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Introducing PHARMAC

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

PHARMAC's role:

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

New Zealand Public Health and Disability Act 2000

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

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

Purpose of the Pharmaceutical Schedule

The purpose of the Schedule is to list:

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

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

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

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

The index lists both chemical entities and product brand names.

Explaining pharmaceutical entries

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

Example

ANATOMICAL HEADING			
		Subsidy (Manufacturer's Price) \$	Fully Brand or Subsidised Generic Per ✓ Manufacturer
THERAPEUTIC HEADING			
CHEMICAL			
▲ Presentation, form and strength	10.00	100	Brand A ✓ Brand B
Presentation - Available on a PSO	15.00	50	✓ Brand C
⊕ Presentation - Retail pharmacy-specialist	18.00	250 ml OP	✓ Brand D
a) Prescriptions must be written by a paediatrician or paediatric cardiologist; or b) on the recommendation of a paediatrician or a paediatric cardiologist			
CHEMICAL			
* Presentation, form and strength	26.53	100	Brand E
(35.27)			
Sole Supply ✓ Fully Subsidised			
▲ Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber or pharmacist.			

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

Practitioner's Supply Order

Safety cap

Conditions of and restrictions on prescribing (including Special Authority where it applies)

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

Brand or manufacturer's name

Sole subsidised supply product

Fully subsidised product

Original Pack - Subsidy is rounded up to a multiple of whole packs

Quantity the Subsidy applies to

Subsidy paid on a product before mark-ups and GST

Manufacturer's Price if different from Subsidy

Glossary

Units of Measure

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

Abbreviations

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

BSO Bulk Supply Order.

CBS Cost Brand Source.

ECP Extemporaneously Compounded Preparation.

OP Original Pack – subsidy is rounded up to a multiple at whole packs.

PSO Practitioner's Supply Order.

Sole Subsidised

Supplier Only brand of this medicine subsidised.

XPharm Pharmacies cannot claim subsidy because PHARMAC has made alternative distribution arrangements.

▲ Three months supply may be dispensed at one time if the exempted medicine is endorsed 'certified exemption' by the practitioner or pharmacist.

* Three months dispensed all-at-once or, in the case of oral contraceptives, six months dispensed all-at-once, unless the medicine meets the Dispensing Frequency Rule criteria.

‡ Safety cap required for oral liquid formulations, including extemporaneously compounded preparations.

✓ Fully subsidised brand of a given medicine. Brands without the tick are not fully subsidised and may cost the patient a manufacturer's surcharge.

Ⓢ29 This medicine is an unapproved medication supplied under Section 29 of the Medicines Act 1981.

HP3 Subsidised when dispensed from a pharmacy that has a contract to dispense Special Foods.

HP4 Subsidised when dispensed from a pharmacy that has a contract to dispense from the Monitored Therapy Variation (for Clozapine Services).

Community Pharmaceutical costs met by the Government

Most of the cost of a subsidised prescription for a Community Pharmaceutical is met by the Government through the Combined Pharmaceutical Budget. The Government pays a subsidy for the Community Pharmaceutical to pharmacies, and a fee covering distribution and pharmacy dispensing services. The subsidy paid to pharmacies does not necessarily represent the final cost to Government of subsidising a particular Community Pharmaceutical. The final cost will depend on the nature of PHARMAC's contractual arrangements with the supplier. Fully subsidised medicines are identified with a ✓ in the product's Schedule listing.

Patient costs

Everyone who is eligible for publicly funded health and disability services should in most circumstances pay only a \$5 co-payment for subsidised medicines, although co-payments can vary from \$0 to \$15. Where the price of a Pharmaceutical is higher than the subsidy, a patient may pay a manufacturer's surcharge in addition to the co-payment. A patient may also pay additional fees for services such as after-hours dispensing and special packaging.

Patients can check whether they are eligible for publicly funded health and disability services by referring to the Guide to eligibility on the Ministry of Health's website.

DHBs have a list of eligible providers in their respective regions. Any provider/prescriber not specifically listed by a DHB as an approved provider/prescriber should be regarded as not approved.

For more information on patient co-payments or eligibility please visit <http://www.moh.govt.nz>.

Special Authority Applications

Special Authority is an application process in which a prescriber requests government subsidy on a Community Pharmaceutical for a particular person.

Subsidy

Once approved, the applicant will be provided a Special Authority number which must appear on the prescription.

The authority number can provide access to subsidy, increased subsidy, or waive certain restrictions otherwise present on the Community Pharmaceutical.

Some approvals are dependent on the availability of funding from the Combined Pharmaceutical Budget.

Criteria

The criteria for approval of Special Authority applications are included below each Community Pharmaceutical listing, and on the application forms available on PHARMAC's website. For some Special Authority Community Pharmaceuticals, not all indications that have been approved by Medsafe are subsidised.

Making a Special Authority application

Application forms can be found at <http://www.pharmac.govt.nz>. Except where stated on the application form, applications are processed by the Ministry of Health, and are sent to:

Ministry of Health Sector Services, Fax: (06) 349 1983 or free fax 0800 100 131
Private Bag 3015, WANGANUI 4540

To register for submission of applications on-line - Contact the Ministry of Health on 0800 505 125 or email at onlinehelpdesk@moh.govt.nz. For Special Authority approval numbers, applicants can phone the Ministry of Health Sector Services Call Centre, free phone 0800 243 666.

Named Patient Pharmaceutical Assessment policy

Named Patient Pharmaceutical Assessment (NPPA) provides a mechanism for individual patients to receive funding for medicines not listed in the Pharmaceutical Schedule (either at all or for their clinical circumstances). PHARMAC will assess applications that meet the prerequisites according to its Factors for Consideration before deciding whether to approve applications for funding. The Factors for Consideration will be used to assess both the individual clinical circumstances of each NPPA applicant, and the implications of each NPPA funding decision on PHARMAC's ability to carry out its legislative functions.

For more information on NPPA, or to apply, visit the PHARMAC website at <http://www.pharmac.govt.nz/nppa>, or call the Panel Coordinators at 0800 660 050 Option 2.

INTRODUCTION

Section A contains the restrictions and other general rules that apply to Subsidies on Community Pharmaceuticals. The amounts payable by the Funder to Contractors are currently determined by:

- the quantities, forms, and strengths, of subsidised Community Pharmaceuticals dispensed under valid prescription by each Contractor;
- the amount of the Subsidy on the Manufacturer's Price payable for each unit of the Community Pharmaceuticals dispensed by each Contractor and;
- the contractual arrangements between the Contractor and the Funder for the payment of the Contractor's dispensing services.

The Pharmaceutical Schedule shows the level of subsidy payable in respect of each Community Pharmaceutical so that the amount payable by the Government to Contractors, for each Community Pharmaceutical, can be calculated. The Pharmaceutical Schedule also shows the standard price (exclusive of GST) at which a Community Pharmaceutical is supplied ex-manufacturer to wholesalers if it differs from the subsidy. The manufacturer's surcharge to patients can be estimated using the subsidy and the standard manufacturer's price as set out in this Schedule.

The cost to Government of subsidising each Community Pharmaceutical and the manufacturer's prices may vary, in that suppliers may provide rebates to other stakeholders in the primary health care sector, including dispensers, wholesalers, and the Government. Rebates are not specified in the Pharmaceutical Schedule.

This Schedule is dated 1 March 2017 and is to be referred to as the Pharmaceutical Schedule Volume 24 Number 0, 2017. Distribution will be from 20 March 2017. This Schedule comes into force on 1 March 2017.

PART I INTERPRETATIONS AND DEFINITIONS

1.1 In this Schedule, unless the context otherwise requires:

"90 Day Lot", means the quantity of a Community Pharmaceutical required for the number of days' treatment covered by the Prescription, being up to 90 consecutive days' treatment;

"180 Day Lot", means the quantity of a Community Pharmaceutical required for the number of days' treatment covered by the Prescription, being up to 180 consecutive days' treatment;

"Access Exemption Criteria", means the criteria under which patients may receive greater than one Month's supply of a Community Pharmaceutical covered by Section F Part II (b) subsidised in one Lot. The specifics of these criteria are conveyed in the Ministry of Health guidelines, which are issued from time to time. The criteria the patient must meet are that they:

- a) have limited physical mobility;
- b) live and work more than 30 minutes from the nearest pharmacy by their normal form of transport;
- c) are relocating to another area;
- d) are travelling extensively and will be out of town when the repeat prescriptions are due.

"Act", means the New Zealand Public Health and Disability Act 2000.

"Advisory Committee", means the Pharmaceutical Services Advisory Committee convened by the Ministry of Health under the terms of the Advice Notice issued to Contractors pursuant to Section 88 of the Act.

"Alternate Subsidy", means a higher level of subsidy that the Government will pay contractors for a particular community Pharmaceutical dispensed to a person who has either been granted a Special Authority for that pharmaceutical, or where the prescription is endorsed in accordance with the requirements of this Pharmaceutical Schedule.

"Annotation", means written annotation of a prescription by a dispensing pharmacist in the pharmacist's own handwriting following confirmation from the Prescriber if required, and "Annotated" has a corresponding meaning. The Annotation must include the details specified in the Schedule, including the date the prescriber was contacted (if applicable) and be initialised by the dispensing pharmacist.

"Authority to Substitute", means an authority for the dispensing pharmacist to change a prescribed medicine in accordance with regulation 42(4) of the Medicines Regulations 1984. An authority to substitute letter, which may be used by Practitioners, is available on the final page of the Schedule.

"Bulk Supply Order", means a written order, on a form supplied by the Ministry of Health, or approved by the Ministry of Health, made by the licensee or manager of an institution certified to provide hospital care under the Health and Disability Services (Safety) Act 2001 for the supply of such Community Pharmaceuticals as are expected to be

required for the treatment of persons who are under the medical or dental supervision of such a Private Hospital or institution.

“Class B Controlled Drug”, means a Class B controlled drug within the meaning of the Misuse of Drugs Act 1975.

“Community Pharmaceutical”, means a Pharmaceutical listed in Sections A to G and Section I of the Pharmaceutical Schedule that is subsidised by the Funder from the Pharmaceutical Budget for use in the community.

“Contractor”, means a person who is entitled to receive a payment from the Crown or a DHB under a notice issued by the Crown or a DHB under Section 88 of the Act or under a contract with the Ministry of Health or a DHB for the supply of Community Pharmaceuticals.

“Controlled Drug”, means a controlled drug within the meaning of the Misuse of Drugs Act 1975 (other than a controlled drug specified in Part VI of the Third Schedule to that Act).

“Cost, Brand, Source of Supply”, means that the Community Pharmaceutical is eligible for Subsidy on the basis of the Contractor’s annotated purchase price, brand, and source of supply. Alternatively a copy of the invoice for the purchase of the Pharmaceutical may be attached to the prescription, in the place of an annotation, in order to be eligible for Subsidy.

“Dentist”, means a person registered with the Dental Council, and who holds a current annual practising certificate, under the HPCA Act 2003.

“Dietitian”, means a person registered as a dietitian with the Dietitians Board, and who holds a current annual practicing certificate under the HPCA Act 2003.

“DHB”, means an organisation established as a District Health Board by or under Section 19 of the Act.

“DHB Hospital”, means a DHB, including its hospital or associated provider unit that the DHB purchases Hospital Pharmaceuticals for.

“Dispensing Frequency Rule”, means the rule in Part IV, Section A of the Pharmaceutical Schedule that defines patient groups or medicines eligible for more frequent dispensing periods.

“Doctor”, means a medical Practitioner registered with the Medical Council of New Zealand and, who holds a current annual practising certificate under the HPCA Act 2003.

“DV Limit”, means, for a particular Hospital Pharmaceutical with HSS, the National DV Limit or the Individual DV Limit.

“DV Pharmaceutical”, means a discretionary variance Pharmaceutical, that does not have HSS and which:

- a) is either listed in Section H Part II of the Schedule as being a DV Pharmaceutical in association with the relevant Hospital Pharmaceutical with HSS; or
- b) is the same chemical entity, at the same strength, and in the same or a similar presentation or form, as the relevant Hospital Pharmaceutical with HSS, but which is not yet listed as being a DV Pharmaceutical.

“Endorsements”, unless otherwise specified, endorsements should be either handwritten or computer generated by the practitioner prescribing the medication. The endorsement can be written as “certified condition”, or state the condition of the patient, where that condition is specified for the Community Pharmaceutical in Section B of the Pharmaceutical Schedule. Where the practitioner writes “certified condition” as the endorsement, he/she is making a declaration that the patient meets the criteria as set out in Section B of the Pharmaceutical Schedule.

“Funder”, means the body or bodies responsible, pursuant to the Act, for the funding of pharmaceuticals listed on the Schedule (which may be one or more DHBs and/or the Ministry of Health) and their successors.

“GST”, means goods and services tax under the Goods and Services Tax Act 1985.

“Hospital Care Operator”, means a person for the time being in charge of providing hospital care, in accordance with the Health and Disability Services (Safety) Act 2001.

“Hospital Pharmaceuticals”, means the list of pharmaceuticals set out in Section H Part II of the Schedule which includes some National Contract Pharmaceuticals.

“Hospital Pharmacy”, means that the Community Pharmaceutical is not eligible for Subsidy unless it is supplied by a hospital or pharmacy contracted to the Funder to dispense as a hospital pharmacy to an person on the Prescription of a Practitioner.

“Hospital Pharmacy-Specialist”, means that the Community Pharmaceutical is not eligible for Subsidy unless it is supplied by a hospital or pharmacy contracted to the Funder to dispense as a hospital pharmacy to an Outpatient either:

- a) on a Prescription signed by a Specialist, or
- b) where the treatment with the Community Pharmaceutical has been recommended by a Specialist, on the Prescription of a practitioner which is either:
 - i) endorsed with the words “recommended by [name of specialist and year of authorisation]” and signed by

- the Practitioner, or
- ii) endorsed with the word 'protocol' which means "initiated in accordance with DHB hospital approved protocol",
 - iii) annotated by the dispensing pharmacist, following verbal confirmation from the Practitioner of the name of the Specialist and date of recommendation, with the words "recommended by [name of specialist and date of authorisation], confirmed by [practitioner]". Where the Contractor has an electronic record of such an Endorsement or Annotation from a previous prescription for the same Community Pharmaceutical written by a prescriber for the same patient, they may annotate the prescription accordingly.

"As recommended by a Specialist" to be interpreted as either:

- i) follows a substantive consultation with an appropriate Specialist;
 - ii) the consultation to relate to the Patient for whom the Prescription is written;
 - iii) consultation to mean communication by referral, telephone, letter, facsimile or email;
 - iv) except in emergencies consultation to precede annotation of the Prescription; and
 - v) both the specialist and the General Practitioner must keep a written record of the consultation; or
- a) treatment with the Community Pharmaceutical has been initiated in accordance with a DHB hospital approved protocol.

For the purposes of the definition it makes no difference whether or not the Specialist is employed by a hospital.

"Hospital Pharmacy-Specialist Prescription", means that the Community Pharmaceutical is not eligible for Subsidy unless it is supplied by a hospital or pharmacy contracted to the Funder to dispense as a hospital pharmacy:

- a) to an Outpatient; and
- b) on a Prescription signed by a Specialist.

For the purposes of this definition, a "specialist" means a doctor who holds a current annual practicing certificate and who satisfies the criteria set out in paragraphs (a) or (b) or (c) of the definitions of Specialist below.

"HSS", means hospital supply status, the status of being the brand of the relevant Hospital Pharmaceutical listed in Section H Part II as HSS, that DHBs are obliged to purchase subject to any DV Limit for that Hospital Pharmaceutical for the period of hospital supply, as awarded under an agreement between PHARMAC and the relevant pharmaceutical supplier.

"In Combination", means that the Community Pharmaceutical is only subsidised when prescribed in combination with another subsidised pharmaceutical as specified in Section B or C of the Pharmaceutical Schedule.

"Individual DV Limit", means, for a particular Hospital Pharmaceutical with HSS and a particular DHB Hospital, the discretionary variance limit, being the specified percentage of that DHB Hospital's Total Market Volume up to which that DHB Hospital may purchase DV Pharmaceuticals of that Hospital Pharmaceutical.

"Licensed Hospital", means a place or institution that is certified to provide hospital care within the meaning of the Health and Disability Services (Safety) Act 2001.

"Lot", means a quantity of a Community Pharmaceutical supplied in one dispensing.

"Manufacturer's Price", means the standard price at which a Community Pharmaceutical is supplied to wholesalers (excluding GST), as notified to PHARMAC by the supplier.

"Maternity hospital", means that the Community Pharmaceutical is not eligible for Subsidy unless it is supplied pursuant to a Bulk Supply Order to a maternity hospital certified under the Health and Disability Services (Safety) Act 2001.

"Midwife", means a person registered as a midwife with the Midwifery Council, and who holds a current annual practising certificate under the HPCA Act 2003.

"Month", means a period of 30 consecutive days.

"Monthly Lot", means the quantity of a Community Pharmaceutical required for the number of days' treatment covered by the Prescription, being up to 30 consecutive days' treatment;

"Named Patient Pharmaceutical Assessment Advisory Panel", means the panel of clinicians, appointed by the PHARMAC Board, that is responsible for advising, within its Terms of Reference, on Named Patient Pharmaceutical Assessment applications and Exceptional Circumstances renewal applications submitted after 1 March 2012 (EC renewal application form located at <http://www.pharmac.govt.nz/nppa#oldec>)

"National Contract Pharmaceutical", means a Hospital Pharmaceutical for which PHARMAC has negotiated a national contract and the Price.

"National DV Limit", means, for a particular Hospital Pharmaceutical with HSS, the discretionary variance limit, being the specified percentage of the Total Market Volume up to which all DHB Hospitals may collectively purchase DV Pharmaceuticals of that Hospital Pharmaceutical.

“National Immunisation Schedule”, means Section I of the Pharmaceutical Schedule, which is a schedule administered by PHARMAC, being a schedule specifying a programme of vaccinations to promote immunity against the diseases specified in the schedule.

“Not In Combination”, means that no Subsidy is available for any Prescription containing the Community Pharmaceutical in combination with other ingredients unless the particular combination of ingredients is separately specified in Section B or C of the Schedule, and then only to the extent specified.

“Nurse Practitioner”, means a nurse registered with Nursing Council of New Zealand, who holds a current annual practising certificate under the HPCA Act 2003 and for whom the Nursing Council has authorised a scope of practice that includes prescribing medicines

“Optional Pharmaceuticals”, means the list of National Contract Pharmaceuticals set out in Section H Part II of the Schedule

“Optometrist”, means a person registered with the Optometrists and Dispensing Opticians Board with a scope of practice that includes prescribing medicines (TPA endorsement)

“Outpatient”, in relation to a Community Pharmaceutical, means a person who, as part of treatment at a hospital or other institution under the control of a DHB, is prescribed the Community Pharmaceutical for consumption or use in the person's home.

“PCT”, means Pharmaceutical Cancer Treatment in respect of which DHB hospital pharmacies and other Contractors can claim Subsidies.

“PCT only”, means Pharmaceutical Cancer Treatment in respect of which only DHB hospital pharmacies can claim Subsidies.

“Penal Institution”, means a penal institution, as that term is defined in The Penal Institutions Act 1954;

“PHARMAC”, means the Pharmaceutical Management Agency established by Section 46 of the Act (PHARMAC).

“Pharmaceutical”, means a medicine, therapeutic medical device, or related product or related thing listed in Sections B to I of the Schedule.

“Pharmaceutical Benefits”, means the right of:

- a) a person; and
- b) any member under 16 years of age of that person's family, to have made by the Government on his or her behalf, subject to any conditions for the time being specified in the Schedule, such payment in respect of any Community Pharmaceutical supplied to that person or family member under the order of a Practitioner in the course of his or her practice.

“Pharmaceutical Budget”, means the pharmaceutical budget set for PHARMAC by the Crown for the subsidised supply of Community Pharmaceuticals and Pharmaceutical Cancer Treatments including for named patients in exceptional circumstances.

“Pharmaceutical Cancer Treatment”, means Pharmaceuticals for the treatment of cancer, listed in Sections A to G of the Schedule and identified therein as a “PCT” or “PCT only” Pharmaceutical that DHBs must provide access to, for use in their hospitals, and/or in association with Outpatient services provided in their DHB Hospitals, in relation to the treatment of cancers.

“Pharmacist Prescriber”, means a person registered with the Pharmacy Council of New Zealand, who holds a current annual practising certificate under the HPCA Act 2003, and is approved by the Pharmacy Council of New Zealand to prescribe specified prescription medicines relating to his/her scope of practice.

“Pharmacist”, means a person registered with the Pharmacy Council of New Zealand and who holds a current annual practicing certificate under the HPCA Act 2003.

“Practitioner”, means a Doctor, a Dentist, a Dietitian, a Midwife, a Nurse Practitioner, a Registered Nurse Prescriber, an Optometrist, a Quitcard Provider, or a Pharmacist Prescriber as those terms are defined in the Pharmaceutical Schedule.

“Practitioner's Supply Order”, means a written order made by a Practitioner on a form supplied by the Ministry of Health, or approved by the Ministry of Health, for the supply of Community Pharmaceuticals to the Practitioner, which the Practitioner requires to ensure medical supplies are available for emergency use, teaching and demonstration purposes, and for provision to certain patient groups where individual prescription is not practicable.

“Prescription”, means a quantity of a Community Pharmaceutical prescribed for a named person on a document signed by a Practitioner.

“Prescription Medicine”, means any Pharmaceutical listed in Part I of Schedule 1 of the Medicines Regulations 1984.

“Private Hospital”, means a hospital certified under the Health and Disability Services (Safety) Act 2001 that is

not owned or operated by a DHB.

“Quitcard Provider”, means a person registered with the Ministry of Health as a Quitcard Provider.

“Registered Nurse Prescriber”, means a registered nurse who meets specified requirements for qualifications, training and competence to be a designated prescriber for the purpose of prescribing specified prescription medicines under the Medicines (Designated Prescriber-Registered Nurses) Regulations 2016.

“Residential Disability Care Institution”, means premises used to provide residential disability care in accordance with the Health and Disability Services (Safety) Act 2001.

“Rest Home”, means premises used to provide rest home care in accordance with the Health and Disability Services (Safety) Act 2001.

“Restricted Medicine”, means any Pharmaceutical listed in Part II of Schedule 1 of the Medicines Regulations 1984.

“Retail Pharmacy-Specialist”, means that the Community Pharmaceutical is only eligible for Subsidy if it is either:

- a) supplied on a Prescription or Practitioner's Supply Order signed by a Specialist, or,
- b) in the case of treatment recommended by a Specialist, supplied on a Prescription or Practitioner's Supply Order and either:
 - i) endorsed with the words “recommended by [name of Specialist and year of authorisation]” and signed by the Practitioner, or
 - ii) endorsed with the word ‘protocol’ which means “initiated in accordance with DHB hospital approved protocol”, or
 - iii) Annotated by the dispensing pharmacist, following verbal confirmation from the Practitioner of the name of the Specialist and date of recommendation, with the words “recommended by [name of specialist and year of authorisation], confirmed by [practitioner]”. Where the Contractor has an electronic record of such an Endorsement or Annotation from a previous prescription for the same Community Pharmaceutical written by a prescriber for the same patient, they may annotate the prescription accordingly.

“As recommended by a Specialist” to be interpreted as either:

- a)
 - i) follows a substantive consultation with an appropriate Specialist;
 - ii) the consultation to relate to the Patient for whom the Prescription is written;
 - iii) consultation to mean communication by referral, telephone, letter, facsimile or email;
 - iv) except in emergencies consultation to precede annotation of the Prescription; and
 - v) both the Specialist and the General Practitioner must keep a written record of consultation; or
- b) treatment with the Community Pharmaceutical has been initiated in accordance with a DHB hospital approved protocol.

“Retail Pharmacy-Specialist Prescription”, means that the Community Pharmaceutical is only eligible for Subsidy if it is supplied on a Prescription, or Practitioner's Supply Order, signed by a Specialist.

For the purposes of this definition, a “specialist” means a doctor who holds a current annual practicing certificate and who satisfies the criteria set out in paragraphs (a) or (b) or (c) of the definitions of Specialist below.

“Safety Medicine”, means a Community Pharmaceutical defined in Section A, Part IV of the Pharmaceutical Schedule.

“Schedule”, means this Pharmaceutical Schedule and all its sections and appendices.

“Special Authority”, means that the Community Pharmaceutical or Pharmaceutical Cancer Treatment is only eligible for Subsidy or additional Subsidy for a particular person if an application meeting the criteria specified in the Schedule has been approved, and the valid Special Authority number is present on the prescription.

“Specialist”, in relation to a Prescription, means a doctor or nurse practitioner who holds a current annual practising certificate and who satisfies the criteria set out in paragraphs (a) or (b) or (c) or (d) below:

- a) the doctor is vocationally registered in accordance with the criteria set out by the Medical Council of New Zealand and the HPCA Act 2003 and who has written the Prescription in the course of practising in that area of medicine; or
- b) the doctor is recognised by the Ministry of Health as a specialist for the purposes of this Schedule and receives remuneration from a DHB at a level which that DHB considers appropriate for specialists and who has written that prescription in the course of practising in that area of competency; or
- c) the doctor is recognised by the Ministry of Health as a specialist in relation to a particular area of medicine for the purpose of writing Prescriptions and who has written the Prescription in the course of practising in that area of competency; or
- d) the doctor or nurse practitioner writes the prescription on DHB stationery and is appropriately authorised by

the relevant DHB to do so.

“Subsidy”, means the maximum amount that the Government will pay Contractors for a Community Pharmaceutical dispensed to a person eligible for Pharmaceutical Benefits and is different from the cost to Government of subsidising that Community Pharmaceutical. For the purposes of a DHB hospital pharmacy claiming for Pharmaceutical Cancer Treatments, Subsidy refers to any payment made to the DHB hospital pharmacy or service provider to which that pharmacy serves, and does not relate to a specific payment that might be made on submission of a claim.

“Supply Order”, means a Bulk Supply Order or a Practitioner’s Supply Order.

“Unapproved Indication”, means, for a Pharmaceutical, an indication for which it is not approved under the Medicines Act 1981. Practitioners prescribing Pharmaceuticals for Unapproved Indications should be aware of, and comply with, their obligations under Section 25 and/or Section 29 of the Medicines Act 1981 and as set out in Section A: General Rules, Part IV (Miscellaneous Provisions) rule 5.5.

“Unlisted Pharmaceutical”, means a Pharmaceutical that is within the scope of a Hospital Pharmaceutical but is not listed in Section H Part II

“Unusual Clinical Circumstances (UCC)”, means the pathway under the Named Patient Pharmaceutical Assessment policy for funding consideration for named patients whose clinical circumstances are so unusual that PHARMAC is unlikely, for administrative reasons, to consider listing treatments for these circumstances on the Schedule.

“Urgent Assessment (UA)”, means the pathway under the Named Patient Pharmaceutical Assessment policy for funding consideration for treatments for named patients where PHARMAC is also considering or is likely to consider the treatment for Schedule listing, but the patient’s clinical circumstances justify urgent assessment, prior to a decision on Schedule listing.

- 1.2 In addition to the above interpretations and definitions, unless the content requires otherwise, a reference in the Schedule to:
 - a) the singular includes the plural; and
 - b) any legislation includes a modification and re-enactment of, legislation enacted in substitution for, and a regulation, Order in Council, and other instrument from time to time issued or made under that legislation, where that legislation, regulation, Order in Council or other instrument has an effect on the prescribing, dispensing or subsidising of Community Pharmaceuticals.

PART II

COMMUNITY PHARMACEUTICALS SUBSIDY

- 2.1 Community Pharmaceuticals eligible for Subsidy include every medicine, therapeutic medical device or related product, or related thing listed in Sections B to G and I of the Schedule subject to:
 - 2.1.1 clauses 2.2 of the Schedule; and
 - 2.1.2 clauses 3.1 to 5.4 of the Schedule; and
 - 2.1.3 the conditions (if any) specified in Sections B to G and I of the Schedule;
- 2.2 No claim by a Contractor for payment in respect of the supply of Community Pharmaceuticals will be allowed unless the Community Pharmaceuticals so supplied:
 - 2.2.1 comply with the appropriate standards prescribed by regulations for the time being in force under the Medicines Act 1981; or
 - 2.2.2 in the absence of any such standards, comply with the appropriate standards for the time being prescribed by the British Pharmacopoeia; or
 - 2.2.3 in the absence of the standards prescribed in clauses 2.2.1 and 2.2.2, comply with the appropriate standards for the time being prescribed by the British Pharmaceutical Codex; or
 - 2.2.4 in the absence of the standards prescribed in clauses 2.2.1, 2.2.2 and 2.2.3 are of a grade and quality not lower than those usually applicable to Community Pharmaceuticals intended to be used for medical purposes.

**PART III
PERIOD AND QUANTITY OF SUPPLY****3.1 Doctors', Dentists', Dietitians', Midwives', Nurse Practitioners', Registered Nurse Prescribers', Optometrists and Pharmacist Prescribers' Prescriptions (other than oral contraceptives)**

The following provisions apply to all Prescriptions, other than those for an oral contraceptive, written by a Doctor, Dentist, Dietitian, Midwife, Nurse Practitioner, Registered Nurse Prescriber, Optometrist, or Pharmacist Prescriber unless specifically excluded:

- 3.1.1 For a Community Pharmaceutical other than a Class B Controlled Drug, only a quantity sufficient to provide treatment for a period not exceeding three Months will be subsidised.
- 3.1.2 For methylphenidate hydrochloride and dexamfetamine sulphate (except for Dentist prescriptions), only a quantity sufficient to provide treatment for a period not exceeding one Month will be subsidised.
- 3.1.3 For a Class B Controlled Drug:
 - a) other than Dentist prescriptions and methylphenidate hydrochloride and dexamfetamine sulphate, only a quantity:
 - i) sufficient to provide treatment for a period not exceeding 10 days; and
 - ii) which has been dispensed pursuant to a Prescription sufficient to provide treatment for a period not exceeding one Month, will be subsidised.
 - b) for a Dentist prescription only such quantity as is necessary to provide treatment for a period not exceeding five days will be subsidised.
- 3.1.4 Subject to clauses 3.1.3 and 3.1.7, for a Doctor, Dentist, Dietitian, Midwife, Nurse Practitioner or Registered Nurse Prescriber and 3.1.7 for an Optometrist, where a practitioner has prescribed a quantity of a Community Pharmaceutical sufficient to provide treatment for:
 - A) one Month or less than one Month, but dispensed by the Contractor in quantities smaller than the quantity prescribed, the Community Pharmaceutical will only be subsidised as if that Community Pharmaceutical had been dispensed in a Monthly Lot;
 - B) more than one Month, the Community Pharmaceutical will be subsidised only if it is dispensed:
 - i) in a 90 Day Lot, where the Community Pharmaceutical is a Pharmaceutical covered by Section F Part I of the Pharmaceutical Schedule; or
 - ii) if the Community Pharmaceutical is not a Pharmaceutical referred to in Section F Part I of the Pharmaceutical Schedule, in Monthly Lots, unless:
 - a) the eligible person or his/her nominated representative endorses the back of the Prescription form with a statement identifying which Access Exemption Criterion (Criteria) applies and signs that statement to this effect; or
 - b) both:
 - 1) the Practitioner endorses the Community Pharmaceutical on the Prescription with the words "certified exemption" written in the Practitioner's own handwriting, or signed or initialled by the Practitioner; and
 - 2) every Community Pharmaceutical endorsed as "certified exemption" is covered by Section F Part II of the Pharmaceutical Schedule.
- 3.1.5 A Community Pharmaceutical is only eligible for Subsidy if the Prescription under which it has been dispensed was presented to the Contractor:
 - a) for a Class B Controlled Drug, within eight days of the date on which the Prescription was written; or
 - b) for any other Community Pharmaceutical, within three Months of the date on which the Prescription was written.
- 3.1.6 No subsidy will be paid for any Prescription, or part thereof, that is not fulfilled within:
 - a) in the case of a Prescription for a total supply of from one to three Months, three Months from the date the Community Pharmaceutical was first dispensed; or
 - b) in any other case, one Month from the date the Community Pharmaceutical was first dispensed. Only that part of any Prescription that is dispensed within the time frames specified above is eligible for Subsidy.
- 3.1.7 If a Community Pharmaceutical:
 - a) is stable for a limited period only, and the Practitioner has endorsed the Prescription with the words

- “unstable medicine” and has specified the maximum quantity that may be dispensed at any one time; or
- b) is stable for a limited period only, and the Contractor has endorsed the Prescription with the words “unstable medicine” and has specified the maximum quantity that should be dispensed at any one time in all the circumstances of the particular case; or
- c) is under the Dispensing Frequency Rule,

The actual quantity dispensed will be subsidised in accordance with any such specification.

3.2 Oral Contraceptives

The following provisions apply to all Prescriptions written by a Doctor, Midwife, Nurse Practitioner, Registered Nurse Prescriber or a Pharmacist Prescriber for an oral contraceptive:

- 3.2.1 The prescribing Doctor, Midwife, Nurse Practitioner, Registered Nurse Prescriber, or a Pharmacist Prescriber must specify on the Prescription the period of treatment for which the Community Pharmaceutical is to be supplied. This period must not exceed six Months.
- 3.2.2 Where the period of treatment specified in the Prescription does not exceed six Months, the Community Pharmaceutical is to be dispensed:
 - a) in Lots as specified in the Prescription if the Community Pharmaceutical is under the Dispensing Frequency Rule; or
 - b) where no Lots are specified, in one Lot sufficient to provide treatment for the period prescribed.
- 3.2.3 An oral contraceptive is only eligible for Subsidy if the Prescription under which it has been dispensed was presented to the Contractor within three Months of the date on which it was written.
- 3.2.4 Where a Community Pharmaceutical on a Prescription is under the Dispensing Frequency Rule and a repeat on the Prescription remains unfulfilled after six Months from the date the Community Pharmaceutical was first dispensed only the actual quantity supplied by the Contractor within this time limit will be eligible for Subsidy.

3.3 Original Packs, Certain Antibiotics and Unapproved Medicines

- 3.3.1 Notwithstanding clauses 3.1 and 3.3 of the Schedule, if a Practitioner prescribes or orders a Community Pharmaceutical that is identified as an Original Pack (OP) on the Pharmaceutical Schedule and is packed in a container from which it is not practicable to dispense lesser amounts, every reference in those clauses to an amount or quantity eligible for Subsidy, is deemed to be a reference:
 - a) where an amount by weight or volume of the Community Pharmaceutical is specified in the Prescription, to the smallest container of the Community Pharmaceutical, or the smallest number of containers of the Community Pharmaceutical, sufficient to provide that amount; and
 - b) in every other case, to the amount contained in the smallest container of the Community Pharmaceutical that is manufactured in, or imported into, New Zealand.
- 3.3.2 If a Community Pharmaceutical is either:
 - a) the liquid oral form of an antibiotic to which a diluent must be added by the Contractor at the time of dispensing; or
 - b) an unapproved medicine supplied under Section 29 of the Medicines Act 1981, but excluding any medicine listed as Cost, Brand, Source of Supply, or
 - c) any other pharmaceutical that PHARMAC determines, from time to time and notes in the Pharmaceutical Schedule

and it is prescribed or ordered by a Practitioner in an amount that does not coincide with the amount contained in one or more standard packs of that Community Pharmaceutical, Subsidy will be paid for the amount prescribed or ordered by the Practitioner in accordance with either clause 3.1 or clause 3.3 of the Schedule, and for the balance of any pack or packs from which the Community Pharmaceutical has been dispensed. At the time of dispensing the Contractor must keep a record of the quantity discarded. To ensure wastage is reduced, the Contractor should reduce the amount dispensed to make it equal to the quantity contained in a whole pack where:

- a) the difference between the amount dispensed and the amount prescribed by the Practitioner is less than 10% (eg: if a prescription is for 105 mls then a 100 ml pack would be dispensed); and
- b) in the reasonable opinion of the Contractor the difference would not affect the efficacy of the course of treatment prescribed by the Practitioner.

Note: For the purposes of audit and compliance it is an act of fraud to claim wastage and then use the wastage amount for any subsequent prescription.

3.4 Pharmacist Prescribers' Prescriptions

The following apply to every prescription written by a Pharmacist Prescriber

- 3.4.1 Prescriptions written by a Pharmacist Prescriber for a Community Pharmaceutical will only be subsidised where they are for either:
- a) a Community Pharmaceutical classified as a Prescription Medicine and which a Pharmacist Prescriber is permitted under regulations to prescribe; or
 - b) any other Community Pharmaceutical that is a Restricted Medicine (Pharmacist Only Medicine), a Pharmacy Only Medicine or a General Sales Medicine.
- 3.4.2 Any Pharmacist Prescribers' prescriptions for a medication requiring a Special Authority will only be subsidised if it is for a repeat prescription (ie after the initial prescription with Special Authority approval was dispensed).

3.5 Registered Nurse Prescribers' Prescriptions

The following apply to every prescription written by a Registered Nurse Prescriber:

- 3.5.1 Prescriptions written by a Registered Nurse Prescriber for a Community Pharmaceutical will only be subsidised where they are for either:
- a) a Community Pharmaceutical classified as a Prescription Medicine and which a Registered Nurse Prescriber is permitted under regulations to prescribe; or
 - b) any other Community Pharmaceutical that is a Restricted Medicine (Pharmacist Only Medicine), a Pharmacy Only Medicine or a General Sale Medicine.
- 3.5.2 Any Registered Nurse Prescribers' prescriptions for a medication requiring a Special Authority will only be subsidised if it is for a repeat prescription (ie after the initial prescription with Special Authority approval was dispensed). Registered Nurse Prescribers are not eligible to apply for Special Authority approvals (initial or renewal).

3.6 Quitcard Providers' Prescriptions

Prescriptions written by a Quitcard Provider will only be subsidised where they are:

- a) for any of the following Community Pharmaceuticals: nicotine patches, nicotine lozenges or nicotine gum; and
- b) written on a Quitcard.

**PART IV
DISPENSING FREQUENCY RULE**

Rule 3.1.4 of the Pharmaceutical Schedule specifies, for community patients, a default period of supply for each Community Pharmaceutical (a Monthly Lot, 90 Day Lot or for oral contraceptives 180 Day Lot). This Dispensing Frequency Rule defines patient groups or medicines eligible for more frequent dispensing periods for Community Pharmaceuticals; and the conditions that must be met to enable any pharmacy to claim for payment of handling fees for the additional dispensings made. This Dispensing Frequency Rule relates to the circumstances in which a subsidy is payable for the Community Pharmaceutical; it does not override alternative dispensing frequencies as expressly stated in the Medicines Act, Medicines Regulations, Pharmacy Services Agreement or Pharmaceutical Schedule.

For the purposes of this Dispensing Frequency Rule:

"Frequent Dispensing" means:

- i) for a Community Pharmaceutical referred to in Section F Part I, (the Stat exemption) dispensing in quantities less than one 90 Day Lot (or for oral contraceptives, less than one 180 Day Lot); or
- ii) for any other Community Pharmaceutical dispensing in quantities less than a Monthly Lot

"Safety Medicine"

- i) an antidepressant listed under the "Cyclic and Related Agents" subheading;
- ii) an antipsychotic;
- iii) a benzodiazepine;
- iv) a Class B Controlled Drug;
- v) codeine (includes combination products);
- vi) buprenorphine with naloxone; or
- vii) zopiclone.

The Dispensing Frequency Rule covers 5 different circumstances where Frequent Dispensing for patients may be

clinically or otherwise appropriate. These are:

- 1) Long Term Condition (LTC) patients and Core patients, or
- 2) Persons in residential care, or
- 3) Trial periods, or
- 4) Safety and co-prescribed medicines, or
- 5) Pharmaceutical Supply Management.

4.1 Frequent Dispensing for patients registered as Long Term Condition (LTC) or Core patients

If a Pharmacist considers Frequent Dispensing is required, then:

- 4.1.1 For LTC registered patients, Frequent Dispensing can occur as often as the dispensing Pharmacist deems appropriate to meet that patient's compliance and adherence needs;
- 4.1.2 For Core (non-LTC) patients, Frequent Dispensing should be no more often than a Monthly Lot. Pharmacists may authorise monthly dispensing on a Stat exemption Community Pharmaceutical without prescriber authority. If the Pharmacist considers more frequent (than monthly) dispensing is necessary, prescriber approval is required. Verbal approval from the prescriber is acceptable provided it is annotated by the Pharmacist on the Prescription and dated.

4.2 Frequent Dispensings for persons in residential care

4.2.1 Community Pharmaceuticals can be dispensed to:

- any person whose placement in a Residential Disability Care Institution is funded by the Ministry of Health or a DHB; or
- a person assessed as requiring long term residential care services and residing in an age related residential care facility;

on the request of the person, their agent or caregiver or community residential service provider via Frequent Dispensing, provided the following conditions are met:

- a) the quantity or period of supply to be dispensed at any one time is not less than:
 - i) 7 days' supply for a Class B Controlled Drug; or
 - ii) 7 days' supply for clozapine in accordance with a Clozapine Dispensing Protocol; or
 - iii) 28 days' supply for any other Community Pharmaceutical (except under conditions outlined in 4.3 (Trial periods) below; and
- b) the prescribing Practitioner or dispensing Pharmacist has
 - i) included the name of the patient's residential placement or facility on the Prescription; and
 - ii) included the patient's NHI number on the Prescription; and
 - iii) specified the maximum quantity or period of supply to be dispensed at any one time.

4.2.2 Any person meeting the criteria above who is being initiated onto a new medicine or having their dose changed is able to have their medicine dispensed in accordance with 4.3 (Trial periods) below.

4.3 Frequent Dispensings for Trial Periods

Frequent Dispensing can occur when a Community Pharmaceutical has been prescribed for a patient who requires close monitoring due to recent initiation onto, or dose change for, the Community Pharmaceutical (applicable to the patient's first changed Prescription only) and the prescribing Practitioner has:

- endorsed each Community Pharmaceutical on the Prescription clearly with the words "Trial Period", or "Trial"; and
- specified the maximum quantity or period of supply to be dispensed for each Community Pharmaceutical at any one time.

Patients who reside in Penal Institutions are not eligible for Trial Periods.

4.4 Frequent Dispensing for Safety and co-prescribed medicines

4.4.1 For a Safety Medicine to be dispensed via Frequent Dispensing, both of the following conditions must be met:

- a) The patient is not a resident in a Penal Institution, or one of the residential placements or facilities referenced in 4.2 on the previous page; and
- b) The prescribing Practitioner has:
 - i) Assessed clinical risk and determined the patient requires increased Frequent Dispensing; and
 - ii) Specified the maximum quantity or period of supply to be dispensed for each Safety Medicine at each dispensing.

4.4.2 A Community Pharmaceutical that is co-prescribed with a Safety Medicine, which can be dispensed in accordance with rule 4.4.1 above, may be dispensed at the same frequency as the Safety Medicine if the dispensing pharmacist has:

- Assessed clinical risk and determined the patient requires Frequent Dispensing of their co-dispensed medicines; and
- Annotated the Prescription with the amended dispensing quantity and frequency.

4.5 Frequent Dispensing for Pharmaceutical Supply Management

4.5.1 Frequent Dispensing may be required from time to time to manage stock supply issues or emergency situations. Pharmacists may dispense more frequently than the Schedule would otherwise allow when all of the following conditions are met:

- a) PHARMAC has approved and notified pharmacists to annotate Prescriptions for a specified Community Pharmaceutical(s) "out of stock" without prescriber endorsement for a specified time; and
- b) the dispensing pharmacist has:
 - i) clearly annotated each of the approved Community Pharmaceuticals that appear on the Prescription with the words "out of stock" or "OOS"; and
 - ii) initialled the annotation in their own handwriting; and
 - iii) has complied with maximum quantity or period of supply to be dispensed at any one time, as specified by PHARMAC at the time of notification.

Note – no claim shall be made to any DHB for subsidised dispensing under this rule where dispensing occurs more frequently than specified by PHARMAC to manage the supply management issue.

PART V**MISCELLANEOUS PROVISIONS****5.1 Bulk Supply Orders**

The following provisions apply to the supply of Community Pharmaceuticals under Bulk Supply Orders:

- 5.1.1 No Community Pharmaceutical supplied under a Bulk Supply Order will be subsidised unless all the requirements in Section B, C or D of the Schedule applicable to that pharmaceutical are met.
- 5.1.2 The person who placed the Bulk Supply Order may be called upon by the Ministry of Health to justify the amount ordered.
- 5.1.3 Class B Controlled Drugs will be subsidised only if supplied under Bulk Supply Orders placed by an institution certified to provide hospital care under the Health and Disability Services (Safety) Act 2001.
- 5.1.4 Any order for a Class B Controlled Drug or for buprenorphine hydrochloride must be written on a Special Bulk Supply Order Controlled Drug Form supplied by the Ministry of Health.
- 5.1.5 Community Pharmaceuticals listed in Part I of the First Schedule to the Medicines Regulations 1984 will be subsidised only if supplied under a Bulk Supply Order placed by an institution certified to provide hospital care under the Health and Disability Services (Safety) Act 2001 and:
 - a) that institution employs a registered general nurse, registered with the Nursing Council and who holds a current annual practicing certificate under the HPCA Act 2003; and
 - b) the Bulk Supply Order is supported by a written requisition signed by a Hospital Care Operator.
- 5.1.6 No Subsidy will be paid for any quantity of a Community Pharmaceutical supplied under a Bulk Supply Order in excess of what is a reasonable monthly allocation for the particular institution, after taking into account stock on hand.
- 5.1.7 The Ministry of Health may, at any time, by public notification, declare that any approved institution within its particular region, is not entitled to obtain supplies of Community Pharmaceuticals under Bulk Supply Orders

with effect from the date specified in that declaration. Any such notice may in like manner be revoked by the Ministry of Health at any time.

5.2 Practitioner's Supply Orders

The following provisions apply to the supply of Community Pharmaceuticals to Practitioners under a Practitioner's Supply Order:

- 5.2.1 Subject to clause 5.2.3 and 5.2.6, a Practitioner may only order under a Practitioner's Supply Order those Community Pharmaceuticals listed in Section E Part I and only in such quantities as set out in Section E Part I that the Practitioner requires to ensure medical supplies are available for emergency use, teaching and demonstration purposes, and for provision to certain patient groups where individual prescription is not practicable.
- 5.2.2 Any order for a Class B Controlled Drug or for buprenorphine hydrochloride must be written on a Special Practitioner's Supply Order Controlled Drug Form supplied by the Ministry of Health.
- 5.2.3 A Practitioner may order such Community Pharmaceuticals as he or she expects to be required for personal administration to patients under the Practitioner's care if:
 - a) the Practitioner's normal practice is in the specified areas listed in Section E Part II of the Schedule, or if the Practitioner is a locum for a Practitioner whose normal practice is in such an area.
 - b) the quantities ordered are reasonable for up to one Month's supply under the conditions normally existing in the practice. (The Practitioner may be called on by the Ministry of Health to justify the amounts of Community Pharmaceuticals ordered.)
- 5.2.4 No Community Pharmaceutical ordered under a Practitioner's Supply order will be eligible for Subsidy unless:
 - a) the Practitioner's Supply Order is made on a form supplied for that purpose by the Ministry of Health, or approved by the Ministry of Health and which:
 - i) is personally signed and dated by the Practitioner; and
 - ii) sets out the Practitioner's address; and
 - iii) sets out the Community Pharmaceuticals and quantities; and;
 - b) all the requirements of Sections B and C of the Schedule applicable to that pharmaceutical are met.
- 5.2.5 The Ministry of Health may, at any time, on the recommendation of an Advisory Committee appointed by the Ministry of Health for that purpose, by public notification, declare that a Practitioner specified in such a notice is not entitled to obtain supplies of Community Pharmaceuticals under Practitioner's Supply Orders until such time as the Ministry of Health notifies otherwise.
- 5.2.6 A Practitioner working in the Rheumatic Fever Prevention Programme (RFPP) may order under a Practitioner's Supply Order such Community Pharmaceuticals (identified below) as he or she requires to ensure medical supplies are available for patients with suspected or confirmed Group A Streptococcal throat infections for the purposes of the RFPP in the following circumstances:
 - a) the RFPP provider name is written on the Practitioner's Supply Order; and
 - b) the total quantity ordered does not exceed a multiple of:
 - i) ten times the Practitioner's Supply Order current maximum listed in Section E Part I for amoxicillin grans for oral liq 250 mg per 5 ml, amoxicillin cap 250 mg and amoxicillin cap 500 mg; or
 - ii) two times the Practitioner's Supply Order current maximum listed in Section E Part I for phenoxymethyl penicillin grans for oral liquid 250 mg per 5 ml, phenoxymethyl penicillin cap 500 mg, erythromycin ethyl succinate grans for oral liq 200 mg per 5 ml and erythromycin ethyl succinate tab 400 mg; and
 - c) the practitioner must specify the order quantity in course-specific amounts on the Practitioner's Supply Order (e.g. 10 x 300 ml amoxicillin grans for oral liq 250 mg per 5 ml). This will enable the pharmacy to dispense each course separately and claim multiple service fees as per the Community Pharmacy Services Agreement.

5.3 Retail Pharmacy and Hospital Pharmacy-Specialist Restriction

The following provisions apply to Prescriptions for Community Pharmaceuticals eligible to be subsidised as "Retail Pharmacy-Specialist" and "Hospital Pharmacy-Specialist":

5.3.1 Record Keeping

It is expected that a record will be kept by both the General Practitioner and the Specialist of the fact of consultation and enough of the clinical details to justify the recommendation. This means referral by telephone will need to be followed up by written consultation.

5.3.2 **Expiry**

The recommendation expires at the end of two years and can be renewed by a further consultation.

5.3.3 The circulation by Specialists of the circumstances under which they are prepared to recommend a particular Community Pharmaceutical is acceptable as a guide. It must however be followed up by the procedure in subclauses 5.3.1 and 5.3.2, for the individual Patient.

5.3.4 The use of preprinted forms and named lists of Specialists (as circulated by some pharmaceutical companies) is regarded as inappropriate.

5.3.5 The Rules for Retail Pharmacy-Specialist and Hospital Pharmacy-Specialist will be audited as part of the Ministry of Health's routine auditing procedures.

5.4 **Pharmaceutical Cancer Treatments**

5.4.1 DHBs must provide access to Pharmaceutical Cancer Treatments for the treatment of cancers in their DHB hospitals, and/or in association with Outpatient services provided in their DHB hospitals.

5.4.2 DHBs must only provide access to Pharmaceuticals for the treatment of cancer that are listed as Pharmaceutical Cancer Treatments in Sections A to G of the Schedule, provided that DHBs may provide access to an unlisted pharmaceutical for the treatment of cancer where that unlisted pharmaceutical:

- a) has Named Patient Pharmaceutical Assessment (NPPA) approval;
- b) is being used as part of a bona fide clinical trial which has Ethics Committee approval;
- c) is being used and funded as part of a paediatric oncology service; or
- d) was being used to treat the patient in question prior to 1 July 2005.

5.4.3 A DHB hospital pharmacy that holds a claiming agreement for Pharmaceutical Cancer Treatments with the Funder may claim a Subsidy for a Pharmaceutical Cancer Treatment marked as "PCT" or "PCT only" in Sections A to G of this Schedule subject to that Pharmaceutical Cancer Treatment being dispensed in accordance with:

- a) Part 1;
- b) clauses 2.1 to 2.2;
- c) clauses 3.1 to 3.4; and
- d) clause 5.4,

of Section A of the Schedule

5.4.4 A Contractor (other than a DHB hospital pharmacy) may only claim a Subsidy for a Pharmaceutical Cancer Treatment marked as "PCT" in Sections A to G of the Schedule subject to that Pharmaceutical Cancer Treatment being dispensed in accordance with the rules applying to Sections A to G of the Schedule.

5.4.5 Some indications for Pharmaceutical Cancer Treatments listed in the Schedule are Unapproved Indications. Some of these formed part of the October 2001 decision by the Minister of Health as to pharmaceuticals and indications for which DHBs must provide access. As far as reasonably practicable, these Unapproved Indications are marked in the Schedule. However, PHARMAC makes no representation and gives no guarantee as to the accuracy of this information. Practitioners prescribing Pharmaceutical Cancer Treatments for such Unapproved Indications should:

- a) be aware of and comply with their obligations under sections 25 and 29 of the Medicines Act 1981, as applicable, and otherwise under that act and the Medicines Regulations 1984;
- b) be aware of and comply with their obligations under the Health and Disability Commissioner's Code of Consumer Rights, including the requirement to obtain informed consent from the patient (PHARMAC recommends that Practitioners obtain written consent); and
- c) exercise their own skill, judgement, expertise and discretion, and make their own prescribing decisions with respect to the use of an unapproved Pharmaceutical Cancer Treatment or a Pharmaceutical Cancer Treatment for an Unapproved Indication.

