's |
| Inj 1 mg for ECP | 0.54 | 1 ma | | Baxter |
| SA2141 Special Authority for Subsidy | 0.54 | 1 mg | • | Daxiei |

⇒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);

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

continued...

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 Pric | | Fully Subsidised | Generic |
|---|---|-----------|---------------------|------------------------------------|
| | \$ | Per | | Manufacturer |
| ALCIUM FOLINATE | | | | |
| Tab 15 mg – PCT – Retail pharmacy-Specialist | 135.33 | 10 | | DBL Leucovorin Calcium |
| Inj 3 mg per ml, 1 ml – PCT – Retail pharmacy-Specialist | | 5 | | Hospira |
| Inj 10 mg per ml, 5 ml vial – PCT – Retail pharmacy-Speci | alist7.28 | 1 | 1 | Calcium Folinate Sandoz |
| | | | 1 | Calcium Folinate Sandoz S29 S29 |
| | 112.20 | 5 | 1 | Eurofolic S29 |
| Inj 50 mg – PCT – Retail pharmacy-Specialist | | 10 | 1 | Leucovorin |
| , | | | | Pharmacia S29 |
| Inj 10 mg per ml, 10 ml vial - PCT only - Specialist | 9.49 | 1 | 1 | Calcium Folinate |
| | | | - | Sandoz |
| | 163.35 | 5 | 1 | Eurofolic S29 |
| Inj 100 mg – PCT only – Specialist | | 1 | | Calcium Folinate |
| , | | | | Ebewe |
| | 94.90 | 10 | ~ | Leucovorin |
| | | | | Pharmacia S29 |
| Inj 300 mg - PCT only - Specialist | 21.55 | 1 | 1 | Leucovorin DBL S29 |
| | 22.51 | | 1 | Calcium Folinate Ebewe |
| Inj 10 mg per ml, 35 ml vial – PCT only – Specialist | | 1 | 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 | 1 | Calcium Folinate Sandoz |
| | 139.48 | | 1 | Eurofolic S29 |
| Inj 1 mg for ECP – PCT only – Specialist | | 1 mg | | Baxter |
| lcium Folinate Sandoz Inj 10 mg per ml, 5 ml vial to be delis | | 0 | | |
| alcium Folinate Sandoz S29 329 Inj 10 mg per ml, 5 ml vial alcium Folinate Sandoz Inj 10 mg per ml, 10 ml vial to be del alcium Folinate Ebewe Inj 100 mg to be delisted 1 November alcium Folinate Ebewe Inj 300 mg to be delisted 1 November | to be delisted 1 Nov isted 1 November 20 [,] 2025) | ember 20 | 025) | |
| alcium Folinate Ebewe inj 300 mg to be delisted i November alcium Folinate Sandoz Inj 10 mg per ml, 35 ml vial to be deli | , | 125) | | |
| alcium Folinate Sandoz III 10 mg per mi, 35 mi via 10 be den alcium Folinate Sandoz S29 S29 Inj 10 mg per ml, 35 ml via | | , | 00251 | |
| alcium Folinate Sandoz S29 see "inj To mg per mi, 35 mi via alcium Folinate Ebewe Inj 1 g to be delisted 1 November 202 alcium Folinate Sandoz Inj 10 mg per ml, 100 ml vial to be de | 25) | | .020) | |
| | | .020) | | |
| PECITABINE – Retail pharmacy-Specialist | 0.00 | <u></u> | | Conceitables Vistels |
| Tab 150 mg | | 60 120 | | Capecitabine Viatris |
| Tab 500 mg | | 120 | • | Capecitabine Viatris |
| ADRIBINE – PCT only – Specialist | 740.00 | | | Louistatin |
| Inj 1 mg per ml, 10 ml | | 1 | - | Leustatin |
| Inj 10 mg for ECP | | 10 mg O | г 🗸 | Baxter |

| | Subsidy (Manufacturer's | Price) Subs | Fully Brand or idised Generic |
|--|----------------------------|-------------|--|
| | (inditidated of 0 \$ | Per | Manufacturer |
| CYTARABINE | | | |
| Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Speci | ialist472.00 | 5 | Pfizer |
| Inj 100 mg per ml, 20 ml vial – PCT – Retail | | | |
| pharmacy-Specialist | | 1 | Cytarabine DBL |
| | | | Pfizer |
| | | | Pfizer S29 S29 |
| Inj 1 mg for ECP – PCT only – Specialist | 0.29 | 10 mg | Baxter |
| Inj 100 mg intrathecal syringe for ECP - PCT only - Speci | ialist94.40 | 100 mg OP | Baxter |
| FLUDARABINE PHOSPHATE | | - | |
| Tab 10 mg - PCT - Retail pharmacy-Specialist | | 20 | Fludara Oral |
| Inj 50 mg vial – PCT only – Specialist | | 1 | ✓ Fludarabine |
| ,,, | | - | Sagent S29 |
| | 634.00 | 5 | ✓ Fludarabine Ebewe |
| Inj 50 mg for ECP – PCT only – Specialist | | 50 mg OP | ✓ Baxter |
| FLUOROUBACIL | | oo nig or | Build |
| Ini 50 mg per ml, 20 ml vial – PCT only – Specialist | 10 51 | 1 | Fluorouracil Accord |
| Inj 50 mg per ml, 50 ml vial – PCT only – Specialist | | 1 | Fluorouracii Accor Fluorouracii Accor |
| Inj 50 mg per ml, 100 ml vial – PCT only – Specialist | | 1 | Fluorouracil Accor Fluorouracil Accor |
| Inj 1 mg for ECP – PCT only – Specialist | | 100 mg | ✓ Pluorouracii Accor ✓ Baxter |
| | | Too mg | |
| GEMCITABINE HYDROCHLORIDE – PCT only – Specialist | | | |
| Inj 43.3 mg per ml (equivalent to 38 mg per ml gemcitabine | , | | |
| 26.3 ml vial | | 1 | ✓ DBL Gemcitabine |
| Inj 1 g | | 1 | Gemcitabine Ebew Bowter |
| Inj 1 mg for ECP | 0.02 | 1 mg | Baxter |
| RINOTECAN HYDROCHLORIDE – PCT only – Specialist | | | |
| Inj 20 mg per ml, 5 ml vial | | 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 |
| Oral suspension 20 mg per ml - Retail pharmacy-Speciali | st – | | |
| Special Authority see SA1725 below | | 100 ml OP | Allmercap |
| · · · · | | | • |

➡SA1725 Special Authority for Subsidy

Initial application only from a paediatric haematologist or paediatric oncologist. Approvals valid for 12 months where the patient requires a total dose of less than one full 50 mg tablet per day.

Renewal only from a paediatric haematologist or paediatric oncologist. Approvals valid for 12 months where patient still requires a total dose of less than one full 50 mg tablet per day.

| | Subsidy | | Fully | Brand or |
|--|-------------------------|----------|---------|-------------------------|
| | Manufacturer's Pr \$ | Per Subs | sidised | Generic Manufacturer |
| ETHOTBEXATE | • | | | |
| Tab 2.5 mg – PCT – Retail pharmacy-Specialist | 7 80 | 90 | 1 | Trexate |
| Tab 2.5 mg – PCT – Retail pharmacy-Specialist | | 90 | | Trexate |
| Inj 2.5 mg per ml, 2 ml – PCT – Retail pharmacy-Specialist | | 5 | | Methotrexate DBL |
| Inj 7.5 mg prefilled syringe | | 1 | | Methotrexate |
| | | I | • | Sandoz |
| k Inj 10 mg prefilled syringe | 19.09 | 1 | 1 | Methotrexate |
| | | | • | Sandoz |
| Inj 15 mg prefilled syringe | 24 53 | 1 | 1 | Methotrexate |
| | | | • | Sandoz |
| k Inj 20 mg prefilled syringe | 16.64 | 1 | 1 | Methotrexate |
| Inj 20 mg premied synnge | 10.04 | I | • | Sandoz |
| k Ini OE ma profilled ouringe | 00.70 | 4 | | |
| Inj 25 mg prefilled syringe | | 1 | v | Methotrexate Sandoz |
| | 55.00 | | | Sandoz Mathatravata |
| Inj 30 mg prefilled syringe | 55.00 | 1 | ~ | Methotrexate |
| | | _ | | Sandoz |
| Inj 25 mg per ml, 2 ml vial – PCT – Retail pharmacy-Specialis | t30.00 | 5 | ~ | Methotrexate DBL |
| | | | | Onco-Vial |
| Inj 25 mg per ml, 20 ml vial – PCT – Retail pharmacy-Speciali | st45.00 | 1 | ~ | DBL Methotrexate |
| | | | | Onco-Vial |
| Inj 100 mg per ml, 10 ml – PCT – Retail pharmacy-Specialist. | 25.00 | 1 | 1 | Methotrexate Ebewe |
| k Inj 100 mg per ml, 50 ml vial – PCT – Retail | | | | |
| pharmacy-Specialist | 67.99 | 1 | 1 | Methotrexate Ebewe |
| Inj 1 mg for ECP – PCT only – Specialist | 0.06 | 1 mg | 1 | Baxter |
| Inj 5 mg intrathecal syringe for ECP – PCT only – Specialist | 4.73 | 5 mg OP | ✓ | Baxter |
| PEMETREXED – PCT only – Specialist | | - | | |
| Inj 100 mg vial | 8 99 | 1 | 1 | Pemetrexed-AFT |
| | 60.89 | • | | Juno Pemetrexed |
| Inj 500 mg vial | | 1 | | Pemetrexed-AFT |
| | 217.77 | · | | Juno Pemetrexed |
| Inj 1 mg for ECP | | 1 mg | | Baxter |
| | | 1.119 | | Baxton |
| HIOGUANINE – PCT – Retail pharmacy-Specialist Tab 40 mg | 106.01 | 25 | | Lanvis |
| Tab 40 mg | 120.31 | 20 | • | Lativis |
| Other Cytotoxic Agents | | | | |
| MSACRINE – PCT only – Specialist | | | | |
| Inj 50 mg per ml, 1.5 ml ampoule | 4,736.00 | 6 | 1 | Amsidine S29 |
| Inj 75 mg | | 5 | | AmsaLyo S29 |
| | | - | | , |
| NAGRELIDE HYDROCHLORIDE – PCT – Retail pharmacy-Spe | | 100 | ./ | Agnulin |
| Cap 0.5 mg | 1,1/5.8/ | 100 | v | Agrylin |
| RSENIC TRIOXIDE – PCT only – Specialist | | | | |
| Inj 1 mg per ml, 10 ml vial | | 10 | | Phenasen |
| Inj 10 mg for ECP | | 10 mg OP | 1 | Baxter |
| BLEOMYCIN SULPHATE – PCT only – Specialist | | | | |
| | 105 16 | 1 | 1 | DBL Bleomycin |
| Inj 15,000 iu, vial | 100.10 | 1 | | |
| Inj 15,000 iu, vial | 103.10 | | | Sulfate |

| | Subsidy | | Fully Brand or |
|---|-------------------|------------------|--|
| | (Manufacturer's F | | idised Generic |
| | \$ | Per | Manufacturer |
| BORTEZOMIB - PCT only - Specialist - Special Authority see S | SA2355 below | | |
| Inj 3.5 mg vial | 74.93 | 1 | DBL Bortezomib |
| Inj 1 mg for ECP | 22.26 | 1 mg | Baxter |
| ■ SA2355 Special Authority for Subsidy | | | |
| Initial application - (plasma cell dyscrasia) from any relevant | t practitioner. A | pprovals valid w | vithout further renewal unless |
| notified where the patient has plasma cell dyscrasia, not including | g Waldenström r | nacroglobulinae | emia, requiring treatment. |
| DACARBAZINE – PCT only – Specialist | | | |
| Inj 200 mg vial | 72.11 | 1 | DBL Dacarbazine |
| Inj 200 mg for ECP | 72.11 | 200 mg OP | Baxter |
| DACTINOMYCIN [ACTINOMYCIN D] - PCT only - Specialist | | | |
| Inj 0.5 mg vial | | 1 | Cosmegen |
| Inj 0.5 mg for ECP | | 0.5 mg OP | ✓ Baxter |
| DAUNORUBICIN – PCT only – Specialist | | - | |
| Inj 2 mg per ml, 10 ml | | 1 | ✓ Pfizer |
| Inj 20 mg for ECP | | 20 mg OP | ✓ Baxter |
| DOCETAXEL – PCT only – Specialist | | - 5 - | |
| Inj 20 mg | 48 75 | 1 | Docetaxel Sandoz |
| Inj 10 mg per ml, 8 ml vial | | 1 | ✓ DBL Docetaxel |
| Inj 20 mg per ml, 4 ml vial | | 1 | ✓ Docetaxel |
| | | | Accord S29 |
| Inj 80 mg | 195.00 | 1 | ✓ Docetaxel Sandoz |
| Inj 1 mg for ECP | | 1 mg | ✓ Baxter |
| DOXORUBICIN HYDROCHLORIDE – PCT only – Specialist | | i iig | Bunton |
| Inj 2 mg per ml, 5 ml vial | 10.00 | 1 | Doxorubicin Ebewe |
| Inj 2 mg per ml, 25 ml vial | | 1 | Doxorubicin Ebewe Doxorubicin Ebewe |
| 11) z 119 per 111, zo 111 viai | 11.50 | I | Arrow-Doxorubicin |
| Inj 2 mg per ml, 50 ml vial | | 1 | ✓ Doxorubicin Ebewe |
| Inj 2 mg per ml, 100 ml vial | | 1 | ✓ Arrow-Doxorubicin |
| | 69.99 | | ✓ Doxorubicin Ebewe |
| Inj 1 mg for ECP | | 1 mg | ✓ Baxter |
| EPIRUBICIN HYDROCHLORIDE - PCT only - Specialist | | 5 | |
| Inj 2 mg per ml, 5 ml vial | 25.00 | 1 | Epirubicin Ebewe |
| Inj 2 mg per ml, 25 ml vial | | 1 | Epirubicin Ebewe |
| Inj 2 mg per ml, 100 ml vial | | 1 | Epirubicin Ebewe |
| Inj 1 mg for ECP | | 1 mg | ✓ Baxter |
| ETOPOSIDE | | 0 | |
| Cap 50 mg – PCT – Retail pharmacy-Specialist | 340.73 | 20 | ✓ Vepesid |
| Cap 100 mg – PCT – Retail pharmacy-Specialist | | 10 | ✓ Vepesid |
| Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Special | | 1 | ✓ Rex Medical |
| Inj 1 mg for ECP – PCT only – Specialist | | 1 mg | ✓ Baxter |
| ETOPOSIDE PHOSPHATE – PCT only – Specialist | | Ū | |
| Inj 100 mg (of etoposide base) | | 1 | Etopophos |
| Inj 1 mg (of etoposide base) for ECP | | 1 mg | ✓ Baxter |
| HYDROXYUREA [HYDROXYCARBAMIDE] – PCT – Retail pha | | 0 | |
| Cap 500 mg | | 100 | Devatis |
| | | 100 | - Devans |
| IBRUTINIB – Special Authority see SA2168 on the next page – | | 00 | . Imbuudaa |
| Tab 140 mg | , | 30 | Imbruvica Imbruvica |
| Tab 420 mg | 9,052.00 | 30 | Imbruvica |
| | | | |

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

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

⇒SA2168 Special Authority for Subsidy

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

All of the following:

- 1 Patient has chronic lymphocytic leukaemia (CLL) requiring therapy; and
- 2 Patient has not previously received funded ibrutinib; and
- 3 Ibrutinib is to be used as monotherapy; and
- 4 Any of the following:
 - 4.1 Both:
 - 4.1.1 There is documentation confirming that patient has 17p deletion or TP53 mutation; and
 - 4.1.2 Patient has experienced intolerable side effects with venetoclax monotherapy; or
 - 4.2 All of the following:
 - 4.2.1 Patient has received at least one prior immunochemotherapy for CLL; and
 - 4.2.2 Patient's CLL has relapsed within 36 months of previous treatment; and
 - 4.2.3 Patient has experienced intolerable side effects with venetoclax in combination with rituximab regimen; or
 - 4.3 Patient's CLL is refractory to or has relapsed within 36 months of a venetoclax regimen.

Renewal — (chronic lymphocytic leukaemia (CLL)) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

1 No evidence of clinical disease progression; and

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

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

IDARUBICIN HYDROCHLORIDE

| Inj 5 mg vial – PCT only – Specialist Inj 10 mg vial – PCT only – Specialist Inj 1 mg for ECP – PCT only – Specialist | 233.64 | 1 1 1 mg | ✓ Zavedos✓ Zavedos✓ Baxter |
|---|-------------------------|----------------|--|
| LENALIDOMIDE (VIATRIS) - Special Authority see SA23 | 53 below – Retail pharm | acy | |
| Cap 5 mg | | 21 | ✓ <u>Lenalidomide</u> <u>Viatris</u> |
| Cap 10 mg | | 21 | ✓ <u>Lenalidomide</u> <u>Viatris</u> |
| Cap 15 mg | 62.13 | 21 | ✓ <u>Lenalidomide</u> <u>Viatris</u> |
| Cap 25 mg | 65.09 | 21 | ✓ <u>Lenalidomide</u> Viatris |

⇒SA2353 Special Authority for Subsidy

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

Both:

- 1 Patient has plasma cell dyscrasia, not including Waldenström macroglobulinaemia, requiring treatment; and
- 2 Patient is not refractory to prior lenalidomide use.

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

Both:

1 Patient has low or intermediate-1 risk myelodysplastic syndrome (based on IPSS or an IPSS-R score of less than 3.5)

| | Subsidy (Manufacturer's Price | e) (| Fully Subsidised | Brand or Generic |
|---|----------------------------------|------------|--|---|
| | \$ | Per | ✓ | Manufacturer |
| continued | | | | |
| associated with a deletion 5q cytogenetic abnormality; and | l | | | |
| 2 Patient has transfusion-dependent anaemia. | | | | |
| Renewal — (Myelodysplastic syndrome) from any relevant pra the following criteria: Both: | ctitioner. Approva | ls valid f | for 12 mon | ths for applications meeting |
| Patient has not needed a transfusion in the last 4 months; No evidence of disease progression. | and | | | |
| MESNA | | | | |
| Tab 400 mg – PCT – Retail pharmacy-Specialist | 314.00 | 50 | Image: A second s | Uromitexan |
| Tab 600 mg - PCT - Retail pharmacy-Specialist | | 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 | 517.65 | 1 | ✓ | Mitomycin (Fresenius Kabi) ^{S29} |
| | 526.00 | | ✓ | Mitomycin (Sagent) 829 |
| | 641.70 | | ✓ , | Accord S29 |
| Inj 20 mg vial | 1.250.00 | 1 | 1 | Omegapharm S29 |
| | | • | | Teva |
| Inj 1 mg for ECP | | 1 mg | ✓ | Baxter |
| MITOZANTRONE – PCT only – Specialist | | 0 | | |
| Inj 2 mg per ml, 10 ml vial | 97 50 | 1 | Image: A second s | Mitozantrone Ebewe |
| Inj 1 mg for ECP | | 1 mg | | Baxter |
| NIRAPARIB – Special Authority see SA2325 below – Retail phar Wastage claimable | | | | |
| Tab 100 mg | 13,393.50 | 84 | ✓ : | Zejula |
| Cap 100 mg | | 56 | | Zejula |
| | 13,393.50 | 84 | ✓ : | Zejula |
| SA2325 Special Authority for Subsidy | | | | |

SA2325 Special Authority for Subsidy

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

- 1 Patient has advanced high-grade serous* epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
- 2 Patient has received at least one line** of treatment with platinum-based chemotherapy; and
- 3 Patient has experienced a partial or complete response to the preceding treatment with platinum-based chemotherapy; and
- 4 Patient has not previously received funded treatment with a PARP inhibitor; and
- 5 Either:
 - 5.1 Treatment will be commenced within 12 weeks of the patient's last dose of the preceding platinum-based regimen; or
 - 5.2 Patient commenced treatment with niraparib prior to 1 May 2024; and
- 6 Treatment to be administered as maintenance treatment; and
- 7 Treatment not to be administered in combination with other chemotherapy.

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

continued...

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

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

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

continued...

All of the following:

- 1 No evidence of progressive disease; and
- 2 Treatment to be administered as maintenance treatment; and
- 3 Treatment not to be administered in combination with other chemotherapy; and
- 4 Either:
 - 4.1 Treatment with niraparib to cease after a total duration of 36 months from commencement; or
 - 4.2 Treatment with niraparib is being used in the second-line or later maintenance setting.

Notes: * "high-grade serous" includes tumours with high-grade serous features or a high-grade serous component. **A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments

| OLAPARIB - Retai | pharmacy-Specialist - Specia | I Authority see SA2163 below |
|------------------|------------------------------|------------------------------|
|------------------|------------------------------|------------------------------|

| 🗸 Lynparza | 56 | Tab 100 mg |
|------------------------------|----|----------------|
| Lynparza | 56 | Tab 150 mg |

⇒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
- 4 Treatment will be commenced within 12 weeks of the patient's last dose of the immediately preceding platinum-based regimen; and
- 5 Treatment to be administered as maintenance treatment; and
- 6 Treatment not to be administered in combination with other chemotherapy.

Renewal — (Ovarian cancer) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Treatment remains clinically appropriate and patient is benefitting from treatment; and
- 2 Either:
 - 2.1 No evidence of progressive disease; or
 - 2.2 Evidence of residual (not progressive) disease and the patient would continue to benefit from treatment in the clinician's opinion; and
- 3 Treatment to be administered as maintenance treatment; and
- 4 Treatment not to be administered in combination with other chemotherapy; and

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

continued...

5 Either:

- 5.1 Both:
 - 5.1.1 Patient has received one line** of previous treatment with platinum-based chemotherapy; and
 - 5.1.2 Documentation confirming that the patient has been informed and acknowledges that the funded treatment period of olaparib will not be continued beyond 2 years if the patient experiences a complete response to treatment and there is no radiological evidence of disease at 2 years: or
- 5.2 Patient has received at least two lines** of previous treatment with platinum-based chemotherapy.

Notes: *Note "high-grade serous" includes tumours with high-grade serous features or a high-grade serous component. **A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

| PACLITAXEL – PCT only – Specialist | | | |
|---|--------------|------|----------------------------------|
| Inj 30 mg | | 5 | Paclitaxel Ebewe |
| Inj 6 mg per ml, 16.7 ml vial | | 1 | Anzatax |
| | 24.00 | | Paclitaxel Ebewe |
| | 91.67 | | Paclitaxel Actavis |
| lnj 150 mg | | 1 | Paclitaxel Ebewe |
| , 0 | 137.50 | | Anzatax |
| | | | Paclitaxel Actavis |
| Inj 6 mg per ml, 50 ml vial | | 1 | Anzatax |
| | 44.00 | | Paclitaxel Ebewe |
| | 275.00 | | Paclitaxel Actavis |
| Inj 1 mg for ECP | 0.17 | 1 mg | Baxter |
| PEGASPARGASE - PCT only - Special Authority see | SA1979 below | | |
| Inj 750 iu per ml, 5 ml vial | | 1 | Oncaspar LYO |
| | | | |

► SA1979 Special Authority for Subsidy

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

- 1 The patient has newly diagnosed acute lymphoblastic leukaemia: and
- 2 Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol.

Initial application - (Lymphoma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months where the patient has lymphoma requiring L-asparaginase containing protocols (e.g. SMILE).

Renewal — (Acute lymphoblastic leukaemia) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria: Both:

1 The patient has relapsed acute lymphoblastic leukaemia: and

2 Pegaspargase to be used with a contemporary intensive multi-agent chemotherapy treatment protocol.

PENTOSTATIN [DEOXYCOFORMYCIN] - PCT only - Specialist

| Inj 10 mg | CBS | 1 | Nipent S29 |
|---|----------------------------|------|--------------------------------|
| POMALIDOMIDE - Special Authority see SA2354 on th | e next page – Retail pharm | nacy | |
| Cap 1 mg | | 14 | Pomolide |
| | 71.18 | 21 | Pomolide |
| Cap 2 mg | | 14 | Pomolide |
| | 142.35 | 21 | Pomolide |
| Cap 3 mg | | 14 | Pomolide |
| | 213.53 | 21 | Pomolide |
| Cap 4 mg | | 14 | Pomolide |
| | 284.71 | 21 | Pomolide |

▲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) \$ | Subs Per | Fully idised | Brand or Generic Manufacturer |
|---|---|--------------|-----------------|-------------------------------------|
| SA2354 Special Authority for Subsidy | | | | |
| Initial application — (Relapsed/refractory plasma cell dyscra | sia) from any relevar | nt practitio | ner. Ap | provals valid for 6 months |
| for applications meeting the following criteria: | | | | |
| Both: | | | | |
| Patient has relapsed or refractory plasma cell dyscrasia, r treatment; and | not including Waldens | tröm macr | oglobul | inaemia, requiring |
| 2 Patient has not received prior funded pomalidomide. | | | | |
| Renewal — (Relapsed/refractory plasma cell dyscrasia) from there is no evidence of disease progression. | any relevant practitic | oner. App | rovals v | alid for 12 months where |
| PROCARBAZINE HYDROCHLORIDE - PCT - Retail pharmacy | -Specialist | | | |
| Cap 50 mg | | 50 | 🗸 N | atulan S29 |
| TEMOZOLOMIDE – Special Authority see SA2275 below – Reta | | | | |
| Cap 5 mg | | 5 | 🖌 Т | emaccord |
| oup o mg | | 0 | - | emozolomide- |
| | | | • | Taro S29 |
| Cap 20 mg | | 5 | 🗸 T | emaccord |
| | 18.30 | | 🗸 A | po-Temozolomide |
| Cap 100 mg | | 5 | 🖌 T | emaccord |
| | 40.20 | | 🗸 A | po-Temozolomide |
| Cap 140 mg | | 5 | 🗸 T | emaccord |
| Cap 250 mg | | 5 | 🗸 T | emaccord |

► SA2275 Special Authority for Subsidy

Initial application — (gliomas) only from a relevant specialist. Approvals valid for 12 months where the patient has a glioma. **Renewal** — (gliomas) only from a relevant specialist. Approvals valid for 12 months where treatment remains appropriate and patient is benefitting from treatment.

Initial application — (neuroendocrine tumours) only from a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 Patient has been diagnosed with metastatic or unresectable well-differentiated neuroendocrine tumour*; and
- 2 Temozolomide is to be given in combination with capecitabine; and
- 3 Temozolomide is to be used in 28 day treatment cycles for a maximum of 5 days treatment per cycle at a maximum dose of 200 mg/m² per day; and
- 4 Temozolomide to be discontinued at disease progression.

Renewal — (neuroendocrine tumours) only from a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

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

Initial application — (ewing's sarcoma) only from a relevant specialist. Approvals valid for 9 months where the patient has relapsed/refractory Ewing's sarcoma.

Renewal — (ewing's sarcoma) only from a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

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

Note: Indication marked with a * is an unapproved indication. Temozolomide is not subsidised for the treatment of relapsed high grade glioma.

| | Subsidy (Manufacturer's Price) \$ | Su Per | Fully bsidised | Brand or Generic Manufacturer |
|--|---|-----------|-------------------|-------------------------------------|
| THALIDOMIDE - Retail pharmacy-Specialist - Special Authority | see SA2356 below | | | |
| Cap 50 mg | | 28 | 🗸 T | halomid |
| Cap 100 mg | 756.00 | 28 | 🗸 T | halomid |

⇒SA2356 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 12 months where the patient has plasma cell dyscrasia, not including Waldenström macroglobulinaemia, requiring treatment.

Renewal from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has obtained a response from treatment during the initial approval period.

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

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

TRETINOIN

| Cap 10 mg – PCT – Retail pharmacy-Specialist | 479.50 | 100 | Vesanoid |
|---|--------------|-------|-------------------------------|
| VENETOCLAX - Retail pharmacy-Specialist - Special Authority see | SA1868 below | | |
| Tab 14 × 10 mg, 7 × 50 mg, 21 × 100 mg | 1,771.86 | 42 OP | Venclexta |
| Tab 10 mg | | 2 OP | Venclexta |
| Tab 50 mg | 239.44 | 7 OP | Venclexta |
| Tab 100 mg - Wastage claimable | 8,209.41 | 120 | Venclexta |

➡SA1868 Special Authority for Subsidy

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

All of the following:

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

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

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

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

All of the following:

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

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

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

| | Subsidy (Manufacturer's Price) \$ | Per | Fully Subsidised | |
|---|---|---------------|---------------------|----------------------------|
| VINBLASTINE SULPHATE | | - | | |
| Inj 1 mg per ml, 10 ml vial – PCT – Retail pharmacy-Specia | alist270.37 | 5 | 1 | Hospira |
| Inj 1 mg for ECP - PCT only - Specialist | | 1 mg | | Baxter |
| /INCRISTINE SULPHATE | | 0 | | |
| Inj 1 mg per ml, 1 ml vial – PCT – Retail pharmacy-Special | ist 74.52 | 5 | 1 | DBL Vincristine |
| | | Ũ | | Sulfate |
| Inj 1 mg per ml, 2 ml vial – PCT – Retail pharmacy-Special | ist102.73 | 5 | 1 | DBL Vincristine |
| | | | | Sulfate |
| Inj 1 mg for ECP – PCT only – Specialist | | 1 mg | 1 | Baxter |
| /INORELBINE | | | | |
| Cap 20 mg | 30.00 | 1 | 1 | Vinorelbine Te Arai |
| Cap 30 mg | | 1 | | Vinorelbine Te Arai |
| Cap 80 mg | | 1 | | Vinorelbine Te Arai |
| Inj 10 mg per ml, 1 ml vial – PCT only – Specialist | | 1 | | Vinorelbine Ebewe |
| Inj 10 mg per ml, 5 ml vial - PCT only - Specialist | | 1 | 1 | Navelbine S29 S29 |
| | 210.00 | | | Vinorelbine Ebewe |
| Inj 1 mg for ECP – PCT only – Specialist | | 1 mg | 1 | Baxter |
| ALECTINIB – Retail pharmacy-Specialist – Special Authority se Wastage claimable | e SA1870 below | | | |
| Cap 150 mg | 7 935 00 | 224 | 1 | Alecensa |
| SA1870 Special Authority for Subsidy Initial application only from a medical oncologist or medical pra Approvals valid for 6 months for applications meeting the followi All of the following: Patient has locally advanced, or metastatic, unresectable There is documentation confirming that the patient has a ALK test; and Patient has an ECOG performance score of 0-2. Renewal only from a medical oncologist or medical practitioner for 6 months for applications meeting the following criteria: Both: No evidence of progressive disease according to RECIS The patient is basefiliating from and following transmitted | ng criteria: e, non-small cell lung c n ALK tyrosine kinase on the recommendatio | ancei gene | r; and rearrange | ement using an appropriate |
| 2 The patient is benefitting from and tolerating treatment. AXITINIB – Special Authority see SA2458 below – Retail pharm Wastage claimable | nacy | | | |
| Tab 1 mg | | 28 | 1 | Inlyta |
| Tab 5 mg | | 28 | ✓ | Inlyta |
| SA2458 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals val All of the following: 1 The patient has metastatic renal cell carcinoma; and | id for 4 months for ap | plicati | ons meeti | ng the following criteria: |

- 2 The disease is of predominant clear cell histology; and
- 3 The patient has documented disease progression following one previous line of treatment; and
- 4 The patient has ECOG performance status of 0-2.

Renewal from any relevant practitioner. Approvals valid for 4 months where there is no evidence of disease progression..

| | Subsidy (Manufacturer's Price) \$ | S Per | Fully ubsidised | Brand or Generic Manufacturer |
|--|---|----------|--------------------|-------------------------------------|
| CRIZOTINIB – Special Authority see SA2459 below – Retail pha | irmacy | | | |
| Cap 200 mg | 7,250.00 | 60 | 🗸 Xa | alkori |
| Cap 250 mg | 7,250.00 | 60 | 🗸 Xa | alkori |

► SA2459 Special Authority for Subsidy

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

- 1 Patient has locally advanced or metastatic, unresectable, non-squamous non-small cell lung cancer; and
- 2 There is documentation confirming that the patient has a ROS1 rearrangement using an appropriate ROS1 test; and
- 3 Patient has ECOG performance score of 0-3; and
- 4 Baseline measurement of overall tumour burden is documented clinically and radiologically.

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

- 1 Response to treatment has been determined by comparable radiological assessment following the most recent treatment period; and
- 2 No evidence of disease progression..

DASATINIB - Special Authority see SA2385 below - Retail pharmacy

a) Brand switch fee payable (Pharmacode 2700441) - see page 272 for details

| b) Wastage claimable | | |
|----------------------|--------|------------------------------------|
| Tab 20 mg | 60 | Dasatinib-Teva |
| Tab 50 mg | 60 | Dasatinib-Teva |
| Tab 70 mg | 60 | Dasatinib-Teva |

► SA2385 Special Authority for Subsidy

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

Any of the following:

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

- 2 The patient has a diagnosis of Philadelphia chromosome-positive acute lymphoid leukaemia (Ph+ ALL); or
- 3 Both:
 - 3.1 The patient has a diagnosis of CML in chronic phase; and
 - 3.2 Any of the following:
 - 3.2.1 Patient has documented treatment failure* with imatinib; or
 - 3.2.2 Patient has experienced treatment-limiting toxicity with imatinib precluding further treatment with imatinib; or
 - 3.2.3 Patient has high-risk chronic-phase CML defined by the Sokal or EURO scoring system.

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

Both:

- 1 Lack of treatment failure while on dasatinib*; and
- 2 Dasatinib treatment remains appropriate and the patient is benefiting from treatment.
- Note: *treatment failure for CML as defined by Leukaemia Net Guidelines.

| ERLOTINIB - Retail pharmacy-Specialist - Special Authority | v see SA2422 below | | |
|--|--------------------|----|-----------------------------|
| Tab 100 mg | | 30 | Alchemy |
| Tab 150 mg | | 30 | Alchemy |

► SA2422 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

1 Patient has locally advanced or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and

| | Subsidy | | Fully Brand or |
|---|------------------------------|----------------|---------------------------------|
| | (Manufacturer's Price) \$ | Subsidi Per | ised Generic Manufacturer |
| continued | | | |
| continued | and activating mutati | one of ECE | D: and |
| 2 There is documentation confirming that the disease expres3 Any of the following: | ses activating mutati | ONS OF EGF | n, and |
| 3.1 Patient is treatment naive; or | | | |
| 3.2 Patient has received prior treatment in the adjuvant | setting and/or while | awaiting EG | FR results: or |
| 3.3 Both: | | | , |
| 3.3.1 The patient has discontinued osimertinib or | gefitinib due to intoler | rance; and | |
| 3.3.2 The cancer did not progress while on osime | rtinib or gefitinib. | | |
| Renewal from any relevant practitioner. Approvals valid for 6 mo | nths where radiologic | al assessm | ent (preferably including CT |
| scan) indicates NSCLC has not progressed. | | | |
| $\label{eq:GEFITINIB} - \textbf{Retail pharmacy-Specialist} - \textbf{Special Authority see}$ | | | _ |
| Tab 250 mg | 918.00 | 30 | ✓ Iressa |
| ⇒SA2423 Special Authority for Subsidy | | | |
| Initial application from any relevant practitioner. Approvals valid | for 4 months for app | lications me | eting the following criteria: |
| All of the following: | non oguamaua Nan (| | ung Concer (NCCLC), and |
| Patient has locally advanced, or metastatic, unresectable, Any of the following: | non-squamous Non a | Small Cell L | ung Cancer (NSCLC); and |
| 2.1 Patient is treatment naive; or | | | |
| 2.2 Patient has received prior treatment in the adjuvant | setting and/or while | awaiting EG | FR results: or |
| 2.3 Both: | | a | |
| 2.3.1 The patient has discontinued osimertinib or | erlotinib due to intole | rance; and | |
| 2.3.2 The cancer did not progress whilst on osime | rtinib or erlotinib; and | ł | |
| 3 There is documentation confirming that disease expresses | activating mutations | of EGFR. | |
| Renewal from any relevant practitioner. Approvals valid for 6 mo scan) indicates NSCLC has not progressed. | nths where radiologic | al assessm | ent (preferably including CT |
| IMATINIB MESILATE | | | |
| * Cap 100 mg | | 60 | ✓ Imatinib-Rex |
| * Cap 400 mg | | 30 | Imatinib-Rex |
| LENVATINIB - Special Authority see SA2442 below - Retail pha | rmacy | | |
| Wastage claimable | | | <i>.</i> |
| Cap 4 mg | | 30 | Lenvima |
| Cap 10 mg | 3,407.40 | 30 | Lenvima |
| ► SA2442 Special Authority for Subsidy | | | h . f l' t' |
| Initial application — (thyroid cancer) from any relevant practiti following criteria: | oner. Approvais valio | a for 6 mont | ns for applications meeting the |
| Either: | | | |
| 1 Patient is currently on treatment with lenvatinib and met al | remaining criteria pr | ior to comm | encina treatment: or |
| 2 All of the following: | remaining criteria pri | | ending treatment, of |
| 2.1 The patient has locally advanced or metastatic difference2.2 Either: | rentiated thyroid can | cer; and | |
| 2.2.1 Patient must have symptomatic progressive | disease prior to treat | ment: or | |
| 2.2.2 Patient must progressive disease at critical | | | of morbidity or mortality where |
| local control cannot be achieved by other m | | 0 | ,, |
| 2.3 Any of the following: | | | |
| | | | |

- 2.3.1 A lesion without iodine uptake in a RAI scan; or
- 2.3.2 Receiving cumulative RAI greater than or equal to 600 mCi; or

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

continued...

- 2.3.3 Experiencing disease progression after a RAI treatment within 12 months; or
- 2.3.4 Experiencing disease progression after two RAI treatments administered within 12 months of each other; and
- 2.4 Patient has thyroid stimulating hormone (TSH) adequately supressed; and
- 2.5 Patient is not a candidate for radiotherapy with curative intent; and
- 2.6 Surgery is clinically inappropriate; and
- 2.7 Patient has an ECOG performance status of 0-2.

Renewal — (thyroid cancer) from any relevant practitioner. Approvals valid for 6 months where there is no evidence of disease progression.

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

All of the following:

- 1 Patient has unresectable hepatocellular carcinoma; and
- 2 Patient has preserved liver function (Childs-Pugh A); and
- 3 Transarterial chemoembolisation (TACE) is unsuitable; and
- 4 Patient has an ECOG performance status of 0-2; and
- 5 Either:
 - 5.1 Patient has not received prior systemic therapy for their disease in the palliative setting; or
 - 5.2 Both:
 - 5.2.1 Patient has experienced treatment-limiting toxicity from treatment with atezolizumab with bevacizumab; and
 - 5.2.2 No disease progression since initiation of atezolizumab with bevacizumab.

Renewal — (unresectable hepatocellular carcinoma) from any relevant practitioner. Approvals valid for 6 months where there is no evidence of disease progression.

Initial application — (renal cell carcinoma) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

1 All of the following:

- 1.1 The patient has metastatic renal cell carcinoma; and
- 1.2 The disease is of predominant clear-cell histology; and
- 1.3 The patient has documented disease progression following one previous line of treatment; and
- 1.4 The patient has an ECOG performance status of 0-2; and
- 1.5 Lenvatinib is to be used in combination with everolimus; or
- 2 All of the following:
 - 2.1 Patient has received funded treatment with nivolumab for the second line treatment of metastatic renal cell carcinoma; and
 - 2.2 Patient has experienced treatment limiting toxicity from treatment with nivolumab; and
 - 2.3 Lenvatinib is to be used in combination with everolimus; and
 - 2.4 There is no evidence of disease progression.

Renewal — (renal cell carcinoma) from any relevant practitioner. Approvals valid for 4 months where there is no evidence of disease progression.

MIDOSTAURIN - PCT only - Special Authority see SA2342 below

Cap 25 mg...... 10,981.00 56 🗸 Rydapt

► SA2342 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria: All of the following:

1 Patient has a diagnosis of acute myeloid leukaemia; and

| | (Manufacturer's Price) \$ | Per | Subsidised | Generic Manufacturer |
|---|--|----------------------|--------------------------------|--|
| 2 Condition must be FMS tyrosine kinase 3 (FLT3) mutati 3 Patient must not have received a prior line of intensive of 4 Patient is to receive standard intensive chemotherapy in 5 Midostaurin to be funded for a maximum of 4 cycles. | chemotherapy for acute | | | ia; and |
| ILOTINIB – Special Authority see SA2301 below – Retail pha Wastage claimable Cap 150 mg Cap 200 mg SA2301 Special Authority for Subsidy itial application only from a haematologist. Approvals valid | | 120 120 ations | ✓ Т | asigna a signa e following criteria: |
| Il of the following: Patient has a diagnosis of chronic myeloid leukaemia (Cand) Either: Patient has documented CML treatment failure* Patient has experienced treatment limiting toxici and Maximum nilotinib dose of 800 mg/day; and Subsidised for use as monotherapy only. treatment failure as defined by Leukaemia Net Guidelin enewal only from a haematologist. Approvals valid for 6 mor | with a tyrosine kinase in ty with a tyrosine kinase | nhibite e inhit | or (TKI); or bitor (TKI) pr | ecluding further treatme |
| I of the following: 1 Lack of treatment failure while on nilotinib as defined by 2 Nilotinib treatment remains appropriate and the patient 3 Maximum nilotinib dose of 800 mg/day; and 4 Subsidised for use as monotherapy only. | v Leukaemia Net Guidel | ines; | and | g on on a |
| SIMERTINIB – Special Authority see SA2418 below – Retail Tab 40 mg Tab 80 mg SA2418 Special Authority for Subsidy itial application — (NSCLC – first line) from any relevant p te following criteria: ither: | | 30 30 valid | √ T | agrisso agrisso s for applications meetin |
| Patient is currently on treatment with osimertinib and me All of the following: 2.1 Patient has locally advanced or metastatic, incur | | | | - |
| 2.2 Any of the following:2.2.1 Patient is treatment naïve; or2.2.2 Patient has received prior chemotherapy2.2.3 Both: | in the adjuvant setting | and/o | r while awai | ting EGFR results; or |
| 2.2.3.1 The patient has discontinued gefiti 2.2.3.2 The cancer did not progress while 2.3 There is documentation confirming that the canc | on gefitinib or erlotinib; | and | · | |

- 2.4 Patient has an ECOG performance status 0-3; and
- 2.5 Baseline measurement of overall tumour burden is documented clinically and radiologically.

| Subsidy | | Fully | Brand or | |
|------------------------|-----|------------|--------------|--|
| (Manufacturer's Price) | 9 | Subsidised | Generic | |
| \$ | Per | 1 | Manufacturer | |

continued...

Renewal — (NSCLC – first line) from any relevant practitioner. Approvals valid for 6 months where response to or stable disease with treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period.

Initial application — (NSCLC – second line) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

1 Patient is currently on treatment with osimertinib and met all remaining criteria prior to commencing treatment; or

- 2 All of the following:
 - 2.1 Patient has locally advanced or metastatic, incurable, non-squamous non-small cell lung cancer (NSCLC); and
 - 2.2 Patient has an ECOG performance status 0-3; and
 - 2.3 The patient must have received previous treatment with erlotinib or gefitinib; and
 - 2.4 There is documentation confirming that the cancer expresses T790M mutation of EGFR following progression on or after erlotinib or gefittinib; and
 - 2.5 The treatment must be given as monotherapy; and
 - 2.6 Baseline measurement of overall tumour burden is documented clinically and radiologically.

Renewal — (NSCLC – second line) from any relevant practitioner. Approvals valid for 6 months where response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period.

PALBOCICLIB - Special Authority see SA2345 below - Retail pharmacy

Wastage claimable

| Tab 75 mg | 4,000.00 | 21 | Ibrance |
|------------|----------|----|-----------------------------|
| Tab 100 mg | 4,000.00 | 21 | Ibrance |
| Tab 125 mg | 4,000.00 | 21 | Ibrance |

⇒SA2345 Special Authority for Subsidy

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

- 1 All of the following:
 - 1.1 Patient has unresectable locally advanced or metastatic breast cancer; and
 - 1.2 There is documentation confirming disease is hormone-receptor positive and HER2-negative; and
 - 1.3 Patient has an ECOG performance score of 0-2; and
 - 1.4 Either:
 - 1.4.1 Disease has relapsed or progressed during prior endocrine therapy; or
 - 1.4.2 Both:
 - 1.4.2.1 Patient is amenorrhoeic, either naturally or induced, with endocrine levels consistent with a postmenopausal or without menstrual-potential state; and
 - 1.4.2.2 Patient has not received prior systemic treatment for metastatic disease; and
 - 1.5 Treatment must be used in combination with an endocrine partner; and
 - 1.6 Patient has not received prior funded treatment with a CDK4/6 inhibitor; or
- 2 All of the following:
 - 2.1 Patient has an active Special Authority approval for ribociclib; and
 - 2.2 Patient has experienced a grade 3 or 4 adverse reaction to ribociclib that cannot be managed by dose reductions and requires treatment discontinuation; and
 - 2.3 Treatment must be used in combination with an endocrine partner; and
 - 2.4 There is no evidence of progressive disease since initiation of ribociclib.

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

- 1 Treatment must be used in combination with an endocrine partner; and
- 2 There is no evidence of progressive disease since initiation of palbociclib.

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 | |
|---|---|-----|---------------------|----------------|
| PAZOPANIB - Special Authority see SA2429 below - Retail pha | rmacy | | | |
| Tab 200 mg | | 30 | ✓ | Pazopanib Teva |
| - | 1,334.70 | | ✓ | Votrient |
| Pazopanib Teva to be Principal Supply on 1 May 2025 | | | | |
| Tab 400 mg | | 30 | ✓ | Pazopanib Teva |
| C C | 2,669.40 | | ✓ | Votrient |
| Pazopanib Teva to be Principal Supply on 1 May 2025 | · | | | |

(Votrient Tab 200 mg to be delisted 1 May 2025)

(Votrient Tab 400 mg to be delisted 1 May 2025)

➡SA2429 Special Authority for Subsidy

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

- Either:
 - 1 All of the following:
 - 1.1 The patient has metastatic renal cell carcinoma of predominantly clear cell histology; and
 - 1.2 Either:
 - 1.2.1 The patient is treatment naive; or
 - 1.2.2 The patient has only received prior cytokine treatment; and
 - 1.3 The patient has an ECOG performance score of 0-2; and The patient has intermediate or poor prognosis defined as:
 - 1.4 Any of the following:
 - 1.4.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or
 - 1.4.2 Haemoglobin level < lower limit of normal; or
 - 1.4.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or
 - 1.4.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or
 - 1.4.5 Karnofsky performance score of less than or equal to 70; or
 - 1.4.6 2 or more sites of organ metastasis; and
 - 1.5 Pazopanib to be used for a maximum of 3 months; or
 - 2 All of the following:
 - 2.1 The patient has metastatic renal cell carcinoma; and
 - 2.2 The patient has discontinued sunitinib within 3 months of starting treatment due to intolerance; and
 - 2.3 The cancer did not progress whilst on sunitinib; and
 - 2.4 Pazopanib to be used for a maximum of 3 months.

Renewal only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 3 months where there is no evidence of disease progression.

RIBOCICLIB - Special Authority see SA2343 below - Retail pharmacy

Wastage claimable

| Tab 200 mg | 1,883.00 | 21 | 🗸 Kisqali |
|------------|----------|----|-----------------------------|
| - | 3,767.00 | 42 | 🗸 Kisqali |
| | 5,650.00 | 63 | Kisqali |

⇒SA2343 Special Authority for Subsidy

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

- 1 All of the following:
 - 1.1 Patient has unresectable locally advanced or metastatic breast cancer; and
 - 1.2 There is documentation confirming disease is hormone-receptor positive and HER2-negative; and
 - 1.3 Patient has an ECOG performance score of 0-2; and

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

continued...

- 1.4 Any of the following:
 - 1.4.1 Disease has relapsed or progressed during prior endocrine therapy; or
 - 1.4.2 Both:
 - 1.4.2.1 Patient is amenorrhoeic, either naturally or induced, with endocrine levels consistent with a postmenopausal or without menstrual-potential state; and
 - 1.4.2.2 Patient has not received prior systemic endocrine treatment for metastatic disease; or
 - 1.4.3 Both:
 - 1.4.3.1 Patient commenced treatment with ribociclib in combination with an endocrine partner prior to 1 July 2024; and
 - 1.4.3.2 There is no evidence of progressive disease; and
- 1.5 Treatment to be used in combination with an endocrine partner; and
- 1.6 Patient has not received prior funded treatment with a CDK4/6 inhibitor; or
- 2 All of the following:
 - 2.1 Patient has an active Special Authority approval for palbociclib; and
 - 2.2 Patient has experienced a grade 3 or 4 adverse reaction to palbociclib that cannot be managed by dose reductions and requires treatment discontinuation; and
 - 2.3 Treatment must be used in combination with an endocrine partner; and
 - 2.4 There is no evidence of progressive disease since initiation of palbociclib.

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

- 1 Treatment must be used in combination with an endocrine partner; and
- 2 There is no evidence of progressive disease since initiation of ribociclib.

RUXOLITINIB – Special Authority see SA1890 below – Retail pharmacy Wastage claimable

| Wastage claimable | | | |
|-------------------|----------|----|----------|
| Tab 5 mg | 2,500.00 | 56 | 🖌 Jakavi |
| Tab 10mg | | 56 | 🖌 Jakavi |
| Tab 15 mg | | 56 | 🖌 Jakavi |
| Tab 20 mg | | 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 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.

| | Subsidy (Manufacturer's Price) \$ | Sut Per | Fully osidised | Brand or Generic Manufacturer |
|--|---|----------------|-------------------|---|
| SUNITINIB – Special Authority see SA2452 below – Retail pharm Cap 12.5 mg Cap 25 mg Cap 50 mg | 208.38 416.77 | 28 28 28 | ✓ s | unitinib Pfizer unitinib Pfizer unitinib Pfizer |

➡SA2452 Special Authority for Subsidy

Initial application — (RCC) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 The patient has metastatic renal cell carcinoma; and
- 2 The patient has not previously received funded sunitinib.

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

- 1 The patient has unresectable or metastatic malignant gastrointestinal stromal tumour (GIST); and
- 2 Either:
 - 2.1 The patient's disease has progressed following treatment with imatinib; or
 - 2.2 The patient has documented treatment-limiting intolerance, or toxicity to, imatinib.

Renewal — (RCC) from any relevant practitioner. Approvals valid for 4 months where there is no evidence of disease progression.

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

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

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

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

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

All of the following:

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

Endocrine Therapy

For GnRH ANALOGUES - refer to HORMONE PREPARATIONS, Trophic Hormones, page 86

ABIRATERONE ACETATE - Retail pharmacy-Specialist - Special Authority see SA2118 on the next page

- Wastage claimable

| Subsidy (Manufacturer's Price) | F Subsidis | ully sed | Brand or Generic | |
|-----------------------------------|---------------|-------------|---------------------|--|
| \$ | Per | 1 | Manufacturer | |

⇒SA2118 Special Authority for Subsidy

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

- 1 Patient has prostate cancer; and
- 2 Patient has metastases; and
- 3 Patient's disease is castration resistant; and
- 4 Either:
 - 4.1 All of the following:
 - 4.1.1 Patient is symptomatic; and
 - 4.1.2 Patient has disease progression (rising serum PSA) after second line anti-androgen therapy; and
 - 4.1.3 Patient has ECOG performance score of 0-1; and
 - 4.1.4 Patient has not had prior treatment with taxane chemotherapy; or
 - 4.2 All of the following:
 - 4.2.1 Patient's disease has progressed following prior chemotherapy containing a taxane; and
 - 4.2.2 Patient has ECOG performance score of 0-2; and
 - 4.2.3 Patient has not had prior treatment with abiraterone.

Renewal — (abiraterone acetate) only from a medical oncologist, radiation oncologist, urologist or medical practitioner on the recommendation of a medical oncologist, radiation oncologist or urologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 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.