5.4.6 Applications to add pharmaceuticals, and add or amend indications for Pharmaceutical Cancer Treatments, may be made in writing by pharmaceutical suppliers and/or clinicians to PHARMAC. Applications should follow the Guidelines for Funding Applications to PHARMAC 2010 and Recommended methods to derive clinical inputs for proposals to PHARMAC, copies of which are available from PHARMAC or PHARMAC's website.

5.5 **Practitioners prescribing unapproved Pharmaceuticals**

Practitioners should, where possible, prescribe Pharmaceuticals that are approved under the Medicines Act 1981. However, the access criteria under which a Pharmaceutical is listed on the Pharmaceutical Schedule may:

- a) in some case, explicitly permit Government funded access to a Pharmaceutical that is not approved under

- the Medicines Act 1981 or for an Unapproved Indication; or
- b) not explicitly preclude Government funded access to a Pharmaceutical when it is used for an Unapproved Indication;

Accordingly, if Practitioners are planning on prescribing an unapproved Pharmaceutical or a Pharmaceutical for an Unapproved Indication, Practitioners should:

- a) be aware of and comply with their obligations under sections 25 and 29 of the Medicines Act 1981, as applicable, and otherwise under that Act and the Medicines Regulations 1984;
- b) be aware of and comply with their obligations under the Health and Disability Commissioner's Code of Consumer Rights, including the requirement to obtain informed consent from the patient (PHARMAC recommends that Practitioners obtain written consent); and
- c) exercise their own skill, judgment, expertise and discretion, and make their own prescribing decisions with respect to the use of an unapproved Pharmaceutical or a Pharmaceutical for an Unapproved Indication.

Practitioners should be aware that simply by listing a Pharmaceutical on the Pharmaceutical Schedule PHARMAC makes no representations about whether that Pharmaceutical has any form of approval or consent under, or whether the supply or use of the Pharmaceutical otherwise complies with, the Medicines Act 1981. Further, the Pharmaceutical Schedule does not constitute an advertisement, advertising material or a medical advertisement as defined in the Medicines Act or otherwise.

5.6 **Substitution**

Where a Practitioner has prescribed a brand of a Community Pharmaceutical that has no Subsidy or has a Manufacturer's Price that is greater than the Subsidy and there is an alternative fully subsidised Community Pharmaceutical available, a Contractor may dispense the fully subsidised Community Pharmaceutical, unless either or both of the following circumstances apply:

- a) there is a clinical reason why substitution should not occur; or
- b) the prescriber has marked the prescription with a statement such as 'no brand substitution permitted'

Such an Authority to Substitute is valid whether or not there is a financial implication for the Pharmaceutical Budget. When dispensing a subsidised alternative brand, the Contractor must annotate and sign the prescription and inform the patient of the brand change.

5.7 **Alteration to Presentation of Pharmaceutical Dispensed**

A Contractor, when dispensing a subsidised Community Pharmaceutical, may alter the presentation of a Pharmaceutical dispensed to another subsidised presentation but may not alter the dose, frequency and/or total daily dose. This may only occur when it is not practicable for the contractor to dispense the requested presentation. If the change will result in additional cost to the DHBs, then annotation of the prescription by the dispensing pharmacist must occur stating the reason for the change, and the Contractor must initial the change for the purposes of Audit.

5.8 **Other DHB Funding**

A DHB may fund a Community Pharmaceutical outside of the mechanisms established in the Pharmaceutical Schedule, provided that:

- a) specific prior agreement is obtained from PHARMAC for such funding;
- b) any funding restrictions set out in the Pharmaceutical Schedule for those Community Pharmaceuticals are applied; and
- c) a Contractor (including a DHB Hospital Pharmacy) may not claim a Subsidy for a Community Pharmaceutical dispensed and funded by the DHB via such an alternate mechanism.

5.9 **Conflict in Provisions**

If any rules in Sections B-G and Section I of this Schedule conflict with the rules in Section A, the rules in Sections B-G and Section I apply.

SECTION B: ALIMENTARY TRACT AND METABOLISM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Antacids and Antiflatulants				
Antacids and Reflux Barrier Agents				
ALGINIC ACID				
Sodium alginate 225 mg and magnesium alginate 87.5 mg per sachet	5.31	30	✓	Gaviscon Infant
SODIUM ALGINATE				
* Tab 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg - peppermint flavour	1.80 (8.60)	60		Gaviscon Double Strength
* Oral liq 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml	1.50 (4.95)	500 ml		Acidex
Phosphate Binding Agents				
ALUMINIUM HYDROXIDE				
* Tab 600 mg	12.56	100	✓	Alu-Tab
CALCIUM CARBONATE				
Oral liq 1,250 mg per 5 ml (500 mg elemental per 5 ml) – Subsidy by endorsement	39.00	500 ml	✓	Roxane
Only when prescribed for children under 12 years of age for use as a phosphate binding agent and the prescription is endorsed accordingly.				
Antidiarrhoeals				
Agents Which Reduce Motility				
LOPERAMIDE HYDROCHLORIDE – Up to 30 cap available on a PSO				
* Tab 2 mg	10.75	400	✓	Nodia
* Cap 2 mg	7.05	400	✓	Diamide Relief
Rectal and Colonic Anti-inflammatories				
BUDESONIDE				
Cap 3 mg – Special Authority see SA1155 below – Retail pharmacy	166.50	90	✓	Entocort CIR
►SA1155 Special Authority for Subsidy				
Initial application — (Crohn's disease) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:				
Both:				
1 Mild to moderate ileal, ileocaecal or proximal Crohn's disease; and				
2 Any of the following:				
2.1 Diabetes; or				
2.2 Cushingoid habitus; or				
2.3 Osteoporosis where there is significant risk of fracture; or				
2.4 Severe acne following treatment with conventional corticosteroid therapy; or				
2.5 History of severe psychiatric problems associated with corticosteroid treatment; or				
continued...				

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

- 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 allogeneic bone marrow transplantation*.

Note: Indication marked with * is an Unapproved Indication.

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

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

HYDROCORTISONE ACETATE

Rectal foam 10%, CFC-Free (14 applications)	26.55	21.1 g OP	✓ <u>Colifoam</u>
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MESALAZINE

Tab 400 mg	49.50	100	✓ <u>Asacol</u>
Tab EC 500 mg	49.50	100	✓ <u>Asamax</u>
Tab long-acting 500 mg	59.05	100	✓ <u>Pentasa</u>
Tab 800 mg	85.50	90	✓ <u>Asacol</u>
Modified release granules, 1 g	141.72	120 OP	✓ <u>Pentasa</u>
Enema 1 g per 100 ml	41.30	7	✓ <u>Pentasa</u>
Suppos 500 mg	22.80	20	✓ <u>Asacol</u>
Suppos 1 g	54.60	30	✓ <u>Pentasa</u>

OLSALAZINE

Tab 500 mg	59.86	100	✓ <u>Dipentum</u>
Cap 250 mg	31.51	100	✓ <u>Dipentum</u>

SODIUM CROMOGLYCATE

Cap 100 mg	92.91	100	✓ <u>Nalcrom</u>
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SULPHASALAZINE

* Tab 500 mg – For sulphasalazine oral liquid formulation refer, page 224	14.00	100	✓ <u>Salazopyrin</u>
* Tab EC 500 mg	13.50	100	✓ <u>Salazopyrin EN</u>

Local preparations for Anal and Rectal Disorders

Antihaemorrhoidal Preparations

FLUOCORTOLONE CAPROATE WITH FLUOCORTOLONE PIVALATE AND CINCHOCAINE

Oint 950 mcg, with fluocortolone pivalate 920 mcg, and cin- chocaine hydrochloride 5 mg per g	6.35	30 g OP	✓ <u>Ultraproct</u>
Suppos 630 mcg, with fluocortolone pivalate 610 mcg, and cinchocaine hydrochloride 1 mg	2.66	12	✓ <u>Ultraproct</u>

HYDROCORTISONE WITH CINCHOCAINE

Oint 5 mg with cinchocaine hydrochloride 5 mg per g	15.00	30 g OP	✓ <u>Proctosedyl</u>
Suppos 5 mg with cinchocaine hydrochloride 5 mg per g	9.90	12	✓ <u>Proctosedyl</u>

‡ safety cap

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

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

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

GLYCERYL TRINITRATE – Special Authority see SA1329 below – Retail pharmacy

* Oint 0.2%	22.00	30 g OP	✓ Rectogesic
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►SA1329 Special Authority for Subsidy

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

Antispasmodics and Other Agents Altering Gut Motility

GLYCOPYRRONIUM BROMIDE

Inj 200 mcg per ml, 1 ml ampoule – Up to 10 inj available on a PSO	17.14	10	✓ Max Health
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HYOSCINE N-BUTYLBROMIDE

* Tab 10 mg	2.18	20	✓ Gastrosoothe
* Inj 20 mg, 1 ml – Up to 5 inj available on a PSO	9.57	5	✓ Buscopan

MEBEVERINE HYDROCHLORIDE

* Tab 135 mg	18.00	90	✓ Colofac
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Antiulcerants

Antisecretory and Cytoprotective

MISOPROSTOL

* Tab 200 mcg	41.50	120	✓ Cytotec
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Helicobacter Pylori Eradication

CLARITHROMYCIN

Tab 500 mg – Subsidy by endorsement	10.40	14	✓ Apo-Clarithromycin
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a) Maximum of 14 tab per prescription

b) Subsidised only if prescribed for helicobacter pylori eradication and prescription is endorsed accordingly.

Note: the prescription is considered endorsed if clarithromycin is prescribed in conjunction with a proton pump inhibitor and either amoxicillin or metronidazole.

H2 Antagonists

RANITIDINE – Only on a prescription

* Tab 150 mg	10.30	500	✓ Ranitidine Relief
* Tab 300 mg	14.73	500	✓ Ranitidine Relief
* Oral liq 150 mg per 10 ml	4.92	300 ml	✓ Peptisoothe
* Inj 25 mg per ml, 2 ml	8.75	5	✓ Zantac

Proton Pump Inhibitors

LANSOPRAZOLE

* Cap 15 mg	5.08	100	✓ Lanzol Relief
* Cap 30 mg	5.93	100	✓ Lanzol Relief

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
OMEPRAZOLE				
For omeprazole suspension refer Standard Formulae, page 227				
* Cap 10 mg	2.23	90	✓	Omezol Relief
* Cap 20 mg	2.91	90	✓	Omezol Relief
* Cap 40 mg	4.42	90	✓	Omezol Relief
* Powder – Only in combination	42.50	5 g	✓	Midwest
Only in extemporaneously compounded omeprazole suspension.				
* Inj 40 mg ampoule with diluent	33.98	5	✓	Dr Reddy's Omeprazole
PANTOPRAZOLE				
* Tab EC 20 mg	2.41	100	✓	Panzop Relief
* Tab EC 40 mg	3.35	100	✓	Panzop Relief

Site Protective Agents

COLLOIDAL BISMUTH SUBCITRATE

Tab 120 mg	14.51	50	✓	Gastrodenol ^{S29}
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SUCRALFATE

Tab 1 g	35.50 (48.28)	120		Carafate
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Bile and Liver Therapy

RIFAXIMIN – Special Authority see SA1461 below – Retail pharmacy

Tab 550 mg	625.00	56	✓	Xifaxan
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►SA1461 Special Authority for Subsidy

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

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

Diabetes

Hyperglycaemic Agents

DIAZOXIDE – Special Authority see SA1320 below – Retail pharmacy

Cap 25 mg	110.00	100	✓	Proglucem ^{S29}
Cap 100 mg	280.00	100	✓	Proglucem ^{S29}
Oral liq 50 mg per ml	620.00	30 ml OP	✓	Proglucem ^{S29}

►SA1320 Special Authority for Subsidy

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

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

GLUCAGON HYDROCHLORIDE

Inj 1 mg syringe kit – Up to 5 kit available on a PSO	32.00	1	✓	Glucagen Hypokit
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‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Insulin - Short-acting Preparations				
INSULIN NEUTRAL				
▲ Inj human 100 u per ml	25.26	10 ml OP	✓	Actrapid
			✓	Humulin R
▲ Inj human 100 u per ml, 3 ml	42.66	5	✓	Actrapid Penfill
			✓	Humulin R
Insulin - Intermediate-acting Preparations				
INSULIN ASPART WITH INSULIN ASPART PROTAMINE				
▲ Inj 100 iu per ml, 3 ml prefilled pen	52.15	5	✓	NovoMix 30 FlexPen
INSULIN ISOPHANE				
▲ Inj human 100 u per ml	17.68	10 ml OP	✓	Humulin NPH
			✓	Protaphane
▲ Inj human 100 u per ml, 3 ml	29.86	5	✓	Humulin NPH
			✓	Protaphane Penfill
INSULIN ISOPHANE WITH INSULIN NEUTRAL				
▲ Inj human with neutral insulin 100 u per ml	25.26	10 ml OP	✓	Humulin 30/70
			✓	Mixtard 30
▲ Inj human with neutral insulin 100 u per ml, 3 ml	42.66	5	✓	Humulin 30/70
			✓	PenMix 30
			✓	PenMix 40
			✓	PenMix 50
INSULIN LISPRO WITH INSULIN LISPRO PROTAMINE				
▲ Inj lispro 25% with insulin lispro protamine 75% 100 u per ml, 3 ml	42.66	5	✓	Humalog Mix 25
▲ Inj lispro 50% with insulin lispro protamine 50% 100 u per ml, 3 ml	42.66	5	✓	Humalog Mix 50
Insulin - Long-acting Preparations				
INSULIN GLARGINE				
▲ Inj 100 u per ml, 10 ml	63.00	1	✓	Lantus
▲ Inj 100 u per ml, 3 ml	94.50	5	✓	Lantus
▲ Inj 100 u per ml, 3 ml disposable pen	94.50	5	✓	Lantus SoloStar
Insulin - Rapid Acting Preparations				
INSULIN ASPART				
▲ Inj 100 u per ml, 3 ml syringe	51.19	5	✓	NovoRapid FlexPen
▲ Inj 100 u per ml, 3 ml	51.19	5	✓	NovoRapid Penfill
▲ Inj 100 u per ml, 10 ml	30.03	1	✓	NovoRapid
INSULIN GLULISINE				
▲ Inj 100 u per ml, 10 ml	27.03	1	✓	Apidra
▲ Inj 100 u per ml, 3 ml	46.07	5	✓	Apidra
▲ Inj 100 u per ml, 3 ml disposable pen	46.07	5	✓	Apidra SoloStar
INSULIN LISPRO				
▲ Inj 100 u per ml, 10 ml	34.92	10 ml OP	✓	Humalog
▲ Inj 100 u per ml, 3 ml	59.52	5	✓	Humalog

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

ACARBOSE

* Tab 50 mg	4.28	90	✓ <u>Glucobay</u>
* Tab 100 mg	7.78	90	✓ <u>Glucobay</u>

Oral Hypoglycaemic Agents

GLIBENCLAMIDE

* Tab 5 mg	5.00	100	✓ <u>Daonil</u>
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GLICLAZIDE

* Tab 80 mg	11.50	500	✓ <u>Glizide</u>
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GLIPIZIDE

* Tab 5 mg	2.85	100	✓ <u>Minidiab</u>
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METFORMIN HYDROCHLORIDE

* Tab immediate-release 500 mg	9.59	1,000	✓ <u>Metchek</u>
* Tab immediate-release 850 mg	7.82	500	✓ <u>Apotex</u>
			✓ <u>Metformin Mylan</u>

PIOGLITAZONE

* Tab 15 mg	3.47	90	✓ <u>Vexazone</u>
* Tab 30 mg	5.06	90	✓ <u>Vexazone</u>
* Tab 45 mg	7.10	90	✓ <u>Vexazone</u>

Diabetes Management

Ketone Testing

BLOOD KETONE DIAGNOSTIC TEST METER – Up to 1 meter available on a PSO

Meter funded for the purposes of blood ketone diagnostics only. Patient has had one or more episodes of ketoacidosis and is at risk of future episodes or patient is on an insulin pump. Only one meter per patient will be subsidised every 5 years.

Meter	40.00	1	✓ <u>Freestyle Optium Neo</u>
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KETONE BLOOD BETA-KETONE ELECTRODES

a) Maximum of 20 strip per prescription

b) Up to 10 strip available on a PSO

Test strip – Not on a BSO	15.50	10 strip OP	✓ <u>Freestyle Optium Ketone</u>
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SODIUM NITROPRUSSIDE – Maximum of 50 strip per prescription

* Test strip – Not on a BSO	6.00	50 strip OP	✓ <u>Accu-Chek Ketur-Test</u>
	14.14		✓ <u>Ketostix</u>

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

BLOOD GLUCOSE DIAGNOSTIC TEST METER – Subsidy by endorsement

- Maximum of 1 pack per prescription
 - Up to 1 pack available on a PSO
 - A diagnostic blood glucose test meter is subsidised for a patient who:
 - is receiving insulin or sulphonylurea therapy; or
 - is pregnant with diabetes; or
 - is on home TPN at risk of hypoglycaemia or hyperglycaemia; or
 - has a genetic or an acquired disorder of glucose homeostasis excluding type 1 or type 2 diabetes and metabolic syndrome.
- Only one CareSens meter per patient. No further prescriptions will be subsidised for patients who already have a CareSens meter. For the avoidance of doubt patients who have previously received a funded meter, other than CareSens, are eligible for a CareSens meter. The prescription must be endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of insulin or sulphonylureas.
- Meter with 50 lancets, a lancing device and 10 diagnostic test

strips	20.00	1 OP	✓ CareSens II ✓ CareSens N ✓ CareSens N POP
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Note: Only 1 meter available per PSO

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

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

- Prescribed for a patient on insulin or a sulphonylurea and endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of insulin or sulphonylurea; or
- Prescribed on the same prescription as insulin or a sulphonylurea in which case the prescription is deemed to be endorsed; or
- Prescribed for a pregnant woman with diabetes and endorsed accordingly; or
- Prescribed for a patient on home TPN at risk of hypoglycaemia or hyperglycaemia and endorsed accordingly; or
- 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 – Note differing brand requirements

below	10.56	50 test OP	✓ CareSens ✓ CareSens N ✓ Accu-Chek Performa ✓ Freestyle Optium
	28.75		

- Accu-Chek Performa brand: Special Authority see SA1294 below – Retail pharmacy
- Freestyle Optium brand: Special Authority see SA1291 below – Retail pharmacy
- Note: Accu-Chek Performa and Freestyle Optium are not available on a PSO

►SA1294 Special Authority for Subsidy

Notes: Application details may be obtained from PHARMAC's website <http://www.pharmac.govt.nz> and can be sent to:

PHARMAC
PO Box 10 254 Facsimile: (04) 974 4788
Wellington Email: bgstrips@pharmac.govt.nz

►SA1291 Special Authority for Subsidy

Notes: Application details may be obtained from PHARMAC's website <http://www.pharmac.govt.nz> and can be sent to:

PHARMAC
PO Box 10 254 Facsimile: (04) 974 4788
Wellington Email: bgstrips@pharmac.govt.nz

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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BLOOD GLUCOSE TEST STRIPS (VISUALLY IMPAIRED)

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

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

Blood glucose test strips26.20 50 test OP ✓ **SensoCard**

Insulin Syringes and Needles

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

INSULIN PEN NEEDLES – Maximum of 100 dev per prescription

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

INSULIN SYRINGES, DISPOSABLE WITH ATTACHED NEEDLE – Maximum of 100 dev per prescription

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

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Insulin Pumps				
INSULIN PUMP – Special Authority see SA1603 below – Retail pharmacy				
a) Maximum of 1 dev per prescription				
b) Only on a prescription				
c) Maximum of 1 insulin pump per patient each four year period.				
Min basal rate 0.025 U/h; black colour	4,500.00	1	✓	Animas Vibe
Min basal rate 0.025 U/h; blue colour	4,500.00	1	✓	Animas Vibe
Min basal rate 0.025 U/h; green colour	4,500.00	1	✓	Animas Vibe
Min basal rate 0.025 U/h; pink colour	4,500.00	1	✓	Animas Vibe
Min basal rate 0.025 U/h; silver colour	4,500.00	1	✓	Animas Vibe
Min basal rate 0.05 U/h; blue colour	4,400.00	1	✓	Paradigm 522
			✓	Paradigm 722
Min basal rate 0.05 U/h; clear colour	4,400.00	1	✓	Paradigm 522
			✓	Paradigm 722
Min basal rate 0.05 U/h; pink colour	4,400.00	1	✓	Paradigm 522
			✓	Paradigm 722
Min basal rate 0.05 U/h; purple colour	4,400.00	1	✓	Paradigm 522
			✓	Paradigm 722
Min basal rate 0.05 U/h; smoke colour	4,400.00	1	✓	Paradigm 522
			✓	Paradigm 722

SA1603 Special Authority for Subsidy

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

All of the following:

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

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

All of the following:

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

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

All of the following:

continued...

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

continued...

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

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

All of the following:

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

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

All of the following:

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

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

All of the following:

continued...

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

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

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

All of the following:

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

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

All of the following:

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

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

Insulin Pump Consumables

►SA1604 Special Authority for Subsidy

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

continued...

‡ safety cap

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

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

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

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

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

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

All of the following:

continued...

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

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

INSULIN PUMP ACCESSORIES – Special Authority see SA1604 on page 31 – Retail pharmacy

- a) Maximum of 1 cap per prescription
 - b) Only on a prescription
 - c) Maximum of 1 prescription per 180 days.
- | | | | |
|-------------------|-------|---|----------------------|
| Battery cap | 32.00 | 1 | ✓ Animas Battery Cap |
|-------------------|-------|---|----------------------|

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
INSULIN PUMP INFUSION SET (STEEL CANNULA) – Special Authority see SA1604 on page 31 – Retail pharmacy			
a) Maximum of 3 sets per prescription			
b) Only on a prescription			
c) Maximum of 13 infusion sets will be funded per year.			
10 mm steel needle; 29 G; manual insertion; 60 cm tubing × 10 with 10 needles 130.00	130.00	1 OP	✓ Paradigm Sure-T MMT-884
10 mm steel needle; 29 G; manual insertion; 60 cm tubing × 10 with 10 needles; luer lock 130.00	130.00	1 OP	✓ Sure-T MMT-883
10 mm steel needle; 29 G; manual insertion; 80 cm tubing × 10 with 10 needles 130.00	130.00	1 OP	✓ Paradigm Sure-T MMT-886
10 mm steel needle; 29 G; manual insertion; 80 cm tubing × 10 with 10 needles; luer lock 130.00	130.00	1 OP	✓ Sure-T MMT-885
6 mm steel cannula; straight insertion; 60 cm grey line × 10 with 10 needles 130.00	130.00	1 OP	✓ Contact-D
6 mm steel needle; 29 G; manual insertion; 60 cm tubing × 10 with 10 needles 130.00	130.00	1 OP	✓ Paradigm Sure-T MMT-864
6 mm steel needle; 29 G; manual insertion; 60 cm tubing × 10 with 10 needles; luer lock 130.00	130.00	1 OP	✓ Sure-T MMT-863
6 mm steel needle; 29 G; manual insertion; 80 cm tubing × 10 with 10 needles 130.00	130.00	1 OP	✓ Paradigm Sure-T MMT-866
6 mm steel needle; 29 G; manual insertion; 80 cm tubing × 10 with 10 needles; luer lock 130.00	130.00	1 OP	✓ Sure-T MMT-865
8 mm steel cannula; straight insertion; 110 cm grey line × 10 with 10 needles 130.00	130.00	1 OP	✓ Contact-D
8 mm steel cannula; straight insertion; 60 cm grey line × 10 with 10 needles 130.00	130.00	1 OP	✓ Contact-D
8 mm steel needle; 29 G; manual insertion; 60 cm tubing × 10 with 10 needles 130.00	130.00	1 OP	✓ Paradigm Sure-T MMT-874
8 mm steel needle; 29 G; manual insertion; 60 cm tubing × 10 with 10 needles; luer lock 130.00	130.00	1 OP	✓ Sure-T MMT-873
8 mm steel needle; 29 G; manual insertion; 80 cm tubing × 10 with 10 needles 130.00	130.00	1 OP	✓ Paradigm Sure-T MMT-876
8 mm steel needle; 29 G; manual insertion; 80 cm tubing × 10 with 10 needles; luer lock 130.00	130.00	1 OP	✓ Sure-T MMT-875

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

INSULIN PUMP INFUSION SET (TEFLON CANNULA, ANGLE INSERTION WITH INSERTION DEVICE) – Special Authority see SA1604 on page 31 – Retail pharmacy

a) Maximum of 3 sets per prescription

b) Only on a prescription

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

13 mm teflon cannula; angle insertion; insertion device;

110 cm grey line × 10 with 10 needles 140.00 1 OP ✓ Inset 30

13 mm teflon cannula; angle insertion; insertion device;

60 cm blue line × 10 with 10 needles 140.00 1 OP ✓ Inset 30

13 mm teflon cannula; angle insertion; insertion device;

60 cm grey line × 10 with 10 needles 140.00 1 OP ✓ Inset 30

13 mm teflon cannula; angle insertion; insertion device;

60 cm pink line × 10 with 10 needles 140.00 1 OP ✓ Inset 30

INSULIN PUMP INFUSION SET (TEFLON CANNULA, ANGLE INSERTION) – Special Authority see SA1604 on page 31 – Retail pharmacy

a) Maximum of 3 sets per prescription

b) Only on a prescription

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

13 mm teflon cannula; angle insertion; 60 cm grey line ×

5 with 10 needles 120.00 1 OP ✓ Comfort Short

13 mm teflon cannula; angle insertion; 120 cm line × 10 with

10 needles 130.00 1 OP ✓ Paradigm Silhouette
MMT-382

13 mm teflon cannula; angle insertion; 45 cm line × 10 with

10 needles 130.00 1 OP ✓ Paradigm Silhouette
MMT-368

13 mm teflon cannula; angle insertion; 60 cm line × 10 with

10 needles 130.00 1 OP ✓ Paradigm Silhouette
MMT-381

13 mm teflon cannula; angle insertion; 80 cm line × 10 with

10 needles 130.00 1 OP ✓ Paradigm Silhouette
MMT-383

17 mm teflon cannula; angle insertion; 110 cm grey line ×

5 with 10 needles 120.00 1 OP ✓ Comfort

17 mm teflon cannula; angle insertion; 110 cm line × 10 with

10 needles 130.00 1 OP ✓ Paradigm Silhouette
MMT-377

17 mm teflon cannula; angle insertion; 110 cm line × 10 with

10 needles; luer lock 130.00 1 OP ✓ Silhouette MMT-371

17 mm teflon cannula; angle insertion; 60 cm grey line ×

5 with 10 needles 120.00 1 OP ✓ Comfort

17 mm teflon cannula; angle insertion; 60 cm line × 10 with

10 needles 130.00 1 OP ✓ Paradigm Silhouette
MMT-378

17 mm teflon cannula; angle insertion; 60 cm line × 10 with

10 needles; luer lock 130.00 1 OP ✓ Silhouette MMT-373

17 mm teflon cannula; angle insertion; 80 cm line × 10 with

10 needles 130.00 1 OP ✓ Paradigm Silhouette
MMT-384

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
INSULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIGHT INSERTION WITH INSERTION DEVICE) – Special Authority				
see SA1604 on page 31 – Retail pharmacy				
a) Maximum of 3 sets per prescription				
b) Only on a prescription				
c) Maximum of 13 infusion sets will be funded per year.				
6 mm teflon cannula; straight insertion; insertion device;				
110 cm grey line × 10 with 10 needles	140.00	1 OP	✓	Inset II
6 mm teflon cannula; straight insertion; insertion device;				
45 cm blue tubing × 10 with 10 needles	130.00	1 OP	✓	Paradigm Mio MMT-941
6 mm teflon cannula; straight insertion; insertion device;				
45 cm pink tubing × 10 with 10 needles	130.00	1 OP	✓	Paradigm Mio MMT-921
6 mm teflon cannula; straight insertion; insertion device;				
60 cm blue tubing × 10 with 10 needles	130.00	1 OP	✓	Paradigm Mio MMT-943
6 mm teflon cannula; straight insertion; insertion device;				
60 cm pink tubing × 10 with 10 needles	130.00	1 OP	✓	Paradigm Mio MMT-923
6 mm teflon cannula; straight insertion; insertion device;				
80 cm blue tubing × 10 with 10 needles	130.00	1 OP	✓	Paradigm Mio MMT-945
6 mm teflon cannula; straight insertion; insertion device;				
80 cm clear tubing × 10 with 10 needles	130.00	1 OP	✓	Paradigm Mio MMT-965
6 mm teflon cannula; straight insertion; insertion device;				
80 cm pink tubing × 10 with 10 needles	130.00	1 OP	✓	Paradigm Mio MMT-925
6 mm teflon cannula; straight insertion; insertion device;				
60 cm blue line × 10 with 10 needles	140.00	1 OP	✓	Inset II
6 mm teflon cannula; straight insertion; insertion device;				
60 cm grey line × 10 with 10 needles	140.00	1 OP	✓	Inset II
6 mm teflon cannula; straight insertion; insertion device;				
60 cm pink line × 10 with 10 needles	140.00	1 OP	✓	Inset II
9 mm teflon cannula; straight insertion; insertion device;				
60 cm blue line × 10 with 10 needles	140.00	1 OP	✓	Inset II
9 mm teflon cannula; straight insertion; insertion device;				
60 cm grey line × 10 with 10 needles	140.00	1 OP	✓	Inset II
9 mm teflon cannula; straight insertion; insertion device;				
60 cm pink line × 10 with 10 needles	140.00	1 OP	✓	Inset II
9 mm teflon cannula; straight insertion; insertion device;				
80 cm clear tubing × 10 with 10 needles	130.00	1 OP	✓	Paradigm Mio MMT-975
9 mm teflon cannula; straight insertion; insertion device;				
110 cm grey line × 10 with 10 needles	140.00	1 OP	✓	Inset II

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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INSULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIGHT INSERTION) – Special Authority see SA1604 on page 31 –

Retail pharmacy

a) Maximum of 3 sets per prescription

b) Only on a prescription

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

6 mm teflon cannula; straight insertion; 110 cm tubing ×

10 with 10 needles	130.00	1 OP	✓ Paradigm Quick-Set MMT-398
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6 mm teflon cannula; straight insertion; 110 cm tubing ×

10 with 10 needles; luer lock	130.00	1 OP	✓ Quick-Set MMT-391
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6 mm teflon cannula; straight insertion; 60 cm tubing ×

10 with 10 needles	130.00	1 OP	✓ Paradigm Quick-Set MMT-399
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6 mm teflon cannula; straight insertion; 60 cm tubing ×

10 with 10 needles; luer lock	130.00	1 OP	✓ Quick-Set MMT-393
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6 mm teflon cannula; straight insertion; 80 cm tubing ×

10 with 10 needles	130.00	1 OP	✓ Paradigm Quick-Set MMT-387
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9 mm teflon cannula; straight insertion; 106 cm tubing ×

10 with 10 needles	130.00	1 OP	✓ Paradigm Quick-Set MMT-396
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9 mm teflon cannula; straight insertion; 110 cm tubing ×

10 with 10 needles; luer lock	130.00	1 OP	✓ Quick-Set MMT-390
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9 mm teflon cannula; straight insertion; 60 cm tubing ×

10 with 10 needles	130.00	1 OP	✓ Paradigm Quick-Set MMT-397
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9 mm teflon cannula; straight insertion; 60 cm tubing ×

10 with 10 needles; luer lock	130.00	1 OP	✓ Quick-Set MMT-392
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9 mm teflon cannula; straight insertion; 80 cm tubing ×

10 with 10 needles	130.00	1 OP	✓ Paradigm Quick-Set MMT-386
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INSULIN PUMP RESERVOIR – Special Authority see SA1604 on page 31 – Retail pharmacy

a) Maximum of 3 sets per prescription

b) Only on a prescription

c) Maximum of 13 packs of reservoir sets will be funded per year.

10 × luer lock conversion cartridges 1.8 ml for Paradigm

pumps	50.00	1 OP	✓ ADR Cartridge 1.8
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Cartridge 200 U, luer lock × 10

50.00	1 OP	✓ Animas Cartridge
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Cartridge for 5 and 7 series pump; 1.8 ml × 10

50.00	1 OP	✓ Paradigm 1.8
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Reservoir

Cartridge for 7 series pump; 3.0 ml × 10

50.00	1 OP	✓ Paradigm 3.0
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Reservoir

Syringe and cartridge for 50X pump, 3.0 ml × 10

50.00	1 OP	✓ 50X 3.0 Reservoir
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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Digestives Including Enzymes				
PANCREATIC ENZYME				
Cap pancreatin 150 mg (amylase 8,000 Ph Eur U, lipase 10,000 Ph Eur U, total protease 600 Ph Eur U)	34.93	100	✓	Creon 10000
Cap pancreatin (175 mg (25,000 U lipase, 22,500 U amylase, 1,250 U protease))	94.40	100	✓	Panzytrat
Cap pancreatin 300 mg (amylase 18,000 Ph Eur U, lipase 25,000 Ph Eur U, total protease 1,000 Ph Eur U)	94.38	100	✓	Creon 25000
URSODEOXYCHOLIC ACID – Special Authority see SA1383 below – Retail pharmacy				
Cap 250 mg – For ursodeoxycholic acid oral liquid formula- tion refer, page 224.....	53.40	100	✓	Ursosan

►SA1383 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 — (Cirrhosis) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Primary biliary cirrhosis confirmed by antimitochondrial antibody titre (AMA) > 1:80, and raised cholestatic liver enzymes with or without raised serum IgM or, if AMA is negative, by liver biopsy; and
- 2 Patient not requiring a liver transplant (bilirubin > 100 umol/l; decompensated cirrhosis).

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

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

Both:

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

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

Both:

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

continued...

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

continued...

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

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

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

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

Laxatives

Bulk-forming Agents

ISPAHULA (PSYLLIUM) HUSK – Only on a prescription

* Powder for oral soln	5.51	500 g OP	✓ Konsyl-D
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MUCILAGINOUS LAXATIVES WITH STIMULANTS

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

Faecal Softeners

DOCUSATE SODIUM – Only on a prescription

* Tab 50 mg	2.31	100	✓ Coloxyl
* Tab 120 mg	3.13	100	✓ Coloxyl
* Enema conc 18%	5.40	100 ml OP	✓ Coloxyl

DOCUSATE SODIUM WITH SENNOSIDES

* Tab 50 mg with sennosides 8 mg	4.40	200	✓ Laxsol
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POLOXAMER – Only on a prescription

Not funded for use in the ear.

* Oral drops 10%	3.78	30 ml OP	✓ Coloxyl
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Osmotic Laxatives

GLYCEROL

* Suppos 3.6 g – Only on a prescription	6.50	20	✓ PSM
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LACTULOSE – Only on a prescription

* Oral liq 10 g per 15 ml	3.18	500 ml	✓ Laevolac
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MACROGOL 3350 WITH POTASSIUM CHLORIDE, SODIUM BICARBONATE AND SODIUM CHLORIDE – Special Authority see SA1473 on the next page – Retail pharmacy

Powder for oral soln 13.125 g with potassium chloride

46.6 mg, sodium bicarbonate 178.5 mg and sodium chlo-

ride 350.7 mg – Maximum of 90 sach per prescription	7.65	30	✓ Lax-Sachets
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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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►SA1473 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 problematic constipation despite an adequate trial of other oral pharmacotherapies including lactulose where lactulose is not contraindicated; and
- 2 The patient would otherwise require a per rectal preparation.

Renewal from any relevant practitioner. Approvals valid for 12 months where the patient is compliant and is continuing to gain benefit from treatment.

SODIUM ACID PHOSPHATE – Only on a prescription

Enema 16% with sodium phosphate 8%	2.50	1	✓ Fleet Phosphate Enema
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SODIUM CITRATE WITH SODIUM LAURYL SULPHOACETATE – Only on a prescription

Enema 90 mg with sodium lauryl sulphoacetate 9 mg per ml, 5 ml	19.95	50	✓ Micolette
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Stimulant Laxatives

BISACODYL – Only on a prescription

* Tab 5 mg	5.99	200	✓ Lax-Tab
* Suppos 10 mg	3.78	10	✓ Lax-Suppositories

SENNA – Only on a prescription

* Tab, standardised	2.17	100	
	(6.84)		Senokot
	0.43	20	
	(1.72)		Senokot

Metabolic Disorder Agents

ALGLUCOSIDASE ALFA – Special Authority see SA1622 below – Retail pharmacy

Inj 50 mg vial	1,142.60	1	✓ Myozyme
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►SA1622 Special Authority for Subsidy

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

All of the following:

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

continued...

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

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

All of the following:

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

GALSULFASE – Special Authority see SA1593 below – Retail pharmacy

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

►►SA1593 | Special Authority for Subsidy

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

Both:

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

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

All of the following:

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

IDURSULFASE – Special Authority see SA1623 below – Retail pharmacy

Inj 2 mg per ml, 3 ml vial 4,608.30 1 ✓ **Elaprase**

►►SA1623 | Special Authority for Subsidy

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

All of the following:

- 1 The patient has been diagnosed with Hunter Syndrome (mucopolysaccharidosis II); and
- 2 Either:
 - 2.1 Diagnosis confirmed by demonstration of iduronate 2-sulfatase deficiency in white blood cells by either enzyme assay in cultured skin fibroblasts; or
 - 2.2 Detection of a disease causing mutation in the iduronate 2-sulfatase gene; and
- 3 Patient is going to proceed with a haematopoietic stem cell transplant (HSCT) within the next 3 months and treatment with idursulfase would be bridging treatment to transplant; and

continued...

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

continued...

- Patient has not required long-term invasive ventilation for respiratory failure prior to starting Enzyme Replacement Therapy (ERT); and
- Idursulfase to be administered for a total of 24 weeks (equivalent to 12 weeks pre- and 12 weeks post-HSCT) at doses no greater than 0.5 mg/kg every week.

SODIUM BENZOATE – Special Authority see SA1599 below – Retail pharmacy

Soln 100 mg per ml CBS 100 ml ✓ **Amzoate** ^{\$29}

►SA1599 Special Authority for Subsidy

Initial application only from a metabolic physician. Approvals valid for 12 months where the patient has a diagnosis of a urea cycle disorder.

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

SODIUM PHENYLBUTYRATE – Special Authority see SA1598 below – Retail pharmacy

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

►SA1598 Special Authority for Subsidy

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

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

Gaucher's Disease

IMIGLUCERASE – Special Authority see SA0473 below – Retail pharmacy

Inj 40 iu per ml, 200 iu vial 1,072.00 1 ✓ **Cerezyme**
Inj 40 iu per ml, 400 iu vial 2,144.00 1 ✓ **Cerezyme**

►SA0473 Special Authority for Subsidy

Special Authority approved by the Gaucher's Treatment Panel

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

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

The Co-ordinator, Gaucher's Treatment Panel Phone: (04) 460 4990
PHARMAC, PO Box 10 254 Facsimile: (04) 916 7571
Wellington Email: gaucherpanel@pharmac.govt.nz

Mouth and Throat

Agents Used in Mouth Ulceration

BENZDAMINE HYDROCHLORIDE

Soln 0.15% – Higher subsidy of up to \$17.01 per 500 ml with
Endorsement 9.00 500 ml
(17.01) Difflam
3.60 200 ml
(8.50) Difflam

Additional subsidy by endorsement for a patient who has oral mucositis as a result of treatment for cancer, and the prescription is endorsed accordingly.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
CARMELLOSE SODIUM WITH GELATIN AND PECTIN				
Paste	17.20	56 g OP	✓	Stomahesive
	4.55	15 g OP		
	(7.90)			Orabase
	1.52	5 g OP		
	(3.60)			Orabase
Powder	8.48	28 g OP		Stomahesive
	(10.95)			
CHLORHEXIDINE GLUCONATE				
Mouthwash 0.2%	2.57	200 ml OP	✓	healthE
CHOLINE SALICYLATE WITH CETALKONIUM CHLORIDE				
* Adhesive gel 8.7% with cetalkonium chloride 0.01%	2.06	15 g OP		
	(6.00)			Bonjela
TRIAMCINOLONE ACETONIDE				
Paste 0.1%	5.33	5 g OP	✓	Kenalog in Orabase
Oropharyngeal Anti-infectives				
AMPHOTERICIN B				
Lozenges 10 mg	5.86	20	✓	Fungilin
MICONAZOLE				
Oral gel 20 mg per g	4.79	40 g OP	✓	Decozol
NYSTATIN				
Oral liq 100,000 u per ml	2.55	24 ml OP	✓	m-Nystatin
Other Oral Agents				
For folinic mouthwash, pilocarpine oral liquid or saliva substitute formula refer Standard Formulae, page 227				
HYDROGEN PEROXIDE				
* Soln 3% (10 vol) – Maximum of 200 ml per prescription	1.40	100 ml	✓	Pharmacy Health
THYMOL GLYCERIN				
* Compound, BPC	9.15	500 ml	✓	PSM
Vitamins				
Vitamin A				
VITAMIN A WITH VITAMINS D AND C				
* Soln 1000 u with Vitamin D 400 u and ascorbic acid 30 mg per 10 drops	4.50	10 ml OP	✓	Vitadol C
Vitamin B				
HYDROXOCOBALAMIN				
* Inj 1 mg per ml, 1 ml ampoule – Up to 6 inj available on a PSO	2.31	3	✓	Neo-B12
PYRIDOXINE HYDROCHLORIDE				
a) No more than 100 mg per dose				
b) Only on a prescription				
* Tab 25 mg – No patient co-payment payable	2.15	90	✓	Vitamin B6 25
* Tab 50 mg	11.55	500	✓	Apo-Pyridoxine

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
THIAMINE HYDROCHLORIDE – Only on a prescription				
* Tab 50 mg	5.62	100	✓	Apo-Thiamine
VITAMIN B COMPLEX				
* Tab, strong, BPC	7.15	500	✓	Bplex
Vitamin C				
ASCORBIC ACID				
a) No more than 100 mg per dose				
b) Only on a prescription				
* Tab 100 mg	8.10	500	✓	Cvite
Vitamin D				
ALFACALCIDOL				
* Cap 0.25 mcg	26.32	100	✓	One-Alpha
* Cap 1 mcg	87.98	100	✓	One-Alpha
* Oral drops 2 mcg per ml	60.68	20 ml OP	✓	One-Alpha
CALCITRIOL				
* Cap 0.25 mcg	9.95	100	✓	Calcitriol-AFT
* Cap 0.5 mcg	18.39	100	✓	Calcitriol-AFT
COLECALCIFEROL				
* Cap 1.25 mg (50,000 iu) – Maximum of 12 cap per prescription	3.85	12	✓	Vit.D3
Multivitamin Preparations				
MULTIVITAMIN RENAL – Special Authority see SA1546 below – Retail pharmacy				
* Cap	8.39	30	✓	Clinicians Renal Vit
►SA1546 Special Authority for Subsidy				
Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:				
Either:				
1 The patient has chronic kidney disease and is receiving either peritoneal dialysis or haemodialysis; or				
2 The patient has chronic kidney disease grade 5, defined as patient with an estimated glomerular filtration rate of < 15 ml/min/1.73 m ² body surface area (BSA).				
MULTIVITAMINS – Special Authority see SA1036 below – Retail pharmacy				
* Powder	72.00	200 g OP	✓	Paediatric Seravit
►SA1036 Special Authority for Subsidy				
Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has inborn errors of metabolism.				
Renewal from any relevant practitioner. Approvals valid without further renewal unless notified where patient has had a previous approval for multivitamins.				
VITAMINS				
* Tab (BPC cap strength)	10.50	1,000	✓	Mvite
* Cap (fat soluble vitamins A, D, E, K) – Special Authority see SA1002 on the next page – Retail pharmacy	23.40	60	✓	Vitabdeck

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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►SA1002 Special Authority for Subsidy

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

Either:

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

Minerals

Calcium

CALCIUM CARBONATE

* Tab eff 1.75 g (1 g elemental)	2.07	10	✓ Calsource
* Tab 1.25 g (500 mg elemental)	5.38	250	✓ Arrow-Calcium

CALCIUM GLUCONATE

* Inj 10%, 10 ml ampoule	34.24	10	✓ Hamelin \$29 ✓ Hospira
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Fluoride

SODIUM FLUORIDE

* Tab 1.1 mg (0.5 mg elemental)	5.00	100	✓ PSM
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Iodine

POTASSIUM IODATE

* Tab 253 mcg (150 mcg elemental iodine)	3.65	90	✓ NeuroTabs
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Iron

FERROUS FUMARATE

* Tab 200 mg (65 mg elemental)	2.89	100	✓ Ferro-tab
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FERROUS FUMARATE WITH FOLIC ACID

* Tab 310 mg (100 mg elemental) with folic acid 350 mcg	4.75	60	✓ Ferro-F-Tabs
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FERROUS SULPHATE

* Tab long-acting 325 mg (105 mg elemental)	2.06	30	✓ Ferrograd
* ‡ Oral liq 30 mg (6 mg elemental) per 1 ml	10.80	500 ml	✓ Ferodan

FERROUS SULPHATE WITH FOLIC ACID

* Tab long-acting 325 mg (105 mg elemental) with folic acid 350 mcg	1.80 (4.29)	30	Ferrograd F
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IRON POLYMALTOSE

* Inj 50 mg per ml, 2 ml ampoule	15.22	5	✓ Ferrum H
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Magnesium

For magnesium hydroxide mixture refer Standard Formulae, page 227

MAGNESIUM SULPHATE

* Inj 2 mmol per ml, 5 ml ampoule	12.65	10	✓ DBL
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‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Fully Subsidised ✓ Per	Brand or Generic Manufacturer
Zinc			
ZINC SULPHATE			
* Cap 137.4 mg (50 mg elemental)	11.00	100	✓ <u>Zincaps</u>

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

Hypoplastic and Haemolytic

►SA1469 Special Authority for Subsidy

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

All of the following:

- 1 Patient in chronic renal failure; and
- 2 Haemoglobin \leq 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 \leq 30ml/min; or
 - 3.2 Both:
 - 3.2.1 Patient has diabetes mellitus; and
 - 3.2.2 Glomerular filtration rate \leq 45ml/min; or
 - 3.3 Patient is on haemodialysis or peritoneal dialysis.

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

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

All of the following:

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

Note: Indication marked with * is an Unapproved Indication

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

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

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

All of the following:

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

Note: Indication marked with * is an Unapproved Indication

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
EPOETIN ALFA [ERYTHROPOIETIN ALFA] – Special Authority see SA1469 on the previous page – Retail pharmacy			
Wastage claimable – see rule 3.3.2 on page 13			
Inj 1,000 iu in 0.5 ml, syringe	48.68	6	✓ Eprex
Inj 2,000 iu in 0.5 ml, syringe	120.18	6	✓ Eprex
Inj 3,000 iu in 0.3 ml, syringe	166.87	6	✓ Eprex
Inj 4,000 iu in 0.4 ml, syringe	193.13	6	✓ Eprex
Inj 5,000 iu in 0.5 ml, syringe	243.26	6	✓ Eprex
Inj 6,000 iu in 0.6 ml, syringe	291.92	6	✓ Eprex
Inj 8,000 iu in 0.8 ml, syringe	352.69	6	✓ Eprex
Inj 10,000 iu in 1 ml, syringe	395.18	6	✓ Eprex
Inj 40,000 iu in 1 ml, syringe	263.45	1	✓ Eprex

Megaloblastic

FOLIC ACID

* Tab 0.8 mg	20.60	1,000	✓ Apo-Folic Acid
* Tab 5 mg	10.92	500	✓ Apo-Folic Acid
Oral liq 50 mcg per ml	24.00	25 ml OP	✓ Biomed

Antifibrinolytics, Haemostatics and Local Sclerosants

ELTROMBOPAG – Special Authority see SA1418 below – Retail pharmacy

Wastage claimable – see rule 3.3.2 on page 13

Tab 25 mg	1,771.00	28	✓ Revolade
Tab 50 mg	3,542.00	28	✓ Revolade

►SA1418 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 \leq 20,000 platelets per microlitre and has evidence of active bleeding; or
 - 3.3 Patient has a platelet count of \leq 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.

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.

EPTACOG ALFA [RECOMBINANT FACTOR VIIA] – [Xpharm]

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

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

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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FACTOR EIGHT INHIBITOR BYPASSING FRACTION – [Xpharm]

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

Inj 500 U	1,450.00	1	✓ FEIBA NF
Inj 1,000 U	2,900.00	1	✓ FEIBA NF
Inj 2,500 U	7,250.00	1	✓ FEIBA NF

MOROCTOCOG ALFA [RECOMBINANT FACTOR VIII] – [Xpharm]

Preferred Brand of recombinant factor VIII for patients with haemophilia from 1 March 2016 until 28 February 2019. Access to funded treatment is managed by the Haemophilia Treaters Group in conjunction with the National Haemophilia Management Group.

Inj 250 iu prefilled syringe	210.00	1	✓ Xyntha
Inj 500 iu prefilled syringe	420.00	1	✓ Xyntha
Inj 1,000 iu prefilled syringe	840.00	1	✓ Xyntha
Inj 2,000 iu prefilled syringe	1,680.00	1	✓ Xyntha
Inj 3,000 iu prefilled syringe	2,520.00	1	✓ Xyntha

NONACOG ALFA [RECOMBINANT FACTOR IX] – [Xpharm]

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

Inj 250 iu vial	310.00	1	✓ BeneFIX
Inj 500 iu vial	620.00	1	✓ BeneFIX
Inj 1,000 iu vial	1,240.00	1	✓ BeneFIX
Inj 2,000 iu vial	2,480.00	1	✓ BeneFIX
Inj 3,000 iu vial	3,720.00	1	✓ BeneFIX

NONACOG GAMMA, [RECOMBINANT FACTOR IX] – [Xpharm]

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

Inj 250 iu vial	287.50	1	✓ RIXUBIS
Inj 500 iu vial	575.00	1	✓ RIXUBIS
Inj 1,000 iu vial	1,150.00	1	✓ RIXUBIS
Inj 2,000 iu vial	2,300.00	1	✓ RIXUBIS
Inj 3,000 iu vial	3,450.00	1	✓ RIXUBIS

OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (ADVATE) – [Xpharm]

Rare Clinical Circumstances Brand of recombinant factor VIII for patients with haemophilia from 1 March 2016 until 28 February 2019. Access to funded treatment by application to the Haemophilia Treatments Panel. Application details may be obtained from PHARMAC's website <http://www.pharmac.govt.nz> or:

The Co-ordinator, Haemophilia Treatments Panel Phone: 0800 023 588 Option 2
 PHARMAC PO Box 10 254 Facsimile: (04) 974 4881
 Wellington Email: haemophilia@pharmac.govt.nz

Inj 250 iu vial	287.50	1	✓ Advate
Inj 500 iu vial	575.00	1	✓ Advate
Inj 1,000 iu vial	1,150.00	1	✓ Advate
Inj 1,500 iu vial	1,725.00	1	✓ Advate
Inj 2,000 iu vial	2,300.00	1	✓ Advate
Inj 3,000 iu vial	3,450.00	1	✓ Advate

BLOOD AND BLOOD FORMING ORGANS

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (KOGENATE FS) – [Xpharm]			
Second Brand of recombinant factor VIII for patients with haemophilia from 1 March 2016 until 28 February 2019. Access to funded treatment by application to the Haemophilia Treatments Panel. Application details may be obtained from PHARMAC's website http://www.pharmac.govt.nz or:			
The Co-ordinator, Haemophilia Treatments Panel	Phone: 0800 023 588 Option 2		
PHARMAC PO Box 10 254	Facsimile: (04) 974 4881		
Wellington	Email: haemophilia@pharmac.govt.nz		
Inj 250 iu vial	237.50	1	✓ Kogenate FS
Inj 500 iu vial	475.00	1	✓ Kogenate FS
Inj 1,000 iu vial	950.00	1	✓ Kogenate FS
Inj 2,000 iu vial	1,900.00	1	✓ Kogenate FS
Inj 3,000 iu vial	2,850.00	1	✓ Kogenate FS
SODIUM TETRADECYL SULPHATE			
* Inj 3% 2 ml	28.50 (73.00)	5	Fibro-vein
TRANEXAMIC ACID			
Tab 500 mg	20.67	100	✓ Cyklokapron
Vitamin K			
PHYTOMENADIONE			
Inj 2 mg per 0.2 ml – Up to 5 inj available on a PSO	8.00	5	✓ Konaktion MM
Inj 10 mg per ml, 1 ml – Up to 5 inj available on a PSO	9.21	5	✓ Konaktion MM
Antithrombotic Agents			
Antiplatelet Agents			
ASPIRIN			
* Tab 100 mg	12.50	990	✓ Ethics Aspirin EC
CLOPIDOGREL			
* Tab 75 mg – For clopidogrel oral liquid formulation refer, page 224	5.44	84	✓ Arrow - Clopid
Arrow - Clopid to be Sole Supply on 1 April 2017			
DIPYRIDAMOLE			
* Tab long-acting 150 mg	11.52	60	✓ Pytazen SR
PRASUGREL – Special Authority see SA1201 below – Retail pharmacy			
Tab 5 mg	108.00	28	✓ Effient
Tab 10 mg	120.00	28	✓ Effient
►SA1201 Special Authority for Subsidy			
Initial application — (coronary angioplasty and bare metal stent) from any relevant practitioner. Approvals valid for 6 months where the patient has undergone coronary angioplasty in the previous 4 weeks and is clopidogrel-allergic*.			
Initial application — (drug eluting stent) from any relevant practitioner. Approvals valid for 12 months where the patient has had a drug-eluting cardiac stent inserted in the previous 4 weeks and is clopidogrel-allergic*.			
Initial application — (stent thrombosis) from any relevant practitioner. Approvals valid without further renewal unless notified where patient has experienced cardiac stent thrombosis whilst on clopidogrel.			

continued...