2

✓ Faslodex

BICALUTAMIDE

| Tab 50 mg | 4.18 | 28 | Binarex |
|---|------------------|-----|------------------------------|
| FLUTAMIDE | | | |
| Tab 250 mg | | 90 | Prostacur S29 |
| | 119.50 | 100 | Flutamin |
| FULVESTRANT - Retail pharmacy-Specialist - Special Author | tv see SA1895 be | ow | |

► 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

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

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

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.

OCTREOTIDE

| | Inj 50 mcg per ml, 1 ml vial | 27.58 | 5 | Omega S29 |
|----|----------------------------------|--------|----|---------------------------------------|
| | Inj 100 mcg per ml, 1 ml vial | | 5 | Omega S29 |
| | Inj 500 mcg per ml, 1 ml vial | 113.10 | 5 | Omega S29 |
| | Inj 50 mcg per ml, 1 ml ampoule | | 5 | Max Health |
| | | | | Octreotide GH S29 |
| | Inj 100 mcg per ml, 1 ml ampoule | 32.71 | 5 | Max Health |
| | | | | Octreotide GH S29 |
| | | | | Sun Pharma S29 |
| | Inj 500 mcg per ml, 1 ml ampoule | 113.10 | 5 | Max Health |
| | | | | Octreotide GH S29 |
| | | | | Sun Pharma S29 |
| ТА | MOXIFEN CITRATE | | | |
| | Tab 10 mg | | 60 | Tamoxifen Sandoz |
| * | Tab 20 mg | 5.32 | 60 | Tamoxifen Sandoz |
| | | | | |

Long-acting Somatostatin Analogues

SA2445 Special Authority for Subsidy

Initial application - (Malignant Bowel Obstruction) from any relevant practitioner. Approvals valid for 2 months for applications meeting the following criteria:

All of the following:

- 1 The patient has nausea* and vomiting* due to malignant bowel obstruction*; and
- 2 Treatment with antiemetics, rehydration, antimuscarinic agents, corticosteroids and analgesics for at least 48 hours has not been successful: and
- 3 Treatment to be given for up to 4 weeks.

Note: Indications marked with * are unapproved indications.

Renewal — (Malignant Bowel Obstruction) from any relevant practitioner. Approvals valid for 3 months where the treatment remains appropriate and the patient is benefiting from treatment.

Initial application - (Acromegaly) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

1 The patient has acromegaly; and

2 Either:

- 2.1 Treatment with surgery and radiotherapy is not suitable or was unsuccessful; or
- 2.2 Treatment is for an interim period while awaiting the beneficial effects of radiotherapy; and

3 Treatment with a dopamine agonist has been unsuccessful.

Renewal - (Acromegaly) from any relevant practitioner. Approvals valid for 2 years where iGF1 levels have decreased since

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

continued...

starting treatment.

Note: In patients with acromegaly, treatment should be discontinued if IGF1 levels have not decreased 3 months after treatment. In patients treated with radiotherapy treatment should be withdrawn every 2 years, for 1 month, for assessment of remission. Treatment should be stopped where there is biochemical evidence of remission (normal IGF1 levels) following treatment withdrawal for at least 4 weeks

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

All of the following:

- 1 Patient has acromegaly; and
- 2 Patient has a large pituitary tumour, greater than 10 mm at its widest; and
- 3 Patient is scheduled to undergo pituitary surgery in the next six months.

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

Any of the following:

- 1 VIPomas and Glucagonomas for patients who are seriously ill in order to improve their clinical state prior to definitive surgery; or
- 2 Both:
 - 2.1 Gastrinoma; and
 - 2.2 Either:
 - 2.2.1 Surgery has been unsuccessful; or
 - 2.2.2 Patient has metastatic disease after treatment with H2 antagonist or proton pump inhibitors has been unsuccessful; or
- 3 Both:
 - 3.1 Insulinomas; and
 - 3.2 Surgery is contraindicated or has not been successful; or
- 4 For pre-operative control of hypoglycaemia and for maintenance therapy; or
- 5 Both:
 - 5.1 Carcinoid syndrome (diagnosed by tissue pathology and/or urinary 5HIAA analysis); and
 - 5.2 Disabling symptoms not controlled by maximal medical therapy.

Note: The use of a long-acting somatostatin analogue in patients with fistulae, oesophageal varices, miscellaneous diarrhoea and hypotension will not be funded under Special Authority

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

| LANREOTIDE - Special Authority see SA2445 on the previ | oue page - Retail pharm | nacy | |
|--|-------------------------|--------------------------|---------------------------------------|
| Inj 60 mg per 0.5 ml, 0.5 ml syringe | | 1 | Mytolac |
| Inj 90 mg per 0.5 ml, 0.5 ml syringe | | 1 | ✓ Mytolac |
| Inj 120 mg per 0.5 ml, 0.5 ml syringe | | 1 | Mytolac |
| OCTREOTIDE LONG-ACTING - Special Authority see SA2 | | <mark>ge</mark> – Retail | pharmacy |
| Inj depot 10 mg prefilled syringe | | 1 | Sandostatin LAR |
| Inj depot 20 mg prefilled syringe | | 1 | Sandostatin LAR |
| Inj depot 30 mg prefilled syringe | | 1 | Sandostatin LAR |
| Aromatase Inhibitors | | | |
| ANASTROZOLE | 4.00 | 20 | Anotrolo |
| * Tab 1 mg | 4.39 | 30 | Anatrole |
| EXEMESTANE | | | |
| * Tab 25 mg | 9.86 | 30 | Pfizer Exemestane |

| | Subsidy (Manufacturer's Price | a) S | Fully Subsidised | Brand or Generic |
|--|----------------------------------|-----------|---------------------|-------------------------|
| | (Manulacturer's Flice \$ | Per | | Manufacturer |
| LETROZOLE | | | | |
| * Tab 2.5 mg | 4.36 | 28 | ✓ | Accord S29 |
| | 4.67 | 30 | 1 | Letrole |
| Immunosuppressants | | | | |
| Cytotoxic Immunosuppressants | | | | |
| AZATHIOPRINE | | | | |
| * Tab 25 mg | | 60 | | Azamun |
| * Tab 50 mg | 8.10 | 100 | - | Azamun |
| 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 | | 165 ml O | | Cellcept |
| Mycophenolate powder for oral liquid is subsidised only for the prescription is endorsed accordingly. | or patients unable t | to swallo | w tablets | and capsules, and when |
| Fusion Proteins | | | | |
| ETANERCEPT - Special Authority see SA2399 below - Retail ph | armacy | | | |
| Inj 25 mg | 690.00 | 4 | ✓ | Enbrel |
| Inj 25 mg autoinjector | | 4 | | Enbrel |
| Inj 50 mg autoinjector | | 4 | | Enbrel |
| Inj 50 mg prefilled syringe | 1,050.00 | 4 | 1 | Enbrel |
| ■ SA2399 Special Authority for Subsidy | | | | |
| Initial application — (adult-onset Still's disease) only from a rh | aumatologist Δη | nrovals v | alid for 6 | months for applications |

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

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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 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

▲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

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- 3 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and
- 4 Etanercept to be administered at doses no greater than 50 mg every 7 days.

Initial application — (polyarticular course juvenile idiopathic arthritis) only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

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

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- 2.3 Any of the following:
 - 2.3.1 At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
 - 2.3.2 Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose); or
 - 2.3.3 High disease activity (cJADAS10 score greater than 4) after a 6-month trial of methotrexate.

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

Both:

- 1 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2 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:

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

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

All of the following:

- 1 Patient has pyoderma gangrenosum*; and
- 2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate) and not received an adequate response; and
- 3 A maximum of 8 doses.

Note: Indications marked with * are unapproved indications.

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

Renewal — (Arthritis - rheumatoid) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

2 Either:

- 2.1 Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

Initial application — (severe chronic plaque psoriasis) only from a dermatologist or any relevant practitioner on the recommendation of a dermatologist. Approvals valid for 4 months for applications meeting the following criteria: 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 Any of the following:
 - 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
 - 2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; or
 - 2.1.3 Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10; and
 - 2.2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
 - 2.3 A PASI assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
 - 2.4 The most recent PASI or DLQI assessment is no more than 1 month old at the time of application.

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

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

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Both:

- 1 Any of the following:
 - 1.1 Both:
 - 1.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
 - 1.1.2 Either:
 - 1.1.2.1 Following each prior etanercept treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-treatment baseline value; or
 - 1.1.2.2 Following each prior etanercept treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value; or
 - 1.2 Both:
 - 1.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
 - 1.2.2 Either:
 - 1.2.2.1 Following each prior etanercept treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
 - 1.2.2.2 Following each prior etanercept treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or

1.3 Both:

- 1.3.1 Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment; and
- 1.3.2 Either:
 - 1.3.2.1 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or
 - 1.3.2.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing etanercept; and
- 2 Etanercept to be administered at doses no greater than 50 mg every 7 days.
- Note: A treatment course is defined as a minimum of 12 weeks of etanercept treatment

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

All of the following:

- 1 Patient has undifferentiated peripheral spondyloarthritis* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
- 3 Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day (or maximum tolerated dose); and
- 4 Patient has tried and not responded to at least three months of leflunomide at a dose of up to 20 mg daily (or maximum tolerated dose); and
- 5 Any of the following:
 - 5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
 - 5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour measured no more than one month prior to the date of this application; or
 - 5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Note: Indications marked with * are unapproved indications.

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

1 Fither:

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

Immune Modulators

| ANTITHYMOCYTE GLOBULIN (EQUINE) – PCT only – Speciali Inj 50 mg per ml, 5 ml | | 5 | ✓ ATGAM |
|--|------------|---|------------------------------|
| BACILLUS CALMETTE-GUERIN (BCG) VACCINE – PCT only – Subsidised only for bladder cancer. | Specialist | | |
| 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 SA2400 be | elow – Retail pharn | nacy | |
|---|---------------------|------|------------------------------|
| Inj 20 mg per 0.4 ml prefilled syringe | | 1 | Amgevita |
| Inj 40 mg per 0.8 ml prefilled pen | | 2 | Amgevita |
| Inj 40 mg per 0.8 ml prefilled syringe | 375.00 | 2 | Amgevita |

⇒SA2400 Special Authority for Subsidy

Initial application — (Behcet's disease - severe) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria: Both:

Both:

- 1 The patient has severe Behcet's disease* that is significantly impacting the patient's quality of life; and
- 2 Either:
 - 2.1 The patient has severe ocular, neurological, and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s); or
 - 2.2 The patient has severe gastrointestinal, rheumatological, and/or mucocutaneous symptoms and has not responded adequately to two or more treatments appropriate for the particular symptom(s).

Note: Indications marked with * are unapproved indications.

Initial application — (Hidradenitis suppurativa) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has hidradenitis suppurativa Hurley Stage II or Hurley Stage III lesions in distinct anatomic areas; and
- 2 Patient has tried, but had an inadequate response to at least a 90 day trial of systemic antibiotics or has demonstrated intolerance to or has contraindications for systemic antibiotics; and
- 3 Patient has 3 or more active lesions; and

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4 The patient has a DLQI of 10 or more and the assessment is no more than 1 month old at time of application.

Renewal — (Hidradenitis suppurativa) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline; and
- 2 The patient has a DLQI improvement of 4 or more from baseline.

Initial application — (Plaque psoriasis - severe chronic) only from a dermatologist or any relevant practitioner on the recommendation of a dermatologist. Approvals valid for 4 months for applications meeting the following criteria: Either:

1 Both:

- 1.1 Patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and 1.2 Either:
 - 1.2.1 Patient has experienced intolerable side effects; or
 - 1.2.2 Patient has received insufficient benefit to meet the renewal criteria for etanercept for severe chronic plaque psoriasis; or
- 2 All of the following:
 - 2.1 Any of the following:
 - 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a PASI score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
 - 2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; or
 - 2.1.3 Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10; and
 - 2.2 Patient has tried, but had an inadequate response to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
 - 2.3 A PASI assessment or DLQI assessment has been completed for at least the most recent prior treatment course but no longer than 1 month following cessation of each prior treatment course and is no more than 1 month old at the time of application.

Renewal — (Plaque psoriasis - severe chronic) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 Both:
 - 1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced a 75% or more reduction in PASI score, or is sustained at this level, when compared with the pre-treatment baseline value; or
 - 1.2.2 The patient has a DLQI improvement of 5 or more, when compared with the pre-treatment baseline value; or
- 2 Both:
 - 2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
 - 2.2 Either:
 - 2.2.1 The patient has experienced reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or

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- 2.2.2 The patient has experienced reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre treatment baseline value; or
- 3 Both:
 - 3.1 Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment; and
 - 3.2 Either:
 - 3.2.1 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or
 - 3.2.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing adalimumab.

Initial application — (pyoderma gangrenosum) only from a dermatologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

- Both:
 - 1 Patient has pyoderma gangrenosum*; and
 - 2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate) and has not received an adequate response.

Note: Indications marked with * are unapproved indications.

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

All of the following:

- 1 Patient has active Crohn's disease; and
- 2 Any of the following:
 - 2.1 Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10; or
 - 2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
 - 2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
 - 2.4 Patient has an ileostomy or colostomy and has intestinal inflammation; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids.

Renewal — (Crohn's disease - adults) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 CDAI score has reduced by 100 points from the CDAI score, or HBI score has reduced by 3 points, from when the patient was initiated on adalimumab; or
- 2 CDAI score is 150 or less, or HBI is 4 or less; or
- 3 The patient has demonstrated an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed.

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

All of the following:

- 1 Paediatric patient has active Crohn's disease; and
- 2 Either:
 - 2.1 Patient has a PCDAI score of greater than or equal to 30; or
 - 2.2 Patient has extensive small intestine disease; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids.

Renewal — (Crohn's disease - children) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

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

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

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- 1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab; or
- 2 PCDAI score is 15 or less; or
- 3 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed.

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

All of the following:

- 1 Patient has confirmed Crohn's disease; and
- 2 Any of the following:
 - 2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
 - 2.2 Patient has one or more rectovaginal fistula(e); or
 - 2.3 Patient has complex peri-anal fistula; and
- 3 A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application.

Renewal — (Crohn's disease - fistulising) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

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 had an initial Special Authority approval for infliximab for chronic ocular inflammation; or

2 Both:

- 2.1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and
- 2.2 Any of the following:
 - 2.2.1 Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven 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 — (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 Patient has had an initial Special Authority approval for infliximab for severe ocular inflammation; or

2 Both:

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- 2.1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and
- 2.2 Any of the following:
 - 2.2.1 Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms; or
 - 2.2.2 Patient developed new inflammatory symptoms while receiving high dose steroids; or
 - 2.2.3 Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms.

Renewal — (Ocular inflammation - severe) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

- 1 The patient has had a good clinical response following 3 initial doses; or
- 2 Following each 2 year treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < 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 Both:

- - 1.1 Patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects; or
 - 1.2.2 The patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis; or
- 2 All of the following:
 - 2.1 Patient has a confirmed diagnosis of ankylosing spondylitis for more than six months; and
 - 2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
 - 2.3 Patient has bilateral sacroiliitis demonstrated by radiology imaging; and
 - 2.4 Patient has not responded adequately to treatment with two or more NSAIDs, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and
 - 2.5 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 BASMI measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or
 - 2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender; and
 - 2.6 A BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment and is no more than 1 month old at the time of application.

Renewal — (ankylosing spondylitis) from any relevant practitioner. Approvals valid for 2 years where treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less.

Initial application — (Arthritis - oligoarticular course juvenile idiopathic) only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria: Either:

1 Both:

1.1 The patient has had an initial Special Authority approval for etanercept for oligoarticular course juvenile idiopathic arthritis (JIA); and

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- 1.2 Either:
 - 1.2.1 Patient has experienced intolerable side effects; or
 - 1.2.2 Patient has received insufficient benefit to meet the renewal criteria for oligoarticular course JIA; or
- 2 All of the following:
 - 2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
 - 2.2 Patient has had oligoarticular course JIA for 6 months duration or longer; and
 - 2.3 Either:
 - 2.3.1 At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
 - 2.3.2 Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose).

Renewal — (Arthritis - oligoarticular course juvenile idiopathic) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 Following initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
- 2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

Initial application — (Arthritis - polyarticular course juvenile idiopathic) only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 Patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA); and
 - 1.2 Either:
 - 1.2.1 Patient has experienced intolerable side effects; or
 - 1.2.2 Patient has received insufficient benefit to meet the renewal criteria for polyarticular course JIA; or
- 2 All of the following:
 - 2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
 - 2.2 Patient has had polyarticular course JIA for 6 months duration or longer; and
 - 2.3 Any of the following:
 - 2.3.1 At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or
 - 2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose); or
 - 2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

Renewal — (Arthritis - polyarticular course juvenile idiopathic) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

- Either:
 - 1 Following initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline; or
 - 2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline.

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

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Either:

1 Both:

- 1.1 Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis; and
- 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects; or
 - 1.2.2 The patient has received insufficient benefit from to meet the renewal criteria for psoriatic arthritis; or
- 2 All of the following:
 - 2.1 Patient has had active psoriatic arthritis for six months duration or longer; and
 - 2.2 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
 - 2.3 Patient has tried and not responded to at least three months of sulfasalazine or leflunomide at maximum tolerated doses (unless contraindicated); and
 - 2.4 Either:
 - 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
 - 2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
 - 2.5 Any of the following:
 - 2.5.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
 - 2.5.2 Patient has an ESR greater than 25 mm per hour; or
 - 2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Renewal — (Arthritis - psoriatic) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

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 Both:

- 1.1 The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis; and
- 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects; or
 - 1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for rheumatoid arthritis; or
- 2 All of the following:
 - 2.1 Patient has had rheumatoid arthritis (either confirmed by radiology imaging, or the patient is CCP antibody positive) for six months duration or longer; and
 - 2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
 - 2.3 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
 - 2.4 Patient has tried and not responded to at least three months of methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate at maximum tolerated doses (unless contraindicated); and

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

Renewal — (Arthritis - rheumatoid) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician.

Initial application — (Still's disease - adult-onset (AOSD)) only from a rheumatologist. Approvals valid without further renewal unless notified for applications meeting the following criteria: Fither:

1 Both:

- 1.1 The patient has had an initial Special Authority approval for etanercept and/or tocilizumab for AOSD; and
- 1.2 Either:
 - 1.2.1 Patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
 - 1.2.2 Patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab; or
- 2 All of the following:
 - 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria; and
 - 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, NSAIDs and methotrexate; and
 - 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

Initial application — (ulcerative colitis) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has active ulcerative colitis; and
- 2 Either:
 - 2.1 Patient's SCCAI score is greater than or equal to 4; or
 - 2.2 Patient's PUCAI score is greater than or equal to 20; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from prior therapy with immunomodulators and systemic corticosteroids; and
- 4 Surgery (or further surgery) is considered to be clinically inappropriate.

Renewal — (ulcerative colitis) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 The SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on biologic therapy; or
- 2 The PUCAI score has reduced by 10 points or more from the PUCAI score when the patient was initiation on biologic therapy.

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

All of the following:

- 1 Patient has undifferentiated peripheral spondyloarthritis* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 2 Patient has tried and not responded to at least three months of each of methotrexate, sulfasalazine and leflunomide, at maximum tolerated doses (unless contraindicated); and
- 3 Any of the following:
 - 3.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
 - 3.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; or
 - 3.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Note: Indications marked with * are unapproved indications

Renewal — (undifferentiated spondyloarthritis) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 Following initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response in the opinion of the treating physician.

Initial application — (inflammatory bowel arthritis – axial) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
- 2 Patient has axial inflammatory pain for six months or more; and
- 3 Patient is unable to take NSAIDs; and
- 4 Patient has unequivocal sacroiliitis demonstrated by radiological imaging or MRI; and
- 5 Patient has not responded adequately to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist; and
- 6 A BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment.

Renewal — (inflammatory bowel arthritis – axial) from any relevant practitioner. Approvals valid for 2 years where treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less.

Initial application — (inflammatory bowel arthritis – peripheral) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
- 2 Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular; and
- 3 Patient has tried and not experienced a response to at least three months of methotrexate, or azathioprine at a maximum tolerated dose (unless contraindicated); and
- 4 Patient has tried and not experienced a response to at least three months of sulfasalazine at a maximum tolerated dose (unless contraindicated); and
- 5 Any of the following:
 - 5.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this

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- application; or
- 5.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; or
- 5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Renewal — (inflammatory bowel arthritis – peripheral) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

- Either:
 - 1 Following initial treatment, patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 2 Patient has experienced at least a continuing 30% improvement in active joint count from baseline in the opinion of the treating physician.

ADALIMUMAB (HUMIRA - ALTERNATIVE BRAND) - Special Authority see SA2157 below - Retail pharmacy

| Inj 20 mg per 0.2 ml prefilled syringe | | 2 | 🖌 Humira |
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| Inj 40 mg per 0.4 ml prefilled pen | 1,599.96 | 2 | HumiraPen |
| Inj 40 mg per 0.4 ml prefilled syringe | | 2 | Humira |

► 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:
 - 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:

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- 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
 - 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

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- 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 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.

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

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- 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
 - 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.

▲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

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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
 - 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

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- 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.

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

▲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

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- 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:

- 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

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

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- 1.3 There is no structural damage to the central fovea of the treated eye; and
- 1.4 Patient has not previously been treated with ranibizumab for longer than 3 months; or
- 2 Either:
 - 2.1 Patient has current approval to use ranibizumab for treatment of wAMD and was found to be intolerant to ranibizumab within 3 months; or
 - 2.2 Patient has previously* (*before June 2018) received treatment with ranibizumab for wAMD and disease was stable while on treatment.

Initial application — (diabetic macular oedema) only from an ophthalmologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has centre involving diabetic macular oedema (DMO); and
- 2 Patient's disease is non responsive to 4 doses of intravitreal bevacizumab when administered 4-6 weekly; and
- 3 Patient has reduced visual acuity between 6/9 6/36 with functional awareness of reduction in vision; and
- 4 Patient has DMO within central OCT (ocular coherence tomography) subfield > 350 micrometers; and
- 5 There is no centre-involving sub-retinal fibrosis or foveal atrophy.

Renewal — (wet age related macular degeneration) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Documented benefit must be demonstrated to continue; and
- 2 Patient's vision is 6/36 or better on the Snellen visual acuity score; and
- 3 There is no structural damage to the central fovea of the treated eye.

Renewal — (diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 There is stability or two lines of Snellen visual acuity gain; and
- 2 There is structural improvement on OCT scan (with reduction in intra-retinal cysts, central retinal thickness, and sub-retinal fluid); and
- 3 Patient's vision is 6/36 or better on the Snellen visual acuity score; and
- 4 There is no centre-involving sub-retinal fibrosis or foveal atrophy; and
- 5 After each consecutive 12 months treatment with (2nd line anti-VEGF agent), patient has retrialled with at least one injection of bevacizumab and had no response.

BENRALIZUMAB – Special Authority see SA2151 below – Retail pharmacy

⇒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

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- 6 Either:
 - 6.1 Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral corticosteroids; or
 - 6.2 Patient has received continuous oral corticosteroids of at least the equivalent of 10 mg per day over the previous 3 months; and
- 7 Treatment is not to be used in combination with subsidised mepolizumab; and
- 8 Patient has an Asthma Control Test (ACT) score of 10 or less. Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 52 weeks after the first dose to assess response to treatment; and
- 9 Either:
 - 9.1 Patient has not previously received an anti-IL5 biological therapy for their severe eosinophilic asthma; or
 - 9.2 Both:
 - 9.2.1 Patient was refractory or intolerant to previous anti-IL5 biological therapy; and
 - 9.2.2 Patient was not eligible to continue treatment with previous anti-IL5 biological therapy and discontinued within 12 months of commencing treatment.

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

Both:

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

BEVACIZUMAB - PCT only - Special Authority see SA2453 below

| Inj 25 mg per ml, 4 ml vial |) 1 | Vegzelma |
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| Inj 25 mg per ml, 16 ml vial | | Vegzelma |
| Inj 1 mg for ECP0.71 | 1 mg | Baxter |

➡SA2453 Special Authority for Subsidy

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

Either:

1 Patient is currently on treatment with bevacizumab, and met all remaining criteria prior to commencing treatment; or

- 2 All of the following:
 - 2.1 Patient has locally advanced or metastatic, unresectable hepatocellular carcinoma; and
 - 2.2 Patient has preserved liver function (Child-Pugh A); and
 - 2.3 Transarterial chemoembolisation (TACE) is unsuitable; and
 - 2.4 Any of the following:
 - 2.4.1 Patient has not received prior systemic therapy for the treatment of hepatocellular carcinoma; or
 - 2.4.2 Patient received funded lenvatinib before 1 March 2025; or
 - 2.4.3 Both:
 - 2.4.3.1 Patient has experienced treatment-limiting toxicity from treatment with lenvatinib; and
 - 2.4.3.2 No disease progression since initiation of lenvatinib; and
 - 2.5 Patient has an ECOG performance status of 0-2; and
 - 2.6 To be given in combination with atezolizumab.

Renewal - (unresectable hepatocellular carcinoma) from any relevant practitioner. Approvals valid for 6 months where there

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is no evidence of disease progression.

Initial application — (advanced or metastatic ovarian cancer) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

1 Either:

1.1 The patient has FIGO Stage IV epithelial ovarian, fallopian tube, or primary peritoneal cancer; or

1.2 Both:

- 1.2.1 The patient has previously untreated advanced (FIGO Stage IIIB or IIIC) epithelial ovarian, fallopian tube, or primary peritoneal cancer; and
- 1.2.2 Either:
 - 1.2.2.1 Debulking surgery is inappropriate; or
 - 1.2.2.2 The cancer is sub-optimally debulked (maximum diameter of any gross residual disease greater than 1cm); and
- 2 Bevacizumab to be administered at a maximum dose of 15 mg/kg every three weeks; and
- 3 18 weeks concurrent treatment with chemotherapy is planned.

Renewal — (advanced or metastatic ovarian cancer) from any relevant practitioner. Approvals valid for 4 months where there is no evidence of disease progression.

Initial application — (Recurrent Respiratory Papillomatosis) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Maximum of 6 doses; and
- 2 The patient has recurrent respiratory papillomatosis; and
- 3 The treatment is for intra-lesional administration.

Renewal — (Recurrent Respiratory Papillomatosis) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Maximum of 6 doses; and
- 2 The treatment is for intra-lesional administration; and
- 3 There has been a reduction in surgical treatments or disease regrowth as a result of treatment.

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

Either:

- 1 Ocular neovascularisation; or
- 2 Exudative ocular angiopathy.

BRENTUXIMAB VEDOTIN - PCT only - Special Authority see SA2289 below

► SA2289 Special Authority for Subsidy

Initial application — (relapsed/refractory Hodgkin lymphoma) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 Either:

- 1.1 Both:
 - 1.1.1 Patient has relapsed/refractory CD30-positive Hodgkin lymphoma after two or more lines of chemotherapy; and
 - 1.1.2 Patient is ineligible for autologous stem cell transplant; or
- 1.2 Both:

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AThree 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

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- 1.2.1 Patient has relapsed/refractory CD30-positive Hodgkin lymphoma; and
- 1.2.2 Patient has previously undergone autologous stem cell transplant; and
- 2 Patient has not previously received funded brentuximab vedotin; and
- 3 Response to brentuximab vedotin treatment is to be reviewed after a maximum of 6 treatment cycles; and
- 4 Brentuximab vedotin to be administered at doses no greater than 1.8 mg/kg every 3 weeks.

Renewal — (relapsed/refractory Hodgkin lymphoma) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 Patient has achieved a partial or complete response to brentuximab vedotin after 6 treatment cycles; and
- 2 Treatment remains clinically appropriate and the patient is benefitting from treatment and treatment is being tolerated; and 3 Patient is to receive a maximum of 16 total cycles of brentuximab vedotin treatment.

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

All of the following:

- 1 Patient has relapsed/refractory CD30-positive systemic anaplastic large cell lymphoma; and
- 2 Patient has an ECOG performance status of 0-1; and
- 3 Patient has not previously received brentuximab vedotin; and
- 4 Response to brentuximab vedotin treatment is to be reviewed after a maximum of 6 treatment cycles; and
- 5 Brentuximab vedotin to be administered at doses no greater than 1.8 mg/kg every 3 weeks.

Renewal — (anaplastic large cell lymphoma) from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 Patient has achieved a partial or complete response to brentuximab vedotin after 6 treatment cycles; and
- 2 Treatment remains clinically appropriate and the patient is benefitting from treatment and treatment is being tolerated; and
- 3 Patient is to receive a maximum of 16 total cycles of brentuximab vedotin treatment.

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
- 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 SA2401 on the next page

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| Inj 5 mg per ml, 20 ml vial | | 1 | Erbitux |
| Inj 5 mg per ml, 100 ml vial | | 1 | Erbitux |
| Inj 1 mg for ECP | | 1 mg | Baxter |

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⇒SA2401 Special Authority for Subsidy

Initial application — (head and neck cancer, locally advanced) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Patient has locally advanced, non-metastatic, squamous cell cancer of the head and neck; and
- 2 Cisplatin is contraindicated or has resulted in intolerable side effects; and
- 3 Patient has an ECOG performance score of 0-2; and
- 4 To be administered in combination with radiation therapy.

Initial application — (colorectal cancer, metastatic) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Patient has metastatic colorectal cancer located on the left side of the colon (see Note); and
- 2 There is documentation confirming disease is RAS and BRAF wild-type; and
- 3 Patient has an ECOG performance score of 0-2; and
- 4 Patient has not received prior funded treatment with cetuximab; and
- 5 Either:
 - 5.1 Cetuximab is to be used in combination with chemotherapy; or
 - 5.2 Chemotherapy is determined to not be in the best interest of the patient based on clinician assessment.

Renewal — (colorectal cancer, metastatic) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where there is no evidence of disease progression.

Note: Left-sided colorectal cancer comprises of the distal one-third of the transverse colon, the splenic flexure, the descending colon, the sigmoid colon, or the rectum.

GEMTUZUMAB OZOGAMICIN - PCT only - Specialist - Special Authority see SA2269 below

➡SA2269 Special Authority for Subsidy

Initial application only from a haematologist, paediatric haematologist or paediatric oncologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has not received prior chemotherapy for this condition; and
- 2 Patient has de novo CD33-positive acute myeloid leukaemia; and
- 3 Patient does not have acute promyelocytic leukaemia; and
- 4 Gemtuzumab ozogamicin will be used in combination with standard anthracycline and cytarabine (AraC); and
- 5 Patient is being treated with curative intent; and
- 6 Patient's disease risk has been assessed by cytogenetic testing to be good or intermediate; and
- 7 Patient must be considered eligible for standard intensive remission induction chemotherapy with standard anthracycline and cytarabine (AraC); and
- 8 Gemtuzumab ozogamicin to be funded for one course only (one dose at 3 mg per m² body surface area or up to 2 vials of 5 mg as separate doses).

Note: Acute myeloid leukaemia excludes acute promyelocytic leukaemia and acute myeloid leukaemia that is secondary to another haematological disorder (eg myelodysplasia or myeloproliferative disorder).

INFLIXIMAB – PCT only – Special Authority see SA2402 below

| Inj 100 mg | | 1 | Remicade |
|------------------|------|------|------------------------------|
| Inj 1 mg for ECP | 4.40 | 1 mg | Baxter |

⇒SA2402 Special Authority for Subsidy

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

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All of the following:

- 1 Patient has active Crohn's disease; and
- 2 Any of the following:
 - 2.1 Patient has a CDAI score of greater than or equal to 300 or HBI score of greater than or equal to 10; or
 - 2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
 - 2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
 - 2.4 Patient has an ileostomy or colostomy, and has intestinal inflammation; and
- 3 Patient has tried but has experienced an inadequate response to, or intolerable side effects from, prior therapy with immunomodulators and corticosteroids.

Renewal — (Crohn's disease (adults)) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

1 Any of the following:

- 1.1 CDAI score has reduced by 100 points from the CDAI score, or HBI score has reduced by 3 points, from when the patient was initiated on infliximab; or
- 1.2 CDAI score is 150 or less, or HBI is 4 or less; or
- 1.3 The patient has demonstrated an adequate response to treatment but CDAI score and/or HBI score cannot be assessed; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

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

All of the following:

- 1 Paediatric patient has active Crohn's disease; and
- 2 Either:
 - 2.1 Patient has a PCDAI score of greater than or equal to 30; or
 - 2.2 Patient has extensive small intestine disease; and
- 3 Patient has tried but experienced an inadequate response to, or intolerable side effects from, prior therapy with immunomodulators and corticosteroids.

Renewal — (Crohn's disease (children)) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Any of the following:
 - 1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on infliximab; or
 - 1.2 PCDAI score is 15 or less; or
 - 1.3 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

Initial application — (Graft vs host disease) from any relevant practitioner. Approvals valid without further renewal unless notified where patient has steroid-refractory acute graft vs. host disease of the gut.

Initial application — (Pulmonary sarcoidosis) from any relevant practitioner. Approvals valid without further renewal unless notified where patient has life-threatening pulmonary sarcoidosis diagnosed by a multidisciplinary team that is refractory to other

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treatments.

Initial application — (acute fulminant ulcerative colitis) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 weeks for applications meeting the following criteria:

- Both:
 - 1 Patient has acute, fulminant ulcerative colitis; and
 - 2 Treatment with intravenous or high dose oral corticosteroids has not been successful.

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:

ner:

- 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,</p>

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or resolution of uveitic cystoid macular oedema); or

3 Following each 12 month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.

Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if infliximab is withdrawn.

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

Both:

- 1 Patient has confirmed Crohn's disease; and
- 2 Any of the following:
 - 2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
 - 2.2 Patient has one or more rectovaginal fistula(e); or
 - 2.3 Patent has complex peri-anal fistula.

Renewal — (fistulising Crohn's disease) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 2 years for applications meeting the following criteria: Both:

1 Fither:

- 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 any relevant practitioner on the recommendation of a dermatologist. Approvals valid for 3 months for applications meeting the following criteria: Either:

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- 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:
 - 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 Any of the following:
 - 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
 - 2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; or
 - 2.1.3 Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10; and
- 2.2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
- 2.3 A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 2.4 The most recent PASI assessment is no more than 1 month old at the time of initiation.

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

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

Both:

- 1 Any of the following:
 - 1.1 Both:
 - 1.1.1 Patient had "whole body" severe chronic 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

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value; or

1.3 Both:

- 1.3.1 Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment; and
- 1.3.2 Either:
 - 1.3.2.1 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or
 - 1.3.2.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing infliximab; and
- 2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

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

Both:

- 1 Patient was being treated with infliximab prior to 1 February 2019; and
- 2 Any of the following:
 - 2.1 Rheumatoid arthritis; or
 - 2.2 Ankylosing spondylitis; or
 - 2.3 Psoriatic arthritis; or
 - 2.4 Severe ocular inflammation; or
 - 2.5 Chronic ocular inflammation; or
 - 2.6 Crohn's disease (adults); or
 - 2.7 Crohn's disease (children); or
 - 2.8 Fistulising Crohn's disease; or
 - 2.9 Severe fulminant ulcerative colitis; or
 - 2.10 Severe ulcerative colitis; or
 - 2.11 Plaque psoriasis; or
 - 2.12 Neurosarcoidosis; or
 - 2.13 Severe Behcet's disease.

Initial application — (psoriatic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept and/or secukinumab for psoriatic arthritis; and
- 2 Either:
 - 2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept and/or secukinumab; or
 - 2.2 Following 3-4 months' initial treatment with adalimumab and/or etanercept and/or secukinumab, the patient did not meet the renewal criteria for adalimumab and/or etanercept and/or secukinumab for psoriatic arthritis.

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

1 Either:

- 1.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 1.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior infliximab treatment in the opinion of the treating physician; and
- 2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

Initial application — (rheumatoid arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

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All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and 2 Either:
 - 2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
 - 2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept; and
- 3 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance.

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

All of the following:

- 1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2 Either:
 - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 3 Infliximab to be administered at doses no greater than 3 mg/kg every 8 weeks.

Initial application — (severe Behcet's disease) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The patient has severe Behcet's disease which is significantly impacting the patient's quality of life (see Notes); and
- 2 Either:
 - 2.1 The patient has severe ocular, neurological and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s) (see Notes); or
 - 2.2 The patient has severe gastrointestinal, rheumatologic and/or mucocutaneous symptoms and has not responded adequately to two or more treatment appropriate for the particular symptom(s) (see Notes); and
- 3 The patient is experiencing significant loss of quality of life.

Notes: Behcet's disease diagnosed according to the International Study Group for Behcet's Disease. Lancet 1990;335(8697):1078-80. Quality of life measured using an appropriate quality of life scale such as that published in Gilworth et al J Rheumatol. 2004;31:931-7.

Treatments appropriate for the particular symptoms are those that are considered standard conventional treatments for these symptoms, for example intravenous/oral steroids and other immunosuppressants for ocular symptoms; azathioprine, steroids, thalidomide, interferon alpha and ciclosporin for mucocutaneous symptoms; and colchicine, steroids and methotrexate for rheumatological symptoms.

Renewal — (severe Behcet's disease) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has had a good clinical response to initial treatment with measurably improved quality of life; and
- 2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

Renewal — (fulminant ulcerative colitis) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Where maintenance treatment is considered appropriate, infliximab should be used in combination with immunomodulators and reassessed every 6 months; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be

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used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019.

Initial application — (severe ocular inflammation) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

1 Both:

- 1.1 The patient has had an initial Special Authority approval for adalimumab for severe ocular inflammation; and
- 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
 - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe ocular inflammation; or

2 Both:

- 2.1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and
- 2.2 Any of the following:
 - 2.2.1 Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms; or
 - 2.2.2 Patient developed new inflammatory symptoms while receiving high dose steroids; or
 - 2.2.3 Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms.

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

Any of the following:

- 1 The patient has had a good clinical response following 3 initial doses; or
- 2 Following each 12 month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema); or
- 3 Following each 12 month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old.

Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if infliximab is withdrawn.

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

All of the following:

- 1 Patient has active ulcerative colitis; and
- 2 Either:
 - 2.1 Patients SCCAI is greater than or equal to 4; or
 - 2.2 Patients PUCAI score is greater than or equal to 20; and
- 3 Patient has tried but has experienced an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and systemic corticosteroids.

Renewal — (ulcerative colitis) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Either:
 - 1.1 The SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab; or

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- 1.2 The PUCAI score has reduced by 10 points or more from the PUCAI score when the patient was initiated on infliximab: and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be 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 — (pvoderma gangrenosum) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has pvoderma gangrenosum*: and
- 2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate) and not received an adequate response; and 3 A maximum of 8 doses.

Note: Note: Indications marked with * are unapproved indications.

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

All of the following:

- 1 Patient has shown clinical improvement; and
- 2 Patient continues to require treatment: and
- 3 A maximum of 8 doses.

Initial application — (inflammatory bowel arthritis – axial) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
- 2 Patient has had axial inflammatory pain for six months or more; and
- 3 Patient is unable to take NSAIDs: and
- 4 Patient has unequivocal sacroiliitis demonstrated by radiological imaging or MRI: and
- 5 Patient's disease has not responded adequately to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist; and
- 6 Patient has a BASDAI of at least 6 on a 0 10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment .

Renewal — (inflammatory bowel arthritis - axial) from any relevant practitioner. Approvals valid for 2 years where treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10-point scale, or an improvement in BASDAI of 50%, whichever is less.

Initial application --- (inflammatory bowel arthritis -- peripheral) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
- 2 Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular; and
- 3 Patient has tried and not experienced a response to at least three months of methotrexate or azathioprine at a maximum tolerated dose (unless contraindicated): and
- 4 Patient has tried and not experienced a response to at least three months of sulfasalazine at a maximum tolerated dose (unless contraindicated): and
- 5 Any of the following:
 - 5.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application: or

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| 5.2 Patient has an ESR greater than 25 mm per hour application; or | measured no more t | han or | e month prie | or to the date of this |
| 5.3 ESR and CRP not measured as patient is currentli day and has done so for more than three months. | y receiving predniso | ne thei | rapy at a dos | se of greater than 5 mg per |
| Renewal — (inflammatory bowel arthritis – peripheral) from applications meeting the following criteria: Either: | any relevant practitio | oner. / | Approvals va | alid for 2 years for |
| Following initial treatment, patient has experienced at leacelinically significant response to treatment in the opinion of Patient has experienced at least a continuing 30% improvite treating physician. | of the physician; or | | | |
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| SA2460 Special Authority for Subsidy Initial application only from a relevant specialist or any relevant Approvals valid for 4 months for applications meeting the followir All of the following: 1 Patient has relapsed or refractory CD22-positive B-cell ac | ng criteria: | | | · |
| residual disease; and Patient has ECOG performance status of 0-2; and | | unaen | na/iymphom | |
| 3 Either: | | | | |
| 3.1 Both: | | | | |
| 3.1.1 Patient has Philadelphia chromosome posi 3.1.2 Patient has previously received a tyrosine I | | | | |
| 3.2 Patient has received one prior line of treatment inv | Ū | mothe | rapy; and | |
| 4 Treatment is to be administered for a maximum of 3 cycle | | | | |
| Renewal only from a relevant specialist or any relevant practitior valid for 4 months for applications meeting the following criteria: All of the following: | ier on the recommen | ndation | i of a relevar | nt specialist. Approvals |
| 1 Patient is not proceeding to a stem cell transplant; and 2 Either: | | | | |
| 2.1 Patient has experienced complete disease respon2.2 Patient has experienced complete remission with i3 Treatment with inotuzumab ozogamicin is to cease after a | ncomplete haemato | • | recovery; a | nd |
| MEPOLIZUMAB – Special Authority see SA2331 below – Retail Inj 100 mg prefilled pen | | 1 | 🗸 N | lucala |
| ► SA2331 Special Authority for Subsidy Initial application — (Severe eosinophilic asthma) only from for 12 months for applications meeting the following criteria: All of the following: | | an or c | clinical immu | inologist. Approvals valid |
| Patient must be aged 12 years or older; and Patient must have a diagnosis of severe eosinophilic asth | ma documented by | a resp | iratory physi | cian or clinical |
| immunologist; and 3 Conditions that mimic asthma eg. vocal cord dysfunction | , central airway obst | ruction | , bronchiolit | is etc. have been |
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excluded; and

- 4 Patient has a blood eosinophil count of greater than $0.5 \times 10^{\circ}9$ 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
- 2 Either:
 - 2.1 Exacerbations have been reduced from baseline by 50% as a result of treatment with mepolizumab; or
 - 2.2 Reduction in continuous oral corticosteroid use by 50% or by 10 mg/day while maintaining or improving asthma control.

Initial application — (eosinophilic granulomatosis with polyangiitis) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has eosinophilic granulomatosis with polyangiitis; and
- 2 The patient has trialled and not received adequate benefit from at least one of the following for at least three months (unless contraindicated to all): azathioprine, cyclophosphamide, leflunomide, methotrexate, mycophenolate, or rituximab; and
- 3 Either:
 - 3.1 The patient has trialled prednisone for a minimum of three months and is unable to maintain disease control at doses below 7.5 mg per day; or

3.2 Corticosteroids are contraindicated.

Renewal — (eosinophilic granulomatosis with polyangiitis) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months where patient has no evidence of clinical disease progression.

| OBINUTUZUMAB - PCT only - Specialist - Special Auth | nority see SA2155 on the | next page | |
|---|--------------------------|-----------|----------------------------|
| Inj 25 mg per ml, 40 ml vial | 5,910.00 | 1 | 🗸 Gazyva |
| Inj 1 mg for ECP | 6.21 | 1 mg | Baxter |

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⇒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 1.5×10^{9} /L and platelets greater than or equal to 75×10^{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 below - Retail pharmacy

| Inj 150 mg prefilled syringe | 450.00 | 1 | ✓ Xolair |
|------------------------------|--------|---|---|
| Inj 150 mg vial | 450.00 | 1 | ✓ Xolair AU ✓ Xolair |

➡SA1744 Special Authority for Subsidy

Initial application — (severe asthma) only from a respiratory specialist or clinical immunologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient must be aged 6 years or older; and
- 2 Patient has a diagnosis of severe asthma; and

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- 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

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.

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| Complete response is defined as UAS7 less than or equal to 6 ar chronic urticaria on stopping prednisone/ciclosporin does not just | | | T of 16. Relapse of |
| PALIVIZUMAB – PCT only – Special Authority see SA2419 below Inj 100 mg per ml, 1 ml vial | | 1 🗸 5 | Synagis |
| SA2419 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid Both: | d for 6 months for app | plications meeting | the following criteria: |
| 1 Palivizumab to be administered during the annual RSV se 2 Either: | ason; and | | |
| 2.1 Both: | | | |
| 2.1.1 Infant was born in the last 12 months; and | dovo' gostation: or | | |
| 2.1.2 Infant was born at less than 32 weeks zero 2.2 Both: | days gestation; or | | |
| 2.2.1 Child was born in the last 24 months; and | | | |
| 2.2.2 Any of the following: | | | |
| 2.2.2.1 Child has severe lung, airway, neurol ventilatory/respiratory support (see N | • | | requires ongoing |
| 2.2.2.2 Both: | ote A) in the commu | nity, or | |
| 2.2.2.2.1 Child has haemodynamically s 2.2.2.2.2 Any of the following: | ignificant heart disea | se; and | |
| 2.2.2.2.1 Child has unoperated si (see Note B); or | mple congenital hear | t disease with sig | nificant left to right shunt |
| 2.2.2.2.2 Child has unoperated or 2.2.2.2.2.3 Child has severe pulmor 2.2.2.2.2.4 Child has moderate or s | nary hypertension (se | ee Note C); or | |
| 2.2.2.3 Child has severe combined immune stem cell transplant; or | | . , . | <i>/</i> · |
| 2.2.2.4 Child has inborn errors of immunity (respiratory infections, confirmed by a | , | ease susceptibility | y to life-threatening viral |
| Renewal from any relevant practitioner. Approvals valid for 6 mc All of the following: | onths for applications | meeting the follo | wing criteria: |
| 1 Palivizumab to be administered during the annual RSV se | ason; and | | |
| 2 Child was born in the last 24 months; and3 Any of the following: | | | |
| 3.1 Child has severe lung, airway, neurological or neur | omuscular disease th | hat requires ongo | ing ventilatory/respiratory |
| support (see Note A) in the community, or 3.2 Both: | | | |
| 3.2.1 Child has haemodynamically significant hea 3.2.2 Any of the following: | art disease; and | | |
| 3.2.2.1 Child has unoperated simple congen or | ital heart disease with | h significant left to | o right shunt (see Note B); |
| 3.2.2.2 Child has unoperated or surgically pa 3.2.2.3 Child has severe pulmonary hyperter | | | ise; or |
| 3.2.2.4 Child has moderate or severe left ver | | | |
| 3.3 Child has severe combined immune deficiency, con transplant; or | nfirmed by an immun | ologist, but has n | ot received a stem cell |

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3.4 Child has inborn errors of immunity (see Note E) that increase susceptibility to life-threatening viral respiratory infections, confirmed by an immunologist.

Notes:

- a) Ventilatory/respiratory support includes those on home oxygen, CPAP/VPAP and those with tracheostomies in situ managed at home
- b) Child requires/will require heart failure medication, and/or child has significant pulmonary hypertension, and/or infant will require surgical palliation/definitive repair within the next 3 months
- c) Mean pulmonary artery pressure more than 25 mmHg
- d) LV Ejection Fraction less than 40%
- e) Inborn errors of immunity include, but are not limited to, IFNAR deficiencies

PERTUZUMAB - PCT only - Specialist - Special Authority see SA2276 below

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

⇒SA2276 Special Authority for Subsidy

Initial application — (metastatic breast cancer) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 Either:
 - 2.1 Patient is chemotherapy treatment naïve; or
 - 2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
- 3 The patient has good performance status (ECOG grade 0-1); and
- 4 Pertuzumab to be administered in combination with trastuzumab; and
- 5 Pertuzumab maximum first dose of 840 mg, followed by maximum of 420 mg every 3 weeks; and
- 6 Pertuzumab to be discontinued at disease progression.

Renewal — (metastatic breast cancer) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Either:

1 Both:

- 1.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 1.2 The cancer has not progressed at any time point during the previous 12 months whilst on pertuzumab and trastuzumab; or
- 2 All of the following:
 - 2.1 Patient has previously discontinued treatment with pertuzumab and trastuzumab for reasons other than severe toxicity or disease progression; and
 - 2.2 Patient has signs of disease progression; and
 - 2.3 Disease has not progressed during previous treatment with pertuzumab and trastuzumab.

RITUXIMAB (MABTHERA) - PCT only - Specialist - Special Authority see SA1976 on the next page

| Inj 100 mg per 10 ml vial1,075.50 | 2 | Mabthera |
|-----------------------------------|------|---------------------------------------|
| Inj 500 mg per 50 ml vial2,688.30 | 1 | Mabthera |
| Inj 1 mg for ECP5.64 | 1 mg | Baxter (Mabthera) |

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➡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 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.

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Renewal — (rheumatoid arthritis - re-treatment in 'partial responders' to rituximab) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
 - 1.1 At 4 months following the initial course of rituximab infusions the patient had between a 30% and 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 1.2 At 4 months following the second course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 1.3 At 4 months following the third and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and

3 Either:

- 3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
- 3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and 4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

Renewal — (rheumatoid arthritis - re-treatment in 'responders' to rituximab) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

1 Either:

- 1.1 At 4 months following the initial course of rituximab infusions the patient had at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 1.2 At 4 months following the second and subsequent courses of rituximab infusions, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the 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 SA2233 below

| Inj 100 mg per 10 ml vial | 2 | Riximyo |
|---------------------------|----------|--------------------------------------|
| Inj 500 mg per 50 ml vial | 1 | Riximyo |
| Inj 1 mg for ECP | 1 mg | Baxter (Riximyo) |

➡SA2233 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:

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- 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/m² of body-surface area per week for a total of 4 weeks.

Note: Indications marked with * are unapproved indications.

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

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

All of the following:

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

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

Both:

1 Either:

- 1.1 The patient's disease has relapsed within 36 months of previous treatment and rituximab treatment is to be used in combination with funded venetoclax; or
- 1.2 All of the following:
 - 1.2.1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and
 - 1.2.2 The patient has had an interval of 36 months or more since commencement of initial rituximab treatment; and
 - 1.2.3 The patient does not have chromosome 17p deletion CLL; and
 - 1.2.4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustine; and
- 2 Rituximab to be administered in combination with fludarabine and cyclophosphamide, bendamustine or venetoclax for a maximum of 6 treatment cycles.

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

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

Both:

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

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

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

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

Both:

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

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

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

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- 1 The patient has had a rituximab treatment-free interval of 12 months or more; and
- 2 The patient has B-cell post-transplant lymphoproliferative disorder*; and
- 3 To be used for no more than 6 treatment cycles.
- Note: Indications marked with * are unapproved indications.

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

- 1 One of the following dose regimens is to be used: 375 mg/m2 of body surface area per week for a total of four weeks, or 500 mg once weekly for four weeks, or two 1,000 mg doses given two weeks apart; and
- 2 Either:
 - 2.1 Treatment with corticosteroids and at least one other immunosuppressant for at least a period of 12 months has been ineffective; or
 - 2.2 Both:
 - 2.2.1 Treatment with at least one other immunosuppressant for a period of at least 12 months; and
 - 2.2.2 Corticosteroids have been trialed for at least 12 months and have been discontinued due to unacceptable side effects.

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

All of the following:

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

Initial application — (Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS))

only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 8 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient is a child with SDNS* or FRNS*; and
- 2 Treatment with steroids for at least a period of 3 months has been ineffective or associated with evidence of steroid toxicity; and
- 3 Treatment with ciclosporin for at least a period of 3 months has been ineffective and/or discontinued due to unacceptable side effects; and
- 4 Treatment with mycophenolate for at least a period of 3 months with no reduction in disease relapses; and
- 5 The total rituximab dose used would not exceed the equivalent of 375 mg/m² 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:

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- 1 Patient who was previously treated with rituximab for nephrotic syndrome*; and
- 2 Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks.

Note: Indications marked with * are unapproved indications.

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/m² of body surface area per week for a total of 4 weeks.

Note: Indications marked with * are unapproved indications.