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

continued...

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

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

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

TICAGRELOR – Special Authority see SA1382 below – Retail pharmacy

* Tab 90 mg	90.00	56	✓ Brilinta
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►SA1382 Special Authority for Subsidy

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

Both:

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

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

Both:

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

Heparin and Antagonist Preparations

DALTEPARIN SODIUM – Special Authority see SA1270 below – Retail pharmacy

Inj 2,500 iu per 0.2 ml prefilled syringe	19.97	10	✓ Fragmin
Inj 5,000 iu per 0.2 ml prefilled syringe	39.94	10	✓ Fragmin
Inj 7,500 iu per 0.75 ml graduated syringe	60.03	10	✓ Fragmin
Inj 10,000 iu per 1 ml graduated syringe	77.55	10	✓ Fragmin
Inj 12,500 iu per 0.5 ml prefilled syringe	99.96	10	✓ Fragmin
Inj 15,000 iu per 0.6 ml prefilled syringe	120.05	10	✓ Fragmin
Inj 18,000 iu per 0.72 ml prefilled syringe	158.47	10	✓ Fragmin

►SA1270 Special Authority for Subsidy

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

Either:

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

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

Any of the following:

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

continued...

‡ safety cap

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

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

continued...

- 5 To be used in association with cardioversion of atrial fibrillation.

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

Either:

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

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

ENOXAPARIN SODIUM – Special Authority see SA1174 below – Retail pharmacy

Inj 20 mg in 0.2 ml syringe	30.91	10	✓ Clexane
Inj 40 mg in 0.4 ml syringe	41.24	10	✓ Clexane
Inj 60 mg in 0.6 ml syringe	62.18	10	✓ Clexane
Inj 80 mg in 0.8 ml syringe	82.88	10	✓ Clexane
Inj 100 mg in 1 ml syringe	103.80	10	✓ Clexane
Inj 120 mg in 0.8 ml syringe	128.98	10	✓ Clexane
Inj 150 mg in 1 ml syringe	147.41	10	✓ Clexane

►SA1174 Special Authority for Subsidy

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

Either:

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

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

Any of the following:

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

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

Either:

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

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

HEPARIN SODIUM

Inj 1,000 iu per ml, 5 ml	13.36	10	✓ Hospira
	61.04	50	✓ Pfizer
	66.80		✓ Hospira
Inj 1,000 iu per ml, 35 ml vial	17.76	1	✓ Hospira
Inj 5,000 iu per ml, 1 ml	14.20	5	✓ Hospira
Inj 5,000 iu per ml, 5 ml	236.60	50	✓ Pfizer
Inj 25,000 iu per ml, 0.2 ml	9.50	5	✓ Hospira

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
HEPARINISED SALINE				
Inj 10 iu per ml, 5 ml	23.40	30	✓	Becton Dickinson PosiFlush ^{\$29}
	39.00	50	✓	Pfizer
<i>(Becton Dickinson PosiFlush ^{\$29} Inj 10 iu per ml, 5 ml to be delisted 1 June 2017)</i>				
PROTAMINE SULPHATE				
* Inj 10 mg per ml, 5 ml	22.40 (119.23)	10		Artex

Oral Anticoagulants

DABIGATRAN				
Cap 75 mg – No more than 2 cap per day	76.36	60	✓	Pradaxa
Cap 110 mg	76.36	60	✓	Pradaxa
Cap 150 mg	76.36	60	✓	Pradaxa
RIVAROXABAN – Special Authority see SA1066 below – Retail pharmacy				
Tab 10 mg	153.00	15	✓	Xarelto

►SA1066 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 5 weeks for applications meeting the following criteria:
Either:

- 1 For the prophylaxis of venous thromboembolism following a total hip replacement; or
- 2 For the prophylaxis of venous thromboembolism following a total knee replacement.

Note: Rivaroxaban is only currently indicated and subsidised for up to 5 weeks therapy for prophylaxis of venous thromboembolism following a total hip replacement and up to 2 weeks therapy for prophylaxis of venous thromboembolism following a total knee replacement.

Renewal from any relevant practitioner. Approvals valid for 5 weeks where prophylaxis for venous thromboembolism is required for patients following a subsequent total hip or knee replacement.

WARFARIN SODIUM

Note: Marevan and Coumadin are not interchangeable.

* Tab 1 mg	3.46	50	✓	Coumadin
	6.86	100	✓	Marevan
* Tab 2 mg	4.31	50	✓	Coumadin
* Tab 3 mg	9.70	100	✓	Marevan
* Tab 5 mg	5.93	50	✓	Coumadin
	11.75	100	✓	Marevan

Blood Colony-stimulating Factors

FILGRASTIM – Special Authority see SA1259 below – Retail pharmacy				
Inj 300 mcg per 0.5 ml prefilled syringe	270.00	5	✓	Zarzio
Inj 480 mcg per 0.5 ml prefilled syringe	432.00	5	✓	Zarzio

►SA1259 Special Authority for Subsidy

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

Any of the following:

- 1 Prevention of neutropenia in patients undergoing high risk chemotherapy for cancer (febrile neutropenia risk \geq 20%*); or
- 2 Peripheral blood stem cell mobilisation in patients undergoing haematological transplantation; or

continued...

‡ safety cap

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

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

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

- 3 Peripheral blood stem cell mobilisation or bone marrow donation from healthy donors for transplantation; or
- 4 Treatment of severe chronic neutropenia ($ANC < 0.5 \times 10/L$); or
- 5 Treatment of drug-induced prolonged neutropenia ($ANC < 0.5 \times 10/L$).

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

PEGFILGRASTIM – Special Authority see SA1384 below – Retail pharmacy

Inj 6 mg per 0.6 ml syringe	1,080.00	1	✓ Neulastim
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►SA1384 Special Authority for Subsidy

Initial application only from a relevant specialist, vocationally registered general practitioner or medical practitioner on the recommendation of a relevant specialist. Approvals valid without further renewal unless notified where used for prevention of neutropenia in patients undergoing high risk chemotherapy for cancer (febrile neutropenia risk ≥ 20

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

Fluids and Electrolytes

Intravenous Administration

GLUCOSE [DEXTROSE]

* Inj 50%, 10 ml ampoule – Up to 5 inj available on a PSO	27.50	5	✓ Biomed
* Inj 50%, 90 ml bottle – Up to 5 inj available on a PSO	14.50	1	✓ Biomed

POTASSIUM CHLORIDE

* Inj 75 mg per ml, 10 ml	55.00	50	✓ AstraZeneca
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SODIUM BICARBONATE

Inj 8.4%, 50 ml	19.95	1	✓ Biomed
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- a) Up to 5 inj available on a PSO
- b) Not in combination

Inj 8.4%, 100 ml	20.50	1	✓ Biomed
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- a) Up to 5 inj available on a PSO
- b) Not in combination

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

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

Inj 0.9%, bag – Up to 2000 ml available on a PSO.....	1.23	500 ml	✓ Baxter
	1.26	1,000 ml	✓ Baxter

Only if prescribed on a prescription for renal dialysis, maternity or post-natal care in the home of the patient, or on a PSO for emergency use. (500 ml and 1,000 ml packs)

Inj 23.4% (4 mmol/ml), 20 ml ampoule	33.00	5	✓ Biomed
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For Sodium chloride oral liquid formulation refer Standard Formulae, page 227

Inj 0.9%, 5 ml ampoule – Up to 5 inj available on a PSO	7.00	50	✓ InterPharma
	(10.85)		Multichem
	(15.50)		Pfizer

InterPharma to be Sole Supply on 1 June 2017

Inj 0.9%, 10 ml ampoule – Up to 5 inj available on a PSO	6.63	50	✓ Pfizer
	(11.50)		Multichem

Pfizer to be Sole Supply on 1 June 2017

Inj 0.9%, 20 ml ampoule	7.50	30	✓ InterPharma
	(11.79)		Pharmacia
	5.00	20	
	(8.41)		Multichem
	1.50	6	
	(4.72)		Pharmacia

InterPharma to be Sole Supply on 1 June 2017

(Multichem Inj 0.9%, 5 ml ampoule to be delisted 1 June 2017)

(Pfizer Inj 0.9%, 5 ml ampoule to be delisted 1 June 2017)

(Multichem Inj 0.9%, 10 ml ampoule to be delisted 1 June 2017)

(Pharmacia Inj 0.9%, 20 ml ampoule to be delisted 1 June 2017)

(Multichem Inj 0.9%, 20 ml ampoule to be delisted 1 June 2017)

(Pharmacia Inj 0.9%, 20 ml ampoule to be delisted 1 June 2017)

TOTAL PARENTERAL NUTRITION (TPN) – Retail pharmacy-Specialist

Infusion	CBS	1 OP	✓ TPN
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WATER

- 1) On a prescription or Practitioner's Supply Order only when on the same form as an injection listed in the Pharmaceutical Schedule requiring a solvent or diluent; or
- 2) On a bulk supply order; or
- 3) When used in the extemporaneous compounding of eye drops.

Inj 5 ml ampoule – Up to 5 inj available on a PSO	7.00	50	✓ InterPharma
	(10.25)		Multichem

InterPharma to be Sole Supply on 1 June 2017

Inj 10 ml ampoule – Up to 5 inj available on a PSO	6.63	50	✓ Pfizer
	(11.25)		Multichem

Pfizer to be Sole Supply on 1 June 2017

Inj 20 ml ampoule – Up to 5 inj available on a PSO	7.50	30	✓ InterPharma
	5.00	20	
	(6.50)		Multichem

InterPharma to be Sole Supply on 1 June 2017

(Multichem Inj 5 ml ampoule to be delisted 1 June 2017)

(Multichem Inj 10 ml ampoule to be delisted 1 June 2017)

(Multichem Inj 20 ml ampoule to be delisted 1 June 2017)

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Oral Administration				
CALCIUM POLYSTYRENE SULPHONATE				
Powder	169.85	300 g OP	✓	Calcium Resonium
COMPOUND ELECTROLYTES				
Powder for oral soln – Up to 10 sach available on a PSO	2.30	10	✓	Enerlyte
DEXTROSE WITH ELECTROLYTES				
Soln with electrolytes (2 × 500 ml)	6.55	1,000 ml OP	✓	Pedialyte - Bubblegum
PHOSPHORUS				
Tab eff 500 mg (16 mmol)	82.50	100	✓	Phosphate-Sandoz
POTASSIUM CHLORIDE				
* Tab eff 548 mg (14 m eq) with chloride 285 mg (8 m eq)	5.26 (11.85)	60		Chlorvescent
* Tab long-acting 600 mg (8 mmol)	3.71	100	✓	Duro-K <small>\$29</small>
	7.42	200	✓	Slow-K <small>\$29</small>
			✓	Span-K
SODIUM BICARBONATE				
Cap 840 mg	8.52	100	✓	Sodibic
			✓	Sodibic
SODIUM POLYSTYRENE SULPHONATE				
Powder	84.65	454 g OP	✓	Resonium-A

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

DOXAZOSIN

* Tab 2 mg	6.75	500	✓ <u>Apo-Doxazosin</u>
* Tab 4 mg	9.67	500	✓ <u>Apo-Doxazosin</u>

PHENOXYBENZAMINE HYDROCHLORIDE

* Cap 10 mg	65.00	30	✓ <u>BNM S29</u>
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PAZOSIN

* Tab 1 mg	5.53	100	✓ <u>Apo-Prazosin</u>
* Tab 2 mg	7.00	100	✓ <u>Apo-Prazosin</u>
* Tab 5 mg	11.70	100	✓ <u>Apo-Prazosin</u>

TERAZOSIN

* Tab 1 mg	0.59	28	✓ <u>Actavis</u>
* Tab 2 mg	0.45	28	✓ <u>Arrow</u>
	7.50	500	✓ <u>Apo-Terazosin</u>
* Tab 5 mg	10.90	500	✓ <u>Apo-Terazosin</u>
	0.57	28	
	(0.68)		Arrow

Apo-Terazosin to be Sole Supply on 1 May 2017

(Arrow Tab 5 mg to be delisted 1 May 2017)

Agents Affecting the Renin-Angiotensin System

ACE Inhibitors

CAPTOPRIL

*† Oral liq 5 mg per ml	94.99	95 ml OP	✓ <u>Capoten</u>
Oral liquid restricted to children under 12 years of age.			

CILAZAPRIL

* Tab 0.5 mg	2.00	90	✓ <u>Zapril</u>
* Tab 2.5 mg	7.20	200	✓ <u>Apo-Cilazapril</u>
* Tab 5 mg	12.00	200	✓ <u>Apo-Cilazapril</u>

ENALAPRIL MALEATE

* Tab 5 mg	0.96	100	✓ <u>Ethics Enalapril</u>
* Tab 10 mg	1.24	100	✓ <u>Ethics Enalapril</u>
* Tab 20 mg – For enalapril maleate oral liquid formulation re-fer, page 224	1.78	100	✓ <u>Ethics Enalapril</u>

LISINOPRIL

* Tab 5 mg	1.80	90	✓ <u>Ethics Lisinopril</u>
* Tab 10 mg	2.05	90	✓ <u>Ethics Lisinopril</u>
* Tab 20 mg	2.76	90	✓ <u>Ethics Lisinopril</u>

PERINDOPRIL

* Tab 2 mg	3.75	30	✓ <u>Apo-Perindopril</u>
* Tab 4 mg	4.80	30	✓ <u>Apo-Perindopril</u>

QUINAPRIL

* Tab 5 mg	4.31	90	✓ <u>Arrow-Quinapril 5</u>
* Tab 10 mg	3.15	90	✓ <u>Arrow-Quinapril 10</u>
* Tab 20 mg	5.97	90	✓ <u>Arrow-Quinapril 20</u>

† safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ACE Inhibitors with Diuretics				
CILAZAPRIL WITH HYDROCHLOROTHIAZIDE				
* Tab 5 mg with hydrochlorothiazide 12.5 mg	10.18	100	✓	<u>Apo-Cilazapril/ Hydrochlorothiazide</u>
QUINAPRIL WITH HYDROCHLOROTHIAZIDE				
* Tab 10 mg with hydrochlorothiazide 12.5 mg	3.65	30	✓	<u>Accuretic 10</u>
* Tab 20 mg with hydrochlorothiazide 12.5 mg	4.78	30	✓	<u>Accuretic 20</u>
Angiotensin II Antagonists				
CANDESARTAN CILEXETIL – Special Authority see SA1223 below – Retail pharmacy				
* Tab 4 mg	2.50	90	✓	<u>Candestar</u>
* Tab 8 mg	3.68	90	✓	<u>Candestar</u>
* Tab 16 mg	6.12	90	✓	<u>Candestar</u>
* Tab 32 mg	10.66	90	✓	<u>Candestar</u>
►SA1223 Special Authority for Subsidy				
Initial application — (ACE inhibitor intolerance) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:				
Either:				
1 Patient has persistent ACE inhibitor induced cough that is not resolved by ACE inhibitor retrial (same or new ACE inhibitor); or				
2 Patient has a history of angioedema.				
Initial application — (Unsatisfactory response to ACE inhibitor) from any relevant practitioner. Approvals valid without further renewal unless notified where patient is not adequately controlled on maximum tolerated dose of an ACE inhibitor.				
LOSARTAN POTASSIUM				
* Tab 12.5 mg	1.55	84	✓	<u>Losartan Actavis</u>
* Tab 25 mg	1.90	84	✓	<u>Losartan Actavis</u>
* Tab 50 mg	2.25	84	✓	<u>Losartan Actavis</u>
* Tab 100 mg	2.60	84	✓	<u>Losartan Actavis</u>
Angiotensin II Antagonists with Diuretics				
LOSARTAN POTASSIUM WITH HYDROCHLOROTHIAZIDE				
Tab 50 mg with hydrochlorothiazide 12.5 mg	2.18	30	✓	<u>Arrow-Losartan & Hydrochlorothiazide</u>
Antiarrhythmics				
For lignocaine hydrochloride refer to NERVOUS SYSTEM, Anaesthetics, Local, page 131				
AMIODARONE HYDROCHLORIDE				
▲ Tab 100 mg – Retail pharmacy-Specialist	4.66	30	✓	<u>Cordarone-X</u>
▲ Tab 200 mg – Retail pharmacy-Specialist	7.63	30	✓	<u>Cordarone-X</u>
Inj 50 mg per ml, 3 ml ampoule – Up to 6 inj available on a PSO	22.80	6	✓	<u>Cordarone-X</u>
ATROPINE SULPHATE				
* Inj 600 mcg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	71.00	50	✓	<u>AstraZeneca</u>

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
DIGOXIN				
* Tab 62.5 mcg – Up to 30 tab available on a PSO.....	6.67	240	✓	Lanoxin PG
* Tab 250 mcg – Up to 30 tab available on a PSO.....	14.52	240	✓	Lanoxin
*‡ Oral liq 50 mcg per ml	16.60	60 ml	✓	Lanoxin
DISOPYRAMIDE PHOSPHATE				
▲ Cap 100 mg	15.00 (23.87)	100		Rythmodan
▲ Cap 150 mg	26.21	100	✓	Rythmodan
<i>(Rythmodan Cap 150 mg to be delisted 1 April 2017)</i>				
FLECAINIDE ACETATE – Retail pharmacy-Specialist				
▲ Tab 50 mg	38.95	60	✓	Tambacor
▲ Cap long-acting 100 mg	38.95	30	✓	Tambacor CR
▲ Cap long-acting 200 mg	68.78	30	✓	Tambacor CR
Inj 10 mg per ml, 15 ml ampoule	52.45	5	✓	Tambacor
MEXILETINE HYDROCHLORIDE				
▲ Cap 150 mg	162.00	100	✓	Mexiletine Hydrochloride USP ^{S29}
▲ Cap 250 mg	202.00	100	✓	Mexiletine Hydrochloride USP ^{S29}
PROPAFENONE HYDROCHLORIDE – Retail pharmacy-Specialist				
▲ Tab 150 mg	40.90	50	✓	Rytmonorm

Antihypotensives

MIDODRINE – Special Authority see SA1474 below – Retail pharmacy

Tab 2.5 mg	53.00	100	✓	Gutron
Tab 5 mg	79.00	100	✓	Gutron

►SA1474 Special Authority for Subsidy

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

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

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

Beta Adrenoceptor Blockers

ATENOLOL

* Tab 50 mg	4.61	500	✓	Mylan Atenolol
* Tab 100 mg	7.67	500	✓	Mylan Atenolol
* Oral liq 25 mg per 5 ml	21.25	300 ml OP	✓	Atenolol AFT
Restricted to children under 12 years of age.				

BISOPROLOL FUMARATE

Tab 2.5 mg	2.40	30	✓	Bosvate
Tab 5 mg	3.50	30	✓	Bosvate
Tab 10 mg	6.40	30	✓	Bosvate

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
CARVEDILOL				
* Tab 6.25 mg	3.90	60	✓	<u>Dicarz</u>
* Tab 12.5 mg	5.10	60	✓	<u>Dicarz</u>
* Tab 25 mg – For carvedilol oral liquid formulation refer, page 224	6.30	60	✓	<u>Dicarz</u>
CELIPROLOL				
* Tab 200 mg	21.40	180	✓	<u>Celol</u>
LABETALOL				
* Tab 50 mg	8.99	100	✓	<u>Hybloc</u>
* Tab 100 mg – For labetalol oral liquid formulation refer, page 224	11.36	100	✓	<u>Hybloc</u>
* Tab 200 mg	29.74	100	✓	<u>Hybloc</u>
* Inj 5 mg per ml, 20 ml ampoule	59.06 (88.60)	5		Trandate
METOPROLOL SUCCINATE				
Tab long-acting 23.75 mg	0.80	30	✓	<u>Myloc CR</u>
	2.39	90	✓	<u>Metoprolol - AFT CR</u>
Tab long-acting 47.5 mg	3.48	90	✓	<u>Metoprolol - AFT CR</u>
	7.50	30	✓	<u>Betaloc CR</u>
Tab long-acting 95 mg	1.91	30	✓	<u>Myloc CR</u>
	5.73	90	✓	<u>Metoprolol - AFT CR</u>
	7.50	30	✓	<u>Betaloc CR</u>
Tab long-acting 190 mg	3.85	30	✓	<u>Myloc CR</u>
	11.54	90	✓	<u>Metoprolol - AFT CR</u>
METOPROLOL TARTRATE				
* Tab 50 mg – For metoprolol tartrate oral liquid formulation refer, page 224	4.64	100	✓	<u>Apo-Metoprolol</u>
* Tab 100 mg	6.09	60	✓	<u>Apo-Metoprolol</u>
* Tab long-acting 200 mg	23.40	28	✓	<u>Slow-Lopresor</u>
* Inj 1 mg per ml, 5 ml vial	24.00	5	✓	<u>Lopresor</u>
NADOLOL				
* Tab 40 mg	16.05	100	✓	<u>Apo-Nadolol</u>
* Tab 80 mg	24.70	100	✓	<u>Apo-Nadolol</u>
PINDOLOL				
* Tab 5 mg	9.72	100	✓	<u>Apo-Pindolol</u>
* Tab 10 mg	15.62	100	✓	<u>Apo-Pindolol</u>
* Tab 15 mg	23.46	100	✓	<u>Apo-Pindolol</u>
PROPRANOLOL				
* Tab 10 mg	3.65	100	✓	<u>Apo- Propranolol</u> ^{S29}
* Tab 40 mg	4.65	100	✓	<u>Apo- Propranolol</u> ^{S29}
Cap long-acting 160 mg	18.17	100	✓	<u>Cardinol LA</u>
* Oral liq 4 mg per ml – Special Authority see SA1327 on the next page – Retail pharmacy	CBS	500 ml	✓	<u>Roxane</u> ^{S29}

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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►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 arrhythmias 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 arrhythmias or congenital cardiac abnormalities.

SOTALOL

* Tab 80 mg – For sotalol oral liquid formulation refer, page 224	39.53	500	✓ <u>Mylan</u>
* Tab 160 mg	12.48	100	✓ <u>Mylan</u>
* Inj 10 mg per ml, 4 ml ampoule	65.39	5	✓ <u>Sotacor</u>

TIMOLOL

* Tab 10 mg	10.55	100	✓ <u>Apo-Timol</u>
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Calcium Channel Blockers

Dihydropyridine Calcium Channel Blockers

AMLODIPINE

* Tab 2.5 mg	2.21	100	✓ <u>Apo-Amlodipine</u>
* Tab 5 mg – For amlodipine oral liquid formulation refer, page 224	5.04	250	✓ <u>Apo-Amlodipine</u>
* Tab 10 mg	7.21	250	✓ <u>Apo-Amlodipine</u>

FELODIPINE

* Tab long-acting 2.5 mg	1.45	30	✓ <u>Plendil ER</u>
* Tab long-acting 5 mg	1.55	30	✓ <u>Plendil ER</u>
* Tab long-acting 10 mg	2.30	30	✓ <u>Plendil ER</u>

ISRADIPINE

* Cap long-acting 2.5 mg	7.50	30	✓ <u>Dynacirc-SRO</u>
* Cap long-acting 5 mg	7.85	30	✓ <u>Dynacirc-SRO</u>

NIFEDIPINE

* Tab long-acting 10 mg	17.72	60	✓ <u>Adalat 10</u>
* Tab long-acting 20 mg	9.59	100	✓ <u>Nyefax Retard</u>
* Tab long-acting 30 mg	3.75	30	✓ <u>Adefin XL</u>
* Tab long-acting 60 mg	5.75	30	✓ <u>Adefin XL</u>

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Other Calcium Channel Blockers				
DILTIAZEM HYDROCHLORIDE				
* Tab 30 mg	4.60	100	✓	Dilzem
* Tab 60 mg – For diltiazem hydrochloride oral liquid formula- tion refer, page 224.....	8.50	100	✓	Dilzem
* Cap long-acting 120 mg	1.91	30	✓	Cardizem CD
	31.83	500	✓	Apo-Diltiazem CD
* Cap long-acting 180 mg	7.56	30	✓	Cardizem CD
	47.67	500	✓	Apo-Diltiazem CD
* Cap long-acting 240 mg	10.22	30	✓	Cardizem CD
	63.58	500	✓	Apo-Diltiazem CD
PERHEXILINE MALEATE				
* Tab 100 mg	62.90	100	✓	Pexsig
VERAPAMIL HYDROCHLORIDE				
* Tab 40 mg	7.01	100	✓	Isoptin
* Tab 80 mg – For verapamil hydrochloride oral liquid formula- tion refer, page 224.....	11.74	100	✓	Isoptin
* Tab long-acting 120 mg	15.20	250	✓	Verpamil SR
* Tab long-acting 240 mg	25.00	250	✓	Verpamil SR
* Inj 2.5 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO.....	25.00	5	✓	Isoptin
Centrally-Acting Agents				
CLONIDINE				
* Patch 2.5 mg, 100 mcg per day – Only on a prescription.....	12.80	4	✓	Catapres-TTS-1
* Patch 5 mg, 200 mcg per day – Only on a prescription.....	18.04	4	✓	Catapres-TTS-2
* Patch 7.5 mg, 300 mcg per day – Only on a prescription.....	22.68	4	✓	Catapres-TTS-3
CLONIDINE HYDROCHLORIDE				
* Tab 25 mcg	10.53	112	✓	Clonidine BNM
* Tab 150 mcg	34.32	100	✓	Catapres
* Inj 150 mcg per ml, 1 ml ampoule	16.07	5	✓	Catapres
METHYLDOPA				
* Tab 125 mg	14.25	100	✓	Prodopa
* Tab 250 mg	15.10	100	✓	Methyldopa Mylan
			✓	Prodopa
* Tab 500 mg	23.15	100	✓	Prodopa
<i>(Prodopa Tab 125 mg to be delisted 1 September 2017)</i>				
<i>(Prodopa Tab 250 mg to be delisted 1 September 2017)</i>				
<i>(Prodopa Tab 500 mg to be delisted 1 June 2017)</i>				
Diuretics				
Loop Diuretics				
BUMETANIDE				
* Tab 1 mg	16.36	100	✓	Burinex
* Inj 500 mcg per ml, 4 ml vial	7.95	5	✓	Burinex

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
FUROSEMIDE [FRUSEMIDE]				
* Tab 40 mg – Up to 30 tab available on a PSO.....	8.00	1,000	✓	Diurin 40
* Tab 500 mg	25.00	50	✓	Urex Forte
*‡ Oral liq 10 mg per ml	10.66	30 ml OP	✓	Lasix
* Inj 10 mg per ml, 25 ml ampoule	57.77	6	✓	Lasix
* Inj 10 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO.....	1.20	5	✓	Frusemide-Claris

Potassium Sparing Diuretics

AMILORIDE HYDROCHLORIDE				
* Tab 5 mg	15.00	100	✓	Apo-Amiloride
‡ Oral liq 1 mg per ml	30.00	25 ml OP	✓	Biomed
METOLAZONE – Special Authority see SA1349 below – Retail pharmacy				
Tab 5 mg	CBS	1	✓	Metolazone <small>\$29</small>
		50	✓	Zaroxolyn <small>\$29</small>

▶▶SA1349 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where used for the treatment of patients with refractory heart failure who are intolerant or have not responded to loop diuretics and/or loop-thiazide combination therapy.

SPIRONOLACTONE				
* Tab 25 mg	4.38	100	✓	Spiractin
* Tab 100 mg	11.80	100	✓	Spiractin
‡ Oral liq 5 mg per ml	30.00	25 ml OP	✓	Biomed

Potassium Sparing Combination Diuretics

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

Thiazide and Related Diuretics

BENDROFLUMETHIAZIDE [BENDROFLUAZIDE]				
* Tab 2.5 mg – Up to 150 tab available on a PSO.....	5.48	500	✓	Arrow-Bendrofluazide
May be supplied on a PSO for reasons other than emergency.				
* Tab 5 mg	8.95	500	✓	Arrow-Bendrofluazide
CHLOROTHIAZIDE				
‡ Oral liq 50 mg per ml	26.00	25 ml OP	✓	Biomed
CHLORTALIDONE [CHLORTHALIDONE]				
* Tab 25 mg	8.00	50	✓	Hygroton
INDAPAMIDE				
* Tab 2.5 mg	2.60	90	✓	Dapa-Tabs

‡ safety cap

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

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

Subsidy
(Manufacturer's Price)
\$

Fully
Subsidised
✓

Brand or
Generic
Manufacturer

Lipid-Modifying Agents

Fibrates

BEZAFIBRATE

* Tab 200 mg	9.05	90	✓ Bezalip
* Tab long-acting 400 mg	6.78	30	✓ Bezalip Retard

GEMFIBROZIL

* Tab 600 mg	19.56	60	✓ Lipazil
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Other Lipid-Modifying Agents

ACIPIMOX

* Cap 250 mg	18.75	30	✓ Olbetam
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NICOTINIC ACID

* Tab 50 mg	3.96	100	✓ Apo-Nicotinic Acid
* Tab 500 mg	17.37	100	✓ Apo-Nicotinic Acid

Resins

CHOLESTYRAMINE

Powder for oral liq 4 g	19.25 (52.68)	50	Questran-Lite
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COLESTIPOL HYDROCHLORIDE

Grans for oral liq 5 g	22.00	30	✓ Colestid
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HMG CoA Reductase Inhibitors (Statins)

Prescribing Guidelines

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

ATORVASTATIN

a) Brand switch fee payable (Pharmacode 2514206) - see page 221 for details

b) See prescribing guideline above

* Tab 10 mg	9.29	500	✓ Lorstat
* Tab 20 mg	13.32	500	✓ Lorstat
* Tab 40 mg	21.23	500	✓ Lorstat
* Tab 80 mg	36.26	500	✓ Lorstat

PRAVASTATIN – See prescribing guideline above

* Tab 20 mg	3.45	30	✓ Cholvastin
* Tab 40 mg	6.36	30	✓ Cholvastin

SIMVASTATIN – See prescribing guideline above

* Tab 10 mg	0.95	90	✓ Arrow-Simva 10mg
* Tab 20 mg	1.61	90	✓ Arrow-Simva 20mg
* Tab 40 mg	2.83	90	✓ Arrow-Simva 40mg
* Tab 80 mg	7.91	90	✓ Arrow-Simva 80mg

Selective Cholesterol Absorption Inhibitors

EZETIMIBE – Special Authority see SA1045 on the next page – Retail pharmacy

Tab 10 mg	3.35	30	✓ Ezemibe
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Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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►SA1045 Special Authority for Subsidy

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

All of the following:

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

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

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

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

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

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

Tab 10 mg with simvastatin 10 mg	5.15	30	✓ <u>Zimybe</u>
Tab 10 mg with simvastatin 20 mg	6.15	30	✓ <u>Zimybe</u>
Tab 10 mg with simvastatin 40 mg	7.15	30	✓ <u>Zimybe</u>
Tab 10 mg with simvastatin 80 mg	8.15	30	✓ <u>Zimybe</u>

►SA1046 Special Authority for Subsidy

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

All of the following:

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

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

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

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

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

Nitrates

GLYCERYL TRINITRATE

* Tab 600 mcg – Up to 100 tab available on a PSO	8.00	100 OP	✓ <u>Lycinate</u>
* Oral pump spray, 400 mcg per dose – Up to 250 dose available on a PSO	4.45	250 dose OP	✓ <u>Nitrolingual Pump Spray</u>
* Oral spray, 400 mcg per dose – Up to 250 dose available on a PSO	4.45	250 dose OP	✓ <u>Glytrin</u>
* Patch 25 mg, 5 mg per day	15.73	30	✓ <u>Nitroderm TTS</u>
* Patch 50 mg, 10 mg per day	18.62	30	✓ <u>Nitroderm TTS</u>

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ISOSORBIDE MONONITRATE				
* Tab 20 mg	17.10	100	✓	Ismo 20
* Tab long-acting 40 mg	7.50	30	✓	Ismo 40 Retard
* Tab long-acting 60 mg	8.49	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
	5.25		✓	Hospira
Inj 1 in 10,000, 10 ml ampoule – Up to 5 inj available on a PSO	27.00	5	✓	Hospira
	49.00	10	✓	Aspen Adrenaline
ISOPRENALINE				
* Inj 200 mcg per ml, 1 ml ampoule	36.80	25		Isuprel
	(164.20)			

Vasodilators

AMYL NITRITE				
* Liq 98% in 0.3 ml cap	62.92	12		Baxter
	(73.40)			
HYDRALAZINE HYDROCHLORIDE				
* Tab 25 mg – Special Authority see SA1321 below – Retail pharmacy	CBS	1	✓	Hydralazine
		56	✓	Onelink ^{\$29}
* Inj 20 mg ampoule	25.90	5	✓	Apresoline

►SA1321 Special Authority for Subsidy

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

Either:

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

MINOXIDIL – Special Authority see SA1271 below – Retail pharmacy

▲ Tab 10 mg	70.00	100	✓	Loniten
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►SA1271 Special Authority for Subsidy

Initial application only from a relevant specialist. Approvals valid without further renewal unless notified where patient has severe refractory hypertension which has failed to respond to extensive multiple therapies.

NICORANDIL

▲ Tab 10 mg	27.95	60	✓	Ikorel
▲ Tab 20 mg	33.28	60	✓	Ikorel

PAPAVERINE HYDROCHLORIDE

* Inj 12 mg per ml, 10 ml ampoule	217.90	5	✓	Hospira
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PENTOXIFYLLINE [OXPENTIFYLLINE]

Tab 400 mg	36.94	50		Trental 400
	(42.26)			

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

Endothelin Receptor Antagonists

►SA0967 Special Authority for Subsidy

Special Authority approved by the Pulmonary Arterial Hypertension Panel

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

The Coordinator, PAH Panel

PHARMAC, PO Box 10-254, WELLINGTON

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

AMBRISENTAN – Special Authority see SA0967 above – Retail pharmacy

Tab 5 mg	4,585.00	30	✓ Volibris
Tab 10 mg	4,585.00	30	✓ Volibris

BOSENTAN – Special Authority see SA0967 above – Retail pharmacy

Tab 62.5 mg	375.00	56	✓ Mylan-Bosentan
Tab 125 mg	375.00	56	✓ Mylan-Bosentan

Phosphodiesterase Type 5 Inhibitors

►SA1293 Special Authority for Subsidy

Initial application — (Raynaud's Phenomenon* - for Pulmonary Arterial Hypertension see note below) 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).

Notes: Sildenafil is also funded for patients with Pulmonary Arterial Hypertension who are approved by the Pulmonary Arterial Hypertension Panel (an application must be made using form [SA1293-PAH](#)).

Application details may be obtained from:

The Coordinator, PAH Panel

PHARMAC, PO Box 10 254, Wellington

Phone: (04) 916 7561 Facsimile: (04) 974 4858 Email: PAH@pharmac.govt.nz

Indications marked with * are Unapproved Indications.

SILDENAFIL – Special Authority see SA1293 above – Retail pharmacy

Tab 25 mg	0.75	4	✓ VEDAFIL
Tab 50 mg	0.75	4	✓ VEDAFIL
Tab 100 mg – For sildenafil oral liquid formulation refer, page 224	2.75	4	✓ VEDAFIL

Prostacyclin Analogues

►SA0969 Special Authority for Subsidy

Special Authority approved by the Pulmonary Arterial Hypertension Panel

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

The Coordinator, PAH Panel

PHARMAC, PO Box 10-254, WELLINGTON

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

ILOPROST – Special Authority see SA0969 above – Retail pharmacy

Nebuliser soln 10 mcg per ml, 2 ml	1,185.00	30	✓ Ventavis
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‡ safety cap

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

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

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

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 97

ADAPALENE

a) Maximum of 30 g per prescription

b) Only on a prescription

Crm 0.1%	22.89	30 g OP	✓ Differin
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Gel 0.1%	22.89	30 g OP	✓ Differin
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ISOTRETINOIN – Special Authority see SA1475 below – Retail pharmacy

Cap 10 mg	12.47	100	✓ Isotane 10
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	14.96	120	✓ Oratane
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Cap 20 mg	19.27	100	✓ Isotane 20
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	23.12	120	✓ Oratane
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►SA1475 Special Authority for Subsidy

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

All of the following:

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

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

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

Either:

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

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

TRETINOIN

Crm 0.5 mg per g – Maximum of 50 g per prescription	13.90	50 g OP	✓ ReTrieve
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Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Antibacterials Topical

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 97

FUSIDIC ACID

Crm 2%	2.52	15 g OP	✓ DP Fusidic Acid Cream
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- a) Maximum of 15 g per prescription
- b) Only on a prescription
- c) Not in combination

Oint 2%	3.45	15 g OP	✓ Foban
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- a) Maximum of 15 g per prescription
- b) Only on a prescription
- c) Not in combination

HYDROGEN PEROXIDE

* Crm 1%	8.56	15 g OP	✓ Crystaderm
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MUIPIROCIN

Oint 2%	6.60 (9.26)	15 g OP	Bactroban
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- a) Only on a prescription
- b) Not in combination

SILVER SULPHADIAZINE

Crm 1%	12.30	50 g OP	✓ Flamazine
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- a) Up to 250 g available on a PSO
- b) Not in combination

Antifungals Topical

For systemic antifungals, refer to INFECTIONS, Antifungals, page 103

AMOROLFINE

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

Nail soln 5%	19.95	5 ml OP	✓ MycoNail
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CICLOPIROX OLAMINE

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

Nail-soln 8%	6.50	7 ml OP	✓ Apo-Ciclopirox
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CLOTRIMAZOLE

* Crm 1%	0.52	20 g OP	✓ Clomazol
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- a) Only on a prescription
- b) Not in combination

* Soln 1%	4.36 (7.55)	20 ml OP	Canesten
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- a) Only on a prescription
- b) Not in combination

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ECONAZOLE NITRATE				
Crm 1%	1.00 (7.48)	20 g OP		Pevaryl
a) Only on a prescription				
b) Not in combination				
Foaming soln 1%, 10 ml sachets	9.89 (17.23)	3		Pevaryl
a) Only on a prescription				
b) Not in combination				
MICONAZOLE NITRATE				
* Crm 2%	0.55	15 g OP	✓	Multichem
a) Only on a prescription				
b) Not in combination				
* Lotn 2%	4.36 (10.03)	30 ml OP		Daktarin
a) Only on a prescription				
b) Not in combination				
* Tinct 2%	4.36 (12.10)	30 ml OP		Daktarin
a) Only on a prescription				
b) Not in combination				
NYSTATIN				
Crm 100,000 u per g	1.00 (7.90)	15 g OP		Mycostatin
a) Only on a prescription				
b) Not in combination				
Antipruritic Preparations				
CALAMINE				
a) Only on a prescription				
b) Not in combination				
Crm, aqueous, BP	1.49	100 g	✓	Pharmacy Health
Lotn, BP	12.94	2,000 ml	✓	PSM
CROTAMITON				
a) Only on a prescription				
b) Not in combination				
Crm 10%	3.37	20 g OP	✓	Itch-Soothe
MENTHOL – Only in combination				
1) Only in combination with a dermatological base or proprietary Topical Corticosteroid – Plain, refer dermatological base, page 223				
2) With or without other dermatological galenicals.				
Crystals	6.50 6.92 29.60	25 g	✓	PSM MidWest MidWest

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

Corticosteroids Topical

For systemic corticosteroids, refer to CORTICOSTEROIDS AND RELATED AGENTS, page 86

Corticosteroids - Plain

BETAMETHASONE DIPROPIONATE

Crm 0.05%	2.96	15 g OP	✓ Diprosone
	8.97	50 g OP	✓ Diprosone
Crm 0.05% in propylene glycol base	4.33	30 g OP	✓ Diprosone OV
Oint 0.05%	2.96	15 g OP	✓ Diprosone
	8.97	50 g OP	✓ Diprosone
Oint 0.05% in propylene glycol base	4.33	30 g OP	✓ Diprosone OV

BETAMETHASONE VALERATE

* Crm 0.1%	3.15	50 g OP	✓ Beta Cream
* Oint 0.1%	3.15	50 g OP	✓ Beta Ointment
* Lotn 0.1%	10.05	50 ml OP	✓ Betnovate

CLOBETASOL PROPIONATE

* Crm 0.05%	2.20	30 g OP	✓ Dermol
* Oint 0.05%	2.20	30 g OP	✓ Dermol

CLOBETASONE BUTYRATE

Crm 0.05%	5.38	30 g OP	
	(7.09)		Eumovate

DIFLUCORTOLONE VALERATE

Crm 0.1%	8.97	50 g OP	
	(15.86)		Nerisone
Fatty oint 0.1%	8.97	50 g OP	
	(15.86)		Nerisone

HYDROCORTISONE

* Crm 1% – Only on a prescription	1.11	30 g OP	✓ DermAssist
	16.25	500 g	✓ Pharmacy Health
DermAssist to be Sole Supply on 1 May 2017			
* Powder – Only in combination	59.50	25 g	✓ ABM
Up to 5% in a dermatological base (not proprietary Topical Corticosteroid – Plain) with or without other dermatological galenicals. Refer, page 223			

HYDROCORTISONE AND PARAFFIN LIQUID AND LANOLIN

Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% – Only on a prescription	10.57	250 ml	✓ DP Lotn HC
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HYDROCORTISONE BUTYRATE

Lipocream 0.1%	2.30	30 g OP	✓ Locoid Lipocream
	6.85	100 g OP	✓ Locoid Lipocream
Oint 0.1%	6.85	100 g OP	✓ Locoid
Milky emul 0.1%	6.85	100 ml OP	✓ Locoid Crelo

METHYLPREDNISOLONE ACEPONATE

Crm 0.1%	4.95	15 g OP	✓ Advantan
Oint 0.1%	4.95	15 g OP	✓ Advantan

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
MOMETASONE FUROATE				
Crm 0.1%	1.51	15 g OP	✓	<u>Elocon Alcohol Free</u>
	2.90	50 g OP	✓	<u>Elocon Alcohol Free</u>
Oint 0.1%	1.51	15 g OP	✓	<u>Elocon</u>
	2.90	50 g OP	✓	<u>Elocon</u>
Lotn 0.1%	7.35	30 ml OP	✓	<u>Elocon</u>
TRIAMCINOLONE ACETONIDE				
Crm 0.02%	6.30	100 g OP	✓	<u>Aristocort</u>
Oint 0.02%	6.35	100 g OP	✓	<u>Aristocort</u>

Corticosteroids - Combination

BETAMETHASONE VALERATE WITH CLIOQUINOL – Only on a prescription				
Crm 0.1% with clioquinol 3%	3.49 (4.90)	15 g OP		Betnovate-C
BETAMETHASONE VALERATE WITH FUSIDIC ACID				
Crm 0.1% with fusidic acid 2%	3.49 (10.45)	15 g OP		Fucicort
a) Maximum of 15 g per prescription				
b) Only on a prescription				
HYDROCORTISONE WITH MICONAZOLE – Only on a prescription				
* Crm 1% with miconazole nitrate 2%	2.00	15 g OP	✓	<u>Micreme H</u>
HYDROCORTISONE WITH NATAMYCIN AND NEOMYCIN – Only on a prescription				
Crm 1% with natamycin 1% and neomycin sulphate 0.5%	2.79	15 g OP	✓	<u>Pimafucort</u>
Oint 1% with natamycin 1% and neomycin sulphate 0.5%	2.79	15 g OP	✓	<u>Pimafucort</u>
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCIN AND NYSTATIN				
Crm 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 mcg per g – Only on a prescription	3.49 (6.60)	15 g OP		Viaderm KC

Disinfecting and Cleansing Agents

CHLORHEXIDINE GLUCONATE – Subsidy by endorsement				
a) No more than 500 ml per month				
b) Only if prescribed for a dialysis patient and the prescription is endorsed accordingly.				
* Handrub 1% with ethanol 70%	4.29	500 ml	✓	<u>healthE</u>
* Soln 4% wash	3.98	500 ml	✓	<u>healthE</u>
TRICLOSAN – Subsidy by endorsement				
a) Maximum of 500 ml per prescription				
b)				
a) Only if prescribed for a patient identified with Methicillin-resistant Staphylococcus aureus (MRSA) prior to elective surgery in hospital and the prescription is endorsed accordingly; or				
b) Only if prescribed for a patient with recurrent Staphylococcus aureus infection and the prescription is endorsed accordingly				
Soln 1%	5.90	500 ml OP	✓	<u>healthE</u>

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

Barrier Creams

DIMETHICONE

* Crm 5% pump bottle	4.59	500 ml OP	✓ <u>healthE</u> <u>Dimethicone 5%</u>
* Crm 10% pump bottle	4.90	500 ml OP	✓ <u>healthE</u> <u>Dimethicone 10%</u>

ZINC AND CASTOR OIL

* Oint BP	3.83	500 g	✓ <u>Multichem</u>
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Emollients

AQUEOUS CREAM

* Crm	1.99	500 g	✓ <u>AFT SLS-free</u>
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CETOMACROGOL

* Crm BP	2.74	500 g	✓ <u>healthE</u>
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CETOMACROGOL WITH GLYCEROL

Crm 90% with glycerol 10%	2.82	500 ml OP	✓ <u>Pharmacy Health</u> <u>Sorbolene with</u> <u>Glycerin</u>
	3.87	1,000 ml OP	✓ <u>Pharmacy Health</u> <u>Sorbolene with</u> <u>Glycerin</u>

EMULSIFYING OINTMENT

* Oint BP	2.73	500 g	✓ <u>AFT</u>
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OIL IN WATER EMULSION

* Crm	2.25	500 g	✓ <u>O/W Fatty Emulsion</u> <u>Cream</u>
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UREA

* Crm 10%	1.37	100 g OP	✓ <u>healthE Urea Cream</u>
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WOOL FAT WITH MINERAL OIL – Only on a prescription

* Lotn hydrous 3% with mineral oil	5.60 (11.95)	1,000 ml	DP Lotion
	1.40 (4.53)	250 ml OP	DP Lotion
	5.60 (20.53)	1,000 ml	Alpha-Keri Lotion
	(23.91)		BK Lotion
	1.40 (7.73)	250 ml OP	BK Lotion

Other Dermatological Bases

PARAFFIN

White soft – Only in combination	20.20	2,500 g	✓ <u>IPW</u>
	3.58	500 g	
	(7.78)		IPW
	(8.69)		PSM

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

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Minor Skin Infections				
POVIDONE IODINE				
Oint 10%	3.27	25 g OP	✓	Betadine
a) Maximum of 100 g per prescription				
b) Only on a prescription				
Antiseptic soln 10%	6.20	500 ml	✓	Betadine
			✓	Riodine
	1.28	100 ml		
	(4.20)			Riodine
	(8.25)			Betadine
	0.19	15 ml		
	(4.45)			Betadine
Skin preparation, povidone iodine 10% with 30% alcohol	10.00	500 ml	✓	Betadine Skin Prep
	1.63	100 ml		
	(3.65)			Betadine Skin Prep
Skin preparation, povidone iodine 10% with 70% alcohol	8.13	500 ml		
	(18.63)			Orion
	1.63	100 ml		
	(6.04)			Orion

Parasiticial Preparations

IVERMECTIN – Special Authority see SA1225 below – Retail pharmacy

- | | | | | |
|--|-------|---|---|-------------------|
| Tab 3 mg – Up to 100 tab available on a PSO..... | 17.20 | 4 | ✓ | Stromectol |
|--|-------|---|---|-------------------|
- 1) PSO for institutional use only. Must be endorsed with the name of the institution for which the PSO is required and a valid Special Authority for patient of that institution.
 - 2) Ivermectin available on BSO provided the BSO includes a valid Special Authority for a patient of the institution.
 - 3) For the purposes of subsidy of ivermectin, institution means age related residential care facilities, disability care facilities or penal institutions.

►SA1225 Special Authority for Subsidy

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

Both:

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

continued...

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

- 2.2.3.1 Patient has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
- 2.2.3.2 The patient is physically or mentally unable to comply with the application instructions of topical therapy; or
- 2.2.3.3 Previous topical therapy has been tried and failed to clear the infestation.

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

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

Any of the following:

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

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

Both:

- 1 Applying clinician has discussed the diagnosis of scabies with a dermatologist, infectious disease physician or clinical microbiologist; and
- 2 Either:

2.1 Both:

2.1.1 The patient is in the community; and

2.1.2 Any of the following:

- 2.1.2.1 Patient has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
- 2.1.2.2 The community patient is physically or mentally unable to comply with the application instructions of topical therapy; or
- 2.1.2.3 The patient has previously tried and failed to clear infestation using topical therapy; or

2.2 All of the following:

2.2.1 The Patient is a resident in an institution; and

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

2.2.3 Any of the following:

- 2.2.3.1 Patient has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
- 2.2.3.2 The patient is physically or mentally unable to comply with the application instructions of topical therapy; or
- 2.2.3.3 Previous topical therapy has been tried and failed to clear the infestation.

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

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

Any of the following:

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

PERMETHRIN

Crm 5%	4.20	30 g OP	✓ Lyderm
Lotn 5%	3.19	30 ml OP	✓ A-Scabies

PHENOTHRIN

Shampoo 0.5%	5.68	100 ml OP	✓ Parasidose
	11.36	200 ml OP	✓ Parasidose

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

ACITRETIN – Special Authority see SA1476 below – Retail pharmacy

Cap 10 mg	17.86	60	✓ Novatretin
Cap 25 mg	41.36	60	✓ Novatretin

►SA1476 Special Authority for Subsidy

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

All of the following:

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

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

Either:

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

BETAMETHASONE DIPROPIONATE WITH CALCIPOTRIOL

Gel 500 mcg with calcipotriol 50 mcg per g	26.12	30 g OP	✓ Daivobet
Oint 500 mcg with calcipotriol 50 mcg per g	26.12	30 g OP	✓ Daivobet

CALCIPOTRIOL

Crm 50 mcg per g	16.00	30 g OP	✓ Daivonex
	45.00	100 g OP	✓ Daivonex
Oint 50 mcg per g	45.00	100 g OP	✓ Daivonex
Soln 50 mcg per ml	16.00	30 ml OP	✓ Daivonex

(Daivonex Crm 50 mcg per g to be delisted 1 April 2017)

(Daivonex Crm 50 mcg per g to be delisted 1 April 2017)

(Daivonex Soln 50 mcg per ml to be delisted 1 April 2017)

COAL TAR

Soln BP – Only in combination	32.95	200 ml	✓ Midwest
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- 1) Up to 10% only in combination with a dermatological base or proprietary Topical Corticosteroid – Plain, refer dermatological base, page 223
- 2) With or without other dermatological galenicals.

COAL TAR WITH ALLANTOIN, MENTHOL, PHENOL AND SULPHUR

Soln 5% with sulphur 0.5%, menthol 0.75%, phenol 0.5% and allantoin crm 2.5%	6.59 (8.00)	75 g OP	Egopsoryl TA
	3.43 (4.35)	30 g OP	Egopsoryl TA

COAL TAR WITH SALICYLIC ACID AND SULPHUR

Soln 12% with salicylic acid 2% and sulphur 4% oint	7.95	40 g OP	✓ Coco-Scalp
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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PINE TAR WITH TROLAMINE LAURILSULFATE AND FLUORESCIN – Only on a prescription				
* Soln 2.3% with trolamine laurilsulfate and fluorescein sodium	3.36	500 ml	✓	Pinetarsol
SALICYLIC ACID				
Powder – Only in combination	18.88	250 g	✓	PSM
1) Only in combination with a dermatological base or proprietary Topical Corticosteroid – Plain or collodion flexible, refer dermatological base, page 223				
2) With or without other dermatological galenicals.				
SULPHUR				
Precipitated – Only in combination	6.35	100 g	✓	Midwest
1) Only in combination with a dermatological base or proprietary Topical Corticosteroid – Plain, refer dermatological base, page 223				
2) With or without other dermatological galenicals.				

Scalp Preparations

BETAMETHASONE VALERATE				
* Scalp app 0.1%	7.75	100 ml OP	✓	Beta Scalp
CLOBETASOL PROPIONATE				
* Scalp app 0.05%	6.96	30 ml OP	✓	Dermol
HYDROCORTISONE BUTYRATE				
Scalp lotn 0.1%	3.65	100 ml OP	✓	Locoid
KETOCONAZOLE				
Shampoo 2%	2.99	100 ml OP	✓	Sebizole
a) Maximum of 100 ml per prescription				
b) Only on a prescription				

Sunscreens

SUNSCREENS, PROPRIETARY – Subsidy by endorsement

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

Crm	3.30	100 g OP		
	(5.89)			
Lotn,	3.30	100 g OP	✓	Hamilton Sunscreen Marine Blue Lotion SPF 50+
	5.10	200 g OP	✓	Marine Blue Lotion SPF 50+
Lotn	4.13	125 ml OP		
	(6.94)			Aquasun 30+

(Aquasun 30+ Lotn to be delisted 1 April 2017)

Wart Preparations

For salicylic acid preparations refer to PSORIASIS AND ECZEMA PREPARATIONS, page 76

IMIQUIMOD				
Crm 5%, 250 mg sachet	17.98	12	✓	Apo-Imiquimod Cream 5%
PODOPHYLLOTOXIN				
Soln 0.5%	33.60	3.5 ml OP	✓	Condyline
a) Maximum of 3.5 ml per prescription				
b) Only on a prescription				

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

Antineoplastics

FLUOROURACIL SODIUM			
Crn 5%	8.95	20 g OP	✓ <u>Efudix</u>

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

Condoms

CONDOMS

* 49 mm – Up to 144 dev available on a PSO.....	13.36	144	✓ MarquisTantiliza ✓ Shield 49
* 52 mm – Up to 144 dev available on a PSO.....	13.36	144	✓ Marquis Selecta
* 52 mm extra strength – Up to 144 dev available on a PSO.....	13.36	144	✓ Marquis Protecta
* 53 mm – Up to 144 dev available on a PSO.....	1.11	12	✓ Gold Knight ✓ Shield Blue
	13.36	144	✓ Marquis Black ✓ Shield Blue
* 53 mm (chocolate) – Up to 144 dev available on a PSO.....	1.11	12	✓ Gold Knight
	13.36	144	✓ Gold Knight
* 53 mm (strawberry) – Up to 144 dev available on a PSO	1.11	12	✓ Gold Knight
	13.36	144	✓ Gold Knight
* 55 mm – Up to 144 dev available on a PSO.....	13.36	144	✓ Marquis Conform
* 56 mm – Up to 144 dev available on a PSO.....	1.11	12	✓ Gold Knight
	13.36	144	✓ Durex Extra Safe ✓ Gold Knight
* 56 mm, shaped – Up to 144 dev available on a PSO.....	1.11	12	✓ Durex Confidence
	13.36	144	✓ Durex Confidence
* 60 mm – Up to 144 dev available on a PSO.....	13.36	144	✓ Shield XL

(MarquisTantiliza 49 mm to be delisted 1 June 2017)
(Marquis Selecta 52 mm to be delisted 1 June 2017)
(Marquis Protecta 52 mm extra strength to be delisted 1 June 2017)
(Marquis Black 53 mm to be delisted 1 June 2017)
(Marquis Conform 55 mm to be delisted 1 June 2017)

Contraceptive Devices

DIAPHRAGM – Up to 1 dev available on a PSO

One of each size is permitted on a PSO.

* 65 mm	42.90	1	✓ Ortho All-flex
* 70 mm	42.90	1	✓ Ortho All-flex
* 75 mm	42.90	1	✓ Ortho All-flex
* 80 mm	42.90	1	✓ Ortho All-flex

(Ortho All-flex 65 mm to be delisted 1 April 2017)
(Ortho All-flex 70 mm to be delisted 1 April 2017)
(Ortho All-flex 75 mm to be delisted 1 April 2017)
(Ortho All-flex 80 mm to be delisted 1 April 2017)

INTRA-UTERINE DEVICE

a) Up to 40 dev available on a PSO

b) Only on a PSO

* IUD 29.1 mm length × 23.2 mm width	31.60	1	✓ Choice TT380 Short
* IUD 33.6 mm length × 29.9 mm width	31.60	1	✓ Choice TT380 Standard
* IUD 35.5 mm length × 19.6 mm width	31.60	1	✓ Choice Load 375

‡ safety cap

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

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

Subsidy
(Manufacturer's Price)
\$

Fully
Subsidised
Per ✓

Brand or
Generic
Manufacturer

Contraceptives - Hormonal

Combined Oral Contraceptives

►SA0500 Special Authority for Alternate Subsidy

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

Both:

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

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

Either:

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

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

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

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

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

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

ETHINYLOESTRADIOL WITH DESOGESTREL

* Tab 20 mcg with desogestrel 150 mcg and 7 inert tab	6.62	84	
	(19.80)		Mercilon 28
a) Higher subsidy of \$13.80 per 84 tab with Special Authority see SA0500 above			
b) Up to 84 tab available on a PSO			
* Tab 30 mcg with desogestrel 150 mcg and 7 inert tab	6.62	84	
	(19.80)		Marvelon 28
a) Higher subsidy of \$13.80 per 84 tab with Special Authority see SA0500 above			
b) Up to 84 tab available on a PSO			

ETHINYLOESTRADIOL WITH LEVONORGESTREL

* Tab 20 mcg with levonorgestrel 100 mcg and 7 inert tab – Up			
to 84 tab available on a PSO	2.65	84	✓ Ava 20 ED
* Tab 50 mcg with levonorgestrel 125 mcg and 7 inert tab – Up			
to 84 tab available on a PSO	9.45	84	✓ Microgynon 50 ED
* Tab 30 mcg with levonorgestrel 150 mcg	6.62	63	
	(16.50)		Microgynon 30
a) Higher subsidy of \$15.00 per 63 tab with Special Authority see SA0500 above			
b) Up to 63 tab available on a PSO			
* Tab 30 mcg with levonorgestrel 150 mcg and 7 inert tab – Up			
to 84 tab available on a PSO	2.30	84	✓ Ava 30 ED

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ETHINYLOESTRADIOL WITH NORETHISTERONE				
* Tab 35 mcg with norethisterone 1 mg – Up to 63 tab available on a PSO	6.62	63	✓	Brevinor 1/21
* Tab 35 mcg with norethisterone 1 mg and 7 inert tab – Up to 84 tab available on a PSO	6.62	84	✓	Brevinor 1/28
* Tab 35 mcg with norethisterone 500 mcg – Up to 63 tab available on a PSO	6.62	63	✓	Brevinor 21
* Tab 35 mcg with norethisterone 500 mcg and 7 inert tab – Up to 84 tab available on a PSO	6.62	84	✓	Norimin

Progestogen-only Contraceptives

►SA0500 | Special Authority for Alternate Subsidy

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

Both:

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

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

Either:

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

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

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

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

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

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

LEVONORGESTREL

* Tab 30 mcg	6.62	84		
	(16.50)			Microlut
a) Higher subsidy of \$13.80 per 84 tab with Special Authority see SA0500 above				
b) Up to 84 tab available on a PSO				

* Subdermal implant (2 × 75 mg rods) – Up to 3 pack available on a PSO	133.65	1	✓	Jadelle
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MEDROXYPROGESTERONE ACETATE

* Inj 150 mg per ml, 1 ml syringe – Up to 5 inj available on a PSO	7.25	1	✓	Depo-Provera
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NORETHISTERONE

* Tab 350 mcg – Up to 84 tab available on a PSO	6.25	84	✓	Noriday 28
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‡ safety cap

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

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

Emergency Contraceptives

LEVONORGESTREL

* Tab 1.5 mg	3.50	1	✓ Postinor-1
a) Maximum of 2 tab per prescription			
b) Up to 5 tab available on a PSO			

Antiandrogen Oral Contraceptives

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

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

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

CYPROTERONE ACETATE WITH ETHINYLOESTRADIOL

* Tab 2 mg with ethinyloestradiol 35 mcg and 7 inert tabs – Up to 168 tab available on a PSO	5.36	168	✓ Ginet
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Gynaecological Anti-infectives

ACETIC ACID WITH HYDROXYQUINOLINE AND RICINOLEIC ACID

Jelly with glacial acetic acid 0.94%, hydroxyquinoline sul- phate 0.025%, glycerol 5% and ricinoleic acid 0.75% with applicator	8.43 (24.00)	100 g OP	Aci-Jel
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CLOTRIMAZOLE

* Vaginal crm 1% with applicators	1.60	35 g OP	✓ Clomazol
* Vaginal crm 2% with applicators	2.10	20 g OP	✓ Clomazol

MICONAZOLE NITRATE

* Vaginal crm 2% with applicator	3.95	40 g OP	✓ Micreme
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NYSTATIN

Vaginal crm 100,000 u per 5 g with applicator(s)	4.71	75 g OP	✓ Niostat
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Myometrial and Vaginal Hormone Preparations

ERGOMETRINE MALEATE

Inj 500 mcg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	94.70	5	✓ DBL Ergometrine
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OESTRIOL

* Crm 1 mg per g with applicator	6.30	15 g OP	✓ Ovestin
* Pessaries 500 mcg	6.53	15	✓ Ovestin

OXYTOCIN – Up to 5 inj available on a PSO

Inj 5 iu per ml, 1 ml ampoule	4.03	5	✓ Oxytocin BNM
Inj 10 iu per ml, 1 ml ampoule	5.03	5	✓ Oxytocin BNM

OXYTOCIN WITH ERGOMETRINE MALEATE – Up to 5 inj available on a PSO

Inj 5 iu with ergometrine maleate 500 mcg per ml, 1 ml	11.13	5	✓ Syntometrine
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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

Pregnancy Tests - hCG Urine

PREGNANCY TESTS - HCG URINE

a) Up to 200 test available on a PSO

b) Only on a PSO

Cassette 17.60 40 test OP ✓ EasyCheck

Urinary Agents

For urinary tract Infections refer to INFECTIONS, Antibacterials, page 118

5-Alpha Reductase Inhibitors

FINASTERIDE – Special Authority see SA0928 below – Retail pharmacy

* Tab 5 mg 2.08 30 ✓ Finpro

►SA0928 Special Authority for Subsidy

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

Both:

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

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

Alpha-1A Adrenoreceptor Blockers

TAMSULOSIN HYDROCHLORIDE – Special Authority see SA1032 below – Retail pharmacy

* Cap 400 mcg 13.51 100 ✓ Tamsulosin-Rex

►SA1032 Special Authority for Subsidy

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

Both:

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

Other Urinary Agents

OXYBUTYNIN

* Tab 5 mg 8.85 500 ✓ Apo-Oxybutynin

* Oral liq 5 mg per 5 ml 60.40 473 ml ✓ Apo-Oxybutynin

POTASSIUM CITRATE

Oral liq 3 mmol per ml – Special Authority see SA1083 below

– Retail pharmacy 30.00 200 ml OP ✓ Biomed

►SA1083 Special Authority for Subsidy

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

Both:

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
SODIUM CITRO-TARTRATE				
* Grans eff 4 g sachets	2.93	28	✓	Ural
SOLIFENACIN SUCCINATE – Special Authority see SA0998 below – Retail pharmacy				
Tab 5 mg	37.50	30	✓	Vesicare
Tab 10 mg	37.50	30	✓	Vesicare

►SA0998 Special Authority for Subsidy

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

TOLTERODINE – Special Authority see SA1272 below – Retail pharmacy

Tab 1 mg	14.56	56	✓	Arrow-Tolterodine
Tab 2 mg	14.56	56	✓	Arrow-Tolterodine

►SA1272 Special Authority for Subsidy

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

Detection of Substances in Urine

ORTHO-TOLIDINE

* Compound diagnostic sticks	7.50 (8.25)	50 test OP		Hemastix
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TETRABROMOPHENOL

* Blue diagnostic strips	7.02 (13.92)	100 test OP		Albustix
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Calcium Homeostasis

* Inj 100 iu per ml, 1 ml ampoule	121.00	5	✓ Miacalcic
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CINACALCET – Special Authority see SA1618 below – Retail pharmacy

Tab 30 mg – Wastage claimable – see rule 3.3.2 on page 13	403.70	28	✓ Sensipar
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Either:

- Both:

- Note: This does not include parathyroid adenomas unless these have become malignant.

Inj 4 mg per 5 ml, vial – Special Authority see SA1512 below

- Retail pharmacy	84.50	1	✓ Zoledronic acid Mylan
	550.00		✓ Zometa

Any of the following:

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

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Corticosteroids and Related Agents for Systemic Use				
BETAMETHASONE SODIUM PHOSPHATE WITH BETAMETHASONE ACETATE				
* Inj 3.9 mg with betamethasone acetate 3 mg per ml, 1 ml	19.20 (36.96)	5		Celestone Chronodose
DEXAMETHASONE				
* Tab 0.5 mg – Retail pharmacy-Specialist	0.88	30	✓	<u>Dexamethasone</u>
Up to 60 tab available on a PSO				
* Tab 4 mg – Retail pharmacy-Specialist	1.84	30	✓	<u>Dexamethasone</u>
Up to 30 tab available on a PSO				
Oral liq 1 mg per ml – Retail pharmacy-Specialist	45.00	25 ml OP	✓	<u>Biomed</u>
Oral liq prescriptions:				
1) Must be written by a Paediatrician or Paediatric Cardiologist; or				
2) On the recommendation of a Paediatrician or Paediatric Cardiologist.				
DEXAMETHASONE PHOSPHATE				
Dexamethasone phosphate injection will not be funded for oral use.				
* Inj 4 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	14.19	10	✓	<u>Max Health</u>
* Inj 4 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	12.59	5	✓	<u>Max Health</u>
FLUDROCORTISONE ACETATE				
* Tab 100 mcg	14.32	100	✓	<u>Florinef</u>
HYDROCORTISONE				
* Tab 5 mg	8.10	100	✓	<u>Douglas</u>
* Tab 20 mg – For hydrocortisone oral liquid formulation refer, page 224	20.32	100	✓	<u>Douglas</u>
* Inj 100 mg vial	5.30	1	✓	<u>Solu-Cortef</u>
a) Up to 5 inj available on a PSO				
b) Only on a PSO				
METHYLPREDNISOLONE – Retail pharmacy-Specialist				
* Tab 4 mg	80.00	100	✓	<u>Medrol</u>
* Tab 100 mg	180.00	20	✓	<u>Medrol</u>
METHYLPREDNISOLONE (AS SODIUM SUCCINATE) – Retail pharmacy-Specialist				
Inj 40 mg vial	10.50	1	✓	<u>Solu-Medrol</u>
Inj 125 mg vial	22.25	1	✓	<u>Solu-Medrol</u>
Inj 500 mg vial	9.00	1	✓	<u>Solu-Medrol</u>
Inj 1 g vial	16.00	1	✓	<u>Solu-Medrol</u>
METHYLPREDNISOLONE ACETATE				
Inj 40 mg per ml, 1 ml vial	40.00	5	✓	<u>Depo-Medrol</u>
METHYLPREDNISOLONE ACETATE WITH LIDOCAINE [LIGNOCAINE]				
Inj 40 mg per ml with lidocaine [lignocaine] 1 ml vial	9.25	1	✓	<u>Depo-Medrol with Lidocaine</u>
PREDNISOLONE				
* Oral liq 5 mg per ml – Up to 30 ml available on a PSO	7.50	30 ml OP	✓	<u>Redipred</u>
Restricted to children under 12 years of age.				

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PREDNISONE				
* Tab 1 mg	10.68	500	✓	Apo-Prednisone
* Tab 2.5 mg	12.09	500	✓	Apo-Prednisone
* Tab 5 mg – Up to 30 tab available on a PSO.....	11.09	500	✓	Apo-Prednisone
* Tab 20 mg	29.03	500	✓	Apo-Prednisone
TETRACOSACTRIN				
* Inj 250 mcg per ml, 1 ml ampoule	75.00	1	✓	Synacthen
* Inj 1 mg per ml, 1 ml ampoule	690.00	1	✓	Synacthen Depot
TRIAMCINOLONE ACETONIDE				
Inj 10 mg per ml, 1 ml ampoule	20.80	5	✓	Kenacort-A 10
Inj 40 mg per ml, 1 ml ampoule	51.10	5	✓	Kenacort-A 40

Sex Hormones Non Contraceptive

Androgen Agonists and Antagonists

CYPROTERONE ACETATE – Retail pharmacy-Specialist				
Tab 50 mg	15.87	50	✓	Procur
Tab 100 mg	30.40	50	✓	Procur
TESTOSTERONE				
Transdermal patch, 2.5 mg per day	80.00	60	✓	Androderm
TESTOSTERONE CYPIONATE – Retail pharmacy-Specialist				
Inj 100 mg per ml, 10 ml vial	76.50	1	✓	Depo-Testosterone
TESTOSTERONE ESTERS – Retail pharmacy-Specialist				
Inj 250 mg per ml, 1 ml	12.98	1	✓	Sustanon Ampoules
TESTOSTERONE UNDECANOATE – Retail pharmacy-Specialist				
Cap 40 mg	16.80	60	✓	Andriol Testocaps
Inj 250 mg per ml, 4 ml vial	86.00	1	✓	Reandron 1000

Hormone Replacement Therapy - Systemic

Prescribing Guideline

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

‡ safety cap

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

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

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Oestrogens				
OESTRADIOL – See prescribing guideline on the previous page				
* Tab 1 mg	4.12 (11.10)	28 OP		Estrofem
* Tab 2 mg	4.12 (11.10)	28 OP		Estrofem
* Patch 25 mcg per day	6.12	8	✓	<u>Estradot</u>
a) No more than 2 patch per week				
b) Only on a prescription				
* Patch 50 mcg per day	7.04	8	✓	<u>Estradot 50 mcg</u>
a) No more than 2 patch per week				
b) Only on a prescription				
* Patch 75 mcg per day	7.91	8	✓	<u>Estradot</u>
a) No more than 2 patch per week				
b) Only on a prescription				
c) Estradot to be Sole Supply on 1 April 2017				
* Patch 100 mcg per day	7.91	8	✓	<u>Estradot</u>
a) No more than 2 patch per week				
b) Only on a prescription				
OESTRADIOL VALERATE – See prescribing guideline on the previous page				
* Tab 1 mg	12.36	84	✓	<u>Progynova</u>
* Tab 2 mg	12.36	84	✓	<u>Progynova</u>
OESTROGENS – See prescribing guideline on the previous page				
* Conjugated, equine tab 300 mcg	3.01 (11.48)	28		Premarin
* Conjugated, equine tab 625 mcg	4.12 (11.48)	28		Premarin
Progestogens				
MEDROXYPROGESTERONE ACETATE – See prescribing guideline on the previous page				
* Tab 2.5 mg	3.75	30	✓	<u>Provera</u>
* Tab 5 mg	14.00	100	✓	<u>Provera</u>
* Tab 10 mg	7.15	30	✓	<u>Provera</u>
Progestogen and Oestrogen Combined Preparations				
OESTRADIOL WITH NORETHISTERONE – See prescribing guideline on the previous page				
* Tab 1 mg with 0.5 mg norethisterone acetate	5.40 (18.10)	28 OP		Kliovance
* Tab 2 mg with 1 mg norethisterone acetate	5.40 (18.10)	28 OP		Kliogest
* Tab 2 mg with 1 mg norethisterone acetate (10), and 2 mg oestradiol tab (12) and 1 mg oestradiol tab (6)	5.40 (18.10)	28 OP		Trisequens

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
OESTROGENS WITH MEDROXYPROGESTERONE – See prescribing guideline on page 87				
* Tab 625 mcg conjugated equine with 2.5 mg medroxyprogest- terone acetate tab (28)	5.40 (22.96)	28 OP		Premia 2.5 Continuous
* Tab 625 mcg conjugated equine with 5 mg medroxyproges- terone acetate tab (28)	5.40 (22.96)	28 OP		Premia 5 Continuous
Other Oestrogen Preparations				
ETHINYLOESTRADIOL				
* Tab 10 mcg	17.60	100	✓	<u>NZ Medical and Scientific</u>
OESTRIOL				
* Tab 2 mg	7.00	30	✓	<u>Ovestin</u>
Other Progestogen Preparations				
LEVONORGESTREL				
* Intra-uterine system 20 mcg per day – Special Authority see SA1608 below – Retail pharmacy	269.50	1	✓	<u>Mirena</u>
▶SA1608 Special Authority for Subsidy				
Initial application — (No previous use) only from a relevant specialist or general practitioner. Approvals valid for 6 months for applications meeting the following criteria:				
All of the following:				
1 The patient has a clinical diagnosis of heavy menstrual bleeding; and				
2 The patient has failed to respond to or is unable to tolerate other appropriate pharmaceutical therapies as per the Heavy Menstrual Bleeding Guidelines; and				
3 Either:				
3.1 serum ferritin level < 16 mcg/l (within the last 12 months); or				
3.2 haemoglobin level < 120 g/l.				
Note: Applications are not to be made for use in patients as contraception except where they meet the above criteria.				
Renewal only from a relevant specialist or general practitioner. Approvals valid for 6 months for applications meeting the following criteria:				
Both:				
1 Either:				
1.1 Patient demonstrated clinical improvement of heavy menstrual bleeding; or				
1.2 Previous insertion was removed or expelled within 3 months of insertion; and				
2 Applicant to state date of the previous insertion.				
MEDROXYPROGESTERONE ACETATE				
* Tab 100 mg – Retail pharmacy-Specialist	101.00	100	✓	<u>Provera HD</u>
NORETHISTERONE				
* Tab 5 mg – Up to 30 tab available on a PSO	18.29	100	✓	<u>Primolut N</u>
PROGESTERONE				
Cap 100 mg – Special Authority see SA1609 on the next page – Retail pharmacy	16.50	30	✓	<u>Utrogestan</u>

‡ safety cap

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

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

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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►SA1609 Special Authority for Subsidy

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

Both:

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

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

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

Note: Indications marked with * are Unapproved Indications (refer to Interpretations and Definitions).

Thyroid and Antithyroid Agents

CARBIMAZOLE

* Tab 5 mg	10.80	100	✓ AFT
			Carbimazole ^{S29}
			✓ Neo-Mercazole

LEVOTHYROXINE

* Tab 25 mcg	3.89	90	✓ Synthroid
‡ Safety cap for extemporaneously compounded oral liquid preparations.			
* Tab 50 mcg	4.05	90	✓ Synthroid
	64.28	1,000	✓ Eltroxin
‡ Safety cap for extemporaneously compounded oral liquid preparations.			
* Tab 100 mcg	4.21	90	✓ Synthroid
	66.78	1,000	✓ Eltroxin
‡ Safety cap for extemporaneously compounded oral liquid preparations.			

LEVOTHYROXINE (MERCURY PHARMA)

* Tab 50 mcg	1.71	28	✓ Mercury Pharma
‡ Safety cap for extemporaneously compounded oral liquid preparations.			
* Tab 100 mcg	1.78	28	✓ Mercury Pharma
‡ Safety cap for extemporaneously compounded oral liquid preparations.			

PROPYLTHIOURACIL – Special Authority see SA1199 below – Retail pharmacy

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

Tab 50 mg	35.00	100	✓ PTU ^{S29}
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►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.

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

Trophic Hormones

Growth Hormones

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

* Inj 5 mg cartridge	109.50	1	✓ Omnitrope
* Inj 10 mg cartridge	219.00	1	✓ Omnitrope
* Inj 15 mg cartridge	328.50	1	✓ Omnitrope

►SA1629 | Special Authority for Subsidy

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

Either:

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

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

All of the following:

- 1 A current bone age is ≤ 14 years (female patients) or ≤ 16 years (male patients); and
- 2 Height velocity is ≥ 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 ≥ 2.0 cm per year, as calculated over 6 months; and
- 4 No serious adverse effect that the patients specialist considers is likely to be attributable to growth hormone treatment has occurred; and
- 5 No malignancy has developed since starting growth hormone.

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

All of the following:

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

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

All of the following:

- 1 Height velocity ≥ 50th percentile for age (while on growth hormone calculated over 6 to 12 months using the Ranke's Turner Syndrome growth velocity charts); and

continued...

‡ safety cap

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

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

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

- 2 Height velocity is ≥ 2 cm per year, calculated over six months; and
- 3 A current bone age is ≤ 14 years; 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 < 25 th 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 (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 ≥ 50 th 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 ≥ 2 cm per year as calculated over six months; and
- 3 A current bone age is ≤ 14 years (female patients) or ≤ 16 years (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 < 25 th 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 ≤ 14 years (female patients) or ≤ 16 years (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 $GFR \leq 30$ ml/min/1.73m² as measured by the Schwartz method (Height(cm)/plasma creatinine (umol/l) $\times 40$ = corrected GFR (ml/min/1.73m² in a child who may or may not be receiving dialysis; or
 - 6.2 The patient has received a renal transplant and has received < 5 mg/ 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 ≥ 50 th 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 ≥ 2 cm per year as calculated over six months; and

continued...

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

- 3 A current bone age is \leq 14 years (female patients) or \leq 16 years (male patients); and
- 4 No serious adverse effect that the patients specialist considers is likely to be attributable to growth hormone has occurred; and
- 5 No malignancy has developed after growth hormone therapy was commenced; and
- 6 The patient has not experienced significant biochemical or metabolic deterioration confirmed by diagnostic results; and
- 7 The patient has not received renal transplantation since starting growth hormone treatment; and
- 8 If the patient requires transplantation, growth hormone prescription should cease before transplantation and a new application should be made after transplantation based on the above criteria.

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

All of the following:

- 1 The patient has a diagnosis of Prader-Willi syndrome that has been confirmed by genetic testing or clinical scoring criteria; and
- 2 The patient is aged six months or older; and
- 3 A current bone age is $<$ 14 years (female patients) or $<$ 16 years (male patients); and
- 4 Sleep studies or overnight oximetry have been performed and there is no obstructive sleep disorder requiring treatment, or if an obstructive sleep disorder is found, it has been adequately treated under the care of a paediatric respiratory physician and/or ENT surgeon; and
- 5 Either:
 - 5.1 Both:
 - 5.1.1 The patient is aged two years or older; and
 - 5.1.2 There is no evidence of type II diabetes or uncontrolled obesity defined by BMI that has increased by \geq 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 \geq 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 \geq 2 cm per year as calculated over six months; and
- 3 A current bone age is \leq 14 years (female patients) or \leq 16 years (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 \geq 0.5 standard deviations in the preceding 12 months.

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

All of the following:

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

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HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Notes: For the purposes of adults and adolescents, severe growth hormone deficiency is defined as a peak serum growth hormone level of ≤ 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 ≤ 0.4 mcg per litre.

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

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

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

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

Either:

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

GnRH Analogues

GOSERELIN

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
LEUPRORELIN				
Additional subsidy by endorsement where the patient is a child or adolescent and is unable to tolerate administration of goserelin and the prescription is endorsed accordingly.				
Inj 3.75 mg prefilled dual chamber syringe – Higher subsidy of \$221.60 per 1 inj with Endorsement.....	66.48 (221.60)	1		Lucrin Depot 1-month
Inj 7.5 mg syringe with diluent – Higher subsidy of \$166.20 per 1 inj with Endorsement.....	66.48 (166.20)	1		Eligard 1 Month
Inj 11.25 mg prefilled dual chamber syringe – Higher subsidy of \$591.68 per 1 inj with Endorsement.....	177.50 (591.68)	1		Lucrin Depot 3-month
Inj 22.5 mg syringe with diluent – Higher subsidy of \$443.76 per 1 inj with Endorsement.....	177.50 (443.76)	1		Eligard 3 Month
Inj 30 mg prefilled dual chamber syringe – Higher subsidy of \$1109.40 per 1 inj with Endorsement.....	332.82 (1,109.40)	1		Lucrin Depot 6-month
Inj 45 mg syringe with diluent – Higher subsidy of \$832.05 per 1 inj with Endorsement.....	332.82 (832.05)	1		Eligard 6 Month

(Eligard 1 Month Inj 7.5 mg syringe with diluent to be delisted 1 June 2017)

(Eligard 3 Month Inj 22.5 mg syringe with diluent to be delisted 1 June 2017)

(Lucrin Depot 6-month Inj 30 mg prefilled dual chamber syringe to be delisted 1 August 2017)

(Eligard 6 Month Inj 45 mg syringe with diluent to be delisted 1 June 2017)

Vasopressin Agonists

DESMOPRESSIN ACETATE

Tab 100 mcg – Special Authority see SA1401 below – Retail pharmacy	25.00	30	✓	<u>Minirin</u>
Tab 200 mcg – Special Authority see SA1401 below – Retail pharmacy	54.45	30	✓	<u>Minirin</u>
▲ Nasal drops 100 mcg per ml – Retail pharmacy-Specialist.....	39.03	2.5 ml OP	✓	<u>Minirin</u>
▲ Nasal spray 10 mcg per dose – Retail pharmacy-Specialist	22.95	6 ml OP	✓	<u>Desmopressin- PH&T</u>
Inj 4 mcg per ml, 1 ml – Special Authority see SA1401 below – Retail pharmacy	67.18	10	✓	<u>Minirin</u>

►SA1401 Special Authority for Subsidy

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

All of the following:

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

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

Both:

- 1 The patient has cranial diabetes insipidus; and

continued...

‡ safety cap

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

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

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

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

2 The nasal forms of desmopressin are contraindicated.

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

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

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

Other Endocrine Agents

CABERGOLINE

Tab 0.5 mg – Maximum of 2 tab per prescription; can be				
waived by Special Authority see SA1370 below	4.75	2	✓	Dostinex
	19.00	8	✓	Dostinex

►SA1370 Special Authority for Waiver of Rule

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

Either:

- 1 pathological hyperprolactinemia; or
- 2 acromegaly*.

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

Note: Indication marked with * is an Unapproved indication.

CLOMIPHENE CITRATE

Tab 50 mg	29.84	10	✓	Mylan
				Clomiphene <small>\$29</small>
			✓	Serophene

DANAZOL

Cap 100 mg	68.33	100	✓	Azol
Cap 200 mg	97.83	100	✓	Azol

METYRAPONE

Cap 250 mg – Retail pharmacy-Specialist	520.00	50	✓	Metopirone
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Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Anthelmintics

ALBENDAZOLE – Special Authority see SA1318 below – Retail pharmacy

Tab 400 mg	469.20	60	✓ Eskazole S29
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►SA1318 Special Authority for Subsidy

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

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

MEBENDAZOLE – Only on a prescription

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

PRAZIQUANTEL

Tab 600 mg	68.00	8	✓ Biltricide
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Antibacterials

a) For topical antibacterials, refer to DERMATOLOGICALS, page 69

b) For anti-infective eye preparations, refer to SENSORY ORGANS, page 216

Cephalosporins and Cephamycins

CEFACLOR MONOHYDRATE

Cap 250 mg	24.70	100	✓ <u>Ranbaxy-Cefaclor</u>
Grans for oral liq 125 mg per 5 ml – Wastage claimable – see rule 3.3.2 on page 13	3.53	100 ml	✓ <u>Ranbaxy-Cefaclor</u>

CEFALEXIN

Cap 250 mg	3.50	20	✓ <u>Cephalexin ABM</u>
Cap 500 mg	3.95	20	✓ <u>Cephalexin ABM</u>
Grans for oral liq 25 mg per ml – Wastage claimable – see rule 3.3.2 on page 13	8.00	100 ml	✓ <u>Cefalexin Sandoz</u>
Note: Cefalexin grans for oral liq will not be funded in amounts more than 14 days treatment per dispensing.			
Grans for oral liq 50 mg per ml – Wastage claimable – see rule 3.3.2 on page 13	11.00	100 ml	✓ <u>Cefalexin Sandoz</u>
Note: Cefalexin grans for oral liq will not be funded in amounts more than 14 days treatment per dispensing.			

CEFTRIAZONE – Subsidy by endorsement

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

Inj 500 mg vial	3.99	5	✓ <u>AFT</u>
Inj 1 g vial	3.38	5	✓ <u>AFT</u>

CEFTRIAZONE – Subsidy by endorsement

a) Up to 5 inj available on a PSO

b) Subsidised only if prescribed for a dialysis or cystic fibrosis patient, or the treatment of gonorrhoea, or the treatment of pelvic inflammatory disease, or the treatment of suspected meningitis in patients who have a known allergy to penicillin, and the prescription or PSO is endorsed accordingly.

Inj 500 mg vial	1.20	1	✓ <u>DEVA</u>
Inj 1 g vial	0.84	1	✓ <u>DEVA</u>

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
CEFUROXIME AXETIL – Subsidy by endorsement				
Only if prescribed for prophylaxis of endocarditis and the prescription is endorsed accordingly.				
Tab 250 mg	29.40	50	✓	Zinnat
Macrolides				
AZITHROMYCIN – Maximum of 5 days treatment per prescription; can be waived by endorsement				
For Endorsement, patient has either:				
1) Received a lung transplant and requires treatment or prophylaxis for bronchiolitis obliterans syndrome*; or				
2) Cystic fibrosis and has chronic infection with <i>Pseudomonas aeruginosa</i> or <i>Pseudomonas</i> related gram negative organisms*.				
Indications marked with * are Unapproved Indications				
Tab 250 mg	9.00	30	✓	Apo-Azithromycin
Tab 500 mg – Up to 8 tab available on a PSO.....	1.05	2	✓	Apo-Azithromycin
Grans for oral liq 200 mg per 5 ml (40 mg per ml) – Wastage claimable – see rule 3.3.2 on page 13.....	12.50	15 ml	✓	Zithromax
CLARITHROMYCIN – Maximum of 500 mg per prescription; can be waived by Special Authority see SA1131 below				
Tab 250 mg	3.98	14	✓	Apo-Clarithromycin
Grans for oral liq 250 mg per 5 ml – Wastage claimable – see rule 3.3.2 on page 13	23.12	50 ml	✓	Klacid
►SA1131 Special Authority for Waiver of Rule				
Initial application — (Mycobacterial infections) only from a respiratory specialist, infectious disease specialist or paediatrician. Approvals valid for 2 years for applications meeting the following criteria:				
Either:				
1 Atypical mycobacterial infection; or				
2 Mycobacterium tuberculosis infection where there is drug-resistance or intolerance to standard pharmaceutical agents.				
Renewal — (Mycobacterial infections) only from a respiratory specialist, infectious disease specialist or paediatrician. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.				
ERYTHROMYCIN ETHYL SUCCINATE				
Tab 400 mg	16.95	100	✓	E-Mycin
a) Up to 20 tab available on a PSO				
b) Up to 2 x the maximum PSO quantity for RFPP – see rule 5.2.6 on page 17				
Grans for oral liq 200 mg per 5 ml	5.00	100 ml	✓	E-Mycin
a) Up to 300 ml available on a PSO				
b) Up to 2 x the maximum PSO quantity for RFPP – see rule 5.2.6 on page 17				
c) Wastage claimable – see rule 3.3.2 on page 13				
Grans for oral liq 400 mg per 5 ml	6.77	100 ml	✓	E-Mycin
a) Up to 200 ml available on a PSO				
b) Wastage claimable – see rule 3.3.2 on page 13				
ERYTHROMYCIN LACTOBIONATE				
Inj 1 g	16.00	1	✓	Erythrocin IV
ERYTHROMYCIN STEARATE				
Tab 250 mg – Up to 30 tab available on a PSO.....	14.95 (22.29)	100		ERA
Tab 500 mg	29.90 (44.58)	100		ERA

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ROXITHROMYCIN				
Tab 150 mg	7.48	50	✓	Arrow- Roxithromycin
Tab 300 mg	14.40	50	✓	Arrow- Roxithromycin
Penicillins				
AMOXICILLIN				
Cap 250 mg	14.97	500	✓	<u>Apo-Amoxi</u>
a) Up to 30 cap available on a PSO				
b) Up to 10 x the maximum PSO quantity for RFPP – see rule 5.2.6 on page 17				
Cap 500 mg	16.75	500	✓	<u>Apo-Amoxi</u>
a) Up to 30 cap available on a PSO				
b) Up to 10 x the maximum PSO quantity for RFPP – see rule 5.2.6 on page 17				
Grans for oral liq 125 mg per 5 ml	0.88	100 ml	✓	Amoxicillin Actavis
	2.00		✓	Ospamox
a) Up to 200 ml available on a PSO				
b) Wastage claimable – see rule 3.3.2 on page 13				
Grans for oral liq 250 mg per 5 ml	0.97	100 ml	✓	Amoxicillin Actavis
	2.00		✓	Ospamox
a) Up to 300 ml available on a PSO				
b) Up to 10 x the maximum PSO quantity for RFPP – see rule 5.2.6 on page 17				
c) Wastage claimable – see rule 3.3.2 on page 13				
Inj 250 mg vial	10.67	10	✓	<u>Ibiamox</u>
Inj 500 mg vial	12.41	10	✓	<u>Ibiamox</u>
Inj 1 g vial – Up to 5 inj available on a PSO.....	17.29	10	✓	<u>Ibiamox</u>
AMOXICILLIN WITH CLAVULANIC ACID				
Tab 500 mg with clavulanic acid 125 mg – Up to 30 tab avail- able on a PSO	1.95	20	✓	<u>Augmentin</u>
Grans for oral liq amoxicillin 125 mg with clavulanic acid 31.25 mg per 5 ml	3.83	100 ml	✓	<u>Augmentin</u>
a) Up to 200 ml available on a PSO				
b) Wastage claimable – see rule 3.3.2 on page 13				
Grans for oral liq amoxicillin 250 mg with clavulanic acid 62.5 mg per 5 ml	4.97	100 ml	✓	<u>Augmentin</u>
a) Up to 200 ml available on a PSO				
b) Wastage claimable – see rule 3.3.2 on page 13				
BENZATHINE BENZYL PENICILLIN				
Inj 900 mg (1.2 million units) in 2.3 ml syringe – Up to 5 inj available on a PSO.....	315.00	10	✓	<u>Bicillin LA</u>
BENZYL PENICILLIN SODIUM (PENICILLIN G)				
Inj 600 mg (1 million units) vial – Up to 5 inj available on a PSO.....	10.35	10	✓	<u>Sandoz</u>

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
FLUCLOXACILLIN				
Cap 250 mg – Up to 30 cap available on a PSO	18.70	250	✓	Staphlex
Cap 500 mg	62.90	500	✓	Staphlex
Grans for oral liq 25 mg per ml	2.29	100 ml	✓	AFT
a) Up to 200 ml available on a PSO				
b) Wastage claimable – see rule 3.3.2 on page 13				
Grans for oral liq 50 mg per ml	3.08	100 ml	✓	AFT
a) Up to 200 ml available on a PSO				
b) Wastage claimable – see rule 3.3.2 on page 13				
Inj 250 mg vial	8.80	10	✓	Flucloxin
Inj 500 mg vial	9.20	10	✓	Flucloxin
Inj 1 g vial – Up to 10 inj available on a PSO.....	11.60	10	✓	Flucloxin
PHENOXYMETHYLPENICILLIN (PENICILLIN V)				
Cap 250 mg – Up to 30 cap available on a PSO	2.88	50	✓	Cilicaine VK
Cap 500 mg	4.73	50	✓	Cilicaine VK
a) Up to 20 cap available on a PSO				
b) Up to 2 x the maximum PSO quantity for RFPP – see rule 5.2.6 on page 17				
Grans for oral liq 125 mg per 5 ml	1.48	100 ml	✓	AFT
a) Up to 200 ml available on a PSO				
b) Wastage claimable – see rule 3.3.2 on page 13				
Grans for oral liq 250 mg per 5 ml	1.58	100 ml	✓	AFT
a) Up to 300 ml available on a PSO				
b) Up to 2 x the maximum PSO quantity for RFPP – see rule 5.2.6 on page 17				
c) Wastage claimable – see rule 3.3.2 on page 13				
PROCAINE PENICILLIN				
Inj 1.5 g in 3.4 ml syringe – Up to 5 inj available on a PSO.....	123.50	5	✓	Cilicaine
Tetracyclines				
DOXYCYCLINE				
* Tab 50 mg – Up to 30 tab available on a PSO.....	2.90 (6.00)	30		Doxy-50
* Tab 100 mg – Up to 30 tab available on a PSO.....	6.75	250	✓	Doxine
MINOCYCLINE HYDROCHLORIDE				
* Tab 50 mg – Additional subsidy by Special Authority see SA1355 below – Retail pharmacy	5.79 (12.05)	60		Mino-tabs
* Cap 100 mg	19.32 (52.04)	100		Minomycin
►SA1355 Special Authority for Manufacturers Price				
Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has rosacea.				
TETRACYCLINE – Special Authority see SA1332 below – Retail pharmacy				
Cap 500 mg	46.00	30	✓	Tetracyclin Wolff §29
►SA1332 Special Authority for Subsidy				
Initial application from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:				
Both:				
1 For the eradication of helicobacter pylori following unsuccessful treatment with appropriate first-line therapy; and				
2 For use only in combination with bismuth as part of a quadruple therapy regimen.				

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

For topical antibiotics, refer to DERMATOLOGICALS, page 69

CIPROFLOXACIN

Recommended for patients with any of the following:

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

Tab 250 mg – Up to 5 tab available on a PSO.....	1.75	28	✓ Cipflox
Tab 500 mg – Up to 5 tab available on a PSO.....	2.00	28	✓ Cipflox
Tab 750 mg	3.75	28	✓ Cipflox

CLINDAMYCIN

Cap hydrochloride 150 mg – Maximum of 4 cap per prescription; can be waived by endorsement - Retail pharmacy -

Specialist	4.10	16	✓ Clindamycin ABM
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Inj phosphate 150 mg per ml, 4 ml ampoule – Retail pharmacy-Specialist

65.00	10	✓ Dalacin C
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CO-TRIMOXAZOLE

* Tab trimethoprim 80 mg and sulphamethoxazole 400 mg –

Up to 30 tab available on a PSO	22.90	500	✓ Trisul
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* Oral liq trimethoprim 40 mg and sulphamethoxazole 200 mg

per 5 ml – Up to 200 ml available on a PSO.....	2.15	100 ml	✓ Deprim
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COLISTIN SULPHOMETHATE – Retail pharmacy-Specialist – Subsidy by endorsement

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

Inj 150 mg	65.00	1	✓ Colistin-Link
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FUSIDIC ACID

Tab 250 mg – Retail pharmacy-Specialist

34.50	12	✓ Fucidin
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Prescriptions must be written by, or on the recommendation of, an infectious disease physician or a clinical microbiologist

GENTAMICIN SULPHATE

Inj 10 mg per ml, 1 ml – Subsidy by endorsement

8.56	5	✓ Hospira
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Only if prescribed for a dialysis or cystic fibrosis patient or complicated urinary tract infection and the prescription is endorsed accordingly.

Inj 10 mg per ml, 2 ml – Subsidy by endorsement

175.10	25	✓ APP
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Pharmaceuticals S29

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

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

6.00	10	✓ Pfizer
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Only if prescribed for a dialysis or cystic fibrosis patient or complicated urinary tract infection and the prescription is endorsed accordingly.

MOXIFLOXACIN – Special Authority see SA1358 on the next page – Retail pharmacy

No patient co-payment payable

Tab 400 mg	52.00	5	✓ Avelox
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‡ safety cap

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

▲Three months supply may be dispensed at one time

if endorsed "certified exemption" by the prescriber or pharmacist.

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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►SA1358 Special Authority for Subsidy

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

Either:

- 1 Both:
 - 1.1 Active tuberculosis*; and
 - 1.2 Any of the following:
 - 1.2.1 Documented resistance to one or more first-line medications; or
 - 1.2.2 Suspected resistance to one or more first-line medications (tuberculosis assumed to be contracted in an area with known resistance), as part of regimen containing other second-line agents; or
 - 1.2.3 Impaired visual acuity (considered to preclude ethambutol use); or
 - 1.2.4 Significant pre-existing liver disease or hepatotoxicity from tuberculosis medications; or
 - 1.2.5 Significant documented intolerance and/or side effects following a reasonable trial of first-line medications; or
- 2 Mycobacterium avium-intracellulare complex not responding to other therapy or where such therapy is contraindicated.*.

Note: Indications marked with * are Unapproved Indications (refer to Interpretations and Definitions).

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) from any relevant practitioner. 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
- 2 Has tried and failed to clear infection using azithromycin; 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 (refer to Interpretations and Definitions).

PAROMOMYCIN – Special Authority see SA1324 below – Retail pharmacy

Cap 250 mg	126.00	16	✓ Humatin ^{\$29}
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►SA1324 Special Authority for Subsidy

Initial application only from an infectious disease specialist or clinical microbiologist. Approvals valid for 1 month where the patient has confirmed cryptosporidium infection.

Renewal only from an infectious disease specialist or clinical microbiologist. Approvals valid for 1 month where the patient has confirmed cryptosporidium infection.

PYRIMETHAMINE – Special Authority see SA1328 below – Retail pharmacy

Tab 25 mg	26.14	30	✓ Daraprim ^{\$29}
	36.95	50	✓ Daraprim ^{\$29}

►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.

SULFADIAZINE SODIUM – Special Authority see SA1331 on the next page – Retail pharmacy

Tab 500 mg	288.00	56	✓ Wockhardt ^{\$29}
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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

►SA1331 Special Authority for Subsidy

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

Any of the following:

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

TOBRAMYCIN

Inj 40 mg per ml, 2 ml vial – Subsidy by endorsement 15.00 5 ✓ **DBL Tobramycin**
✓ **Tobramycin Mylan**

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

b) Tobramycin Mylan to be Sole Supply on 1 May 2017

Solution for inhalation 60 mg per ml, 5 ml – Subsidy by endorsement 2,200.00 56 dose ✓ **TOBI**

a) Wastage claimable – see rule 3.3.2 on page 13

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

(DBL Tobramycin Inj 40 mg per ml, 2 ml vial to be delisted 1 May 2017)

TRIMETHOPRIM

* Tab 300 mg – Up to 30 tab available on a PSO 15.00 50 ✓ **TMP**

VANCOMYCIN – Subsidy by endorsement

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

Inj 500 mg 2.64 1 ✓ **Mylan**

Antifungals

a) For topical antifungals refer to DERMATOLOGICALS, page 69

b) For topical antifungals refer to GENITO URINARY, page 82

FLUCONAZOLE

Cap 50 mg – Retail pharmacy-Specialist 3.49 28 ✓ **Ozole**

Cap 150 mg – Subsidy by endorsement 0.71 1 ✓ **Ozole**

a) Maximum of 1 cap per prescription; can be waived by endorsement - Retail pharmacy - Specialist

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

Cap 200 mg – Retail pharmacy-Specialist 9.69 28 ✓ **Ozole**

Powder for oral suspension 10 mg per ml – Special Authority
see SA1359 below – Retail pharmacy 34.56 35 ml ✓ **Diflucan S29**
98.50 ✓ **Diflucan**

Wastage claimable – see rule 3.3.2 on page 13

►SA1359 Special Authority for Subsidy

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

Both:

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

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

All of the following:

continued...

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
continued...				
<ol style="list-style-type: none"> 1 Patient is immunocompromised; and 2 Patient is at moderate to high risk of invasive fungal infection; and 3 Patient is unable to swallow capsules. 				
Renewal — (Systemic candidiasis) from any relevant practitioner. Approvals valid for 6 weeks for applications meeting the following criteria:				
Both:				
<ol style="list-style-type: none"> 1 Patient requires prophylaxis for, or treatment of systemic candidiasis; and 2 Patient is unable to swallow capsules. 				
Renewal — (Immunocompromised) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:				
All of the following:				
<ol style="list-style-type: none"> 1 Patient remains immunocompromised; and 2 Patient remains at moderate to high risk of invasive fungal infection; and 3 Patient is unable to swallow capsules. 				
ITRACONAZOLE				
Cap 100 mg – Subsidy by endorsement	2.79	15	✓	Itrazole
Funded for tinea vesicolor where topical treatment has not been successful and diagnosis has been confirmed by mycology, or for tinea unguium where terbinafine has not been successful in eradication or the patient is intolerant to terbinafine and diagnosis has been confirmed by mycology and the prescription is endorsed accordingly. Can be waived by endorsement - Retail pharmacy - Specialist Specialist must be an infectious disease physician, clinical microbiologist, clinical immunologist or dermatologist.				
Oral liq 10 mg per ml – Special Authority see SA1322 below				
– Retail pharmacy	141.80	150 ml OP	✓	Sporanox
►SA1322 Special Authority for Subsidy				
Initial application only from an infectious disease specialist, clinical microbiologist, clinical immunologist or any relevant practitioner on the recommendation of a infectious disease physician, clinical microbiologist or clinical immunologist. Approvals valid for 6 months where the patient has a congenital immune deficiency.				
Renewal from any relevant practitioner. Approvals valid for 6 months where the treatment remains appropriate and the patient is benefitting from the treatment.				
KETOCONAZOLE				
Tab 200 mg – PCT – Retail pharmacy-Specialist – Subsidy by endorsement.....	CBS	30	✓	Link Healthcare <small>\$29</small>
			✓	Nizoral <small>\$29</small>
Prescriptions must be written by, or on the recommendation of an oncologist				
NYSTATIN				
Tab 500,000 u	14.16 (17.09)	50		Nilstat
Cap 500,000 u	12.81 (15.47)	50		Nilstat
POSACONAZOLE – Special Authority see SA1285 on the next page – Retail pharmacy				
Tab modified-release 100 mg	869.86	24	✓	Noxafil
Oral liq 40 mg per ml	761.13	105 ml OP	✓	Noxafil

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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►SA1285 Special Authority for Subsidy

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

Either:

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

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

Either:

- 1 Patient has acute myeloid leukaemia and is to be treated with high dose remission induction, re-induction or consolidation therapy; or
- 2 Patient has received a stem cell transplant and has graft versus host disease and is on significant immunosuppression* and requires on going posaconazole treatment.

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

TERBINAFINE

* Tab 250 mg – For terbinafine oral liquid formulation refer,
page 224 1.50 14 ✓ Dr Reddy's
Terbinafine

VORICONAZOLE – Special Authority see SA1273 on the next page – Retail pharmacy

Tab 50 mg	130.00	56	✓ <u>Vttack</u>
Tab 200 mg	500.00	56	✓ <u>Vttack</u>
Powder for oral suspension 40 mg per ml – Wastage claimable – see rule 3.3.2 on page 13.....	876.00	70 ml	✓ <u>Vfend</u>

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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►SA1273 Special Authority for Subsidy

Initial application — (invasive fungal infection) only from a haematologist, infectious disease specialist or clinical microbiologist.

Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

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

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

All of the following:

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

Antimalarials

PRIMAQUINE PHOSPHATE – Special Authority see SA1326 below – Retail pharmacy

Tab 7.5 mg	117.00	56	✓ Primacin ^{\$29}
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►SA1326 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.

Antiparasitics

Antiprotozoals

QUININE SULPHATE

* Tab 300 mg	61.91	500	✓ Q 300
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‡ Safety cap for extemporaneously compounded oral liquid preparations.

Antitrichomonal Agents

METRONIDAZOLE

Tab 200 mg – Up to 30 tab available on a PSO.....	10.45	100	✓ Trichazole
Tab 400 mg	18.15	100	✓ Trichazole
Oral liq benzoate 200 mg per 5 ml	25.00	100 ml	✓ Flagyl-S
Suppos 500 mg	24.48	10	✓ Flagyl

ORNIDAZOLE

Tab 500 mg	23.00	10	✓ <u>Arrow-Ornidazole</u>
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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

Antituberculosics and Antileprotics

Note: There is no co-payment charge for all pharmaceuticals listed in the Antituberculosics and Antileprotics group regardless of immigration status.

CLOFAZIMINE – Retail pharmacy-Specialist

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

* Cap 50 mg 442.00 100 ✓ **Lamprene** S29

CYCLOSERINE – Retail pharmacy-Specialist

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

Cap 250 mg 1,294.50 100 ✓ **King** S29

DAPSONE – Retail pharmacy-Specialist

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

Tab 25 mg 95.00 100 ✓ **Dapsone**

Tab 100 mg 110.00 100 ✓ **Dapsone**

ETHAMBUTOL HYDROCHLORIDE – Retail pharmacy-Specialist

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

Tab 100 mg 48.01 56 ✓ **Myambutol** S29

Tab 400 mg 49.34 56 ✓ **Myambutol** S29

ISONIAZID – Retail pharmacy-Specialist

- a) No patient co-payment payable
b) Prescriptions must be written by, or on the recommendation of, an internal medicine physician, paediatrician, clinical microbiologist, dermatologist or public health physician

* Tab 100 mg 20.00 100 ✓ **PSM**

* Tab 100 mg with rifampicin 150 mg 85.54 100 ✓ **Rifinah**

* Tab 150 mg with rifampicin 300 mg 170.60 100 ✓ **Rifinah**

PARA-AMINO SALICYLIC ACID – Retail pharmacy-Specialist

- a) No patient co-payment payable
b) Specialist must be an infectious disease specialist, clinical microbiologist or respiratory specialist.