Renewal — (Steroid resistant nephrotic syndrome (SRNS)) only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 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/m² of body surface area per week for a total of 4 weeks.

Note: Indications marked with * are unapproved indications.

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

Either:

- 1 All of the following:
 - 1.1 The patient has treatment naive aggressive CD20 positive NHL; and
 - 1.2 To be used with a multi-agent chemotherapy regimen given with curative intent; and
 - 1.3 To be used for a maximum of 8 treatment cycles; or
- 2 Both:
 - 2.1 The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy; and
 - 2.2 To be used for a maximum of 6 treatment cycles.

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

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

All of the following:

- 1 The patient has had a rituximab treatment-free interval of 12 months or more; and
- 2 The patient has relapsed refractory/aggressive CD20 positive NHL; and
- 3 To be used with a multi-agent chemotherapy regimen given with curative intent; and
- 4 To be used for a maximum of 4 treatment cycles.

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

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

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- 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
 - Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy); and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks.
- Note: Indications marked with * are unapproved indications.

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

- Either:
 - 1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m² weekly for 4 weeks) is now planned; or
 - 2 All of the following:
 - 2.1 Patient was previously treated with rituximab for immune thrombocytopenic purpura*; and
 - 2.2 An initial response lasting at least 12 months was demonstrated; and
 - 2.3 Patient now requires repeat treatment.

Note: Indications marked with * are unapproved indications.

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

1 Both:

- 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.

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

Note: Indications marked with * are unapproved indications.

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

- 1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m² weekly for 4 weeks) is now planned; or
- 2 All of the following:
 - 2.1 Patient was previously treated with rituximab for severe cold haemagglutinin disease*; and
 - 2.2 An initial response lasting at least 12 months was demonstrated; and
 - 2.3 Patient now requires repeat treatment.

Note: Indications marked with * are unapproved indications.

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

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

2 Either:

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

2.2 Patient has acute idiopathic thrombotic thrombocytopenic purpura* with neurological or cardiovascular pathology. Note: Indications marked with * are unapproved indications.

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

All of the following:

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

Note: Indications marked with * are unapproved indications.

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

All of the following:

- 1 The patient has severe, immediately life- or organ-threatening SLE*; and
- 2 The disease has proved refractory to treatment with steroids at a dose of at least 1 mg/kg; and
- 3 The disease has relapsed following prior treatment for at least 6 months with maximal tolerated doses of azathioprine, mycophenolate mofetil and high dose cyclophosphamide, or cyclophosphamide is contraindicated; and
- 4 Maximum of four 1000 mg infusions of rituximab.
- Note: Indications marked with * are unapproved indications.

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

All of the following:

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

Note: Indications marked with * are unapproved indications.

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

- 1 Patient has warm autoimmune haemolytic anaemia*; and
- 2 One of the following treatments has been ineffective: steroids (including if patient requires ongoing steroids at doses equivalent to > 5 mg prednisone daily), cytotoxic agents (e.g. cyclophosphamide monotherapy or in combination), intravenous immunoglobulin; and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m2 of body surface area per week for a total of 4 weeks.

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/m² weekly for 4 weeks) is now planned; or

2 All of the following:

- 2.1 Patient was previously treated with rituximab for warm autoimmune haemolytic anaemia*; and
- 2.2 An initial response lasting at least 12 months was demonstrated; and
- 2.3 Patient now requires repeat treatment.

Note: Indications marked with * are unapproved indications.

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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 $2 \times 1,000$ mg infusions of rituximab given two weeks apart.

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

All of the following:

- 1 Patient has refractory graft versus host disease following transplant; and
- 2 Treatment with at least 3 immunosuppressants (oral steroids, ciclosporin, tacrolimus, mycophenolate, sirolimus) has not be effective at controlling active disease; and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m² of body surface area per week for a total of 4 weeks.

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

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

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

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

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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
 - 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

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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/m² per dose for a maximum of 18 doses.

Note: Indications marked with * are unapproved indications.

Initial application — (desensisation prior to transplant) from any relevant practitioner. Approvals valid for 6 weeks for applications meeting the following criteria:

Both:

- 1 Patient requires desensitisation prior to mismatched allogenic stem cell transplant*; and
- 2 Patient would receive no more than two doses at 375 mg/m2 of body-surface area.

Note: Indications marked with * are unapproved indications.

Initial application — (pemiphigus*) only from a dermatologist or relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

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

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AThree 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

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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.

Initial application — (immunoglobulin G4-related disease (IgG4-RD*)) from any relevant practitioner. Approvals valid for 6 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient has confirmed diagnosis of IgG4-RD*; and
- 2 Either:
 - 2.1 Treatment with corticosteroids and/or disease modifying anti-rheumatic drugs for at least 3 months has been ineffective in lowering corticosteroid dose below 5 mg per day (prednisone equivalent) without relapse; or
 - 2.2 Treatment with corticosteroids and/or disease modifying anti-rheumatic drugs is contraindicated or associated with evidence of toxicity or intolerance; and
- 3 Total rituximab dose used should not exceed a maximum of two 1000 mg infusions of rituximab given two weeks apart.

Note: Indications marked with * are unapproved indications.

Renewal — (immunoglobulin G4-related disease (IgG4-RD*)) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 Either:

- 1.1 Treatment with rituximab for IgG4-RD* was previously successful and patient's disease has demonstrated sustained response, but the condition has relapsed; or
- 1.2 Patient is receiving maintenance treatment for IgG4-RD*; and
- 2 Rituximab re-treatment not to be given within 6 months of previous course of treatment; and
- 3 Maximum of two 1000 mg infusions of rituximab given two weeks apart.

Note: Indications marked with * are unapproved indications.

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| Inj 150 mg per ml, 1 ml prefilled syringe | 799.50 | 1 | Cosentyx |
| | 1,599.00 | 2 | Cosentyx |

⇒SA2403 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

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

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

All of the following:

- 1 Any of the following:
 - 1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
 - 1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; or
 - 1.3 Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10; and
- 2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
- 3 A PASI assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 4 The most recent PASI or DQLI assessment is no more than 1 month old at the time of application.

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

Renewal — (severe chronic plaque psoriasis – first and second-line biologic) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

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

1.2 Both:

- 1.2.1 Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment; and
- 1.2.2 Either:
 - 1.2.2.1 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; or
 - 1.2.2.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing secukinumab; and
- 2 Secukinumab to be administered at a maximum dose of 300 mg monthly.

Initial application — (ankylosing spondylitis – second-line biologic) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 3 months for applications meeting the following criteria: Both:

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- 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:

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 Fither
 - 1.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 1.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior secukinumab treatment in the opinion of the treating physician; and

1 mg

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| 2 Secukinumab to be administered at doses no greater than | n 300 mg monthly. | | |
| SILTUXIMAB – Special Authority see SA1596 below – Retail ph. Note: Siltuximab is to be administered at doses no greater the Inj 100 mg vial | han 11 mg/kg every 3 | | ✓ Sylvant |
| Inj 400 mg vial | | | ✓ Sylvant |
| SA1596 Special Authority for Subsidy Initial application only from a haematologist or rheumatologist. following criteria: All of the following: Patient has severe HHV-8 negative idiopathic multicentric Treatment with an adequate trial of corticosteroids has pro- 3 Siltuximab is to be administered at doses no greater than Renewal only from a haematologist or rheumatologist. Approval | Castleman's Disease oven ineffective; and 11 mg/kg every 3 wee | e; and eks. | |
| and the patient has sustained improvement in inflammatory mark | | | atment remains appropriate |
| TOCILIZUMAB - PCT only - Special Authority see SA2404 belo | | | |
| Inj 20 mg per ml, 4 ml vial | | - | Actemra |
| Inj 20 mg per ml, 10 ml vial | | - | Actemra |
| Inj 20 mg per ml, 20 ml vial | 1,100.00 | 1 | Actemra |

Either: 1 Both:

■ SA2404 Special Authority for Subsidy

unless notified for applications meeting the following criteria:

1.1 The patient has developed grade 3 or 4 cytokine release syndrome associated with the administration of blinatumomab for the treatment of acute lymphoblastic leukaemia; and

Initial application — (cytokine release syndrome) from any relevant practitioner. Approvals valid without further renewal

- 1.2 Tocilizumab is to be administered at doses no greater than 8 mg/kg IV for a maximum of 3 doses (if less than 30kg, maximum of 12 mg/kg); or
- 2 All of the following:
 - 2.1 The patient is enrolled in the Malaghan Institute of Medical Research ENABLE trial programme; and
 - 2.2 The patient has developed CRS or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) following CAR T-cell therapy for the treatment of relapsed or refractory B-cell non-Hodgkin lymphoma; and
 - 2.3 Tocilizumab is to be administered according to the consensus guidelines for CRS or ICANS for CAR T-cell therapy at doses no greater than 8 mg/kg IV for a maximum of 3 doses.

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

Both:

1 Patient was being treated with tocilizumab prior to 1 February 2019; and

- 2 Any of the following:
 - 2.1 rheumatoid arthritis; or
 - 2.2 systemic juvenile idiopathic arthritis; or
 - 2.3 adult-onset Still's disease; or
 - 2.4 polyarticular juvenile idiopathic arthritis; or
 - 2.5 idiopathic multicentric Castleman's disease.

Initial application — (Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept)) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting

▲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

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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.

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:

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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
- 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

▲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

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- 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 (HERZUMA) - PCT only - Special Authority see SA2293 below

| Inj 150 mg vial | | 1 | Herzuma |
|------------------|------|------|-----------------------------|
| Inj 440 mg vial | | 1 | Herzuma |
| Inj 1 mg for ECP | 0.70 | 1 mg | ✓ Baxter |

► SA2293 Special Authority for Subsidy

Initial application — (early breast cancer) from any relevant practitioner. Approvals valid for 15 months for applications meeting the following criteria:

Both:

- 1 The patient has early breast cancer expressing HER-2 IHC 3+ or ISH + (including FISH or other current technology); and
- 2 Maximum cumulative dose of 106 mg/kg (12 months' treatment).

Renewal — (early breast cancer*) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Either:

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

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- 1.2 The patient received prior adjuvant trastuzumab treatment for early breast cancer; and
- 1.3 Any of the following:
 - 1.3.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
 - 1.3.2 The patient discontinued lapatinib within 3 months due to intolerable side effects and the cancer did not progress whilst on lapatinib; or
- 1.3.3 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and 1.4 Fither:
- 1.4 Either:
 - 1.4.1 Trastuzumab will not be given in combination with pertuzumab; or
 - 1.4.2 All of the following:
 - 1.4.2.1 Trastuzumab to be administered in combination with pertuzumab; and
 - 1.4.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
 - 1.4.2.3 The patient has good performance status (ECOG grade 0-1); and
- 1.5 Trastuzumab to be discontinued at disease progression; or
- 2 All of the following:
 - 2.1 Patient has previously discontinued treatment with trastuzumab in the metastatic setting for reasons other than severe toxicity or disease progression; and
 - 2.2 Patient has signs of disease progression; and
 - 2.3 Disease has not progressed during previous treatment with trastuzumab.

Note: * For patients with relapsed HER-2 positive disease who have previously received adjuvant trastuzumab for early breast cancer

Initial application — (metastatic breast cancer) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 Either:
 - 2.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
 - 2.2 The patient discontinued lapatinib within 3 months due to intolerable side effects and the cancer did not progress whilst on lapatinib; and
- 3 Either:
 - 3.1 Trastuzumab will not be given in combination with pertuzumab; or
 - 3.2 All of the following:
 - 3.2.1 Trastuzumab to be administered in combination with pertuzumab; and
 - 3.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
 - 3.2.3 The patient has good performance status (ECOG grade 0-1); and
- 4 Trastuzumab to be discontinued at disease progression.

Renewal — (metastatic breast cancer) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Either:

- 1 All of the following:
 - 1.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
 - 1.2 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and

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- 1.3 Trastuzumab to be discontinued at disease progression; or
- 2 All of the following:
 - 2.1 Patient has previously discontinued treatment with trastuzumab for reasons other than severe toxicity or disease progression; and
 - 2.2 Patient has signs of disease progression; and
 - 2.3 Disease has not progressed during previous treatment with trastuzumab.

Initial application — (gastric, gastro-oesophageal junction and oesophageal cancer) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The patient has locally advanced or metastatic gastric, gastro-oesophageal junction or oesophageal cancer expressing HER-2 IHC 2+ FISH+ or IHC3+ (or other current technology); and
- 2 Patient has an ECOG score of 0-2.

Renewal — (gastric, gastro-oesophageal junction and oesophageal cancer) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
- 2 Trastuzumab to be discontinued at disease progression.

TRASTUZUMAB DERUXTECAN – PCT only – Special Authority see SA2420 below

| Inj 100 mg per ml, 1 ml vial | 2,550.00 | 1 | 🗸 Enhertu |
|------------------------------|----------|------|----------------------------|
| Inj 1 mg for ECP | 27.05 | 1 mg | Baxter |

⇒SA2420 Special Authority for Subsidy

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

- 1 Patient is currently on treatment with trastuzumab deruxtecan and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
 - Patient has metastatic breast cancer expressing HER-2 IHC3+ or ISH+ (including FISH or other current technology); and
 - 2.2 Patient has previously received trastuzumab and chemotherapy, separately or in combination; and
 - 2.3 Either:
 - 2.3.1 The patient has received prior therapy for metastatic disease; or
 - 2.3.2 The patient developed disease recurrence during, or within six months of completing adjuvant therapy; and
 - 2.4 Patient has a good performance status (ECOG 0-1); and
 - 2.5 Patient has not received prior funded trastuzumab deruxtecan treatment; and
 - 2.6 Treatment to be discontinued at disease progression.

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

Both:

- 1 The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab deruxtecan; and
- 2 Treatment to be discontinued at disease progression.

Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

| TRASTUZUMAB EMTANSINE - PCT only - Specialis | st – Special Authority see SA2 | 424 on the | next page |
|--|--------------------------------|------------|-----------------------------|
| Inj 100 mg vial | 2,320.00 | 1 | Kadcyla |
| Inj 160 mg vial | | 1 | Kadcyla |
| Inj 1 mg for ECP | 24.52 | 1 mg | Baxter |

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⇒SA2424 Special Authority for Subsidy

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

1 Patient has early breast cancer expressing HER2 IHC3+ or ISH+; and

- 2 Documentation of pathological invasive residual disease in the breast and/or axiliary lymph nodes following completion of surgery; and
- 3 Patient has completed systemic neoadjuvant therapy with trastuzumab and chemotherapy prior to surgery; and
- 4 Disease has not progressed during neoadjuvant therapy; and
- 5 Patient has left ventricular ejection fraction of 45% or greater; and
- 6 Adjuvant treatment with trastuzumab emtansine to be commenced within 12 weeks of surgery; and
- 7 Trastuzumab emtansine to be discontinued at disease progression; and
- 8 Total adjuvant treatment duration must not exceed 42 weeks (14 cycles).

Initial application — (metastatic breast cancer) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 Patient has previously received trastuzumab and chemotherapy, separately or in combination; and
- 3 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 Either:
 - 6.1 Patient has not received prior funded trastuzumab emtansine or trastuzumab deruxtecan treatment; or
 - 6.2 Both:
 - 6.2.1 Patient has discontinued trastuzumab deruxtecan due to intolerance; and
 - 6.2.2 The cancer did not progress while on trastuzumab deruxtecan; and
- 7 Treatment to be discontinued at disease progression.

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

- Both:
 - 1 The cancer has not progressed at any time point during the previous approval period whilst on trastuzumab emtansine; and
 - 2 Treatment to be discontinued at disease progression.

Note: Prior or adjuvant therapy includes anthracycline, other chemotherapy, biological drugs, or endocrine therapy.

USTEKINUMAB - Special Authority see SA2182 below - Retail pharmacy

➡SA2182 Special Authority for Subsidy

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

Either:

1 Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment; or

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2 Both:

- 2.1 Patient has active Crohn's disease; and
- 2.2 Either:

2.2.1 Patient has had an initial approval for prior biologic therapy for Crohn's disease and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or

2.2.2 Both:

- 2.2.2.1 Patient meets the initiation criteria for prior biologic therapies for Crohn's disease; and
- 2.2.2.2 Other biologics for Crohn's disease are contraindicated.

Renewal — (Crohn's disease - adults) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
 - 1.1 CDAI score has reduced by 100 points, or HBI score has reduced by 3 points, from when the patient was initiated on biologic therapy; or
 - 1.2 CDAI score is 150 or less, or HBI is 4 or less; or
 - 1.3 The patient has experienced an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed; and
- 2 Ustekinumab to be administered at a dose no greater than 90 mg every 8 weeks.

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

Either:

- 1 Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment; or
- 2 Both:
 - 2.1 Patient has active Crohn's disease; and
 - 2.2 Either:
 - 2.2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or
 - 2.2.2 Both:
 - 2.2.2.1 Patient meets the initiation criteria for prior biologic therapies for Crohn's disease; and
 - 2.2.2.2 Other biologics for Crohn's disease are contraindicated.

Note: Indication marked with * is an unapproved indication.

Renewal — (Crohn's disease - children*) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
 - 1.1 PCDAI score has reduced by 10 points from when the patient was initiated on biologic therapy; or
 - 1.2 PCDAI score is 15 or less; or
 - 1.3 The patient has experienced an adequate response to treatment, but CDAI score cannot be assessed; and
- 2 Ustekinumab to administered at a dose no greater than 90 mg every 8 weeks.

Note: Indication marked with * is an unapproved indication.

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

Either:

- 1 Patient is currently on treatment with ustekinumab commenced prior to 1 February 2023 and met all remaining criteria (criterion 2) below at the time of commencing treatment; or
- 2 Both:

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2.1 Patient has active ulcerative colitis; and

2.2 Either:

2.2.1 Patient has had an initial approval for prior biologic therapy for ulcerative colitis and has experienced intolerable side effects or insufficient benefit to meet renewal criteria; or

2.2.2 Both:

2.2.2.1 Patient meets the initiation criteria for prior biologic therapies for ulcerative colitis; and 2.2.2.2 Other biologics for ulcerative colitis are contraindicated.

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

Both:

1 Either:

1.1 The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on biologic therapy; or

PUCAI score has reduced by 10 points or more from the PUCAI score since initiation on biologic therapy*; and
 Ustekinumab will be used at a dose no greater than 90 mg intravenously every 8 weeks.

Note: Criterion marked with * is for an unapproved indication.

VEDOLIZUMAB - PCT only - Special Authority see SA2183 below

➡SA2183 Special Authority for Subsidy

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

All of the following:

- 1 Patient has active Crohn's disease; and
- 2 Any of the following:
 - 2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated); or
 - 2.2 Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10; or
 - 2.3 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
 - 2.4 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
 - 2.5 Patient has an ileostomy or colostomy, and has intestinal inflammation; and

3 Any of the following:

- 3.1 Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
- 3.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
- 3.3 Immunomodulators and corticosteroids are contraindicated.

Renewal — (Crohn's disease - adults) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Any of the following:
 - 1.1 CDAI score has reduced by 100 points, or HBI score has reduced by 3 points, from when the patient was initiated on biologic therapy; or
 - 1.2 CDAI score is 150 or less, or HBI is 4 or less; or
 - 1.3 The patient has experienced an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed; and
- 2 Vedolizumab to administered at a dose no greater than 300 mg every 8 weeks.

Initial application - (Crohn's disease - children*) from any relevant practitioner. Approvals valid for 6 months for applications

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meeting the following criteria:

All of the following:

- 1 Paediatric patient has active Crohn's disease; and
- 2 Any of the following:
 - 2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated); or
 - 2.2 Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30; or
 - 2.3 Patient has extensive small intestine disease; and
- 3 Any of the following:
 - 3.1 Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
 - 3.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
 - 3.3 Immunomodulators and corticosteroids are contraindicated.

Note: Indication marked with * is an unapproved indication.

Renewal — (Crohn's disease - children*) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Any of the following:
 - 1.1 PCDAI score has reduced by 10 points from when the patient was initiated on biologic therapy; or
 - 1.2 PCDAI score is 15 or less; or
 - 1.3 The patient has experienced an adequate response to treatment, but CDAI score cannot be assessed; and
- 2 Vedolizumab to administered at a dose no greater than 300mg every 8 weeks.

Note: Indication marked with * is an unapproved indication.

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

All of the following:

- 1 Patient has active ulcerative colitis; and
- 2 Any of the following:
 - 2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects or insufficient benefit to meet renewal criteria (unless contraindicated); or
 - 2.2 Patient has a SCCAI score is greater than or equal to 4; or
 - 2.3 Patient's PUCAI score is greater than or equal to 20*; and
- 3 Any of the following:
 - 3.1 Patient has tried but experienced an inadequate response to (including lack of initial response and/or loss of initial response) from prior therapy with immunomodulators and corticosteroids; or
 - 3.2 Patient has experienced intolerable side effects from immunomodulators and corticosteroids; or
 - 3.3 Immunomodulators and corticosteroids are contraindicated.

Note: Indication marked with * is an unapproved indication.

Renewal — (ulcerative colitis) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

1 Either:

- 1.1 The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on biologic therapy; or
- 1.2 The PUCAI score has reduced by 10 points or more from the PUCAI score since initiation on biologic therapy *; and
- 2 Vedolizumab will be used at a dose no greater than 300 mg intravenously every 8 weeks.

Note: Indication marked with * is an unapproved indication.

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|---|---|-------------|-----------------|-------------------------------------|
| Programmed Cell Death-1 (PD-1) Inhibitors | φ | | • | |
| ATEZOLIZUMAB – PCT only – Specialist – Special Authority see | SA2443 below | | | |
| Inj 60 mg per ml, 20 ml vial | 9,503.00 | 1 | | ecentriq |
| Inj 1 mg for ECP | 8.08 | 1 mg | ✓ B | axter |
| ■ SA2443 Special Authority for Subsidy | nenetherenu) only | from a ma | diaalar | a alagist ar any relevant |
| Initial application — (non-small cell lung cancer second line r practitioner on the recommendation of a medical oncologist. Appl | | | | |
| criteria: | | 1013 101 44 | piloatio | no meeting the following |
| All of the following: | | | | |
| 1 Patient has locally advanced or metastatic non-small cell lu | ung cancer; and | | | |
| 2 Patient has not received prior funded treatment with an im | | | | |
| 3 For patients with non-squamous histology there is docume | | | ease do | es not express activating |
| mutations of EGFR or ALK tyrosine kinase unless not pose | sible to ascertain; and | b | | |
| 4 Patient has an ECOG 0-2; and 5 Patient has documented disease progression following treater | atmont with at loast t | | of plati | num basad abamatharany |
| and | alment with at least t | wo cycles | oi piati | num-based chemotherapy |
| 6 Atezolizumab is to be used as monotherapy at a dose of 1 | 200 ma every three v | veeks (or | equival | ent) for a maximum of |
| 16 weeks; and | | (| | |
| 7 Baseline measurement of overall tumour burden is docume | ented clinically and ra | adiologica | lly. | |
| Renewal — (non-small cell lung cancer second line monother | | | | |
| on the recommendation of a medical oncologist. Approvals valid | for 4 months for appl | ications m | eeting | the following criteria: |
| All of the following: | | | | |
| 1 Any of the following: | | | | |
| 1.1 Patient's disease has had a complete response to t | | | | |
| 1.2 Patient's disease has had a partial response to trea1.3 Patient has stable disease; and | itment; or | | | |
| 2 Response to treatment in target lesions has been determin | ed by comparable ra | diologic a | eedeem | ent following the most |
| recent treatment period; and | ice by comparable re | laiologic a | 3303311 | ient following the most |
| 3 No evidence of disease progression; and | | | | |
| 4 The treatment remains clinically appropriate and patient is | benefitting from treat | tment; and | ł | |
| 5 Atezolizumab to be used at a maximum dose of 1200 mg e | | | | |
| 6 Treatment with atezolizumab to cease after a total duration | of 24 months from o | commence | ement (| or equivalent of 35 cycles |
| dosed every 3 weeks). | (| | | and a solid for 0 month. f |
| Initial application — (unresectable hepatocellular carcinoma) | from any relevant p | ractitioner | . Appro | ovais valid for 6 months for |
| applications meeting the following criteria: Either: | | | | |
| 1 Patient is currently on treatment with atezolizumab and me | t all remaining criteri | a prior to | comme | ncing treatment: or |
| 2 All of the following: | | | | nong touthon, of |
| 2.1 Patient has locally advanced or metastatic, unresed | table hepatocellular | carcinoma | a; and | |
| 2.2 Patient has preserved liver function (Child-Pugh A) | | | | |
| | | | | |

- 2.3 Transarterial chemoembolisation (TACE) is unsuitable; and
- 2.4 Any of the following:
 - 2.4.1 Patient has not received prior systemic therapy for the treatment of hepatocellular carcinoma; or
 - 2.4.2 Patient received funded lenvatinib before 1 March 2025; or
 - 2.4.3 Both:
 - 2.4.3.1 Patient has experienced treatment-limiting toxicity from treatment with lenvatinib; and
 - 2.4.3.2 No disease progression since initiation of lenvatinib; and

▲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

| (Man | Subsidy ufacturer's Price) | Subsi | Fully dised | Brand or Generic |
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| · · · · · · · · · · · · · · · · · · · | \$ | Per | 1 | Manufacturer |

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- 2.5 Patient has an ECOG performance status of 0-2; and
- 2.6 To be given in combination with bevacizumab.

Renewal — (unresectable hepatocellular carcinoma) from any relevant practitioner. Approvals valid for 6 months where there is no evidence of disease progression.

| Inj 50 mg per ml, 10 ml vial | | 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 |

⇒SA2425 Special Authority for Subsidy

Initial application — (Non-small cell lung cancer) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

- 1 Either:
 - 1.1 Patient has histologically or cytologically documented stage III, locally advanced, unresectable non-small cell lung cancer (NSCLC); or
 - 1.2 Patient has histologically or cytologically documented stage IIb (T1N2a only), locally advanced, unresectable non-small cell lung cancer (NSCLC); and
- 2 Patient has received two or more cycles of platinum-based chemotherapy concurrently with definitive radiation therapy; and
- 3 Patient has no disease progression following the second or subsequent cycle of platinum-based chemotherapy with definitive radiation therapy treatment; and
- 4 Patient has a ECOG performance status of 0 or 1; and
- 5 Patient has completed last radiation dose within 8 weeks of starting treatment with durvalumab; and
- 6 Patient must not have received prior PD-1 or PD-L1 inhibitor therapy for this condition; and

7 Either:

- 7.1 Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks; or
- 7.2 Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks; and
- 8 Treatment with durvalumab to cease upon signs of disease progression.

Renewal — (Non-small cell lung cancer) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

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

- 2 Either:
 - 2.1 Durvalumab is to be used at a maximum dose of no greater than 10 mg/kg every 2 weeks; or
 - 2.2 Durvalumab is to be used at a flat dose of 1500 mg every 4 weeks; and
- 3 Treatment with durvalumab to cease upon signs of disease progression; and
- 4 Total continuous treatment duration must not exceed 12 months.

IPILIMUMAB - PCT only - Specialist - Special Authority see SA2461 below

| Inj 5 mg per ml, 10 ml vial | 5,000.00 | 1 | Yervoy |
|-----------------------------|----------|------|----------------------------|
| Inj 5 mg per ml, 40 ml vial | | 1 | Yervoy |
| Inj 1 mg for ECP | | 1 mg | Baxter |

⇒SA2461 Special Authority for Subsidy

Initial application — (renal cell carcinoma) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

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- 1 The patient is currently on treatment with ipilimumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
 - 2.1 The patient has metastatic renal cell carcinoma; and
 - 2.2 The patient is treatment naive; and
 - 2.3 The patient has ECOG performance status 0-2; and
 - 2.4 The disease is predominantly of clear cell histology; and
 - 2.5 Any of the following:
 - 2.5.1 The patient has sarcomatoid histology; or
 - 2.5.2 Haemoglobin levels less than the lower limit of normal; or
 - 2.5.3 Corrected serum calcium level greater than 10 mg/dL (2.5 mmol/L); or
 - 2.5.4 Neutrophils greater than the upper limit of normal; or
 - 2.5.5 Platelets greater than the upper limit of normal; or
 - 2.5.6 Interval of less than 1 year from original diagnosis to the start of systemic therapy; or
 - 2.5.7 Karnofsky performance score of less than or equal to 70; and
 - 2.6 Ipilimumab is to be used at a maximum dose of 1 mg/kg for up to four cycles in combination with nivolumab..

NIVOLUMAB - PCT only - Specialist - Special Authority see SA2454 below

| Inj 10 mg per ml, 4 ml vial | 3 1 | Opdivo |
|--------------------------------------|--------|----------------------------|
| Inj 10 mg per ml, 10 ml vial2,629.96 | 6 1 | Opdivo |
| Inj 1 mg for ECP | 2 1 mg | Baxter |

➡SA2454 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 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
- 3 The patient has ECOG performance score of 0-2; and
- 4 Either:
 - 4.1 Patient has not received funded pembrolizumab; or
 - 4.2 Both:
 - 4.2.1 Patient has received an initial Special Authority approval for pembrolizumab and has discontinued pembrolizumab within 12 weeks of starting treatment due to intolerance; and
 - 4.2.2 The cancer did not progress while the patient was on pembrolizumab; and
- 5 Documentation confirming that the patient has been informed and acknowledges that funded treatment with nivolumab will not be continued if their disease progresses.

Renewal — (less than 24 months on treatment) 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; or
 - 1.1.2 Patient's disease has had a partial response to treatment; or
 - 1.1.3 Patient has stable disease; and
 - 1.2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; and
 - 1.3 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

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- progression; and
- 2.2 Patient has signs of disease progression; and
- 2.3 Disease has not progressed during previous treatment with nivolumab.

Renewal — (more than 24 months on treatment) 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: Both:

- 1 Patient has been on treatment for more than 24 months; and
- 2 Either:
 - 2.1 All of the following:
 - 2.1.1 Any of the following:
 - 2.1.1.1 Patient's disease has had a complete response to treatment; or
 - 2.1.1.2 Patient's disease has had a partial response to treatment; or
 - 2.1.1.3 Patient has stable disease; and
 - 2.1.2 Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period; and
 - 2.1.3 The treatment remains clinically appropriate and the patient is benefitting from the treatment; or
 - 2.2 All of the following:
 - 2.2.1 Patient has previously discontinued treatment with nivolumab for reasons other than severe toxicity or disease progression; and
 - 2.2.2 Patient has signs of disease progression; and
 - 2.2.3 Disease has not progressed during previous treatment with nivolumab.

Initial application — (renal cell carcinoma, first line) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 Patient is currently on treatment with nivolumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
 - 2.1 The patient has metastatic renal cell carcinoma; and
 - 2.2 The patient is treatment naive; and
 - 2.3 The patient has ECOG performance status 0-2; and
 - 2.4 The disease is predominantly of clear cell histology; and
 - 2.5 Any of the following:
 - 2.5.1 The patient has sarcomatoid histology; or
 - 2.5.2 Haemoglobin levels less than the lower limit of normal; or
 - 2.5.3 Corrected serum calcium level greater than 10 mg/dL (2.5 mmol/L); or
 - 2.5.4 Neutrophils greater than the upper limit of normal; or
 - 2.5.5 Platelets greater than the upper limit of normal; or
 - 2.5.6 Interval of less than 1 year from original diagnosis to the start of systemic therapy; or
 - 2.5.7 Karnofsky performance score of less than or equal to 70; and
 - 2.6 Nivolumab is to be used in combination with ipilimumab for the first four treatment cycles at a maximum dose of 3 mg/kg; and
 - 2.7 Nivolumab is to be used as monotherapy at a maximum maintenance dose of 240 mg every 2 weeks (or equivalent).

Initial application — (Renal cell carcinoma, second line) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has metastatic renal-cell carcinoma; and
- 2 The disease is of predominant clear-cell histology; and

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- 3 Patient has ECOG performance status 0-2; and
- 4 Patient has documented disease progression following one or two previous regimens of antiangiogenic therapy; and
- 5 Patient has not previously received a funded immune checkpoint inhibitor; and
- 6 Nivolumab is to be used as monotherapy at a maximum dose of 240 mg every 2 weeks (or equivalent) and discontinued at disease progression.

Renewal — (Renal cell carcinoma) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
 - 1.1 Patient's disease has had a complete response to treatment; or
 - 1.2 Patient's disease has had a partial response to treatment; or
 - 1.3 Patient has stable disease; and
- 2 No evidence of disease progression; and
- 3 Nivolumab is to be used as monotherapy at a maximum dose of 240 mg every 2 weeks (or equivalent) and discontinued at disease progression.

| PEMBROLIZUMAB - PCT only - Specialist - Special A | uthority see SA2386 below | |
|---|---------------------------|----------------------------|
| Inj 25 mg per ml, 4 ml vial | | 🗸 Keytruda |
| Inj 1 mg for ECP | 47.74 1 mg | Baxter |

⇒SA2386 Special Authority for Subsidy

Initial application — (unresectable or metastatic melanoma) only from a medical oncologist or medical practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

- 1 Patient has metastatic or unresectable melanoma (excluding uveal) stage III or IV; and
- 2 Baseline measurement of overall tumour burden is documented clinically and radiologically; 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 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, less than 24 months on treatment) 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; or
 - 1.1.2 Patient's disease has had a partial response to treatment; or
 - 1.1.3 Patient has stable disease; and
 - 1.2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; and
 - 1.3 The treatment remains clinically appropriate and the patient is benefitting from the treatment; or
- 2 All of the following:

▲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

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- 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.

Renewal — (unresectable or metastatic melanoma, more than 24 months on treatment) 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:

Both:

- 1 Patient has been on treatment for more than 24 months; and
- 2 Either:
 - 2.1 All of the following:
 - 2.1.1 Any of the following:
 - 2.1.1.1 Patient's disease has had a complete response to treatment; or
 - 2.1.1.2 Patient's disease has had a partial response to treatment; or
 - 2.1.1.3 Patient has stable disease; and
 - 2.1.2 Response to treatment in target lesions has been determined by comparable radiologic or clinical assessment following the most recent treatment period; and
 - 2.1.3 The treatment remains clinically appropriate and the patient is benefitting from the treatment; or
 - 2.2 All of the following:
 - 2.2.1 Patient has previously discontinued treatment with pembrolizumab for reasons other than severe toxicity or disease progression; and
 - 2.2.2 Patient has signs of disease progression; and
 - 2.2.3 Disease has not progressed during previous treatment with pembrolizumab.

Initial application — (non-small cell lung cancer first-line monotherapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer; and
- 2 Patient has not had chemotherapy for their disease in the palliative setting; and
- 3 Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
- 4 For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
- 5 Pembrolizumab to be used as monotherapy; and
- 6 Either:
 - 6.1 There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 50% as determined by a validated test unless not possible to ascertain; or
 - 6.2 Both:
 - 6.2.1 There is documentation confirming the disease expresses PD-L1 at a level greater than or equal to 1% as determined by a validated test unless not possible to ascertain; and
 - 6.2.2 Chemotherapy is determined to be not in the best interest of the patient based on clinician assessment; and
- 7 Patient has an ECOG 0-2; and
- 8 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks; and
- 9 Baseline measurement of overall tumour burden is documented clinically and radiologically.

Renewal — (non-small cell lung cancer first line monotherapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria: All of the following:

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- 1 Any of the following:
 - 1.1 Patient's disease has had a complete response to treatment; or
 - 1.2 Patient's disease has had a partial response to treatment; or
 - 1.3 Patient has stable disease; and
- 2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; and
- 3 No evidence of disease progression; and
- 4 The treatment remains clinically appropriate and patient is benefitting from treatment; and
- 5 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 6 Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Initial application — (non-small cell lung cancer first-line combination therapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has locally advanced or metastatic, unresectable, non-small cell lung cancer; and
- 2 The patient has not had chemotherapy for their disease in the palliative setting; and
- 3 Patient has not received prior funded treatment with an immune checkpoint inhibitor for NSCLC; and
- 4 For patients with non-squamous histology there is documentation confirming that the disease does not express activating mutations of EGFR or ALK tyrosine kinase unless not possible to ascertain; and
- 5 Pembrolizumab to be used in combination with platinum-based chemotherapy; and
- 6 Patient has an ECOG 0-2; and
- 7 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks; and
- 8 Baseline measurement of overall tumour burden is documented clinically and radiologically.

Renewal — (non-small cell lung cancer first line combination therapy) only from a medical oncologist or any relevant practitioner on the recommendation of a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
 - 1.1 Patient's disease has had a complete response to treatment; or
 - 1.2 Patient's disease has had a partial response to treatment; or
 - 1.3 Patient has stable disease; and
- 2 Response to treatment in target lesions has been determined by comparable radiologic assessment following the most recent treatment period; and
- 3 No evidence of disease progression; and
- 4 The treatment remains clinically appropriate and patient is benefitting from treatment; and
- 5 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 6 Treatment with pembrolizumab to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Initial application — (breast cancer, advanced) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria: Either:

- 1 Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:

2.1 Either:

2.1.1 Patient has recurrent or de novo unresectable, inoperable locally advanced triple-negative breast cancer

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(that does not express ER, PR or HER2 IHC3+ or ISH+ [including FISH or other technology]); or

- 2.1.2 Patient has recurrent or de novo metastatic triple-negative breast cancer (that does not express ER, PR or HER2 IHC3+ or ISH+ [including FISH or other technology]); and
- 2.2 Patient is treated with palliative intent; and
- 2.3 Patient's cancer has confirmed PD-L1 Combined Positive Score (CPS) is greater than or equal to 10; and
- 2.4 Patient has received no prior systemic therapy in the palliative setting; and
- 2.5 Patient has an ECOG score of 0-2; and
- 2.6 Pembrolizumab is to be used in combination with chemotherapy; and
- 2.7 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
- 2.8 Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks.

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

All of the following:

- 1 Any of the following:
 - 1.1 Patient's disease has had a complete response to treatment; or
 - 1.2 Patient's disease has had a partial response to treatment; or
 - 1.3 Patient has stable disease; and
- 2 No evidence of disease progression; and
- 3 Response to treatment in target lesions has been determined by a comparable radiologic assessment following the most recent treatment period; and
- 4 Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 5 Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Initial application — (head and neck squamous cell carcinoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: Either:

- 1 Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
 - 2.1 Patient has recurrent or metastatic head and neck squamous cell carcinoma of mucosal origin (excluding nasopharyngeal carcinoma) that is incurable by local therapies; and
 - 2.2 Patient has not received prior systemic therapy in the recurrent or metastatic setting; and
 - 2.3 Patient has a positive PD-L1 combined positive score (CPS) of greater than or equal to 1; and
 - 2.4 Patient has an ECOG performance score of 0-2; and
 - 2.5 Either:
 - 2.5.1 Pembrolizumab to be used in combination with platinum-based chemotherapy; or
 - 2.5.2 Pembrolizumab to be used as monotherapy; and
 - 2.6 Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks.

Renewal — (head and neck squamous cell carcinoma) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
 - 1.1 Patient's disease has had a complete response to treatment; or
 - 1.2 Patient's disease has had a partial response to treatment; or
 - 1.3 Patient has stable disease; and
- 2 No evidence of disease progression; and

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

continued...

- 3 Pembrolizumab is to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 4 Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Initial application — (MSI-H/dMMR advanced colorectal cancer) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: Either:

- 1 Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
 - 2.1 Either:
 - 2.1.1 Patient has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer; or
 - 2.1.2 Patient has deficient mismatch repair (dMMR) or microsatellite instability-high (MSI-H) unresectable colorectal cancer; and
 - 2.2 Patient is treated with palliative intent; and
 - 2.3 Patient has not previously received funded treatment with pembrolizumab; and
 - 2.4 Patient has an ECOG performance score of 0-2; and
 - 2.5 Baseline measurement of overall tumour burden is documented clinically and radiologically; and
 - 2.6 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks.

Renewal — (MSI-H/dMMR advanced colorectal cancer) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 No evidence of disease progression; and
- 2 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
- 3 Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Initial application — (Urothelial carcinoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

1 Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or

- 2 All of the following:
 - 2.1 Patient has inoperable locally advanced (T4) or metastatic urothelial carcinoma; and
 - 2.2 Patient has an ECOG performance score of 0-2; and
 - 2.3 Patient has documented disease progression following treatment with chemotherapy; and
 - 2.4 Pembrolizumab to be used as monotherapy at a maximum dose of 200 mg every three weeks (or equivalent) for a maximum of 16 weeks.

Renewal — (Urothelial carcinoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

- All of the following:
 - 1 Any of the following:
 - 1.1 Patient's disease has had a complete response to treatment; or
 - 1.2 Patient's disease has had a partial response to treatment; or
 - 1.3 Patient has stable disease; and
 - 2 No evidence of disease progression; and
 - 3 Pembrolizumab to be used at a maximum dose of 200 mg every three weeks (or equivalent); and
 - 4 Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

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Initial application — (relapsed/refractory Hodgkin lymphoma) only from a relevant specialist or any relevant practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria: Either:

- 1 Patient is currently on treatment with pembrolizumab and met all remaining criteria prior to commencing treatment; or
- 2 All of the following:
 - 2.1 Either:
 - 2.1.1 Both:
 - 2.1.1.1 Patient has relapsed/refractory Hodgkin lymphoma after two or more lines of chemotherapy; and 2.1.1.2 Patient is ineligible for autologous stem cell transplant; or
 - 2.1.2 Patient has relapsed/refractory Hodgkin lymphoma and has previously undergone an autologous stem cell transplant; and
 - 2.2 Patient has not previously received funded pembrolizumab; and
 - 2.3 Pembrolizumab to be administered at doses no greater than 200 mg once every 3 weeks.

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

- 1 Patient has received a partial or complete response to pembrolizumab; and
- 2 Treatment with pembrolizumab is to cease after a total duration of 24 months from commencement (or equivalent of 35 cycles dosed every 3 weeks).

Other Immunosuppressants

CICLOSPORIN

| Cap 25 mg | | 50 | Neoral |
|--|-----------------|----------|------------------------------|
| Cap 50 mg | | 50 | Neoral |
| Cap 100 mg | | 50 | Neoral |
| Oral liq 100 mg per ml | 198.13 | 50 ml OP | Neoral |
| EVEROLIMUS – Special Authority see SA2414 below – I Wastage claimable | Retail pharmacy | | |
| Tab 10 mg | 6,512.29 | 30 | Afinitor |
| Tab 5 mg | 4,555.76 | 30 | Afinitor |

⇒SA2414 Special Authority for Subsidy

Initial application only from a neurologist or oncologist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 Patient has tuberous sclerosis; and
- 2 Patient has progressively enlarging sub-ependymal giant cell astrocytomas (SEGAs) that require treatment.

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

- 1 Documented evidence of SEGA reduction or stabilisation by MRI within the last 3 months; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment; and
- 3 Everolimus to be discontinued at progression of SEGAs.

Initial application — (renal cell carcinoma) from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

1 All of the following:

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

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

continued...

- 1.1 The patient has metastatic renal cell carcinoma; and
- 1.2 The disease is of predominant clear-cell histology; and
- 1.3 The patient has documented disease progression following one previous line of treatment; and
- 1.4 The patient has an ECOG performance status of 0-2; and
- 1.5 Everolimus is to be used in combination with lenvatinib; or
- 2 All of the following:
 - 2.1 Patient has received funded treatment with nivolumab for the second line treatment of metastatic renal cell carcinoma; and
 - 2.2 Patient has experienced treatment limiting toxicity from treatment with nivolumab; and
 - 2.3 Everolimus is to be used in combination with lenvatinib; and
 - 2.4 There is no evidence of disease progression.

Renewal — (renal cell carcinoma) from any relevant practitioner. Approvals valid for 4 months where there is no evidence of disease progression.

SIROLIMUS - Special Authority see SA2270 below - Retail pharmacy

| Tab 1 mg | | 100 | Rapamune |
|----------------------|----------|----------|------------------------------|
| Tab 2 mg | 1,499.99 | 100 | Rapamune |
| Oral liq 1 mg per ml | | 60 ml OP | Rapamune |

⇒SA2270 Special Authority for Subsidy

Initial application from any medical practitioner. Approvals valid without further renewal unless notified where the drug is to be used for rescue therapy for an organ transplant recipient.

Notes: Rescue therapy defined as unresponsive to calcineurin inhibitor treatment as defined by refractory rejection; or intolerant to calcineurin inhibitor treatment due to any of the following:

- GFR< 30 ml/min; or
- Rapidly progressive transplant vasculopathy; or
- · Rapidly progressive obstructive bronchiolitis; or
- HUS or TTP; or
- Leukoencepthalopathy; or
- Significant malignant disease

Initial application — (severe non-malignant lymphovascular malformations*) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has severe non-malignant lymphovascular malformation*; and
- 2 Any of the following:
 - 2.1 Malformations are not adequately controlled by sclerotherapy and surgery; or
 - 2.2 Malformations are widespread/extensive and sclerotherapy and surgery are not considered clinically appropriate; or
 - 2.3 Sirolimus is to be used to reduce malformation prior to consideration of surgery; and
- 3 Patient is being treated by a specialist lymphovascular malformation multi-disciplinary team; and
- 4 Patient has measurable disease as defined by RECIST version 1.1 (see Note).

Renewal — (severe non-malignant lymphovascular malformations*) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 Either:

- 1.1 Patient's disease has had either a complete response or a partial response to treatment, or patient has stable disease according to RECIST version 1.1 (see Note); or
- 1.2 Patient's disease has stabilised or responded clinically and disease response to treatment has been clearly documents in patient notes; and

▲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

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

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

Renewal — (refractory seizures associated with tuberous sclerosis complex*) only from a neurologist. Approvals valid for 12 months where demonstrated significant and sustained improvement in seizure rate (e.g. 50% reduction in seizure frequency) or severity and/or patient quality of life compared with baseline prior to starting sirolimus treatment. Note: Indications marked with * are unapproved indications

| TACROLIMUS – Special Authority see SA2455 on the r | next page – Retail pharmacy | ' | |
|--|-----------------------------|-----|---------------------------------------|
| Cap 0.5 mg | | 100 | Tacrolimus Sandoz |
| Cap 0.75 mg | | 100 | Tacrolimus Sandoz |
| Cap 1 mg | | 100 | Tacrolimus Sandoz |
| Cap 5 mg | | 50 | Tacrolimus Sandoz |

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

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| \$ | Per | 1 | |

➡SA2455 Special Authority for Subsidy

Initial application — (organ transplant) only from a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 The individual is an organ transplant recipient; or
- 2 The individual is receiving induction therapy for an organ transplant.

Note: Subsidy applies for either primary or rescue therapy.

Initial application — (non-transplant indications*) only from a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

1 Patient requires long-term systemic immunosuppression; and

2 Either:

- 2.1 Ciclosporin has been trialled and discontinued treatment because of unacceptable side effects or inadequate clinical response; or
- 2.2 Patient is a child with nephrotic syndrome*.

Note: Indications marked with * are unapproved indications

JAK inhibitors

UPADACITINIB – Special Authority see SA2079 below – Retail pharmacy

RINVOQ

28

► 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: Fither:

- 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 | | | | |
| ADRENALINE – Special Authority see SA2185 below – Retail p a) Maximum of 2 inj per prescription b) Additional prescriptions limited to replacement of up to tw treatment of anaphylaxis. Inj 0.15 mg per 0.3 ml auto-injector | vo devices prior to exp | 1 OP | | pipen Jr |
| Inj 0.3 mg per 0.3 ml auto-injector SA2185 Special Authority for Subsidy Initial application — (anaphylaxis) from any relevant practition applications meeting the following criteria: Both: 1 Either: | | 1 OP vithou | - | i pipen ewal unless notified for |
| 1.1 Patient has experienced an anaphylactic reaction department; or 1.2 Patient has been assessed to be at significant risk 2 Patient is not to be prescribed more than two devices in in | c of anaphylaxis by a r | | | |
| ICATIBANT – Special Authority see SA1558 below – Retail pha Inj 10 mg per ml, 3 ml prefilled syringe | 2,668.00 | 1 valid | | irazyr Is for applications meeting |
| Supply for anticipated emergency treatment of laryngeal/ angioedema (HAE) for patients with confirmed diagnosis The patient has undergone product training and has agree | of C1-esterase inhibit | or de | ficiency; and | |

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

Allergy Desensitisation

⇒SA1367 Special Authority for Subsidy

Initial application only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria: Both:

- 1 RAST or skin test positive; and
- 2 Patient has had severe generalised reaction to the sensitising agent.