Grans for oral liq 4 g sachet 280.00 30 ✓ **Paser** S29

PROTIONAMIDE – Retail pharmacy-Specialist

- a) No patient co-payment payable
b) Specialist must be an infectious disease specialist, clinical microbiologist or respiratory specialist.

Tab 250 mg 305.00 100 ✓ **Peteha** S29

PYRAZINAMIDE – Retail pharmacy-Specialist

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

* Tab 500 mg – For pyrazinamide oral liquid formulation refer,
page 224 59.00 100 ✓ **AFT-Pyrazinamide**
✓ **AFT-Pyrazinamide**
S29 S29

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
RIFABUTIN – Retail pharmacy-Specialist			
a) No patient co-payment payable			
b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, respiratory physician or gastroenterologist			
* Cap 150 mg – For rifabutin oral liquid formulation refer, page 224	275.00	30	✓ Mycobutin

RIFAMPICIN – Subsidy by endorsement			
a) No patient co-payment payable			
b) For confirmed recurrent Staphylococcus aureus infection in combination with other effective anti-staphylococcal antimicrobial based on susceptibilities and the prescription is endorsed accordingly; can be waived by endorsement - Retail pharmacy - Specialist. Specialist must be an internal medicine physician, clinical microbiologist, dermatologist, paediatrician, or public health physician.			
* Cap 150 mg	55.75	100	✓ Rifadin
* Cap 300 mg	116.25	100	✓ Rifadin
* Oral liq 100 mg per 5 ml	12.00	60 ml	✓ Rifadin

Antivirals

For eye preparations refer to Eye Preparations, Anti-Infective Preparations, page 216

Hepatitis B Treatment

ADEFOVIR DIPIVOXIL – Special Authority see SA0829 below – Retail pharmacy			
Tab 10 mg	670.00	30	✓ Hepsera

►SA0829 Special Authority for Subsidy

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

All of the following:

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

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

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

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

continued...

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

continued. . .

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

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

In patients with renal insufficiency adefovir dipivoxil dose should be reduced in accordance with the datasheet guidelines.

Adefovir dipivoxil should be avoided in pregnant women and children.

ENTECAVIR – Special Authority see SA1361 below – Retail pharmacy

Tab 0.5 mg	400.00	30	✓ Baraclude
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➡SA1361 Special Authority for Subsidy

Initial application only from a gastroenterologist or infectious disease specialist. Approvals valid without further renewal unless notified 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 nucleoside analogue treatment-naïve; and
- 3 Entecavir dose 0.5 mg/day; and
- 4 Either:
 - 4.1 ALT greater than upper limit of normal; or
 - 4.2 Bridging fibrosis (Metavir stage 3 or greater or moderate fibrosis) or cirrhosis on liver histology; and
- 5 Either:
 - 5.1 HBeAg positive; or
 - 5.2 patient has $\geq 2,000$ IU HBV DNA units per ml and fibrosis (Metavir stage 2 or greater) on liver histology; and
- 6 No continuing alcohol abuse or intravenous drug use; and
- 7 Not co-infected with HCV, HIV or HDV; and
- 8 Neither ALT nor AST greater than 10 times upper limit of normal; and
- 9 No history of hypersensitivity to entecavir; and
- 10 No previous documented lamivudine resistance (either clinical or genotypic).

Notes:

- Entecavir should be continued for 6 months following documentation of complete HBeAg seroconversion (defined as loss of HBeAg plus appearance of anti-HBe plus loss of serum HBV DNA) for patients who were HBeAg positive prior to commencing this agent. This period of consolidation therapy should be extended to 12 months in patients with advanced fibrosis (Metavir Stage F3 or F4).
- Entecavir should be taken on an empty stomach to improve absorption.

LAMIVUDINE – Special Authority see SA1360 below – Retail pharmacy

Tab 100 mg	6.00	28	✓ Zeffix
Oral liq 5 mg per ml	270.00	240 ml	✓ Zeffix

➡SA1360 Special Authority for Subsidy

Initial application only from a gastroenterologist, infectious disease specialist, paediatrician, general physician or medical practitioner on the recommendation of a gastroenterologist, infectious disease specialist, paediatrician or general physician. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 HBV DNA positive cirrhosis prior to liver transplantation; or
- 2 HBsAg positive and have had a liver, kidney, heart, lung or bone marrow transplant; or
- 3 Hepatitis B virus naïve patient who has received a liver transplant from an anti-HBc (Hepatitis B core antibody) positive donor; or
- 4 Hepatitis B surface antigen (HbsAg) positive patient who is receiving chemotherapy for a malignancy, or high dose steroids (at least 20mg/day for at least 7 days), or who has received such treatment within the previous two months; or
- 5 Hepatitis B surface antigen positive patient who is receiving anti tumour necrosis factor treatment; or

continued. . .

‡ safety cap

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

▲Three months supply may be dispensed at one time

if endorsed "certified exemption" by the prescriber or pharmacist.

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

6 Hepatitis B core antibody (anti-HBc) positive patient who is receiving rituximab plus high dose steroids (e.g. R-CHOP).

Renewal only from a gastroenterologist, infectious disease specialist, paediatrician, general physician or medical practitioner on the recommendation of a gastroenterologist, infectious disease specialist, paediatrician or general physician. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

Renewal for patients who have maintained continuous treatment and response to lamivudine

1 All of the following:

- 1.1 Have maintained continuous treatment with lamivudine; and
- 1.2 Most recent test result shows continuing biochemical response (normal ALT); and
- 1.3 HBV DNA <100,000 copies per ml by quantitative PCR at a reference laboratory; or

Renewal when given in combination with adefovir dipivoxil for patients with cirrhosis and resistance to lamivudine

2 All of the following:

- 2.1 Lamivudine to be used in combination with adefovir dipivoxil; and
- 2.2 Patient is cirrhotic; and
Documented resistance to lamivudine, defined as:
- 2.3 Patient has raised serum ALT ($> 1 \times$ ULN); and
- 2.4 Patient has HBV DNA greater than 100,000 copies per mL, or viral load = 10 fold over nadir; and
- 2.5 Detection of M204I or M204V mutation; or

Renewal when given in combination with adefovir dipivoxil for patients with resistance to adefovir dipivoxil

3 All of the following:

- 3.1 Lamivudine to be used in combination with adefovir dipivoxil; and
Documented resistance to adefovir, defined as:
- 3.2 Patient has raised serum ALT ($> 1 \times$ ULN); and
- 3.3 Patient has HBV DNA greater than 100,000 copies per mL, or viral load = 10 fold over nadir; and
- 3.4 Detection of N236T or A181T/V mutation.

Herpesvirus Treatments

ACICLOVIR

* Tab dispersible 200 mg	1.60	25	✓ <u>Lovir</u>
* Tab dispersible 400 mg	5.38	56	✓ <u>Lovir</u>
* Tab dispersible 800 mg	5.98	35	✓ <u>Lovir</u>

VALACICLOVIR

Tab 500 mg	6.42	30	✓ <u>Vaclarvir</u>
Tab 1,000 mg	12.75	30	✓ <u>Vaclarvir</u>

VALGANCICLOVIR – Special Authority see SA1404 below – Retail pharmacy

Tab 450 mg	1,050.00	60	✓ <u>Valcyte</u>
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►SA1404 Special Authority for Subsidy

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

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

Both:

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

continued...

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

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

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

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

Initial application — (Lung transplant cytomegalovirus prophylaxis) only from a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

- Both:
- 1 Patient has undergone a lung transplant; and
 - 2 Either:
 - 2.1 The donor was cytomegalovirus positive and the patient is cytomegalovirus negative; or
 - 2.2 The recipient is cytomegalovirus positive.

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

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

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

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

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

Hepatitis B/ HIV/AIDS Treatment

TENOFOVIR DISOPROXIL FUMARATE – Subsidy by endorsement; can be waived by Special Authority see SA1362 on the next page

Endorsement for treatment of HIV: Prescription is deemed to be endorsed if tenofovir disoproxil fumarate is co-prescribed with another anti-retroviral subsidised under Special Authority SA1364 and the prescription is annotated accordingly by the Pharmacist or endorsed by the prescriber.

Note: Tenofovir disoproxil fumarate prescribed under endorsement for the treatment of HIV is included in the count of up to 4 subsidised antiretrovirals for the purposes of Special Authority SA1364, page 114

Tab 300 mg	531.00	30	✓ Viread
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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

►SA1362 Special Authority for Waiver of Rule

Initial application — (Chronic Hepatitis B) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 All of the following:
 - 1.1 Patient has confirmed Hepatitis B infection (HBsAg positive for more than 6 months); and
 - 1.2 Patient has had previous lamivudine, adefovir or entecavir therapy; and
 - 1.3 HBV DNA greater than 20,000 IU/mL or increased ≥ 10 fold over nadir; and
 - 1.4 Any of the following:
 - 1.4.1 Lamivudine resistance - detection of M204I/V mutation; or
 - 1.4.2 Adefovir resistance - detection of A181T/V or N236T mutation; or
 - 1.4.3 Entecavir resistance - detection of relevant mutations including I169T, L180M T184S/A/I/L/G/C/M, S202C/G/I, M204V or M250I/V mutation; or
- 2 Patient is either listed or has undergone liver transplantation for HBV; or
- 3 Patient has decompensated cirrhosis with a Mayo score >20 .

Initial application — (Pregnant, Active hepatitis B) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Patient is HBsAg positive and pregnant; and
- 2 HBV DNA $> 20,000$ IU/mL and ALT $> \text{ULN}$.

Renewal — (Confirmed Hepatitis B following funded tenofovir treatment for pregnancy within the previous two years) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 All of the following:
 - 1.1 Patient has confirmed Hepatitis B infection (HBsAg positive for more than 6 months); and
 - 1.2 Patient has had previous lamivudine, adefovir or entecavir therapy; and
 - 1.3 HBV DNA greater than 20,000 IU/mL or increased ≥ 10 fold over nadir; and
 - 1.4 Any of the following:
 - 1.4.1 Lamivudine resistance - detection of M204I/V mutation; or
 - 1.4.2 Adefovir resistance - detection of A181T/V or N236T mutation; or
 - 1.4.3 Entecavir resistance - detection of relevant mutations including I169T, L180M T184S/A/I/L/G/C/M, S202C/G/I, M204V or M250I/V mutation; or
- 2 Patient is either listed or has undergone liver transplantation for HBV.

Renewal — (Subsequent pregnancy or Breastfeeding, Active hepatitis B) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Patient is HBsAg positive and pregnant or breastfeeding; and
- 2 HBV DNA $> 20,000$ IU/mL and ALT $> \text{ULN}$.

Initial application — (Pregnant, prevention of vertical transmission) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient is HBsAg positive and pregnant; and
- 2 HBV DNA > 20 million IU/mL and ALT normal.

Renewal — (Subsequent pregnancy, prevention of vertical transmission) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 6 months for applications meeting the following criteria:

Both:

continued...

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

- 1 Patient is HBsAg positive and pregnant; and
- 2 HBV DNA > 20 million IU/mL and ALT normal.

Notes:

- Tenofovir disoproxil fumarate should be stopped 6 months following HBeAg seroconversion for patients who were HBeAg positive prior to commencing this agent and 6 months following HBsAg seroconversion for patients who were HBeAg negative prior to commencing this agent.
- The recommended dose of Tenofovir disoproxil fumarate for the treatment of all three indications is 300 mg once daily.
- In patients with renal insufficiency (calculated creatinine clearance less than 50ml/min), Tenofovir disoproxil fumarate dose should be reduced in accordance with the approved Medsafe datasheet guidelines.
- Tenofovir disoproxil fumarate is not approved for use in children.

Hepatitis C Treatment

BOCEPREVIR – Special Authority see SA1402 below – Retail pharmacy

Cap 200 mg – Wastage claimable – see rule 3.3.2 on page

13	5,015.00	336	✓ Victrelis
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(Victrelis Cap 200 mg to be delisted 1 April 2017)

►SA1402 | Special Authority for Subsidy

Initial application — (chronic hepatitis C - genotype 1, first-line) 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 not received prior pegylated interferon treatment; and
- 3 Patient has IL-28B genotype CT or TT; and
- 4 Patient is to be treated in combination with pegylated interferon and ribavirin; and
- 5 Patient is hepatitis C protease inhibitor treatment-naïve; and
- 6 Maximum of 44 weeks therapy.

Initial application — (chronic hepatitis C - genotype 1, second-line) 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 received pegylated interferon treatment; and
- 3 Any of the following:
 - 3.1 Patient was a responder relapser; or
 - 3.2 Patient was a partial responder; or
 - 3.3 Patient received pegylated interferon prior to 2004; and
- 4 Patient is to be treated in combination with pegylated interferon and ribavirin; and
- 5 Maximum of 44 weeks therapy.

Notes:

- Due to risk of severe sepsis boceprevir should not be initiated if either Platelet count < 100 x10⁹ /l or Albumin <35 g/l
- The wastage rule applies to boceprevir to allow dispensing to occur more frequently than monthly

LEDIPASVIR WITH SOFOSBUVIR – Special Authority see SA1605 on the next page – [Xpharm]

No patient co-payment payable

Tab 90 mg with sofosbuvir 400 mg	24,363.46	28	✓ Harvoni
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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

►SA1605 Special Authority for Subsidy

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

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

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

Application details may be obtained from PHARMAC's website <http://www.pharmac.govt.nz/hepatitis-c-treatments> or:

The Coordinator, Hepatitis C Treatment Panel

PHARMAC, PO Box 10-254, WELLINGTON Tel: (04) 460 4990,

Email: hepcpanel@pharmac.govt.nz

PARITAPREVR, RITONAVIR AND OMBITASVIR WITH DASABUVIR – [Xpharm]

a) No patient co-payment payable

b) Note – Supply of treatment is via PHARMAC's approved direct distribution supply. Application details for accessing treatment may be obtained from PHARMAC's website <http://www.pharmac.govt.nz/hepatitis-c-treatments>

Tab 75 mg with ritonavir 50 mg, and ombitasvir 12.5 mg (56),

with dasabuvir tab 250 mg (56) 16,500.00 1 OP ✓ Viekira Pak

PARITAPREVR, RITONAVIR AND OMBITASVIR WITH DASABUVIR AND RIBAVIRIN – [Xpharm]

a) No patient co-payment payable

b) Note – Supply of treatment is via PHARMAC's approved direct distribution supply. Application details for accessing treatment may be obtained from PHARMAC's website <http://www.pharmac.govt.nz/hepatitis-c-treatments>

Tab 75 mg with ritonavir 50 mg, and ombitasvir 12.5 mg (56)

with dasabuvir tab 250 mg (56) and ribavirin tab 200 mg

(168) 16,500.00 1 OP ✓ Viekira Pak-RBV

Antiretrovirals

►SA1364 Special Authority for Subsidy

Initial application — (Confirmed HIV) only from a named specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 Confirmed HIV infection; and
- 2 Any of the following:
 - 2.1 Symptomatic patient; or
 - 2.2 Patient aged 12 months and under; or
 - 2.3 Both:
 - 2.3.1 Patient aged 1 to 5 years; and
 - 2.3.2 Any of the following:
 - 2.3.2.1 CD4 counts < 1000 cells/mm³; or
 - 2.3.2.2 CD4 counts < 0.25 × total lymphocyte count; or
 - 2.3.2.3 Viral load counts > 100000 copies per ml; or
 - 2.4 Both:
 - 2.4.1 Patient aged 6 years and over; and
 - 2.4.2 CD4 counts < 500 cells/mm³.

continued...

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

continued...

Notes: Tenofovir disoproxil fumarate prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals.

Subsidies 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 fumarate prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals.

Subsidies for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.

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

Initial application — (post-exposure prophylaxis following non-occupational exposure to HIV) only from a named specialist.

Approvals valid for 4 weeks for applications meeting the following criteria:

Both:

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

Notes: Tenofovir disoproxil fumarate prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals.

Subsidies for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.

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

Both:

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

continued...

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
continued...				
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 fumarate prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals.				
Subsidies 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 SA1364 on page 114 – Retail pharmacy				
Tab 50 mg	63.38	30	✓	<u>Stocrin</u> ^{S29}
Tab 200 mg	190.15	90	✓	<u>Stocrin</u>
Tab 600 mg	63.38	30	✓	<u>Stocrin</u>
Oral liq 30 mg per ml	145.79	180 ml OP	✓	<u>Stocrin</u> ^{S29}
ETRAVIRINE – Special Authority see SA1364 on page 114 – Retail pharmacy				
Tab 200 mg	770.00	60	✓	<u>Intelence</u>
NEVIRAPINE – Special Authority see SA1364 on page 114 – Retail pharmacy				
Tab 200 mg	65.00	60	✓	<u>Nevirapine</u>
				<u>Alphapharm</u>
Oral suspension 10 mg per ml	203.55	240 ml	✓	<u>Viramune</u> Suspension
Nucleosides Reverse Transcriptase Inhibitors				
ABACAVIR SULPHATE – Special Authority see SA1364 on page 114 – Retail pharmacy				
Tab 300 mg	229.00	60	✓	<u>Ziagen</u>
Oral liq 20 mg per ml	256.31	240 ml OP	✓	<u>Ziagen</u>
ABACAVIR SULPHATE WITH LAMIVUDINE – Special Authority see SA1364 on page 114 – Retail pharmacy				
Note: abacavir with lamivudine (combination tablets) counts as two anti-retroviral medications for the purposes of the anti-retroviral Special Authority.				
Tab 600 mg with lamivudine 300 mg	427.29	30	✓	<u>Kivexa</u>
DIDANOSINE [DDI] – Special Authority see SA1364 on page 114 – Retail pharmacy				
Cap 125 mg	115.05	30	✓	<u>Videx EC</u>
Cap 200 mg	184.08	30	✓	<u>Videx EC</u>
Cap 250 mg	230.10	30	✓	<u>Videx EC</u>
Cap 400 mg	368.16	30	✓	<u>Videx EC</u>
<i>(Videx EC Cap 125 mg to be delisted 1 July 2017)</i>				
<i>(Videx EC Cap 200 mg to be delisted 1 July 2017)</i>				
<i>(Videx EC Cap 250 mg to be delisted 1 July 2017)</i>				
<i>(Videx EC Cap 400 mg to be delisted 1 July 2017)</i>				
EFAVIRENZ WITH EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE – Special Authority see SA1364 on page 114 – Retail pharmacy				
Note: Efavirenz with emtricitabine and tenofovir disoproxil fumarate counts as three anti-retroviral medications for the purposes of the anti-retroviral Special Authority				
Tab 600 mg with emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg	1,313.19	30	✓	<u>Atripla</u>

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
EMTRICITABINE – Special Authority see SA1364 on page 114 – Retail pharmacy				
Cap 200 mg	307.20	30	✓	Emtriva
EMTRICITABINE WITH TENOFOVIR DISOPROXIL FUMARATE – Special Authority see SA1364 on page 114 – Retail pharmacy				
Note: Emtricitabine with tenofovir disoproxil fumarate counts as two anti-retroviral medications for the purposes of the anti-retroviral Special Authority				
Tab 200 mg with tenofovir disoproxil fumarate 300 mg	838.20	30	✓	Truvada
LAMIVUDINE – Special Authority see SA1364 on page 114 – Retail pharmacy				
Tab 150 mg	52.50	60	✓	Lamivudine Alphapharm
Oral liq 10 mg per ml	102.50	240 ml OP	✓	3TC
STAVUDINE [D4T] – Special Authority see SA1364 on page 114 – Retail pharmacy				
Cap 40 mg	503.80	60	✓	Zerit
Powder for oral soln 1 mg per ml	100.76	200 ml OP	✓	Zerit ^{S29}
<i>(Zerit Cap 40 mg to be delisted 1 July 2017)</i>				
<i>(Zerit ^{S29} Powder for oral soln 1 mg per ml to be delisted 1 July 2017)</i>				
ZIDOVUDINE [AZT] – Special Authority see SA1364 on page 114 – Retail pharmacy				
Cap 100 mg	152.25	100	✓	Retrovir
Oral liq 10 mg per ml	30.45	200 ml OP	✓	Retrovir
ZIDOVUDINE [AZT] WITH LAMIVUDINE – Special Authority see SA1364 on page 114 – Retail pharmacy				
Note: zidovudine [AZT] with lamivudine (combination tablets) counts as two anti-retroviral medications for the purposes of the anti-retroviral Special Authority.				
Tab 300 mg with lamivudine 150 mg	44.00	60	✓	Alphapharm
Protease Inhibitors				
ATAZANAVIR SULPHATE – Special Authority see SA1364 on page 114 – Retail pharmacy				
Cap 150 mg	568.34	60	✓	Reyataz
Cap 200 mg	757.79	60	✓	Reyataz
DARUNAVIR – Special Authority see SA1364 on page 114 – Retail pharmacy				
Tab 400 mg	837.50	60	✓	Prezista
Tab 600 mg	1,190.00	60	✓	Prezista
INDINAVIR – Special Authority see SA1364 on page 114 – Retail pharmacy				
Cap 200 mg	519.75	360	✓	Crixivan
Cap 400 mg	519.75	180	✓	Crixivan
LOPINAVIR WITH RITONAVIR – Special Authority see SA1364 on page 114 – Retail pharmacy				
Tab 100 mg with ritonavir 25 mg	183.75	60	✓	Kaletra
Tab 200 mg with ritonavir 50 mg	735.00	120	✓	Kaletra
Oral liq 80 mg with ritonavir 20 mg per ml	735.00	300 ml OP	✓	Kaletra
RITONAVIR – Special Authority see SA1364 on page 114 – Retail pharmacy				
Tab 100 mg	43.31	30	✓	Norvir
Oral liq 80 mg per ml	103.98	90 ml OP	✓	Norvir
Strand Transfer Inhibitors				
DOLUTEGRAVIR – Special Authority see SA1364 on page 114 – Retail pharmacy				
Tab 50 mg	1,090.00	30	✓	Tivicay
RALTEGRAVIR POTASSIUM – Special Authority see SA1364 on page 114 – Retail pharmacy				
Tab 400 mg	1,090.00	60	✓	Isentress

‡ safety cap

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

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

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

Antiretrovirals - Additional Therapies

HIV Fusion Inhibitors

ENFUVIRTIDE – Special Authority see SA0845 below – Retail pharmacy

Powder for inj 90 mg per ml × 60	2,380.00	1	✓ Fuzeon
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(Fuzeon Powder for inj 90 mg per ml × 60 to be delisted 1 June 2017)

►SA0845 Special Authority for Subsidy

Initial application only from a named specialist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Confirmed HIV infection; and
- 2 Enfuvirtide to be given in combination with optimized background therapy (including at least 1 other antiretroviral drug that the patient has never previously been exposed to) for treatment failure; and
- 3 Either:
 - 3.1 Patient has evidence of HIV replication, despite ongoing therapy; or
 - 3.2 Patient has treatment-limiting toxicity to previous antiretroviral agents; and
- 4 Previous treatment with 3 different antiretroviral regimens has failed; and
- 5 All of the following:
 - 5.1 Previous treatment with a non-nucleoside reverse transcriptase inhibitor has failed; and
 - 5.2 Previous treatment with a nucleoside reverse transcriptase inhibitor has failed; and
 - 5.3 Previous treatment with a protease inhibitor has failed.

Renewal only from a named specialist. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 Evidence of at least a 10 fold reduction in viral load at 12; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

Immune Modulators

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

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

Patients should be otherwise fit.

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

Criteria for Treatment

a) Diagnosis

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

Exclusion Criteria

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

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

continued...

Dosage

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

Exit Criteria

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

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

- See prescribing guideline on the previous page
 - Prescriptions must be written by, or on the recommendation of, an internal medicine physician or ophthalmologist
- | | | | |
|------------------------------------|-------|---|--------------------|
| Inj 3 m iu prefilled syringe | 31.32 | 1 | ✓ Roferon-A |
|------------------------------------|-------|---|--------------------|

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

- See prescribing guideline on the previous page
 - Prescriptions must be written by, or on the recommendation of, an internal medicine physician or ophthalmologist
- | | | | |
|---|--------|---|-------------------|
| Inj 18 m iu, 1.2 ml multidose pen | 206.71 | 1 | ✓ Intron-A |
| Inj 30 m iu, 1.2 ml multidose pen | 344.52 | 1 | ✓ Intron-A |
| Inj 60 m iu, 1.2 ml multidose pen | 689.04 | 1 | ✓ Intron-A |

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

- See prescribing guideline on the previous page
- | | | | |
|--|----------|------|---|
| Inj 180 mcg prefilled syringe | 900.00 | 4 | ✓ Pegasys |
| Inj 135 mcg prefilled syringe × 4 with ribavirin tab 200 mg ×
168 | 1,975.00 | 1 OP | ✓ Pegasys RBV
Combination Pack |
| Inj 180 mcg prefilled syringe × 4 with ribavirin tab 200 mg ×
112 | 1,159.84 | 1 OP | ✓ Pegasys RBV
Combination Pack |
| Inj 180 mcg prefilled syringe × 4 with ribavirin tab 200 mg ×
168 | 1,290.00 | 1 OP | ✓ Pegasys RBV
Combination Pack |

SA1400 Special Authority for Subsidy

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

Both:

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

Notes:

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

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

All of the following:

- Patient has chronic hepatitis C, genotype 1; and
- Patient has had previous treatment with pegylated interferon and ribavirin; and

continued...

‡ safety cap

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

▲Three months supply may be dispensed at one time

if endorsed "certified exemption" by the prescriber or pharmacist.

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

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

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

All of the following:

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

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

Both:

- 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-naïve; 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 ≥ 2,000 units/ml and significant fibrosis (≥ Metavir Stage F2 or moderate fibrosis); and
- 6 Compensated liver disease; and
- 7 No continuing alcohol abuse or intravenous drug use; and
- 8 Not co-infected with HCV, HIV or HDV; and
- 9 Neither ALT nor AST > 10 times upper limit of normal; and
- 10 No history of hypersensitivity or contraindications to pegylated interferon; and
- 11 Maximum of 48 weeks therapy.

Notes:

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

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

HEXAMINE HIPPURATE

* Tab 1 g	18.40	100	
	(38.10)		Hiprex

NITROFURANTOIN

* Tab 50 mg – For nitrofurantoin oral liquid formulation refer, page 224	22.20	100	✓ Nifuran
* Tab 100 mg	37.50	100	✓ Nifuran

NORFLOXACIN

Tab 400 mg – Subsidy by endorsement	13.50	100	✓ <u>Arrow-Norfloxacin</u>
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Only if prescribed for a patient with an uncomplicated urinary tract infection that is unresponsive to a first line agent or with proven resistance to first line agents and the prescription is endorsed accordingly.

MUSCULOSKELETAL SYSTEM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Anticholinesterases				
NEOSTIGMINE METILSULFATE				
Inj 2.5 mg per ml, 1 ml ampoule	98.00	50	✓	<u>AstraZeneca</u>
PYRIDOSTIGMINE BROMIDE				
▲ Tab 60 mg	42.79	100	✓	<u>Mestinon</u>
Non-Steroidal Anti-Inflammatory Drugs				
DICLOFENAC SODIUM				
* Tab EC 25 mg	1.30	50	✓	<u>Diclofenac Sandoz</u>
* Tab 50 mg dispersible	1.50	20	✓	<u>Voltaren D</u>
* Tab EC 50 mg	1.00	50	✓	<u>Diclofenac Sandoz</u>
* Tab long-acting 75 mg	15.20	500	✓	<u>Apo-Diclo SR</u>
* Tab long-acting 100 mg	26.20	500	✓	<u>Apo-Diclo SR</u>
* Inj 25 mg per ml, 3 ml ampoule – Up to 5 inj available on a PSO	13.20	5	✓	<u>Voltaren</u>
* Suppos 12.5 mg	2.04	10	✓	<u>Voltaren</u>
* Suppos 25 mg	2.44	10	✓	<u>Voltaren</u>
* Suppos 50 mg – Up to 10 supp available on a PSO	4.22	10	✓	<u>Voltaren</u>
* Suppos 100 mg	7.00	10	✓	<u>Voltaren</u>
IBUPROFEN				
* Tab 200 mg	9.45	1,000	✓	<u>Ibugesic</u>
* Tab long-acting 800 mg	7.99	30	✓	<u>Brufen SR</u>
*‡ Oral liq 20 mg per ml	1.89	200 ml	✓	<u>Fenpaed</u>
KETOPROFEN				
* Cap long-acting 200 mg	12.07	28	✓	<u>Oruvail SR</u>
MEFENAMIC ACID				
* Cap 250 mg	1.25 (9.16) 0.50 (5.60)	50 20		Ponstan Ponstan
NAPROXEN				
* Tab 250 mg	18.06	500	✓	<u>Noflam 250</u>
* Tab 500 mg	18.91	250	✓	<u>Noflam 500</u>
* Tab long-acting 750 mg	18.00	90	✓	<u>Naprosyn SR 750</u>
* Tab long-acting 1 g	21.00	90	✓	<u>Naprosyn SR 1000</u>
SULINDAC				
* Tab 100 mg	8.55	50	✓	<u>Aclin</u>
* Tab 200 mg	15.10	50	✓	<u>Aclin</u>
TENOXICAM				
* Tab 20 mg	10.95	100	✓	<u>Tilcotil</u>
* Inj 20 mg vial	9.95	1	✓	<u>AFT</u>
NSAIDs Other				
MELOXICAM – Special Authority see SA1034 on the next page – Retail pharmacy				
* Tab 7.5 mg	11.50	30	✓	<u>Arrow-Meloxicam</u>

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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►SA1034 Special Authority for Subsidy

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

All of the following:

- 1 The patient has moderate to severe haemophilia with less than or equal to 5% of normal circulating functional clotting factor; and
- 2 The patient has haemophilic arthropathy; and
- 3 Pain and inflammation associated with haemophilic arthropathy is inadequately controlled by alternative funded treatment options, or alternative funded treatment options are contraindicated.

Topical Products for Joint and Muscular Pain

CAPSAICIN

Crm 0.025% – Special Authority see SA1289 below – Retail

pharmacy	6.95	25 g OP	✓ Zostrix
	9.95	45 g OP	✓ Zostrix

►SA1289 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has osteoarthritis that is not responsive to paracetamol and oral non-steroidal anti-inflammatories are contraindicated.

Antirheumatoid Agents

AURANOFIN

Tab 3 mg	68.99	60	✓ Ridaura s29 s29
	114.98	100	✓ Ridaura s29 s29

HYDROXYCHLOROQUINE

* Tab 200 mg	10.50	100	✓ <u>Plaquenil</u>
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LEFLUNOMIDE

Tab 10 mg	55.00	30	✓ Arava
Tab 20 mg	76.00	30	✓ Arava

PENICILLAMINE

Tab 125 mg	67.23	100	✓ D-Penamine
Tab 250 mg	110.12	100	✓ D-Penamine

SODIUM AUROTHIOMALATE

Inj 10 mg in 0.5 ml ampoule	76.87	10	✓ Myocrisin
Inj 20 mg in 0.5 ml ampoule	113.17	10	✓ Myocrisin
Inj 50 mg in 0.5 ml ampoule	217.23	10	✓ Myocrisin

Drugs Affecting Bone Metabolism

Alendronate for Osteoporosis

►SA1039 Special Authority for Subsidy

Initial application — (Underlying cause - Osteoporosis) 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) ≥ 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score ≤ -2.5) (see Note); or

continued...

‡ safety cap

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

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

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

continued...

- 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
- History of two significant osteoporotic fractures demonstrated radiologically; or
- Documented T-Score ≤ -3.0 (see Note); or
- A 10-year risk of hip fracture $\geq 3\%$, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or
- Patient has had a Special Authority approval for zoledronic acid (Underlying cause - Osteoporosis) or raloxifene.

Initial application — (Underlying cause - glucocorticosteroid therapy) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- The patient is receiving systemic glucocorticosteroid therapy (≥ 5 mg per day prednisone equivalents) and has already received or is expected to receive therapy for at least three months; and
- Any of the following:
 - The patient has documented BMD ≥ 1.5 standard deviations below the mean normal value in young adults (i.e. T-Score ≤ -1.5) (see Note); or
 - The patient has a history of one significant osteoporotic fracture demonstrated radiologically; or
 - The patient has had a Special Authority approval for zoledronic acid (Underlying cause - glucocorticosteroid therapy) or raloxifene.

Renewal — (Underlying cause was, and remains, glucocorticosteroid therapy) from any relevant practitioner. Approvals valid for 1 year where the patient is continuing systemic glucocorticosteroid therapy (≥ 5 mg per day prednisone equivalents).

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

Any of the following:

- History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) ≥ 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score ≤ -2.5) (see Note); or
- 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
- History of two significant osteoporotic fractures demonstrated radiologically; or
- Documented T-Score ≤ -3.0 (see Note); or
- A 10-year risk of hip fracture $\geq 3\%$, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or
- Patient has had a Special Authority approval for zoledronic acid (Underlying cause was glucocorticosteroid therapy but patient now meets the 'Underlying cause - Osteoporosis' criteria) or raloxifene.

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.
- Evidence suggests patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score ≤ -2.5 and, therefore, do not require BMD measurement for treatment with bisphosphonates.
- 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.
- In line with the Australian guidelines for funding alendronate, 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.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ALENDRONATE SODIUM – Special Authority see SA1039 on page 123 – Retail pharmacy				
* Tab 70 mg	12.90	4	✓	Fosamax
ALENDRONATE SODIUM WITH COLECALCIFEROL – Special Authority see SA1039 on page 123 – Retail pharmacy				
* Tab 70 mg with colecalciferol 5,600 iu	12.90	4	✓	Fosamax Plus

Alendronate for Paget's Disease

►SA0949 | Special Authority for Subsidy

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

Both:

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

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

ALENDRONATE SODIUM – Special Authority see SA0949 above – Retail pharmacy

* Tab 40 mg	133.00	30	✓	Fosamax
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Other Treatments

ETIDRONATE DISODIUM – See prescribing guideline below

* Tab 200 mg	13.50	100	✓	Arrow-Etidronate
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Prescribing Guidelines

Etidronate for osteoporosis should be prescribed for 14 days (400 mg in the morning) and repeated every three months. It should not be taken at the same time of the day as any calcium supplementation (minimum dose – 500 mg per day of elemental calcium). Etidronate should be taken at least 2 hours before or after any food or fluid, except water.

PAMIDRONATE DISODIUM

Inj 3 mg per ml, 10 ml vial	6.80	1	✓	Pamisol
Inj 6 mg per ml, 10 ml vial	13.20	1	✓	Pamisol
Inj 9 mg per ml, 10 ml vial	19.20	1	✓	Pamisol

RALOXIFENE HYDROCHLORIDE – Special Authority see SA1138 below – Retail pharmacy

* Tab 60 mg	53.76	28	✓	Evista
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►SA1138 | 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) ≥ 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score ≤ -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 ≤ -3.0 (see Notes); or
- 5 A 10-year risk of hip fracture $\geq 3\%$, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Notes); or

continued...

‡ safety cap

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

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

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

- 6 Patient has had a prior Special Authority approval for zoledronic acid (Underlying cause - Osteoporosis) or alendronate (Underlying cause - Osteoporosis).

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.
- 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 ≤ -2.5 and, therefore, do not require BMD measurement for raloxifene funding.
- 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.
- 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 mg3.80 4 ✓ **Risedronate Sandoz**
Risedronate Sandoz to be Sole Supply on 1 April 2017

TERIPARATIDE – Special Authority see SA1139 below – Retail pharmacy

Inj 250 mcg per ml, 2.4 ml490.00 1 ✓ **Forteo**

►SA1139 Special Authority for Subsidy

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

All of the following:

- The patient has severe, established osteoporosis; and
- The patient has a documented T-score less than or equal to -3.0 (see Notes); and
- The patient has had two or more fractures due to minimal trauma; and
- 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:

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

ZOLEDRONIC ACID

Inj 0.05 mg per ml, 100 ml, vial – Special Authority see
SA1187 on the next page – Retail pharmacy600.00 100 ml OP ✓ **Aclasta**

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

►SA1187 Special Authority for Subsidy

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

All of the following:

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

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

Both:

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

Initial application — (Underlying cause - glucocorticosteroid therapy) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

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

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

Both:

- 1 Any of the following:
 - 1.1 The patient has relapsed (based on increases in serum alkaline phosphatase); or
 - 1.2 The patient's serum alkaline phosphatase has not normalised following previous treatment with zoledronic acid; or
 - 1.3 Symptomatic disease (prescriber determined); and

continued...

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

- The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period.

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

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

Both:

- The patient is continuing systemic glucocorticosteroid therapy (≥ 5 mg per day prednisone equivalents); and
- The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period.

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

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

Both:

- Any of the following:
 - History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) ≥ 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score ≤ -2.5) (see Note); or
 - 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
 - History of two significant osteoporotic fractures demonstrated radiologically; or
 - Documented T-Score ≤ -3.0 (see Note); or
 - A 10-year risk of hip fracture $\geq 3\%$, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or
 - Patient has had a Special Authority approval for alendronate (Underlying cause was glucocorticosteroid therapy but patient now meets the 'Underlying cause - Osteoporosis' criteria) or raloxifene; and
- The patient will not be prescribed more than 5 mg of zoledronic acid in a 12-month period.

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.
- 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 ≤ -2.5 and, therefore, do not require BMD measurement for treatment with bisphosphonates.
- 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.
- A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Hyperuricaemia and Antigout

ALLOPURINOL

* Tab 100 mg	15.11	1,000	✓ Allopurinol-Apotex ✓ Apo-Allopurinol
* Tab 300 mg – For allopurinol oral liquid formulation refer, page 224	15.91	500	✓ Allopurinol-Apotex ✓ Apo-Allopurinol

(Apo-Allopurinol Tab 100 mg to be delisted 1 June 2017)

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

(Apo-Allopurinol Tab 300 mg to be delisted 1 June 2017)

BENZBROMARONE – Special Authority see SA1537 below – Retail pharmacy

Tab 100 mg	45.00	100	✓ Benzbromaron AL 100 S29
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▶SA1537 Special Authority for Subsidy

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

All of the following:

- 1 Patient has been diagnosed with gout; and
- 2 Any of the following:
 - 2.1 The patient has a serum urate level greater than 0.36 mmol/l despite treatment with allopurinol at doses of at least 600 mg/day and addition of probenecid at doses of up to 2 g per day or maximum tolerated dose; or
 - 2.2 The patient has experienced intolerable side effects from allopurinol such that treatment discontinuation is required and serum urate remains greater than 0.36 mmol/l despite use of probenecid at doses of up to 2 g per day or maximum tolerated dose; or
 - 2.3 Both:
 - 2.3.1 The patient has renal impairment such that probenecid is contraindicated or likely to be ineffective and serum urate remains greater than 0.36 mmol/l despite optimal treatment with allopurinol (see Notes); and
 - 2.3.2 The patient has a rate of creatinine clearance greater than or equal to 20 ml/min; or
 - 2.4 All of the following:
 - 2.4.1 The patient is taking azathioprine and requires urate-lowering therapy; and
 - 2.4.2 Allopurinol is contraindicated; and
 - 2.4.3 Appropriate doses of probenecid are ineffective or probenecid cannot be used due to reduced renal function; and
- 3 The patient is receiving monthly liver function tests.

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

- Both:
- 1 The treatment remains appropriate and the patient is benefitting from the treatment; and
 - 2 There is no evidence of liver toxicity and patient is continuing to receive regular (at least every three months) liver function tests.

Notes: Benzbromarone has been associated with potentially fatal hepatotoxicity.

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

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

COLCHICINE

* Tab 500 mcg	10.08	100	✓ Colgout
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FEBUXOSTAT – Special Authority see SA1538 on the next page – Retail pharmacy

Tab 80 mg	39.50	28	✓ Adenuric
Tab 120 mg	39.50	28	✓ Adenuric

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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SA1538 Special Authority for Subsidy

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

Both:

- 1 Patient has been diagnosed with gout; and
- 2 Any of the following:
 - 2.1 The patient has a serum urate level greater than 0.36 mmol/l despite treatment with allopurinol at doses of at least 600 mg/day and addition of probenecid at doses of up to 2 g per day or maximum tolerated dose; or
 - 2.2 The patient has experienced intolerable side effects from allopurinol such that treatment discontinuation is required and serum urate remains greater than 0.36 mmol/l despite use of probenecid at doses of up to 2 g per day or maximum tolerated dose; or
 - 2.3 The patient has renal impairment such that probenecid is contraindicated or likely to be ineffective and serum urate remains greater than 0.36 mmol/l despite optimal treatment with allopurinol (see Note).

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

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

PROBENECID

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

BACLOFEN

* Tab 10 mg – For baclofen oral liquid formulation refer, page 224	3.85	100	✓ Pacifen
Inj 0.05 mg per ml, 1 ml ampoule – Subsidy by endorsement.....	11.55	1	✓ Lioresal Intrathecal
Subsidised only for use in a programmable pump in patients where oral antispastic agents have been ineffective or have caused intolerable side effects and the prescription is endorsed accordingly.			
Inj 2 mg per ml, 5 ml ampoule – Subsidy by endorsement.....	209.29	1	✓ Lioresal Intrathecal
Subsidised only for use in a programmable pump in patients where oral antispastic agents have been ineffective or have caused intolerable side effects and the prescription is endorsed accordingly.			

DANTROLENE

Cap 25 mg	65.00	100	✓ Dantrium
Cap 50 mg	77.00	100	✓ Dantrium S29 ^{S29}
			✓ Dantrium

ORPHENADRINE CITRATE

Tab 100 mg	18.54	100	✓ Norflex
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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

Agents for Parkinsonism and Related Disorders

Dopamine Agonists and Related Agents

AMANTADINE HYDROCHLORIDE		
▲ Cap 100 mg	38.24	60 ✓ <u>Symmetrel</u>
APOMORPHINE HYDROCHLORIDE		
▲ Inj 10 mg per ml, 2 ml ampoule	119.00	5 ✓ <u>Movapo</u>
BROMOCRIPTINE MESYLATE		
* Tab 2.5 mg	32.08	100 ✓ <u>Apo-Bromocriptine</u>
ENTACAPONE		
▲ Tab 200 mg	28.00	100 ✓ <u>Entapone</u>
LEVODOPA WITH BENSERAZIDE		
* Tab dispersible 50 mg with benserazide 12.5 mg	10.00	100 ✓ <u>Madopar Rapid</u>
* Cap 50 mg with benserazide 12.5 mg	8.00	100 ✓ <u>Madopar 62.5</u>
* Cap 100 mg with benserazide 25 mg	12.50	100 ✓ <u>Madopar 125</u>
* Cap long-acting 100 mg with benserazide 25 mg	17.00	100 ✓ <u>Madopar HBS</u>
* Cap 200 mg with benserazide 50 mg	25.00	100 ✓ <u>Madopar 250</u>
LEVODOPA WITH CARBIDOPA		
* Tab 100 mg with carbidopa 25 mg – For levodopa with carbidopa oral liquid formulation refer, page 224	20.00	100 ✓ <u>Kinson</u> ✓ <u>Sinemet</u>
* Tab long-acting 200 mg with carbidopa 50 mg	47.50	100 ✓ <u>Sinemet CR</u>
* Tab 250 mg with carbidopa 25 mg	40.00	100 ✓ <u>Sinemet</u>
PRAMIPEXOLE HYDROCHLORIDE		
▲ Tab 0.25 mg	7.20	100 ✓ <u>Ramipex</u>
▲ Tab 1 mg	24.39	100 ✓ <u>Ramipex</u>
ROPINIROLE HYDROCHLORIDE		
▲ Tab 0.25 mg	2.78	100 ✓ <u>Apo-Ropinirole</u>
▲ Tab 1 mg	5.00	100 ✓ <u>Apo-Ropinirole</u>
▲ Tab 2 mg	7.72	100 ✓ <u>Apo-Ropinirole</u>
▲ Tab 5 mg	16.51	100 ✓ <u>Apo-Ropinirole</u>
SELEGILINE HYDROCHLORIDE		
* Tab 5 mg	22.00	100 ✓ <u>Apo-Selegiline</u> S29 S29
TOLCAPONE		
▲ Tab 100 mg	132.50	100 ✓ <u>Tasmar</u>

Anticholinergics

BENZTROPINE MESYLATE		
Tab 2 mg	7.99	60 ✓ <u>Benztrop</u>
Inj 1 mg per ml, 2 ml	95.00	5 ✓ <u>Cogentin</u>
	190.00	10 ✓ <u>Omega</u> S29
a) Up to 10 inj available on a PSO		
b) Only on a PSO		
PROCYCLIDINE HYDROCHLORIDE		
Tab 5 mg	7.40	100 ✓ <u>Kemadrin</u>

‡ safety cap

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

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

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Agents for Essential Tremor, Chorea and Related Disorders

RILUZOLE – Special Authority see SA1403 below – Retail pharmacy

Wastage claimable – see rule 3.3.2 on page 13

Tab 50 mg	400.00	56	✓ Rilutek
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►SA1403 Special Authority for Subsidy

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

All of the following:

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

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

All of the following:

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

TETRABENAZINE

Tab 25 mg	91.10	112	✓ Motetis
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Anaesthetics

Local

LIDOCAINE [LIGNOCAINE]

Gel 2%, 10 ml urethral syringe – Subsidy by endorsement.....	43.26	10	✓ Pfizer
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a) Up to 5 each available on a PSO

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

LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE

Oral (viscous) soln 2%	55.00	200 ml	✓ <u>Xylocaine Viscous</u>
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Inj 1%, 5 ml ampoule – Up to 25 inj available on a PSO	8.75	25	✓ <u>Lidocaine-Claris</u>
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17.50

50

(35.00)

Xylocaine

Inj 2%, 5 ml ampoule – Up to 5 inj available on a PSO	6.90	25	✓ <u>Lidocaine-Claris</u>
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Inj 1%, 20 ml ampoule – Up to 5 inj available on a PSO	2.40	1	✓ <u>Lidocaine-Claris</u>
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12.00

5

(20.00)

Xylocaine

Inj 1%, 20 ml vial – Up to 5 inj available on a PSO.....	12.00	5	✓ <u>Lidocaine-Claris</u>
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Inj 2%, 20 ml ampoule – Up to 5 inj available on a PSO	2.40	1	✓ <u>Lidocaine-Claris</u>
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Inj 2%, 20 ml vial – Up to 5 inj available on a PSO.....	12.00	5	✓ <u>Lidocaine-Claris</u>
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Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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LIDOCAINE [LIGNOCAINE] WITH CHLORHEXIDINE

Gel 2% with chlorhexidine 0.05%, 10 ml urethral syringes –

Subsidy by endorsement 43.26 10 ✓ Pfizer

a) Up to 5 each available on a PSO

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

Topical Local Anaesthetics

SA0906 Special Authority for Subsidy

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

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

LIDOCAINE [LIGNOCAINE] – Special Authority see SA0906 above – Retail pharmacy

Crm 4% 27.00 30 g OP ✓ LMX4

Crm 4% (5 g tubes) 27.00 5 ✓ LMX4

LIDOCAINE [LIGNOCAINE] WITH PRILOCAINE – Special Authority see SA0906 above – Retail pharmacy

Crm 2.5% with prilocaïne 2.5% 45.00 30 g OP ✓ EMLA

Crm 2.5% with prilocaïne 2.5% (5 g tubes) 45.00 5 ✓ EMLA

Analgesics

For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, page 122

Non-opioid Analgesics

For aspirin & chloroform application refer Standard Formulae, page 227

ASPIRIN

* Tab dispersible 300 mg – Up to 30 tab available on a PSO 3.90 100 ✓ Ethics Aspirin

CAPSAICIN – Subsidy by endorsement

Subsidised only if prescribed for post-herpetic neuralgia or diabetic peripheral neuropathy and the prescription is endorsed accordingly.