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

| | Subsidy | | Fully | Brand or |
|---|--------------------|---------------|----------|-----------------|
| | (Manufacturer's Pr | rice) Sub | sidised | Generic |
| | \$ | Per | ✓ | Manufacturer |
| BEE VENOM ALLERGY TREATMENT - Special Authority see | SA1367 on the pr | avious nage - | - Rotail | nharmacy |
| Initiation kit - 1 vial freeze dried venom with diluent | | 1 OP | | VENOX S29 |
| | | - | | VENOX S29 |
| Initiation kit - 5 vials freeze dried venom with diluent | | 1 OP | | |
| Maintenance kit - 1 vial freeze dried venom with diluent | | 1 OP | ~ | VENOX S29 |
| Maintenance kit - 6 vials 120 mcg freeze dried venom, with | 005.00 | 4.00 | | V |
| diluent | | 1 OP | v | Venomil S29 |
| Treatment kit - 1 vial 550 mcg freeze dried venom, 1 diluent | 004.00 | 4.00 | | A 11 |
| 9 ml, 3 diluent 1.8 ml | | 1 OP | | Albey |
| Treatment kit - 1 vial 550 mcg freeze dried venom, with dilue | | 1 OP | ~ | Hymenoptera S29 |
| (VENOX S29 Initiation kit - 5 vials freeze dried venom with dilue | ent to be delisted | 1 May 2025) | | |
| WASP VENOM ALLERGY TREATMENT - Special Authority set | e SA1367 on the | previous page | e – Ret | ail pharmacy |
| Treatment kit (Paper wasp venom) - 1 vial 550 mcg freeze | | | | |
| dried polistes venom, 1 diluent 9 ml, 3 diluent 1.8 ml | | 1 OP | ✓ | Albey |
| Treatment kit (Paper wasp venom) - 1 vial 550 mcg freeze | | | | |
| dried venom, with diluent | | 1 OP | ✓ | Hymenoptera S29 |
| Treatment kit (Paper wasp venom) - 6 vials 120 mcg freeze | | | | |
| dried venom, with diluent | | 1 OP | ✓ | Venomil S29 |
| Treatment kit (Yellow Jacket venom) - 1 vial 550 mcg freeze | | | | |
| dried venom, with diluent | | 1 OP | ✓ | Hymenoptera S29 |
| Treatment kit (Yellow jacket venom) - 1 vial 550 mcg freeze | | | | |
| dried vespula venom, 1 diluent 9 ml, 3 diluent 1.8 ml | | 1 OP | ✓ | Albey |
| Treatment kit (Yellow jacket venom) - 6 vials 120 mcg freeze | 9 | | | |
| dried venom, with diluent | | 1 OP | 1 | Venomil S29 |
| | | | | |
| Antihistamines | | | | |
| CETIRIZINE HYDROCHLORIDE | | | | |
| * Tab 10 mg | | 100 | 1 | Zista |
| * Oral liq 1 mg per ml | | 200 ml | | Histaclear |
| | | | | |
| * Tab 2 mg | 2 02 | 40 | | |
| | (8.40) | -10 | | Polaramine |
| | 1.01 | 20 | | r olarannio |
| | (5.99) | | | Polaramine |
| * Oral lig 2 mg per 5 ml | | 100 ml | | |
| | (10.29) | | | Polaramine |
| FEXOFENADINE HYDROCHLORIDE | | | | |
| * Tab 60 mg | | 20 | | |
| · · ·································· | (8.23) | | | Telfast |
| * Tab 120 mg | | 30 | ✓ | Fexaclear |
| Ŭ | 14.22 | | | |
| | (26.44) | | | Telfast |
| Fexaclear to be Principal Supply on 1 July 2025 | | | | |
| * Tab 180 mg | 4.10 | 30 | ✓ | Fexaclear |
| Fexaclear to be Principal Supply on 1 July 2025 | | | | |
| (Telfast Tab 120 mg to be delisted 1 July 2025) | | | | |
| LORATADINE | | | | |
| * Tab 10 mg | 1.78 | 100 | ✓ | Lorafix |
| * Oral liq 1 mg per ml | 1.43 | 100 ml | ✓ | Haylor syrup |
| | | | | |

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 Pi \$ | | Fully Brand or dised Generic ✓ Manufacturer |
|---|-------------------------------------|-------------|---|
| PROMETHAZINE HYDROCHLORIDE | | | |
| * Tab 10 mg | 1.39 | 50 | ✓ <u>Allersoothe</u> |
| * Tab 25 mg | | 50 | ✓ <u>Allersoothe</u> |
| * Oral liq 1 mg per 1 ml | 3.39 | 100 ml | Allersoothe |
| | 10.47 | | Phenergan Elixir |
| Inj 25 mg per ml, 2 ml ampoule – Up to 5 inj available on | a PSO21.09 | 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 | | 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 | | 200 dose OP | Beclazone 250 |
| BUDESONIDE | | | |
| Powder for inhalation, 100 mcg per dose | | 200 dose OP | Pulmicort |
| 3 | | | Turbuhaler |
| Powder for inhalation, 200 mcg per dose | 19.00 | 200 dose OP | ✓ Pulmicort |
| · • • • • • • • • • • • • • • • • • • • | | 200 0000 0. | Turbuhaler |
| Powder for inhalation, 400 mcg per dose | 32.00 | 200 dose OP | ✓ Pulmicort |
| | | 200 0000 01 | Turbuhaler |
| FLUTICASONE | | | · · · · · · · · · · · · · · · · · · · |
| Aerosol inhaler, 50 mcg per dose | 7 19 | 120 dose OP | ✓ Flixotide |
| Powder for inhalation, 50 mcg per dose | | 60 dose OP | Flixotide Accuhaler |
| Powder for inhalation, 100 mcg per dose | | 60 dose OP | ✓ Flixotide Accuhaler |
| Aerosol inhaler, 125 mcg per dose | | 120 dose OP | ✓ Flixotide |
| Aerosol inhaler, 250 mcg per dose | | 120 dose OP | ✓ Flixotide |
| Powder for inhalation, 250 mcg per dose | | 60 dose OP | ✓ Flixotide Accuhaler |
| | | | |

Inhaled Long-acting Beta-adrenoceptor Agonists

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 mcg61.00 Powder for inhalation 300 mcg61.00 | 30 dose OP 30 dose OP | ✓ Onbrez Breezhaler ✓ Onbrez Breezhaler |
| SALMETEROL Aerosol inhaler CFC-free, 25 mcg per dose26.25 Powder for inhalation, 50 mcg per dose, breath activated26.25 | 120 dose OP 60 dose OP | ✓ Serevent ✓ Serevent Accuhaler |

| | Subsidy | | Fully | Brand or |
|---|-----------------|--------------|------------|---------------------------|
| | (Manufacturer's | Price) Subsi | | Generic |
| | \$ | Per | 1 | Manufacturer |
| | | | | |
| Inhaled Corticosteroids with Long-Acting Beta- | Adrenocept | tor Agonists | | |
| BUDESONIDE WITH EFORMOTEROL | | | | |
| Powder for inhalation 160 mcg with 4.5 mcg eformoterol | | | | |
| fumarate per dose (equivalent to 200 mcg budesonide w | ith | | | |
| | | 100 daga OD | | Ne Doon Chinemay |
| 6 mcg eformoterol fumarate metered dose) | | 120 dose OP | • 0 | uoResp Spiromax |
| Powder for inhalation 320 mcg with 9 mcg eformoterol fumar | | | | |
| per dose (equivalent to 400 mcg budesonide with 12 mcg | g | | | |
| eformoterol fumarate metered dose) – No more than 2 | | | | |
| dose per day | | 120 dose OP | ✓ D | uoResp Spiromax |
| Aerosol inhaler 100 mcg with eformoterol fumarate 6 mcg | | 120 dose OP | 🗸 V | annair |
| Powder for inhalation 100 mcg with eformoterol fumarate 6 m | ncg33.74 | 120 dose OP | ✓ s | ymbicort |
| ° ° | Ū | | | Turbuhaler 100/6 |
| Aerosol inhaler 200 mcg with eformoterol fumarate 6 mcg | 21.40 | 120 dose OP | 🗸 V | annair |
| Powder for inhalation 200 mcg with eformoterol fumarate 6 m | | 120 dose OP | | symbicort |
| · owser for initial and zoo meg with clotholefor fullididle off | iog00.74 | | - 3 | Turbuhaler 200/6 |
| Develop for introduction, 400 merces itte of an extend for each | | | | |
| Powder for inhalation 400 mcg with eformoterol fumarate | 00.74 | | | |
| 12 mcg – No more than 2 dose per day | | 60 dose OP | v 5 | Symbicort |
| | | | | Turbuhaler 400/12 |
| FLUTICASONE FUROATE WITH VILANTEROL | | | | |
| Powder for inhalation 100 mcg with vilanterol 25 mcg | | 30 dose OP | 🗸 В | Breo Ellipta |
| FLUTICASONE WITH SALMETEROL | | | | • |
| Aerosol inhaler 50 mcg with salmeterol 25 mcg | 25 70 | 120 dose OP | . | eretide |
| 5 5 | | 120 dose OP | - | eretide |
| Aerosol inhaler 125 mcg with salmeterol 25 mcg | | 120 dose OP | • 3 | erelide |
| Powder for inhalation 100 mcg with salmeterol 50 mcg - No | | | | |
| more than 2 dose per day | | 60 dose OP | ✓ S | eretide Accuhaler |
| Powder for inhalation 250 mcg with salmeterol 50 mcg - No | | | | |
| more than 2 dose per day | | 60 dose OP | ✓ s | eretide Accuhaler |
| Beta-Adrenoceptor Agonists | | | | |
| | | | | |
| SALBUTAMOL | 50.00 | 450 1 | | |
| Oral liq 400 mcg per ml | | 150 ml | ✓ V | entolin |
| Ventolin to be Principal Supply on 1 May 2025 | | <i>,</i> - | | |
| Infusion 1 mg per ml, 5 ml | | 10 | | entolin |
| Inj 500 mcg per ml, 1 ml – Up to 5 inj available on a PSO | | 5 | ✓ V | entolin |
| Inhaled Beta-Adrenoceptor Agonists | | | | |
| SALBUTAMOL | | | | |
| | | | | |
| Aerosol inhaler, 100 mcg per dose CFC free – Up to 1000 | | | | |
| dose available on a PSO | | 200 dose OP | - | alAir |
| | (6.80) | | V | entolin |
| Nebuliser soln, 1 mg per ml, 2.5 ml ampoule – Up to 30 neb | | | | |
| available on a PSO | | 20 | 🗸 A | sthalin |
| Nebuliser soln, 2 mg per ml, 2.5 ml ampoule – Up to 30 neb | | | | |
| available on a PSO | 9.43 | 20 | 🗸 A | sthalin |
| TERBUTALINE SULPHATE | | | | |
| | | | | |
| Powder for inhalation, 200 mcg per dose (equivalent to | 00.00 | 100 data 000 | | waa aa ad Taawka ah ah ah |
| 250 mcg metered dose), breath activated | | 120 dose OP | • 8 | Fricanyl Turbuhaler |
| | | | | |

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

| Fully Brand or bsidised Generic ✔ Manufacturer |
|---|
| |
| |
| Atrovent |
| Pharmascience S29 Univent |
| 5) |
| |
| ⊃ 🖌 Duolin HFA |
| ✓ Duolin |
| |
| ment with subsidised tiotropium or vho have been diagnosed as ed accordingly. |
| |
| bsidised inhaled glycopyrronium o |
| COPD using spirometry if tiotropium dispensed before |
| Spiriva |
| Spiriva Respimat |
| d inhaled glycopyrronium or |
| who have been diagnosed as havin rdingly. Incruse Ellipta |
|) |

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

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 SA15 | 84 above – | Retail pharmacy | | |
| Powder for inhalation 62.5 mcg with vilanterol 25 mcg | 77.00 | 30 dose OP | Anoro Ellipta | |

Inhaled Corticosteroid with Long-Acting Muscarinic Antagonist and Beta Agonist

BUDESONIDE WITH GLYCOPYRRONIUM AND EFORMOTEROL - Special Authority see SA2421 below - Retail pharmacy

Aerosol inhaler budesonide 160 mcg with glycopyrronium

⇒SA2421 Special Authority for Subsidy

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

Both:

- 1 Patient has a diagnosis of COPD confirmed by spirometry or spirometry has been attempted and technically acceptable results are not possible; and
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Patient is currently receiving an inhaled corticosteroid with long acting beta-2 agonist (ICS/LABA) or a long acting muscarinic antagonist with long acting beta-2 agonist (LAMA/LABA); and
 - 2.1.2 Any of the following:
 - Clinical criteria:
 - 2.1.2.1 Patient has a COPD Assessment Test (CAT) score greater than 10; or
 - 2.1.2.2 Patient has had 2 or more exacerbations in the previous 12 months; or
 - 2.1.2.3 Patient has had one exacerbation requiring hospitalisation in the previous 12 months; or
 - 2.1.2.4 Patient has had an eosinophil count greater than or equal to 0.3 × 10°9 cells/L in the previous 12 months; or
 - 2.2 Patient is currently receiving multiple inhaler triple therapy (inhaled corticosteroid with long-acting muscarinic antagonist and long-acting beta-2 agonist ICS/LAMA/LABA) and met at least one of the clinical criteria above prior to commencing multiple inhaler therapy.

| FLUTICASONE FUROATE WITH UMECLIDINIUM AND VILANTEROL – S | Special A | Authority see | SA2326 below - | Retail pharmacy |
|--|-----------|---------------|----------------|-----------------|
| Powder for inhalation fluticasone furoate 100 mcg with | | | | |
| umeclidinium 62.5 mcg and vilanterol 25 mcg 104.2 | .24 | 30 dose OP | Trelegy E | llipta |

| | Subsidy (Manufacturer's Price) \$ | Fully Subsidised Per ✓ | Brand or Generic Manufacturer |
|--|---|-----------------------------------|-------------------------------------|
| SA2326 Special Authority for Subsidy nitial application from any relevant practitioner. Approvals va he following criteria: Both: | lid without further rene | wal unless notified | d for applications meeting |
| Patient has a diagnosis of COPD confirmed by spirometr results are not possible; and Either: 2.1 Both: | ry or spirometry has be | en attempted and | technically acceptable |
| 2.1 Dout. 2.1.1 Patient is currently receiving an inhaled co acting muscarinic antagonist with long act 2.1.2 Any of the following: Clinical criteria: | | | iist (ICS/LABA) or a long |
| 2.1.2.1 Patient has a COPD Assessment T 2.1.2.2 Patient has had 2 or more exacerba 2.1.2.3 Patient has had one exacerbation r 2.1.2.4 Patient has had an eosinophil coun 12 months; or | ations in the previous 1 equiring hospitalisation | 2 months; or in the previous 1 | |
| 2.2 Patient is currently receiving multiple inhaler triple antagonist and long acting beta-2 agonist – ICS/L prior to commencing multiple inhaler triple therap | _AMA/LABA) and met a | | |
| Antifibrotics | | | |

NINTEDANIB - Special Authority see SA2012 below - Retail pharmacy

Note: Nintedanib not subsidised in combination with subsidised pirfenidone.

| Cap 100 mg | 2,554.00 | 60 OP | Ofev |
|------------|----------|-------|--------------------------|
| Cap 150 mg | 3,870.00 | 60 OP | Ofev |

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.

| | Subsidy (Manufacturer's Price) \$ | Per | Fully Subsidised | |
|--|---|-------|---------------------|---------|
| PIRFENIDONE – Retail pharmacy-Specialist – Special Authority Note: Pirfenidone is not subsidised in combination with subs | | | | |
| Tab 801 mg | 3,645.00 | 90 OF | > √ | Esbriet |
| Tab 267 mg | 1,215.00 | 90 | 1 | Esbriet |
| SA2013 Special Authority for Subsidy | | | | |

SA2013 Special Authority for Subsidy

Initial application — (idiopathic pulmonary fibrosis) only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist; and
- 2 Forced vital capacity is between 50% and 90% predicted; and
- 3 Pirfenidone is to be discontinued at disease progression (See Note); and
- 4 Pirfenidone is not to be used in combination with subsidised nintedanib; and
- 5 Any of the following:
 - 5.1 The patient has not previously received treatment with nintedanib: or
 - 5.2 Patient has previously received nintedanib, but discontinued nintedanib within 12 weeks due to intolerance; or
 - 5.3 Patient has previously received nintedanib, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with nintedanib).

Renewal - (idiopathic pulmonary fibrosis) only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and
- 2 Pirfenidone is not to be used in combination with subsidised nintedanib: and
- 3 Pirfenidone is to be discontinued at disease progression (See Note).

Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

Leukotriene Receptor Antagonists

MONTELUKAST

| * | Tab 4 mg | 28 | Montelukast Viatris |
|---|---------------|----|---|
| * | Tab 5 mg | 28 | Montelukast Viatris |
| * | Tab 10 mg2.90 | 28 | Montelukast Viatris |

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 * Oral liq 80 mg per 15 ml | | 100 500 ml | ✓ Nuelin-SR ✓ Nuelin |

Mucolytics

| DORNASE ALFA - Special Authority see SA1978 on the next page - Ret | tail pharmacy | |
|--|---------------|---|
| Nebuliser soln, 2.5 mg per 2.5 ml ampoule | 0.00 | 6 |

Pulmozvme

⇒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:

| Subsidy (Manufacturer's Price) | Full Subsidise | | |
|-----------------------------------|-------------------|--------------|--|
| \$ | Per 🖌 | Manufacturer | |

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</p>
 - 3.4 Patient has a diagnosis of allergic bronchopulmonary aspergillosis (ABPA).

Renewal — (cystic fibrosis) only from a respiratory physician or paediatrician. Approvals valid without further renewal unless notified where the treatment remains appropriate and the patient continues to benefit from treatment.

ELEXACAFTOR WITH TEZACAFTOR, IVACAFTOR AND IVACAFTOR - PCT only - Special Authority see SA2456 below

| Tab elexacaftor 50 mg with tezacaftor 25 mg, ivacaftor 3 | 37.5 mg | | |
|--|--------------------|-------|------------|
| (56) and ivacaftor 75 mg (28) | 27,647.39 | 84 OP | 🗸 Trikafta |
| Tab elexacaftor 100 mg with tezacaftor 50 mg, ivacaftor | [.] 75 mg | | |
| (56) and ivacaftor 150 mg (28) | 27,647.39 | 84 OP | 🗸 Trikafta |

➡SA2456 Special Authority for Subsidy

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

All of the following:

- 1 Patient has been diagnosed with cystic fibrosis; and
- 2 Patient is 6 years of age or older; and
- 3 Either:
 - 3.1 Patient has two cystic fibrosis-causing mutations in the cystic fibrosis transmembrane regulator (CFTR) gene (one from each parental allele); or
 - 3.2 Patient has a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis or by Macroduct sweat collection system; and
- 4 Either:
 - 4.1 Patient has a heterozygous or homozygous F508del mutation; or
 - 4.2 Patient has a G551D mutation or other mutation responsive in vitro to elexacaftor/tezacaftor/ivacaftor (see note a); and
- 5 The treatment must be the sole funded CFTR modulator therapy for this condition; and

6 Treatment with elexacaftor/tezacaftor/ivacaftor must be given concomitantly with standard therapy for this condition.

Notes:

 a) Eligible mutations are listed in the Food and Drug Administration (FDA) Trikafta prescribing information <u>https://nctr-crs.fda.gov/fdalabel/services/spl/set-ids/f354423a-85c2-41c3-a9db-0f3aee135d8d/spl-doc</u>

IVACAFTOR - PCT only - Specialist - Special Authority see SA2017 below

| Tab 150 mg | | 56 | Kalydeco |
|-----------------------------|---|----|------------------------------|
| Oral granules 50 mg, sachet | | 56 | Kalydeco |
| Oral granules 75 mg, sachet | - | 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:

continued...

- 1 Patient has been diagnosed with cystic fibrosis; and
- 2 Either:
 - 2.1 Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; or
 - 2.2 Patient must have other gating (class III) mutation (G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N and S549R) in the CFTR gene on at least 1 allele; and
- 3 Patients must have a sweat chloride value of at least 60 mmol/L by quantitative pilocarpine iontophoresis or by Macroduct sweat collection system; and
- 4 Treatment with ivacaftor must be given concomitantly with standard therapy for this condition; and
- 5 Patient must not have an acute upper or lower respiratory infection, pulmonary exacerbation, or changes in therapy (including antibiotics) for pulmonary disease in the last 4 weeks prior to commencing treatment with ivacaftor; and
- 6 The dose of ivacaftor will not exceed one tablet or one sachet twice daily; and
- 7 Applicant has experience and expertise in the management of cystic fibrosis.

SODIUM CHLORIDE

| Not funded for use as a nasal drop. Soln 7% | 90 ml OP | ✓ Biomed |
|---|-------------|---|
| Nasal Preparations | | |
| Allergy Prophylactics | | |
| BUDESONIDE | | |
| Metered aqueous nasal spray, 50 mcg per dose2.59 | 200 dose OP | ✓ <u>SteroClear</u> |
| Metered aqueous nasal spray, 100 mcg per dose2.89 | 200 dose OP | ✓ <u>SteroClear</u> |
| FLUTICASONE PROPIONATE | | |
| Metered aqueous nasal spray, 50 mcg per dose1.98 | 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 | 1 | e-chamber Mask |
| PEAK FLOW METER | | |
| a) Up to 25 dev available on a PSO | | |
| b) Only on a PSO | | • · · · · · · · · · · · · · · · · · · · |
| Low range9.54 | 1 | Mini-Wright AFS Low Range |
| Normal range9.54 | 1 | Mini-Wright Standard |

| | Subsidy (Manufacturer's Price) \$ |) Per | Fully Subsidised | Generic |
|---|---|----------|---------------------|------------------------|
| SPACER DEVICE | | | | |
| a) Up to 50 dev available on a PSO | | | | |
| b) Only on a PSO | | | | |
| 220 ml (single patient) | 3.65 | 1 | ✓ | e-chamber Turbo |
| 510 ml (single patient) | 5.95 | 1 | ~ | e-chamber La Grande |
| 800 ml | 6.50 | 1 | 1 | Volumatic |
| Respiratory Stimulants | | | | |
| CAFFEINE CITRATE Oral liq 20 mg per ml (10 mg base per ml) | | 25 ml (| OP 🗸 | Biomed |

SENSORY ORGANS

| | Subaidu | | Fully | Brand or |
|--|-------------------------------|---------------|----------|----------------------------|
| | Subsidy (Manufacturer's Pr | ice) Sut | sidised | Generic |
| | (Manulacturer STT | Per | | Manufacturer |
| | * | | | |
| Ear Preparations | | | | |
| FLUMETASONE PIVALATE | | | | |
| Ear drops 0.02% with clioquinol 1% | 4.46 | 7.5 ml OP | 1 | Locacorten-Viaform ED's |
| | | | 1 | Locorten-Vioform |
| | | | • | Loconten-violonni |
| TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYC | IN AND NYSTATI | N | | |
| Ear drops 1 mg with nystatin 100,000 u, neomycin sulphate | 5.40 | | | |
| 2.5 mg and gramicidin 250 mcg per g | 5.16 | 7.5 ml OP | ~ | Kenacomb |
| For/File Dreportions | | | | |
| 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) | 0 111 01 | | Otodex S29 |
| | (9.27) | | | Sofradex |
| (Otodex ^{\$29} Ear/Eye drops 500 mcg with framycetin sulphate 5 2025) | · · · | lin 50 mcg pe | | |
| , | | | | |
| FRAMYCETIN SULPHATE | 4.40 | 0 | | |
| Ear/Eye drops 0.5% | | 8 ml OP | | 0 |
| | (8.65) | | | Soframycin |
| Euo Dronovotiono | | | | |
| Eye Preparations | | | | |
| Eye preparations are only funded for use in the eye, unless explicitly | citly stated otherw | ico | | |
| | Sitty Stated otherw | 130. | | |
| Anti-Infective Preparations | | | | |
| | | | | |
| | 45.00 | 4.5 | | V/ |
| * Eye oint 3% | 15.89 | 4.5 g OP | • | ViruPOS |
| CHLORAMPHENICOL | | | | |
| Eye oint 1% | | 5 g OP | | Devatis |
| Eye drops 0.5% | | 10 ml OP | ✓ | Chlorsig |
| Funded for use in the ear*. Indications marked with * ar | e unapproved ind | ications. | | |
| CIPROFLOXACIN | | | | |
| Eye drops 0.3% – Subsidy by endorsement | | 5 ml OP | ✓ | Ciprofloxacin Teva |
| When prescribed for the treatment of bacterial keratitis of | r severe bacterial | conjunctiviti | s resist | ant to chloramphenicol; or |
| for the second line treatment of chronic suppurative otitis | | | | |
| Note: Indication marked with a * is an unapproved indic | ation. | | | |
| SODIUM FUSIDATE [FUSIDIC ACID] | | | | |
| Eve drops 1% | 5 29 | 5 g OP | 1 | Fucithalmic |
| -, | | 0 9 01 | | Fucithalmic S29 S29 |
| | | | • | |
| TOBRAMYCIN | | | | |
| Eve oint 0.3% | 10.45 | 3.5 g OP | 1 | Tobrex |
| Eye drops 0.3% | | 5 ml OP | | Tobrex |
| | | 0 111 01 | - | |

▲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 P \$ | Price) Subs Per | Fully Brand or sidised Generic Manufacturer |
|---|--|--------------------|--|
| Corticosteroids and Other Anti-Inflam | matory Preparations | | |
| EXAMETHASONE | | | |
| Eye oint 0.1% | | 3.5 g OP | Maxidex |
| Eye drops 0.1% Ocular implant 700 mcg – Special Authority see | | 5 ml OP | Maxidex |
| – Retail pharmacy | | 1 | Ozurdex |
| SA1680 Special Authority for Subsidy | · · · · · · · · · · · · · · · · · · · | | |
| itial application — (Diabetic macular oedema) neeting the following criteria: Il of the following: | , , , | . Approvals va | alid for 12 months for applications |
| 1 Patient has diabetic macular oedema with ps | | | ation in vision and |
| 2 Patient has reduced visual acuity of between3 Either: | 0/9 - 6/48 with functional awa | areness of redu | uction in vision; and |
| 3.1 Patient's disease has progressed des 3.2 Patient is unsuitable or contraindicate | | | |
| 4 Dexamethasone implants are to be administe | ered not more frequently than | once every 4 | months into each eye, and up to |
| maximum of 3 implants per eye per year. enewal — (Diabetic macular oedema) only from | an ophthalmologist Approv | ale valid for 12 | months for applications meeting |
| ne following criteria: | an opninalmologisi. Approva | ais valiu 101 12 | monuls for applications meeting |
| oth: | actives determined), and | | |
| Patient's vision is stable or has improved (pre Dexamethasone implants are to be administer | | once every 4 | months into each eye, and up to |
| maximum of 3 implants per eye per year. | | | |
| nitial application — (Women of child bearing ag | | ema) only from | m an ophthalmologist. Approvals |
| alid for 12 months for applications meeting the follo Il of the following: | wing criteria: | | |
| 1 Patient has diabetic macular oedema; and | | | |
| 2 Patient has reduced visual acuity of between | 6/9 - 6/48 with functional awa | areness of redu | uction in vision; and |
| 3 Patient is of child bearing potential and has n 4 Dexamethasone implants are to be administered | | | months into each eye, and up to |
| maximum of 3 implants per eye per year. | | | |
| enewal — (Women of child bearing age with dia | | ly from an ophi | thalmologist. Approvals valid for |
| 2 months for applications meeting the following crit Il of the following: | | | |
| Patient's vision is stable or has improved (pre Patient is of child bearing potential and has n | , | 4 | |
| 2 Fallent is of child bearing potential and has n | | | months into each eve, and up to |
| 3 Dexamethasone implants are to be administed | | 0 | |
| 3 Dexamethasone implants are to be administer maximum of 3 implants per eye per year. | | | |
| | | IATE | |
| maximum of 3 implants per eye per year. EXAMETHASONE WITH NEOMYCIN SULPHATE EVE oint 0.1% with neomycin sulphate 0.35% ar | AND POLYMYXIN B SULPH nd polymyxin b | | Maniferal |
| maximum of 3 implants per eye per year. EXAMETHASONE WITH NEOMYCIN SULPHATE EVE oint 0.1% with neomycin sulphate 0.35% ar sulphate 6,000 u per g | AND POLYMYXIN B SULPH nd polymyxin b | IATE 3.5 g OP | ✓ Maxitrol |
| maximum of 3 implants per eye per year. EXAMETHASONE WITH NEOMYCIN SULPHATE € Eye oint 0.1% with neomycin sulphate 0.35% ar sulphate 6,000 u per g | AND POLYMYXIN B SULPH nd polymyxin b | | ✓ Maxitrol ✓ Maxitrol |
| maximum of 3 implants per eye per year. EXAMETHASONE WITH NEOMYCIN SULPHATE EVE oint 0.1% with neomycin sulphate 0.35% ar sulphate 6,000 u per g | AND POLYMYXIN B SULPH nd polymyxin b | 3.5 g OP | |
| maximum of 3 implants per eye per year. EXAMETHASONE WITH NEOMYCIN SULPHATE € Eye oint 0.1% with neomycin sulphate 0.35% ar sulphate 6,000 u per g | AND POLYMYXIN B SULPH nd polymyxin b and polymyxin | 3.5 g OP | |

Diclofenac Devatis to be Principal Supply on 1 July 2025

SENSORY ORGANS

| | Subsidy | | Fully | Brand or |
|---|--------------------|----------------|--------|------------------------------|
| | (Manufacturer's Pr | | idised | Generic |
| | \$ | Per | | Manufacturer |
| FLUOROMETHOLONE | | | | |
| * Eye drops 0.1% | 3.09 | 5 ml OP | 1 | FML |
| | 5.20 | 0111101 | | Flucon |
| | 5.20 | | • | Flucon |
| LEVOCABASTINE | | | | |
| Eye drops 0.5 mg per ml | 8.71 | 4 ml OP | | |
| | (10.34) | | | Livostin |
| LODOXAMIDE | | | | |
| Eye drops 0.1% | 8 71 | 10 ml OP | 1 | Lomide |
| | | | • | Lonnae |
| NEPAFENAC | | | | |
| Eye drops 0.3% | 8.80 | 3 ml OP | ~ | llevro |
| (Ilevro Eye drops 0.3% to be delisted 1 July 2025) | | | | |
| PREDNISOLONE ACETATE | | | | |
| Eye drops 1% | 6.92 | 10 ml OP | 1 | Prednisolone-AFT |
| | 7.00 | 5 ml OP | | Pred Forte |
| | | | | Fieu i one |
| PREDNISOLONE SODIUM PHOSPHATE – Special Authority se | | | | |
| Eye drops 0.5%, single dose (preservative free) | | 20 dose | ~ | Minims |
| | | | | Prednisolone |
| ■SA1715 Special Authority for Subsidy | | | | |
| Initial application only from an ophthalmologist or optometrist. | Annrovals valid fo | r 6 months for | annli | cations meeting the |
| following criteria: | | | appi | cations meeting the |
| Both: | | | | |
| | | | | |
| 1 Patient has severe inflammation; and | | | | |
| 2 Patient has a confirmed allergic reaction to preservative in | | | | |
| Renewal from any relevant practitioner. Approvals valid for 6 mc | onths where the tr | eatment rema | ins ap | propriate and the patient is |
| benefiting from treatment. | | | | |
| SODIUM CROMOGLICATE | | | | |
| Eye drops 2% | | 10 ml OP | 1 | Allerfix |
| 7 • • • • • • | | | | |
| Glaucoma Preparations - Beta Blockers | | | | |
| chaucona roparationo Dota Diotitoro | | | | |
| BETAXOLOL | | | | |
| * Eye drops 0.25% | | 5 ml OP | 1 | Betoptic S |
| * Eye drops 0.5% | | 5 ml OP | - | Betoptic |
| (Betoptic S Eye drops 0.25% to be delisted 1 December 2025) | | | | |
| (Betoptic Eye drops 0.5% to be delisted 1 December 2025) | | | | |
| | | | | |
| TIMOLOL | | | _ | |
| * Eye drops 0.25% | 2.42 | 5 ml OP | | Arrow-Timolol |
| * Eye drops 0.5% | 2.50 | 5 ml OP | ~ | Arrow-Timolol |
| | | | | |
| Glaucoma Preparations - Carbonic Anhydrase I | nhibitors | | | |
| | | | | |
| ACETAZOLAMIDE | | | _ | |
| * Tab 250 mg | | 100 | ~ | Medsurge |
| | 17.03 | | 1 | Diamox |
| (Diamox Tab 250 mg to be delisted 1 September 2025) | | | | |
| BRINZOLAMIDE | | | | |
| * Eye drops 1% | 5 11 | 5 ml OP | 1 | Azopt |
| | | 5 m OF | • | Azopi |
| DORZOLAMIDE WITH TIMOLOL | | | | |
| * Eye drops 2% with timolol 0.5% | 3.58 | 5 ml OP | 1 | Dortimopt |
| | | | | |

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

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

| | Subsidy (Manufacturer's I | Price) Subs | Fully Brand or sidised Generic |
|---|------------------------------|--------------------|--|
| | (Manufacturer's I \$ | Price) Subs Per | Manufacturer |
| Glaucoma Preparations - Prostaglandin Analog | jues | | |
| BIMATOPROST | | | 4 1 1 |
| ₭ Eye drops 0.03% | 5.15 | 3 ml OP | Lumigan |
| .ATANOPROST ₭ Eye drops 0.005% | 2.08 | 2.5 ml OP | 🗸 Teva |
| FRAVOPROST | | 2.0 111 01 | <u></u> |
| K Eye drops 0.004% | 6.80 | 2.5 ml OP | ✓ <u>Travatan</u> |
| Glaucoma Preparations - Other | | | |
| BRIMONIDINE TARTRATE | | | . |
| * Eye drops 0.2% | 5.16 | 5 ml OP | <u>Arrow-Brimonidine</u> |
| BRIMONIDINE TARTRATE WITH TIMOLOL MALEATE ★ Eye drops 0.2% with timolol maleate 0.5% | 7 13 | 5 ml OP | Combigan |
| ATANOPROST WITH TIMOLOL | | 0 111 01 | oombigun |
| ★ Eye drops 0.005% with timolol 0.5% | 4.95 | 2.5 ml OP | ✓ Arrow - Lattim |
| PILOCARPINE HYDROCHLORIDE | | | |
| * Eye drops 1% | | 15 ml OP | Isopto Carpine |
| * Eye drops 2% | | 15 ml OP | Isopto Carpine |
| Eye drops 4% Subsidised for oral use pursuant to the Standard Formu | | 15 ml OP | Isopto Carpine |
| PILOCARPINE NITRATE | | | |
| ✤ Eye drops 2% single dose – Special Authority see SA0895 | | | |
| below – Retail pharmacy | | 20 dose | Minims Pilocarpine |
| SA0895 Special Authority for Subsidy nitial application from any relevant practitioner. Approvals val Either: | id for 2 years for | applications me | eeting the following criteria: |
| Patient has to use an unpreserved solution due to an alle Patient wears soft contact lenses. | rgy to the preser | vative; or | |
| Note: Minims for a general practice are considered to be "tools or Renewal from any relevant practitioner. Approvals valid for 2 ye benefiting from treatment. | | | |
| Mydriatics and Cycloplegics | | | |
| ATROPINE SULPHATE | 40.07 | 45 | |
| | 18.2/ | 15 ml OP | Atropt |
| CYCLOPENTOLATE HYDROCHLORIDE ₭ Eye drops 1% | 25.1 <u>6</u> | 15 ml OP | |
| | 20.10 | 15 III OP | Cyclogyl |
| [®] ROPICAMIDE ₭ Eye drops 0.5% | 20.52 | 15 ml OP | Mydriacyl |
| * Lye drops 0.5 % | | | |

Preparations for Tear Deficiency

| For acetylcysteine eye drops refer Standard Formulae, page 274 | | | |
|--|-------|----------|-----------------------------|
| HYPROMELLOSE | | | |
| * Eye drops 0.5% | 19.50 | 15 ml OP | Methopt |

15 ml OP

✓ Mydriacyl

| | Subsidy (Manufacturer's Pric \$ | ce) Subs Per | Fully sidised | Brand or Generic Manufacturer |
|---|---------------------------------------|---------------------------------|------------------|--|
| HYPROMELLOSE WITH DEXTRAN * Eye drops 0.3% with dextran 0.1% | 2.30 | 15 ml OP | ✓ Pe | oly-Tears |
| Preservative Free Ocular Lubricants | | | | |
| SA2431 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals of the following criteria: Both: Confirmed diagnosis by slit lamp or Schirmer test of set | | | notified | I for applications meeting |
| 2 Either:2.1 Patient is using eye drops more than four times2.2 Patient has had a confirmed allergic reaction to | | | | |
| CARBOMER – Special Authority see SA2431 above – Retail Ophthalmic gel 0.3%, 0.5 g | | 30 | ✓ P | oly-Gel |
| POLYETHYLENE GLYCOL 400 AND PROPYLENE GLYCOL Eye drops 0.4% and propylene glycol 0.3%, 0.8 ml | | see <mark>SA2431</mark> a 30 | | Retail pharmacy ystane Unit Dose |
| SODIUM HYALURONATE [HYALURONIC ACID] – Special A Eye drops 1 mg per ml Hylo-Fresh has a 6 month expiry after opening. The month is not relevant and therefore only the prescribe | | 10 ml OP s Manual res | triction a | ylo-Fresh allowing one bottle per |
| Other Eye Preparations | | | | |
| NAPHAZOLINE HYDROCHLORIDE * Eye drops 0.1% | 5.65 | 15 ml OP | ✓ <u>A</u> | lbalon |
| Eye drops 0.1% PARAFFIN LIQUID WITH WOOL FAT | 2.17 | 5 ml OP | ✓ <u>0</u> | lopatadine Teva |
| Eye oint 3% with wool fat 3% RETINOL PALMITATE | 3.63 | 3.5 g OP | ✓ P | oly-Visc |
| Eye oint 138 mcg per g | 3.80 | 5 g OP | 🗸 Vi | itA-POS |

SENSORY ORGANS

| | Quit si tu | | Fully Deceder |
|---|-------------------------------|----------------|--|
| | Subsidy (Manufacturer's Pr | ice) Subs | Fully Brand or idised Generic |
| | \$ | Per | Manufacturer |
| Various | | | |
| valious | | | |
| PHARMACY SERVICES | | | |
| Brand switch fee | 4.50 | 1 fee | ✓ BSF Dasatinib-Teva ✓ BSF Teriflunomide Sandoz |
| a) May only be claimed once per patient. | | | |
| b) The Pharmacode for BSF Dasatinib-Teva is 270044 | | | |
| c) The Pharmacode for BSF Teriflunomide Sandoz is a function of the second state of | | | / Immunication Flu |
| Immunisation administration fee - flu | | 1 fee | Immunisation - Flu |
| Immunisation administration fee - other Immunisation co-administration fee - flu and shingles | | 1 fee 1 fee | Immunisation Other Immunisation Flu |
| | | | and Shingles |
| (BSF Dasatinib-Teva Brand switch fee to be delisted 1 June 202 | 25) | | - |
| BSF Teriflunomide Sandoz Brand switch fee to be delisted 1 Ju | uly 2025) | | |
| | | | |
| Agents Used in the Treatment of Poisonings | | | |
| Antidotes | | | |
| ACETYLCYSTEINE | | | |
| Inj 200 mg per ml, 10 ml ampoule | | 10 | DBL Acetylcysteine |
| ··· j ··· g p ··· ···, · · ··· ··· p · ··· · | 52.88 | | ✓ Martindale Pharma |
| Inj 200 mg per ml, 10 ml vial | | 10 | ✓ Hikma |
| | | | Acetylcysteine S29 |
| (Martindale Pharma Inj 200 mg per ml, 10 ml ampoule to be del | listed 1 November | 2025) | |
| | | 2023) | |
| NALOXONE HYDROCHLORIDE | | | |
| a) Up to 10 inj available on a PSO | | | |
| b) Only on a PSO | 10.00 | _ | |
| Inj 400 mcg per ml, 1 ml ampoule | 13.29 | 5 | <u>DBL Naloxone</u> Hydrochloride |
| | | | nyurocilionue |
| 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 PSOb) Only on a PSO | | | |
| DEFERASIROX – Special Authority see SA1492 below – Retai | il pharmacy | | |
| Wastage claimable | | | |
| Tab 125 mg dispersible | 276.00 | 28 | Exjade |
| Tab 250 mg dispersible | | 28 | Exjade |
| Tab 500 mg dispersible | | 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

| | Subsidy (Manufacturer's Price \$ |) Subs Per | Fully sidised | Brand or Generic Manufacturer |
|---|--|------------------------------|------------------|---|
| continued | | | | |
| 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 deferip | | | | |
| combination therapy have proven ineffective as mea 3.2 Treatment with deferiprone has resulted in severe p | | | | cardiac MRI 12; or |
| 3.3 Treatment with deferiprone has resulted in activity | | | 1, 01 | |
| 3.4 Treatment with deferiprone is contraindicated due to | | ulocytosis (| defined | as an absolute neutrophil |
| count (ANC) of < 0.5 cells per μ L) or recurrent episo 0.5 - 1.0 cells per μ L). | odes (greater than a | 2 episodes) | of mod | lerate neutropenia (ANC |
| Renewal only from a haematologist. Approvals valid for 2 years for Either: | or applications mee | eting the fol | lowing o | criteria: |
| For the first renewal following 2 years of therapy, the treatm improvement in all three parameters namely serum ferritin, For subsequent renewals, the treatment has been tolerated in all three parameters namely serum ferritin, cardiac MRI⁻ | cardiac MRI T2* a and has resulted | nd liver MR in clinical s | I T2* le | vels; or |
| DEFERIPRONE – Special Authority see SA1480 below – Retail p | harmacy | | | |
| Tab 500 mg | | 100 | | erriprox |
| Oral liq 100 mg per 1 ml | 266.59 2 | 50 ml OP | ✓ F | erriprox |
| SA1480 Special Authority for Subsidy Initial application only from a haematologist. Approvals valid with following criteria: Either: 1 The patient has been diagnosed with chronic iron overload | due to congenital i | nherited ar | aemia; | |
| 2 The patient has been diagnosed with chronic iron overload | due to acquired re | d cell aplas | ia. | |
| DESFERRIOXAMINE MESILATE | | | | |
| ✤ Inj 500 mg vial | 151.31 | 10 | ✓ D | eferoxamine Pfizer S29 S29 |
| | 332.88 | | ✓ D | BL Desferrioxamine Mesylate for Inj BP |
| SODIUM CALCIUM EDETATE | | | | |
| * Inj 200 mg per ml, 5 ml | 53.31 | 6 | | |
| | (· · · · | | - | |

| * | Inj 200 mg per ml, 5 ml | 53.31 |
|---|-------------------------|----------|
| | | (156.71) |

Calcium Disodium Versenate

Standard Formulae

| ACETYLCYSTEINE EYE DROPS Acetylcysteine inj 200 mg per ml, 10 ml | qs | PHENOBARBITONE SODIUM PAEDIATRIC ORAL mg per ml) | LIQUID (10 |
|--|--|---|---|
| Suitable eye drop base | qs | Phenobarbitone Sodium | 400 mg |
| CODEINE LINCTUS (3 mg per 5 ml) Codeine phosphate Glycerol Preservative Water CODEINE LINCTUS (15 mg per 5 ml) Codeine phosphate Glycerol | 60 mg 40 ml qs to 100 ml 300 mg 40 ml | Glycerol BP Water PILOCARPINE ORAL LIQUID Pilocarpine 4% eye drops Preservative Water (Preservative should be used if quantity supplied is than 5 days.) | 4 ml to 40 ml qs qs to 500 ml for more |
| Preservative Water | qs to 100 ml | SALIVA SUBSTITUTE FORMULA Methylcellulose Preservative | 5 g qs |
| FOLINIC MOUTHWASH Calcium folinate 15 mg tab Preservative Water | 1 tab qs to 500 ml | Water (Preservative should be used if quantity supplied is than 5 days. Maximum 500 ml per prescription.) | to 500 ml |
| (Preservative should be used if quantity supplied is f than 5 days. Maximum 500 ml per prescription.) | or more | SODIUM CHLORIDE ORAL LIQUID Sodium chloride inj 23.4%, 20 ml Water | qs |
| METHYL HYDROXYBENZOATE 10% SOLUTION Methyl hydroxybenzoate Propylene glycol (Use 1 ml of the 10% solution per 100 ml of oral liqu | 10 g to 100 ml id mixture) | (Only funded if prescribed for treatment of hyponatra VANCOMYCIN ORAL SOLUTION (25 mg per ml) Vancomycin 500 mg injection | qs aemia) 5 vials |
| OMEPRAZOLE SUSPENSION Omeprazole capsules or powder Sodium bicarbonate powder BP Water | qs 8.4 g to 100 ml | Glycerin with sucrose suspension Water (Only funded if prescribed for treatment of Clostridiu following metronidazole failure) | 37.5 ml to 100 ml ım difficile |
| PHENOBARBITONE ORAL LIQUID Phenobarbitone Sodium Glycerol BP | 1 g 70 ml | | |

to 100 ml

Water

EXTEMPORANEOUSLY COMPOUNDED PREPARATIONS AND GALENICALS

| | Subsidy | | Fully Bra | nd or |
|--|------------------------|-----------------|---------------------------------------|---------------------|
| | (Manufacturer's Price | e) Sub | sidised Ger | neric |
| | \$ | Per | 🖌 Mai | nufacturer |
| | | | | |
| Extemporaneously Compounded Preparations | and Galenicals | | | |
| CODEINE PHOSPHATE - Safety medicine; prescriber may det | ermine dispensina fi | reauencv | | |
| Powder – Only in combination | | 25 g | | |
| , | (90.09) | - 3 | Dougla | as |
| Only in extemporaneously compounded codeine linctus | · / | | | |
| COLLODION FLEXIBLE | | | | |
| | | | | |
| Note: This product is no longer being manufactured by the | supplier and will be o | delisted froi | n the Schedu | lie at a date to be |
| determined. | | | < | |
| Collodion flexible | | 100 ml | 🗸 PSM | |
| COMPOUND HYDROXYBENZOATE - Only in combination | | | | |
| Only in extemporaneously compounded oral mixtures. | | | | |
| Soln | | 100 ml | 🖌 Midwe | st |
| | | | | |
| GLYCERIN WITH SODIUM SACCHARIN – Only in combination | | have allowed To | | |
| Only in combination with Ora-Plus or when used in the vanc | | | | |
| Suspension | | 473 ml | Ora-S¹ | weet SF |
| GLYCERIN WITH SUCROSE – Only in combination | | | | |
| Only in combination with Ora-Plus or when used in the vanc | omycin oral Iquuid S | standard Fo | rmulae. | |
| Suspension | | 473 ml | 🗸 Ora-S | weet |
| GLYCEROL | | | | |
| Liquid – Only in combination | 2 02 | 500 ml | . haalth | E Chronrol PD |
| | | 500 mi | • nealth | E Glycerol BP |
| Only in extemporaneously compounded oral liquid prepared | arations. | | | |
| METHYL HYDROXYBENZOATE | | | | |
| Powder | 8.98 | 25 g | 🖌 Midwe | est |
| METHYLCELLULOSE | | | | |
| Powder | 36.95 | 100 g | ✓ MidW | aet |
| Suspension – Only in combination | | 473 ml | ✓ Ora-P | |
| | | | | 103 |
| METHYLCELLULOSE WITH GLYCERIN AND SODIUM SACCH | | | | |
| Suspension | | 473 ml | 🗸 Ora-B | lend SF |
| METHYLCELLULOSE WITH GLYCERIN AND SUCROSE - On | ly in combination | | | |
| Suspension | | 473 ml | 🗸 Ora-B | lend |
| PHENOBARBITONE SODIUM | | | | |
| | 50 50 | 10 - | | 1 |
| Powder – Only in combination | | 10 g | ✓ MidW | |
| O de la dellater en la 40 de est | 325.00 | 100 g | MidWe | est |
| Only in children up to 12 years | | | | |
| PROPYLENE GLYCOL | | | | |
| Only in extemporaneously compounded methyl hydroxyben: | zoate 10% solution. | | | |
| Liq | 11.25 | 500 ml | 🖌 Midwe | est |
| SODIUM BICARBONATE | | | | |
| Powder BP – Only in combination | 10.05 | 500 g | 🗸 Midwe | t |
| | | 0 | • Mildwe | 51 |
| Only in extemporaneously compounded omeprazole an | u iansoprazole susp | GI I BIUI I. | | |
| SYRUP (PHARMACEUTICAL GRADE) – Only in combination | | | | |
| Only in extemporaneously compounded oral liquid preparati | ons. | | | |
| Liq | 14.95 | 500 ml | 🗸 Midwe | est |
| WATER | | | | |
| Tap – Only in combination | 0.00 | 1 ml | 🖌 Tap w | ater |
| | | | - 140 | |
| | | | | |

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

| Subsidy | | Fully | Brand or |
|------------------------|-----|------------|--------------|
| (Manufacturer's Price) | | Subsidised | Generic |
| \$ | Per | 1 | 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, 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 | - Hospit | al pharmacy [| [HP3] |
|-------------------------|--------------------------------------|----------|---------------|---------|
| Powder | | .72 | 400 a 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:

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

- 1 Infant or child aged four years or under; and
- 2 cystic fibrosis.

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria: Both:

- 1 infant or child aged four years or under; and
- 2 Any of the following:
 - 2.1 cancer in children; or
 - 2.2 faltering growth; or
 - 2.3 bronchopulmonary dysplasia; or
 - 2.4 premature and post premature infants.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria: Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

| CARBOHYDRATE AND FAT SU | JPPLEMENT - Special Author | ity see SA1376 on t | he previous pa | ge - | - Hospital pharmacy [HP3] |
|-------------------------|----------------------------|---------------------|----------------|------|---------------------------|
| Powder (neutral) | | | 400 g OP | 1 | Duocal Super |
| | | | - | | Soluble Powder |

Fat

⇒SA2204 Special Authority for Subsidy

Initial application — (Inborn errors of metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified where the patient has an inborn error of metabolism. Initial application — (Indications other than inborn errors of metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria: Any of the following:

- 1 faltering growth in an infant/child; or
- 2 bronchopulmonary dysplasia; or
- 3 fat malabsorption; or
- 4 lymphangiectasia; or
- 5 short bowel syndrome; or
- 6 infants with necrotising enterocolitis; or
- 7 biliary atresia; or
- 8 for use in a ketogenic diet; or
- 9 chyle leak; or

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

- 10 ascites; or
- 11 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula. **Renewal — (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 SA2204 on | the previous page - Hos | spital pharmacy | [HP3] |
|--|-------------------------|-----------------|--|
| Emulsion (neutral) | | 200 ml OP | Calogen |
| | 38.44 | 500 ml OP | Calogen |
| Emulsion (strawberry) | | 200 ml OP | Calogen |
| Oil | | 500 ml OP | MCT oil (Nutricia) |
| MCT Emulsion, 250 ml | 143.65 | 4 OP | Liquigen |

Protein

⇒SA1524 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 protein losing enteropathy; or
- 2 high protein needs; or
- 3 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula. **Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

| PROTEIN SUPPLEMENT - S | Special Authority see SA1524 above – Hospital ph | armacy [HP3] | |
|------------------------|--|--------------|------------------------------|
| Powder | | 227 g OP | Resource |
| | | | Beneprotein |
| | 13.82 | 225 g OP | Protifar |

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 | e SA1095 above – I | -lospital phar | macy [HP3] |
|--|--------------------|----------------|-------------------------------------|
| Liquid, 500 ml bottle | 4.65 | 1 OP | Glucerna Select |
| DIABETIC ORAL FEED 1KCAL/ML - Special Authority see SA | 1095 above – Hosp | oital pharmac | y [HP3] |
| Liquid (strawberry), 200 ml bottle | | 1 OP | ✓ Diasip |
| Liquid (vanilla), 200 ml bottle | 2.10 | 1 OP | Nutren Diabetes |
| | 2.25 | | 🗸 Diasip |

Fat Modified Products

⇒SA2205 Special Authority for Subsidy

Initial application — (Inborn errors of metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified where the patient has an inborn error of metabolism. **Initial application** — (Indications other than errors of inborn metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria: Either:

- 1 Patient has a chyle leak; or
- 2 Modified as a modular feed, made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule, for adults.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula. **Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

| FAT MODIFIED FEED – Special Authority see SA2 | 205 above – Hospital pharm | acy [HP3] | |
|---|----------------------------|-----------|-----------|
| Powder | | 400 g OP | 🗸 Monogen |

| (| Subsidy | F | ully | Brand or |
|---|-----------------------|---------|------|--------------|
| | Manufacturer's Price) | Subsidi | sed | Generic |
| · | \$ | Per | 1 | Manufacturer |

Paediatric Products For Children Awaiting Liver Transplant

⇒SA1098 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient is a child (up to 18 years) who requires a liver transplant.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.
- ENTERAL/ORAL FEED 1KCAL/ML Special Authority see SA1098 above Hospital pharmacy [HP3]

Paediatric Products For Children With Chronic Renal Failure

⇒SA1099 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient is a child (up to 18 years) with acute or chronic kidney disease.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

| ENTERAL/ORAL FEED 1KCAL/ML - | - Special Authority see SA1099 above - | Hospital pharmacy | / [HP3] |
|------------------------------|--|-------------------|-------------------------------|
| Powder | | 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

| | Subsidy (Manufacturer's Pric \$ | e) Subs Per | sidised C | Brand or Generic Manufacturer |
|--|---------------------------------------|----------------------|--------------------------|---|
| continued applications meeting the following criteria: Both: | | | | |
| The treatment remains appropriate and the patient is be General Practitioners must include the name of the dieti practitioner and date contacted. | | | onally regis | tered general |
| PAEDIATRIC ENTERAL FEED 1.5KCAL/ML – Special Author Liquid, 500 ml bottle | | e previous p 1 OP | | pital pharmacy [HP3] r ini Energy RTH |
| PAEDIATRIC ENTERAL FEED 1KCAL/ML – Special Authority Liquid, 500 ml bottle | | previous pao 1 OP | Ped | tal pharmacy [HP3] iasure RTH rini RTH |
| PAEDIATRIC ENTERAL FEED WITH FIBRE 1.5KCAL/ML – S pharmacy [HP3] | Special Authority see | SA1379 on 1 | he previou | <mark>is page</mark> – Hospital |
| Liquid, 500 ml bottle | 7.14 | 1 OP | | rini Energy Multi bre |
| PAEDIATRIC ORAL FEED 1.5KCAL/ML - Special Authority se | ee SA1379 on the pr | evious page | – Hospital | pharmacy [HP3] |
| Liquid (strawberry), 200 ml bottle | | 1 OP | Fort | |
| Liquid (vanilla), 200 ml bottle | | 1 OP | ✓ Fort | |
| Liquid (vanilla), 500 ml bottle | | 1 OP | | iasure Plus |
| PAEDIATRIC ORAL FEED 1KCAL/ML – Special Authority see | | ious page – 1 OP | Hospital p | |
| Liquid (chocolate), 200 ml bottle Liquid (strawberry), 200 ml bottle | | 1 OP 1 OP | ✓ Ped | |
| Liquid (vanilla), 200 ml bottle | | 1 OP | ✓ Ped | |
| Liquid (vanilla), 250 ml can | | 1 OP | ✓ Ped | iasure |
| PAEDIATRIC ORAL FEED WITH FIBRE 1.5KCAL/ML – Speci | ial Authority see SA1 | 379 on the p | revious pa | <mark>ige</mark> – Hospital |
| Liquid (chocolate), 200 ml bottle | 1.90 | 1 OP | 🗸 Fort | ini Multi Fibre |
| Liquid (strawberry), 200 ml bottle | | 1 OP | 🗸 Fort | ini Multi Fibre |
| Liquid (unflavoured), 200 ml bottle | | 1 OP | | ini Multi Fibre |
| Liquid (vanilla), 200 ml bottle | 1.90 | 1 OP | Fort | ini Multi Fibre |
| PEPTIDE-BASED ORAL FEED – Special Authority see SA137 | | • | | |
| Powder | | 400 g OP | Pep | tamen Junior |

Renal Products

⇒SA1101 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient has acute or chronic kidney disease.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

| RENAL ORAL FEED 1.8 KCAL/ML - Special Autho | rity see SA1101 above - Hospit | al pharmac | cy [HP3] |
|---|--------------------------------|------------|----------------------|
| Liquid, 220 ml carton | | 1 OP | Nepro HP |
| | | | (strawberry) |
| | | | 🖌 Nepro HP (vanilla) |

fully subsidised

SPECIAL FOODS

| | Subsidy (Manufacturer's Price) \$ | Sı Per | Fully ubsidised | Brand or Generic Manufacturer |
|---|---|----------------------|--------------------|-------------------------------------|
| RENAL ORAL FEED 2 KCAL/ML – Special Authority see SA110 | 1 on the previous pa | <mark>ge</mark> – Ho | spital phar | macy [HP3] |
| Liquid, 200 ml bottle | | 4 OP | 🗸 N | ovaSource Renal |
| Liquid (apricot) 125 ml | | 4 OP | 🗸 R | enilon 7.5 |
| Liquid (caramel) 125 ml | 13.72 | 4 OP | ✓ R | enilon 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.

| ORAL ELEMENTAL FEED 0.8KCAL/ML – Special Authority see SA1377 above – Hospital pharmacy [HP3] Liquid (grapefruit), 250 ml carton |
|---|
| |
| |
| Liquid (pineapple & orange), 250 ml carton |
| Liquid (summer fruits), 250 ml carton179.46 18 OP Clemental 028 Extra |
| ORAL ELEMENTAL FEED 1KCAL/ML – Special Authority see SA1377 above – Hospital pharmacy [HP3] |
| Powder (unflavoured), 80 g sachet |
| SEMI-ELEMENTAL ENTERAL FEED 1KCAL/ML - Special Authority see SA1377 above - Hospital pharmacy [HP3] |
| Liquid, 500 ml bottle |
| Peptisorb |

Paediatric Products For Children With Low Energy Requirements

⇒SA1196 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria: Both:

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

- 1 Child aged one to eight years; and
- 2 The child has a low energy requirement but normal protein and micronutrient requirements.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

PAEDIATRIC ENTERAL FEED WITH FIBRE 0.76 KCAL/ML – Special Authority see SA1196 on the previous page – Hospital pharmacy [HP3]

| Liquid, 500 ml bottle6. | 27 1 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: 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.

| | Subsidy | Fully | Brand or |
|------|--------------------|------------|--------------|
| (Man | ufacturer's Price) | Subsidised | Generic |
| | \$ F | Per 🗸 | Manufacturer |

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/m²; or
 - 1.2 Patient has unintentional weight loss greater than 10% within the last 3-6 months; or
 - Patient has a BMI of less than 20 kg/m² and unintentional weight loss greater than 5% within the last 3-6 months; and
- 2 Any of the following:
 - Patient has not responded to first-line dietary measures over a 4 week period by:
 - 2.1 Increasing their food intake frequency (eg snacks between meals); or
 - 2.2 Using high-energy foods (e.g. milkshakes, full fat milk, butter, cream, cheese, sugar etc); or
 - 2.3 Using over the counter supplements (e.g. Complan); and
- 3 A nutrition goal has been set (e.g. to reach a specific weight or BMI).