Crm 0.075% 12.50 45 g OP ✓ Zostrix HP

NEFOPAM HYDROCHLORIDE

Tab 30 mg 23.40 90 ✓ Acupan

PARACETAMOL

* Tab 500 mg – Up to 30 tab available on a PSO 8.47 1,000 ✓ Pharmacare

* ‡ Oral liq 120 mg per 5 ml 4.15 1,000 ml ✓ Paracare

a) Up to 200 ml available on a PSO

b) Not in combination

* ‡ Oral liq 250 mg per 5 ml 4.35 1,000 ml ✓ Paracare Double Strength

a) Up to 100 ml available on a PSO

b) Not in combination

* Suppos 125 mg 3.69 10 ✓ Gacet

* Suppos 250 mg 3.79 10 ✓ Gacet

* Suppos 500 mg 12.60 50 ✓ Paracare

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Opioid Analgesics				
CODEINE PHOSPHATE – Safety medicine; prescriber may determine dispensing frequency				
Tab 15 mg	5.75	100	✓	PSM
PSM to be Sole Supply on 1 May 2017				
Tab 30 mg	6.80	100	✓	PSM
PSM to be Sole Supply on 1 May 2017				
Tab 60 mg	13.50	100	✓	PSM
PSM to be Sole Supply on 1 May 2017				
DIHYDROCODEINE TARTRATE				
Tab long-acting 60 mg	9.55	60	✓	<u>DHC Continus</u>
FENTANYL				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
Inj 50 mcg per ml, 2 ml ampoule	3.95	10	✓	<u>Boucher and Muir</u>
Inj 50 mcg per ml, 10 ml ampoule	10.45	10	✓	<u>Boucher and Muir</u>
Patch 12.5 mcg per hour	2.92	5	✓	<u>Fentanyl Sandoz</u>
Patch 25 mcg per hour	3.66	5	✓	<u>Fentanyl Sandoz</u>
Patch 50 mcg per hour	6.64	5	✓	<u>Fentanyl Sandoz</u>
Patch 75 mcg per hour	9.18	5	✓	<u>Fentanyl Sandoz</u>
Patch 100 mcg per hour	11.29	5	✓	<u>Fentanyl Sandoz</u>
METHADONE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
d) Extemporaneously compounded methadone will only be reimbursed at the rate of the cheapest form available (methadone powder, not methadone tablets).				
e) For methadone hydrochloride oral liquid refer Standard Formulae, page 227				
Tab 5 mg	1.85	10	✓	<u>Methatabs</u>
‡ Oral liq 2 mg per ml	5.55	200 ml	✓	<u>Biodone</u>
‡ Oral liq 5 mg per ml	5.00	200 ml	✓	<u>Biodone Forte</u>
‡ Oral liq 10 mg per ml	6.55	200 ml	✓	<u>Biodone Extra Forte</u>
Inj 10 mg per ml, 1 ml	61.00	10	✓	<u>AFT</u>
MORPHINE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
‡ Oral liq 1 mg per ml	8.84	200 ml	✓	<u>RA-Morph</u>
‡ Oral liq 2 mg per ml	14.00	200 ml	✓	<u>RA-Morph</u>
‡ Oral liq 5 mg per ml	18.00	200 ml	✓	<u>RA-Morph</u>
‡ Oral liq 10 mg per ml	26.00	200 ml	✓	<u>RA-Morph</u>

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

a) Only on a controlled drug form			
b) No patient co-payment payable			
c) Safety medicine; prescriber may determine dispensing frequency			
Tab immediate-release 10 mg	2.80	10	✓ <u>Sevredol</u>
Tab long-acting 10 mg	1.93	10	✓ <u>Arrow-Morphine LA</u>
Tab immediate-release 20 mg	5.52	10	✓ <u>Sevredol</u>
Tab long-acting 30 mg	2.85	10	✓ <u>Arrow-Morphine LA</u>
Tab long-acting 60 mg	5.60	10	✓ <u>Arrow-Morphine LA</u>
Tab long-acting 100 mg	6.10	10	✓ <u>Arrow-Morphine LA</u>
Cap long-acting 10 mg	1.70	10	✓ <u>m-Eslon</u>
Cap long-acting 30 mg	2.50	10	✓ <u>m-Eslon</u>
Cap long-acting 60 mg	5.40	10	✓ <u>m-Eslon</u>
Cap long-acting 100 mg	6.38	10	✓ <u>m-Eslon</u>
Inj 5 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	12.48	5	✓ <u>DBL Morphine Sulphate</u>
Inj 10 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	9.09	5	✓ <u>DBL Morphine Sulphate</u>
Inj 15 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	9.77	5	✓ <u>DBL Morphine Sulphate</u>
Inj 30 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	12.43	5	✓ <u>DBL Morphine Sulphate</u>

MORPHINE TARTRATE

a) Only on a controlled drug form			
b) No patient co-payment payable			
c) Safety medicine; prescriber may determine dispensing frequency			
Inj 80 mg per ml, 1.5 ml ampoule	42.72	5	✓ <u>DBL Morphine Tartrate</u>
Inj 80 mg per ml, 5 ml	107.67	5	✓ <u>Hospira</u>

OXYCODONE HYDROCHLORIDE

a) Only on a controlled drug form			
b) No patient co-payment payable			
c) Safety medicine; prescriber may determine dispensing frequency			
Tab controlled-release 5 mg	2.63	20	✓ <u>BNM</u>
Tab controlled-release 10 mg	2.76	20	✓ <u>BNM</u>
Tab controlled-release 20 mg	4.72	20	✓ <u>BNM</u>
Tab controlled-release 40 mg	7.69	20	✓ <u>BNM</u>
Tab controlled-release 80 mg	14.11	20	✓ <u>BNM</u>
Cap immediate-release 5 mg	1.98	20	✓ <u>OxyNorm</u>
Cap immediate-release 10 mg	3.91	20	✓ <u>OxyNorm</u>
Cap immediate-release 20 mg	6.84	20	✓ <u>OxyNorm</u>
‡ Oral liq 5 mg per 5 ml	11.20	250 ml	✓ <u>OxyNorm</u>
Inj 10 mg per ml, 1 ml ampoule	8.57	5	✓ <u>OxyNorm</u>
Inj 10 mg per ml, 2 ml ampoule	16.89	5	✓ <u>OxyNorm</u>
Inj 50 mg per ml, 1 ml ampoule	51.00	5	✓ <u>OxyNorm</u>

PARACETAMOL WITH CODEINE – Safety medicine; prescriber may determine dispensing frequency

* Tab paracetamol 500 mg with codeine phosphate 8 mg	21.06	1,000	✓ <u>Paracetamol + Codeine (Relieve)</u>
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‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PETHIDINE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
Tab 50 mg	4.46	10	✓	PSM
Tab 100 mg	6.25	10	✓	PSM
Inj 50 mg per ml, 1 ml – Up to 5 inj available on a PSO	5.51	5	✓	DBL Pethidine Hydrochloride
Inj 50 mg per ml, 2 ml – Up to 5 inj available on a PSO	5.83	5	✓	DBL Pethidine Hydrochloride
TRAMADOL HYDROCHLORIDE				
Tab sustained-release 100 mg	2.00	20	✓	Tramal SR 100
Tab sustained-release 150 mg	3.00	20	✓	Tramal SR 150
Tab sustained-release 200 mg	4.00	20	✓	Tramal SR 200
Cap 50 mg – For tramadol hydrochloride oral liquid formula- tion refer, page 224.....	2.50	100	✓	Arrow-Tramadol
Antidepressants				
Cyclic and Related Agents				
AMITRIPTYLINE – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	1.68	100	✓	Arrow-Amitriptyline
Tab 25 mg	1.68	100	✓	Arrow-Amitriptyline
Tab 50 mg	2.82	100	✓	Arrow-Amitriptyline
CLOMIPRAMINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	12.60	100	✓	Apo-Clomipramine
Tab 25 mg	8.68	100	✓	Apo-Clomipramine
DOSULEPIN [DOTHIEPIN] HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 75 mg	11.19	100	✓	Dopress
Cap 25 mg	6.45	100	✓	Dopress
DOXEPIN HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Cap 10 mg	6.30	100	✓	Anten
Cap 25 mg	6.86	100	✓	Anten
Cap 50 mg	8.55	100	✓	Anten
IMIPRAMINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	5.48	50	✓	Tofranil
	6.58	60	✓	Tofranil s29 ^{s29}
	10.96	100	✓	Tofranil
Tab 25 mg	8.80	50	✓	Tofranil
MAPROTILINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 25 mg	7.52	30	✓	Ludiomil
	12.53	50	✓	Ludiomil
	25.06	100	✓	Ludiomil
Tab 75 mg	14.01	20	✓	Ludiomil
	21.01	30	✓	Ludiomil
NORTRIPTYLINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	3.22	100	✓	Norpress
Tab 25 mg	7.08	180	✓	Norpress

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

Monoamine-Oxidase Inhibitors (MAOIs) - Non Selective

PHENELZINE SULPHATE

* Tab 15 mg95.00 100 ✓ **Nardil**

TRANLYCYPROMINE SULPHATE

* Tab 10 mg22.94 50 ✓ **Parnate**

Monoamine-Oxidase Type A Inhibitors

MOCLOBEMIDE

* Tab 150 mg85.10 500 ✓ **Apo-Moclobemide**

* Tab 300 mg30.70 100 ✓ **Apo-Moclobemide**

Selective Serotonin Reuptake Inhibitors

CITALOPRAM HYDROBROMIDE

* Tab 20 mg1.79 84 ✓ **PSM Citalopram**

ESCITALOPRAM

* Tab 10 mg1.40 28 ✓ **Accord
Escitalopram**

* Tab 20 mg2.40 28 ✓ **Air Flow Products
Loxalate**

(Accord Escitalopram Tab 10 mg to be delisted 1 July 2017)

FLUOXETINE HYDROCHLORIDE

* Tab dispersible 20 mg, scored – Subsidy by endorsement2.47 30 ✓ **Arrow-Fluoxetine**
Subsidised by endorsement

1) When prescribed for a patient who cannot swallow whole tablets or capsules and the prescription is endorsed accordingly;
or

2) When prescribed in a daily dose that is not a multiple of 20 mg in which case the prescription is deemed to be endorsed.

Note: Tablets should be combined with capsules to facilitate incremental 10 mg doses.

* Cap 20 mg1.99 90 ✓ **Arrow-Fluoxetine**

PAROXETINE

* Tab 20 mg4.02 90 ✓ **Apo-Paroxetine**
4.32 ✓ **Loxamine**

SERTRALINE

Tab 50 mg3.05 90 ✓ **Arrow-Sertraline**

Tab 100 mg5.25 90 ✓ **Arrow-Sertraline**

Other Antidepressants

MIRTAZAPINE

Tab 30 mg2.55 30 ✓ **Apo-Mirtazapine**

Tab 45 mg3.25 30 ✓ **Apo-Mirtazapine**

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
VENLAFAXINE				
Tab 37.5 mg	5.06	28	✓	Arrow-Venlafaxine XR
Tab 75 mg	6.44	28	✓	Arrow-Venlafaxine XR
Tab 150 mg	8.86	28	✓	Arrow-Venlafaxine XR
Tab 225 mg	14.34	28	✓	Arrow-Venlafaxine XR
Cap 37.5 mg – Special Authority see SA1061 below – Retail pharmacy	5.69	28	✓	Efexor XR
Cap 75 mg – Special Authority see SA1061 below – Retail pharmacy	11.40	28	✓	Efexor XR
Cap 150 mg – Special Authority see SA1061 below – Retail pharmacy	13.98	28	✓	Efexor XR

►SA1061 Special Authority for Subsidy

Initial application only from a relevant specialist or vocationally registered general practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 The patient has 'treatment-resistant' depression; and
- 2 Either:
 - 2.1 The patient must have had a trial of two different antidepressants and have had an inadequate response from an adequate dose over an adequate period of time (usually at least four weeks); or
 - 2.2 Both:
 - 2.2.1 The patient is currently a hospital in-patient as a result of an acute depressive episode; and
 - 2.2.2 The patient must have had a trial of one other antidepressant and have had an inadequate response from an adequate dose over an adequate period of time.

Renewal from any medical practitioner. Approvals valid for 2 years where the patient has a high risk of relapse (prescriber determined).

Antiepilepsy Drugs

Agents for Control of Status Epilepticus

CLONAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Inj 1 mg per ml, 1 ml	19.00	5	✓	Rivotril
DIAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Inj 5 mg per ml, 2 ml ampoule – Subsidy by endorsement.....	11.83	5	✓	Hospira
a) Up to 5 inj available on a PSO				
b) Only on a PSO				
c) PSO must be endorsed "not for anaesthetic procedures".				
Rectal tubes 5 mg – Up to 5 tube available on a PSO	33.07	5	✓	Stesolid
Rectal tubes 10 mg – Up to 5 tube available on a PSO	40.87	5	✓	Stesolid
PARALDEHYDE				
* Inj 5 ml	1,500.00	5	✓	AFT

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PHENYTOIN SODIUM				
* Inj 50 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO.....	88.63	5	✓	Hospira
* Inj 50 mg per ml, 5 ml ampoule – Up to 5 inj available on a PSO.....	133.92	5	✓	Hospira
Control of Epilepsy				
CARBAMAZEPINE				
* Tab 200 mg	14.53	100	✓	Tegretol
* Tab long-acting 200 mg	16.98	100	✓	Tegretol CR
* Tab 400 mg	34.58	100	✓	Tegretol
* Tab long-acting 400 mg	39.17	100	✓	Tegretol CR
*‡ Oral liq 20 mg per ml	26.37	250 ml	✓	Tegretol
CLOBAZAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	9.12	50	✓	Frisium
‡ Safety cap for extemporaneously compounded oral liquid preparations.				
CLONAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
‡ Oral drops 2.5 mg per ml	7.38	10 ml OP	✓	Rivotril
ETHOSUXIMIDE				
Cap 250 mg	16.45	100	✓	Zarontin
	32.90	200	✓	Zarontin
‡ Oral liq 250 mg per 5 ml	13.60	200 ml	✓	Zarontin
GABAPENTIN – Special Authority see SA1477 below – Retail pharmacy				
▲ Cap 100 mg	7.16	100	✓	Arrow-Gabapentin
			✓	Neurontin
			✓	Nupentin
▲ Cap 300 mg – For gabapentin oral liquid formulation refer, page 224	11.00	100	✓	Arrow-Gabapentin
			✓	Neurontin
			✓	Nupentin
▲ Cap 400 mg	13.75	100	✓	Arrow-Gabapentin
			✓	Neurontin
			✓	Nupentin

►SA1477 **Special Authority for Subsidy**

Initial application — (Epilepsy) from any relevant practitioner. Approvals valid for 15 months for applications meeting the following criteria:

Either:

- 1 Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents; or
- 2 Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents.

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

Initial application — (Neuropathic pain or Chronic Kidney Disease associated pruritus) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:

Either:

- 1 The patient has been diagnosed with neuropathic pain; or

continued...

‡ safety cap

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

▲Three months supply may be dispensed at one time

if endorsed "certified exemption" by the prescriber or pharmacist.

continued...

2 Both:

2.1 The patient has Chronic Kidney Disease Stage 5-associated pruritus* where no other cause for pruritus can be identified (e.g. scabies, allergy); and

2.2 The patient has persistent pruritus not relieved with a trial of emollient/moisturising creams alone.

Renewal — (Epilepsy) from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life.

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

Renewal — (Neuropathic pain or Chronic Kidney Disease associated pruritus) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Either:

- 1 The patient has demonstrated a marked improvement in their control of pain or itch (prescriber determined); or
- 2 The patient has previously demonstrated clinical responsiveness to gabapentin and has now developed neuropathic pain in a new site.

Note: Indications marked with * are Unapproved Indications (see Interpretations and Definitions). Dosage adjustment of gabapentin is recommended for patients with renal impairment.

LACOSAMIDE – Special Authority see SA1125 below – Retail pharmacy

▲ Tab 50 mg	25.04	14	✓ Vimpat
▲ Tab 100 mg	50.06	14	✓ Vimpat
	200.24	56	✓ Vimpat
▲ Tab 150 mg	75.10	14	✓ Vimpat
	300.40	56	✓ Vimpat
▲ Tab 200 mg	400.55	56	✓ Vimpat

►SA1125 Special Authority for Subsidy

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

Both:

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

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

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
LAMOTRIGINE				
▲ Tab dispersible 2 mg	6.74	30	✓	Lamictal
▲ Tab dispersible 5 mg	9.64	30	✓	Lamictal
	15.00	56	✓	Arrow-Lamotrigine
▲ Tab dispersible 25 mg	14.74	56	✓	Motrig
	19.38		✓	Logem
	20.40		✓	Arrow-Lamotrigine
	29.09		✓	Lamictal
▲ Tab dispersible 50 mg	24.73	56	✓	Motrig
	32.97		✓	Logem
	34.70		✓	Arrow-Lamotrigine
	47.89		✓	Lamictal
▲ Tab dispersible 100 mg	42.34	56	✓	Motrig
	56.91		✓	Logem
	59.90		✓	Arrow-Lamotrigine
	79.16		✓	Lamictal
LEVETIRACETAM				
Tab 250 mg	24.03	60	✓	Everet
Tab 500 mg – For levetiracetam oral liquid formulation refer, page 224	28.71	60	✓	Everet
Tab 750 mg	45.23	60	✓	Everet
Tab 1,000 mg	59.12	60	✓	Everet
PHENOBARBITONE				
For phenobarbitone oral liquid refer Standard Formulae, page 227				
* Tab 15 mg	30.00	500	✓	PSM
* Tab 30 mg	31.00	500	✓	PSM
PHENYTOIN SODIUM				
* Tab 50 mg	50.51	200	✓	Dilantin Infatab
Cap 30 mg	22.00	200	✓	Dilantin
Cap 100 mg	19.79	200	✓	Dilantin
*‡ Oral liq 30 mg per 5 ml	22.03	500 ml	✓	Dilantin
PRIMIDONE				
* Tab 250 mg	17.25	100	✓	Apo-Primidone
SODIUM VALPROATE				
Tab 100 mg	13.65	100	✓	Epilim Crushable
Tab 200 mg EC	27.44	100	✓	Epilim
Tab 500 mg EC	52.24	100	✓	Epilim
*‡ Oral liq 200 mg per 5 ml	20.48	300 ml	✓	Epilim S/F Liquid
			✓	Epilim Syrup
			✓	Epilim IV
* Inj 100 mg per ml, 4 ml	41.50	1		
STIRIPENTOL – Special Authority see SA1330 on the next page – Retail pharmacy				
Cap 250 mg	509.29	60	✓	Diacomit ^{S29}
Powder for oral liq 250 mg sachet	509.29	60	✓	Diacomit ^{S29}

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
►SA1330 Special Authority for Subsidy				
Initial application only from a paediatric neurologist or Practitioner on the recommendation of a paediatric neurologist. Approvals valid for 6 months for applications meeting the following criteria:				
Both:				
1 Patient has confirmed diagnosis of Dravet syndrome; and				
2 Seizures have been inadequately controlled by appropriate courses of sodium valproate, clobazam and at least two of the following: topiramate, levetiracetam, ketogenic diet.				
Renewal from any relevant practitioner. Approvals valid without further renewal unless notified where the patient continues to benefit from treatment as measured by reduced seizure frequency from baseline.				
TOPIRAMATE				
▲ Tab 25 mg	11.07	60	✓	Arrow-Topiramate
	26.04		✓	Topiramate Actavis
			✓	Topamax
▲ Tab 50 mg	18.81	60	✓	Arrow-Topiramate
	44.26		✓	Topiramate Actavis
			✓	Topamax
▲ Tab 100 mg	31.99	60	✓	Arrow-Topiramate
	75.25		✓	Topiramate Actavis
			✓	Topamax
▲ Tab 200 mg	55.19	60	✓	Arrow-Topiramate
	129.85		✓	Topiramate Actavis
			✓	Topamax
▲ Sprinkle cap 15 mg	20.84	60	✓	Topamax
▲ Sprinkle cap 25 mg	26.04	60	✓	Topamax
VIGABATRIN – Special Authority see SA1072 below – Retail pharmacy				
▲ Tab 500 mg	119.30	100	✓	Sabril

►SA1072 Special Authority for Subsidy

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

Both:

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

continued...

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

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

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

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

- Both:
- 1 The patient has demonstrated a significant and sustained improvement in seizure rate or severity and or quality of life; and
 - 2 Either:

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

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

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

Antimigraine Preparations

For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, page 122

Acute Migraine Treatment

ERGOTAMINE TARTRATE WITH CAFFEINE

Tab 1 mg with caffeine 100 mg	31.00	100	✓ Cafergot ✓ Cafergot S29 <small>S29</small>
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RIZATRIPTAN

Tab orodispersible 10 mg	8.10	30	✓ Rizamelt
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SUMATRIPTAN

Tab 50 mg	29.80	100	✓ Arrow-Sumatriptan
Tab 100 mg	54.80	100	✓ Arrow-Sumatriptan
Inj 12 mg per ml, 0.5 ml cartridge – Maximum of 10 inj per prescription	13.80	2 OP	✓ Arrow-Sumatriptan
Inj 12 mg per ml, 0.5 ml prefilled pen – Maximum of 10 inj per prescription	42.67	2 OP	✓ Clustran ✓ Sun Pharma <small>S29</small>

(Arrow-Sumatriptan Inj 12 mg per ml, 0.5 ml cartridge to be delisted 1 July 2017)

Prophylaxis of Migraine

For Beta Adrenoceptor Blockers refer to CARDIOVASCULAR SYSTEM, page 59

PIZOTIFEN

* Tab 500 mcg	23.21	100	✓ Sandomigran
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Antinausea and Vertigo Agents

For Antispasmodics refer to ALIMENTARY TRACT, page 22

APREPITANT – Special Authority see SA0987 on the next page – Retail pharmacy

Cap 2 × 80 mg and 1 × 125 mg	100.00	3 OP	✓ Emend Tri-Pack
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‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
►SA0987 Special Authority for Subsidy				
Initial application from any relevant practitioner. Approvals valid for 12 months where the patient is undergoing highly emetogenic chemotherapy and/or anthracycline-based chemotherapy for the treatment of malignancy.				
Renewal from any relevant practitioner. Approvals valid for 12 months where the patient is undergoing highly emetogenic chemotherapy and/or anthracycline-based chemotherapy for the treatment of malignancy.				
BETAHISTINE DIHYDROCHLORIDE				
* Tab 16 mg	4.95	84	✓	<u>Vergo 16</u>
CYCLIZINE HYDROCHLORIDE				
Tab 50 mg	0.59	20	✓	<u>Nauzene</u>
CYCLIZINE LACTATE				
Inj 50 mg per ml, 1 ml	14.95	5	✓	<u>Nausicalm</u>
DOMPERIDONE				
* Tab 10 mg – For domperidone oral liquid formulation refer, page 224	3.20	100	✓	<u>Prokinex</u>
GRANISETRON				
* Tab 1 mg	5.98	50	✓	<u>Granirex</u>
HYOSCINE HYDROBROMIDE				
* Inj 400 mcg per ml, 1 ml ampoule	46.50	5	✓	<u>Hospira</u>
	93.00	10	✓	<u>Martindale</u> <small>\$29</small>
Patch 1.5 mg – Special Authority see SA1387 below – Retail pharmacy	11.95	2	✓	<u>Scopoderm TTS</u>
►SA1387 Special Authority for Subsidy				
Initial application from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria: Either:				
1 Control of intractable nausea, vomiting, or inability to swallow saliva in the treatment of malignancy or chronic disease where the patient cannot tolerate or does not adequately respond to oral anti-nausea agents; or				
2 Control of clozapine-induced hypersalivation where trials of at least two other alternative treatments have proven ineffective.				
Renewal from any relevant practitioner. Approvals valid for 1 year where the treatment remains appropriate and the patient is benefiting from treatment.				
METOCLOPRAMIDE HYDROCHLORIDE				
* Tab 10 mg – For metoclopramide hydrochloride oral liquid formulation refer, page 224	1.82	100	✓	<u>Metamide</u>
* Inj 5 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	4.50	10	✓	<u>Pfizer</u>
ONDANSETRON				
* Tab 4 mg	3.36	50	✓	<u>Apo-Ondansetron</u>
	5.51		✓	<u>Onrex</u>
* Tab disp 4 mg	1.00	10	✓	<u>Dr Reddy's</u>
				<u>Ondansetron</u>
* Tab 8 mg	4.77	50	✓	<u>Apo-Ondansetron</u>
	6.19		✓	<u>Onrex</u>
* Tab disp 8 mg	1.50	10	✓	<u>Ondansetron</u>
				<u>ODT-DRLA</u>
PROCHLORPERAZINE				
* Tab 3 mg buccal	5.97	50		Buccastem
	(15.00)			
* Tab 5 mg – Up to 30 tab available on a PSO	9.75	500	✓	<u>Antinaus</u>
* Inj 12.5 mg per ml, 1 ml – Up to 5 inj available on a PSO	25.81	10	✓	<u>Stemetil</u>

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PROMETHAZINE THEOCLATE				
* Tab 25 mg	1.20 (6.24)	10		Avomine

Antipsychotics

General

AMISULPRIDE – Safety medicine; prescriber may determine dispensing frequency

Tab 100 mg – Brand switch fee payable (Pharmacode 2514192) - see page 221 for details	4.56	30	✓ <u>Sulprix</u>
Tab 200 mg – Brand switch fee payable (Pharmacode 2514192) - see page 221 for details	14.75	60	✓ <u>Sulprix</u>
Tab 400 mg – Brand switch fee payable (Pharmacode 2514192) - see page 221 for details	27.70	60	✓ <u>Sulprix</u>
Oral liq 100 mg per ml	65.53	60 ml	✓ <u>Solian</u>

ARIPIRAZOLE – Special Authority see SA1539 below – Retail pharmacy

Safety medicine; prescriber may determine dispensing frequency

Tab 5 mg – No more than 1 tab per day	123.54	30	✓ <u>Abilify</u>
Tab 10 mg	123.54	30	✓ <u>Abilify</u>
Tab 15 mg	175.28	30	✓ <u>Abilify</u>
Tab 20 mg	213.42	30	✓ <u>Abilify</u>
Tab 30 mg	260.07	30	✓ <u>Abilify</u>

►SA1539 | Special Authority for Subsidy

Initial application — (Schizophrenia or related psychoses) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

- Both:
- 1 Patient is suffering from schizophrenia or related psychoses; and
 - 2 Either:
 - 2.1 An effective dose of risperidone or quetiapine has been trialled and has been discontinued, or is in the process of being discontinued, because of unacceptable side effects; or
 - 2.2 An effective dose of risperidone or quetiapine has been trialled and has been discontinued, or is in the process of being discontinued, because of inadequate clinical response.

Initial application — (Autism spectrum disorder*) only from a paediatrician or psychiatrist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has been diagnosed with an autism spectrum disorder* and has symptoms of severe irritability; and
- 2 An effective dose of risperidone has been trialled and has been discontinued because of unacceptable side effects or inadequate response; and
- 3 The patient is aged less than 18 years.

Renewal — (Schizophrenia or related psychoses) from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Renewal — (Autism spectrum disorder*) only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Note: Indications marked with * are Unapproved Indications

‡ safety cap

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

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

NERVOUS SYSTEM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
CHLORPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg – Up to 30 tab available on a PSO.....	12.36	100	✓	Largactil
Tab 25 mg – Up to 30 tab available on a PSO.....	13.02	100	✓	Largactil
Tab 100 mg – Up to 30 tab available on a PSO.....	30.61	100	✓	Largactil
Inj 25 mg per ml, 2 ml – Up to 5 inj available on a PSO	25.66	10	✓	Largactil
CLOZAPINE – Hospital pharmacy [HP4]				
Safety medicine; prescriber may determine dispensing frequency				
Tab 25 mg	5.69	50	✓	Clozaril
	6.69		✓	Clopine
	11.36	100	✓	Clozaril
	13.37		✓	Clopine
Tab 50 mg	8.67	50	✓	Clopine
	17.33	100	✓	Clopine
Tab 100 mg	14.73	50	✓	Clozaril
	17.33		✓	Clopine
	29.45	100	✓	Clozaril
	34.65		✓	Clopine
Tab 200 mg	34.65	50	✓	Clopine
	69.30	100	✓	Clopine
Suspension 50 mg per ml	17.33	100 ml	✓	Clopine
HALOPERIDOL – Safety medicine; prescriber may determine dispensing frequency				
Tab 500 mcg – Up to 30 tab available on a PSO.....	6.23	100	✓	Serenace
Tab 1.5 mg – Up to 30 tab available on a PSO.....	9.43	100	✓	Serenace
Tab 5 mg – Up to 30 tab available on a PSO.....	29.72	100	✓	Serenace
Oral liq 2 mg per ml – Up to 200 ml available on a PSO	23.84	100 ml	✓	Serenace
Inj 5 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	21.55	10	✓	Serenace
LEVOMEPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Inj 25 mg per ml, 1 ml ampoule	47.89	10	✓	Wockhardt
LEVOMEPROMAZINE MALEATE – Safety medicine; prescriber may determine dispensing frequency				
Tab 25 mg	16.93	100	✓	Nozinan
Tab 100 mg	43.96	100	✓	Nozinan
LITHIUM CARBONATE – Safety medicine; prescriber may determine dispensing frequency				
Tab 250 mg	34.30	500	✓	Lithicarb FC
Tab 400 mg	12.83	100	✓	Lithicarb FC
Tab long-acting 400 mg	19.20	100	✓	Priadel
Cap 250 mg	9.42	100	✓	Douglas
OLANZAPINE – Safety medicine; prescriber may determine dispensing frequency				
Tab 2.5 mg	0.75	28	✓	Zypine
Tab 5 mg	1.65	28	✓	Zypine
Tab orodispersible 5 mg	1.75	28	✓	Zypine ODT
Tab 10 mg	2.55	28	✓	Zypine
Tab orodispersible 10 mg	3.05	28	✓	Zypine ODT
PERICYZINE – Safety medicine; prescriber may determine dispensing frequency				
Tab 2.5 mg	12.49	100	✓	Neulactil
Tab 10 mg	44.45	100	✓	Neulactil

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
QUETIAPINE – Safety medicine; prescriber may determine dispensing frequency				
Tab 25 mg	2.10	90	✓	<u>Quetapel</u>
Tab 100 mg	4.20	90	✓	<u>Quetapel</u>
Tab 200 mg	7.20	90	✓	<u>Quetapel</u>
Tab 300 mg	12.00	90	✓	<u>Quetapel</u>
RISPERIDONE – Safety medicine; prescriber may determine dispensing frequency				
Tab orodispersible 0.5 mg – Special Authority see SA0927				
below – Retail pharmacy	21.42	28	✓	<u>Risperdal Quicklet</u>
Tab 0.5 mg	1.90	60	✓	<u>Actavis</u>
Tab 1 mg	2.10	60	✓	<u>Actavis</u>
Tab orodispersible 1 mg – Special Authority see SA0927				
below – Retail pharmacy	42.84	28	✓	<u>Risperdal Quicklet</u>
Tab 2 mg	2.34	60	✓	<u>Actavis</u>
Tab orodispersible 2 mg – Special Authority see SA0927				
below – Retail pharmacy	85.71	28	✓	<u>Risperdal Quicklet</u>
Tab 3 mg	2.55	60	✓	<u>Actavis</u>
Tab 4 mg	3.50	60	✓	<u>Actavis</u>
Oral liq 1 mg per ml	9.75	30 ml	✓	<u>Risperon</u>

(Risperdal Quicklet Tab orodispersible 0.5 mg to be delisted 1 June 2017)

(Risperdal Quicklet Tab orodispersible 1 mg to be delisted 1 June 2017)

(Risperdal Quicklet Tab orodispersible 2 mg to be delisted 1 June 2017)

▶SA0927 Special Authority for Subsidy

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

Both:

- 1 For a non-adherent patient on oral therapy with standard risperidone tablets or risperidone oral liquid; and
- 2 The patient is under direct supervision for administration of medicine.

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

Both:

- 1 The patient is unable to take standard risperidone tablets or oral liquid, or once stabilized refuses to take risperidone tablets or oral liquid; and
- 2 The patient is under direct supervision for administration of medicine.

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

Both:

- 1 The patient is unable to take standard risperidone tablets or oral liquid, or once stabilized refuses to take risperidone tablets or oral liquid; and
- 2 The patient is under direct supervision for administration of medicine.

Note: Risperdal Quicklets cost significantly more than risperidone tablets and should only be used where necessary.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
TRIFLUOPERAZINE HYDROCHLORIDE – Subsidy by endorsement				
a) Safety medicine; prescriber may determine dispensing frequency				
b) Subsidised for patients who were taking trifluoperazine hydrochloride prior to 1 January 2017 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of trifluoperazine hydrochloride.				
Tab 1 mg	9.83	100	✓	Stelazine
	11.01	112	✓	Mercury
				Pharma ^{§29}
	19.75	100	✓	Apo-
				Trifluoperazine ^{§29}
Tab 2 mg	14.64	100	✓	Stelazine
Tab 5 mg	16.66	100	✓	Stelazine
	26.23		✓	Apo-
				Trifluoperazine ^{§29}

(Stelazine Tab 1 mg to be delisted 1 July 2017)

(Mercury Pharma ^{§29} Tab 1 mg to be delisted 1 July 2017)

(Apo-Trifluoperazine ^{§29} Tab 1 mg to be delisted 1 December 2017)

(Stelazine Tab 2 mg to be delisted 1 July 2017)

(Stelazine Tab 5 mg to be delisted 1 July 2017)

(Apo-Trifluoperazine ^{§29} Tab 5 mg to be delisted 1 December 2017)

ZIPRASIDONE – Safety medicine; prescriber may determine dispensing frequency

Cap 20 mg	14.56	60	✓	Zusdone
Cap 40 mg	24.75	60	✓	Zusdone
Cap 60 mg	33.87	60	✓	Zusdone
Cap 80 mg	39.74	60	✓	Zusdone

ZUCLOPENTHIXOL HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency

Tab 10 mg	31.45	100	✓	Clopixol
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Depot Injections

FLUPENTHIXOL DECANOATE – Safety medicine; prescriber may determine dispensing frequency

Inj 20 mg per ml, 1 ml – Up to 5 inj available on a PSO	13.14	5	✓	Fluanxol
Inj 20 mg per ml, 2 ml – Up to 5 inj available on a PSO	20.90	5	✓	Fluanxol
Inj 100 mg per ml, 1 ml – Up to 5 inj available on a PSO	40.87	5	✓	Fluanxol

FLUPHENAZINE DECANOATE – Subsidy by endorsement

a) Safety medicine; prescriber may determine dispensing frequency

b) Subsidised for patients who were taking fluphenazine decanoate prior to 1 December 2016 and the prescription or PSO is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of fluphenazine decanoate.

Inj 12.5 mg per 0.5 ml, 0.5 ml – Up to 5 inj available on a PSO	17.60	5	✓	Modecate
Inj 25 mg per ml, 1 ml – Up to 5 inj available on a PSO	27.90	5	✓	Modecate
			✓	Modecate ^{§29}
Inj 25 mg per ml, 2 ml – Up to 5 inj available on a PSO	77.25	5	✓	Modecate ^{§29}
Inj 100 mg per ml, 1 ml – Up to 5 inj available on a PSO	154.50	5	✓	Modecate

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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HALOPERIDOL DECANOATE – Safety medicine; prescriber may determine dispensing frequency

Inj 50 mg per ml, 1 ml – Up to 5 inj available on a PSO	28.39	5	✓ Haldol
Inj 100 mg per ml, 1 ml – Up to 5 inj available on a PSO	55.90	5	✓ Haldol Concentrate
			✓ Haldol

Decanoas S29

OLANZAPINE – Special Authority see SA1428 below – Retail pharmacy

Safety medicine; prescriber may determine dispensing frequency

Inj 210 mg vial	280.00	1	✓ Zyprexa Relprevv
Inj 300 mg vial	460.00	1	✓ Zyprexa Relprevv
Inj 405 mg vial	560.00	1	✓ Zyprexa Relprevv

►►**SA1428** | **Special Authority for Subsidy**

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

Either:

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

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

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

PALIPERIDONE – Special Authority see SA1429 below – Retail pharmacy

Safety medicine; prescriber may determine dispensing frequency

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

►►**SA1429** | **Special Authority for Subsidy**

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

Either:

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

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

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

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PIPOTHIAZINE PALMITATE – Subsidy by endorsement				
a) Safety medicine; prescriber may determine dispensing frequency				
b) Subsidised for patients who were taking pipothiazine palmitate prior to 1 August 2014 and the prescription or PSO is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of pipothiazine palmitate.				
Inj 50 mg per ml, 1 ml – Up to 5 inj available on a PSO	178.48	10	✓	Piportil
Inj 50 mg per ml, 2 ml – Up to 5 inj available on a PSO	353.32	10	✓	Piportil
RISPERIDONE – Special Authority see SA1427 below – Retail pharmacy				
Safety medicine; prescriber may determine dispensing frequency				
Inj 25 mg vial	135.98	1	✓	Risperdal Consta
Inj 37.5 mg vial	178.71	1	✓	Risperdal Consta
Inj 50 mg vial	217.56	1	✓	Risperdal Consta

►SA1427 Special Authority for Subsidy

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

Either:

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

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

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

ZUCLOPENTHIXOL DECANOATE – Safety medicine; prescriber may determine dispensing frequency

Inj 200 mg per ml, 1 ml – Up to 5 inj available on a PSO	19.80	5	✓	Clopixol
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Anxiolytics

ALPRAZOLAM – Subsidy by endorsement

- a) Safety medicine; prescriber may determine dispensing frequency
- b) Subsidised for patients who were taking alprazolam prior to 1 December 2016 and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of alprazolam.

Tab 250 mcg	2.50	50	
	(4.84)		Xanax
‡ Safety cap for extemporaneously compounded oral liquid preparations.			
Tab 500 mcg	3.25	50	
	(5.92)		Xanax
‡ Safety cap for extemporaneously compounded oral liquid preparations.			
Tab 1 mg	5.00	50	
	(12.00)		Xanax
‡ Safety cap for extemporaneously compounded oral liquid preparations.			

(Xanax Tab 250 mcg to be delisted 1 September 2017)

(Xanax Tab 500 mcg to be delisted 1 September 2017)

(Xanax Tab 1 mg to be delisted 1 September 2017)

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
BUSPIRONE HYDROCHLORIDE				
* Tab 5 mg	23.80	100	✓	<u>Orion</u>
* Tab 10 mg	14.96	100	✓	<u>Orion</u>
CLONAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 500 mcg	7.53	100	✓	<u>Paxam</u>
Tab 2 mg	14.37	100	✓	<u>Paxam</u>
DIAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 2 mg	11.44	500	✓	<u>Arrow-Diazepam</u>
‡ Safety cap for extemporaneously compounded oral liquid preparations.				
Tab 5 mg	13.71	500	✓	<u>Arrow-Diazepam</u>
‡ Safety cap for extemporaneously compounded oral liquid preparations.				
LORAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 1 mg	10.79	250	✓	<u>Ativan</u>
‡ Safety cap for extemporaneously compounded oral liquid preparations.				
Tab 2.5 mg	13.88	100	✓	<u>Ativan</u>
‡ Safety cap for extemporaneously compounded oral liquid preparations.				
OXAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	6.17	100	✓	<u>Ox-Pam</u>
‡ Safety cap for extemporaneously compounded oral liquid preparations.				
Tab 15 mg	8.53	100	✓	<u>Ox-Pam</u>
‡ Safety cap for extemporaneously compounded oral liquid preparations.				

Multiple Sclerosis Treatments

DIMETHYL FUMARATE – Special Authority see SA1559 below – Retail pharmacy

Wastage claimable – see rule 3.3.2 on page 13

Cap 120 mg	520.00	14	✓	<u>Tecfidera</u>
Cap 240 mg	2,000.00	56	✓	<u>Tecfidera</u>

►SA1559 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

Notes: Special Authority approved by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (below). Application details may be obtained from PHARMAC's website <http://www.pharmac.govt.nz> or:

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

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

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

Entry Criteria

- Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
- patients must have Clinically Definite Relapsing Remitting MS with or without underlying progression; and
- patients must have:
 - EDSS score 0 - 4.0 and:
 - Experienced at least 1 significant relapse of MS in the previous 12 months or 2 significant relapses in the past 24 months; and
 - Evidence of new inflammatory activity on an MR scan within the past 24 months, any of the following:
 - a gadolinium enhancing lesion; or

continued...

‡ safety cap

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

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

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

- ii) a Diffusion Weighted Imaging positive lesion; or
- iii) a T2 lesion with associated local swelling; or
- iv) a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse; or
- v) new T2 lesions compared with a previous MR scan; and
- d) A significant relapse must:
 - a) be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
 - b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);
 - c) last at least one week;
 - d) start at least one month after the onset of a previous relapse;
 - e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least 1 point;
 - f) be distinguishable from the effects of general fatigue; and
 - g) not be associated with a fever ($T > 37.5^{\circ}\text{C}$); and
- e) applications must be made by the patient's neurologist or general physician; and
- f) patients must have no previous history of lack of response to dimethyl fumarate; and
- g) patients must have not previously had intolerance to dimethyl fumarate; and
- h) patient must not be co-prescribed beta interferon or glatiramer acetate.

Stopping Criteria

Any of the following:

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

Note: Switching between natalizumab, fingolimod, dimethyl fumarate and teriflunomide is permitted provided the EDSS stopping criteria are not met. Switching to interferon or glatiramer acetate is only permitted provided the EDSS stopping criteria are not met and both fingolimod and natalizumab are either not tolerated or treatment with both agents would be clinically inappropriate. Continued relapses on treatment would be expected to lead to a switch of treatment provided the stopping criteria are not met. If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse for recovery to occur.

FINGOLIMOD – Special Authority see SA1562 on the next page – Retail pharmacy

Wastage claimable – see rule 3.3.2 on page 13

Cap 0.5 mg	2,650.00	28	✓ Gilenya
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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

►SA1562 | Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

Notes: Special Authority approved by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (below). Application details may be obtained from PHARMAC's website <http://www.pharmac.govt.nz> or:

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

Wellington

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

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

Entry Criteria

- a) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
- b) patients must have Clinically Definite Relapsing Remitting MS with or without underlying progression; and
- c) patients must have:
 - a) EDSS score 0 - 4.0 and:
 - Experienced at least 1 significant relapse of MS in the previous 12 months or 2 significant relapses in the past 24 months; and
 - Evidence of new inflammatory activity on an MR scan within the past 24 months, any of the following:
 - i) a gadolinium enhancing lesion; or
 - ii) a Diffusion Weighted Imaging positive lesion; or
 - iii) a T2 lesion with associated local swelling; or
 - iv) a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse; or
 - v) new T2 lesions compared with a previous MR scan; and
- d) A significant relapse must:
 - a) be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
 - b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);
 - c) last at least one week;
 - d) start at least one month after the onset of a previous relapse;
 - e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least 1 point;
 - f) be distinguishable from the effects of general fatigue; and
 - g) not be associated with a fever ($T > 37.5^{\circ}\text{C}$); and
- e) applications must be made by the patient's neurologist or general physician; and
- f) patients must have no previous history of lack of response to fingolimod; and
- g) patients must have not previously had intolerance to fingolimod; and
- h) patient must not be co-prescribed beta interferon or glatiramer acetate.

Stopping Criteria

Any of the following:

- a) Confirmed progression of disability that is sustained for six months. Progression of disability is defined as progress by any of the following EDDSS points:
 - a) from starting at EDSS 0 increasing to (i.e. stopping on reaching) EDSS 3.0; or
 - b) 1.0 to 3.0; or
 - c) 1.5 to 3.5; or
 - d) 2.0 to 4.0; or

continued...

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- e) 2.5 to 4.5; or
- f) 3.0 to 4.5; or
- g) 3.5 to 4.5; or
- h) 4.0 to 4.5.

- b) increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment)(see note); or
- c) intolerance to fingolimod; or
- d) non-compliance with treatment, including refusal to undergo annual assessment.

Note: Switching between natalizumab, fingolimod, dimethyl fumarate and teriflunomide is permitted provided the EDSS stopping criteria are not met. Switching to interferon or glatiramer acetate is only permitted provided the EDSS stopping criteria are not met and both fingolimod and natalizumab are either not tolerated or treatment with both agents would be clinically inappropriate. Continued relapses on treatment would be expected to lead to a switch of treatment provided the stopping criteria are not met. If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse for recovery to occur.

NATALIZUMAB – Special Authority see SA1563 below – Retail pharmacy

Inj 20 mg per ml, 15 ml vial	1,750.00	1	✓ Tysabri
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►SA1563 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

Notes: Special Authority approved by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (below). Application details may be obtained from PHARMAC's website <http://www.pharmac.govt.nz> or:

The coordinator

Multiple Sclerosis Treatment Assessment Committee

PHARMAC PO Box 10 254

Wellington

Phone: 04 460 4990

Facsimile: 04 916 7571

Email: mstaccoordinator@pharmac.govt.nz

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

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

Entry Criteria

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

continued...

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

continued...

- e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least 1 point;
- f) be distinguishable from the effects of general fatigue; and
- g) not be associated with a fever ($T > 37.5^{\circ}\text{C}$); and
- e) applications must be made by the patient's neurologist or general physician; and
- f) treatment must be initiated and supervised by a neurologist who is registered in the Tysabri Australasian Prescribing Programme operated by the supplier; and
- g) patients must have no previous history of lack of response to natalizumab; and
- h) patients must have not previously had intolerance to natalizumab; and
- i)
 - a) Patient is JC virus negative, or
 - b) Patient is JC virus positive and has given written informed consent acknowledging an understanding of the risk of progressive multifocal leucoencephalopathy (PML) associated with natalizumab
- j) patient must not be co-prescribed beta interferon or glatiramer acetate.

Stopping Criteria

Any of the following:

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

Note: Natalizumab can only be dispensed from a pharmacy registered in the Tysabri Australasian Prescribing Programme operated by the supplier.

Switching between natalizumab, fingolimod, dimethyl fumarate and teriflunomide is permitted provided the EDSS stopping criteria are not met. Switching to interferon or glatiramer acetate is only permitted provided the EDSS stopping criteria are not met and both fingolimod and natalizumab are either not tolerated or treatment with both agents would be clinically inappropriate. Continued relapses on treatment would be expected to lead to a switch of treatment provided the stopping criteria are not met. If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse for recovery to occur.

TERIFLUNOMIDE – Special Authority see SA1560 below – Retail pharmacy

Wastage claimable – see rule 3.3.2 on page 13

Tab 14 mg 1,582.62 28 ✓ Aubagio

►SA1560 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

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

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

The coordinator

Multiple Sclerosis Treatment Assessment Committee

PHARMAC PO Box 10 254

Wellington

Phone: 04 460 4990

Facsimile: 04 916 7571

Email: mstacordinator@pharmac.govt.nz

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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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Completed application forms must be sent to the coordinator for MSTAC and will be considered by MSTAC at the next practicable opportunity.

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

Entry Criteria

- a) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
- b) patients must have Clinically Definite Relapsing Remitting MS with or without underlying progression; and
- c) patients must have:
 - a) EDSS score 0 - 4.0 and:
 - Experienced at least 1 significant relapse of MS in the previous 12 months or 2 significant relapses in the past 24 months; and
 - Evidence of new inflammatory activity on an MR scan within the past 24 months, any of the following:
 - i) a gadolinium enhancing lesion; or
 - ii) a Diffusion Weighted Imaging positive lesion; or
 - iii) a T2 lesion with associated local swelling; or
 - iv) a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse; or
 - v) new T2 lesions compared with a previous MR scan; and
 - d) A significant relapse must:
 - a) be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
 - b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);
 - c) last at least one week;
 - d) start at least one month after the onset of a previous relapse;
 - e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least 1 point;
 - f) be distinguishable from the effects of general fatigue; and
 - g) not be associated with a fever ($T > 37.5^{\circ}\text{C}$); and
 - e) applications must be made by the patient's neurologist or general physician; and
 - f) patients must have no previous history of lack of response to teriflunomide; and
 - g) patients must have not previously had intolerance to teriflunomide; and
 - h) patient must not be co-prescribed beta interferon or glatiramer acetate.

Stopping Criteria

Any of the following:

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

continued...

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

continued...

Note: Switching between natalizumab, fingolimod, dimethyl fumarate and teriflunomide is permitted provided the EDSS stopping criteria are not met. Switching to interferon or glatiramer acetate is only permitted provided the EDSS stopping criteria are not met and both fingolimod and natalizumab are either not tolerated or treatment with both agents would be clinically inappropriate. Continued relapses on treatment would be expected to lead to a switch of treatment provided the stopping criteria are not met. If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse for recovery to occur.

Other Multiple Sclerosis Treatments

►SA1564 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

Notes: Special Authority approved by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (below). Application details may be obtained from PHARMAC's website <http://www.pharmac.govt.nz> or:

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

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

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

These agents will NOT be subsidised if dispensed from a community or hospital pharmacy. Regular supplies will be distributed to all approved patients or their clinicians by courier.

Prescribers must send quarterly prescriptions for approved patients to the MSTAC coordinator.

Only prescriptions for 6 million iu of interferon beta-1-alpha per week, or 8 million iu of interferon beta-1-beta every other day, or 20 mg glatiramer acetate daily will be subsidised.

Switching between treatments is permitted within the 12 month approval period without reapproval by MSTAC. The MSTAC coordinator should be notified of the change and a new prescription provided.

Entry Criteria

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

continued...

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
continued...			
e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least 1 point;			
f) be distinguishable from the effects of general fatigue; and			
g) not be associated with a fever ($T > 37.5^{\circ}\text{C}$); and			
e) applications must be made by the patient's neurologist; and			
f) patients must have no previous history of lack of response to beta-interferon or glatiramer acetate; and			
g) patients must have either:			
a) intolerance to both natalizumab and fingolimod; or			
b) treatment with both natalizumab and fingolimod is considered clinically inappropriate; and			
h) patient will not be co-prescribed natalizumab or fingolimod.			
Stopping Criteria			
Any of the following:			
a) Confirmed progression of disability that is sustained for six months during a minimum of one year of treatment. Progression of disability is defined as progress by any of the following EDDSS Points:			
a) from starting at EDSS 0 increasing to (i.e. stopping on reaching) EDSS 3.0; or			
b) 1.0 to 3.0; or			
c) 1.5 to 3.5; or			
d) 2.0 to 4.0; or			
e) 2.5 to 4.5; or			
f) 3.0 to 4.5; or			
g) 3.5 to 4.5; or			
h) 4.0 to 4.5.			
b) increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment)(see note); or			
c) intolerance to interferon beta-1-alpha, and/or interferon beta-1-beta and/or glatiramer acetate; or			
d) non-compliance with treatment, including refusal to undergo annual assessment.			
Note: Treatment with interferon beta -1-beta, interferon beta-1-alpha and glatiramer acetate, is permitted only if treatment with both natalizumab and fingolimod is not tolerated or treatment with both would be clinically inappropriate. Beta-interferon or glatiramer acetate will not be funded as second line treatments if EDSS progression has occurred on treatment with natalizumab or fingolimod. Patients who have an increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment) and who do not meet the EDSS Stopping Criteria at annual review may switch from either of the beta-interferon's [interferon beta-1-beta or interferon beta-1-alpha] to glatiramer acetate or vice versa. Patients may switch from either of the beta-interferon's [interferon beta-1-beta or interferon beta-1-alpha] to glatiramer acetate or vice versa for increased relapses only once, after which they will be required to stop funded treatment if they meet any of the Stopping Criteria at annual review (including the criterion relating to increasing relapse rate over 12 months of treatment). If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse for recovery to occur. In this setting anti-JCV antibody positive status may be accepted as a clinically inappropriate reason for treatment with natalizumab.			
GLATIRAMER ACETATE – Special Authority see SA1564 on the previous page – [Xpharm]			
Inj 20 mg prefilled syringe	1,089.25	28	✓ Copaxone
INTERFERON BETA-1-ALPHA – Special Authority see SA1564 on the previous page – [Xpharm]			
Inj 6 million iu prefilled syringe	1,170.00	4	✓ Avonex
Injection 6 million iu per 0.5 ml pen injector	1,170.00	4	✓ Avonex Pen
Inj 6 million iu per vial	1,170.00	4	✓ Avonex
<i>(Avonex Inj 6 million iu per vial to be delisted 1 September 2017)</i>			
INTERFERON BETA-1-BETA – Special Authority see SA1564 on the previous page – [Xpharm]			
Inj 8 million iu per 1 ml	1,322.89	15	✓ Betaferon

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

LORMETAZEPAM – Safety medicine; prescriber may determine dispensing frequency

Tab 1 mg	3.11	30	
	(23.50)		Noctamid

‡ Safety cap for extemporaneously compounded oral liquid preparations.

MIDAZOLAM – Safety medicine; prescriber may determine dispensing frequency

Inj 1 mg per ml, 5 ml ampoule	4.30	10	✓ Hypnovel
	10.00		✓ Midazolam-Clarix
			✓ Pfizer
Inj 5 mg per ml, 3 ml ampoule	2.50	5	✓ Hypnovel
			✓ Midazolam-Clarix
	11.90		✓ Pfizer

(Hypnovel Inj 1 mg per ml, 5 ml ampoule to be delisted 1 August 2017)

(Hypnovel Inj 5 mg per ml, 3 ml ampoule to be delisted 1 July 2017)

NITRAZEPAM – Safety medicine; prescriber may determine dispensing frequency

Tab 5 mg	5.22	100	✓ <u>Nitrados</u>
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‡ Safety cap for extemporaneously compounded oral liquid preparations.

PHENOBARBITONE SODIUM – Special Authority see SA1386 below – Retail pharmacy

Inj 200 mg per ml, 1 ml ampoule	46.20	10	✓ <u>Martindale</u> <small>S29</small>
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►SA1386 Special Authority for Subsidy

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

Both:

- 1 For the treatment of terminal agitation that is unresponsive to other agents; and
- 2 The applicant is part of a multidisciplinary team working in palliative care.

TEMAZEPAM – Safety medicine; prescriber may determine dispensing frequency

Tab 10 mg	1.27	25	✓ <u>Normison</u>
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‡ Safety cap for extemporaneously compounded oral liquid preparations.

TRIAZOLAM – Safety medicine; prescriber may determine dispensing frequency

Tab 125 mcg	5.10	100	
	(9.85)		Hypam

‡ Safety cap for extemporaneously compounded oral liquid preparations.

Tab 250 mcg	4.10	100	
	(11.20)		Hypam

‡ Safety cap for extemporaneously compounded oral liquid preparations.

ZOPICLONE – Safety medicine; prescriber may determine dispensing frequency

Tab 7.5 mg	8.99	500	✓ <u>Zopiclone Actavis</u>
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Stimulants/ADHD Treatments

ATOMOXETINE – Special Authority see SA1416 on the next page – Retail pharmacy

Cap 10 mg	107.03	28	✓ <u>Strattera</u>
Cap 18 mg	107.03	28	✓ <u>Strattera</u>
Cap 25 mg	107.03	28	✓ <u>Strattera</u>
Cap 40 mg	107.03	28	✓ <u>Strattera</u>
Cap 60 mg	107.03	28	✓ <u>Strattera</u>
Cap 80 mg	139.11	28	✓ <u>Strattera</u>
Cap 100 mg	139.11	28	✓ <u>Strattera</u>

‡ safety cap

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

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

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

►SA1416 Special Authority for Subsidy

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

All of the following:

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

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

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

DEXAMFETAMINE SULFATE – Special Authority see SA1149 below – Retail pharmacy

a) Only on a controlled drug form

b) Safety medicine; prescriber may determine dispensing frequency

Tab 5 mg 17.00 100 ✓ **PSM**

►SA1149 Special Authority for Subsidy

Initial application — (ADHD in patients 5 or over) only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

All of the following:

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

Initial application — (ADHD in patients under 5) only from a paediatrician or psychiatrist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

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

Initial application — (Narcolepsy) only from a neurologist or respiratory specialist. Approvals valid for 24 months where the patient suffers from narcolepsy.

Renewal — (ADHD in patients 5 or over) only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and

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

2 Either:

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

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

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

METHYLPHENIDATE HYDROCHLORIDE – Special Authority see SA1150 below – Retail pharmacy

a) Only on a controlled drug form			
b) Safety medicine; prescriber may determine dispensing frequency			
Tab immediate-release 5 mg	3.20	30	✓ Rubifen
Tab immediate-release 10 mg	3.00	30	✓ Ritalin
			✓ Rubifen
Tab immediate-release 20 mg	7.85	30	✓ Rubifen
Tab sustained-release 20 mg	10.95	30	✓ Rubifen SR
	50.00	100	✓ Ritalin SR

►SA1150 Special Authority for Subsidy

Initial application — (ADHD in patients 5 or over) only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

All of the following:

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

Initial application — (ADHD in patients under 5) only from a paediatrician or psychiatrist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

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

Initial application — (Narcolepsy) only from a neurologist or respiratory specialist. Approvals valid for 24 months where the patient suffers from narcolepsy.

Renewal — (ADHD in patients 5 or over) only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 Either:
 - 2.1 Applicant is a paediatrician or psychiatrist; or
 - 2.2 Applicant is a medical practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing.

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

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

‡ safety cap

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

▲Three months supply may be dispensed at one time

if endorsed "certified exemption" by the prescriber or pharmacist.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE – Special Authority see SA1151 below – Retail pharmacy				
a) Only on a controlled drug form				
b) Safety medicine; prescriber may determine dispensing frequency				
Tab extended-release 18 mg	58.96	30	✓	Concerta
Tab extended-release 27 mg	65.44	30	✓	Concerta
Tab extended-release 36 mg	71.93	30	✓	Concerta
Tab extended-release 54 mg	86.24	30	✓	Concerta
Cap modified-release 10 mg	15.60	30	✓	Ritalin LA
Cap modified-release 20 mg	20.40	30	✓	Ritalin LA
Cap modified-release 30 mg	25.52	30	✓	Ritalin LA
Cap modified-release 40 mg	30.60	30	✓	Ritalin LA

►SA1151 Special Authority for Subsidy

Initial application only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

All of the following:

- 1 ADHD (Attention Deficit and Hyperactivity Disorder); and
- 2 Diagnosed according to DSM-IV or ICD 10 criteria; and
- 3 Either:
 - 3.1 Applicant is a paediatrician or psychiatrist; or
 - 3.2 Applicant is a medical practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing; and
- 4 Either:
 - 4.1 Patient is taking a currently subsidised formulation of methylphenidate hydrochloride (immediate-release or sustained-release) which has not been effective due to significant administration and/or compliance difficulties; or
 - 4.2 There is significant concern regarding the risk of diversion or abuse of immediate-release methylphenidate hydrochloride.

Renewal only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 Either:
 - 2.1 Applicant is a paediatrician or psychiatrist; or
 - 2.2 Applicant is a medical practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing.

MODAFINIL – Special Authority see SA1126 below – Retail pharmacy

Tab 100 mg	72.50	30	✓	Modavigil
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►SA1126 Special Authority for Subsidy

Initial application only from a neurologist or respiratory specialist. Approvals valid for 24 months for applications meeting the following criteria:

All of the following:

- 1 The patient has a diagnosis of narcolepsy and has excessive daytime sleepiness associated with narcolepsy occurring almost daily for three months or more; and
- 2 Either:
 - 2.1 The patient has a multiple sleep latency test with a mean sleep latency of less than or equal to 10 minutes and 2 or more sleep onset rapid eye movement periods; or
 - 2.2 The patient has at least one of: cataplexy, sleep paralysis or hypnagogic hallucinations; and

continued...

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

3 Either:

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

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

Treatments for Dementia

DONEPEZIL HYDROCHLORIDE

* Tab 5 mg	5.48	90	✓ Donepezil-Rex
* Tab 10 mg	10.51	90	✓ Donepezil-Rex

RIVASTIGMINE – Special Authority see SA1488 below – Retail pharmacy

Patch 4.6 mg per 24 hour	90.00	30	✓ Exelon
Patch 9.5 mg per 24 hour	90.00	30	✓ Exelon

▶SA1488 Special Authority for Subsidy

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

Both:

- 1 The patient has been diagnosed with dementia; and
- 2 The patient has experienced intolerable nausea and/or vomiting from donepezil tablets.

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

Both:

- 1 The treatment remains appropriate; and
- 2 The patient has demonstrated a significant and sustained benefit from treatment.

Treatments for Substance Dependence

BUPRENORPHINE WITH NALOXONE – Special Authority see SA1203 below – Retail pharmacy

a) No patient co-payment payable			
b) Safety medicine; prescriber may determine dispensing frequency			
Tab sublingual 2 mg with naloxone 0.5 mg	57.40	28	✓ Suboxone
Tab sublingual 8 mg with naloxone 2 mg	166.00	28	✓ Suboxone

▶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.

continued...

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

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

BUPROPION HYDROCHLORIDE

Tab modified-release 150 mg	11.00	30	✓ Zyban
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DISULFIRAM

Tab 200 mg	44.30	100	✓ Antabuse
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NALTREXONE HYDROCHLORIDE – Special Authority see SA1408 below – Retail pharmacy

Tab 50 mg	131.00	30	✓ Naltracord
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►SA1408 Special Authority for Subsidy

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

Both:

- 1 Patient is currently enrolled in a recognised comprehensive treatment programme for alcohol dependence; and
- 2 Applicant works in or with a community Alcohol and Drug Service contracted to one of the District Health Boards or accredited against the New Zealand Alcohol and Other Drug Sector Standard or the National Mental Health Sector Standard.

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

Both:

- 1 Compliance with the medication (prescriber determined); and
- 2 Any of the following:
 - 2.1 Patient is still unstable and requires further treatment; or
 - 2.2 Patient achieved significant improvement but requires further treatment; or
 - 2.3 Patient is well controlled but requires maintenance therapy.

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

Nicotine will not be funded under the Dispensing Frequency Rule in amounts less than 4 weeks of treatment.

Patch 7 mg – Up to 28 patch available on a PSO	10.57	28	✓ Habitrol
Patch 14 mg – Up to 28 patch available on a PSO	11.31	28	✓ Habitrol
Patch 21 mg – Up to 28 patch available on a PSO	11.95	28	✓ Habitrol
Lozenge 1 mg – Up to 216 loz available on a PSO	12.91	216	✓ Habitrol
Lozenge 2 mg – Up to 216 loz available on a PSO	14.14	216	✓ Habitrol
Gum 2 mg (Fruit) – Up to 384 piece available on a PSO	22.26	384	✓ Habitrol
Gum 2 mg (Mint) – Up to 384 piece available on a PSO	22.26	384	✓ Habitrol
Gum 4 mg (Fruit) – Up to 384 piece available on a PSO	25.67	384	✓ Habitrol
Gum 4 mg (Mint) – Up to 384 piece available on a PSO	25.67	384	✓ Habitrol

VARENICLINE TARTRATE – Special Authority see SA1575 below – Retail pharmacy

a) Varenicline will not be funded under the Dispensing Frequency Rule in amounts less than 2 weeks of treatment.

b) A maximum of 12 weeks' varenicline will be subsidised on each Special Authority approval, including the starter pack

Tab 1 mg	67.74	28	✓ Champix
	135.48	56	✓ Champix
Tab 0.5 mg × 11 and 1 mg × 14	60.48	25 OP	✓ Champix

▶SA1575 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:

- Short-term therapy as an aid to achieving abstinence in a patient who has indicated that they are ready to cease smoking; and
- 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
- Either:
 - 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
 - The patient has tried but failed to quit smoking using bupropion or nortriptyline; and
- The patient has not used funded varenicline in the last 12 months; and
- Varenicline is not to be used in combination with other pharmacological smoking cessation treatments and the patient has agreed to this; and
- The patient is not pregnant; and
- 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:

- Short-term therapy as an aid to achieving abstinence in a patient who has indicated that they are ready to cease smoking; and
- 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
- The patient has not used funded varenicline in the last 12 months; and
- Varenicline is not to be used in combination with other pharmacological smoking cessation treatments and the patient has agreed to this; and
- The patient is not pregnant; and
- The patient will not be prescribed more than 12 weeks' funded varenicline (see note).

The patient must not have had an approval in the past 12 months.

Notes: a maximum of 12 weeks' varenicline will be subsidised on each Special Authority approval.

This includes the 2-week 'starter' pack.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Chemotherapeutic Agents				
Alkylating Agents				
BUSULFAN – PCT – Retail pharmacy-Specialist				
Tab 2 mg	89.25	100	✓	Myleran
CARBOPLATIN – PCT only – Specialist				
Inj 10 mg per ml, 5 ml vial	15.07	1	✓	DBL Carboplatin
	20.00		✓	Carboplatin Ebewe
Inj 10 mg per ml, 15 ml vial	14.05	1	✓	DBL Carboplatin
	19.50		✓	Carbaccord
	22.50		✓	Carboplatin Ebewe
Inj 10 mg per ml, 45 ml vial	32.59	1	✓	DBL Carboplatin
	48.50		✓	Carbaccord
	50.00		✓	Carboplatin Ebewe
Inj 1 mg for ECP	0.08	1 mg	✓	Baxter
CARMUSTINE – PCT only – Specialist				
Inj 100 mg vial	532.00	1	✓	BiCNU
Inj 100 mg for ECP	532.00	100 mg OP	✓	Baxter
CHLORAMBUCIL – PCT – Retail pharmacy-Specialist				
Tab 2 mg	29.06	25	✓	Leukeran FC
CISPLATIN – PCT only – Specialist				
Inj 1 mg per ml, 50 ml vial	12.29	1	✓	DBL Cisplatin
	15.00		✓	Cisplatin Ebewe
Inj 1 mg per ml, 100 ml vial	21.00	1	✓	Cisplatin Ebewe
	22.46		✓	DBL Cisplatin
Inj 1 mg for ECP	0.28	1 mg	✓	Baxter
CYCLOPHOSPHAMIDE				
Tab 50 mg – PCT – Retail pharmacy-Specialist	79.00	50	✓	Endoxan ^{\$29}
	158.00	100	✓	Procytox ^{\$29}
Wastage claimable – see rule 3.3.2 on page 13				
Inj 1 g vial – PCT – Retail pharmacy-Specialist	35.03	1	✓	Endoxan
	127.80	6	✓	Cytoxan
Inj 2 g vial – PCT only – Specialist	70.06	1	✓	Endoxan
Inj 1 mg for ECP – PCT only – Specialist	0.04	1 mg	✓	Baxter
IFOSFAMIDE – PCT only – Specialist				
Inj 1 g	96.00	1	✓	Holoxan
Inj 2 g	180.00	1	✓	Holoxan
Inj 1 mg for ECP	0.10	1 mg	✓	Baxter
LOMUSTINE – PCT – Retail pharmacy-Specialist				
Cap 10 mg	132.59	20	✓	CeeNU
Cap 40 mg	399.15	20	✓	CeeNU
MELPHALAN				
Tab 2 mg – PCT – Retail pharmacy-Specialist	40.70	25	✓	Alkeran
Inj 50 mg – PCT only – Specialist	67.80	1	✓	Alkeran
	3,068.83		✓	Mylan
				Melphalan ^{\$29}

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
OXALIPLATIN – PCT only – Specialist				
Inj 5 mg per ml, 10 ml vial	13.32	1	✓	Oxalliccord
Inj 50 mg vial	15.32	1	✓	Oxaliplatin Actavis 50
	55.00		✓	Oxaliplatin Ebewe
	200.00		✓	Eloxatin
Inj 100 mg vial	25.01	1	✓	Oxaliplatin Actavis 100
	110.00		✓	Oxaliplatin Ebewe
	400.00		✓	Eloxatin
Inj 5 mg per ml, 20 ml vial	16.00	1	✓	Oxalliccord
Inj 1 mg for ECP	0.18	1 mg	✓	Baxter
<i>(Eloxatin Inj 50 mg vial to be delisted 1 April 2017)</i>				
<i>(Eloxatin Inj 100 mg vial to be delisted 1 April 2017)</i>				
THIOTEPA – PCT only – Specialist				
Inj 15 mg vial	CBS	1	✓	Bedford ^{\$29}
			✓	THIO-TEPA ^{\$29}
			✓	Tepadina ^{\$29}
Inj 100 mg vial	CBS	1	✓	Tepadina ^{\$29}

Antimetabolites

AZACITIDINE – PCT only – Specialist – Special Authority see SA1467 below

Inj 100 mg vial	605.00	1	✓	Vidaza
Inj 1 mg for ECP	6.66	1 mg	✓	Baxter

►SA1467 Special Authority for Subsidy

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

All of the following:

- Any of the following:
 - The patient has International Prognostic Scoring System (IPSS) intermediate-2 or high risk myelodysplastic syndrome; or
 - The patient has chronic myelomonocytic leukaemia (10%-29% marrow blasts without myeloproliferative disorder); or
 - The patient has acute myeloid leukaemia with 20-30% blasts and multi-lineage dysplasia, according to World Health Organisation Classification (WHO); and
- The patient has performance status (WHO/ECOG) grade 0-2; and
- The patient does not have secondary myelodysplastic syndrome resulting from chemical injury or prior treatment with chemotherapy and/or radiation for other diseases; and
- 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:

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

‡ safety cap

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

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

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
CALCIUM FOLINATE				
Tab 15 mg – PCT – Retail pharmacy-Specialist.....	104.26	10	✓	DBL Leucovorin Calcium
Inj 3 mg per ml, 1 ml – PCT – Retail pharmacy-Specialist	17.10	5	✓	Hospira
Inj 50 mg – PCT – Retail pharmacy-Specialist.....	18.25	5	✓	Calcium Folate Ebewe
Inj 100 mg – PCT only – Specialist.....	7.33	1	✓	Calcium Folate Ebewe
Inj 300 mg – PCT only – Specialist.....	22.51	1	✓	Calcium Folate Ebewe
Inj 1 g – PCT only – Specialist.....	67.51	1	✓	Calcium Folate Ebewe
Inj 1 mg for ECP – PCT only – Specialist	0.06	1 mg	✓	Baxter
CAPECITABINE – Retail pharmacy-Specialist				
Tab 150 mg	11.15	60	✓	Brinov
			✓	Capecitabine Winthrop
Brinov to be Sole Supply on 1 April 2017				
Tab 500 mg	62.28	120	✓	Brinov
			✓	Capecitabine Winthrop
Brinov to be Sole Supply on 1 April 2017				
<i>(Capecitabine Winthrop Tab 150 mg to be delisted 1 April 2017)</i>				
<i>(Capecitabine Winthrop Tab 500 mg to be delisted 1 April 2017)</i>				
CLADRIBINE – PCT only – Specialist				
Inj 1 mg per ml, 10 ml	5,249.72	7	✓	Leustatin
Inj 10 mg for ECP	749.96	10 mg OP	✓	Baxter
CYTARABINE				
Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specialist	55.00	5	✓	Pfizer
	80.00		✓	Hospira
Inj 500 mg – PCT – Retail pharmacy-Specialist.....	18.15	1	✓	Pfizer
	95.36	5	✓	Hospira
Inj 100 mg per ml, 10 ml vial – PCT – Retail pharmacy-Specialist.....	8.83	1	✓	Pfizer
	42.65		✓	Hospira
Inj 100 mg per ml, 20 ml vial – PCT – Retail pharmacy-Specialist.....	17.65	1	✓	Pfizer
	34.47		✓	Hospira
Inj 1 mg for ECP – PCT only – Specialist	0.11	10 mg	✓	Baxter
Inj 100 mg intrathecal syringe for ECP – PCT only – Specialist	11.00	100 mg OP	✓	Baxter
<i>(Pfizer Inj 500 mg to be delisted 1 September 2017)</i>				
FLUDARABINE PHOSPHATE				
Tab 10 mg – PCT – Retail pharmacy-Specialist.....	412.00	20	✓	Fludara Oral
Inj 50 mg vial – PCT only – Specialist	525.00	5	✓	Fludarabine Ebewe
	1,430.00		✓	Fludara
Inj 50 mg for ECP – PCT only – Specialist.....	105.00	50 mg OP	✓	Baxter
<i>(Fludara Inj 50 mg vial to be delisted 1 April 2017)</i>				

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
FLUOROURACIL				
Inj 50 mg per ml, 20 ml vial – PCT only – Specialist	10.00	1	✓	Fluorouracil Ebewe
Inj 50 mg per ml, 50 ml vial – PCT only – Specialist	17.00	1	✓	Fluorouracil Ebewe
Inj 50 mg per ml, 100 ml vial – PCT only – Specialist	30.00	1	✓	Fluorouracil Ebewe
Inj 1 mg for ECP – PCT only – Specialist	0.66	100 mg	✓	Baxter
GEMCITABINE HYDROCHLORIDE – PCT only – Specialist				
Inj 1 g	15.89	1	✓	Gemcitabine Ebewe
	62.50		✓	DBL Gemcitabine
	349.20		✓	Gemzar
Inj 200 mg	8.36	1	✓	Gemcitabine Ebewe
	78.00		✓	Gemzar
Inj 1 mg for ECP	0.02	1 mg	✓	Baxter
IRINOTECAN HYDROCHLORIDE – PCT only – Specialist				
Inj 20 mg per ml, 2 ml vial	11.50	1	✓	Irinotecan Actavis 40
	41.00		✓	Camptosar
			✓	Irinotecan-Rex
Inj 20 mg per ml, 5 ml vial	17.80	1	✓	Irinotecan Actavis 100
	100.00		✓	Camptosar
			✓	Irinotecan-Rex
Inj 1 mg for ECP	0.19	1 mg	✓	Baxter
MERCAPTOPURINE – PCT – Retail pharmacy-Specialist				
Tab 50 mg	49.41	25	✓	Puri-nethol
METHOTREXATE				
* Tab 2.5 mg – PCT – Retail pharmacy-Specialist	3.18	30	✓	Trexate
* Tab 10 mg – PCT – Retail pharmacy-Specialist	21.00	50	✓	Trexate
* Inj 2.5 mg per ml, 2 ml – PCT – Retail pharmacy-Specialist	23.65	5	✓	Hospira
* Inj 7.5 mg prefilled syringe	14.61	1	✓	Methotrexate Sandoz
* Inj 10 mg prefilled syringe	14.66	1	✓	Methotrexate Sandoz
* Inj 15 mg prefilled syringe	14.77	1	✓	Methotrexate Sandoz
* Inj 20 mg prefilled syringe	14.88	1	✓	Methotrexate Sandoz
* Inj 25 mg prefilled syringe	14.99	1	✓	Methotrexate Sandoz
* Inj 30 mg prefilled syringe	15.09	1	✓	Methotrexate Sandoz
* Inj 25 mg per ml, 2 ml vial – PCT – Retail pharmacy-Specialist	30.00	5	✓	DBL Methotrexate Onco-Vial
* Inj 25 mg per ml, 20 ml vial – PCT – Retail pharmacy-Specialist	45.00	1	✓	DBL Methotrexate Onco-Vial
* Inj 100 mg per ml, 10 ml – PCT – Retail pharmacy-Specialist	25.00	1	✓	Methotrexate Ebewe
* Inj 100 mg per ml, 50 ml – PCT – Retail pharmacy-Specialist	99.99	1	✓	Methotrexate Ebewe
* Inj 1 mg for ECP – PCT only – Specialist	0.06	1 mg	✓	Baxter
* Inj 5 mg intrathecal syringe for ECP – PCT only – Specialist	4.73	5 mg OP	✓	Baxter

‡ safety cap

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

▲Three months supply may be dispensed at one time

if endorsed "certified exemption" by the prescriber or pharmacist.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
THIOGUANINE – PCT – Retail pharmacy-Specialist				
Tab 40 mg	126.31	25	✓	Lanvis
Other Cytotoxic Agents				
AMSACRINE – PCT only – Specialist				
Inj 50 mg per ml, 1.5 ml ampoule	1,500.00	6	✓	Amsidine ^{\$29}
Inj 75 mg	1,250.00	5	✓	AmsaLyo ^{\$29}
ANAGRELIDE HYDROCHLORIDE – PCT – Retail pharmacy-Specialist				
Cap 0.5 mg	CBS	100	✓	Agrylin ^{\$29}
			✓	Teva ^{\$29}
ARSENIC TRIOXIDE – PCT only – Specialist				
Inj 10 mg	4,817.00	10	✓	AFT ^{\$29}
BLEOMYCIN SULPHATE – PCT only – Specialist				
Inj 15,000 iu, vial	150.48	1	✓	DBL Bleomycin Sulfate
Inj 1,000 iu for ECP	11.64	1,000 iu	✓	Baxter
BORTEZOMIB – PCT only – Specialist – Special Authority see SA1576 below				
Inj 3.5 mg vial	1,892.50	1	✓	Velcade
Inj 1 mg for ECP	594.77	1 mg	✓	Baxter

➡SA1576 **Special Authority for Subsidy**

Initial application — (Treatment naive multiple myeloma/amyloidosis) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Either:
 - 1.1 The patient has treatment-naive symptomatic multiple myeloma; or
 - 1.2 The patient has treatment-naive symptomatic systemic AL amyloidosis *; and
- 2 Maximum of 9 treatment cycles.

Note: Indications marked with * are Unapproved Indications.

Initial application — (Relapsed/refractory multiple myeloma/amyloidosis) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 The patient has relapsed or refractory multiple myeloma; or
 - 1.2 The patient has relapsed or refractory systemic AL amyloidosis *; and
- 2 The patient has received only one prior front line chemotherapy for multiple myeloma or amyloidosis; and
- 3 The patient has not had prior publicly funded treatment with bortezomib; and
- 4 Maximum of 4 treatment cycles.

Note: Indications marked with * are Unapproved Indications.

Renewal — (Relapsed/refractory multiple myeloma/amyloidosis) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria:

Both:

- 1 The patient's disease obtained at least a partial response from treatment with bortezomib at the completion of cycle 4; and
- 2 Maximum of 4 further treatment cycles (making a total maximum of 8 consecutive treatment cycles).

Notes: Responding relapsed/refractory multiple myeloma patients should receive no more than 2 additional cycles of treatment beyond the cycle at which a confirmed complete response was first achieved. A line of therapy is considered to comprise either:

continued...

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
continued...				
a) a known therapeutic chemotherapy regimen and supportive treatments; or				
b) a transplant induction chemotherapy regimen, stem cell transplantation and supportive treatments.				
Refer to datasheet for recommended dosage and number of doses of bortezomib per treatment cycle.				
COLASPASE [L-ASPARAGINASE] – PCT only – Specialist				
Inj 10,000 iu	102.32	1	✓	Leunase
Inj 10,000 iu for ECP	102.32	10,000 iu OP	✓	Baxter
DACARBAZINE – PCT only – Specialist				
Inj 200 mg vial	58.06	1	✓	DBL Dacarbazine
Inj 200 mg for ECP	58.06	200 mg OP	✓	Baxter
DACTINOMYCIN [ACTINOMYCIN D] – PCT only – Specialist				
Inj 0.5 mg vial	145.00	1	✓	Cosmegen
Inj 0.5 mg for ECP	145.00	0.5 mg OP	✓	Baxter
DAUNORUBICIN – PCT only – Specialist				
Inj 2 mg per ml, 10 ml	118.72	1	✓	Pfizer
Inj 20 mg for ECP	118.72	20 mg OP	✓	Baxter
DOCETAXEL – PCT only – Specialist				
Inj 20 mg	13.70	1	✓	DBL Docetaxel
	48.75		✓	Docetaxel Sandoz
Inj 20 mg per ml, 1 ml	48.75	1	✓	Taxotere
Inj 20 mg per ml, 4 ml	195.00	1	✓	Taxotere
Inj 80 mg	29.99	1	✓	DBL Docetaxel
	195.00		✓	Docetaxel Sandoz
Inj 1 mg for ECP	0.61	1 mg	✓	Baxter
<i>(Taxotere Inj 20 mg per ml, 1 ml to be delisted 1 April 2017)</i>				
<i>(Taxotere Inj 20 mg per ml, 4 ml to be delisted 1 April 2017)</i>				
DOXORUBICIN HYDROCHLORIDE – PCT only – Specialist				
Inj 2 mg per ml, 5 ml vial	10.00	1	✓	Doxorubicin Ebewe
Inj 2 mg per ml, 25 ml vial	11.50	1	✓	Doxorubicin Ebewe
	17.00		✓	Arrow-Doxorubicin
Inj 50 mg vial	40.00	1	✓	DBL Doxorubicin
			✓	DBL Doxorubicin
			S29 S29	
Inj 2 mg per ml, 50 ml vial	23.00	1	✓	Doxorubicin Ebewe
Inj 2 mg per ml, 100 ml vial	46.00	1	✓	Doxorubicin Ebewe
	65.00		✓	Arrow-Doxorubicin
	150.00		✓	Adriamycin
Inj 1 mg for ECP	0.25	1 mg	✓	Baxter

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
EPIRUBICIN HYDROCHLORIDE – PCT only – Specialist				
Inj 2 mg per ml, 5 ml vial	25.00	1	✓	Epirubicin Ebewe
Inj 2 mg per ml, 25 ml vial	30.00	1	✓	Epirubicin Ebewe
	39.38		✓	DBL Epirubicin Hydrochloride
Inj 2 mg per ml, 50 ml vial	32.50	1	✓	Epirubicin Ebewe
	58.20		✓	DBL Epirubicin Hydrochloride
Inj 2 mg per ml, 100 ml vial	65.00	1	✓	Epirubicin Ebewe
	94.50		✓	DBL Epirubicin Hydrochloride
Inj 1 mg for ECP	0.36	1 mg	✓	Baxter
ETOPOSIDE				
Cap 50 mg – PCT – Retail pharmacy-Specialist	340.73	20	✓	Vepesid
Cap 100 mg – PCT – Retail pharmacy-Specialist	340.73	10	✓	Vepesid
Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specialist	7.90	1	✓	Rex Medical
Inj 1 mg for ECP – PCT only – Specialist	0.09	1 mg	✓	Baxter
ETOPOSIDE PHOSPHATE – PCT only – Specialist				
Inj 100 mg (of etoposide base)	40.00	1	✓	Etopophos
Inj 1 mg (of etoposide base) for ECP	0.47	1 mg	✓	Baxter
HYDROXYUREA – PCT – Retail pharmacy-Specialist				
Cap 500 mg	31.76	100	✓	Hydrea
IDARUBICIN HYDROCHLORIDE				
Inj 5 mg vial – PCT only – Specialist	125.00	1	✓	Zavedos
Inj 10 mg vial – PCT only – Specialist	250.00	1	✓	Zavedos
Inj 1 mg for ECP – PCT only – Specialist	27.75	1 mg	✓	Baxter
LENALIDOMIDE – Retail pharmacy-Specialist – Special Authority see SA1468 below				
Wastage claimable – see rule 3.3.2 on page 13				
Cap 10 mg	6,207.00	21	✓	Revlimid
Cap 25 mg	7,627.00	21	✓	Revlimid

►SA1468 Special Authority for Subsidy

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

All of the following:

- 1 Patient has relapsed or refractory multiple myeloma with progressive disease; and
- 2 Either:
 - 2.1 Lenalidomide to be used as third line* treatment for multiple myeloma; or
 - 2.2 Both:
 - 2.2.1 Lenalidomide to be used as second line treatment for multiple myeloma; and
 - 2.2.2 The patient has experienced severe (grade ≥ 3), dose limiting, peripheral neuropathy with either bortezomib or thalidomide that precludes further treatment with either of these treatments; and
- 3 Lenalidomide to be administered at a maximum dose of 25 mg/day in combination with dexamethasone.

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

Both:

- 1 No evidence of disease progression; and

continued...

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

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

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

MESNA

Tab 400 mg – PCT – Retail pharmacy-Specialist.....	273.00	50	✓ Uromitexan
Tab 600 mg – PCT – Retail pharmacy-Specialist.....	407.50	50	✓ Uromitexan
Inj 100 mg per ml, 4 ml ampoule – PCT only – Specialist.....	161.25	15	✓ Uromitexan
Inj 100 mg per ml, 10 ml ampoule – PCT only – Specialist.....	370.35	15	✓ Uromitexan
Inj 1 mg for ECP – PCT only – Specialist.....	2.69	100 mg	✓ Baxter

MITOMYCIN C – PCT only – Specialist

Inj 5 mg vial	204.08	1	✓ Arrow
Inj 1 mg for ECP	42.04	1 mg	✓ Baxter

MITOZANTRONE – PCT only – Specialist

Inj 2 mg per ml, 10 ml vial	97.50	1	✓ Mitozantrone Ebewe
Inj 1 mg for ECP	5.51	1 mg	✓ Baxter

PACLITAXEL – PCT only – Specialist

Inj 30 mg	45.00	5	✓ Paclitaxel Ebewe
Inj 100 mg	19.02	1	✓ Paclitaxel Ebewe
	91.67		✓ Paclitaxel Actavis
Inj 150 mg	26.69	1	✓ Paclitaxel Ebewe
	137.50		✓ Anzatax
			✓ Paclitaxel Actavis
Inj 300 mg	36.53	1	✓ Paclitaxel Ebewe
	275.00		✓ Anzatax
			✓ Paclitaxel Actavis
Inj 600 mg	73.06	1	✓ Paclitaxel Ebewe
Inj 1 mg for ECP	0.17	1 mg	✓ Baxter

PEGASPARGASE – PCT only – Special Authority see SA1325 below

Inj 3,750 IU per 5 ml	3,005.00	1	✓ Oncaspar ^{S29}
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►SA1325 | Special Authority for Subsidy

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

All of the following:

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

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

All of the following:

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

PENTOSTATIN [DEOXYCOFORMYCIN] – PCT only – Specialist

Inj 10 mg	CBS	1	✓ Nipent ^{S29}
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‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PROCARBAZINE HYDROCHLORIDE – PCT – Retail pharmacy-Specialist				
Cap 50 mg	498.00	50	✓	Natulan ^{S29}
TEMOZOLOMIDE – Special Authority see SA1616 below – Retail pharmacy				
Cap 5 mg	8.00 10.20	5	✓	Temaccord
			✓	Orion Temozolomide
Orion Temozolomide to be Sole Supply on 1 May 2017				
Cap 20 mg	18.30	5	✓	Orion Temozolomide
			✓	Temaccord
Orion Temozolomide to be Sole Supply on 1 May 2017				
Cap 100 mg	40.20	5	✓	Orion Temozolomide
			✓	Temaccord
Orion Temozolomide to be Sole Supply on 1 May 2017				
Cap 250 mg	96.80	5	✓	Orion Temozolomide
			✓	Temaccord
Orion Temozolomide to be Sole Supply on 1 May 2017				
(Temaccord Cap 5 mg to be delisted 1 May 2017)				
(Temaccord Cap 20 mg to be delisted 1 May 2017)				
(Temaccord Cap 100 mg to be delisted 1 May 2017)				
(Temaccord Cap 250 mg to be delisted 1 May 2017)				

►SA1616 Special Authority for Subsidy

Initial application — (high grade gliomas) only from a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Patient has newly diagnosed glioblastoma multiforme; or
 - 1.2 Patient has newly diagnosed anaplastic astrocytoma*; and
- 2 Temozolomide is to be (or has been) given concomitantly with radiotherapy; and
- 3 Following concomitant treatment temozolomide is to be used for a maximum of 5 days treatment per cycle, at a maximum dose of 200 mg/m² per day.

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

All of the following:

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

Renewal — (high grade gliomas) only from a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 Patient has glioblastoma multiforme; and
 - 1.2 The treatment remains appropriate and the patient is benefitting from treatment; or

continued...

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

continued...

2 All of the following:

- 2.1 Patient has anaplastic astrocytoma*; and
- 2.2 The treatment remains appropriate and the patient is benefitting from treatment; and
- 2.3 Adjuvant temozolomide is to be used for a maximum of 24 months.

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

Both:

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

Note: Indication marked with a * is an Unapproved Indication. Temozolomide is not subsidised for the treatment of relapsed glioblastoma multiforme.

THALIDOMIDE – PCT only – Specialist – Special Authority see SA1124 below

Cap 50 mg	378.00	28	✓ Thalomid
Cap 100 mg	756.00	28	✓ Thalomid

►SA1124 Special Authority for Subsidy

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

Either:

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

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

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

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

Indication marked with * is an Unapproved Indication.

TRETINOIN

Cap 10 mg – PCT – Retail pharmacy-Specialist	479.50	100	✓ Vesanoid
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VINBLASTINE SULPHATE

Inj 1 mg per ml, 10 ml vial – PCT – Retail pharmacy-Specialist	37.29	1	✓ Hospira
	186.46	5	✓ Hospira
Inj 1 mg for ECP – PCT only – Specialist	4.14	1 mg	✓ Baxter

VINCISTINE SULPHATE

Inj 1 mg per ml, 1 ml vial – PCT – Retail pharmacy-Specialist	74.52	5	✓ DBL Vincristine Sulfate
Inj 1 mg per ml, 2 ml vial – PCT – Retail pharmacy-Specialist	85.61	5	✓ DBL Vincristine Sulfate
Inj 1 mg for ECP – PCT only – Specialist	11.30	1 mg	✓ Baxter

VINORELBINE – PCT only – Specialist

Inj 10 mg per ml, 1 ml vial	8.00	1	✓ Navelbine
	42.00		✓ Vinorelbine Ebewe
Inj 10 mg per ml, 5 ml vial	40.00	1	✓ Navelbine
	210.00		✓ Vinorelbine Ebewe
Inj 1 mg for ECP	0.90	1 mg	✓ Baxter

‡ safety cap

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

▲Three months supply may be dispensed at one time

if endorsed "certified exemption" by the prescriber or pharmacist.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Protein-tyrosine Kinase Inhibitors				
DASATINIB – Special Authority see SA0976 below – [Xpharm]				
Tab 20 mg	3,774.06	60	✓	Sprycel
Tab 50 mg	6,214.20	60	✓	Sprycel
Tab 70 mg	7,692.58	60	✓	Sprycel
Tab 100 mg	6,214.20	30	✓	Sprycel

►SA0976 Special Authority for Subsidy

Special Authority approved by the CML/GIST Co-ordinator

Notes: Application details may be obtained from PHARMAC's website <http://www.pharmac.govt.nz>, and prescriptions should be sent to:

The CML/GIST Co-ordinator Phone: (04) 460 4990
 PHARMAC Facsimile: (04) 916 7571
 PO Box 10 254 Email: cmlgistcoordinator@pharmac.govt.nz
 Wellington

Special Authority criteria for CML - access by application

- Funded for patients with diagnosis (confirmed by a haematologist) of a chronic myeloid leukaemia (CML) in blast crisis, accelerated phase, or in chronic phase.
- Maximum dose of 140 mg/day for accelerated or blast phase, and 100 mg/day for chronic phase CML.
- Subsidised for use as monotherapy only.
- Initial approvals valid seven months.
- Subsequent approval(s) are granted on application and are valid for six months. The first reapplication (after seven months) should provide details of the haematological response. The third reapplication should provide details of the cytogenetic response after 14-18 months from initiating therapy. All other reapplications should provide details of haematological response, and cytogenetic response if such data is available. Applications to be made and subsequent prescriptions can be written by a haematologist or an oncologist.

Note: Dasatinib is indicated for the treatment of adults with chronic, accelerated or blast phase CML with resistance or intolerance to prior therapy including imatinib.

Guideline on discontinuation of treatment for patients with CML

- Prescribers should consider discontinuation of treatment if, after 6 months from initiating therapy, a patient did not obtain a haematological response as defined as any one of the following three levels of response:
 - complete haematologic response (as characterised by an absolute neutrophil count (ANC) $> 1.5 \times 10^9/L$, platelets $> 100 \times 10^9/L$, absence of peripheral blood (PB) blasts, bone marrow (BM) blasts $< 5\%$ (or FISH Ph+ 0-35% metaphases), and absence of extramedullary disease); or
 - no evidence of leukaemia (as characterised by an absolute neutrophil count (ANC) $> 1.0 \times 10^9/L$, platelets $> 20 \times 10^9/L$, absence of peripheral blood (PB) blasts, bone marrow (BM) blasts $< 5\%$ (or FISH Ph+ 0-35% metaphases), and absence of extramedullary disease); or
 - return to chronic phase (as characterised by BM and PB blasts $< 15\%$, BM and PB blasts and promyelocytes $< 30\%$, PB basophils $< 20\%$ and absence of extramedullary disease other than spleen and liver).
- Prescribers should consider discontinuation of treatment if, after 18 months from initiating therapy, a patient did not obtain a major cytogenetic response defined as 0-35% Ph+ metaphases.

ERLOTINIB – Retail pharmacy-Specialist – Special Authority see SA1577 on the next page

Tab 100 mg	764.00	30	✓	Tarceva
Tab 150 mg	1,146.00	30	✓	Tarceva

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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►SA1577 Special Authority for Subsidy

Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has locally advanced or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
- 2 There is documentation confirming that the disease expresses activating mutations of EGFR tyrosine kinase; and
- 3 Any of the following:
 - 3.1 Patient is treatment naive; or
 - 3.2 Both:
 - 3.2.1 Patient has documented disease progression following treatment with first line platinum based chemotherapy; and
 - 3.2.2 Patient has not received prior treatment with gefitinib; or
 - 3.3 Both:
 - 3.3.1 The patient has discontinued gefitinib within 12 weeks of starting treatment due to intolerance; and
 - 3.3.2 The cancer did not progress while on gefitinib; and
- 4 Erlotinib is to be given for a maximum of 3 months.

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

GEFITINIB – Retail pharmacy-Specialist – Special Authority see SA1578 below

Tab 250 mg	1,700.00	30	✓ Iressa
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►SA1578 Special Authority for Subsidy

Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has locally advanced, or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
- 2 Either:
 - 2.1 Patient is treatment naive; or
 - 2.2 Both:
 - 2.2.1 The patient has discontinued erlotinib within 12 weeks of starting treatment due to intolerance; and
 - 2.2.2 The cancer did not progress whilst on erlotinib; and
- 3 There is documentation confirming that disease expresses activating mutations of EGFR tyrosine kinase; and
- 4 Gefitinib is to be given for a maximum of 3 months.

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

IMATINIB MESILATE

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

Tab 100 mg – Special Authority see SA1460 on the next page

– [Xpharm].....	2,400.00	60	✓ Glivec
* Cap 100 mg	298.90	60	✓ Imatinib-AFT
* Cap 400 mg	597.80	30	✓ Imatinib-AFT

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

►SA1460 Special Authority for Subsidy

Special Authority approved by the CML/GIST Co-ordinator

Notes: Application details may be obtained from PHARMAC's website <http://www.pharmac.govt.nz>, and prescriptions should be sent to:

The CML/GIST Co-ordinator Phone: (04) 460 4990
 PHARMAC Facsimile: (04) 916 7571
 PO Box 10 254 Email: cmlgistoordinator@pharmac.govt.nz
 Wellington

Special Authority criteria for GIST – access by application

Funded for patients:

- With a diagnosis (confirmed by an oncologist) of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST).
- Maximum dose of 400 mg/day.
- Applications to be made and subsequent prescriptions can be written by an oncologist.
- Initial and subsequent applications are valid for one year. The re-application criterion is an adequate clinical response to the treatment with imatinib (prescriber determined).

LAPATINIB DITOSYLATE – Special Authority see SA1191 below – Retail pharmacy

Tab 250 mg	1,899.00	70	✓ Tykerb
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►SA1191 Special Authority for Subsidy

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

Either:

- All of the following:
 - The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
 - The patient has not previously received trastuzumab treatment for HER 2 positive metastatic breast cancer; and
 - Lapatinib not to be given in combination with trastuzumab; and
 - Lapatinib to be discontinued at disease progression; or
- All of the following:
 - The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
 - The patient started trastuzumab for metastatic breast cancer but discontinued trastuzumab within 3 months of starting treatment due to intolerance; and
 - The cancer did not progress whilst on trastuzumab; and
 - Lapatinib not to be given in combination with trastuzumab; and
 - Lapatinib to be discontinued at disease progression.

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

All of the following:

- The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- The cancer has not progressed at any time point during the previous 12 months whilst on lapatinib; and
- Lapatinib not to be given in combination with trastuzumab; and
- Lapatinib to be discontinued at disease progression.

NILOTINIB – Special Authority see SA1489 on the next page – Retail pharmacy

Wastage claimable – see rule 3.3.2 on page 13

Cap 150 mg	4,680.00	120	✓ Tasigna
Cap 200 mg	6,532.00	120	✓ Tasigna

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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►SA1489 Special Authority for Subsidy

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

All of the following:

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

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

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

All of the following:

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

PAZOPANIB – Special Authority see SA1190 below – Retail pharmacy

Tab 200 mg	1,334.70	30	✓ Votrient
Tab 400 mg	2,669.40	30	✓ Votrient

►SA1190 Special Authority for Subsidy

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

All of the following:

- 1 The patient has metastatic renal cell carcinoma; and
- 2 Any of the following:
 - 2.1 The patient is treatment naive; or
 - 2.2 The patient has only received prior cytokine treatment; or
 - 2.3 Both:
 - 2.3.1 The patient has discontinued sunitinib within 3 months of starting treatment due to intolerance; and
 - 2.3.2 The cancer did not progress whilst on sunitinib; and
- 3 The patient has good performance status (WHO/ECOG grade 0-2); and
- 4 The disease is of predominant clear cell histology; and
The patient has intermediate or poor prognosis defined as:
- 5 Any of the following:
 - 5.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or
 - 5.2 Haemoglobin level < lower limit of normal; or
 - 5.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or
 - 5.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or
 - 5.5 Karnofsky performance score of ≤ 70; or
 - 5.6 ≥ 2 sites of organ metastasis; and
- 6 Pazopanib to be used for a maximum of 3 months.

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

Both:

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

continued...

‡ safety cap

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

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

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

Notes: Pazopanib treatment should be stopped if disease progresses.

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

SUNITINIB – Special Authority see SA1266 below – Retail pharmacy

Cap 12.5 mg	2,315.38	28	✓ Sutent
Cap 25 mg	4,630.77	28	✓ Sutent
Cap 50 mg	9,261.54	28	✓ Sutent

►SA1266 Special Authority for Subsidy

Initial application — (RCC) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist.

Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

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

Initial application — (GIST) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist.

Approvals valid for 3 months for applications meeting the following criteria:

Both:

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

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

Both:

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

continued...

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

continued. . .

Notes: Sunitinib treatment should be stopped if disease progresses.

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

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

- Both:
- The patient has responded to treatment or has stable disease as determined by Choi's modified CT response evaluation criteria as follows:
 - 1 Any of the following:
 - 1.1 The patient has had a complete response (disappearance of all lesions and no new lesions); or
 - 1.2 The patient has had a partial response (a decrease in size of $\geq 10\%$ or decrease in tumour density in Hounsfield Units (HU) of $\geq 15\%$ 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 $\geq 10\%$ and not meeting criteria of partial response (PR) by tumour density (HU) on CT; or: new lesions, or new intratumoral nodules, or increase in the size of the existing intratumoral nodules.

Endocrine Therapy

For GnRH ANALOGUES – refer to HORMONE PREPARATIONS, Tropic Hormones, page 91

ABIRATERONE ACETATE – Retail pharmacy-Specialist – Special Authority see SA1515 below

Wastage claimable – see rule 3.3.2 on page 13

Tab 250 mg 4,276.19 120 ✓ Zytiga

►SA1515 | 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 5 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 5 months for applications meeting the following criteria:

All of the following:

continued. . .

‡ safety cap

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

▲Three months supply may be dispensed at one time

if endorsed "certified exemption" by the prescriber or pharmacist.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
continued...				
1 Significant decrease in serum PSA from baseline; and				
2 No evidence of clinical disease progression; and				
3 No initiation of taxane chemotherapy with abiraterone; and				
4 The treatment remains appropriate and the patient is benefiting from treatment.				
BICALUTAMIDE				
Tab 50 mg	4.90	28	✓	Bicalaccord
FLUTAMIDE – Retail pharmacy-Specialist				
Tab 250 mg	55.00	100	✓	Flutamin
MEGESTROL ACETATE – Retail pharmacy-Specialist				
Tab 160 mg	54.30	30	✓	Apo-Megestrol
OCTREOTIDE				
Inj 50 mcg per ml, 1 ml vial	13.50	5	✓	DBL
Inj 100 mcg per ml, 1 ml vial	22.40	5	✓	DBL
Inj 500 mcg per ml, 1 ml vial	89.40	5	✓	DBL
OCTREOTIDE LAR (SOMATOSTATIN ANALOGUE) – Special Authority see SA1016 below – Retail pharmacy				
Inj LAR 10 mg prefilled syringe	1,772.50	1	✓	Sandostatin LAR
Inj LAR 20 mg prefilled syringe	2,358.75	1	✓	Sandostatin LAR
Inj LAR 30 mg prefilled syringe	2,951.25	1	✓	Sandostatin LAR

►SA1016 Special Authority for Subsidy

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

All of the following:

- 1 The patient has nausea* and vomiting* due to malignant bowel obstruction*; and
- 2 Treatment with antiemetics, rehydration, antimuscarinic agents, corticosteroids and analgesics for at least 48 hours has failed; and
- 3 Octreotide to be given at a maximum dose 1500 mcg daily for up to 4 weeks.

Note: Indications marked with * are Unapproved Indications.

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

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

Both:

- 1 The patient has acromegaly; and
- 2 Any of the following:
 - 2.1 Treatment with surgery, radiotherapy and a dopamine agonist has failed; or
 - 2.2 Treatment with octreotide is for an interim period while awaiting the effects of radiotherapy and a dopamine agonist has failed; or
 - 2.3 The patient is unwilling, or unable, to undergo surgery and/or radiotherapy.

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

Both:

- 1 IGF1 levels have decreased since starting octreotide; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

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Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Note: In patients with Acromegaly octreotide treatment should be discontinued if IGF1 levels have not decreased after 3 months treatment. In patients treated with radiotherapy octreotide treatment should be withdrawn every 2 years, for 1 month, for assessment of remission. Octreotide treatment should be stopped where there is biochemical evidence of remission (normal IGF1 levels) following octreotide treatment withdrawal for at least 4 weeks

Initial application — (Other Indications) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

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

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

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

TAMOXIFEN CITRATE

* Tab 10 mg	17.50	100	✓ Genox
* Tab 20 mg	2.63	30	✓ Genox
	8.75	100	✓ Genox

Aromatase Inhibitors

ANASTROZOLE

* Tab 1 mg	26.55	30	✓ Aremed
			✓ Arimidex
			✓ DP-Anastrozole

EXEMESTANE

* Tab 25 mg	14.50	30	✓ <u>Pfizer Exemestane</u>
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LETROZOLE

* Tab 2.5 mg	2.95	30	✓ <u>Letrole</u>
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Immunosuppressants

Cytotoxic Immunosuppressants

AZATHIOPRINE – Retail pharmacy-Specialist

* Tab 25 mg	8.28	60	✓	Azamun
* Tab 50 mg – For azathioprine oral liquid formulation refer, page 224	13.22	100	✓	Azamun
* Inj 50 mg vial	60.00	1	✓	Imuran

MYCOPHENOLATE MOFETIL

Tab 500 mg	25.00	50	✓	Cellcept
Cap 250 mg	25.00	100	✓	Cellcept
Powder for oral liq 1 g per 5 ml – Subsidy by endorsement	187.25	165 ml OP	✓	Cellcept

Mycophenolate powder for oral liquid is subsidised only for patients unable to swallow tablets and capsules, and when the prescription is endorsed accordingly.

Fusion Proteins

ETANERCEPT – Special Authority see SA1620 below – Retail pharmacy

Inj 25 mg	799.96	4	✓	Enbrel
Inj 50 mg autoinjector	1,599.96	4	✓	Enbrel
Inj 50 mg prefilled syringe	1,599.96	4	✓	Enbrel

►SA1620 Special Authority for Subsidy

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

Either:

1 Both:

- 1.1 The patient has had an initial Special Authority approval for adalimumab for juvenile idiopathic arthritis (JIA); and
- 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
 - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for JIA; or

2 All of the following:

- 2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2.2 Patient diagnosed with Juvenile Idiopathic Arthritis (JIA); and
- 2.3 Patient has had severe active polyarticular course JIA for 6 months duration or longer; and
- 2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m² weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and
- 2.5 Both:
 - 2.5.1 Either:
 - 2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; or
 - 2.5.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and
 - 2.5.2 Physician's global assessment indicating severe disease.

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Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Initial application — (rheumatoid arthritis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for adalimumab for rheumatoid arthritis; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
 - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for rheumatoid arthritis; or
- 2 All of the following:
 - 2.1 Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
 - 2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
 - 2.3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
 - 2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with sulphasalazine and hydroxychloroquine sulphate (at maximum tolerated doses); and
 - 2.5 Any of the following:
 - 2.5.1 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of ciclosporin; or
 - 2.5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or
 - 2.5.3 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate; and
 - 2.6 Either:
 - 2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or
 - 2.6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
 - 2.7 Either:
 - 2.7.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
 - 2.7.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

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

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for adalimumab for severe chronic plaque psoriasis; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
 - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe chronic plaque psoriasis; or
- 2 All of the following:
 - 2.1 Either:

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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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- 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 15, where lesions have been present for at least 6 months from the time of initial diagnosis; or
- 2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
- 2.2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
- 2.3 A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 2.4 The most recent PASI assessment is no more than 1 month old at the time of application.

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 15, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

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

Either:

1 Both:

- 1.1 The patient has had an initial Special Authority approval for adalimumab for ankylosing spondylitis; and
- 1.2 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.

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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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Notes: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure must be no more than 1 month old at the time of initial application.

Average normal chest expansion corrected for age and gender:

18-24 years - Male: 7.0 cm; Female: 5.5 cm

25-34 years - Male: 7.5 cm; Female: 5.5 cm

35-44 years - Male: 6.5 cm; Female: 4.5 cm

45-54 years - Male: 6.0 cm; Female: 5.0 cm

55-64 years - Male: 5.5 cm; Female: 4.0 cm

65-74 years - Male: 4.0 cm; Female: 4.0 cm

75+ years - Male: 3.0 cm; Female: 2.5 cm

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

Either:

1 Both:

1.1 The patient has had an initial Special Authority approval for adalimumab for psoriatic arthritis; and

1.2 Either:

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

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

2 All of the following:

2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and

2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and

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

2.4 Either:

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

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

2.5 Any of the following:

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

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

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

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

All of the following:

1 Patient has pyoderma gangrenosum*; and

2 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate) and not received an adequate response; and

3 A maximum of 4 doses.

Note: Indications marked with * are Unapproved Indications (refer to Interpretations and Definitions).

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

Either:

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‡ safety cap

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

▲Three months supply may be dispensed at one time

if endorsed "certified exemption" by the prescriber or pharmacist.

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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- 1 Both:
 - 1.1 Either:
 - 1.1.1 The patient has had an initial Special Authority approval for adalimumab for adult-onset Still's disease (AOSD); or
 - 1.1.2 The patient has been started on tocilizumab for AOSD in a DHB hospital in accordance with the HML rules; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab and/or tocilizumab; or
 - 1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or tocilizumab such that they do not meet the renewal criteria for AOSD; or
- 2 All of the following:
 - 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and
 - 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal anti-inflammatory drugs (NSAIDs) and methotrexate; and
 - 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

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

All of the following:

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

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

All of the following:

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

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Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Renewal — (severe chronic plaque psoriasis) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Applicant is a dermatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
 - 2.1.2 Following each prior etanercept treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-treatment baseline value; or
 - 2.2 Both:
 - 2.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
 - 2.2.2 Either:
 - 2.2.2.1 Following each prior etanercept treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
 - 2.2.2.2 Following each prior etanercept treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; and
- 3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

Note: A treatment course is defined as a minimum of 12 weeks of etanercept treatment

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

All of the following:

- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 Following 12 weeks' initial treatment and for subsequent renewals, treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less; and
- 3 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and
- 4 Etanercept to be administered at doses no greater than 50 mg every 7 days.

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

All of the following:

- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 Either:
 - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or

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	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior etanercept treatment in the opinion of the treating physician; and

3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

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

All of the following:

- 1 Patient has shown clinical improvement; and
- 2 Patient continues to require treatment; and
- 3 A maximum of 4 doses.

Renewal — (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 The patient has a sustained improvement in inflammatory markers and functional status.

Immune Modulators

ANTITHYMOCYTE GLOBULIN (EQUINE) – PCT only – Specialist			
Inj 50 mg per ml, 5 ml	2,351.25	5	✓ ATGAM
BACILLUS CALMETTE-GUERIN (BCG) VACCINE – PCT only – Specialist			
Subsidised only for bladder cancer.			
Inj 2-8 × 100 million CFU	149.37	1	✓ OncoTICE

Monoclonal Antibodies

ADALIMUMAB – Special Authority see SA1621 below – Retail pharmacy			
Inj 10 mg per 0.2 ml prefilled syringe	1,599.96	2	✓ Humira
Inj 20 mg per 0.4 ml prefilled syringe	1,599.96	2	✓ Humira
Inj 40 mg per 0.8 ml prefilled pen	1,599.96	2	✓ HumiraPen
Inj 40 mg per 0.8 ml prefilled syringe	1,599.96	2	✓ Humira

(Humira Inj 10 mg per 0.2 ml prefilled syringe to be delisted 1 August 2017)

►SA1621 Special Authority for Subsidy

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

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from etanercept; or
 - 1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for rheumatoid arthritis; or
- 2 All of the following:
 - 2.1 Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and

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Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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- 2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2.3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
- 2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with sulphasalazine and hydroxychloroquine sulphate (at maximum tolerated doses); and
- 2.5 Any of the following:
 - 2.5.1 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of ciclosporin; or
 - 2.5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or
 - 2.5.3 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate; and
- 2.6 Either:
 - 2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or
 - 2.6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 2.7 Either:
 - 2.7.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
 - 2.7.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Initial application — (Crohn's disease) only from a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has severe active Crohn's disease; and
- 2 Any of the following:
 - 2.1 Patient has a Crohn's Disease Activity Index (CDAI) score of greater than or equal to 300; or
 - 2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
 - 2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
 - 2.4 Patient has an ileostomy or colostomy, and has intestinal inflammation; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and
- 4 Surgery (or further surgery) is considered to be clinically inappropriate.