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

- 1 A nutrition goal has been set (eg reach a specific weight or BMI); and
- 2 Any of the following:
 - Patient is Malnourished
 - 2.1 Patient has a body mass index (BMI) of less than 18.5 kg/m²; 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/m² 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</p>
 - 5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or
 - 5.2.3 Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met.

Renewal — (Short-term medical condition) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 Is being fed via a nasogastric tube; or
- 2 Malignancy and is considered likely to develop malnutrition as a result; or
- 3 Has undergone a bone marrow transplant; or

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

- 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</p>
 - 5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or
 - 5.2.3 Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met.

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

Any of the following:

- 1 Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube refer to specific medical condition criteria); or
- 2 Cystic Fibrosis; or
- 3 Liver disease; or
- 4 Chronic Renal failure; or
- 5 Inflammatory bowel disease; or
- 6 Chronic obstructive pulmonary disease with hypercapnia; or
- 7 Short bowel syndrome; or
- 8 Bowel fistula; or
- 9 Severe chronic neurological conditions; or
- 10 Epidermolysis bullosa; or
- 11 AIDS (CD4 count < 200 cells/mm³); or
- 12 Chronic pancreatitis.

Renewal — (Chronic disease OR tube feeding for patients who have previously been funded under Special Authority

forms SA0702 or SA0583) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube refer to specific medical condition criteria); or
- 2 Cystic Fibrosis; or
- 3 Liver disease; or
- 4 Chronic Renal failure; or
- 5 Inflammatory bowel disease; or
- 6 Chronic obstructive pulmonary disease with hypercapnia; or
- 7 Short bowel syndrome; or
- 8 Bowel fistula; or
- 9 Severe chronic neurological conditions.

| ENTERAL FEED 1.5KCAL/ML - Special Authority see SA1859 | on page 283 – Hos | spital pharma | acy [HP3] |
|--|-------------------|---------------|-------------------------------------|
| Liquid, 1,000 ml bottle | | 1 OP | Ensure Plus HN |
| | | | RTH |
| | 9.00 | | Nutrison Energy |
| Liquid, 250 ml can | 2.17 | 1 OP | Ensure Plus HN |

| | Subsidy | | Fully Brand or |
|---|--|--|---|
| | (Manufacturer's P | rice) Subs Per | sidised Generic Manufacturer |
| ENTERAL FEED 1KCAL/ML – Special Authority see SA1859 | \$ 00 0000 000 Hoo | | |
| Liquid, 1,000 ml bottle | | 1 OP | ✓ Osmolite RTH |
| - 1 | 6.90 | | ✓ Nutrison RTH |
| Liquid, 250 ml bottle | 1.24 | 1 OP | Isosource Standard |
| ENTERAL FEED WITH FIBRE 0.83 KCAL/ML – Special Author Liquid, 1,000 ml bottle | | n page 283 – F 1 OP | Iospital pharmacy [HP3] Vutrison 800 Complete Multi Fibre |
| ENTERAL FEED WITH FIBRE 1 KCAL/ML - Special Authority | | - | |
| Liquid, 1,000 ml bottle | | 1 OP | Jevity RTH Nutric on Multi Fibro |
| | 7.21 | | ✓ Nutrison Multi Fibre |
| ENTERAL FEED WITH FIBRE 1.2KCAL/ML – Special Authori Liquid, 1,000 ml bottle | | page 283 – Ho 1 OP | spital pharmacy [HP3] Jevity Plus RTH |
| ENTERAL FEED WITH FIBRE 1.5KCAL/ML - Special Author | | | |
| Liquid, 1,000 ml bottle | 8.68 | 1 OP | Jevity HiCal RTH Nutrison Energy Multi Fibre |
| ORAL FEED (POWDER) - Special Authority see SA1859 on | page 283 – Hospita | I pharmacy [H | P3] |
| Powder (chocolate) | | 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 |
| ORAL FEED 1.5KCAL/ML – Special Authority see SA1859 on | page 200 - nuspil | | |
| Additional subsidy by endorsement is available for patients epidermolysis bullosa, or as exclusive enteral nutrition in c disease, or for patients with COPD and hypercapnia, defin endorsed accordingly. Liquid (banana), 200 ml bottle – Higher subsidy of up to \$ per 1 btl with Endorsement | s being bolus fed th hildren under the a led as CO2 value e 1.76 | rough a feedin ge of 18 years | g tube, who have severe for the treatment of Crohn's |
| epidermolysis bullosa, or as exclusive enteral nutrition in c disease, or for patients with COPD and hypercapnia, defin endorsed accordingly. Liquid (banana), 200 ml bottle – Higher subsidy of up to \$ | s being bolus fed th hildren under the a led as CO2 value e 1.76 0.72 (1.56) | rough a feedin ge of 18 years xceeding 55mi | ig tube, who have severe for the treatment of Crohn's mHg. The prescription must be Ensure Plus |
| epidermolysis bullosa, or as exclusive enteral nutrition in c disease, or for patients with COPD and hypercapnia, defin endorsed accordingly. Liquid (banana), 200 ml bottle – Higher subsidy of up to \$ per 1 btl with Endorsement | s being bolus fed th hildren under the a led as CO2 value e 1.76 (1.76) (1.76) | rough a feedin ge of 18 years xceeding 55mi | ig tube, who have severe for the treatment of Crohn's mHg. The prescription must be |
| epidermolysis bullosa, or as exclusive enteral nutrition in c disease, or for patients with COPD and hypercapnia, defin endorsed accordingly. Liquid (banana), 200 ml bottle – Higher subsidy of up to \$ per 1 btl with Endorsement Liquid (chocolate), 200 ml bottle – Higher subsidy of up to \$ | s being bolus fed th hildren under the a led as CO2 value e 1.76 (1.76) (1.76) | rough a feedin ge of 18 years xceeding 55m 1 OP | ig tube, who have severe for the treatment of Crohn's mHg. The prescription must be Ensure Plus |
| epidermolysis bullosa, or as exclusive enteral nutrition in c disease, or for patients with COPD and hypercapnia, defin endorsed accordingly. Liquid (banana), 200 ml bottle – Higher subsidy of up to \$ per 1 btl with Endorsement | s being bolus fed th hildren under the a led as CO2 value e 1.76 (1.56) (1.76) (1.76) | rough a feedin ge of 18 years xceeding 55mi | ig tube, who have severe for the treatment of Crohn's mHg. The prescription must be Ensure Plus Fortisip |
| epidermolysis bullosa, or as exclusive enteral nutrition in c disease, or for patients with COPD and hypercapnia, defin endorsed accordingly. Liquid (banana), 200 ml bottle – Higher subsidy of up to \$ per 1 btl with Endorsement Liquid (chocolate), 200 ml bottle – Higher subsidy of up to \$ | s being bolus fed th hildren under the a led as CO2 value e 1.76 (1.76) (1.76) | rough a feedin ge of 18 years xceeding 55m 1 OP | ig tube, who have severe for the treatment of Crohn's mHg. The prescription must be Ensure Plus |
| epidermolysis bullosa, or as exclusive enteral nutrition in c disease, or for patients with COPD and hypercapnia, defin endorsed accordingly. Liquid (banana), 200 ml bottle – Higher subsidy of up to \$ per 1 btl with Endorsement Liquid (chocolate), 200 ml bottle – Higher subsidy of up to \$ | s being bolus fed th hildren under the a led as CO2 value e 1.76 (1.56) (1.76) 0 0.72 (1.56) (1.76) (1.76) | rough a feedin ge of 18 years xceeding 55m 1 OP | ig tube, who have severe for the treatment of Crohn's mHg. The prescription must be Ensure Plus Fortisip Ensure Plus |
| epidermolysis bullosa, or as exclusive enteral nutrition in c disease, or for patients with COPD and hypercapnia, defin endorsed accordingly. Liquid (banana), 200 ml bottle – Higher subsidy of up to \$ per 1 btl with Endorsement Liquid (chocolate), 200 ml bottle – Higher subsidy of up to \$1.76 per 1 btl with Endorsement | s being bolus fed th hildren under the a led as CO2 value e 1.76 (1.56) (1.76) 0 0.72 (1.56) (1.76) 0 0.72 (1.56) (1.76) 0 0.72 | rough a feedin ge of 18 years xceeding 55m 1 OP | ig tube, who have severe for the treatment of Crohn's mHg. The prescription must be Ensure Plus Fortisip Ensure Plus Fortisip |
| epidermolysis bullosa, or as exclusive enteral nutrition in c disease, or for patients with COPD and hypercapnia, defin endorsed accordingly. Liquid (banana), 200 ml bottle – Higher subsidy of up to \$ per 1 btl with Endorsement Liquid (chocolate), 200 ml bottle – Higher subsidy of up to \$1.76 per 1 btl with Endorsement Liquid (fruit of the forest), 200 ml bottle – Higher subsidy of \$1.56 per 1 btl with Endorsement | s being bolus fed th hildren under the a led as CO2 value e 1.76 (1.56) (1.76) (1.76) (1.56) (1.76) of 0.72 (1.56) (1.76) | rough a feedin ge of 18 years xceeding 55m 1 OP 1 OP | ig tube, who have severe for the treatment of Crohn's mHg. The prescription must be Ensure Plus Fortisip Ensure Plus |
| epidermolysis bullosa, or as exclusive enteral nutrition in c disease, or for patients with COPD and hypercapnia, defin endorsed accordingly. Liquid (banana), 200 ml bottle – Higher subsidy of up to \$ per 1 btl with Endorsement Liquid (chocolate), 200 ml bottle – Higher subsidy of up to \$1.76 per 1 btl with Endorsement Liquid (fruit of the forest), 200 ml bottle – Higher subsidy of \$1.56 per 1 btl with Endorsement Liquid (strawberry), 200 ml bottle – Higher subsidy of \$1.7 | s being bolus fed th hildren under the a led as CO2 value e 1.76 (1.56) (1.76) (1.56) (1.76) of (1.76) of (1.76) of (1.56) 76 per | rough a feedin ge of 18 years xceeding 55m 1 OP 1 OP 1 OP | ig tube, who have severe for the treatment of Crohn's mHg. The prescription must be Ensure Plus Fortisip Ensure Plus Fortisip |
| epidermolysis bullosa, or as exclusive enteral nutrition in c disease, or for patients with COPD and hypercapnia, defin endorsed accordingly. Liquid (banana), 200 ml bottle – Higher subsidy of up to \$ per 1 btl with Endorsement Liquid (chocolate), 200 ml bottle – Higher subsidy of up to \$1.76 per 1 btl with Endorsement Liquid (fruit of the forest), 200 ml bottle – Higher subsidy of \$1.56 per 1 btl with Endorsement | s being bolus fed th hildren under the a led as CO2 value e 1.76 (1.56) (1.76) (1.76) (1.56) (1.76) of (1.76) of (1.56) (1.76) of (1.56) 76 per | rough a feedin ge of 18 years xceeding 55m 1 OP 1 OP | ig tube, who have severe for the treatment of Crohn's mHg. The prescription must be Ensure Plus Fortisip Ensure Plus Fortisip Ensure Plus |
| epidermolysis bullosa, or as exclusive enteral nutrition in c disease, or for patients with COPD and hypercapnia, defin endorsed accordingly. Liquid (banana), 200 ml bottle – Higher subsidy of up to \$ per 1 btl with Endorsement Liquid (chocolate), 200 ml bottle – Higher subsidy of up to \$1.76 per 1 btl with Endorsement Liquid (fruit of the forest), 200 ml bottle – Higher subsidy of \$1.56 per 1 btl with Endorsement Liquid (strawberry), 200 ml bottle – Higher subsidy of \$1.7 1 btl with Endorsement | s being bolus fed th hildren under the a led as CO2 value e 1.76 (1.56) (1.76) 0 (1.76) 0 (1.56) (1.76) 0 (1.56) 0 (1.56) 76 per (1.76) | rough a feedin ge of 18 years xceeding 55m 1 OP 1 OP 1 OP | ig tube, who have severe for the treatment of Crohn's mHg. The prescription must be Ensure Plus Fortisip Ensure Plus Fortisip |
| epidermolysis bullosa, or as exclusive enteral nutrition in c disease, or for patients with COPD and hypercapnia, defin endorsed accordingly. Liquid (banana), 200 ml bottle – Higher subsidy of up to \$ per 1 btl with Endorsement Liquid (chocolate), 200 ml bottle – Higher subsidy of up to \$1.76 per 1 btl with Endorsement Liquid (fruit of the forest), 200 ml bottle – Higher subsidy of \$1.56 per 1 btl with Endorsement Liquid (strawberry), 200 ml bottle – Higher subsidy of \$1.77 | s being bolus fed th hildren under the a led as CO2 value e 1.76 (1.56) (1.76) 0 (1.76) 0 (1.56) (1.76) 0 (1.56) 0 (1.56) 0 (1.56) 76 per (1.76) .76 | rough a feedin ge of 18 years xceeding 55m 1 OP 1 OP 1 OP | ig tube, who have severe for the treatment of Crohn's mHg. The prescription must be Ensure Plus Fortisip Ensure Plus Fortisip Ensure Plus |
| epidermolysis bullosa, or as exclusive enteral nutrition in c disease, or for patients with COPD and hypercapnia, defin endorsed accordingly. Liquid (banana), 200 ml bottle – Higher subsidy of up to \$ per 1 btl with Endorsement Liquid (chocolate), 200 ml bottle – Higher subsidy of up to \$1.76 per 1 btl with Endorsement Liquid (fruit of the forest), 200 ml bottle – Higher subsidy of \$1.56 per 1 btl with Endorsement Liquid (strawberry), 200 ml bottle – Higher subsidy of \$1.7 1 btl with Endorsement Liquid (vanilla), 200 ml bottle – Higher subsidy of \$1.7 1 btl with Endorsement | s being bolus fed th hildren under the a led as CO2 value e 1.76 (1.56) (1.76) 0 (1.76) 0 (1.76) 0 (1.76) 0 (1.76) 0 (1.56) 76 per (1.76) .76 (1.76) .76 (1.56) | rough a feedin ge of 18 years xceeding 55m 1 OP 1 OP 1 OP 1 OP | ig tube, who have severe for the treatment of Crohn's mHg. The prescription must be Ensure Plus Fortisip Ensure Plus Fortisip Ensure Plus Fortisip Ensure Plus |
| epidermolysis bullosa, or as exclusive enteral nutrition in c disease, or for patients with COPD and hypercapnia, defin endorsed accordingly. Liquid (banana), 200 ml bottle – Higher subsidy of up to \$ per 1 btl with Endorsement Liquid (chocolate), 200 ml bottle – Higher subsidy of up to \$1.76 per 1 btl with Endorsement Liquid (fruit of the forest), 200 ml bottle – Higher subsidy of \$1.76 per 1 btl with Endorsement Liquid (strawberry), 200 ml bottle – Higher subsidy of \$1.7 1 btl with Endorsement Liquid (vanilla), 200 ml bottle – Higher subsidy of \$1.7 1 btl with Endorsement | s being bolus fed th hildren under the a led as CO2 value e 1.76 (1.56) (1.76) 0 (1.76) 0 (1.56) (1.76) 0 (1.56) 0 (1.56) 76 per (1.76) 76 pr (1.76) 76 pr (1.76) | rough a feedin ge of 18 years xceeding 55m 1 OP 1 OP 1 OP 1 OP | g tube, who have severe for the treatment of Crohn's mHg. The prescription must be Ensure Plus Fortisip Ensure Plus Fortisip Ensure Plus Fortisip |
| epidermolysis bullosa, or as exclusive enteral nutrition in c disease, or for patients with COPD and hypercapnia, defin endorsed accordingly. Liquid (banana), 200 ml bottle – Higher subsidy of up to \$ per 1 btl with Endorsement Liquid (chocolate), 200 ml bottle – Higher subsidy of up to \$1.76 per 1 btl with Endorsement Liquid (fruit of the forest), 200 ml bottle – Higher subsidy of \$1.56 per 1 btl with Endorsement Liquid (strawberry), 200 ml bottle – Higher subsidy of \$1.7 1 btl with Endorsement Liquid (vanilla), 200 ml bottle – Higher subsidy of up to \$1 per 1 btl with Endorsement Liquid (vanilla), 237 ml can – Higher subsidy of \$1.65 per | s being bolus fed th hildren under the a led as CO2 value e 1.76 (1.56) (1.76) 0 (1.76) 0 (1.76) 0 (1.76) 0 (1.56) 76 per (1.76) .76 (1.76) .76 (1.56) (1.76) | rough a feedin ge of 18 years xceeding 55m 1 OP 1 OP 1 OP 1 OP 1 OP | ig tube, who have severe for the treatment of Crohn's mHg. The prescription must be Ensure Plus Fortisip Ensure Plus Fortisip Ensure Plus Fortisip Ensure Plus |
| epidermolysis bullosa, or as exclusive enteral nutrition in c disease, or for patients with COPD and hypercapnia, defin endorsed accordingly. Liquid (banana), 200 ml bottle – Higher subsidy of up to \$ per 1 btl with Endorsement Liquid (chocolate), 200 ml bottle – Higher subsidy of up to \$1.76 per 1 btl with Endorsement Liquid (fruit of the forest), 200 ml bottle – Higher subsidy of \$1.76 per 1 btl with Endorsement Liquid (strawberry), 200 ml bottle – Higher subsidy of \$1.7 1 btl with Endorsement Liquid (vanilla), 200 ml bottle – Higher subsidy of \$1.7 1 btl with Endorsement | s being bolus fed th hildren under the a led as CO2 value e 1.76 (1.56) (1.76) 0 (1.76) 0 (1.76) 0 (1.76) 0 (1.56) 76 per (1.76) .76 (1.76) .76 (1.56) (1.76) | rough a feedin ge of 18 years xceeding 55m 1 OP 1 OP 1 OP 1 OP | ig tube, who have severe for the treatment of Crohn's mHg. The prescription must be Ensure Plus Fortisip Ensure Plus Fortisip Ensure Plus Fortisip Ensure Plus |

| | Subsidy | | Fully | Brand or |
|--|-----------------------|---------------|---------|----------------------|
| | (Manufacturer's Price | e) Subsi | dised | Generic |
| | \$ | Per | 1 | Manufacturer |
| ORAL FEED WITH FIBRE 1.5 KCAL/ML - Special Authority see | SA1859 on page 2 | 83 – Hospita | l pharr | macy [HP3] |
| Additional subsidy by endorsement is available for patients b | eing bolus fed throu | ugh a feeding | tube, | or who have severe |
| epidermolysis bullosa. The prescription must be endorsed a | ccordingly. | | | |
| Liquid (chocolate), 200 ml bottle - Higher subsidy of \$1.76 p | ber | | | |
| 1 btl with Endorsement | | 1 OP | | |
| | (1.76) | | F | Fortisip Multi Fibre |
| Liquid (strawberry), 200 ml bottle - Higher subsidy of \$1.76 | per | | | |
| 1 btl with Endorsement | 0.72 | 1 OP | | |
| | (1.76) | | F | ortisip Multi Fibre |
| Liquid (vanilla), 200 ml bottle - Higher subsidy of \$1.76 per | | | | |
| 1 btl with Endorsement | 0.72 | 1 OP | | |
| | (1.76) | | F | Fortisip Multi Fibre |
| | | | | |

High Calorie Products

⇒SA1195 Special Authority for Subsidy

Initial application — (Cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

- All of the following:
 - 1 Cystic fibrosis; and
 - 2 other lower calorie products have been tried; and
 - 3 patient has substantially increased metabolic requirements.

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria: All of the following:

- 1 Any of the following:
 - 1.1 any condition causing malabsorption; or
 - 1.2 faltering growth in an infant/child; or
 - 1.3 increased nutritional requirements; or
 - 1.4 fluid restricted; and
- 2 other lower calorie products have been tried; and
- 3 patient has substantially increased metabolic requirements or is fluid restricted.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria: Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

| (λ | Subsidy /anufacturer's Price; \$ | | Fully lised | Brand or Generic Manufacturer |
|---|--|---|----------------|-------------------------------------|
| ENTERAL FEED 2 KCAL/ML – Special Authority see SA1195 on the Liquid, 1,000 ml bottle | | Hospital ph 1 OP | 🗸 E | cy [HP3] nsure Two Cal HN RTH |
| Liquid, 500 ml bottle | 6.82 | 1 OP | | utrison Concentrated |
| DRAL FEED 2 KCAL/ML – Special Authority see SA1195 on the pr Additional subsidy by endorsement is available for patients beir epidermolysis bullosa. The prescription must be endorsed accord Liquid (vanilla), 200 ml bottle – Higher subsidy of \$2.34 per | ng bolus fed throug prdingly. | gh a feeding | | |
| 1 btl with Endorsement | 0.96 (2.34) | 1 OP | T | wo Cal HN |

■ SA1106 Special Authority for Subsidy

Food Thickeners

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 vear where the patient has motor neurone disease with swallowing disorder.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

| FOOD THICKENER | 8 – Special Authority see SA1106 above – Hospital pharmac | y [HP3] | |
|----------------|---|----------|----------------------------------|
| Powder | | 300 g OP | Nutilis |
| | 24.00 | 380 g OP | Aptamil Feed |
| | | - | Thickener |

Gluten Free Foods

The funding of gluten free foods is no longer being actively managed by Pharmac from 1 April 2011. This means that we are no longer considering the listing of new products, or making subsidy, or other changes to the existing listings. As a result we anticipate that the range of funded items will reduce over time. Management of Coeliac disease with a gluten free diet is necessary for good outcomes. A range of gluten free options are available through retail outlets.

Healtheries Simple Baking Mix

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 | 1,000 g OP |
| (5.15) | |

SPECIAL FOODS

| | Subsidy (Manufacturer's P \$ | | Fully Brand or ised Generic ✓ Manufacturer |
|---|------------------------------------|-------------------|--|
| GLUTEN FREE BREAD MIX - Special Authority see SA172 | 9 on the previous par | ge – Hospital pha | armacy [HP3] |
| Powder | | 1,000 g OP | <i></i> |
| | (7.32) | · · · | NZB Low Gluten Bread Mix |
| | 3.51 | | Dieau Wix |
| | (10.87) | | Horleys Bread Mix |
| | () | | , |
| GLUTEN FREE FLOUR - Special Authority see SA1729 on | | | cy [HP3] |
| Powder | | 2,000 g OP | |
| | (18.10) | | Horleys Flour |
| GLUTEN FREE PASTA - Special Authority see SA1729 on t | the previous page - | | cy [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 | | 375 g OP | |
| | (2.92) | | Orgran |
| Vegetable and Rice Spirals | | 250 g OP | |
| | (2.92) | | Orgran |
| Italian long style spaghetti | | 220 g OP | |
| | (3.11) | | Orgran |
| (Orgran Buckwheat Spirals to be delisted 1 July 2025) | | | |

(Orgran Buckwheat Spirals to be delisted 1 July 2025)

(Orgran Corn and Vegetable Shells to be delisted 1 July 2025)

(Orgran Corn and Vegetable Spirals to be delisted 1 July 2025)

(Orgran Rice and Corn Lasagne Sheets to be delisted 1 July 2025)

(Orgran Rice and Corn Macaroni to be delisted 1 July 2025)

(Orgran Rice and Corn Penne to be delisted 1 July 2025)

(Orgran Rice and Maize Pasta Spirals to be delisted 1 July 2025)

(Orgran Rice and Millet Spirals to be delisted 1 July 2025)

(Orgran Rice and corn spaghetti noodles to be delisted 1 July 2025)

(Orgran Vegetable and Rice Spirals to be delisted 1 July 2025)

(Orgran Italian long style spaghetti to be delisted 1 July 2025)

Foods And Supplements For Inherited Metabolic Disease

⇒SA2357 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where patient requires dietary management of inherited metabolic disorders.

| | Subsidy Manufacturer's Price) \$ | F Subsidi Per | sed | Brand or Generic Manufacturer |
|---|--|---------------------|---------|-------------------------------------|
| Supplements For Homocystinuria | | | | |
| AMINOACID FORMULA WITHOUT METHIONINE – Special Autho (HP3] | prity see SA2357 or | n the previou | is page | e – Hospital pharmacy |
| Powder (neutral), 36 g sachets | 750.30 | 30 | ✔ НС | U Anamix Junior |
| Powder, 12.5 g sachets | 349.65 | 30 | ✔ НС | U Explore 5 |
| Powder, 25 g sachets | 1,048.95 | 30 | ✔ НС | U Express 15 |
| Powder (neutral), can | 480.42 50 | 00 g OP | 🗸 XM | ET Maxamum |
| Powder (unflavoured), can | | 0 g OP | ✔ НС | U Anamix Infant |
| Liquid (juicy berries), 125 ml bottle | 1,684.80 | 30 | ✔ НС | U Lophlex LQ |
| Liquid (orange), 125 ml bottle | | 36 | | U Anamix Junior |

Supplements For MSUD and short chain enoyl coA hydratase deficiency

AMINOACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE – Special Authority see SA2357 on the previous page – Hospital pharmacy [HP3]

| Powder (neutral) 36 g sachets750.0 | 00 30 | MSUD Anamix Junior |
|--|-------------|---|
| Powder, 12.5 g sachets | 65 30 | MSUD Explore 5 |
| Powder, 25 g sachets | | MSUD Express 15 |
| Powder (neutral), can | | MSUD Maxamum |
| Powder (orange), can454.7 | 71 500 g OP | MSUD Maxamum |
| Powder (unflavoured), can260.0 | | MSUD Anamix Infant |
| Liquid (orange) 125 ml bottles941.4 | 40 36 | MSUD Anamix Junior LQ |
| Liquid (juicy berries) 125 ml pouches1,684.8 | 30 30 | MSUD Lophlex LQ 20 |

| | Subsidy (Manufacturer's Pric | | Fully sidised | Brand or Generic |
|--|---------------------------------|-------------|------------------|--------------------------------|
| | \$ | Per | 1 | Manufacturer |
| pplements For PKU | | | | |
| NOACID FORMULA WITHOUT PHENYLALANINE - S | pecial Authority see SA | 2357 on pag | je 289 - | - Hospital pharmacy [|
| Tabs | | 75 OP | 🗸 F | Phlexy 10 |
| Powder (Lemon), 34 g sachets | | 30 | 🗸 F | PKU Express 20 |
| Powder (Neutral), 12.5 g sachets | | 30 | 🖌 F | PKU Explore 5 |
| Powder (Neutral), 34 g sachets | | 30 | 🖌 F | PKU Express 20 |
| Powder (Orange), 25 g sachets | | 30 | 🗸 F | PKU Explore 10 |
| Powder (Orange), 34 g sachets | | 30 | 🖌 F | PKU Express 20 |
| Powder (Raspberry), 25 g sachets | | 30 | 🖌 F | PKU Explore 10 |
| Powder (Tropical), 34 g sachets | | 30 | 🖌 F | PKU Express 20 |
| Powder (berry) 28 g sachets | 936.00 | 30 | ✓ F | PKU Lophlex Powder |
| Powder (chocolate) 36 g sachet | | 30 | √ F | PKU Anamix Junior Chocolate |
| Powder (neutral) 28 g sachets | 936.00 | 30 | √ F | PKU Lophlex Powder |
| Powder (neutral) 36 g sachets | 303.00 | 30 | ~ 1 | PKU Anamix Junior |
| Powder (orange) 28 g sachets | | 30 | - | PKU Lophlex |
| Fowder (orange) 20 g sachets | | 30 | • • | Powder |
| Powder (orange) 36 g sachet | | 30 | ✓ F | PKU Anamix Junior Orange |
| Powder (unflavoured) 12.5 g sachets | | 30 | 🖌 F | PKU First Spoon |
| Powder (vanilla) 36 g sachet | | 30 | | PKU Anamix Junior Vanilla |
| Infant formula | | 400 g OP | 🖌 F | PKU Anamix Infant |
| Powder (neutral), 4 × 400 g can | | 1,600 g OP | 🗸 F | Pku Start |
| Powder (orange) | | 500 g OP | > | KP Maxamum |
| Powder (unflavoured) | | 500 g OP | > | KP Maxamum |
| Liquid (berry), 125 ml bottle | | 1 OP | √ F | PKU Anamix Junior |
| Liquid (orange), 125 ml bottle | 13.10 | 1 OP | ✓ F | PKU Anamix Junior LQ |
| Liquid (forest berries), 250 ml carton | | 18 OP | | Easiphen Liquid |
| Liquid (juicy tropical) 125 ml | | 30 OP | | PKU Lophlex LQ 20 |
| Oral semi-solid (berries) 109 g | 1,123.20 | 36 OP | √ F | PKU Lophlex Sensation 20 |
| Liquid (juicy berries) 62.5 ml | | 60 OP | 🖌 F | PKU Lophlex LQ 10 |
| Liquid (juicy berries) 125 ml | | 30 OP | | PKU Lophlex LQ 20 |
| Liquid (juicy orange) 125 ml | | 30 OP | | PKU Lophlex LQ 20 |

SPECIAL FOODS

| | Subsidy | | Fully Brand or |
|--|------------------------------|-------|------------------------------------|
| | (Manufacturer's Price) \$ | Per | Subsidised Generic Manufacturer |
| YCOMACROPEPTIDE AND AMINO ACID CONTAINS SC | OME PHENYLALANINE | – Spe | ecial Authority see SA2357 on |
| ge 289 – Hospital pharmacy [HP3] | | | |
| Powder (Banana) 35 g sachets | 930.00 | 30 | 🗸 PKU |
| | | | sphere20 Banana |
| Powder (Berry), 20 g sachets | | 60 | PKU Restore |
| | | | Powder |
| Powder (Chocolate) 32 g sachets | | 30 | PKU Build |
| | | | 20 Chocolate |
| Powder (Chocolate) 35 g sachets | | 30 | 🖌 PKU |
| | | | sphere20 Chocolate |
| Powder (Lemon) 35 g sachets | | 30 | ✓ PKU |
| | | | sphere20 Lemon |
| Powder (Lemonade) 33.4 g sachets | | 30 | PKU GMPro Ultra |
| | | | Lemonade |
| Powder (Neutral), 15 g sachets | | 30 | PKU Build 10 |
| Powder (Orange), 20 g sachets | | 60 | PKU Restore |
| | | | Powder |
| Powder (Raspberry Lemonade) 31 g sachets | | 30 | 🗸 PKU Build |
| · · · · · · · · · · · · · · · · · · · | | | 20 Raspberry |
| | | | Lemonade |
| Powder (Smooth) 31 g sachets | 898.56 | 30 | ✓ PKU Build |
| | | | 20 Smooth |
| Powder (Vanilla) 33 g sachets | 898.56 | 30 | ✓ PKU Build 20 Vanilla |
| Powder (neutral), 40 g sachets | | 30 | ✓ Glytactin Bettermilk |
| Powder (unflavoured) 12.5 g sachets | | 30 | ✓ PKU GMPro Mix-In |
| Powder (vanilla) 33.4 g sachets | | 30 | ✓ PKU GMPro Ultra |
| | | | Vanilla |
| Powder (Red Berry) 35 g sachets | 930.00 | 30 | PKU sphere20 Red |
| | | | Berry |
| Powder (Vanilla) 35 g sachets | 930.00 | 30 | ✓ PKU |
| | | 00 | sphere20 Vanilla |
| Liquid (neutral), 250 ml carton | 280.80 | 18 | ✓ PKU GMPro LQ |
| Liquid (riginal), 250 ml carton | | 30 OF | |
| | | 00 01 | 15 |
| Liquid (Coffee Mocha), 250 ml carton | | 30 OF | P Y PKU Glytactin RTD |
| · · · // | | | 15 Lite |
| Liquid (chocolate), 250 ml carton | | 30 OF | P V PKU Glytactin RTD |
| $\gamma = \sqrt{2}$ | | | 15 |
| Liquid (vanilla), 250 ml carton | | 30 OF | |
| | | 20 01 | 15 Lite |

Foods

| LOW PROTEIN BAKING MIX - Special Authority see SA2357 on page | 289 – Hos | pital pharmacy | / [HP3] |
|---|-----------|----------------|----------------------------------|
| Powder | .8.55 | 500 g OP | Loprofin Mix |

SPECIAL FOODS

| | Subsidy | | Fully Brand or |
|--|---------------------------------------|----------------|---------------------------------------|
| | (Manufacturer's Pri | ce) Subsi | dised Generic |
| | `\$ | Per | Manufacturer |
| LOW PROTEIN RACTA Creation Authority and CA02ET on page | o 000 I loonitol n | hormooy [LIDC | 01 |
| LOW PROTEIN PASTA – Special Authority see SA2357 on page | | | |
| Animal shapes | | 500 g OP | Loprofin |
| Lasagne | 6.19 | 250 g OP | Loprofin |
| Low protein rice pasta | | 500 g OP | Loprofin |
| Macaroni | | 250 g OP | ✓ Loprofin |
| Penne | | 500 g OP | ✓ Loprofin |
| | | 500 g OP | ✓ Loprofin |
| Spaghetti | | | |
| Spirals | | 500 g OP | Loprofin |
| Supplements for Tyrosinaemia | | | |
| AMINOACID FORMULA WITHOUT PHENYLALANINE AND TYF | | Authority coo | SA2257 on page 280 Hospits |
| | 103INE - Specia | Authonity See | - 3A2337 011 page 209 - 1105pila |
| pharmacy [HP3] | | | |
| Powder (Neutral), 12.5 g sachets | | 30 | TYR Explore 5 |
| Powder (neutral) 36 g sachets | 471.00 | 30 | TYR Anamix Junior |
| Powder, can | | 400 g OP | TYR Anamix Infant |
| Liquid (juicy berries) 125 ml pouches | | 30 | TYR Lophlex LQ 20 |
| Liquid (orange) 125 ml bottle | | 36 | ✓ TYR Anamix Junior |
| | | 50 | LQ |
| | | | |
| GLYCOMACROPEPTIDE AND AMINO ACID CONTAINS SOME | TYROSINE AND | PHENYLALA | NINE – Special Authority see |
| SA2357 on page 289 – Hospital pharmacy [HP3] | | | |
| Powder (Red Berry), 35 g sachets | 1,398,60 | 30 | TYR Sphere 20 |
| Powder (Vanilla), 35 g sachets | 1 398 60 | 30 | ✓ TYR Sphere 20 |
| | 1,030.00 | 50 | • Thisphere 20 |
| Supplements for Organic Acidaemias | | | |
| AMINOACID FORMULA WITHOUT ISOLEUCINE, METHIONINE | E. THREONINE AN | ND VALINE - | Special Authority see SA2357 |
| on page 289 – Hospital pharmacy [HP3] | , - | | -p |
| Powder, can | 260.00 | 400 g OP | MMA/PA Anamix |
| F Uwuei, caii | | 400 y OF | |
| | | | Infant |
| AMINOACID FORMULA WITHOUT METHIONINE, THREONINE | AND VALINE - S | Special Author | rity see SA2357 on page 289 - |
| Hospital pharmacy [HP3] | | | |
| Powder (neutral), 18 g sachets | 750.30 | 30 | MMA/PA Anamix |
| | | 00 | Junior |
| | | | |
| Powder, 12.5 g sachets | | 30 | MMA/PA Explore 5 |
| Powder, 25 g sachets | 1,048.95 | 30 | MMA/PA Express 15 |
| | | | |
| Supplements for Glutaric Aciduria type 1 | | | |
| | | | |
| AMINOACID FORMULA WITHOUT LYSINE - Special Authority | see SA2357 on p | age 289 – Hos | spital pharmacy [HP3] |
| Powder (neutral), 18 g sachets | | 30 | ✓ GA1 Anamix Junior |
| (), G | | | |
| Powder, 12.5 g sachets | | 30 | ✓ GA Explore 5 |
| Powder, can | | 400 g OP | GA1 Anamix Infant |
| | | | |
| Supplements for Glycogen Storage Disease | | | |
| | 040057 | | |
| HIGH AMYLOPECTIN CORN-STARCH – Special Authority see | | 289 – Hospital | |
| Powder, 60 g sachets | 241.62 | 30 | Glycosade |
| | | | |
| Single dose amino acids | | | |
| • | | | |
| ARGININE - Special Authority see SA2357 on page 289 - Hosp | ital pharmacy [HP | 3] | |
| Powder, 4 g sachets | · · · · · · · · · · · · · · · · · · · | 30 | Arginine2000 |
| ······································ | | | |
| | | | |

| | Subsidy (Manufacturer's Pric \$ | | Fully Brand or dised Generic ✓ Manufacturer |
|--|---------------------------------------|----------------------------|---|
| CITRULLINE – Special Authority see SA2357 on page 289 – Ho Powder, 4 g sachets | | P3] 30 | ✓ Citrulline1000 |
| ISOLEUCINE – Special Authority see SA2357 on page 289 – Ho Powder, 4 g sachets | | IP3] 30 | ✓ Isoleucine50 |
| LEUCINE – Special Authority see SA2357 on page 289 – Hospit Powder, 4 g sachets | | 30 | ✓ Leucine100 |
| PHENYLALANINE – Special Authority see SA2357 on page 289 Powder, 4 g sachets | | icy [HP3] 30 | Phenylalanine50 |
| TYROSINE - Special Authority see SA2357 on page 289 - Hosp Powder, 4 g sachets | 211.45 | 3] 30 | ✓ Tyrosine1000 |
| VALINE – Special Authority see SA2357 on page 289 – Hospital Powder, 4 g sachets | | 30 | ✓ Valine50 |
| Other Fat Modified Products | | | |
| ELEMENTAL FEED WITH HIGH MEDIUM CHAIN TRIGLYCERII pharmacy [HP3] | DES – Special Aut | hority see <mark>SA</mark> | 2357 on page 289 – Hospital |
| Powder (neutral), 100 g sachets | 47.01 | 10 | Emsogen |
| Carbohydrate and Fat with added vitamins and | minerals | | |
| PROTEIN FREE SUPPLEMENT CONTAINING CARBOHYDRAT Authority see SA2357 on page 289 – Hospital pharmacy [HP3] | TE, FAT WITH ADD | DED VITAMIN | S AND MINERALS – Special |
| Powder (neutral), can | 49.29 | 400 g OP | Energivit |
| Essential Amino Acids | | | |
| ESSENTIAL AMINOACID FORMULA – Special Authority see SA Powder (neutral), can | | – Hospital ph 200 g OP | aarmacy [HP3] ✓ Essential Amino Acid Mix |
| Infant Formulae | | | |

For Williams Syndrome

⇒SA1110 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient is an infant suffering from Williams Syndrome and associated hypercalcaemia.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

| LOW CALCIUM INFANT FORMULA | - Special Authority see SA1110 | above – Hospital pharmacy [HP3] |
|----------------------------|--------------------------------|---------------------------------|
|----------------------------|--------------------------------|---------------------------------|

| Powder | 400 g OP | Locasol |
|--------|----------|-----------------------------|
|--------|----------|-----------------------------|

| | Subsidy | | Fully | Brand or |
|---|-------------------|------------|---------|-------------------------------|
| | (Manufacturer's F | Price) Sub | sidised | Generic |
| | \$ | Per | 1 | Manufacturer |
| Gastrointestinal and Other Malabsorptive Prob | lems | | | |
| AMINO ACID FORMULA - Special Authority see SA2092 below | – Hospital pharr | macy [HP3] | | |
| Powder | | 400 g OP | 🗸 🖌 | Alfamino |
| | | Ū | ✓ # | Alfamino Junior |
| Powder (unflavoured) | | 400 g OP | 🗸 N | leocate Gold |
| | | - | ✓ N | leocate Junior Unflavoured |
| | | | 🗸 N | leocate SYNEO |
| | 65.72 | | 🖌 E | Elecare |
| | | | ✓ E | Elecare LCP |
| Powder (vanilla) | 55.61 | 400 g OP | ✓ N | leocate Junior Vanilla |
| | 65.72 | | ✓ E | lecare |

► SA2092 Special Authority for Subsidy

Initial application — (Infants under 12 months of age) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Any of the following:

- 1 History of anaphylaxis to cow's milk protein formula or dairy products; or
- 2 Eosinophilic oesophagitis; or
- 3 Ultra-short gut; or
- 4 Severe Immune deficiency; or
- 5 Extensively hydrolysed formula has been trialled in an inpatient setting and is clinically inappropriate; or
- 6 Both:
 - 6.1 Extensively hydrolysed formula has been reasonably trialled for 2-4 weeks and is inappropriate due to documented severe intolerance or allergy or malabsorption; and
 - 6.2 Either:
 - 6.2.1 The patient has a valid Special Authority approval for extensively hydrolysed formula: approval number; or
 - 6.2.2 Patient has IgE mediated allergy.

Initial application — (Children 12 months of age and over) only from a paediatrician, paediatric gastroenterologist, paediatric immunologist or dietitian on the recommendation of a paediatrician, paediatric gastroenterologist or paediatric immunologist. Approvals valid for 6 months for applications meeting the following criteria: Both:

- 1 Either:
 - 1.1 Applicant is a paediatrician, paediatric gastroenterologist or paediatric immunologist; or
 - 1.2 Applicant is a dietitian and confirms that a paediatrician, paediatric gastroenterologist or paediatric immunologist has been consulted within the last 12 months and has recommended treatment for the patient; and
- 2 Any of the following:
 - 2.1 History of anaphylaxis to cow's milk protein formula or dairy products; or
 - 2.2 Eosinophilic oesophagitis; or
 - 2.3 Ultra-short gut; or
 - 2.4 Severe Immune deficiency; or
 - 2.5 Extensively hydrolysed formula has been trialled in an inpatient setting and is clinically inappropriate; or
 - 2.6 Both:
 - 2.6.1 Extensively hydrolysed formula has been reasonably trialled for 2-4 weeks and is inappropriate due to documented severe intolerance or allergy or malabsorption; and
 - 2.6.2 Either:
 - 2.6.2.1 The patient has a valid Special Authority approval for extensively hydrolysed formula: approval

continued...

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

continued...

number; or

2.6.2.2 Patient has IgE mediated allergy.

Renewal — (Infants up to 12 months of age) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 Both:

- 1.1 Patient has IgE mediated allergy; and
- 1.2 All of the following:
 - 1.2.1 Patient remains allergic to cow's milk; and
 - 1.2.2 An assessment as to whether the infant can be transitioned to a cow's milk protein, soy or extensively hydrolysed infant formula has been undertaken; and
 - 1.2.3 The outcome of the assessment is that the infant continues to require an amino acid infant formula; and
 - 1.2.4 Amino acid formula is required for a nutritional deficit; and
 - 1.2.5 It has been more than three months from the previous approval; or

2 Both:

- 2.1 Patient has non IgE mediated severe gastrointestinal intolerance (including eosinophilic oesophagitis, ultra-short gut and severe immune deficiency); and
- 2.2 All of the following:
 - 2.2.1 An assessment as to whether the infant can be transitioned to a cow's milk protein, soy, or extensively hydrolysed infant formula has been undertaken; and
 - 2.2.2 The outcome of the assessment is that the infant continues to require an amino acid infant formula; and
 - 2.2.3 Amino acid formula is required for a nutritional deficit; and
 - 2.2.4 It has been more than three months from the previous approval.

Renewal — (Children 12 months of age and over) only from a paediatrician, paediatric gastroenterologist, paediatric immunologist or dietitian on the recommendation of a paediatrician, paediatric gastroenterologist or paediatric immunologist. Approvals valid for 6 months for applications meeting the following criteria: Both:

1 Either:

- 1.1 Applicant is a paediatrician, paediatric gastroenterologist or paediatric immunologist; or
- 1.2 Applicant is a dietitian and confirms that a paediatrician, paediatric gastroenterologist or paediatric immunologist has been consulted within the last 12 months and has recommended treatment for the patient; and
- 2 Any of the following:
 - 2.1 History of anaphylaxis to cow's milk protein formula or dairy products; or
 - 2.2 Eosinophilic oesophagitis; or
 - 2.3 Ultra-short gut; or
 - 2.4 Severe Immune deficiency; or
 - 2.5 Extensively hydrolysed formula has been trialled in an inpatient setting and is clinically inappropriate; or

2.6 Both:

2.6.1 Extensively hydrolysed formula has been reasonably trialled for 2-4 weeks and is inappropriate due to documented severe intolerance or allergy or malabsorption; and

2.6.2 Either:

- 2.6.2.1 The patient has a valid Special Authority approval for extensively hydrolysed formula: approval number; or
- 2.6.2.2 Patient has IgE mediated allergy.

Initial application — (for patients who have a current funding under Special Authority form SA1557) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 months for applications meeting the following criteria:

continued...

| Subsidy | | Fully | Brand or | |
|----------------------|-----|------------|--------------|--|
| (Manufacturer's Pric | e) | Subsidised | Generic | |
| \$ | Per | 1 | Manufacturer | |

continued...

All of the following:

- 1 Patient has a valid Special Authority approval for extensively hydrolysed formula (SA1557); and
- 2 Extensively hydrolysed formula (Aptamil Gold+ Pepti Junior, AllerPro SYNEO 1 and 2) is unable to be supplied at this time; and
- 3 The approval only applies to funded dispensings of Neocate Gold and Neocate Syneo.

Note: This criteria is short term funding to cover an out-of-stock situation on some extensively hydrolysed formula powder funded under Special Authority form SA1557. There is no renewal criteria under this restriction.

| ENTERAL LIQUID PEPTIDE FORMULA | - Special Authority see SA1953 below | - Hospital ph | narmacy [HP3] |
|--------------------------------|--------------------------------------|---------------|---------------|
| Liquid 1 kool/ml 500 ml bottlo | 10// | 1 00 | 🖌 Nutrini Don |

| Liquid 1 kcai/mi, 500 mi bottie | I OP | Nutrini Peptisorb |
|-----------------------------------|------|---------------------------------------|
| Liquid 1.5 kcal/ml, 500 ml bottle | 1 OP | Nutrini Peptisorb |
| | | Energy |

➡SA1953 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has impaired gastrointestinal function and either cannot tolerate polymeric feeds, or polymeric feeds are unsuitable; and
- 2 Any of the following:
 - 2.1 Severe malabsorption; or
 - 2.2 Short bowel syndrome; or
 - 2.3 Intractable diarrhoea; or
 - 2.4 Biliary atresia; or
 - 2.5 Cholestatic liver diseases causing malabsorption; or
 - 2.6 Cystic fibrosis; or
 - 2.7 Proven fat malabsorption; or
 - 2.8 Severe intestinal motility disorders causing significant malabsorption; or
 - 2.9 Intestinal failure; or
 - 2.10 Both:
 - 2.10.1 The patient is currently receiving funded amino acid formula; and
 - 2.10.2 The patient is to be trialled on, or transitioned to, an enteral liquid peptide formula; and
- 3 Either:
 - 3.1 A semi-elemental or partially hydrolysed powdered feed has been reasonably trialled and considered unsuitable; or
 - 3.2 For step down from intravenous nutrition.

Note: A reasonable trial is defined as a 2-4 week trial.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 An assessment as to whether the patient can be transitioned to a cows milk protein or soy infant formula or extensively hydrolysed formula has been undertaken; and
- 2 The outcome of the assessment is that the patient continues to require an enteral liquid peptide formula; and
- 3 General practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.

| EXTENSIVELY HYDROLYSED FORMULA | - Special Authority see SA1557 on t | he next page - | Hospital pharmacy [HP3] |
|--------------------------------|-------------------------------------|----------------|--------------------------------------|
| Powder | | 450 g OP | Pepti-Junior |
| | 36.20 | 900 g OP | Allerpro Syneo 1 |
| | | | Allerpro Syneo 2 |

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

⇒SA1557 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Any of the following:

- 1 Both:
 - 1.1 Cows milk formula is inappropriate due to severe intolerance or allergy to its protein content; and
 - 1.2 Either:
 - 1.2.1 Soy milk formula has been reasonably trialled without resolution of symptoms; or
 - 1.2.2 Soy milk formula is considered clinically inappropriate or contraindicated; or
- 2 Severe malabsorption; or
- 3 Short bowel syndrome; or
- 4 Intractable diarrhoea; or
- 5 Biliary atresia; or
- 6 Cholestatic liver diseases causing malsorption; or
- 7 Cystic fibrosis; or
- 8 Proven fat malabsorption; or
- 9 Severe intestinal motility disorders causing significant malabsorption; or
- 10 Intestinal failure; or
- 11 All of the following:
 - 11.1 For step down from Amino Acid Formula; and
 - 11.2 The infant is currently receiving funded amino acid formula; and
 - 11.3 The infant is to be trialled on, or transitioned to, an extensively hydrolysed formula; and
 - 11.4 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.
- Note: A reasonable trial is defined as a 2-4 week trial, or signs of an immediate IgE mediated allergic reaction.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 An assessment as to whether the infant can be transitioned to a cows milk protein or soy infant formula has been undertaken; and
- 2 The outcome of the assessment is that the infant continues to require an extensively hydrolysed infant formula; and
- 3 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.

Fluid Restricted

| PAEDIATRIC ORAL/ENTERAL FEED 1 KCAL/ML | - Special Authority see SA1698 | below - | Hospital pharmacy [HP3] |
|--|--------------------------------|---------|-------------------------------|
| Liquid, 125 ml bottle | 2.80 | 1 OP | Infatrini |

⇒SA1698 Special Authority for Subsidy

Initial application only from a paediatrician, dietitian or general practitioner on the recommendation of a paediatrician or dietitian. Approvals valid for 12 months for applications meeting the following criteria: All of the following:

- 1 Patient is fluid restricted or volume intolerant and has been diagnosed with faltering growth; and
- 2 Patient is under the care of a paediatrician or dietitian who has recommended treatment with a high energy infant formula; and
- 3 Patient is under 18 months of age or weighs less than 8 kg.

| Subsidy | | Fully | Brand or |
|------------------------|-------|-------|--------------|
| (Manufacturer's Price) | Subsi | dised | Generic |
| \$ | Per | 1 | Manufacturer |

continued...

Note: 'Volume intolerant' patients are those who are unable to tolerate an adequate volume of infant formula to achieve expected growth rate. These patients should have first trialled appropriate clinical alternative treatments, such as concentrating, fortifying and adjusting the frequency of feeding.

Renewal only from a paediatrician, dietitian or general practitioner on the recommendation of a paediatrician or dietitian. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient continues to be fluid restricted or volume intolerant and has faltering growth; and
- 2 Patient is under the care of a hospital paediatrician or dietitian who has recommended treatment with a high energy infant formula; and
- 3 Patient is under 18 months of age or weighs less than 8 kg.

Note: 'Volume intolerant' patients are those who are unable to tolerate an adequate volume of infant formula to achieve expected growth rate. These patients should have first trialled appropriate clinical alternative treatments, such as concentrating, fortifying and adjusting the frequency of feeding.

Ketogenic Diet

➡SA1197 Special Authority for Subsidy

Initial application only from a metabolic physician or paediatric neurologist. Approvals valid for 3 months where the patient has intractable epilepsy, pyruvate dehydrogenase deficiency or glucose transported type-1 deficiency and other conditions requiring a ketogenic diet.

Renewal only from a metabolic physician or paediatric neurologist. Approvals valid for 2 years where the patient is on a ketogenic diet and the patient is benefiting from the diet.

| HIGH FAT LOW CARBOHYDRATE FORMULA - Special Authority | see <mark>SA1197</mark> | above - Hospit | al pharmacy [HP3] |
|---|-------------------------|----------------|---------------------------------|
| Powder (unflavoured) | 36.92 | 300 g OP | KetoCal 4:1 |
| | | - | Ketocal 3:1 |
| Powder (vanilla) | 36.92 | 300 g OP | KetoCal 4:1 |

SECTION I: NATIONAL IMMUNISATION SCHEDULE

| | Subsidy (Manufacturer's Price) \$ | Su Per | Fully bsidised | Brand or Generic Manufacturer |
|---|---|-------------|-------------------|-------------------------------------|
| Vaccinations | | | | |
| ACILLUS CALMETTE-GUERIN VACCINE – [Xpharm] | | | | |
| For infants at increased risk of tuberculosis. Increased risk | | | | |
| 1) living in a house or family with a person with current | | | | |
| having one or more household members or carers w equal to 40 per 100,000 for 6 months or longer; or | no within the last 5 yea | rs lived ir | i a count | ry with a rate of TB > 0 |
| 3) during their first 5 years will be living 3 months or longer, of | ger in a country with a | rate of TE | 3 > or eq | ual to 40 per 100,000 |
| Note a list of countries with high rates of TB are available a | | | | |
| www.bcgatlas.org/index.php. | | | | |
| Inj Mycobacterium bovis BCG (Bacillus Calmette-Guerin), | 0.00 | 10 | ./ 5 | CC Veesine A IV |
| Danish strain 1331, live attenuated, vial with diluent | 0.00 | 10 | • - | CG Vaccine AJV |
| OVID-19 VACCINE – [Xpharm] Inj 3 mcg bretovameran per 0.3 ml, 0.48 ml vial; infant vac | oino | | | |
| yellow cap | | 10 | ✓ 0 | comirnaty Omicron |
| | | | | (JN.1) |
| Up to three doses for previously unvaccinated childrer | n aged 6 months - 4 yea | ars at hig | h risk of | severe illness. |
| Inj 10 mcg bretovameran per 0.3 ml, 0.48 ml vial; paediatri | c | | | |
| vaccine, light blue cap | | 10 | ✓ (| comirnaty Omicron |
| | | | | (JN.1) |
| Either: | | | | |
| One dose for previously unvaccinated children a Up to three doses for immunocompromised children | | Ч | | |
| 2) Op to three doses for initiatiocompromised child | liell ageu 5-11 years of | u. | | |
| Inj 30 mcg bretovameran per 0.3 ml, 0.48 ml vial; adult vao | cine, | | | |
| light grey cap | 0.00 | 10 | ✓ 0 | omirnaty Omicron |
| Any of the following: | | | | (JN.1) |
| Any of the following: 1) One dose for previously unvaccinated people ag | ed 12-15 years old: or | | | |
| 2) Up to three doses for immunocompromised people ag | • | d: or | | |
| 3) Up to two doses for previously unvaccinated per | | | | |
| 4) Up to four doses for people aged 16-29 at high r | , | | | |
| One dose for previously unvaccinated people ag One additional dose every 6 months for previous | | and 00 | | over additional dese |

6) One additional dose every 6 months for previously vaccinated people aged 30 years and over – additional dose is given at least 6 months after last dose.

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

DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE

- a) Only on a prescription
- b) No patient co-payment payable
- C)
- A) Funded for any of the following criteria:
 - 1) A single dose for pregnant women in the second or third trimester of each pregnancy; or
 - 2) A single dose for parents or primary caregivers of infants admitted to a Neonatal Intensive Care Unit or Specialist Care Baby Unit for more than 3 days, who had not been exposed to maternal vaccination at least 14 days prior to birth; or
 - A course of up to four doses is funded for children from age 7 up to the age of 18 years inclusive to complete full primary immunisation; or
 - 4) An additional four doses (as appropriate) are funded for (re-)immunisation for patients post haematopoietic stem cell transplantation or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens; or
 - 5) A single dose for vaccination of patients aged from 65 years old; or
 - 6) A single dose for vaccination of patients aged from 45 years old who have not had 4 previous tetanus doses; or
 - 7) For vaccination of previously unimmunised or partially immunised patients; or
 - 8) For revaccination following immunosuppression; or
 - 9) For boosting of patients with tetanus-prone wounds.
 - Notes: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.
- B) Contractors will be entitled to claim payment from the Funder for the supply of diphtheria, tetanus and pertussis vaccine to patients eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the diphtheria, tetanus and pertussis vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraphs 1 – 9 above.
- Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg

pertussis toxoid, 8 mcg pertussis filamentous haemaodutinin and 2.5 mcg pertactin in 0.5 ml prefilled

| maemaggiutinin and 2.5 mcg pertactin in 0.5 mi premied | | | |
|--|------|----|------------------------------|
| syringe | 0.00 | 10 | Boostrix |

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

10

Infanrix IPV

DIPHTHERIA, TETANUS, PERTUSSIS AND POLIO VACCINE

- a) Only on a prescription
- b) No patient co-payment payable
- C)

A) Funded for any of the following:

- 1) A single dose for children up to the age of 7 who have completed primary immunisation; or
- A course of four vaccines is funded for catch up programmes for children (to the age of 10 years) to complete full primary immunisation; or
- 3) An additional four doses (as appropriate) are funded for (re-)immunisation for people post HSCT, or chemotherapy; pre- or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens; or
- 4) Five doses will be funded for children requiring solid organ transplantation.
- B) Contractors will be entitled to claim payment from the Funder for the supply of Diphtheria, tetanus, pertussis and polio vaccine to people eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Diphtheria, tetanus, pertussis and polio vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

Inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg

pertussis toxoid, 25 mcg pertussis filamentous

haemagglutinin, 8 mcg pertactin and 80 D-antigen units

poliomyelitis virus in 0.5ml syringe0.00

DIPHTHERIA, TETANUS, PERTUSSIS, POLIO, HEPATITIS B AND HAEMOPHILUS INFLUENZAE TYPE B VACCINE

- a) Only on a prescription
- b) No patient co-payment payable

C)

- A) Funded for children meeting any of the following criteria
 - 1) Up to four doses for children under the age of 10 years for primary immunisation; or
 - An additional four doses (as appropriate) for (re-)immunisation of children under the age of 18 years post haematopoietic stem cell transplantation; or
 - 3) An additional four doses (as appropriate) for (re-)immunisation of children under the age of 10 years who are post chemotherapy; pre or post splenectomy; undergoing renal dialysis and other severely immunosuppressive regimens; or
 - 4) Up to five doses for children under the age of 10 years receiving solid organ transplantation.
- B) Contractors will be entitled to claim payment from the Funder for the supply of Diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type b vaccine to people eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type b vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

Note: A course of up-to four vaccines is funded for catch up programmes for children (up to and under the age of 10 years) to complete full primary immunisation. Please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.

Inj 30IU diphtheria with 40IU tetanus and 25mcg pertussis toxoids, 25mcg pertussis filamentous haemagglutinin, 8mcg pertactin, 80D-AgU polio virus, 10mcg hepatitis B antigen, 10mcg H. influenzae type b with tetanus toxoid 20-40mcg in 0.5ml syringe0.00

10



| Subsidy (Manufacturer's Price) | Full Subsidise | | |
|-----------------------------------|-------------------|--------------|--|
| \$ | Per 🖌 | Manufacturer | |

HAEMOPHILUS INFLUENZAE TYPE B VACCINE

- a) Only on a prescription
- b) No patient co-payment payable
- C)

A) One dose for people meeting any of the following:

- 1) For primary vaccination in children; or
- 2) An additional dose (as appropriate) is funded for (re-)immunisation for people 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
- For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.
- B) Contractors will be entitled to claim payment from the Funder for the supply of Haemophilus influenzae type b vaccine to people eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Haemophilus influenzae type b vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

| Inj 10 mcg vial with diluent syringe | 0.00 | 1 | ✓ <u>Act-HIB</u> |
|---|-------------|---|-----------------------------------|
| HEPATITIS A VACCINE – [Xpharm] | | | |
| Funded for patients meeting any of the following criteria: | | | |
| Two vaccinations for use in transplant patients; or | | | |
| Two vaccinations for use in children with chronic liver dis | sease; or | | |
| One dose of vaccine for close contacts of known hepatit | is A cases. | | |
| | | | . |
| Inj 1440 ELISA units in 1 ml syringe | | 1 | Havrix 1440 |
| Inj 720 ELISA units in 0.5 ml syringe | 0.00 | 1 | Havrix Junior |
| | | | |

| | | Subsidy (Manufacturer's Price) \$ | Sub Per | Fully sidised | Brand or Generic Manufacturer | | | |
|---|--|---|------------|------------------|-------------------------------------|--|--|--|
| HEPATITIS E | RECOMBINANT VACCINE - [Xpharm] | | | | | | | |
| lnj 10 mc | g per 0.5 ml prefilled syringe | 0.00 | 1 | ✓ <u>E</u> | ngerix-B | | | |
| | led 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 inc | | | | achieved a positive | | | |
| | serology and require additional vaccination or requ | ire a primary course o | of vaccina | ition; or | | | | |
| | for HIV positive patients; or | | | | | | | |
| | for hepatitis C positive patients; or for patients following non-consensual sexual interc | | | | | | | |
| , | for patients prior to planned immunosuppression for | | e: or | | | | | |
| , | for patients following immunosuppression; or | i greater than 20 day | 5, 01 | | | | | |
| | for solid organ transplant patients; or | | | | | | | |
| | for post-haematopoietic stem cell transplant (HSC) | F) patients; or | | | | | | |
| | following needle stick injury. | | | | | | | |
| lnj 20 mc | g per 1 ml prefilled syringe | 0.00 | 1 | ✓ <u>E</u> | ngerix-B | | | |
| Func | led for patients meeting any of the following criteria: | | | | | | | |
| | for household or sexual contacts of known acute he | | | | s; or | | | |
| | for children born to mothers who are hepatitis B su | | | | | | | |
| 3) | for children up to and under the age of 18 years inc | | | | achieved a positive | | | |
| 4) | serology and require additional vaccination or requ for HIV positive patients; or | ire a primary course o | or vaccina | tion; or | | | | |
| | for hepatitis C positive patients; or | | | | | | | |
| , | for patients following non-consensual sexual interc | OUISE. OL | | | | | | |
| , | for patients prior to planned immunosuppression for | | s: or | | | | | |
| , | for patients following immunosuppression; or | 30 wwy | -, | | | | | |
| | for solid organ transplant patients; or | | | | | | | |
| 10) | for post-haematopoietic stem cell transplant (HSC) | Γ) patients; or | | | | | | |
| , | following needle stick injury; or | | | | | | | |
| , | for dialysis patients; or | | | | | | | |
| 13) | for liver or kidney transplant patients. | | | | | | | |

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

HUMAN PAPILLOMAVIRUS (6, 11, 16, 18, 31, 33, 45, 52 AND 58) VACCINE [HPV]

- a) Maximum of 1 inj per prescription
- b) Only on a prescription
- c) No patient co-payment payable

d)

- a) A) Any of the following:
 - 1) Maximum of two doses for children aged 14 years and under; or
 - 2) Maximum of three doses for people meeting any of the following criteria:
 - 1) People aged 15 to 26 years inclusive; or
 - 2) Either:
 - People aged 9 to 26 years inclusive who have
 - 1) Confirmed HIV infection; or
 - 2) Received a transplant (including stem cell): or
 - 3) Maximum of four doses for people aged 9 to 26 years inclusive post chemotherapy
 - B) Contractors will be entitled to claim payment from the Funder for the supply of Human papillomavirus vaccine to people eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Human papillomavirus vaccine listed in the Pharmaceutical Schedule.
 - C) Contractors may only claim for populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraphs A above.

| Inj 270 mcg in 0.5 ml syringe | 0.00 | 10 | Gardasil 9 |
|-------------------------------|------|----|--------------------------------|
|-------------------------------|------|----|--------------------------------|

| | Subsidy (Manufacturer's Price) \$ | Per | Fully Subsidised | Brand or Generic Manufacturer |
|--|---|-----|---------------------|-------------------------------------|
| INFLUENZA VACCINE Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine) | | 10 | 🗸 Ir | nfluvac Tetra (2025 formulation) |

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

- a) Maximum of 1 inj per prescription
- b) Only on a prescription
- c) No patient co-payment payable

d)

A) INFLUENZA VACCINE

is available each year for patients who meet the following criteria, as set by Pharmac:

- a) all people 65 years of age and over; or
- b) people under 65 years of age who:
 - i) have any of the following cardiovascular diseases:
 - a) ischaemic heart disease, or
 - b) congestive heart failure, or
 - c) rheumatic heart disease, or
 - d) congenital heart disease, or
 - e) cerebo-vascular disease; or
 - ii) have either of the following chronic respiratory diseases:
 - a) asthma, if on a regular preventative therapy, or
 - b) other chronic respiratory disease with impaired lung function; or
 - iii) have diabetes; or
 - iv) have chronic renal disease; or
 - v) have any cancer, excluding basal and squamous skin cancers if not invasive; or
 - vi) have any of the following other conditions:
 - a) autoimmune disease, or
 - b) immune suppression or immune deficiency, or
 - c) HIV, or
 - d) transplant recipients, or
 - e) neuromuscular and CNS diseases/disorders, or
 - f) haemoglobinopathies, or
 - g) are children on long term aspirin, or
 - h) have a cochlear implant, or
 - i) errors of metabolism at risk of major metabolic decompensation, or
 - j) pre and post splenectomy, or
 - k) Down syndrome, or
 - vii) are pregnant; or
- c) children 4 years of age and under who have been hospitalised for respiratory illness or have a history of significant respiratory illness; or
- d) people under 65 years of age who:
 - i) have any of the following serious mental health conditions:
 - a) schizophrenia, or
 - b) major depressive disorder, or
 - c) bipolar disorder, or
 - d) schizoaffective disorder, or
 - ii) are currently accessing secondary or tertiary mental health and addiction services; or

Unless meeting the criteria set out above, the following conditions are excluded from funding:

- a) asthma not requiring regular preventative therapy,
- b) hypertension and/or dyslipidaemia without evidence of end-organ disease.
- B) Contractors will be entitled to claim payment for the supply of influenza vaccine to patients eligible under the above criteria pursuant to their contract with Health NZ for subsidised immunisation, and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

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
 10

 diluent 0.5 ml
 10

Priorix

| | Subsidy | Fully | y Brand or |
|--|------------------------------|-----------------|-----------------------------|
| | (Manufacturer's Price) \$ | Subsidised | |
| MENINGOCOCCAL (GROUPS A, C, Y AND W-135) CONJU | | | inanalaotaroi |
| Inj 10 mcg of each meningococcal polysaccharide conju | gated | | |
| to a total of approximately 55 mcg of tetanus toxoid | | | |
| per 0.5 ml vial | 0.00 | 1 🗸 | MenQuadfi |
| a) Only on a prescription | | | |
| b) No patient co-payment payable | | | |
| c)A) Any of the following: | | | |
| 1) Up to three doses and a booster ever | y five years for patients p | re- and post sp | lenectomy and for patients |
| with functional or anatomic asplenia, | | | |
| solid organ transplant; or | | | |
| One dose for close contacts of menin | | | |
| One dose for person who has previou A maximum of two doses for here and | , , | , , | roup; or |
| A maximum of two doses for bone ma A maximum of two doses for person p | | | |
| B) Both: | ne- and post-inimunosup | 016331011, 01 | |
| 1) Person is aged between 13 and 25 ye | ears, inclusive; and | | |
| 2) Either: | | | |
| One dose for individuals who ar | | | |
| in boarding school hostels, tertia | ary education halls of resid | dence, military | barracks, Youth Justice |
| residences, or prisons; or 2) One dose for individuals who tu | rn 12 years of ago while li | vina in boardin | a sobool bostole |
| C) Contractors will be entitled to claim payment | , , | • | • |
| W-135 vaccine to patients eligible under the | | | |
| (Health NZ) for subsidised immunisation, a | | | |
| W-135 vaccine listed in the Pharmaceutica | | | |
| D) Contractors may only claim for patient population | | | ed by their contract, which |
| may be a sub-set of the population describ Note: children under seven years of age require | | | a three years after the |
| primary series and then five yearly. | two uoses o weeks apair | , a booster uos | e intee years after the |
| *Immunosuppression due to steroid or other imm | unosuppressive therapy i | must be for a p | eriod of greater than |
| 28 days. | | | Ū |
| Inj 5 mcg of each meningococcal polysaccharide conjug | | | |
| a total of approximately 44 mcg of tetanus toxoid ca | | | |
| per 0.5 ml vial – [Xpharm] | 0.00 | 1 🗸 | Nimenrix |
| A) Both: | | | |
| The child is under 12 months of age; and Any of the following: | | | |
| 1) A maximum of three doses (depend | lant on age at first dose) f | or natients nre | - and nost- splenectomy and |
| for patients with functional or anato | | | |
| pre- or post- solid organ transplant; | | | , (, |
| 2) A maximum of three doses (depend | | or close contac | cts of meningococcal cases |
| of any group; or | | | |
| A maximum of three doses (depend maningaccoord diagona of any gray | | or child who ha | as previously had |
| meningococcal disease of any grou 4) A maximum of three doses (dependent | | or hone marro | w transplant patients: or |
| 4) A maximum of three doses (depend 5) A maximum of three doses (depend | | | |

5) A maximum of three doses (dependant on age at first dose) for child pre- and post-immunosuppression*.

Note: infants from 6 weeks to less than 6 months of age require a 2+1 schedule, infants from 6 months to less than 12 months of age require a 1+1 schedule. Refer to the Immunisation Handbook for recommended booster schedules with meningococcal ACWY vaccine.

*Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.

MENINGOCOCCAL B MULTICOMPONENT VACCINE

- a) Only on a prescription
- b) No patient co-payment payable
- c) Any of the following:
 - A) Three doses for children up to 12 months of age (inclusive) for primary immunisation; or
 - B) Up to three doses (dependent on age at first dose) for a catch-up programme for children from 13 months to
 - 59 months of age (inclusive) for primary immunisation, from 1 March 2023 to 31 August 2025; or
 - C) 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*; or
 - D) Both:
 - 1) Person is aged between 13 and 25 years (inclusive); and
 - 2) Either:
 - Two doses for individuals who are entering within the next three months, or in their first year of living in boarding school hostels, tertiary education halls of residence, military barracks, Youth Justice residences or prisons; or
 - ii) Two doses for individuals who turn 13 years of age while living in boarding school hostels.
 - E) Contractors will be entitled to claim payment from the Funder for the supply of Meningococcal B multicomponent vaccine to patients eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Meningococcal B multicomponent vaccine listed in the Pharmaceutical Schedule.
 - F) Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraphs A-D above.

*Immunosuppression due to corticosteroid or other immunosuppressive therapy must be for a period of greater than 28 days.

| Inj 175 mcg per 0.5 ml prefilled syringe | 0.00 | 1 | Bexsero |
|--|------|----|-----------------------------|
| | | 10 | Bexsero |

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

PNEUMOCOCCAL (PCV13) CONJUGATE VACCINE

- a) Only on a prescription
- b) No patient co-payment payable
- C)

A) Any of the following:

- 1) A course of three doses for previously unvaccinated children up to the age of 59 months inclusive; or
- Two doses are funded for high risk individuals (over the age of 12 months and under 18 years) who have previously received two doses of the primary course of PCV10; or
- 3) Up to an additional four doses (as appropriate) are funded for the (re)immunisation of high risk children aged under 5 years with any of the following:
 - a) on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or
 - b) primary immune deficiencies; or
 - c) HIV infection; or
 - d) renal failure, or nephrotic syndrome; or
 - e) who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
 - f) cochlear implants or intracranial shunts; or
 - g) cerebrospinal fluid leaks; or
 - receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
 - i) chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or
 - j) pre term infants, born before 28 weeks gestation; or
 - k) cardiac disease, with cyanosis or failure; or
 - I) diabetes; or
 - m) Down syndrome; or
 - n) who are pre-or post-splenectomy, or with functional asplenia; or
- 4) Up to an additional four doses (as appropriate) are funded for the (re-)immunisation of individuals 5 years and over with HIV, pre or post haematopoietic stem cell transplantation, or chemotherapy; pre- or post splenectomy; functional asplenia, pre- or post- solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, intracranial shunts, cerebrospinal fluid leaks or primary immunodeficiency; or
- 5) For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.
- B) Contractors will be entitled to claim payment from the Funder for the supply of Pneumococcal (PCV13) conjugate vaccine to people eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Pneumococcal (PCV13) conjugate vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

Note: please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes Inj 30.8 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) \$ | Fully Subsidised Per ✓ | Brand or Generic Manufacturer |
|--|---|------------------------------|-------------------------------------|
| PNEUMOCOCCAL (PPV23) POLYSACCHARIDE VACCINE - Any of the following: | - [Xpharm] | | |
| Up to three doses (as appropriate) for patients with F | IIV. for patients post had | ematopoietic ster | n cell transplant, or |
| chemotherapy; pre- or post-splenectomy or with func | | | |
| complement deficiency (acquired or inherited), cochl | ear implants, or primary | immunodeficien | cy; or |
| 2) All of the following: | | | |
| a) Patient is a child under 18 years for (re-)immun | isation; and | | |
| b) Treatment is for a maximum of two doses; andc) Any of the following: | | | |
| i) on immunosuppressive therapy or radiation | on therapy, vaccinate wh | on there is expe | cted to be a sufficient |
| immune response; or | in therapy, vaccinate wi | | |
| ii) with primary immune deficiencies; or | | | |
| iii) with HIV infection; or | | | |
| iv) with renal failure, or nephrotic syndrome; | | | |
| v) who are immune-suppressed following or or | gan transplantation (incl | uding naematop | pietic stem cell transplant); |
| vi) with cochlear implants or intracranial shur | nts: or | | |
| vii) with cerebrospinal fluid leaks; or | | | |
| viii) receiving corticosteroid therapy for more t | | | |
| prednisone of 2 mg/kg per day or greater, | or children who weigh r | nore than 10 kg | on a total daily dosage of |
| 20 mg or greater; or | asthma tracted with his | h daga gartiagat | araid tharany), ar |
| ix) with chronic pulmonary disease (including x) pre term infants, born before 28 weeks get | | gn-dose conicosi | erold therapy); or |
| xi) with cardiac disease, with cyanosis or fail | | | |
| xii) with diabetes; or | , - | | |
| xiii) with Down syndrome; or | | | |
| xiv) who are pre-or post-splenectomy, or with | • | | |
| For use in testing for primary immunodeficiency diser paediatrician | ases, on the recommend | dation of an inter | nal medicine physician or |
| Inj 575 mcg in 0.5 ml prefilled syringe (25 mcg of each | | | |
| 23 pneumococcal serotype) | 0.00 | 1 ✓ <u>F</u> | neumovax 23 |
| POLIOMYELITIS VACCINE - [Xpharm] | | | |
| Up to three doses for patients meeting either of the following | - | | |
| For partially vaccinated or previously unvaccinated in For revaccination following immunosuppression. | aiviauais; or | | |
| Note: Please refer to the Immunisation Handbook for app | ropriate schedule for cat | ch-up programm | es |
| Inj 80D antigen units in 0.5 ml syringe | | | POL |
| | | - | |

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

ROTAVIRUS ORAL VACCINE

- a) Only on a prescription
- b) No patient co-payment payable
- c)
- A) Maximum of two doses for people meeting the following:
 - 1) first dose to be administered in infants aged under 14 weeks of age; and
 - 2) no vaccination being administered to children aged 24 weeks or over.
- B) Contractors will be entitled to claim payment from the Funder for the supply of Rotavirus oral vaccine to people eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Rotavirus oral vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

| Oral susp live attenuated human rotavirus | | |
|--|----|-----------------------------|
| 1,000,000 CCID50 per dose, squeezable tube0.00 | 10 | Rotarix |
| Oral susp live attenuated human rotavirus | | |
| 1,000,000 CCID50 per dose, squeezable tube (PVC free) 0.00 | 10 | Rotarix |
| Oral susp live attenuated human rotavirus | | |
| 1,000,000 CCID50 per dose, prefilled oral applicator0.00 | 10 | Rotarix |
| | | |

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

VARICELLA VACCINE [CHICKENPOX VACCINE]

- a) Only on a prescription
- b) No patient co-payment payable

c)

A) Either:

- 1) Maximum of one dose for primary vaccination for either:
 - a) Any infant born on or after 1 April 2016; or
 - 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 individuals:
 - i) with chronic liver disease who may in future be candidates for transplantation; or
 - ii) with deteriorating renal function before transplantation; or
 - iii) prior to solid organ transplant; or
 - iv) prior to any elective immunosuppression*; or
 - v) for post exposure prophylaxis who are immune competent inpatients; or
 - b) For individuals at least 2 years after bone marrow transplantation, on advice of their specialist; or
 - c) For individuals at least 6 months after completion of chemotherapy, on advice of their specialist; or
 - For HIV positive non immune to varicella with mild or moderate immunosuppression on advice of HIV specialist; or
 - e) For individuals with inborn errors of metabolism at risk of major metabolic decompensation, with no clinical history of varicella; or
 - f) For household contacts of paediatric patients who are immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella; or
 - g) For household contacts of adult patients who have no clinical history of varicella and who are severely immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella.
- B) Contractors will be entitled to claim payment from the Funder for the supply of Varicella vaccine [Chickenpox vaccine] vaccine to people eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Varicella vaccine [Chickenpox vaccine] listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraphs A above.

* immunosuppression due to steroid or other immunosuppressive therapy must be for a treatment period of greater than 28 days

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

VARICELLA ZOSTER VACCINE [SHINGLES VACCINE]

- a) Only on a prescription
- b) No patient co-payment payable
- c)
- A) Funded for patients meeting the following criteria:
 - 1) Either:
 - 1) Two doses for all people aged 65 years, or
 - 2) Two doses for people 18 years of age or older with any of the following:
 - a) pre- and post-haematopoietic stem cell transplant or cellular therapy; or
 - b) pre- or post-solid organ transplant; or
 - c) haematological malignancies; or
 - d) people living with poorly controlled HIV infection; or
 - e) planned or receiving disease modifying anti-rheumatic drugs (DMARDs targeted synthetic, biologic, or conventional synthetic) for polymyalgia rheumatica, systemic lupus erythematosus or rheumatoid arthritis; or
 - f) end stage kidney disease (CKD 4 or 5); or
 - g) primary immunodeficiency
- B) Contractors will be entitled to claim payment from the Funder for the supply of Varicella zoster vaccine (Shingles vaccine) to patients eligible under the above criteria pursuant to their contract with Health New Zealand (Health NZ) for subsidised immunisation, and they may only do so in respect of the Varicella zoster vaccine [Shingles 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.

| Inj 50 mcg per 0.5 ml vial plus vial | 0.00 | 1 | Shingrix |
|--------------------------------------|------|----|------------------------------|
| | | 10 | Shingrix |

Diagnostic Agents

| TUBERCULIN PPD [MANTOUX] TEST – [Xpharm] | | | |
|--|------|---|------------------------------|
| Inj 5 TU per 0.1 ml, 1 ml vial | 0.00 | 1 | Tubersol |

į

| 3TC110 |
|---------------------------------------|
| - A - |
| A-Scabies71 |
| Abacavir sulphate 110 |
| Abacavir sulphate with |
| lamivudine 110 |
| Abacavir/Lamivudine Viatris 110 |
| Abilify Maintena |
| Abilify Maintena S29135 |
| Abiraterone acetate |
| Acarbose |
| Accarb |
| Acetazolamide |
| Acetec |
| Acetic acid with hydroxyquinoline and |
| |
| ricinoleic acid |
| Acetylcysteine |
| Aci-Jel |
| Aciclovir |
| Infection105 |
| Sensory |
| Acidex |
| Acipimox51 |
| Acitretin |
| Act-HIB |
| Actemra233 |
| Actinomycin D157 |
| Actrapid10 |
| Actrapid Penfill10 |
| Acupan 122 |
| Adalimumab (Amgevita) 183 |
| Adalimumab (Humira - Alternative |
| brand) 192 |
| Adapalene65 |
| Adcetris |
| ADR Cartridge 1.821 |
| Adrenaline |
| Cardiovascular53 |
| Respiratory256 |
| Advantan |
| Advate |
| Adynovate |
| Afinitor |
| Aflibercept198 |
| AFT-Pyrazinamide |
| Agents Affecting the |
| Renin-Angiotensin System |
| Agents for Parkinsonism and Related |
| Disorders |
| Agents Used in the Treatment of |
| Poisonings |
| Agrylin |
| Albalon |
| |

| Albendazole | 92 |
|----------------------------------|-----|
| Albey | 257 |
| Albustix | 80 |
| Alchemy Oxaliplatin | 152 |
| Alchemy Oxybutynin | |
| Aldurazyme | 27 |
| Alecensa | 164 |
| Alectinib | 164 |
| Alendronate sodium | 115 |
| Alendronate sodium with | |
| colecalciferol | 115 |
| Alfacalcidol | 31 |
| Alfamino | 295 |
| Alfamino Junior | 295 |
| Alginic acid | 6 |
| Alglucosidase alfa | 25 |
| Alkeran | 152 |
| Allerfix | 269 |
| Allerpro Syneo 1 | 297 |
| Allerpro Syneo 2 | 297 |
| Allersoothe | 258 |
| Allmercap | 155 |
| Allopurinol | |
| Almarytm | |
| Alpha-Adrenoceptor Blockers | 44 |
| Alpha-Keri Lotion | 69 |
| Alphamox 125 | |
| Alphamox 250 | |
| Alprolix | |
| Alu-Tab | 6 |
| Aluminium hydroxide | 6 |
| Alyacen | 77 |
| Amantadine hydrochloride | 120 |
| Ambrisentan | 54 |
| Ambrisentan Viatris | 54 |
| Amgevita | 183 |
| Amiloride hydrochloride | 49 |
| Amiloride hydrochloride with | |
| furosemide | 50 |
| Amiloride hydrochloride with | |
| hydrochlorothiazide | 50 |
| Aminophylline | 263 |
| Amiodarone hydrochloride | 46 |
| Amisulpride | |
| Amitriptyline | 126 |
| Amlodipine | 48 |
| Amorolfine | |
| Amoxicillin | |
| Amoxicillin with clavulanic acid | |
| Amoxiclav Devatis Forte | 95 |
| Amphotericin B | |
| Amsacrine | |
| AmsaLyo | |
| Amsidine | 156 |
| | |

| Amzoate | 28 |
|-------------------------------------|-------|
| Anaesthetics | |
| Anafranil | . 126 |
| Anagrelide hydrochloride | . 156 |
| Analgesics | . 122 |
| Anastrozole | |
| Anatrole | . 175 |
| Anoro Ellipta | .261 |
| Antabuse | . 148 |
| Antacids and Antiflatulents | |
| Anthelmintics | 92 |
| Antiacne Preparations | 65 |
| Antiallergy Preparations | |
| Antianaemics | 35 |
| Antiandrogen Oral | |
| Contraceptives | 78 |
| Antiarrhythmics | 46 |
| Antibacterials | |
| Antibacterials Topical | |
| Anticholinergic Agents | .260 |
| Anticholinesterases | . 114 |
| Antidepressants | . 126 |
| Antidiarrhoeals | |
| Antiepilepsy Drugs | . 128 |
| Antifibrinolytics, Haemostatics and | |
| Local Sclerosants | 36 |
| Antifibrotics | .262 |
| Antifungals | 99 |
| Antifungals Topical | 66 |
| Antihistamines | .257 |
| Antihypotensives | |
| Antimalarials | . 102 |
| Antimigraine Preparations | . 131 |
| Antinausea and Vertigo Agents | . 131 |
| Antipruritic Preparations | |
| Antipsychotics | |
| Antiretrovirals | |
| Antirheumatoid Agents | . 115 |
| Antispasmodics and Other Agents | |
| Altering Gut Motility | 8 |
| Antithrombotic Agents | |
| Antithymocyte alobulin | |
| (equine) | . 183 |
| Antitrichomonal Agents | . 103 |
| Antituberculotics and | |
| Antileprotics | . 103 |
| Antiulcerants | |
| Antivirals | |
| Anxiolytics | . 137 |
| Anzatax | |
| Apidra | |
| Apidra SoloStar | 11 |
| APO Clomipramine | |
| APO Health Macrogol | |

| INDEX: Ge | eneric Chei | micals an | d Brands |
|-----------|-------------|-----------|----------|
|-----------|-------------|-----------|----------|

| APO-Atomoxetine142 |
|------------------------------|
| APO-Alomoxeline |
| Apo-Azithromycin |
| APO-Candesartan HC1Z |
| 16/12.5 |
| APO-Candesartan HCTZ |
| 32/12.5 |
| Apo-Temozolomide162 |
| Apomorphine hydrochloride120 |
| Aprepitant 131 |
| Apresoline54 |
| Aptamil Feed Thickener |
| Aqueous cream |
| Aratac |
| Arava |
| |
| Arginine |
| Arginine2000 |
| Aripiprazole133, 135 |
| Aripiprazole Sandoz 133 |
| Aristocort68 |
| Arrotex-Prazosin S2944 |
| Arrow - Clopid |
| Arrow - Lattim 270 |
| Arrow-Amitriptyline 126 |
| Arrow-Bendrofluazide50 |
| Arrow-Brimonidine |
| Arrow-Diazepam137 |
| Arrow-Doxorubicin |
| Arrow-Fluoxetine |
| Arrow-Losartan & |
| Hydrochlorothiazide 45 |
| Arrow-Norfloxacin |
| Arrow-Ornidazole |
| Arrow-Quinapril 1045 |
| Arrow-Quinapril 2045 |
| Arrow-Quinapril 5 |
| Arrow-Roxithromycin |
| |
| Arrow-Timolol |
| Arrow-Topiramate |
| Arrow-Tramadol126 |
| Arsenic trioxide 156 |
| Asacol |
| Asacol S297 |
| Ascend |
| Ascend Aripiprazole 133 |
| Ascend-Cefuroxime |
| Ascorbic acid31 |
| Aspen Adrenaline53 |
| Aspirin |
| Blood |
| Nervous122 |
| Asthalin259 |
| Atazanavir Mylan110 |
| Atazanavir sulphate 110 |
| Atazanavir Viatris |
| Atenolol |
| Atenolol AFT47 |
| |

=

| Atenolol Viatris47 |
|--|
| Atezolizumab243 |
| ATGAM183 |
| Ativan137 |
| Atnahs Olsalazine |
| Atomoxetine |
| Atorvastatin |
| Atropine sulphate |
| Cardiovascular46 |
| |
| Sensory |
| |
| Atrovent |
| Augmentin |
| Aurorix |
| AutoSoft 30 |
| AutoSoft 9020 |
| Avelox |
| Avonex |
| Avonex Pen |
| Axitinib164 |
| Azacitidine152 |
| Azacitidine Dr Reddy's152 |
| Azamun 176 |
| Azathioprine176 |
| Azilect120 |
| Azithromycin93 |
| Azopt |
| AZT110 |
| _ |
| - B - |
| B-D Micro-Fine |
| B-D Micro-Fine 16 B-D Ultra Fine 16 B-D Ultra Fine II. 16 Bacillus Calmette-Guerin (BCG) vaccine 183 Bacillus Calmette-Guerin vaccine 300 Baclofen 118 Bactroban 65 Balance 27 |
| B-D Micro-Fine 16 B-D Ultra Fine 16 B-D Ultra Fine II. 16 Bacillus Calmette-Guerin (BCG) vaccine 183 Bacillus Calmette-Guerin vaccine 300 Baclofen 118 Bactroban 65 Balance 27 Barrier Creams and Emollients 69 |
| B-D Micro-Fine |
| B-D Micro-Fine |
| B-D Micro-Fine 16 B-D Ultra Fine 16 B-D Ultra Fine 16 Bacillus Calmette-Guerin (BCG) 183 Vaccine 183 Bacillus Calmette-Guerin 300 Baclofen 118 Bactroban 65 Balance 27 Barrier Creams and Emollients 69 BCG Vaccine AJV 300 Beclazone 100 258 Beclazone 250 258 |
| B-D Micro-Fine 16 B-D Ultra Fine 16 B-D Ultra Fine 16 Bacillus Calmette-Guerin (BCG) 183 vaccine 183 Bacillus Calmette-Guerin 300 Baclofen 118 Bactofen 118 Batroban 65 Balance 27 Barrier Creams and Emollients 69 BCG Vaccine AJV 300 Beclazone 100 258 Beclazone 250 258 Beclazone 50 258 |
| B-D Micro-Fine 16 B-D Ultra Fine 16 B-D Ultra Fine 16 Bacillus Calmette-Guerin (BCG) 183 vaccine 183 Bacillus Calmette-Guerin 300 Baclofen 118 Bactoban 65 Balance 27 Barrier Creams and Emollients 69 BCG Vaccine AJV 300 Beclazone 100 258 Beclazone 50 258 Beclazone 50 258 Beclazone 50 258 Beclazone 50 258 |
| B-D Micro-Fine 16 B-D Ultra Fine 16 B-D Ultra Fine 16 Bacillus Calmette-Guerin (BCG) 183 vaccine 183 Bacillus Calmette-Guerin 300 Baclofen 118 Bactoban 65 Balance 27 Barrier Creams and Emollients 69 BCG Vaccine AJV 300 Beclazone 100 258 Beclazone 50 258 Beclazone 50 258 Beclomethasone dipropionate 258 Bedaquiline 103 |
| B-D Micro-Fine 16 B-D Ultra Fine 16 B-D Ultra Fine 16 Bacillus Calmette-Guerin (BCG) 183 vaccine 183 Bacillus Calmette-Guerin 300 Baclofen 118 Bactroban 65 Balance 27 Barrier Creams and Emollients 69 BCG Vaccine AJV 300 Beclazone 100 258 Beclazone 50 258 Beclazone 50 258 Beclomethasone dipropionate 258 Bedaquiline 103 Bee venom allergy treatment 257 |
| B-D Micro-Fine 16 B-D Ultra Fine 16 B-D Ultra Fine 16 Bacillus Calmette-Guerin (BCG) 183 vaccine 183 Bacillus Calmette-Guerin 300 Baclofen 118 Bactroban 65 Balance 27 Barrier Creams and Emollients 69 BCG Vaccine AJV 300 Beclazone 100 258 Beclazone 50 258 Beclarone 50 258 Beclanuethyabaan |
| B-D Micro-Fine 16 B-D Ultra Fine 16 B-D Ultra Fine 16 Bacillus Calmette-Guerin (BCG) 183 vaccine 183 Bacillus Calmette-Guerin 300 Baclofen 118 Bactroban 65 Balance 27 Barrier Creams and Emollients 69 BCG Vaccine AJV 300 Beclazone 100 258 Beclazone 50 258 Beclarone 50 258 Beclarone 50 258 Beclayone 50 257 B |
| B-D Micro-Fine 16 B-D Ultra Fine 16 B-D Ultra Fine 16 Bacillus Calmette-Guerin (BCG) 183 vaccine 183 Bacillus Calmette-Guerin 300 Baclofen 118 Bactroban 65 Balance 27 Barrier Creams and Emollients 69 BCG Vaccine AJV 300 Beclazone 100 258 Beclazone 50 258 Beclazone 50 258 Bedaquiline 103 Bee venom allergy treatment 257 Bendamustine hydrochloride 150 Bendamustine Sandoz 150 Bendrofluazide 50 |
| B-D Micro-Fine 16 B-D Ultra Fine 16 B-D Ultra Fine 16 Bacillus Calmette-Guerin (BCG) vaccine vaccine 300 Bacillus Calmette-Guerin 300 Baclofen 118 Bactroban 65 Balance 27 Barrier Creams and Emollients 69 BCG Vaccine AJV 300 Beclazone 100 258 Beclazone 50 258 Beclazone 50 258 Beclamethasone dipropionate 257 Bendamustine hydrochloride 150 Bendamustine Sandoz 150 Bendrofluazide 50 |
| B-D Micro-Fine 16 B-D Ultra Fine 16 B-D Ultra Fine 16 Bacillus Calmette-Guerin (BCG) vaccine vaccine 300 Bacillus Calmette-Guerin 300 Baclofen 118 Bactroban 65 Balance 27 Barrier Creams and Emollients 69 BCG Vaccine AJV 300 Beclazone 100 258 Beclazone 50 258 Beclazone 50 258 Beclaquiline 103 Bee venom allergy treatment 257 Bendamustine Nydrochloride 150 Bendrofluazide 50 Bendrofluazide 50 |
| B-D Micro-Fine 16 B-D Ultra Fine 16 B-D Ultra Fine 16 Bacillus Calmette-Guerin (BCG) vaccine vaccine 183 Bacillus Calmette-Guerin vaccine vaccine 300 Baclofen 118 Bactroban 65 Balance 27 Barrier Creams and Emollients 69 BCG Vaccine AJV 300 Beclazone 100 258 Beclazone 250 258 Beclazone 50 258 Beclayone 50 258 Bedaquiline 103 Bee venom allergy treatment 257 Bendamustine Sandoz 150 Bendrofluazide 50 Bendroflumethiazide [Bendroflumethiazide [Bendroflumethiazide] 50 Benralizumab 199 |
| B-D Micro-Fine 16 B-D Ultra Fine 16 B-D Ultra Fine 16 Bacillus Calmette-Guerin (BCG) vaccine vaccine 183 Bacillus Calmette-Guerin vaccine vaccine 300 Baclofen 118 Bactroban 65 Balance 27 Barrier Creams and Emollients 69 BCG Vaccine AJV 300 Beclazone 100 258 Beclazone 250 258 Beclazone 50 258 Bedaquiline 103 Bee venom allergy treatment 257 Bendamustine Sandoz 150 Bendrofluazide 50 Bendrofluazide 50 Bendrofluazide 50 Bendrofluazide 50 Bendrofluazide 50 |
| B-D Micro-Fine 16 B-D Ultra Fine 16 B-D Ultra Fine 16 Bacillus Calmette-Guerin (BCG) vaccine vaccine 183 Bacillus Calmette-Guerin vaccine vaccine 300 Baclofen 118 Bactroban 65 Balance 27 Barrier Creams and Emollients 69 BCG Vaccine AJV 300 Beclazone 100 258 Beclazone 250 258 Beclazone 50 258 Beclayone 50 258 Bedaquiline 103 Bee venom allergy treatment 257 Bendamustine Sandoz 150 Bendrofluazide 50 Bendroflumethiazide [Bendroflumethiazide [Bendroflumethiazide] 50 Benralizumab 199 |

| Benztrop | . 121 |
|-------------------------------------|-------|
| Benzydamine hydrochloride | 30 |
| Benzylpenicillin sodium [Penicillin | |
| _ G] | 95 |
| Besponsa | |
| Beta Cream | 67 |
| Beta Ointment | |
| Beta Scalp | |
| Beta-Adrenoceptor Agonists | .259 |
| Beta-Adrenoceptor Blockers | 47 |
| Beta-hCG low sensitivity urine test | |
| kit | 79 |
| Betadine | 70 |
| Betadine Skin Prep | |
| Betaferon | |
| Betahistine dihydrochloride | .131 |
| Betaine | |
| Betamethasone dipropionate | 67 |
| Betamethasone dipropionate with | |
| calcipotriol | 71 |
| Betamethasone sodium phosphate | / 1 |
| with betamethasone acetate | 90 |
| Betamethasone valerate | |
| | |
| Betamethasone valerate with sodiur | II |
| fusidate [fusidic acid] | 68 |
| Betaxolol | .269 |
| Betnovate | 67 |
| Betoptic | .269 |
| Betoptic S | .269 |
| Bevacizumab | |
| Bexsero | |
| Bezafibrate | |
| Bezalip | 51 |
| Bezalip Retard | |
| Bicalutamide | .173 |
| Bicillin LA | 95 |
| BiCNU | . 151 |
| BiCNU S29 | . 151 |
| Bile and Liver Therapy | 10 |
| Biltricide | 92 |
| Bimatoprost | .270 |
| Binarex | .173 |
| Binocrit | |
| Biodone | .124 |
| Biodone Extra Forte | . 124 |
| Biodone Forte | . 124 |
| Bisacodyl | 24 |
| Bisacodyl Viatris | 24 |
| Bisoprolol fumarate | |
| BK Lotion | |
| Bleomycin sulphate | |
| Blood Colony-stimulating | |
| Factors | 42 |
| Blood glucose diagnostic test | 42 |
| meter | 15 |
| Blood glucose diagnostic test | IJ |
| Dioou gideose diagnostic test | |

| strip | 15 |
|--|---|
| Blood glucose test strips (visually | |
| impaired) | 15 |
| Blood Ketone Diagnostic Test | |
| Strip | 14 |
| Boostrix | .301 |
| Bortezomib | . 157 |
| Bosentan | 57 |
| Bosentan Dr Reddy's | 57 |
| Bplex | |
| Brentuximab Vedotin | .201 |
| Breo Ellipta | |
| Brevinor 1/28 | 77 |
| Breztri Aerosphere | .261 |
| Bricanyl Turbuhaler | .259 |
| Brimonidine tartrate | |
| Brimonidine tartrate with timolol | |
| maleate | 270 |
| Brinzolamide | |
| BSF Dasatinib-Teva | .272 |
| BSF Teriflunomide Sandoz | |
| Buccastem | |
| Budesonide | |
| Alimentary | 6 |
| Respiratory258 | |
| Budesonide Te Arai | 6 |
| Budesonide with eformoterol | .259 |
| Budesonide with glycopyrronium an | h |
| | |
| eformoterol | 261 |
| eformoterol | 261 |
| eformoterol | 261 49 |
| eformoterol Bumetanide Buprenorphine Naloxone BNM | 261 49 147 |
| eformoterol Bumetanide Buprenorphine Naloxone BNM Buprenorphine with naloxone | . 261 49 . 147 . 147 |
| eformoterol Burnetanide Buprenorphine Naloxone BNM Buprenorphine with naloxone Bupropion hydrochloride | .261 49 .147 .147 .147 |
| eformoterol Burnetanide Buprenorphine Naloxone BNM Buprenorphine with naloxone Bupropion hydrochloride Burel | . 261 49 .147 .147 .147 .147 .100 |
| eformoterol Burnetanide Buprenorphine Naloxone BNM Buprenorphine with naloxone Bupropion hydrochloride Burel Burel | . 261 49 .147 .147 .147 .147 .100 49 |
| eformoterol | . 261 49 .147 .147 .147 .147 .100 49 .137 |
| eformoterol | . 261 49 .147 .147 .147 .147 .147 .100 49 .137 .137 |
| eformoterol | .261 49 .147 .147 .147 .147 .147 .100 49 .137 .137 .151 |
| eformoterol | .261 49 .147 .147 .147 .147 .147 .100 49 .137 .137 .151 |
| eformoterol | . 261 49 .147 .147 .147 .147 .147 .147 .147 .137 .137 .151 |
| eformoterol | . 261 49 .147 .147 .147 .147 .147 .147 .147 .147 |
| eformoterol | . 261 49 .147 .147 .147 .147 .147 .147 .147 .147 |
| eformoterol | . 261 49 .147 .147 .147 .147 .147 .147 .147 .137 .137 .137 .151 90 .266 67 32 |
| eformoterol | . 261 49 .147 .147 .147 .147 .147 .147 .137 .137 .137 .151 90 .266 67 32 71 |
| eformoterol | . 261 49 .147 .147 .147 .100 49 .137 .137 .151 90 .266 67 32 71 81 |
| eformoterol | . 261 49 .147 .147 .147 .100 49 .137 .137 .137 .151 90 .266 67 32 71 81 32 |
| eformoterol | . 261 49 .147 .147 .147 .100 49 .137 .137 .137 .151 90 .266 67 71 81 81 32 32 |
| eformoterol | . 261 49 .147 .147 .147 .147 .147 .147 .147 .147 |
| eformoterol | . 2611 49 .147 .147 .147 .100 49 .137 .137 .151 90 .266 67 32 71 81 32 32 32 32 32 32 32 |
| eformoterol | . 261 49 .147 .147 .147 .100 49 .137 .137 .137 .151 90 .266 67 32 32 32 32 32 32 6 |
| eformoterol | 261 49 .147 .147 .147 .100 49 .137 .137 .151 90 .266 67 32 71 32 33 |
| eformoterol | 261 49 .147 .147 .147 .100 49 .137 .137 .151 90 .266 67 32 71 32 33 |
| eformoterol | 261 49 .147 .147 .147 .100 49 .137 .151 90 .266 67 71 32 71 32 32 32 32 6 6 64 63 64 63 64 |
| eformoterol | 261 49 .147 .147 .147 .100 49 .137 .151 90 .266 67 32 71 32 32 32 32 32 6 6 64 |

| Calcium Folinate Sandoz S291 | 54 |
|------------------------------------|----------------------|
| Calcium gluconate | |
| Calcium Homeostasis | |
| Calcium polystyrene sulphonate | 43 |
| Calcium Resonium | 43 |
| Calogen | 278 |
| Camber | 54 |
| Candesartan cilexetil | 45 |
| Candesartan cilexetil with | |
| hydrochlorothiazide | 45 |
| Candestar | 45 |
| Canesten | 66 |
| Capecitabine1 | 54 |
| Capecitabine Viatris1 | 54 |
| Capsaicin | |
| Musculoskeletal1 | 15 |
| Nervous1 | 22 |
| Captopril | 44 |
| Carafate | . 9 |
| Carbaccord1 | 51 |
| Carbamazepine1 | 28 |
| Carbimazole | 85 |
| Carbomer | |
| Carboplatin1 | 51 |
| Carboplatin Accord 1 | |
| Carbosorb-X | |
| Cardinol LA | 48 |
| Cardizem CD | 49 |
| CareSens Dual | 14 |
| CareSens N | 15 |
| CareSens N POP | 15 |
| CareSens N Premier | 15 |
| CareSens PRO | 15 |
| Carmellose sodium with gelatin and | |
| pectin | 30 |
| Carmustine 1 | 51 |
| Carnitor | |
| Carvedilol | |
| Carvedilol Sandoz | 47 |
| Casirivimab and imdevimab | |
| Catapres | 49 |
| Cefaclor monohydrate | 92 |
| Cefalexin | 92 |
| Cefalexin Sandoz | |
| Cefazolin | 92 |
| Cefazolin-AFT | |
| Ceftriaxone | |
| Ceftriaxone-AFT | |
| Cefuroxime axetil | |
| Celapram1 | |
| Celebrex | 14 |
| Celecoxib1 | |
| Coloopyih Dfizer | 14 |
| Celecoxib Pfizer | 14 14 |
| Celestone Chronodose | 14 14 82 |
| | 14 14 82 76 |

| Cephalexin ABM | 92 |
|---------------------------------|-----------------|
| Cerazette | 77 |
| Cetirizine hydrochloride | 257 |
| Cetomacrogol | |
| Cetomacrogol with glycerol | 69 |
| Cetomacrogol-AFT | 69 |
| Cetuximab | 00 2∩2 |
| Champix | 1/02 |
| Charcoal | 070 |
| CheckTop | 212 |
| Chemotherapeutic Agents | |
| Chemotherapeutic Agents | 150 |
| Chickenpox vaccine | |
| Chlorambucil | 151 |
| Chloramphenicol | 267 |
| Chlorothiazide | 50 |
| Chlorpromazine hydrochloride | 133 |
| Chlorsig | 267 |
| Chlortalidone [Chlorthalidone] | |
| Chlorthalidone | |
| Chlorvescent | 43 |
| Choice 380 7med Nsha Silver/cop | oper |
| Short | <mark>76</mark> |
| Ciclosporin | 252 |
| Cidomycin P/Free | <mark>97</mark> |
| Cilicaine VK | 96 |
| Cinacalcet | 81 |
| Cinacalet Devatis | |
| Ciprofloxacin | |
| Infection | 97 |
| Sensory | 267 |
| Ciprofloxacin Teva | 267 |
| Cisplatin | 151 |
| Cisplatin Accord | 151 |
| Cisplatin Ebewe | |
| Citalopram hydrobromide | 127 |
| Citrulline1000 | 294 |
| Cladribine | 154 |
| Clarithromycin | |
| Alimentary | g |
| Infection | 93 |
| Clexane | |
| Clexane Forte | |
| Clindamycin | |
| Clinicians | 25 32 |
| Clinicians Renal Vit | 30 |
| Clobazam | 128 |
| Clobetasol propionate | 67 73 |
| Clobetasone butvrate | |
| Clofazimine | |
| Clomazol | 103 |
| | 60 |
| Dermatological | 00 |
| Genito-Urinary | |
| Clomifene citrate | |
| Clomipramine hydrochloride | |
| Clonipramine Teva | 120 |
| Clonazepam 12 | .ơ, 13/ |

| Clonidine |
|------------------------------------|
| Clonidine hydrochloride |
| Clonidine Teva49 |
| Clopidogrel |
| Clopine |
| Clopixol135, 137 |
| Clotrimazole |
| Dermatological |
| Genito-Urinary78 |
| Clozapine133 |
| Clozaril133 |
| Clustran |
| Co-trimoxazole |
| Coal tar71 |
| Coal tar with allantoin, menthol, |
| phenol and sulphur 72 |
| Coal tar with salicylic acid and |
| sulphur |
| Cobal-B12 |
| Cobalin-H |
| Coco-Scalp72 |
| Codeine phosphate |
| Extemporaneous275 |
| Nervous |
| Coenzyme Q10 |
| Colchicine 118 |
| Colecalciferol |
| Colestyramine |
| Colestyramine - Mylan |
| Colgout |
| Colifoam |
| Colistin sulphomethate |
| Colistin-Link |
| Collodion flexible |
| Colloidal bismuth subcitrate |
| Colofac |
| Colomycin |
| Coloxyl |
| Combigan |
| Comirnaty Omicron (JN.1) |
| Compound electrolytes |
| Compound electrolytes with glucose |
| [Dextrose] |
| Compound hydroxybenzoate |
| Comtan |
| Concerta |
| Condoms |
| Condyline |
| Continuous glucose monitor |
| (interoperable) |
| Continuous glucose monitor |
| (standalone) |
| Contraceptives - Hormonal |
| Contraceptives - Non-hormonal |
| Copaxone |
| Cordarone-X |

| Corticosteroids and Related Agents | |
|------------------------------------|---|
| Conticosterolos ano metateo Agents | |
| for Systemic Use8 | 2 |
| Corticosteroids Topical6 | 7 |
| Cosentyx23 | С |
| Cosmegen 15 | 7 |
| Coumadin4 | 1 |
| Country Life2 | 8 |
| Coversyl4 | 4 |
| COVID-19 vaccine | С |
| Creon 100002 | |
| Creon 250002 | 2 |
| Creon Micro2 | 2 |
| Crizotinib16 | 5 |
| Crotamiton6 | 7 |
| Crystaderm6 | 5 |
| Cu 375 Standard7 | |
| Curam9 | |
| Curam Duo 500/1259 | 5 |
| Cvite | 1 |
| Cyclizine hydrochloride13 | 2 |
| Cyclizine lactate | 2 |
| Cyclogyl | C |
| Cyclonex15 | 2 |
| Cyclopentolate hydrochloride | c |
| Cyclophosphamide | 2 |
| Cyclorin10 | 3 |
| Cycloserine10 | 3 |
| Cyklokapron | R |
| Cyproterone acetate | 3 |
| Cyproterone acetate with | Č |
| ethinyloestradiol | R |
| Cystadane | 5 |
| Cytarabine | |
| Cytotec | |
| Cytoxan15 | 0 |
| - D - | - |
| D-Penamine11 | 5 |
| Dabigatran | 1 |
| Dacarbazine | 7 |
| Dactinomycin [Actinomycin D]15 | 7 |
| Daivobet | i |
| Daivonex | 1 |
| Daktarin | 7 |
| Dalacin C | 7 |
| Dantrium | ć |
| Dantrium S2911 | c |
| Dantrolene | c |
| Daonil | |
| Dapa-Tabs5 | |
| Dapsone | |
| Daraprim | |
| Darunavir | |
| Darunavir Viatris11 | n |
| Dasatinib | |
| Dasatinib-Teva | |
| Dasauriib-reva | |
| Daunorubicin15 | |

| David One Step Cassette Pregnancy |
|--------------------------------------|
| Test |
| DBL Acetylcysteine |
| DBL Adrenaline |
| DBL Aminophylline |
| DBL Bleomycin Sulfate156 |
| DBL Bortezomib157 |
| DBL Carboplatin 151 |
| DBL Carboplatin S29151 |
| DBL Cisplatin151 |
| DBL Dacarbazine |
| DBL Desferrioxamine Mesylate for Inj |
| BP |
| DBL Docetaxel |
| |
| DBL Ergometrine |
| DBL Gemcitabine |
| DBL Gentamicin97 |
| DBL Leucovorin Calcium 154 |
| DBL Methotrexate Onco-Vial156 |
| DBL Naloxone Hydrochloride272 |
| DBL Pethidine Hydrochloride 126 |
| DBL Vincristine Sulfate164 |
| Decozol |
| Deferasirox |
| Deferiprone273 |
| Deferoxamine Pfizer S29273 |
| Denosumab 115 |
| Deolate |
| Deoxycoformycin |
| Depo-Medrol |
| Depo-Provera |
| Depo-Testosterone |
| Deprim |
| |
| Dermol |
| |
| Desmopressin |
| Desmopressin acetate |
| Desmopressin-PH&T90 |
| Desogestrel |
| Detection of Substances in |
| Urine 80 |
| Dexamethasone |
| Hormone82 |
| Sensory268 |
| Dexamethasone phosphate82 |
| Dexamethasone with framycetin and |
| gramicidin 267 |
| Dexamethasone with neomycin |
| sulphate and polymyxin B |
| sulphate 268 |
| Dexamfetamine sulfate |
| Dexcom G6 |
| Dexcom G7 |
| Dexcom ONE+ |
| Dexmethsone |
| Dextrochlorpheniramine |
| |

| maleate257 |
|--|
| Dextrose |
| DHC Continus124 |
| Diabetes10 |
| Diabetes Management14 |
| Diacomit |
| Diagnostic Agents |
| Diamide Relief |
| Diamox |
| Diasip |
| Diazepam |
| Diazoxide |
| Dibenzyline |
| Diclofenac Devatis |
| Diclofenac Sandoz |
| Diclofenac sodium |
| Musculoskeletal |
| Sensory |
| Differin |
| Difflam |
| Diflucan |
| Digestives Including Enzymes |
| Digoxin |
| Dihydrocodeine tartrate |
| Dilantin |
| Dilantin Infatab |
| Dilantin Paediatric |
| Diltiazem CD Clinect |
| Diltiazem hydrochloride |
| Dimethicone |
| Dimethyl fumarate |
| |
| Dipentum 8 |
| Dipentum |
| Diphtheria, tetanus and pertussis |
| Diphtheria, tetanus and pertussis vaccine |
| Diphtheria, tetanus and pertussis vaccine |

| | - 262 |
|--|--|
| Dornase alfa | |
| Dortimopt | |
| Dorzolamide with timolol | |
| Dostinex | 90 |
| Dosulepin [Dothiepin] | |
| hydrochloride | 126 |
| Dosulepin Viatris | 126 |
| Dothiepin | |
| Dovato | |
| | |
| Doxazosin | |
| Doxazosin Clinect | |
| Doxine | 96 |
| Doxorubicin Ebewe | 157 |
| Doxorubicin hydrochloride | 157 |
| Doxycycline | 96 |
| DP Lotion | 69 |
| DP Lotn HC | 68 |
| DP-Captopril | |
| Dr Reddy's Omeprazole | ····· 44 0 |
| Drafata | 9 |
| Drofate | 48 |
| Drugs Affecting Bone | |
| Metabolism | |
| Dual blood glucose and blood keto | |
| diagnostic test meter | 14 |
| Dulaglutide | 12 |
| Dulcolax SP Drop | |
| Duocal Super Soluble Powder | 277 |
| Duolin | |
| | |
| | 080 |
| Duolin HFA | |
| DuoResp Spiromax | 259 |
| DuoResp Spiromax Duride | 259 53 |
| DuoResp Spiromax Duride Durvalumab | 259 53 |
| DuoResp Spiromax Duride Durvalumab - E - | 259 53 244 |
| DuoResp Spiromax Duride Durvalumab - E - e-chamber La Grande | 259 53 244 266 |
| DuoResp Spiromax Duride Durvalumab - E - | 259 53 244 266 |
| DuoResp Spiromax Duride Durvalumab e-chamber La Grande e-chamber Mask | 259 53 244 266 265 |
| DuoResp Spiromax Duride Durvalumab e-chamber La Grande e-chamber Mask e-chamber Turbo | 259 53 244 266 265 266 |
| DuoResp Spiromax Duride Durvalumab e-chamber La Grande e-chamber Mask e-chamber Turbo E-Mycin | 259 53 244 266 265 266 94 |
| DuoResp Spiromax Duride Durvalumab e-chamber La Grande e-chamber Mask e-chamber Turbo E-Mycin e5 Pharma | 259 23 244 266 265 94 10 |
| DuoResp Spiromax Duride Durvalumab e-chamber La Grande e-chamber Mask e-chamber Turbo E-Mycin e5 Pharma Ear Preparations | 259 244 266 265 266 94 10 267 |
| DuoResp Spiromax Duride Durvalumab e-chamber La Grande e-chamber Mask e-chamber Turbo E-Mycin e5 Pharma Ear Preparations Ear/Eye Preparations | 259 244 266 265 266 94 10 267 267 |
| DuoResp Spiromax Duride Durvalumab e-chamber La Grande e-chamber Mask e-chamber Turbo E-Mycin e5 Pharma Ear Preparations Ear/Eye Preparations Easiphen Liquid | 259 53 244 266 94 94 94 |
| DuoResp Spiromax Duride Durvalumab e-chamber La Grande e-chamber Mask e-chamber Turbo E-Mycin e5 Pharma Ear Preparations Ear/Eye Preparations Easiphen Liquid Econazole nitrate | 259 53 244 266 265 266 94 10 267 291 66 |
| DuoResp Spiromax Duride Durvalumab e-chamber La Grande e-chamber Mask e-chamber Turbo E-Mycin e5 Pharma Ear Preparations Ear/Eye Preparations Ear/Eye Preparations Easiphen Liquid Econazole nitrate Efavirenz | 259 244 266 265 266 94 10 267 267 291 66 109 |
| DuoResp Spiromax Duride Durvalumab e-chamber La Grande e-chamber Turbo E-Mycin e5 Pharma Ear Preparations Ear/Eye Preparations Easiphen Liquid Econazole nitrate Efavirenz Efavirenz Milpharm | 259 244 266 265 266 94 10 267 267 291 66 109 |
| DuoResp Spiromax Duride Durvalumab - E - e-chamber La Grande e-chamber Turbo E-Mycin e5 Pharma Ear Preparations Ear/Eye Preparations Easiphen Liquid Econazole nitrate Efavirenz Efavirenz Milpharm Efavirenz with emtricitabine and | 259 244 266 265 266 94 10 267 291 66 109 109 |
| DuoResp Spiromax Duride Durvalumab | 259 53 244 266 94 94 10 267 267 291 66 109 109 110 |
| DuoResp Spiromax Duride Durvalumab - E - e-chamber La Grande e-chamber Turbo E-Mycin e5 Pharma Ear Preparations Ear/Eye Preparations Easiphen Liquid Econazole nitrate Efavirenz Efavirenz Milpharm Efavirenz with emtricitabine and | 259 53 244 266 94 94 10 267 267 291 66 109 109 110 |
| DuoResp Spiromax Duride Durvalumab | 259 53 244 266 265 265 265 265 267 267 267 267 267 291 66 109 109 109 109 258 |
| DuoResp Spiromax Duride Durvalumab | 259 53 244 266 265 265 266 94 10 267 267 267 267 109 109 109 109 109 |
| DuoResp Spiromax Duride Durvalumab | 259 53 244 266 265 265 266 94 10 267 267 267 267 201 109 109 109 258 36 |
| DuoResp Spiromax Duride | 259 53 244 266 265 265 266 94 10 267 267 267 267 291 109 109 109 258 36 73 |
| DuoResp Spiromax Duride | 259 53 244 266 265 265 245 267 267 267 267 267 267 267 267 267 109 109 109 258 36 373 272 |
| DuoResp Spiromax Duride | 259 53 244 266 265 265 265 267 267 267 201 109 109 109 110 258 36 73 272 262 |
| DuoResp Spiromax Duride Durvalumab | 259 53 264 265 265 265 265 265 266 267 267 267 291 66 109 267 291 267 30 272 28 28 28 267 267 267 267 271 267 271 267 271 271 271 27 271 271 27 |
| DuoResp Spiromax Duride | 259 53 264 265 265 265 267 267 267 267 267 267 267 267 267 267 |
| DuoResp Spiromax Duride Durvalumab | 259 53 264 265 265 265 267 267 267 267 267 267 267 267 267 267 |

| Elemental 028 Extra | . 282 |
|--|-------|
| Elexacaftor with tezacaftor, ivacaftor | |
| and ivacaftor | 264 |
| Elidel | 72 |
| Elocon | 60 |
| | |
| Elocon Alcohol Free | 68 |
| Eltrombopag | 36 |
| Eltroxin | 85 |
| EMB Fatol | . 104 |
| Emend Tri-Pack | |
| Emicizumab | |
| | |
| EMLA | |
| Empagliflozin | 13 |
| Empagliflozin with metformin | |
| hydrochloride | 14 |
| Emsogen | .294 |
| Emtricitabine | 110 |
| Emtricitabine with tenofovir | |
| disoproxil | 407 |
| disoproxii | 107 |
| Emtriva | . 110 |
| Emulsifying ointment | 69 |
| Emulsifying Ointment ADE | 69 |
| Enalapril maleate | 44 |
| Enbrel | 176 |
| Endocrine Therapy | 170 |
| | . 172 |
| Endoxan | . 152 |
| Energivit | .294 |
| Engerix-B | . 304 |
| Enhertu | .238 |
| Enlafax XR | .127 |
| Enoxaparin sodium | |
| Enstilar | |
| | |
| Ensure | |
| Ensure Plus | |
| Ensure Plus HN | .285 |
| Ensure Plus HN RTH | . 285 |
| Ensure Two Cal HN RTH | .288 |
| Entacapone | 120 |
| Entacapone Viatris | |
| Entecavir | |
| | 105 |
| Entecavir (Rex) | . 105 |
| Entresto 24/26 | |
| Entresto 49/51 | 45 |
| Entresto 97/103 | 45 |
| Entyvio | |
| Epilim | 130 |
| Epilim Crushable | 130 |
| | |
| Epilim IV | . 130 |
| Epilim S/F Liquid | . 130 |
| Epilim Syrup | . 130 |
| Epipen | .256 |
| Epipen Jr | .256 |
| Epirubicin Ebewe | 157 |
| Epirubicin hydrochloride | 157 |
| Eplerenone | |
| | |
| Epoetin alfa | 35 |

| Epoprostenol | 60 |
|---|----------|
| Eptacog alfa [Recombinant factor VIIa] | |
| Erbitux | |
| Ergometrine maleate | |
| Erlotinib | |
| Erythrocin IV | |
| Erythromycin (as lactobionate) | |
| Erythromycin ethyl succinate | 94 |
| Esbriet | |
| Escitalopram | |
| Escitalopram (Ethics) | 107 |
| Eskazole | |
| Essential Amino Acid Mix | |
| Essential Ethosuximide | |
| Estraderm MX | |
| Estradiol Sandoz | |
| Estradiol TDP Mylan | |
| Estradiol Viatris | 04 01 |
| Estradot | |
| Estrator | |
| Estrogel | |
| | |
| Etanercept Ethambutol hydrochloride | 104 |
| | |
| Ethics Aspirin | 122 |
| Ethics Aspirin EC | |
| Ethics Lisinopril Ethinyloestradiol with | 44 |
| desogestrel | 70 |
| Cesogestredial with | /0 |
| Ethinyloestradiol with | |
| levonorgestrel | / / |
| Ethinyloestradiol with | |
| norethisterone | |
| Ethosuximide | 128 |
| Etopophos | |
| Etoposide | 15/ |
| Etoposide phosphate | |
| Etravirine | |
| Eumovate | |
| Eurofolic | |
| Evara | 69 |
| EVARA White Soft Paraffin | |
| Everet | 129 |
| | |
| Evista | 116 |
| Evrysdi | 142 |
| Exelon Patch 10 | |
| Exelon Patch 5 | |
| Exemestane | |
| Exjade | 272 |
| Extemporaneously Compounded | |
| Preparations and | 0 |
| Galenicals | |
| Eye Preparations | 267 |
| Eylea | 198 |
| Ezemibe Viatris | 53 |

| Ezetimibe | 53 |
|--|---|
| Ezetimibe Sandoz | 53 |
| Ezetimibe with simvastatin | 53 |
| | |
| Factor eight inhibitor bypassing | |
| fraction | 38 |
| Famotidine | 00 |
| Famotidine Hovid | |
| Fasenra | |
| Faslodex | |
| Fatty Emulsion Cream (Evara) | . 173 |
| Febuxostat | |
| Febuxostat (Teva) | . 110 |
| | |
| FEIBA NF | |
| Felo 10 ER | |
| Felo 5 ER | |
| Felodipine | |
| Fentanyl | . 124 |
| Fentanyl Sandoz | . 124 |
| Ferinject | |
| Ferodan | |
| Ferriprox | 273 |
| Ferro-F-Tabs | |
| Ferro-Liquid | |
| Ferro-tab | |
| Ferrograd | 33 |
| Ferrosig | 34 |
| Ferrous fumarate | 33 |
| | |
| Ferrous fumarate with folic acid | |
| | 33 |
| Ferrous fumarate with folic acid | 33 33 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexaclear | 33 33 257 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexaclear Fexofenadine hydrochloride | 33 33 257 257 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexaclear Fexofenadine hydrochloride Fibro-vein | 33 33 257 257 38 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexaclear Fexofenadine hydrochloride Fibro-vein Filgrastim | 33 257 257 38 42 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexaclear Fexofenadine hydrochloride Fibro-vein Filgrastim Finasteride | 33 257 257 38 42 79 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexaclear Fexofenadine hydrochloride Fibro-vein Filgrastim Finasteride Fingolimod | 33 257 257 38 42 79 138 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexaclear Fexofenadine hydrochloride Fibro-vein Filgrastim Finasteride Fingolimod Firazyr | 33 257 257 38 42 79 138 256 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexofenadine hydrochloride Fibro-vein Filgrastim Finasteride Fingolimod Firazyr Flagyl | 33 257 257 38 42 79 138 256 103 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexofenadine hydrochloride Fibro-vein Filgrastim Finasteride Fingolimod Firazyr Flagyl Flagyl-S | 33 257 257 38 42 79 138 256 103 103 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexofenadine hydrochloride Fibro-vein Filgrastim Fingolimod Fingolimod Firazyr Flagyl Flagyl Flagyl.S Flamazine | 33 257 257 38 42 79 138 256 103 103 66 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexofenadine hydrochloride Fibro-vein Filgrastim Fingolimod Fingolimod Firazyr Flagyl Flagyl.S Flamazine Flecainide acetate | 33 257 257 38 42 79 138 256 103 103 66 46 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexofenadine hydrochloride Fibro-vein. Filgrastim Finasteride Fingolimod Firazyr FlagyI.S FlagyI.S Flamazine Flecainide acetate Flecainide BNM | 33 257 257 38 42 79 138 256 103 103 66 46 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexofenadine hydrochloride Fibro-vein Filgrastim Finasteride Fingolimod Firazyr Flagyl Flagyl Flamazine Flecainide acetate Flecainide BNM Flecainide Controlled Release | 33 257 257 38 42 79 138 256 103 103 66 46 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexofenadine hydrochloride Fibro-vein. Filgrastim Finasteride Fingolimod Firazyr Flagyl Flagyl.S Flamazine Flecainide acetate Flecainide BNM Flecainide Controlled Release Teva | 33 257 257 38 42 79 138 256 103 103 66 46 46 46 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexofenadine hydrochloride Fibro-vein Filgrastim Finasteride Fingolimod Firazyr Flagyl Flagyl Flagyl.S Flamazine Flecanide acetate Flecanide BNM Flecanide Controlled Release Teva Fleet Phosphate Enema | 33 257 257 38 42 79 138 256 103 103 46 46 46 46 46 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexofenadine hydrochloride Fibro-vein Filgrastim Finasteride Fingolimod Firazyr Flagyl Flagyl Flagyl.S Flamazine Flecainide acetate Flecainide BNM Flecainide Controlled Release Teva Fleet Phosphate Enema Flixonase Hayfever & Allergy | 33 257 257 257 38 42 79 138 256 103 103 46 46 46 46 24 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexofenadine hydrochloride Fibro-vein Filgrastim Finasteride Fingolimod Firazyr FlagyI FlagyI.S Flamazine Flecainide acetate Flecainide BNM Flecainide BNM Flecainide BNM Flecainide Controlled Release Teva Fleet Phosphate Enema Flixonase Hayfever & Allergy Flixotide | 33 257 257 257 38 42 79 138 256 46 46 46 46 46 42 425 258 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexofenadine hydrochloride Fibro-vein Filgrastim Finasteride Finasteride Finasteride Finasteride Filgrazyr Flagyl Flagyl Flagyl Flagyl Flecainide acetate Flecainide acetate Flecainide BNM Flecainide Controlled Release Teva Fleet Phosphate Enema Flixonase Hayfever & Allergy Flixotide Flixotide Accuhaler | 33 257 257 38 42 79 138 256 103 46 46 46 46 46 245 258 258 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexaclear Fexofenadine hydrochloride Filgrastim Finasteride Finasteride Finasteride Finagyl Flagyl Flagyl Flagyl Flagyl Flamazine Flecainide acetate Flecainide BNM Flecainide BNM Flecainide BNM Flecainide BNM Flecainide BNM Flecainide BNM Flecainide BNM Flecainide Controlled Release Teva Flet Phosphate Enema Flixonase Hayfever & Allergy Flixotide Flixotide Accuhaler Florinef | 33 257 257 38 42 79 138 256 103 66 46 46 46 46 245 258 258 258 258 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexofenadine hydrochloride Fibro-vein Filgrastim Finasteride Finagylioned Firazyr Flagyl Flagyl Flagyl Flamazine Flecainide acetate Flecainide BNM Flecainide BNM Flecainide BNM Flecainide Controlled Release Teva Flete Phosphate Enema Flixotide Accuhaler Flixotide Accuhaler Florinef Fluanxol | 33 257 257 257 38 42 79 138 256 103 66 46 46 46 46 46 265 258 258 258 258 258 258 258 258 258 258 258 258 258 258 258 258 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexofenadine hydrochloride Fibro-vein. Filgrastim. Finasteride Fingolimod Firazyr. Flagyl. Flagyl. Flagyl. Flagyl. Flamazine Flecainide acetate Flecainide acetate Flecainide BNM. Flecainide Controlled Release Teva. Flete Phosphate Enema Flixonase Hayfever & Allergy Flixotide Accuhaler Florinef Fluanxol. Flucil. | 33 33 257 257 38 42 79 38 256 103 46 46 46 46 46 46 46 258 258 258 258 258 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexofenadine hydrochloride Fibro-vein Filgrastim Fingolimod Fingolimod Firazyr Flagyl Flagyl Flayl.S Flamazine Flecainide acetate Flecainide BNM Flecainide Controlled Release Teva Fleat Phosphate Enema Fleixonase Hayfever & Allergy Flixotide Flixotide Accuhaler Florinef Fluanxol Fluci Fluci | 33 257 257 38 42 79 138 256 103 46 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexofenadine hydrochloride Fibro-vein Filgrastim Finasteride Finagolimod Firazyr Flagyl Flagyl Flagyl Flecainide acetate Flecainide BNM Flecainide BNM Flecainide Controlled Release Teva Fleet Phosphate Enema Fleixonase Hayfever & Allergy Flixotide Accuhaler Florinef Fluanxol Flucloxacillin Flucloxacillin | 33 33 257 257 38 42 79 138 256 103 66 46 46 46 46 46 258 258 258 258 96 96 96 96 96 |
| Ferrous fumarate with folic acid Ferrous sulfate Fexofenadine hydrochloride Fibro-vein Filgrastim Finasteride Finagolimod Firazyr Flagyl Flagyl Flagyl Flecainide acetate Flecainide acetate Flecainide BNM Flecainide Controlled Release Teva Fleet Phosphate Enema Fleixonase Hayfever & Allergy Flixotide Accuhaler Florinef Fluanxol Flucloxacillin Flucloxacillin Flucloxacillin | |
| Ferrous fumarate with folic acid Ferrous sulfate Fexofenadine hydrochloride Fibro-vein Filgrastim Finasteride Finagolimod Firazyr Flagyl Flagyl Flagyl Flecainide acetate Flecainide BNM Flecainide BNM Flecainide Controlled Release Teva Fleet Phosphate Enema Fleixonase Hayfever & Allergy Flixotide Accuhaler Florinef Fluanxol Flucloxacillin Flucloxacillin | |

| Fludara Oral | 155 |
|-----------------------------|------------|
| Fludarabine Ebewe | 155 |
| Fludarabine phosphate | 155 |
| Fludarabine Sagent | |
| Fludrocortisone acetate | |
| Fluids and Electrolytes | |
| Flumetasone pivalate | |
| Fluocortolone caproate with | |
| fluocortolone pivalate and | |
| cinchocaine | |
| Fluorometholone | 269 |
| Fluorouracil | 155 |
| Fluorouracil Accord | 155 |
| Fluorouracil sodium | 73 |
| Fluox | 127 |
| Fluoxetine hydrochloride | |
| Flupenthixol decanoate | 135 |
| Flutamide | 173 |
| Flutamin | 170 |
| Fluticasone | 170 0E0 |
| Fluticasone furoate with | 200 |
| umeclidinium and vilanterol | 061 |
| Fluticasone furoate with | 201 |
| vilanterol | 050 |
| Fluticasone propionate | |
| Fluticasone propionale | 200 |
| Fluticasone with salmeterol | |
| Flynn | |
| FML | |
| Foban | |
| Folic acid | |
| Folic Acid multichem | |
| Folic Acid Viatris | 30 |
| Food Thickeners | 288 |
| Foods And Supplements For | |
| Inherited Metabolic Disease | |
| Fortini | 281 |
| Fortini Multi Fibre | 281 |
| Fortisip | 286 |
| Fortisip Multi Fibre | 287 |
| Fosamax | 115 |
| Fosamax Plus | 115 |
| Fosfomycin | 113 |
| Framycetin sulphate | |
| Freestyle Libre 2 | 21 |
| Freestyle Libre 3 Plus | |
| Frisium | |
| Frumil | |
| Frusemide | |
| Fucicort | |
| Fucidin | |
| Fucithalmic | 267 |
| Fucithalmic S29 | 267 |
| Fulvestrant | 173 |
| Fungilin | 30 |
| Furosemide [Frusemide] | 49 |
| Furosemide-Baxter | |

fusidic acid

| fusidic acid |
|------------------------------------|
| Dermatological66, 68 |
| Infection |
| Sensory267 |
| - G - |
| GA Explore 5 |
| GA1 Anamix Infant |
| |
| GA1 Anamix Junior293 |
| Gabapentin128 |
| Gacet123–124 |
| Galsulfase26 |
| Galvumet12 |
| Galvus12 |
| Gardasil 9 |
| |
| Gastrodenol |
| Gaviscon Extra Strength6 |
| Gaviscon Infant6 |
| Gazyva213 |
| Gefitinib 166 |
| Gemcitabine Ebewe 155 |
| Gemcitabine hydrochloride155 |
| Gemtuzumab ozogamicin |
| |
| Gentamicin Amdipharm |
| Gentamicin Noridem |
| Gentamicin sulphate97 |
| Gilenya 138 |
| Ginet78 |
| Glatiramer acetate 138 |
| Glecaprevir with pibrentasvir 107 |
| Glibenclamide11 |
| Gliclazide |
| Glipizide11 |
| |
| Glizide11 |
| Glucagen Hypokit 10 |
| Glucagon hydrochloride10 |
| Glucerna Select |
| Glucose [Dextrose]42 |
| Gluten Free Foods |
| Glycerin with sodium saccharin 275 |
| Glycerin with sucrose |
| Glycerol |
| |
| Alimentary24 |
| Extemporaneous275 |
| Glyceryl trinitrate |
| Alimentary8 |
| Cardiovascular53 |
| Glycopyrronium |
| Glycopyrronium bromide |
| Glycopyrronium with |
| |
| indacaterol |
| Glycosade |
| Glytactin Bettermilk |
| Gold Knight75 |
| |
| Gold Knight XL75 |
| Goserelin |
| Gold Knight XL |

| - H - | |
|--------------------------------------|------------|
| Habitrol | 148 |
| Haemophilus influenzae type B | |
| vaccine | 303 |
| Haldol | 135 |
| Haldol Concentrate | 135 |
| Haldol Decanoas | |
| Haloperidol | 133 |
| Haloperidol decanoate | 135 |
| Harvoni | 107 |
| Havrix 1440 | 303 |
| Havrix Junior | 303 |
| Haylor syrup | |
| HCU Anamix Infant | 290 |
| HCU Anamix Junior | 290 |
| HCU Anamix Junior LQ | 290 |
| HCU Explore 5 | |
| HCU Express 15 | |
| HCU Lophlex LQ | 290 |
| healthE Calamine Aqueous | 67 |
| healthE Dimethicone 10% | 60 |
| healthE Dimethicone 4% Lotion | .00 |
| healthE Dimethicone 5% | |
| healthE Glycerol BP | .03 075 |
| healthE Urea Cream | 60 |
| Healtheries Simple Baking Mix | .09 000 |
| Hemastix | 002 ۵۸ |
| | |
| Hemlibra | |
| Heparin sodium | .41 |
| Heparin Sodium Panpharma | .41 |
| Heparinised saline | .41 |
| Heparon Junior | |
| Hepatitis A vaccine | 303 |
| Hepatitis B recombinant | |
| vaccine | |
| Herzuma | |
| Hikma | |
| Hikma Acetylcysteine | 272 |
| Hiprex | |
| Histaclear | |
| Holoxan | |
| Horleys Bread Mix | 289 |
| Horleys Flour | 289 |
| Hormone Replacement Therapy - | |
| Systemic | |
| HPV | |
| Humalog | .11 |
| Humalog Mix 25 | .11 |
| Humalog Mix 50 | |
| Human papillomavirus (6, 11, 16, 18, | |
| 31, 33, 45, 52 and 58) vaccine | |
| [HPV] | 305 |
| Humatin | |
| Humira | |
| HumiraPen | |
| Humulin 30/70 | |
| | |

| Humulin NPH1 | |
|------------------------------------|-----------|
| | |
| Humulin R1 | |
| Hyaluronic acid27 | 71 |
| Hydralazine | 54 |
| Hydralazine hydrochloride | |
| Hydralyte - Lemonade4 | 10 |
| | ĸ |
| Hydrocortisone | |
| Dermatological6 | |
| Hormone | 32 |
| Hydrocortisone acetate | 7 |
| Hydrocortisone acetate with | |
| pramoxine hydrochloride | - |
| Ludrocorticopo and paroffin liquid | ' |
| Hydrocortisone and paraffin liquid | |
| and lanolin6 | |
| Hydrocortisone butyrate 68, 7 | |
| Hydrocortisone with cinchocaine | 8 |
| Hydrocortisone with miconazole | 36 |
| Hydrocortisone with natamycin and | |
| neomycin6 | 20 |
| Hydrogen peroxide6 | 20 |
| Hydrogen peroxide | 20 |
| Hydroxocobalamin | |
| Hydroxocobalamin Panpharma | |
| hydroxycarbamide15 | 57 |
| Hydroxychloroquine sulphate11 | 15 |
| Hydroxyurea | |
| [hydroxycarbamide] 15 | 57 |
| Hygroton | |
| Hylo-Fresh | |
| Hymenoptera | |
| | |
| Hyoscine butylbromide | 5 |
| Hyoscine Butylbromide | |
| (Adiramedica) | 8 |
| Hyoscine hydrobromide13 | 32 |
| Hyperuricaemia and Antigout11 | 17 |
| Hypromellose27 | 7(|
| Hypromellose with dextran | 71 |
| -I- | ľ |
| Ibiamox | 16 |
| | |
| Ibrance16 | <u>کر</u> |
| Ibrutinib15 |) / |
| Ibuprofen 11 | 2 |
| Ibuprofen SR BNM 11 | 4 |
| Icatibant | 56 |
| Idarubicin hydrochloride15 | 58 |
| Idursulfase | PF |
| Ifosfamide15 | |
| llevro | 20 |
| |) C |
| lloprost6 | |
| Imatinib mesilate16 | |
| Imatinib-Rex 16 | |
| Imbruvica15 | |
| Imfinzi24 | 4 |
| Imipramine Crescent12 | |
| Imipramine hydrochloride | |
| Imiguimod | |
| Immune Modulators11 | |
| | 1 |

| INDEX: Generic Ch | emicals and | d Brands |
|-------------------|-------------|----------|
|-------------------|-------------|----------|

| Immunisation - Flu272 |
|------------------------------------|
| Immunisation Flu and Shingles 272 |
| Immunisation Other |
| Immunosuppressants 176 |
| Incruse Ellipta |
| Indacaterol |
| Indapamide |
| Infanrix IPV |
| Infanrix-hexa |
| Infant Formulae |
| Infatrini |
| |
| Infliximab |
| Influenza vaccine |
| Influvac Tetra |
| (2025 formulation) 306 |
| Inhaled Corticosteroids258 |
| Inhaled Long-acting |
| Beta-adrenoceptor Agonists 258 |
| Inlyta164 |
| Inotuzumab ozogamicin212 |
| Inresa |
| Inspra50 |
| Instillagel Lido121 |
| Insulin aspart11 |
| Insulin aspart with insulin aspart |
| protamine 10 |
| Insulin glargine11 |
| Insulin glatgine |
| Insulin glulisine |
| Insulin isophane10 |
| Insulin isophane with insulin |
| neutral 11 |
| Insulin lispro11 |
| Insulin lispro with insulin lispro |
| protamine11 |
| Insulin neutral 10 |
| Insulin pen needles16 |
| Insulin pump cartridge17 |
| Insulin pump infusion set (steel |
| cannula) |
| Insulin pump infusion set (steel |
| cannula, straight insertion) |
| Insulin pump infusion set (teflon |
| cannula) 19 |
| |
| Insulin pump infusion set (teflon |
| cannula, angle insertion with |
| insertion device) 20 |
| Insulin pump infusion set (teflon |
| cannula, flexible insertion with |
| insertion device) 20 |
| Insulin pump infusion set (teflon |
| cannula, straight insertion with |
| insertion device) 20 |
| Insulin pump infusion set (teflon |
| cannula, variable insertion) |
| Insulin pump reservoir |
| Insulin pump with algorithm |
| ··· |

| Insulin syringes, disposable with |
|-----------------------------------|
| attached needle 16 |
| Intelence 109 |
| Interferon beta-1-alpha138 |
| Interferon beta-1-beta138 |
| Intra-uterine device76 |
| Invega Sustenna |
| Invega Trinza |
| Ipca-Allopurinol |
| Ipca-Bisoprolol |
| Ipca-Ciprofloxacin |
| ipca-Ciprolioxacin |
| Ipca-Donepezil146 |
| Ipca-Escitalopram127 |
| IPCA-Frusemide49 |
| Ipca-Hydroxychloroquine115 |
| IPCA-Metoprolol47 |
| IPCA-Propranolol48 |
| Ipilimumab244 |
| IPOL |
| Ipratropium bromide260, 265 |
| Iressa |
| Irinotecan Actavis 100 155 |
| Irinotecan hydrochloride155 |
| Irinotecan-Rex 155 |
| Iron (as ferric carboxymaltose) |
| Iron polymaltose |
| Isentress111 |
| Isentress HD111 |
| Ismo 20 |
| Ismo 40 Retard53 |
| Isoleucine50 |
| Isoniazid |
| Isoniazid Teva |
| Isoniazid with rifampicin104 |
| |
| Isoptin |
| Isoptin Retard |
| Isoptin SR |
| Isopto Carpine |
| Isosorbide mononitrate53 |
| Isosource Standard |
| Isotretinoin65 |
| Ispaghula (psyllium) husk23 |
| Itch-Soothe67 |
| Itracap100 |
| Itraconazole100 |
| Itraconazole Kent100 |
| Itrazole100 |
| lvacaftor |
| Ivermectin70 |
| - J - |
| Jadelle |
| Jakavi |
| Jardiamet14 |
| Jardiance |
| Jaydess |
| Jevity HiCal RTH |
| |

| Jevity Plus RTH | |
|-------------------------------|-----|
| Jevity RTH | 286 |
| Jinarc | .51 |
| Juno Pemetrexed | 156 |
| - K - | |
| Kadcyla | 238 |
| Kalydeco | 264 |
| Kemadrin | 121 |
| Kenacomb | |
| Kenacort-A 10 | |
| Kenacort-A 40 | |
| Kenalog in Orabase | .30 |
| Ketocal 3:1 | 299 |
| KetoCal 4:1 | 299 |
| Ketoconazole | |
| Dermatological | .73 |
| Infection | 100 |
| Ketogenic Diet | 299 |
| Ketoprofen | 114 |
| KetoSens | 14 |
| Keytruda | 247 |
| Kindergen | 280 |
| Kisqali | 170 |
| Klacid | |
| Alimentary | q |
| Infection | |
| Klaricid | |
| Kliogest | |
| Kliovance | .85 |
| Kogenate FS | |
| Konakion MM | .39 |
| Konsyl-D | |
| Kuvan | |
| -L- | |
| Labetalol | .47 |
| Lacosamide | 128 |
| Lactulose | .24 |
| Laevolac | .24 |
| Lamictal | 129 |
| Lamivudine 105, | 110 |
| Lamivudine Viatris | 110 |
| Lamivudine/Zidovudine Viatris | |
| Lamotrigine | 129 |
| Lamprene | 103 |
| Lanoxin | |
| Lanoxin PG | |
| Lanoxin S29 | .46 |
| Lanreotide | 175 |
| Lansoprazole | 9 |
| Lantus | .11 |
| Lantus SoloStar | |
| Lanvis | 156 |
| Lanzol Relief | 9 |
| Largactil | |
| Laronidase | |
| Lasix | .49 |

| L otomomroot | 070 |
|-------------------------------|-----|
| Latanoprost2 | 270 |
| Latanoprost with timolol | |
| Lax-Suppositories | 24 |
| Lax-suppositories Glycerol | 24 |
| Laxatives | |
| | |
| Laxsol | |
| Ledipasvir with sofosbuvir1 | 07 |
| Leflunomide 1 | 15 |
| Lenalidomide (Viatris)1 | 158 |
| Lenalidomide Viatris | 100 |
| | |
| Lenvatinib1 | |
| Lenvima 1 | 66 |
| Letrole1 | 76 |
| Letrozole1 | |
| Leucine100 | |
| Leukeran FC1 | |
| | 101 |
| Leukotriene Receptor | |
| Antagonists | 263 |
| Leuprorelin | 90 |
| Leustatin1 | 154 |
| Levetiracetam1 | |
| Levetiracetam-AFT1 | 129 |
| | |
| Levocabastine2 | |
| Levocarnitine | .27 |
| Levodopa with benserazide1 | 20 |
| Levodopa with carbidopa1 | 20 |
| Levodopa with carbidopa and | 20 |
| | |
| entacapone | 120 |
| Levomepromazine | 33 |
| Levomepromazine | |
| hydrochloride 1 | 34 |
| Levonorgestrel | |
| Genito-Urinary | 70 |
| | |
| Hormone | 85 |
| Levonorgestrel BNM | 78 |
| Levothyroxine | 85 |
| Lidocaine [Lignocaine] 121-1 | 22 |
| Lidocaine [Lignocaine] | |
| hydrochloride 1 | 00 |
| | 22 |
| Lidocaine [Lignocaine] with | |
| prilocaine 1 | |
| Lidocaine-Baxter1 | 22 |
| Life Extension | 29 |
| Lignocaine | |
| | |
| Linezolid1 | |
| Lioresal Intrathecal 1 | |
| Lipid-Modifying Agents | 51 |
| Lipitor | |
| Liquigen | |
| Liraglutide | |
| | 12 |
| Lisdexamfetamine dimesilate 1 | |
| Lisinopril | .44 |
| Lithium carbonate1 | 34 |
| Livostin | |
| LMX4 1 | |
| Lo-Oralcon 20 ED | 77 |
| LU-UIAILUII ZU ED | 11 |

| | _ |
|----------------------------------|---|
| Locacorten-Viaform ED's26 | 7 |
| Local preparations for Anal and | |
| Rectal Disorders | |
| Locasol29 | |
| Locoid | |
| Locoid Crelo6 | |
| Locoid Lipocream6 | |
| Locorten-Vioform | |
| Lodoxamide26 | 9 |
| Logem12 | |
| Lomide26 | |
| Lomustine15 | |
| Loniten5 | |
| Loperamide hydrochloride | |
| Lopinavir with ritonavir11 | |
| Lopinavir/Ritonavir Mylan11 | 0 |
| Loprofin | 3 |
| Loprofin Mix29 | |
| Lorafix | |
| Loratadine25 | |
| Lorazepam13 | |
| Lorstat | |
| Losartan Actavis | |
| Losartan potassium | 5 |
| Losartan potassium with | _ |
| hydrochlorothiazide 4 | |
| Lovir | |
| Loxamine | |
| Lucrin Depot 1-month | |
| Lucrin Depot 3-month | 0 |
| | |
| Lumigan27 Lyllana | 4 |
| | |
| Lynparza16 | |
| Lyrica 12 - M - | 9 |
| m-Eslon | 5 |
| Mabthera | |
| Macrobid11 | |
| Macrogol 3350 with potassium | Č |
| chloride, sodium bicarbonate and | |
| sodium chloride2 | 4 |
| Madopar 125 12 | |
| Madopar 250 12 | 0 |
| Madopar 62.5 12 | |
| Madopar HBS 12 | |
| Madopar Rapid 12 | 0 |
| Magnesium hydroxide3 | |
| Magnesium sulphate3 | |
| Mantoux | |
| MAR-Midodrine4 | |
| Marevan4 | 1 |
| Marine Blue Lotion SPF 50+7 | 3 |
| Martindale Pharma27 | 2 |
| Mask for spacer device26 | 5 |
| Maviret | 7 |

| Maxidex | .268 |
|-----------------------------------|-------|
| Maxitrol | |
| MCT oil (Nutricia) | .278 |
| Measles, mumps and rubella | |
| vaccine | 308 |
| Mebendazole | |
| Mebeverine hydrochloride | 8 |
| Medac | |
| Medrol | |
| Medroxyprogesterone acetate | 02 |
| Genito-Urinary | 77 |
| Hormone | |
| Mefenamic acid | |
| Megval | 150 |
| Melatonin | |
| | |
| Melpha | 152 |
| Melphalan | . 152 |
| Meningococcal (groups A, C, Y and | |
| W-135) conjugate vaccine | 309 |
| Meningococcal B multicomponent | |
| vaccine | |
| MenQuadfi | |
| Menthol | |
| Mepolizumab | .212 |
| Mercaptopurine | . 155 |
| Mercilon 28 | |
| Mesalazine | |
| Mesna | . 159 |
| Mestinon | . 114 |
| Metabolic Disorder Agents | 25 |
| Metabolics | 27 |
| Metformin hydrochloride | 11 |
| Metformin Viatris | 11 |
| Methadone BNM | . 124 |
| Methadone hydrochloride | |
| Methenamine (hexamine) | |
| hippurate | 113 |
| Methopt | .270 |
| Methotrexate | |
| Methotrexate DBL Onco-Vial | |
| Methotrexate Ebewe | 156 |
| Methotrexate Sandoz | 156 |
| Methyl hydroxybenzoate | |
| Methylcellulose | |
| Methylcellulose with glycerin and | . 210 |
| sodium saccharin | 275 |
| Methylcellulose with glycerin and | 215 |
| | 075 |
| SUCROSE | 2/5 |
| Methyldopa | |
| Methyldopa Viatris | |
| Methylnaltrexone bromide | |
| Methylphenidate ER - Teva | |
| Methylphenidate hydrochloride | . 144 |
| Methylphenidate hydrochloride | |
| extended-release | |
| Methylprednisolone | 82 |

| Methylprednisolone (as sodium |
|----------------------------------|
| succinate) 82 |
| Methylprednisolone aceponate68 |
| Methylprednisolone acetate83 |
| Methylxanthines263 |
| Metoclopramide Actavis 10 132 |
| Metoclopramide hydrochloride 132 |
| Metolazone50 |
| Metopirone91 |
| Metoprolol IV Mylan47 |
| Metoprolol IV Viatris47 |
| Metoprolol succinate47 |
| Metoprolol tartrate47 |
| Metronidamed103 |
| Metronidazole 103 |
| Metyrapone91 |
| Mexiletine hydrochloride46 |
| Miacalcic |
| Micolette24 |
| Miconazole |
| Miconazole nitrate |
| Dermatological67 |
| Genito-Urinary78 |
| Micreme78 |
| Micreme H68 |
| Microgynon 3077 |
| Microlut77 |
| Midazolam 141 |
| Midazolam Viatris 141 |
| Midazolam-Baxter141 |
| Midazolam-Pfizer141 |
| Midodrine47 |
| Midostaurin 167 |
| Mifegyne 80 |
| Mifepristone 80 |
| Milpharm129 |
| Minerals32 |
| Mini-Wright AFS Low Range265 |
| Mini-Wright Standard265 |
| Minidiab 11 |
| MiniMed 3.0 Reservoir |
| MMT-332A 21 |
| MiniMed Mio MMT-921A 19 |
| MiniMed Mio MMT-923A 19 |
| MiniMed Mio MMT-925A 19 |
| MiniMed Mio MMT-941A 19 |
| MiniMed Mio MMT-943A 19 |
| MiniMed Mio MMT-945A 19 |
| MiniMed Mio MMT-965A 19 |
| MiniMed Mio MMT-975A 19 |
| MiniMed Quick-Set MMT-396A 19 |
| MiniMed Quick-Set MMT-397A 19 |
| MiniMed Quick-Set MMT-398A 19 |
| MiniMed Quick-Set MMT-399A 19 |
| MiniMed Silhouette MMT-377A 19 |
| MiniMed Silhouette MMT-378A 19 |

| MiniMed Silhouette MMT-381A | . 19 |
|-------------------------------------|------|
| MiniMed Sure-T MMT-864A | |
| MiniMed Sure-T MMT-866A | |
| MiniMed Sure-T MMT-874A | |
| MiniMed Sure-T MMT-876A | |
| Minims Pilocarpine | 270 |
| Minims Prednisolone | 260 |
| Minipress | |
| Minipless | |
| Minirin Melt | |
| Mino-tabs | |
| Minocycline hydrochloride | |
| | |
| Minomycin | 90 |
| Minor Skin Infections | |
| Minoxidil | 54 |
| Minoxidil Roma | |
| Mirena | 85 |
| Miro-Amoxicillin | 95 |
| Mirtazapine | 127 |
| Misoprostol | 8 |
| Mitomycin (Fresenius Kabi) | |
| Mitomycin (Sagent) | 159 |
| Mitomycin C | 159 |
| Mitozantrone | 159 |
| Mitozantrone Ebewe | 159 |
| Mixtard 30 | |
| MMA/PA Anamix Infant | 293 |
| MMA/PA Anamix Junior | |
| MMA/PA Explore 5 | |
| MMA/PA Express 15 | 200 |
| Moclobemide | |
| Modafinil | 1/5 |
| Modafinil Max Health | |
| | 140 |
| Modavigil | |
| Moduretic | 50 |
| Molaxole | |
| Moments | |
| Mometasone furoate | 68 |
| Monogen | 279 |
| Montelukast | 263 |
| Montelukast Viatris | 263 |
| Moroctocog alfa [Recombinant factor | ſ |
| VIII] | . 38 |
| Morphine hydrochloride | 124 |
| Morphine sulphate | 125 |
| Motetis | |
| Mouth and Throat | 30 |
| Movapo | 120 |
| Moxifloxacin | |
| MSUD Anamix Infant | |
| MSUD Anamix Junior | |
| MSUD Anamix Junior LQ | 290 |
| MSUD Explore 5 | 290 |
| MSUD Express 15 | |
| MSUD Lophlex LQ 20 | 200 |
| MSUD Maxamum | |
| | 230 |

| Mucosoothe12 Multiple Sclerosis Treatments13 | |
|---|---|
| Multiple Sclerosis Treatments | 22 |
| Multiple Ocierosis Treatments | 37 |
| Multivitamin renal | 32 |
| Multivitamins | |
| Mupirocin6 | 65 |
| Muscle Relaxants 11 | 18 |
| Mvite | |
| Myambutol 10 |)4 |
| Mycobutin 10 | |
| MycoNail | |
| Mycophenolate mofetil17 | |
| Mydriacyl27 | 70 |
| Mylan (24 hr release) | |
| Mylan Clomiphen | 91 |
| Mylan Italy (24 hr release) | 48 |
| Myleran15 | 51 |
| mylife Inset soft | |
| mylife Orbit micro | |
| mylife YpsoPump Reservoir | 21 |
| mylife YpsoPump with CamAPS | |
| FX | |
| Myloc CR | 47 |
| Mylotarg20 |)3 |
| Myometrial and Vaginal Hormone | |
| Preparations | |
| | 25 |
| Myozyme | |
| Mytolac 17 | |
| Mytolac 17 - N - | 75 |
| Mytolac 17 - N - Nadolol | 75 48 |
| Mytolac | 75 48 48 |
| Mytolac | 75 48 48 26 |
| Mytolac | 75 48 48 26 72 |
| Mytolac 17 - N - 17 Nadolol 4 Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 21 Naltraccord 14 | 75 48 48 26 72 48 |
| Mytolac 17 - N - 17 Nadolol 4 Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 21 Naltraccord 14 Naltrexcone AOP 14 | 75 48 26 72 48 48 |
| Mytolac 17 - N - 17 Nadolol 4 Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 21 Naltraccord 14 Naltrexone AOP 14 Naltrexone hydrochloride 14 | 75 48 48 26 72 48 48 48 |
| Mytolac 17 - N - 17 Nadolol 4 Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 2 Naltraccord 14 Naltrexone AOP 14 Naltrexone hydrochloride 14 Naltrexone hydrochloride 14 Naltrexone hydrochloride 14 Naltrexone hydrochloride 14 Naltrexone Max Health 14 | 75 48 26 72 48 48 48 48 |
| Mytolac 17 - N - Nadolol Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 2 Naltrexone AOP 14 Naltrexone hydrochloride 14 Naltrexone Max Health 14 Naltrexone Max Health 14 | 75 48 26 72 48 48 48 48 71 |
| Mytolac 17 - N - 17 Nadolol 4 Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 27 Naltraccord 14 Naltrexone AOP 14 Naltrexone Max Health 14 Naphazoline hydrochloride 27 Naprosyn SR 1000 11 | 75 48 26 72 48 48 48 48 71 |
| Mytolac 17 - N - Nadolol Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 21 Naltraccord 14 Naltrexone AOP 14 Naltrexone Max Health 14 Naphazoline hydrochloride 22 Naprosyn SR 1000 11 Naprosyn SR 750 11 | 75 48 26 72 48 48 48 48 71 14 |
| Mytolac 17 - N - Nadolol Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 21 Naltraccord 14 Naltrexone AOP 14 Naltrexone Max Health 14 Naphazoline hydrochloride 21 Naprosyn SR 1000 11 Naprosyn SR 750 11 Naproxen 11 | 75 48 26 72 48 48 48 71 14 14 |
| Mytolac 17 - N - Nadolol Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 21 Naltraccord 14 Naltrexone AOP 14 Naltrexone hydrochloride 14 Naltrexone Max Health 14 Naphazoline hydrochloride 27 Naprosyn SR 1000 17 Naprosyn SR 750 17 Naproxen 17 | 75 48 26 72 48 48 48 48 71 14 14 14 |
| Mytolac 17 - N - Nadolol Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 2 Naltraccord 14 Naltrexone AOP 14 Naltrexone hydrochloride 14 Naltrexone Max Health 14 Naphazoline hydrochloride 27 Naprosyn SR 1000 11 Naprosyn SR 750 11 Naproxen 14 Narcaricin mite 17 Nasal Preparations 26 | 75 48 26 72 48 48 48 71 14 14 14 18 55 |
| Mytolac 17 - N - Nadolol Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 2 Naltraccord 14 Naltrexone AOP 14 Naltrexone hydrochloride 14 Naltrexone Max Health 14 Naphazoline hydrochloride 27 Naprosyn SR 1000 11 Naprosen 14 Nacraricin mite 15 Nasal Preparations 26 Natalizumab 15 | 75 48 26 72 48 48 48 48 71 14 14 14 18 55 39 |
| Mytolac 17 - N - Nadolol Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 2 Naltraccord 14 Naltrexone AOP 14 Naltrexone hydrochloride 14 Naltrexone Max Health 14 Naphazoline hydrochloride 27 Naprosyn SR 1000 11 Naprosyn SR 750 11 Naprosen 14 Nasal Preparations 26 Natalizumab 15 | 75 48 26 72 48 48 48 48 71 14 14 18 53 9 52 |
| Mytolac 17 - N - Nadolol 4 Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 27 Naltrexone AOP 14 Naltrexone hydrochloride 14 Naltrexone Max Health 14 Naphazoline hydrochloride 27 Naprosyn SR 1000 11 Naprosyn SR 750 11 Naproxen 12 Natrexone Max Health 14 Naphazoline hydrochloride 27 Naprosyn SR 1000 11 Naprosyn SR 750 12 Naproxen 12 Natolan 14 Natalizumab 14 Natulan 14 | 75 48 26 72 48 48 48 71 14 14 18 53 9 52 32 |
| Mytolac 17 - N - Nadolol 4 Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 27 Naltrexone AOP 14 Naltrexone hydrochloride 14 Naltrexone Max Health 14 Naphazoline hydrochloride 27 Naprosyn SR 1000 11 Naprosyn SR 750 11 Naproxen 12 Natrexone Max Health 14 Naphazoline hydrochloride 27 Naprosyn SR 1000 11 Naproxen 12 Natoraricin mite 14 Natalizumab 14 Natulan 16 Natulan 16 Natusafix 13 | 75 48 26 72 48 48 48 48 71 414 14 14 15 39 52 32 32 |
| Mytolac 17 - N - Nadolol Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 2 Naltrexone AOP 14 Nathrexone MAX Health 14 Naphazoline hydrochloride 12 Naphazoline hydrochloride 12 Naprosyn SR 1000 11 Naproxen 12 Naproxen 12 Natalizumab 13 Natual 14 Natalizumab 14 Nausafix 14 Nausafix 14 | 75 48 26 72 48 48 48 48 71 41 4 14 14 15 39 32 32 32 32 32 |
| Mytolac 17 - N - Nadolol Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 2 Naltrexone AOP 14 Nathrexone Max Health 14 Naphazoline hydrochloride 12 Naphazoline hydrochloride 12 Naprosyn SR 1000 11 Naprosyn SR 750 11 Naproxen 12 Natrearcin mite 14 Natalizumab 15 Natualan 16 Nausicalm 16 Navelbine S29 16 | 75 4848267248848848484848484848484848484848484848 |
| Mytolac 17 - N - Nadolol Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 2 Naltrexone AOP 14 Nathrexone Max Health 14 Naphazoline hydrochloride 14 Naphazoline hydrochloride 12 Naprosyn SR 1000 11 Naprosyn SR 750 11 Naproxen 12 Natalizumab 13 Natuali 14 Nausicalm 14 Naprosyn SR 750 15 Naproxen 16 Natual 16 Nausicalm 16 Nausicalm 17 Nauselix 16 Nausicalm 17 Navelbine S29 16 Neo-Cytamen S29 17 | 75 48826 728848 488848 488848 48848 48848 48848 48848 48848 48848 48848 48848 |
| Mytolac 17 - N - Nadolol Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 21 Naltrexone AOP 14 Nathrexone AOP 14 Naltrexone Max Health 14 Naphazoline hydrochloride 22 Naprosyn SR 1000 11 Naprosyn SR 750 11 Naproxen 12 Natrearcin mite 12 Natulal 16 Natusafix 17 Nausafix 16 Nausicalm 17 Nausicalm 16 Navelbine S29 16 Neo-Oytamen S29 16 | 75 488267248848848848848848484848484848484848484 |
| Mytolac 17 - N - Nadolol Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 21 Naltrexone AOP 14 Nathrexone AOP 14 Nathrexone Max Health 14 Naphazoline hydrochloride 22 Natrexone Max Health 14 Naphazoline hydrochloride 21 Naprosyn SR 1000 17 Naprosyn SR 750 11 Naprosyn SR 750 11 Naprosyn SR 750 11 Naprosyn SR 750 12 Natulaan 16 Natalizumab 12 Nausicalm 13 Nausicalm 14 Navelbine S29 16 Neo-Cytamen S29 17 Neo-Mercazole 17 Neocate Gold 26 | 75 488 482 67 72 488 488 488 488 488 488 488 488 488 48 |
| Mytolac 17 - N - Nadolol Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 2 Naltraccord 14 Naltrexone AOP 14 Naltrexone Max Health 14 Naprosyn SR 1000 17 Naprosyn SR 750 17 Naprosyn SR 750 17 Naproxen 17 Nasal Preparations 26 Natulan 16 Nausafix 17 Nausealm 16 Nausealm 17 Nausealm 16 Nausealm 17 Nausealm 16 Nausealm 17 Nausealm 16 Nausealm 17 Navelbine S29 16 Neo-Mercazole 17 Neo-Mercazole 17 Neocate Gold 26 Neocate Gold 26 | 75 4884826 72248848848848848848848848848848848848848 |
| Mytolac 17 - N - Nadolol Nadolol BNM 4 Naglazyme 2 Naloxone hydrochloride 2 Naltrexone AOP 14 Nathrexone MAX Health 14 Nathrexone Max Health 14 Naphazoline hydrochloride 21 Naprosyn SR 1000 11 Naproxen 12 Naproxen 12 Natalizumab 13 Natual 14 Natalizumab 15 Natulan 16 Nausafix 13 Nausafix 14 | 75 4848226 7224884848484848484848484848484848484848 |

| Neostigmine metilsulfate114 |
|---------------------------------|
| Nepafenac |
| Nepro HP (strawberry)281 |
| Nepro HP (vanilla) |
| Neulactil134 |
| NeuroTabs33 |
| Nevirapine 110 |
| Nevirapine Viatris 110 |
| Nicorandil54 |
| Nicotine148 |
| Nifedipine48 |
| Nifuran 113 |
| Nilotinib168 |
| Nilstat |
| Alimentary31 |
| Genito-Urinary78 |
| Infection 100 |
| Nimenrix |
| Nintedanib |
| Nipent |
| Niraparib159 |
| Nirmatrelvir with ritonavir 108 |
| Nitrates53 |
| Nitroderm TTS53 |
| Nitrofurantoin113 |
| Nitrolingual Pump Spray53 |
| Nivestim |
| Nivolumab245 |
| Nodia6 |
| Noflam 250 114 |
| Noflam 500 114 |
| Non-Steroidal Anti-Inflammatory |
| Drugs |
| Nonacog gamma, [Recombinant |
| Factor IX1 |
| Norethinderone - CDC78 |
| Norethisterone |
| Genito-Urinary78 |
| Hormone85 |
| Norflex119 |
| Norfloxacin113 |
| Noriday78 |
| Noriday 28 |
| Norimin77 |
| Normison141 |
| Norpress 127 |
| Nortriptyline hydrochloride127 |
| Norvir |
| Noumed Dexamfetamine142 |
| Noumed Isoniazid |
| Noumed Paracetamol |
| Noumed Pethidine |
| Noumed Phenobarbitone |
| Novadoz |
| NovaSource Renal |
| Novatretin |

| Novitium Sugar Free27 |
|----------------------------------|
| NovoMix 30 FlexPen 10 |
| NovoRapid11 |
| NovoRapid FlexPen11 |
| NovoRapid Penfill 11 |
| NovoSeven RT |
| Nozinan |
| Nozinan (Swiss) |
| Nozinan S29134 |
| Nucala |
| Nuclin |
| Nuelin-SR |
| Nupentin 128 |
| |
| Nusinersen |
| |
| Nutren Diabetes |
| Nutrient Modules |
| Nutrini Energy Multi Fibre |
| Nutrini Energy RTH 281 |
| Nutrini Low Energy Multi Fibre |
| Nutrini Peptisorb297 |
| Nutrini Peptisorb Energy 297 |
| Nutrini RTH281 |
| Nutrison 800 Complete Multi |
| Fibre 286 |
| Nutrison Advanced Peptisorb |
| Nutrison Concentrated |
| Nutrison Energy285 |
| Nutrison Energy Multi Fibre |
| Nutrison Multi Fibre |
| Nutrison RTH |
| Nyefax Retard48 |
| Nystatin |
| Alimentary31 |
| Genito-Urinary78 |
| Infection 100 |
| NZB Low Gluten Bread Mix289 |
| -0- |
| Obinutuzumab |
| Obstetric Preparations |
| Ocicure |
| Ocrelizumab139 |
| Ocrevus |
| Octocog alfa [Recombinant factor |
| VIII] (Advate) |
| Octocog alfa [Recombinant factor |
| VIII] (Kogenate FS) |
| Octreotide 174 |
| |
| Octreotide GH |
| Octreotide long-acting |
| Oestradiol |
| Oestradiol valerate |
| Oestradiol with norethisterone |
| Oestriol |
| Genito-Urinary78 |
| Hormone85 |

| Oestrogens | 84 |
|------------------------------|---------|
| Ofev | 262 |
| Oil in water emulsion | 69 |
| Olanzapine134, | 136 |
| Olaparib | |
| Olbetam | |
| Olopatadine | 271 |
| Olopatadine Teva | 271 |
| Olsalazine | 8 |
| Omalizumab | |
| Omeprazole | |
| Omeprazole actavis 10 | |
| Omeprazole actavis 20 | |
| Omeprazole actavis 40 | |
| Omeprazole Teva | |
| Omnitrope | و مو |
| Onhroz Broosholor | 00 |
| Onbrez Breezhaler | |
| Oncaspar LYO | 161 |
| OncoTICE | |
| Ondansetron | 132 |
| One-Alpha | 31 |
| One-Alpha S29 | 31 |
| Opdivo | |
| Ora-Blend | 275 |
| Ora-Blend SF | 275 |
| Ora-Plus | 275 |
| Ora-Sweet | |
| Ora-Sweet SF | |
| Orabase | |
| Oral and Enteral Feeds | 279 |
| Oralcon 30 ED | 77 |
| Oramorph | 125 |
| Oramorph CDC S29 | 125 |
| | |
| Oratane Orgran | 00 |
| | |
| Ornidazole | 103 |
| Orphenadrine citrate | 119 |
| Ortho-tolidine | |
| Oruvail SR | |
| Osimertinib | 168 |
| Osmolite RTH | 286 |
| Other Endocrine Agents | 90 |
| Other Oestrogen Preparations | 85 |
| Other Progestogen | |
| Preparations | 85 |
| Other Skin Preparations | 73 |
| Otodex | |
| Ovestin | |
| Genito-Urinary | .78 |
| Hormone | |
| Oxaliplatin | |
| Oxaliplatin Accord | |
| Oxaliplatin Actorio 100 | |
| | |
| Oxaliplatin Ebewe | 152 |
| Oxis Turbuhaler | 258 |
| Oxpentifylline | 54 |

| Oxybutynin80 |
|-------------------------------|
| Oxycodone Amneal 125 |
| Oxycodone hydrochloride125 |
| Oxycodone Lucis |
| Oxycodone Sandoz |
| Oxycodone Sandoz S29 |
| OxyContin |
| Oxytocin |
| |
| Oxytocin BNM |
| Oxytocin Panpharma79 |
| Oxytocin with ergometrine |
| maleate79 |
| Ozurdex268 |
| - P - |
| Pacifen118 |
| Pacimol123 |
| Paclitaxel161 |
| Paclitaxel Actavis161 |
| Paclitaxel Ebewe 161 |
| Padagis |
| Paediatric Seravit |
| Palbociclib |
| Paliperidone |
| |
| Paliperidone palmitate |
| Palivizumab |
| Pamidronate disodium116 |
| Pamisol116 |
| Pamol 123 |
| Pancreatic enzyme 22 |
| Pantoprazole9 |
| Panzop Relief9 |
| Papaverine hydrochloride54 |
| Para-amino salicylic acid 104 |
| Paracetamol 123 |
| Paracetamol (Ethics) 123 |
| Paracetamol + Codeine |
| (Relieve) 125 |
| Paracetamol with codeine |
| Paraffin |
| Paraffin liquid with wool fat |
| Parasiticidal Preparations |
| Parnate |
| |
| Paromomycin |
| Paroxetine |
| Paser |
| Paxam |
| Paxlovid 108 |
| Pazopanib170 |
| Pazopanib Teva170 |
| Peak flow meter265 |
| Pediasure |
| Pediasure Plus281 |
| Pediasure RTH281 |
| Pegaspargase161 |
| Pegasys111 |
| Pegfilgrastim |
| |

| Pegylated interferon alfa-2a1 | 111 |
|---|------|
| Pembrolizumab | 247 |
| Pemetrexed 1 | |
| Pemetrexed-AFT 1 | 156 |
| Penicillamine1 | 115 |
| Penicillin G | 95 |
| PenMix 30 | |
| PenMix 50 | 11 |
| Pentasa | 7 |
| Pentostatin [Deoxycoformycin] 1 | 61 |
| Pentoxifylline [Oxpentifylline] | |
| Peptamen Junior2 | 281 |
| Pepti-Junior2 | |
| Perhexiline maleate | .49 |
| Pericyazine 1 | 34 |
| Perindopril | .44 |
| Periset 1 | |
| Periset ODT1 | 32 |
| Perjeta | 217 |
| Permethrin | |
| Perrigo | .73 |
| Pertuzumab2 | 217 |
| Peteha 1 | 04 |
| Pethidine hydrochloride1 | 26 |
| Pevaryl | . 66 |
| Pexsig | .49 |
| Pfizer Exemestane1 | 75 |
| Pfizer S291 | |
| Pharmacy Services | |
| Pharmascience | |
| Pheburane | .29 |
| Phenasen1 | 156 |
| Phenergan Elixir | 258 |
| Phenobarbitone | 129 |
| Phenobarbitone sodium Extemporaneous | |
| Nervous1 | |
| | 141 |
| Phenoxybenzamine hydrochloride | |
| Phenoxymethylpenicillin (Penicillin | 44 |
| V) | 06 |
| Phenylalanine50 | |
| Phenytoin sodium | 120 |
| Phillips Milk of Magnesia | 34 |
| Phlexy 10 | |
| Phosphate Phebra | |
| Phosphorus | 43 |
| Phytomenadione | |
| Pilocarpine hydrochloride | 270 |
| Pilocarpine nitrate | |
| Pimafucort | |
| Pimecrolimus | |
| Pine tar with trolamine laurilsulfate | |
| and fluorescein | 72 |
| Pinetarsol | |
| Pioglitazone | |
| | |

| Pirfenidone | 000 |
|--------------------------------|-------|
| | |
| Pizotifen | |
| PKU Anamix Infant | .291 |
| PKU Anamix Junior | .291 |
| PKU Anamix Junior Chocolate | .291 |
| PKU Anamix Junior LQ | |
| PKU Anamix Junior Orange | .291 |
| PKU Anamix Junior Vanilla | .291 |
| PKU Build 10 | |
| PKU Build 20 Chocolate | . 292 |
| PKU Build 20 Raspberry | |
| Lemonade | 292 |
| PKU Build 20 Smooth | .292 |
| PKU Build 20 Vanilla | .292 |
| PKU Explore 10 | .291 |
| PKU Explore 5 | 291 |
| PKU Express 20 | 291 |
| PKU First Spoon | |
| PKU Glytactin RTD 15 | 201 |
| PKU Glytactin RTD 15 Lite | 202 |
| PKU GMPro LQ | . 292 |
| PKU GIMPIO LQ | . 292 |
| PKU GMPro Mix-In | . 292 |
| PKU GMPro Ultra Lemonade | |
| PKU GMPro Ultra Vanilla | .292 |
| PKU Lophlex LQ 10 | |
| PKU Lophlex LQ 20 | |
| PKU Lophlex Powder | .291 |
| PKU Lophlex Sensation 20 | .291 |
| PKU Restore Powder | . 292 |
| PKU sphere20 Banana | . 292 |
| PKU sphere20 Chocolate | . 292 |
| PKU sphere20 Lemon | .292 |
| PKU sphere20 Red Berry | .292 |
| PKU sphere20 Vanilla | .292 |
| Pku Start | .291 |
| Plaquenil | .115 |
| Plendil ER | |
| Pneumococcal (PCV13) conjugate | |
| vaccine | 311 |
| Pneumococcal (PPV23) | |
| polysaccharide vaccine | 312 |
| Pneumovax 23 | 312 |
| Podophyllotoxin | 73 |
| Polaramine | 257 |
| Poliomyelitis vaccine | 210 |
| Poloxamer | 210. |
| Poly-Gel | 071 |
| | |
| Poly-Tears | |
| Poly-Visc | |
| Polycal | .276 |
| Polyethylene glycol 400 and | |
| propylene glycol | |
| Pomalidomide | |
| Pomolide | |
| Ponstan | |
| Posaconazole | .100 |

| Posaconazole Juno1 | |
|--|---|
| Potassium chloride 42- | |
| Potassium citrate | |
| Potassium iodate | |
| Povidone iodine | 70 |
| Pradaxa | |
| Pramipexole hydrochloride 1 | |
| Pravastatin | |
| Praziquantel | 92 |
| Prazosin | |
| Prazosin Mylan | |
| Pred Forte2 | |
| Prednisolone | 83 |
| Prednisolone acetate2 | 69 |
| Prednisolone sodium | |
| phosphate | 69 |
| Prednisolone-AFT2 | 69 |
| Prednisone | 83 |
| Prednisone Clinect | 83 |
| Pregabalin1 | 29 |
| Pregabalin Pfizer1 | 29 |
| Pregnancy Tests - hCG Urine | 79 |
| Premarin | |
| Prevenar 133 | |
| Priadel1 | 34 |
| Primaquine1 | 02 |
| Primidone1 | |
| Primidone Clinect1 | 29 |
| Primolut N | |
| | 85 |
| Priorix | |
| Priorix | 08 18 |
| Priorix | 08 18 |
| Priorix | 08 18 18 |
| Priorix | 08 18 18 62 |
| Priorix | 08 18 18 62 32 |
| Priorix | 08 18 18 62 32 32 |
| Priorix | 08 18 18 62 32 32 32 |
| Priorix | 08 18 18 62 32 32 32 |
| Priorix 3 Probenecid 1 Probenecid-AFT 1 Procarbazine hydrochloride 1 Prochlorperazine 1 Prochlorperazine Brown & Burk 1 Prochlorperazine Max Health 1 Prochlorperazine Max Health 1 Proctofoam 1 | 08 18 18 62 32 32 32 .7 .8 |
| Priorix 3 Probenecid 1 Probenecid-AFT 1 Procarbazine hydrochloride 1 Prochlorperazine 1 Prochlorperazine Brown & 1 Burk 1 Prochlorperazine Max Health 1 Prochorperazine Max Health 1 Proctosedyl 1 Prockloine hydrochloride 1 | 08 18 18 62 32 32 32 .7 .8 21 |
| Priorix 3 Probenecid 1 Probenecid-AFT 1 Procarbazine hydrochloride 1 Prochlorperazine 1 Prochlorperazine Brown & Burk 1 Prochlorperazine Max Health 1 Proctofoam 1 Proctofoam 1 Procyclidine hydrochloride 1 Progesterone 1 | 08 18 18 62 32 32 32 32 32 32 32 32 32 32 32 32 32 |
| Priorix 3 Probenecid 1 Probenecid-AFT 1 Prochlorperazine 1 Prochlorperazine 1 Prochlorperazine Brown & 1 Burk 1 Procholorperazine Max Health 1 Proctofoam 1 Procyclidine hydrochloride 1 Progesterone 1 Progelicem 1 | 08 18 18 62 32 32 32 .7 .8 21 85 10 |
| Priorix 3 Probenecid 1 Probenecid-AFT 1 Prochlorperazine 1 Prochlorperazine 1 Prochlorperazine Brown & 1 Burk 1 Procholorperazine Max Health 1 Proctofoam 1 Procyclidine hydrochloride 1 Progesterone 1 Progelicem 1 | 08 18 18 62 32 32 32 .7 .8 21 85 10 |
| Priorix 3 Probenecid 1 Probenecid-AFT 1 Procarbazine hydrochloride 1 Prochlorperazine 1 Prochlorperazine Brown & 1 Burk 1 Prochlorperazine Max Health 1 Proctofoam 1 Procyclidine hydrochloride 1 Progesterone 1 Progesterone 1 Prognova 1 Prognova 1 | 08 18 62 32 32 32 .7 .8 21 85 10 84 15 |
| Priorix 3 Probenecid 1 Probenecid-AFT 1 Procarbazine hydrochloride 1 Prochlorperazine 1 Prochlorperazine Brown & 1 Burk 1 Prochlorperazine Max Health 1 Proctofoam 1 Procyclidine hydrochloride 1 Progesterone 1 Proglicem 1 Progunova 1 Promethazine hydrochloride 1 | 08 18 62 32 32 32 .7 .8 21 85 10 84 15 58 |
| Priorix 3 Probenecid 1 Probenecid-AFT 1 Procarbazine hydrochloride 1 Prochlorperazine 1 Prochlorperazine Brown & 1 Burk 1 Prochlorperazine Max Health 1 Proctofoam 1 Procyclidine hydrochloride 1 Progesterone 1 Progesterone 1 Prognova 1 Prognova 1 | 08 18 62 32 32 32 .7 .8 21 85 10 84 15 58 |
| Priorix 3 Probenecid 1 Probenecid-AFT 1 Prochlorperazine hydrochloride 1 Prochlorperazine Brown & Burk 1 Prochlorperazine Brown & Burk 1 Prochlorperazine Max Health 1 Proctofoam 1 Procyclidine hydrochloride 1 Progesterone 1 Proglicem 1 Proglicem 1 Prolia 1 Propafenone hydrochloride 2 Propafenone hydrochloride 2 Propafenone hydrochloride 2 | 08 18 62 32 32 32 32 32 32 32 32 32 32 32 32 32 |
| Priorix 3 Probenecid 1 Probenecid-AFT 1 Procarbazine hydrochloride 1 Prochlorperazine Brown & 1 Burk 1 Prochlorperazine Brown & 1 Prochlorperazine Max Health 1 Prochorperazine Max Health 1 Proctosedyl 1 Procyclidine hydrochloride 1 Progesterone 1 Proglicem 1 Progesterone 1 Progesterone 1 Progesterone 1 Progene 1 Progene 1 Propafenone hydrochloride 2 Propanolol 1 Proprese divcol 2 | 08 18 62 32 32 32 32 32 32 32 32 32 32 32 32 32 |
| Priorix 3 Probenecid 1 Probenecid-AFT 1 Procarbazine hydrochloride 1 Prochlorperazine 1 Prochlorperazine Brown & 1 Burk 1 Prochlorperazine Max Health 1 Prochorperazine Max Health 1 Prochorperazine Max Health 1 Proctofoam 1 Procyclidine hydrochloride 1 Progesterone 1 Proglicem 1 Proglicem 1 Progesterone 1 Progesterone 1 Progenova 1 Progenova 1 Propafenone hydrochloride 2 Propafenone hydrochloride 1 Propalene glycol 2 Proplithiouracil 1 | 08 18 62 32 32 32 32 32 32 32 32 32 32 32 32 32 |
| Priorix 3 Probenecid 1 Probenecid-AFT 1 Procarbazine hydrochloride 1 Prochlorperazine Brown & 1 Burk 1 Prochlorperazine Brown & 1 Prochlorperazine Max Health 1 Prochorperazine Max Health 1 Proctosedyl 1 Procyclidine hydrochloride 1 Progesterone 1 Proglicem 1 Progesterone 1 Progesterone 1 Progesterone 1 Progene 1 Progene 1 Propafenone hydrochloride 2 Propanolol 1 Proprese divcol 2 | 08 18 62 32 32 32 32 32 32 32 32 32 32 32 32 32 |
| Priorix 3 Probenecid 1 Probenecid-AFT 1 Procarbazine hydrochloride 1 Prochlorperazine 1 Prochlorperazine Brown & 1 Burk 1 Prochlorperazine Max Health 1 Prochorperazine Max Health 1 Proctofoam 1 Prockofoam 1 Progesterone 1 Proglicem 1 Progesterone 1 Progesterone 1 Progesterone 1 Propanethazine hydrochloride 2 Propafenone hydrochloride 2 Propranolol 2 Propylthiouracil 1 Prostacur 1 Protaphane 1 | 08 18 62 32 32 7 81 85 10 84 75 86 73 10 |
| Priorix 3 Probenecid 1 Probenecid-AFT 1 Procarbazine hydrochloride 1 Prochlorperazine 1 Prochlorperazine Brown & 1 Burk 1 Prochlorperazine Max Health 1 Prochorperazine Max Health 1 Proctofoam 1 Proctofoam 1 Progesterone 1 Progesterone 1 Progicem 1 Progesterone 1 Progesterone 1 Progenethazine hydrochloride 2 Propafenone hydrochloride 2 Propafenone hydrochloride 2 Propylene glycol 2 Propylene glycol 2 Propylthiouracil 1 Prostaphane 1 Protaphane 1 | 08 18 62 32 32 32 32 32 32 32 32 32 32 32 32 32 |
| Priorix 3 Probenecid 1 Probenecid-AFT 1 Procarbazine hydrochloride 1 Prochlorperazine 1 Prochlorperazine Brown & 1 Burk 1 Prochlorperazine Max Health 1 Prochorperazine Max Health 1 Proctofoam 1 Proctofoam 1 Progesterone 1 Progesterone 1 Progesterone 1 Progesterone 1 Progesterone 2 Propafenone hydrochloride 2 Propafenone hydrochloride 2 Propalene glycol 2 Propylthiouracil 1 Prostacur 1 Protaphane 1 Protaphane 2 Protaphane 2 | 08 18 62 32 32 32 32 32 32 32 32 32 32 32 32 32 |
| Priorix 3 Probenecid 1 Probenecid-AFT 1 Procarbazine hydrochloride 1 Prochlorperazine 1 Prochlorperazine Brown & 1 Burk 1 Prochlorperazine Max Health 1 Prochorperazine Max Health 1 Proctofoam 1 Proctofoam 1 Progesterone 1 Progesterone 1 Progicem 1 Progesterone 1 Progesterone 1 Progenethazine hydrochloride 2 Propafenone hydrochloride 2 Propafenone hydrochloride 2 Propylene glycol 2 Propylene glycol 2 Propylthiouracil 1 Prostaphane 1 Protaphane 1 | 08 18 62 32 32 32 32 32 32 32 32 32 32 32 32 32 |
| Priorix 3 Probenecid 1 Probenecid-AFT 1 Procarbazine hydrochloride 1 Prochlorperazine 1 Prochlorperazine Brown & 1 Burk 1 Prochlorperazine Max Health 1 Prochorperazine Max Health 1 Proctofoam 1 Proctofoam 1 Progesterone 1 Progesterone 1 Progesterone 1 Progesterone 1 Progesterone 2 Propafenone hydrochloride 2 Propafenone hydrochloride 2 Propalene glycol 2 Propylthiouracil 1 Prostacur 1 Protaphane 1 Protaphane 2 Protaphane 2 | 08 18 62 32 32 7 8 10 8 5 8 6 7 30 7 8 10 7 8 5 8 6 7 30 7 8 10 7 8 5 7 8 10 8 10 8 10 8 10 8 10 8 10 8 10 8 |

| Psoriasis and Eczema |
|-----------------------------|
| Preparations71 |
| PTU |
| Pulmicort Turbuhaler 258 |
| Pulmozyme |
| Puri-nethol 155 |
| Puritan's Pride Vitamin |
| B-2 100 mg 28 |
| Pyrazinamide |
| Pyridostigmine bromide |
| Pyridoxine hydrochloride |
| |
| Pyridoxine multichem |
| Pyrimethamine |
| Pytazen SR |
| -Q- |
| Quantalan sugar free51 |
| Quetapel134 |
| Quetiapine134 |
| Quetiapine Viatris 134 |
| Quinapril45 |
| Qvar258 |
| - R - |
| RA-Morph 124 |
| Ralicrom8 |
| Raloxifene hydrochloride116 |
| Raltegravir potassium111 |
| Ramipex |
| Ramipril |
| Ranbaxy-Cefaclor |
| Rapamune |
| Rasagiline |
| Reandron 100083 |
| Recombinant factor IX |
| Recombinant factor VIIa |
| Recombinant factor VIII |
| Rectogesic |
| Dediared 02 |
| Redipred |
| Relieve |
| Relistor |
| Remicade |
| Renilon 7.5 |
| Resonium-A43 |
| Resource Beneprotein |
| Respiratory Devices |
| Respiratory Stimulants266 |
| Retinol palmitate271 |
| ReTrieve65 |
| Retrovir110 |
| Revia |
| Revolade |
| Ribociclib 170 |
| Riboflavin |
| Ribomustin |
| Ricit |
| Ricovir |
| Rifabutin 105 |

| Rifadin | 105 |
|------------------------------------|------|
| Rifadin Sanofi | 105 |
| Rifampicin | 105 |
| Rifaximin | |
| Rifinah | 104 |
| Rilutek | |
| Riluzole | |
| RINVOQ | |
| | |
| Riodine | . /0 |
| Risdiplam | 142 |
| Risedronate Sandoz | 117 |
| Risedronate sodium | 11/ |
| Risperdal | 134 |
| Risperdal Consta | 136 |
| Risperidone134, | 136 |
| Risperidone (Teva) | 134 |
| Risperidone Sandoz | |
| Risperon | 134 |
| Ritalin | 144 |
| Ritalin LA | 145 |
| Ritonavir | 111 |
| Rituximab (Mabthera) | 217 |
| Rituximab (Riximyo) | 219 |
| Rivaroxaban | 41 |
| Rivastigmine | |
| Rivastigmine Patch BNM 10 | 146 |
| Rivastigmine Patch BNM 5 | |
| Rivotril | 129 |
| Riximyo | 210 |
| RIXUBIS | 213 |
| | |
| Rizamelt | 101 |
| Rizatriptan | 131 |
| Robinul | 8 |
| Ronapreve | 202 |
| Ropin | 120 |
| Ropinirole hydrochloride | 120 |
| Rosuvastatin | . 52 |
| Rosuvastatin Viatris | 52 |
| Rotarix | |
| Rotavirus oral vaccine | |
| Roxane-Propranolol | . 48 |
| Roxithromycin | . 94 |
| Rubifen | 144 |
| Rubifen SR | 144 |
| Rugby Capsaicin Topical Cream | |
| Musculoskeletal | 115 |
| Nervous | |
| Rurioctocog alfa pegol [Recombinan | |
| factor VIII] | |
| Ruxolitinib | 171 |
| Rydapt | |
| Rythmodan | |
| Rythmodan - Cheplafarm | |
| | |
| Rytmonorm | . 40 |
| - | 100 |
| Sabril | 130 |

| Sacubitril with valsartan45 |
|--------------------------------|
| |
| SalAir259 |
| Salazopyrin8 |
| Salazopyrin EN8 |
| Salbutamol259 |
| Salbutamol with ipratropium |
| bromide |
| Salicylic acid |
| Salmeterol |
| Sandomigran |
| Sandostatin LAR |
| Sanuosialin LAR |
| Sanofi Primaquine |
| Sapropterin dihydrochloride28 |
| Scalp Preparations73 |
| Scopolamine - Mylan132 |
| Sebizole73 |
| Secukinumab230 |
| Sedatives and Hypnotics140 |
| Seebri Breezhaler |
| Senna |
| Senokot |
| SensoCard15 |
| Serc |
| |
| Serenace |
| Seretide |
| Seretide Accuhaler |
| Serevent 258 |
| Serevent Accuhaler 258 |
| Sertraline 127 |
| Setrona 127 |
| Sevredol 125 |
| Sex Hormones Non |
| Contraceptive 83 |
| Shingles vaccine |
| Shingrix |
| SII-Onco-BCG 183 |
| Sildenafil |
| Siltuximab233 |
| Simvastatin |
| Simvastatin Mylan |
| Simvastatin Viatris |
| Sinemet |
| Sinemet CR |
| Sintetica Baclofen Intrathecal |
| Sirolimus |
| Siroiinius |
| |
| Siterone |
| Slow-Lopresor |
| Sodibic |
| Sodium acid phosphate |
| Sodium alginate |
| Sodium benzoate |
| Sodium bicarbonate |
| Blood |
| Extemporaneous275 |
| Sodium calcium edetate |

| Sodium chloride | |
|--|-------|
| Blood | 43 |
| Respiratory | 265 |
| Sodium citrate with sodium lauryl | |
| sulphoacetate | 24 |
| Sodium citro-tartrate | 80 |
| Sodium cromoglicate | |
| Alimentary | 8 |
| Sensory | 269 |
| Sodium Fusidate [fusidic acid] | |
| Dermatological | 66 |
| Infection | 99 |
| Sensory | 267 |
| Sodium hyaluronate [Hyaluronic | |
| acid] | 271 |
| Sodium phenylbutyrate | 29 |
| Sodium picosulfate | |
| Sodium polystyrene sulphonate | |
| Sodium tetradecyl sulphate | |
| Sodium valproate | . 130 |
| Sofradex | |
| Soframycin | 267 |
| Solgar2 | 25-29 |
| Solifenacin succinate | |
| Solifenacin succinate Max | |
| Health | 80 |
| Solifenacin Viatris | |
| Solu-Cortef | |
| Solu-Medrol | |
| Solu-Medrol-Act-O-Vial | 02 |
| Somatropin (Omnitrope) | 86 |
| Sotalol | 00 |
| Spacer device | |
| Span-K | 200 |
| Spazmol | |
| Spinal Muscular Atrophy | 1/1 |
| Spinraza | 1/1 |
| Spiolto Respimat | 261 |
| Spiractin | |
| Spiriva | |
| Spiriva Respimat | 200 |
| Spironolactone | 200 |
| Stalevo | 120 |
| Staphlex | |
| Stelara | 000 |
| Stemetil | |
| Steril-Gene | . 132 |
| SteroClear | |
| SteroClear | |
| Stesolid Stimulants/ADHD Treatments | . 128 |
| | |
| Stiripentol | |
| Stomahesive | |
| Strides Shasun | |
| Stromectol | |
| Sucralfate | 9 |
| Sulfadiazin-Heyl | 99 |

| | 66 |
|---|--|
| Sulfadiazine sodium | . 99 |
| Sulfasalazine | 8 |
| Sulphur | 72 |
| Sulprix | 133 |
| Sumagran | |
| Sumatriptan | |
| Sunitinib | |
| Sunitinib Pfizer | |
| Sunscreens | 73 |
| Sunscreens, proprietary | 73 |
| Sustagen Hospital Formula | |
| Sustagen Hospital Formula | |
| Active | 286 |
| Sustanon Ampoules | . 83 |
| Sylvant | |
| Symbicort Turbuhaler 100/6 | 259 |
| Symbicort Turbuhaler 200/6 | |
| Symbicort Turbuhaler 400/12 | |
| Symmetrel | 120 |
| Sympathomimetics | 53 |
| Synacthen | |
| Synacthen Depot | |
| Synacthene Retard | |
| Synagis | 216 |
| Synthroid | . 85 |
| Syntometrine | |
| Syrup (pharmaceutical grade) | |
| Systane Unit Dose | |
| -T- | |
| Tacrolimus | |
| Dermatological | 72 |
| Oncology | |
| | 254 |
| Tacrolimus Sandoz | 254 254 |
| Tacrolimus Sandoz Tagrisso | 254 |
| Tagrisso | 254 168 |
| Tagrisso Taliglucerase alfa | 254 168 29 |
| Tagrisso Taliglucerase alfa Tambocor | 254 168 29 46 |
| Tagrisso Taliglucerase alfa Tambocor Tambocor German | 254 168 29 46 46 |
| Tagrisso Taliglucerase alfa Tambocor Tambocor German Tamoxifen citrate | 254 168 29 46 46 174 |
| Tagrisso Taliglucerase alfa Tambocor Tambocor German Tamoxifen citrate Tamoxifen Sandoz | 254 168 29 46 46 174 174 |
| Tagrisso Taliglucerase alfa Tambocor Tambocor German Tamoxifen citrate Tamoxifen Sandoz Tamsulosin hydrochloride | 254 168 29 46 46 174 174 79 |
| Tagrisso Taliglucerase alfa Tambocor Tambocor German Tamoxifen citrate Tamoxifen Sandoz Tamsulosin hydrochloride Tamsulosin-Rex | 254 168 29 46 46 174 174 79 79 |
| Tagrisso Taliglucerase alfa Tambocor Tambocor German Tamoxifen citrate Tamoxifen Sandoz Tamsulosin hydrochloride Tamsulosin-Rex Tandem Cartridge | 254 168 29 46 46 174 174 79 79 17 |
| Tagrisso Taliglucerase alfa Tambocor Tambocor German Tamoxifen citrate Tamoxifen Sandoz Tamsulosin hydrochloride Tamsulosin-Rex | 254 168 29 46 46 174 174 79 79 17 |
| Tagrisso Taliglucerase alfa Tambocor Tambocor German Tamoxifen citrate Tamoxifen Sandoz Tamsulosin hydrochloride Tamsulosin hydrochloride Tamsulosin-Rex Tandem Cartridge Tandem t:slim X2 with Basal-IQ Tandem t:slim X2 with | 254 168 29 46 174 174 174 79 79 17 16 |
| Tagrisso Taliglucerase alfa Tambocor Tambocor German Tamoxifen citrate Tamoxifen Sandoz Tamsulosin hydrochloride Tamsulosin hydrochloride Tamsulosin-Rex Tandem Cartridge Tandem t:slim X2 with Basal-IQ Tandem t:slim X2 with Control-IQ | 254 168 29 46 174 174 79 79 17 16 |
| Tagrisso Taliglucerase alfa Tambocor Tambocor German Tamoxifen citrate Tamoxifen Sandoz Tamsulosin hydrochloride Tamsulosin hydrochloride Tamsulosin-Rex Tandem Cartridge Tandem t:slim X2 with Basal-IQ Tandem t:slim X2 with Control-IQ Tap water | 254 168 29 46 174 174 79 79 17 16 275 |
| Tagrisso Taliglucerase alfa Tambocor Tambocor German Tamoxifen citrate Tamoxifen Sandoz Tamsulosin hydrochloride Tamsulosin hydrochloride Tamsulosin-Rex Tandem Cartridge Tandem t:slim X2 with Basal-IQ Tandem t:slim X2 with Control-IQ Tap water Taro | 254 168 29 46 46 174 174 79 79 17 16 275 100 |
| Tagrisso Taliglucerase alfa Tambocor Tambocor German Tamoxifen citrate Tamoxifen Sandoz Tamsulosin hydrochloride Tamsulosin hydrochloride Tamsulosin-Rex Tandem Cartridge Tandem t:slim X2 with Basal-IQ Tandem t:slim X2 with Control-IQ Tap water Taro Tasigna | 254 168 29 46 174 174 79 79 17 16 275 100 168 |
| Tagrisso Taliglucerase alfa Tambocor Tambocor German Tamoxifen citrate Tamoxifen Sandoz Tamsulosin hydrochloride Tamsulosin-Rex Tandem Cartridge Tandem t.slim X2 with Basal-IQ Tandem t.slim X2 with Control-IQ Tap water Taro Tasigna Tasmar | 254 168 29 46 46 174 174 79 79 17 16 275 100 168 120 |
| Tagrisso Taliglucerase alfa Tambocor German Tamoxifen citrate Tamoxifen Sandoz Tamsulosin hydrochloride Tamsulosin-Rex Tandem Cartridge Tandem t:slim X2 with Basal-IQ Tandem t:slim X2 with Control-IQ Tap water Taro Tasigna Tasigna Taurine | 254 168 29 46 46 174 174 79 79 17 16 275 100 168 120 29 |
| Tagrisso Taliglucerase alfa Tambocor German Tamoxifen citrate Tamoxifen Sandoz Tamsulosin hydrochloride Tamsulosin-Rex Tandem Cartridge Tandem t:slim X2 with Basal-IQ Tandem t:slim X2 with Basal-IQ Tandem t:slim X2 with Control-IQ Tap water Taro Taro Tasigna Tasigna Tasigna Taurine TCu 380 Plus Normal | 254 168 29 46 46 174 174 79 79 17 16 275 100 168 120 29 76 |
| Tagrisso Taliglucerase alfa Tambocor German Tamoxifen citrate Tamoxifen Sandoz Tamsulosin hydrochloride Tamsulosin-Rex Tandem Cartridge Tandem Cartridge Tandem t:slim X2 with Basal-IQ Tandem t:slim X2 with Basal-IQ Tandem t:slim X2 with Control-IQ Tandem t:slim X2 with Control-IQ Tagigna Tasigna Tasigna Tasigna Taurine TCu 380 Plus Normal Tecentriq | 254 168 29 46 46 174 174 174 79 79 17 16 275 100 168 120 29 76 243 |
| Tagrisso | 254 168 29 46 46 174 174 79 79 17 16 275 100 168 120 29 76 243 138 |
| Tagrisso Taliglucerase alfa Tambocor German Tamoxifen citrate Tamoxifen Sandoz Tamsulosin hydrochloride Tamsulosin-Rex Tandem Cartridge Tandem Cartridge Tandem t:slim X2 with Basal-IQ Tandem t:slim X2 with Basal-IQ Tandem t:slim X2 with Control-IQ Tandem t:slim X2 with Control-IQ Tagigna Tasigna Tasigna Tasigna Taurine TCu 380 Plus Normal Tecentriq | 254 168 29 46 174 174 174 79 79 17 16 275 100 168 120 29 76 243 138 128 |

| Tegretol CR |
|------------------------------------|
| Telfast |
| Temaccord162 |
| Temazepam |
| Temozolomide |
| Temozolomide-Taro 162 |
| Tenofovir disoproxil |
| Tenofovir Disoproxil Emtricitabine |
| Viatr |
| Tenofovir Disoproxil Viatris |
| Tenoxicam |
| Tepadina |
| Terbinafine101 |
| Terbutaline sulphate |
| Teriflunomide |
| Teriflunomide Sandoz |
| Teriparatide |
| Teriparatida Tava |
| Teriparatide - Teva |
| |
| Testosterone cipionate |
| Testosterone esters |
| Testosterone undecanoate83 |
| Tetrabenazine |
| Tetrabenazine |
| Tetrabromophenol |
| |
| Tetracycline |
| Teva Lisinopril |
| Thalidomide |
| Thalomid |
| Theophylline |
| Thiamine hydrochloride |
| Thiamine multichem |
| THIO-TEPA |
| Thioguanine |
| Thiotepa |
| Thyroid and Antithyroid Agents |
| Ticagrelor |
| Ticagrelor Sandoz |
| Tilcotil |
| Timolol |
| Tiotropium bromide |
| Tiotropium bromide with |
| olodaterol |
| Tivicay |
| TMP |
| Tobramycin |
| Infection |
| Sensory |
| Tobramycin (Viatris) |
| Tobramycin BNM |
| Tobrex |
| Tocilizumab |
| Tofranil |

| Tolcapone120 |
|------------------------------------|
| Tolvaptan51 |
| Topamax130 |
| Topical Products for Joint and |
| Muscular Pain 115 |
| Topiramate130 |
| Topiramate Actavis130 |
| Total parenteral nutrition (TPN)43 |
| TPN |
| Tramadol hydrochloride126 |
| Tramal SR 100 126 |
| Tramal SR 150 126 |
| Tramal SR 200 126 |
| Trandate |
| Tranexamic acid |
| Tranylcypromine sulphate 127 |
| Trastuzumab (Herzuma)236 |
| Trastuzumab deruxtecan |
| Trastuzumab emtansine |
| Travatan |
| Travoprost |
| Treatments for Dementia |
| Treatments for Substance |
| Dependence |
| Trelegy Ellipta |
| Trental 400 |
| Tretinoin Dermatological65 |
| |
| Oncology |
| Triamcinolone acetonide |
| Alimentary |
| Dermatological |
| Hormone |
| Triamcinolone acetonide with |
| gramicidin, neomycin and nystatin |
| Dermatological |
| Sensory |
| Trientine |
| Trientine Waymade |
| Trikafta |
| Trimethoprim |
| Trimethoprim with |
| sulphamethoxazole |
| [Co-trimoxazole] |
| Triovir |
| Trisequens85 |
| Trisul |
| Trophic Hormones |
| Tropicamide270 |
| Trulicity12 |
| TruSteel |
| Tryzan45 |
| Tuberculin PPD [Mantoux] test315 |
| Tubersol |
| Two Cal HN |
| |

| TYR Anamix Infant | .293 |
|------------------------------------|-------|
| TYR Anamix Junior | .293 |
| TYR Anamix Junior LQ | .293 |
| TYR Explore 5 | 203 |
| TYR Lophlex LQ 20 | 200 |
| TYR Sphere 20 | .230 |
| | .293 |
| Tyrosine1000 | .294 |
| Tysabri | . 139 |
| - U - | |
| UK Synacthen | 83 |
| Ultibro Breezhaler | .261 |
| Ultraproct | 8 |
| Umeclidinium | .260 |
| Umeclidinium with vilanterol | 261 |
| Univent | |
| Upadacitinib | 200 |
| | |
| Ural | |
| Urea | 69 |
| Urex Forte | 49 |
| Urinary Agents | 79 |
| Urinary Tract Infections | .113 |
| UroFos | . 113 |
| Uromitexan | 159 |
| Ursodeoxycholic acid | 20 |
| Ursosan | |
| | 22 |
| Ustekinumab | .239 |
| Utrogestan | 85 |
| - V - | |
| Vaccinations | . 300 |
| Vaclovir | .106 |
| Valaciclovir | .106 |
| Valganciclovir | |
| Valganciclovir Viatris | 106 |
| Valine50 | 204 |
| Vancomycin | |
| Vancomycin | 99 |
| Vannair | |
| Varenicline tartrate | . 148 |
| Varicella vaccine [Chickenpox | |
| vaccine] | . 314 |
| Varicella zoster vaccine [Shingles | |
| vaccine] | 315 |
| Varilrix | .314 |
| Various | 272 |
| VariSoft | |
| Vasodilators | |
| | 54 |
| Vasopressin Agonists | 90 |
| Vasorex | 48 |
| Vebulis | |
| Vedafil | |
| Vedolizumab | .241 |
| Vegzelma | |
| Veletri | |
| Venclexta | |
| Venetoclax | |
| | |
| Venlafaxine | |
| Venomil | .257 |

| VENOX257 |
|--|
| Ventolin259 |
| Vepesid157 |
| Verapamil hydrochloride49 |
| Vermox |
| Versacloz133 |
| Vesanoid163 |
| Vexazone12 |
| Vfend 101 |
| Viaderm KC |
| Victoza12 |
| Vigabatrin 130 |
| Vigisom140 |
| Vildagliptin 12 |
| Vildagliptin with metformin |
| Vildagliptin with metformin hydrochloride12 |
| Vimpat |
| Vinblastine sulphate 164 |
| Vincristine sulphate |
| Vinorelbine |
| Vinorelbine Ebewe |
| Vinorelbine Te Arai |
| Viramune Suspension |
| ViruPOS |
| Vit.D3 |
| Vita-B12 |
| VitA-POS |
| Vitabdeck |
| Vital |
| Vitamin B complex |
| Vitamin B6 25 |
| Vitamins |
| Vitarubin Depot Injection |
| Vivonex TEN |
| Voltaren |
| Voltaren D114 |
| Voltaren SR 114 |
| Volumatic |
| Voriconazole |
| Votrient |
| Vttack |
| Vyvanse |
| - W - |
| Warfarin sodium |
| Wart Preparations |
| Wasp venom allergy treatment |
| Water |
| Blood |
| Extemporaneous |
| White Soft Liquid Paraffin AFT |
| Wool fat with mineral oil |
| - X - |
| Xalkori |
| Xaluprine |
| Xarelto |
| Xgeva 115 |
| |

| Xifaxan10 |
|------------------------------|
| XMET Maxamum |
| Xolair |
| Xolair AU214 |
| XP Maxamum |
| Xylocaine |
| Xylocaine 2% Jelly121 |
| Xylocard 500122 |
| Xyntha |
| - Y - |
| Yervoy |
| -7- |
| Zarontin |
| Zaroxolyn |
| Zavedos |
| Zeffix |
| Zejula |
| |
| Zematop |
| |
| Ziagen |
| Zidovudine [AZT] 110 |
| Zidovudine [AZT] with |
| lamivudine 110 |
| Ziextenzo |
| Ziextenzo AU42 |
| Zimybe53 |
| Zinc and castor oil69 |
| Zinc sulphate34 |
| Zincaps34 |
| Ziprasidone135 |
| Zista257 |
| Zithromax93 |
| Zo-Rub HP122 |
| Zo-Rub Osteo 115 |
| Zoladex90 |
| Zoledronic acid |
| Hormone82 |
| Musculoskeletal 117 |
| Zoledronic acid Viatris |
| Hormone82 |
| Musculoskeletal 117 |
| Zopiclone |
| Zopiclone Actavis |
| Zostrix |
| Zostrix HP |
| Zuclopenthixol decanoate |
| Zuclopenthixol hydrochloride |
| |
| Zusdone |
| Zyban |
| Zypine |
| Zypine ODT |
| Zyprexa Relprevv |
| Zytiga |
| Żyvox104 |