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

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from etanercept; or
 - 1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for severe chronic plaque psoriasis; or
- 2 All of the following:

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2.1 Either:

2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 15, where lesions have been present for at least 6 months from the time of initial diagnosis; or

2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and

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

2.3 A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and

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

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 15, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

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

Either:

1 Both:

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

1.2 Either:

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

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

2 All of the following:

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

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

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

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

2.5 Either:

2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following Bath Ankylosing Spondylitis Metrology Index (BASMI) measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or

2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the following average normal values corrected for age and gender (see Notes); and

2.6 A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 6 on a 0-10 scale.

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Notes: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure must be no more than 1 month old at the time of initial application.

Average normal chest expansion corrected for age and gender:

18-24 years - Male: 7.0 cm; Female: 5.5 cm

25-34 years - Male: 7.5 cm; Female: 5.5 cm

35-44 years - Male: 6.5 cm; Female: 4.5 cm

45-54 years - Male: 6.0 cm; Female: 5.0 cm

55-64 years - Male: 5.5 cm; Female: 4.0 cm

65-74 years - Male: 4.0 cm; Female: 4.0 cm

75+ years - Male: 3.0 cm; Female: 2.5 cm

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

Either:

1 Both:

1.1 The patient has had an initial Special Authority approval for etanercept for psoriatic arthritis; and

1.2 Either:

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

1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for psoriatic arthritis; or

2 All of the following:

2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and

2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and

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

2.4 Either:

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

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

2.5 Any of the following:

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

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

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

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

Either:

1 Both:

1.1 The patient has had an initial Special Authority approval for etanercept for juvenile idiopathic arthritis (JIA); and

1.2 Either:

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

1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for juvenile idiopathic arthritis; or

2 All of the following:

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- 2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2.2 Patient diagnosed with JIA; and
- 2.3 Patient has had severe active polyarticular course JIA for 6 months duration or longer; and
- 2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m² weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and
- 2.5 Both:
 - 2.5.1 Either:
 - 2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; or
 - 2.5.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and
 - 2.5.2 Physician's global assessment indicating severe disease.

Initial application — (fistulising Crohn's disease) only from a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has confirmed Crohn's disease; and
- 2 Either:
 - 2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
 - 2.2 Patient has one or more rectovaginal fistula(e); and
- 3 A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application; and
- 4 The patient will be assessed for response to treatment after 4 months' adalimumab treatment (see Note).

Note: A maximum of 4 months' adalimumab will be subsidised on an initial Special Authority approval for fistulising Crohn's disease.

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

All of the following:

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

Note: Note: Indications marked with * are Unapproved Indications (refer to (Interpretations and Definitions).

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

Either:

- 1 Both:
 - 1.1 Either:
 - 1.1.1 The patient has had an initial Special Authority approval for etanercept for adult-onset Still's disease (AOSD); or
 - 1.1.2 The patient has been started on tocilizumab for AOSD in a DHB hospital in accordance with the HML rules; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
 - 1.2.2 The patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab such that they do not meet the renewal criteria for AOSD; or
- 2 All of the following:

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- 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and
- 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal anti-inflammatory drugs (NSAIDs) and methotrexate; and
- 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

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

All of the following:

- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 3 Either:
 - 3.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 3.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 4 Either:
 - 4.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
 - 4.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

Renewal — (Crohn's disease) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Applicant is a gastroenterologist; or
 - 1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Either:
 - 2.1 Either:
 - 2.1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab; or
 - 2.1.2 CDAI score is 150 or less; or
 - 2.2 Both:
 - 2.2.1 The patient has demonstrated an adequate response to treatment but CDAI score cannot be assessed; and
 - 2.2.2 Applicant to indicate the reason that CDAI score cannot be assessed; and
- 3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

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

All of the following:

- 1 Either:
 - 1.1 Applicant is a dermatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and

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2 Either:

2.1 Both:

- 2.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
- 2.1.2 Following each prior adalimumab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-adalimumab treatment baseline value; or

2.2 Both:

- 2.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and

2.2.2 Either:

- 2.2.2.1 Following each prior adalimumab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
- 2.2.2.2 Following each prior adalimumab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-adalimumab treatment baseline value; and

3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Note: A treatment course is defined as a minimum of 12 weeks adalimumab treatment

Renewal — (ankylosing spondylitis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 Either:

- 1.1 Applicant is a rheumatologist; or
- 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and

2 Following 12 weeks' initial treatment and for subsequent renewals, treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less; and

3 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and

4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

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

All of the following:

1 Either:

- 1.1 Applicant is a rheumatologist; or
- 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and

2 Either:

- 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
- 2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician; and

3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

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

All of the following:

1 Either:

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

Renewal — (fistulising Crohn's disease) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

- Both:
- 1 Either:
 - 1.1 Applicant is a gastroenterologist; or
 - 1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
 - 2 Either:
 - 2.1 The number of open draining fistulae have decreased from baseline by at least 50%; or
 - 2.2 There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain.

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

- All of the following:
- 1 Patient has shown clinical improvement; and
 - 2 Patient continues to require treatment; and
 - 3 A maximum of 4 doses.

Renewal — (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

- Both:
- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
 - 2 The patient has a sustained improvement in inflammatory markers and functional status.

OBINUTUZUMAB – PCT only – Specialist – Special Authority see SA1627 below

Inj 25 mg per ml, 40 ml vial	5,910.00	1	✓ Gazyva
Inj 1 mg for ECP	6.21	1 mg	✓ Baxter

►SA1627 Special Authority for Subsidy

Initial application — (chronic lymphocytic leukaemia) only from a haematologist. Approvals valid for 12 months for applications meeting the following criteria:

- All of the following:
- 1 The patient has progressive Binet stage A, B or C CD20+ chronic lymphocytic leukaemia requiring treatment); and
 - 2 The patient is obinutuzumab treatment naive; and

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- 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
- Patient has adequate neutrophil and platelet counts* unless the cytopenias are a consequence of marrow infiltration by CLL; and
- Patient has good performance status; and
- 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 $\geq 1.5 \times 10^9/L$ and platelets $\geq 75 \times 10^9/L$.

OMALIZUMAB – Special Authority see SA1490 below – Retail pharmacy

Inj 150 mg vial	500.00	1	✓ Xolair
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►SA1490 Special Authority for Subsidy

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

All of the following:

- Patient is over the age of 6; and
- Patient has a diagnosis of severe, life threatening asthma; and
- Past or current evidence of atopy, documented by skin prick testing or RAST; and
- Total serum human immunoglobulin E (IgE) between 76 IU/mL and 1300 IU/ml at baseline; and
- Proven compliance with optimal inhaled therapy including high dose inhaled corticosteroid (budesonide 1600 micrograms per day or fluticasone propionate 1000 micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 micrograms bd or formoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated; and
- Patient has received courses of systemic corticosteroids equivalent to at least 28 days treatment in the past 12 months, unless contraindicated or not tolerated; and
- At least four admissions to hospital for a severe asthma exacerbation over the previous 24 months with at least one of those being in the previous 12 months; and
- An Asthma Control Questionnaire (ACQ-5) score of at least 3.0 as assessed in the previous month.

Renewal only from a respiratory specialist. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- Hospital admissions have been reduced as a result of treatment; and
- A reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 1.0 from baseline; and
- A reduction in the maintenance oral corticosteroid dose of at least 50% from baseline.

PERTUZUMAB – PCT only – Specialist – Special Authority see SA1606 below

Inj 30 mg per ml, 14 ml vial	3,927.00	1	✓ Perjeta
Inj 1 mg for ECP	9.82	1 mg	✓ Baxter

►SA1606 Special Authority for Subsidy

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

All of the following:

- The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- Either:
 - 2.1 Patient is chemotherapy treatment naïve; or

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- 2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
- 3 The patient has good performance status (ECOG grade 0-1); and
- 4 Pertuzumab to be administered in combination with trastuzumab; and
- 5 Pertuzumab maximum first dose of 840 mg, followed by maximum of 420 mg every 3 weeks; and
- 6 Pertuzumab to be discontinued at disease progression.

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

Both:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 The cancer has not progressed at any time point during the previous 12 months whilst on pertuzumab and trastuzumab.

RITUXIMAB – PCT only – Specialist – Special Authority see SA1631 below

Inj 100 mg per 10 ml vial	1,075.50	2	✓ Mabthera
Inj 500 mg per 50 ml vial	2,688.30	1	✓ Mabthera
Inj 1 mg for ECP	5.64	1 mg	✓ Baxter

►SA1631 Special Authority for Subsidy

Initial application — (Post-transplant) 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 B-cell post-transplant lymphoproliferative disorder*; and
- 2 To be used for a maximum of 8 treatment cycles.

Note: Indications marked with * are Unapproved Indications.

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

Either:

- 1 Both:
 - 1.1 The patient has indolent low grade NHL or hairy cell leukaemia* with relapsed disease following prior chemotherapy; and
 - 1.2 To be used for a maximum of 6 treatment cycles; or
- 2 Both:
 - 2.1 The patient has indolent, low grade lymphoma or hairy cell leukaemia* requiring first-line systemic chemotherapy; and
 - 2.2 To be used for a maximum of 6 treatment cycles.

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

Initial application — (Aggressive CD20 positive NHL) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Either:

- 1 All of the following:
 - 1.1 The patient has 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:

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‡ safety cap

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

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

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- 2.1 The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy; and
- 2.2 To be used for a maximum of 6 treatment cycles.

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

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

All of the following:

- 1 The patient has progressive Binet stage A, B or C chronic lymphocytic leukaemia (CLL) requiring treatment; and
- 2 The patient is rituximab treatment naive; and
- 3 Either:
 - 3.1 The patient is chemotherapy treatment naive; or
 - 3.2 Both:
 - 3.2.1 The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment; and
 - 3.2.2 The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy; and
- 4 The patient has good performance status; and
- 5 The patient has good renal function (creatinine clearance \geq 30 ml/min); and
- 6 The patient does not have chromosome 17p deletion CLL; and
- 7 Rituximab to be administered in combination with fludarabine and cyclophosphamide for a maximum of 6 treatment cycles; and
- 8 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration).

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with rituximab is expected to improve symptoms and improve ECOG score to <2 .

Renewal — (Post-transplant) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had a rituximab treatment-free interval of 12 months or more; and
- 2 The patient has B-cell post-transplant lymphoproliferative disorder*; and
- 3 To be used for no more than 6 treatment cycles.

Note: Indications marked with * are Unapproved Indications.

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

All of the following:

- 1 The patient has 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. *Hairy cell leukaemia includes hairy cell leukaemia variant *Unapproved indication.

Renewal — (Aggressive CD20 positive NHL) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had a rituximab treatment-free interval of 12 months or more; and
- 2 The patient has relapsed refractory/aggressive CD20 positive NHL; and
- 3 To be used with a multi-agent chemotherapy regimen given with curative intent; and

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

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

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

Renewal — (Chronic Lymphocytic Leukaemia) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and
- 2 The patient has had a rituximab treatment-free interval of 36 months or more; and
- 3 The patient does not have chromosome 17p deletion CLL; and
- 4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration); and
- 5 Rituximab to be administered in combination with fludarabine and cyclophosphamide 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.

SILTUXIMAB – Special Authority see SA1596 below – Retail pharmacy

Note: Siltuximab is to be administered at doses no greater than 11 mg/kg every 3 weeks.

Inj 100 mg vial	770.57	1	✓ Sylvant
Inj 400 mg vial	3,082.33	1	✓ Sylvant

►SA1596 | Special Authority for Subsidy

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

All of the following:

- 1 Patient has severe HHV-8 negative idiopathic multicentric Castleman's Disease; and
- 2 Treatment with an adequate trial of corticosteroids has proven ineffective; and
- 3 Siltuximab is to be administered at doses no greater than 11 mg/kg every 3 weeks.

Renewal only from a haematologist or rheumatologist. Approvals valid for 12 months where the treatment remains appropriate and the patient has sustained improvement in inflammatory markers and functional status.

TRASTUZUMAB – PCT only – Specialist – Special Authority see SA1632 below

Inj 150 mg vial	1,350.00	1	✓ Herceptin
Inj 440 mg vial	3,875.00	1	✓ Herceptin
Inj 1 mg for ECP	9.36	1 mg	✓ Baxter

►SA1632 | Special Authority for Subsidy

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

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 Either:
 - 2.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
 - 2.2 Both:
 - 2.2.1 The patient started lapatinib treatment for metastatic breast cancer but discontinued lapatinib within 3 months of starting treatment due to intolerance; and
 - 2.2.2 The cancer did not progress whilst on lapatinib; and
- 3 Either:
 - 3.1 Trastuzumab will not be given in combination with pertuzumab; or
 - 3.2 All of the following:

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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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- 3.2.1 Trastuzumab to be administered in combination with pertuzumab; and
- 3.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
- 3.2.3 The patient has good performance status (ECOG grade 0-1); and
- 4 Trastuzumab not to be given in combination with lapatinib; and
- 5 Trastuzumab to be discontinued at disease progression.

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

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
- 3 Trastuzumab not to be given in combination with lapatinib; and
- 4 Trastuzumab to be discontinued at disease progression.

Initial application — (early breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 15 months for applications meeting the following criteria:

All of the following:

- 1 The patient has early breast cancer expressing HER 2 IHC 3+ or ISH + (including FISH or other current technology); and
- 2 Maximum cumulative dose of 106 mg/kg (12 months' treatment); and
- 3 Any of the following:
 - 3.1 9 weeks' concurrent treatment with adjuvant chemotherapy is planned; or
 - 3.2 12 months' concurrent treatment with adjuvant chemotherapy is planned; or
 - 3.3 12 months' sequential treatment following adjuvant chemotherapy is planned; or
 - 3.4 12 months' treatment with neoadjuvant and adjuvant chemotherapy is planned; or
 - 3.5 Other treatment regimen, in association with adjuvant chemotherapy, is planned.

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

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 The patient received prior adjuvant trastuzumab treatment for early breast cancer; and
- 3 Any of the following:
 - 3.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
 - 3.2 Both:
 - 3.2.1 The patient started lapatinib treatment for metastatic breast cancer but discontinued lapatinib within 3 months of starting treatment due to intolerance; and
 - 3.2.2 The cancer did not progress whilst on lapatinib; or
 - 3.3 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
- 4 Either:
 - 4.1 Trastuzumab will not be given in combination with pertuzumab; or
 - 4.2 All of the following:
 - 4.2.1 Trastuzumab to be administered in combination with pertuzumab; and
 - 4.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and

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Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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4.2.3 The patient has good performance status (ECOG grade 0-1); and

- 5 Trastuzumab not to be given in combination with lapatinib; and
- 6 Trastuzumab to be discontinued at disease progression.

Note: * For patients with relapsed HER-2 positive disease who have previously received adjuvant trastuzumab for early breast cancer.

Programmed Cell Death-1 (PD-1) Inhibitors

NIVOLUMAB – PCT only – Specialist – Special Authority see SA1617 below

Inj 10 mg per ml, 4 ml vial	1,051.98	1	✓ Opdivo
Inj 10 mg per ml, 10 ml vial	2,629.96	1	✓ Opdivo
Inj 1 mg for ECP	27.62	1 mg	✓ Baxter

►SA1617 Special Authority for Subsidy

Initial application — (unresectable or metastatic melanoma) only from a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has metastatic or unresectable melanoma stage III or IV; and
- 2 Patient has measurable disease as defined by the presence of at least one CT or MRI measurable lesion; and
- 3 Either:
 - 3.1 Patient has not received funded pembrolizumab; or
 - 3.2 Both:
 - 3.2.1 Patient has received an initial Special Authority approval for pembrolizumab and has discontinued pembrolizumab within 12 weeks of starting treatment due to intolerance; and
 - 3.2.2 The cancer did not progress while the patient was on pembrolizumab; and
- 4 Nivolumab is to be used at a maximum dose of 3 mg/kg every 2 weeks for a maximum of 12 weeks (6 cycles); and
- 5 Baseline measurement of overall tumour burden is documented (see Note); and
- 6 Documentation confirming that the patient has been informed and acknowledges that the initial funded treatment period of nivolumab will not be continued beyond 12 weeks (6 cycles) if their disease progresses during this time.

Renewal — (unresectable or metastatic melanoma) only from a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
 - 1.1 Patient's disease has had a complete response to treatment according to RECIST criteria (see Note); or
 - 1.2 Patient's disease has had a partial response to treatment according to RECIST criteria (see Note); or
 - 1.3 Patient has stable disease according to RECIST criteria (see Note); and
- 2 Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; and
- 3 No evidence of progressive disease according to RECIST criteria (see Note); and
- 4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; and
- 5 Nivolumab will be used at a maximum dose of 3 mg/kg every 2 weeks for a maximum of 12 weeks (6 cycles).

Notes: Disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer EA, et al. Eur J Cancer 2009;45:228-47). Assessments of overall tumour burden and measurable disease to be undertaken on a minimum of one lesion and maximum of 5 target lesions (maximum two lesions per organ). Target lesions should be selected on the basis of their size (lesions with the longest diameter), be representative of all involved organs, and suitable for reproducible repeated measurements. Target lesion measurements should be assessed using CT or MRI imaging with the same method of assessment and the same technique used to characterise each identified and reported lesion at baseline and every 12 weeks. Response definitions as follows:

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‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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- Complete Response: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm.
- Partial Response: At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
- Progressive Disease: At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression).
- Stable Disease: Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease.

PEMBROLIZUMAB – PCT only – Specialist – Special Authority see SA1615 below

Inj 50 mg vial	2,340.00	1	✓ Keytruda
Inj 1 mg for ECP	49.14	1 mg	✓ Baxter

►SA1615 Special Authority for Subsidy

Initial application — (unresectable or metastatic melanoma) only from a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has metastatic or unresectable melanoma stage III or IV; and
- 2 Patient has measurable disease as defined by the presence of at least one CT or MRI measurable lesion; and
- 3 Either:
 - 3.1 Patient has not received funded nivolumab; or
 - 3.2 Both:
 - 3.2.1 Patient has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance; and
 - 3.2.2 The cancer did not progress while the patient was on nivolumab; and
- 4 Pembrolizumab is to be used at a maximum dose of 2 mg/kg every 3 weeks for a maximum of 12 weeks (4 cycles); and
- 5 Baseline measurement of overall tumour burden is documented (see Note); and
- 6 Documentation confirming that the patient has been informed and acknowledges that the initial funded treatment period of pembrolizumab will not be continued beyond 12 weeks (4 cycles) if their disease progresses during this time.

Renewal — (unresectable or metastatic melanoma) only from a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
 - 1.1 Patient's disease has had a complete response to treatment according to RECIST criteria (see Note); or
 - 1.2 Patient's disease has had a partial response to treatment according to RECIST criteria (see Note); or
 - 1.3 Patient has stable disease according to RECIST criteria (see Note); and
- 2 Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; and
- 3 No evidence of progressive disease according to RECIST criteria (see Note); and
- 4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; and
- 5 Pembrolizumab will be used at a maximum dose of 2 mg/kg every 3 weeks for a maximum of 12 weeks (4 cycles).

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Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Notes: Disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer EA, et al. Eur J Cancer 2009;45:228-47). Assessments of overall tumour burden and measurable disease to be undertaken on a minimum of one lesion and maximum of 5 target lesions (maximum two lesions per organ). Target lesions should be selected on the basis of their size (lesions with the longest diameter), be representative of all involved organs, and suitable for reproducible repeated measurements. Target lesion measurements should be assessed using CT or MRI imaging with the same method of assessment and the same technique used to characterise each identified and reported lesion at baseline and every 12 weeks. Response definitions as follows:

- Complete Response: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm.
- Partial Response: At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
- Progressive Disease: At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression).
- Stable Disease: Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease.

Other Immunosuppressants

CICLOSPORIN

Cap 25 mg	44.63	50	✓ Neoral
Cap 50 mg	88.91	50	✓ Neoral
Cap 100 mg	177.81	50	✓ Neoral
Oral liq 100 mg per ml	198.13	50 ml OP	✓ Neoral

EVEROLIMUS – Special Authority see SA1491 below – Retail pharmacy

Wastage claimable – see rule 3.3.2 on page 13

Tab 5 mg	4,555.76	30	✓ Afinitor
Tab 10 mg	6,512.29	30	✓ Afinitor

►SA1491 Special Authority for Subsidy

Initial application only from a neurologist or oncologist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 Patient has tuberous sclerosis; and
- 2 Patient has progressively enlarging sub-ependymal giant cell astrocytomas (SEGAs) that require treatment.

Renewal only from a neurologist or oncologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Documented evidence of SEGA reduction or stabilisation by MRI within the last 3 months; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment; and
- 3 Everolimus to be discontinued at progression of SEGAs.

Note: MRI should be performed at minimum once every 12 months, more frequent scanning should be performed with new onset of symptoms such as headaches, visual complaints, nausea or vomiting, or increase in seizure activity.

SIROLIMUS – Special Authority see SA0866 on the next page – Retail pharmacy

Tab 1 mg	749.99	100	✓ Rapamune
Tab 2 mg	1,499.99	100	✓ Rapamune
Oral liq 1 mg per ml	449.99	60 ml OP	✓ Rapamune

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
►SA0866 Special Authority for Subsidy				
Initial application from any medical practitioner. Approvals valid without further renewal unless notified where the drug is to be used for rescue therapy for an organ transplant recipient.				
Notes: Rescue therapy defined as unresponsive to calcineurin inhibitor treatment as defined by refractory rejection; or intolerant to calcineurin inhibitor treatment due to any of the following:				
<ul style="list-style-type: none"> • GFR<30 ml/min; or • Rapidly progressive transplant vasculopathy; or • Rapidly progressive obstructive bronchiolitis; or • HUS or TTP; or • Leukoencephalopathy; or • Significant malignant disease 				
TACROLIMUS – Special Authority see SA1540 below – Retail pharmacy				
Cap 0.5 mg	85.60	100	✓	<u>Tacrolimus Sandoz</u>
Cap 1 mg	171.20	100	✓	<u>Tacrolimus Sandoz</u>
Cap 5 mg – For tacrolimus oral liquid formulation refer, page 224	428.00	50	✓	<u>Tacrolimus Sandoz</u>

►SA1540 Special Authority for Subsidy				
Initial application — (organ transplant) only from a relevant specialist. Approvals valid without further renewal unless notified where the patient is an organ transplant recipient.				
Initial application — (steroid-resistant nephrotic syndrome*) only from a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:				
Either:				
1 The patient is a child with steroid-resistant nephrotic syndrome* (SRNS) where ciclosporin has been trialled in combination with prednisone and discontinued because of unacceptable side effects or inadequate clinical response; or				
2 All of the following:				
2.1 The patient is an adult with SRNS; and				
2.2 Ciclosporin has been trialled in combination with prednisone and discontinued because of unacceptable side effects or inadequate clinical response; and				
2.3 Cyclophosphamide or mycophenolate have been trialled and discontinued because of unacceptable side effects or inadequate clinical response, or these treatments are contraindicated.				

Note: Indications marked with * are Unapproved Indications

Note: Subsidy applies for either primary or rescue therapy.

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

Antiallergy Preparations

Allergic Emergencies

ICATIBANT – Special Authority see SA1558 below – Retail pharmacy

Inj 10 mg per ml, 3 ml prefilled syringe	2,668.00	1	✓ Firazzy
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▶SA1558 Special Authority for Subsidy

Initial application only from a clinical immunologist or relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Supply for anticipated emergency treatment of laryngeal/oro-pharyngeal or severe abdominal attacks of acute hereditary angioedema (HAE) for patients with confirmed diagnosis of C1-esterase inhibitor deficiency; and
- 2 The patient has undergone product training and has agreed upon an action plan for self-administration.

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

Allergy Desensitisation

▶SA1367 Special Authority for Subsidy

Initial application only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 RAST or skin test positive; and
- 2 Patient has had severe generalised reaction to the sensitising agent.

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

BEE VENOM ALLERGY TREATMENT – Special Authority see SA1367 above – Retail pharmacy

Maintenance kit - 6 vials 120 mcg freeze dried venom, with diluent	285.00	1 OP	✓ Venomil ^{\$29}
Treatment kit - 1 vial 550 mcg freeze dried venom, 1 diluent 9 ml, 3 diluent 1.8 ml	305.00	1 OP	✓ Albey

WASP VENOM ALLERGY TREATMENT – Special Authority see SA1367 above – Retail pharmacy

Treatment kit (Paper wasp venom) - 1 vial 550 mcg freeze dried polister venom, 1 diluent 9 ml, 1 diluent 1.8 ml	305.00	1 OP	✓ Albey
Treatment kit (Paper wasp venom) - 6 vials 120 mcg freeze dried venom, with diluent	305.00	1 OP	✓ Venomil ^{\$29}
Treatment kit (Yellow jacket venom) - 1 vial 550 mcg freeze dried vespula venom, 1 diluent 9 ml, 1 diluent 1.8 ml	305.00	1 OP	✓ Albey
Treatment kit (Yellow jacket venom) - 6 vials 120 mcg freeze dried venom, with diluent	305.00	1 OP	✓ Venomil ^{\$29}

Antihistamines

CETIRIZINE HYDROCHLORIDE

* Tab 10 mg	1.01	100	✓ Zista
*‡ Oral liq 1 mg per ml	2.99	200 ml	✓ Histaclear

CHLORPHENIRAMINE MALEATE

*‡ Oral liq 2 mg per 5 ml	8.06	500 ml	✓ Histafen
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‡ safety cap

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

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

RESPIRATORY SYSTEM AND ALLERGIES

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
DEXTROCHLORPHENIRAMINE MALEATE				
* Tab 2 mg	2.02 (8.40) 1.01 (5.99)	40 20		Polaramine
* ‡ Oral liq 2 mg per 5 ml	1.77 (10.29)	100 ml		Polaramine
FEXOFENADINE HYDROCHLORIDE				
* Tab 60 mg	4.34 (11.53)	20		Telfast
* Tab 120 mg	14.22 (29.81) 4.74 (11.53)	30 10		Telfast
LORATADINE				
* Tab 10 mg	1.28	100	✓	Lorafix
* Oral liq 1 mg per ml	2.15	120 ml	✓	Lorfast
	3.58 (4.25)	200 ml		LoraPaed
Lorfast to be Sole Supply on 1 May 2017 (LoraPaed Oral liq 1 mg per ml to be delisted 1 May 2017)				
PROMETHAZINE HYDROCHLORIDE				
* Tab 10 mg	1.78	50	✓	Allersoothe
* Tab 25 mg	1.99	50	✓	Allersoothe
* ‡ Oral liq 1 mg per 1 ml	2.59	100 ml	✓	Allersoothe
* Inj 25 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO	15.54	5	✓	Hospira
TRIMEPRAZINE TARTRATE				
‡ Oral liq 30 mg per 5 ml	2.79 (8.06)	100 ml OP		Vallergan Forte

Inhaled Corticosteroids

BECLOMETHASONE DIPROPIONATE				
Aerosol inhaler, 50 mcg per dose	9.30	200 dose OP	✓	Qvar
Aerosol inhaler, 50 mcg per dose CFC-free	8.54	200 dose OP	✓	Beclazone 50
Aerosol inhaler, 100 mcg per dose	15.50	200 dose OP	✓	Qvar
Aerosol inhaler, 100 mcg per dose CFC-free	12.50	200 dose OP	✓	Beclazone 100
Aerosol inhaler, 250 mcg per dose CFC-free	22.67	200 dose OP	✓	Beclazone 250
BUDESONIDE				
Powder for inhalation, 100 mcg per dose	17.00	200 dose OP	✓	Pulmicort Turbuhaler
Powder for inhalation, 200 mcg per dose	19.00	200 dose OP	✓	Pulmicort Turbuhaler
Powder for inhalation, 400 mcg per dose	32.00	200 dose OP	✓	Pulmicort Turbuhaler

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
FLUTICASONE				
Aerosol inhaler, 50 mcg per dose	7.50	120 dose OP	✓	Floair
Aerosol inhaler, 50 mcg per dose CFC-free	7.50	120 dose OP	✓	Flixotide
Powder for inhalation, 50 mcg per dose	7.50	60 dose OP	✓	Flixotide Accuhaler
Powder for inhalation, 100 mcg per dose	7.50	60 dose OP	✓	Flixotide Accuhaler
Aerosol inhaler, 125 mcg per dose	13.60	120 dose OP	✓	Floair
Aerosol inhaler, 125 mcg per dose CFC-free	13.60	120 dose OP	✓	Flixotide
Aerosol inhaler, 250 mcg per dose	27.20	120 dose OP	✓	Floair
Aerosol inhaler, 250 mcg per dose CFC-free	27.20	120 dose OP	✓	Flixotide
Powder for inhalation, 250 mcg per dose	13.60	60 dose OP	✓	Flixotide Accuhaler
Inhaled Long-acting Beta-adrenoceptor Agonists				
EFORMOTEROL FUMARATE				
Powder for inhalation, 6 mcg per dose, breath activated	10.32 (16.90)	60 dose OP		Oxis Turbuhaler
Powder for inhalation, 12 mcg per dose, and monodose de- vice	20.64 (35.80)	60 dose		Foradil
INDACATEROL				
Powder for inhalation 150 mcg	61.00	30 dose OP	✓	Onbrez Breezhaler
Powder for inhalation 300 mcg	61.00	30 dose OP	✓	Onbrez Breezhaler
SALMETEROL				
Aerosol inhaler CFC-free, 25 mcg per dose	25.00	120 dose OP	✓	Serevent
Aerosol inhaler 25 mcg per dose	26.46	120 dose OP	✓	Meterol
Powder for inhalation, 50 mcg per dose, breath activated	25.00	60 dose OP	✓	Serevent Accuhaler
Inhaled Corticosteroids with Long-Acting Beta-Adrenoceptor Agonists				
BUDESONIDE WITH EFORMOTEROL				
Aerosol inhaler 100 mcg with eformoterol fumarate 6 mcg	18.23	120 dose OP	✓	Vannair
Powder for inhalation 100 mcg with eformoterol fumarate 6 mcg	33.74	120 dose OP	✓	Symbicort Turbuhaler 100/6
Aerosol inhaler 200 mcg with eformoterol fumarate 6 mcg	21.40	120 dose OP	✓	Vannair
Powder for inhalation 200 mcg with eformoterol fumarate 6 mcg	44.08	120 dose OP	✓	Symbicort Turbuhaler 200/6
Powder for inhalation 400 mcg with eformoterol fumarate 12 mcg – No more than 2 dose per day	44.08	60 dose OP	✓	Symbicort Turbuhaler 400/12
FLUTICASONE FUROATE WITH VILANTEROL				
Powder for inhalation 100 mcg with vilanterol 25 mcg	44.08	30 dose OP	✓	Breo Ellipta

‡ safety cap

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

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

RESPIRATORY SYSTEM AND ALLERGIES

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
FLUTICASONE WITH SALMETEROL				
Aerosol inhaler 50 mcg with salmeterol 25 mcg	33.74	120 dose OP	✓	Seretide
	37.48		✓	RexAir
Aerosol inhaler 125 mcg with salmeterol 25 mcg	44.08	120 dose OP	✓	Seretide
	49.69		✓	RexAir
Powder for inhalation 100 mcg with salmeterol 50 mcg – No more than 2 dose per day.....	33.74	60 dose OP	✓	Seretide Accuhaler
Powder for inhalation 250 mcg with salmeterol 50 mcg – No more than 2 dose per day.....	44.08	60 dose OP	✓	Seretide Accuhaler

Beta-Adrenoceptor Agonists

SALBUTAMOL				
‡ Oral liq 400 mcg per ml	2.06	150 ml	✓	Ventolin
Infusion 1 mg per ml, 5 ml	118.38	10		
	(130.21)			Ventolin
Inj 500 mcg per ml, 1 ml – Up to 5 inj available on a PSO	12.90	5	✓	Ventolin

Inhaled Beta-Adrenoceptor Agonists

SALBUTAMOL				
Aerosol inhaler, 100 mcg per dose CFC free – Up to 1000 dose available on a PSO	3.80	200 dose OP	✓	Respigen
	(6.00)		✓	SalAir
			✓	Salamol
				Ventolin
Nebuliser soln, 1 mg per ml, 2.5 ml ampoule – Up to 30 neb available on a PSO	3.19	20	✓	Asthalin
Nebuliser soln, 2 mg per ml, 2.5 ml ampoule – Up to 30 neb available on a PSO	3.29	20	✓	Asthalin

(Salamol Aerosol inhaler, 100 mcg per dose CFC free to be delisted 1 April 2017)

TERBUTALINE SULPHATE				
Powder for inhalation, 250 mcg per dose, breath activated	22.00	200 dose OP	✓	Bricanyl Turbuhaler

Anticholinergic Agents

IPRATROPIUM BROMIDE				
Aerosol inhaler, 20 mcg per dose CFC-free – Up to 400 dose available on a PSO	16.20	200 dose OP	✓	Atrovent
Nebuliser soln, 250 mcg per ml, 1 ml ampoule – Up to 40 neb available on a PSO	3.35	20	✓	Univent
Nebuliser soln, 250 mcg per ml, 2 ml ampoule – Up to 40 neb available on a PSO	3.52	20	✓	Univent

Inhaled Beta-Adrenoceptor Agonists with Anticholinergic Agents

SALBUTAMOL WITH IPRATROPIUM BROMIDE				
Aerosol inhaler, 100 mcg with ipratropium bromide, 20 mcg per dose CFC-free	12.19	200 dose OP	✓	Duolin HFA
Nebuliser soln, 2.5 mg with ipratropium bromide 0.5 mg per vial, 2.5 ml ampoule – Up to 20 neb available on a PSO	3.59	20	✓	Duolin

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

Long-Acting Muscarinic Antagonists

GLYCOPYRRONIUM – Subsidy by endorsement

a) Inhaled glycopyrronium treatment will not be subsidised if patient is also receiving treatment with subsidised tiotropium or umeclidinium.

b) Glycopyrronium powder for inhalation 50 mcg per dose is subsidised only for patients who have been diagnosed as having COPD using spirometry, and the prescription is endorsed accordingly.

Powder for inhalation 50 mcg per dose61.00 30 dose OP ✓ **Seebri Breezhaler**

TIOTROPIUM BROMIDE – Special Authority see SA1568 below – Retail pharmacy

Tiotropium treatment will not be subsidised if patient is also receiving treatment with subsidised inhaled glycopyrronium or umeclidinium.

Powder for inhalation, 18 mcg per dose50.37 30 dose ✓ **Spiriva**

Soln for inhalation 2.5 mcg per dose50.37 60 dose OP ✓ **Spiriva Respimat**

▶SA1568 | Special Authority for Subsidy

Initial application only from a general practitioner or relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 To be used for the long-term maintenance treatment of bronchospasm and dyspnoea associated with COPD; and
- 2 In addition to standard treatment, the patient has trialled a short acting bronchodilator dose of at least 40 µg ipratropium q.i.d for one month; and
- 3 Either:

The patient's breathlessness according to the Medical Research Council (UK) dyspnoea scale is:

- 3.1 Grade 3 (stops for breath after walking about 100 meters or after a few minutes on the level); or
- 3.2 Grade 4 (too breathless to leave the house, or breathless when dressing or undressing); and

- 4 All of the following:

Applicant must state recent measurement of:

- 4.1 Actual FEV₁ (litres); and
- 4.2 Predicted FEV₁ (litres); and
- 4.3 Actual FEV₁ as a % of predicted (must be below 60%); and

- 5 Either:

- 5.1 Patient is not a smoker (for reporting purposes only); or
- 5.2 Patient is a smoker and has been offered smoking cessation counselling; and

- 6 The patient has been offered annual influenza immunisation.

Renewal only from a general practitioner or relevant specialist. 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).

UMECLIDINIUM – Subsidy by endorsement

a) Umeclidinium will not be subsidised if patient is also receiving treatment with subsidised inhaled glycopyrronium or tiotropium bromide.

b) Umeclidinium powder for inhalation 62.5 mcg per dose is subsidised only for patients who have been diagnosed as having COPD using spirometry, and the prescription is endorsed accordingly.

Powder for inhalation 62.5 mcg per dose61.50 30 dose OP ✓ **Incruse Ellipta**

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic 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 mcg81.00 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 mcg81.00 60 dose OP ✓ **Spiolto Respimat**

UMECLIDINIUM WITH VILANTEROL – Special Authority see SA1584 above – Retail pharmacy

Powder for inhalation 62.5 mcg with vilanterol 25 mcg77.00 30 dose OP ✓ **Anoro Ellipta**

Antifibrotics

PIRFENIDONE – Retail pharmacy-Specialist – Special Authority see SA1628 below

Cap 267 mg3,645.00 270 OP ✓ **Esbriet**

►SA1628 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 as confirmed by histology, CT or biopsy; and
- 2 Forced vital capacity is between 50% and 80% predicted; and
- 3 Pirfenidone is to be discontinued at disease progression (See Notes).

Renewal — (idiopathic pulmonary fibrosis) only from a respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and
- 2 Pirfenidone is to be discontinued at disease progression (See Notes).

Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

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

MONTELUKAST – Special Authority see SA1421 below – Retail pharmacy

Prescribing Guideline: Clinical evidence indicates that the effectiveness of montelukast is strongest when montelukast is used in short treatment courses.

Tab 4 mg	5.25 (18.48)	28	✓ Apo-Montelukast Singulair
Apo-Montelukast to be Sole Supply on 1 April 2017			
Tab 5 mg	5.50 (18.48)	28	✓ Apo-Montelukast Singulair
Apo-Montelukast to be Sole Supply on 1 April 2017			
Tab 10 mg	5.65 (18.48)	28	✓ Apo-Montelukast Singulair

Apo-Montelukast to be Sole Supply on 1 April 2017

(Singulair Tab 4 mg to be delisted 1 April 2017)

(Singulair Tab 5 mg to be delisted 1 April 2017)

(Singulair Tab 10 mg to be delisted 1 April 2017)

►SA1421 Special Authority for Subsidy

Initial application — (Pre-school wheeze) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 To be used for the treatment of intermittent severe wheezing (possibly viral) in children under 5 years; and
- 2 The patient has had at least three episodes in the previous 12 months of acute wheeze severe enough to seek medical attention.

Renewal — (Pre-school wheeze) from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Initial application — (exercise-induced asthma) 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 trialled with maximal asthma therapy, including inhaled corticosteroids and long-acting beta-adrenoceptor agonists; and
- 2 Patient continues to receive optimal inhaled corticosteroid therapy; and
- 3 Patient continues to experience frequent episodes of exercise-induced bronchoconstriction.

Initial application — (aspirin desensitisation) only from a clinical immunologist or allergist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

- 1 Patient is undergoing aspirin desensitisation therapy under the supervision of a Clinical Immunologist or Allergist; and
- 2 Patient has moderate to severe aspirin-exacerbated respiratory disease or Samter's triad; and
- 3 Nasal polyposis, confirmed radiologically or surgically; and
- 4 Documented aspirin or NSAID allergy confirmed by aspirin challenge or a clinical history of severe reaction to aspirin or NSAID where challenge would be considered dangerous.

Mast Cell Stabilisers

NEDOCROMIL

Aerosol inhaler, 2 mg per dose CFC-free	28.07	112 dose OP	✓ Tilade
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SODIUM CROMOGLYCATE

Powder for inhalation, 20 mg per dose	26.35	50 dose	✓ Intal Spincaps
Aerosol inhaler, 5 mg per dose CFC-free	28.07	112 dose OP	✓ Intal Forte CFC Free

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

AMINOPHYLLINE

* Inj 25 mg per ml, 10 ml ampoule – Up to 5 inj available on a PSO	118.25	5	✓	DBL Aminophylline
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THEOPHYLLINE

* Tab long-acting 250 mg	21.51	100	✓	Nuelin-SR
*‡ Oral liq 80 mg per 15 ml	15.50	500 ml	✓	Nuelin

Mucolytics

DORNASE ALFA – Special Authority see SA0611 below – Retail pharmacy Nebuliser soln, 2.5 mg per 2.5 ml ampoule	250.00	6	✓	Pulmozyme
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►SA0611 Special Authority for Subsidy

Special Authority approved by the Cystic Fibrosis Advisory Panel

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

The Co-ordinator, Cystic Fibrosis Advisory Panel	Phone: (04) 460 4990
PHARMAC, PO Box 10 254	Facsimile: (04) 916 7571
Wellington	Email: CFPanel@pharmac.govt.nz

Prescriptions for patients approved for treatment must be written by respiratory physicians or paediatricians who have experience and expertise in treating cystic fibrosis.

SODIUM CHLORIDE

Not funded for use as a nasal drop.				
Soln 7%	23.50	90 ml OP	✓	Biomed

Nasal Preparations

Allergy Prophylactics

BECLOMETHASONE DIPROPIONATE

Metered aqueous nasal spray, 50 mcg per dose	2.35 (5.26)	200 dose OP		Alanase
Metered aqueous nasal spray, 100 mcg per dose	2.46 (6.00)	200 dose OP		Alanase

BUDESONIDE

Metered aqueous nasal spray, 50 mcg per dose	2.35 (5.26)	200 dose OP		Butacort Aqueous
Metered aqueous nasal spray, 100 mcg per dose	2.61 (6.00)	200 dose OP		Butacort Aqueous

FLUTICASONE PROPIONATE

Metered aqueous nasal spray, 50 mcg per dose	2.18	120 dose OP	✓	Flixonase Hayfever & Allergy
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IPRATROPIUM BROMIDE

Aqueous nasal spray, 0.03%	3.95	15 ml OP	✓	Univent
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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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Respiratory Devices

MASK FOR SPACER DEVICE

a) Up to 20 dev available on a PSO			
b) Only on a PSO			
c) Only for children aged six years and under			
Small	2.20	1	✓ <u>e-chamber Mask</u>

PEAK FLOW METER

a) Up to 10 dev available on a PSO			
b) Only on a PSO			
Low range	9.54	1	✓ <u>Mini-Wright AFS</u> <u>Low Range</u>
Normal range	9.54	1	✓ <u>Mini-Wright</u> <u>Standard</u>

SPACER DEVICE

a) Up to 20 dev available on a PSO			
b) Only on a PSO			
220 ml (single patient)	2.95	1	✓ <u>e-chamber Turbo</u>
510 ml (single patient)	5.12	1	✓ <u>e-chamber La</u> <u>Grande</u>
800 ml	6.50	1	✓ <u>Volumatic</u>

Respiratory Stimulants

CAFFEINE CITRATE

Oral liq 20 mg per ml (10 mg base per ml)	14.85	25 ml OP	✓ <u>Biomed</u>
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‡ safety cap

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

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

Ear Preparations

ACETIC ACID WITH 1, 2- PROPANEDIOL DIACETATE AND BENZETHONIUM

For Vosol ear drops with hydrocortisone powder refer Standard Formulae, page 227

Ear drops 2% with 1, 2-Propanediol diacetate 3% and benzethonium chloride 0.02%	6.97	35 ml OP	✓ Vosol
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FLUMETASONE PIVALATE

Ear drops 0.02% with clioquinol 1%	4.46	7.5 ml OP	✓ Locacorten-Viaform ED's ✓ Locorten-Vioform
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TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCIN AND NYSTATIN

Ear drops 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 mcg per g	5.16	7.5 ml OP	✓ Kenacomb
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Ear/Eye Preparations

DEXAMETHASONE WITH FRAMYCETIN AND GRAMICIDIN

Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml	4.50 (9.27)	8 ml OP	Sofradex
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FRAMYCETIN SULPHATE

Ear/Eye drops 0.5%	4.13 (8.65)	8 ml OP	Soframycin
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Eye Preparations

Eye preparations are only funded for use in the eye, unless explicitly stated otherwise.

Anti-Infective Preparations

ACICLOVIR

* Eye oint 3%	14.92	4.5 g OP	✓ ViruPOS
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CHLORAMPHENICOL

Eye oint 1%	2.48	4 g OP	✓ Chlorsig
Eye drops 0.5%	0.98	10 ml OP	✓ Chlorafast

Funded for use in the ear*. Indications marked with * are Unapproved Indications.

CIPROFLOXACIN

Eye Drops 0.3%	12.43	5 ml OP	✓ Ciloxan
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For treatment of bacterial keratitis or severe bacterial conjunctivitis resistant to chloramphenicol.

FUSIDIC ACID

Eye drops 1%	4.50	5 g OP	✓ Fucithalmic
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GENTAMICIN SULPHATE

Eye drops 0.3%	11.40	5 ml OP	✓ Genoptic
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PROPAMIDINE ISETHIONATE

* Eye drops 0.1%	2.97 (7.99)	10 ml OP	Brolene
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TOBRAMYCIN

Eye oint 0.3%	10.45	3.5 g OP	✓ Tobrex
Eye drops 0.3%	11.48	5 ml OP	✓ Tobrex

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Corticosteroids and Other Anti-Inflammatory Preparations				
DEXAMETHASONE				
* Eye oint 0.1%	5.86	3.5 g OP	✓	Maxidex
* Eye drops 0.1%	4.50	5 ml OP	✓	Maxidex
DEXAMETHASONE WITH NEOMYCIN SULPHATE AND POLYMYXIN B SULPHATE				
* Eye oint 0.1% with neomycin sulphate 0.35% and polymyxin b sulphate 6,000 u per g	5.39	3.5 g OP	✓	Maxitrol
* Eye drops 0.1% with neomycin sulphate 0.35% and polymy- xin b sulphate 6,000 u per ml	4.50	5 ml OP	✓	Maxitrol
DICLOFENAC SODIUM				
* Eye drops 0.1%	13.80	5 ml OP	✓	Voltaren Ophtha
FLUOROMETHOLONE				
* Eye drops 0.1%	3.09	5 ml OP	✓	FML
LEVOCABASTINE				
Eye drops 0.5 mg per ml	8.71 (10.34)	4 ml OP		Livostin
LODOXAMIDE				
Eye drops 0.1%	8.71	10 ml OP	✓	Lomide
PREDNISOLONE ACETATE				
* Eye drops 1%	3.93 1.97 (4.50)	10 ml OP 5 ml OP	✓	Prednisolone-AFT Pred Forte
Prednisolone-AFT to be Sole Supply on 1 April 2017 (Pred Forte Eye drops 1% to be delisted 1 April 2017)				
PREDNISOLONE SODIUM PHOSPHATE – Special Authority see SA1547 below – Retail pharmacy				
Eye drops 0.5%, single dose (preservative free)	38.50	20 dose	✓	Minims Prednisolone

►SA1547 Special Authority for Subsidy

Initial application only from an ophthalmologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:

- 1 Patient has severe inflammation; and
- 2 Patient has a confirmed allergic reaction to preservative in eye drops.

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

SODIUM CROMOGLYCATE

Eye drops 2%0.85 5 ml OP ✓ **Rexacrom**

Glaucoma Preparations - Beta Blockers

BETAXOLOL

* Eye drops 0.25%11.80 5 ml OP ✓ **Betoptic S**
* Eye drops 0.5%7.50 5 ml OP ✓ **Betoptic**

LEVOBUNOLOL

* Eye drops 0.5%7.00 5 ml OP ✓ **Betagan**

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
TIMOLOL				
* Eye drops 0.25%	1.45	5 ml OP	✓	<u>Arrow-Timolol</u>
* Eye drops 0.25%, gel forming	3.30	2.5 ml OP	✓	<u>Timoptol XE</u>
* Eye drops 0.5%	1.45	5 ml OP	✓	<u>Arrow-Timolol</u>
* Eye drops 0.5%, gel forming	3.78	2.5 ml OP	✓	<u>Timoptol XE</u>

Glaucoma Preparations - Carbonic Anhydrase Inhibitors

ACETAZOLAMIDE

* Tab 250 mg – For acetazolamide oral liquid formulation refer, page 224	17.03	100	✓	<u>Diamox</u>
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BRINZOLAMIDE

* Eye drops 1%	9.77	5 ml OP	✓	<u>Azopt</u>
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DORZOLAMIDE HYDROCHLORIDE

* Eye drops 2%	9.77 (17.44)	5 ml OP		Trusopt
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DORZOLAMIDE WITH TIMOLOL

* Eye drops 2% with timolol 0.5%	3.45	5 ml OP	✓	<u>Arrow-Dortim</u>
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Glaucoma Preparations - Prostaglandin Analogues

BIMATOPROST

* Eye drops 0.03%	3.65	3 ml OP	✓	<u>Bimatoprost Actavis</u>
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LATANOPROST

* Eye drops 0.005%	1.50	2.5 ml OP	✓	<u>Hysite</u>
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TRAVOPROST

* Eye drops 0.004%	19.50	2.5 ml OP	✓	<u>Travatan</u>
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Glaucoma Preparations - Other

BRIMONIDINE TARTRATE

* Eye drops 0.2%	4.32	5 ml OP	✓	<u>Arrow-Brimonidine</u>
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BRIMONIDINE TARTRATE WITH TIMOLOL MALEATE

* Eye drops 0.2% with timolol maleate 0.5%	18.50	5 ml OP	✓	<u>Combigan</u>
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PILOCARPINE HYDROCHLORIDE

* Eye drops 1%	4.26	15 ml OP	✓	<u>Isopto Carpine</u>
* Eye drops 2%	5.35	15 ml OP	✓	<u>Isopto Carpine</u>
* Eye drops 4%	7.99	15 ml OP	✓	<u>Isopto Carpine</u>

Subsidised for oral use pursuant to the Standard Formulae.

* Eye drops 2% single dose – Special Authority see SA0895 below – Retail pharmacy	31.95	20 dose	✓	<u>Minims Pilocarpine</u>
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►SA0895 Special Authority for Subsidy

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

- 1 Patient has to use an unpreserved solution due to an allergy to the preservative; or
- 2 Patient wears soft contact lenses.

Note: Minims for a general practice are considered to be “tools of trade” and are not approved as special authority items.

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

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

ATROPINE SULPHATE

* Eye drops 1% 17.36 15 ml OP ✓ **Atropt**

CYCLOPENTOLATE HYDROCHLORIDE

* Eye drops 1% 8.76 15 ml OP ✓ **Cyclogyl**

TROPICAMIDE

* Eye drops 0.5% 7.15 15 ml OP ✓ **Mydriacyl**

* Eye drops 1% 8.66 15 ml OP ✓ **Mydriacyl**

Preparations for Tear Deficiency

For acetylcysteine eye drops refer Standard Formulae, page 227

HYPROMELLOSE

* Eye drops 0.5% 2.00 15 ml OP
(3.92) Methopt

HYPROMELLOSE WITH DEXTRAN

* Eye drops 0.3% with dextran 0.1% 2.30 15 ml OP ✓ **Poly-Tears**

POLYVINYL ALCOHOL

* Eye drops 1.4% 2.62 15 ml OP ✓ **Vistil**

* Eye drops 3% 3.68 15 ml OP ✓ **Vistil Forte**

Preservative Free Ocular Lubricants

►SA1388 Special Authority for Subsidy

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

Both:

- 1 Confirmed diagnosis by slit lamp of severe secretory dry eye; and
- 2 Either:
 - 2.1 Patient is using eye drops more than four times daily on a regular basis; or
 - 2.2 Patient has had a confirmed allergic reaction to preservative in eye drop.

Renewal from any relevant practitioner. Approvals valid for 24 months where the patient continues to require lubricating eye drops and has benefited from treatment.

CARBOMER – Special Authority see SA1388 above – Retail pharmacy

Ophthalmic gel 0.3%, 0.5 g 8.25 30 ✓ **Poly-Gel**

MACROGOL 400 AND PROPYLENE GLYCOL – Special Authority see SA1388 above – Retail pharmacy

Eye drops 0.4% and propylene glycol 0.3%, 0.4 ml 4.30 24 ✓ **Systane Unit Dose**

SODIUM HYALURONATE [HYALURONIC ACID] – Special Authority see SA1388 above – Retail pharmacy

Eye drops 1 mg per ml 22.00 10 ml OP ✓ **Hylo-Fresh**

Hylo-Fresh has a 6 month expiry after opening. The Pharmacy Procedures Manual restriction allowing one bottle per month is not relevant and therefore only the prescribed dosage to the nearest OP may be claimed.

Other Eye Preparations

NAPHAZOLINE HYDROCHLORIDE

* Eye drops 0.1% 4.15 15 ml OP ✓ **Naphcon Forte**

OLOPATADINE

Eye drops 0.1% 17.00 5 ml OP ✓ **Patanol**

PARAFFIN LIQUID WITH SOFT WHITE PARAFFIN

* Eye oint with soft white paraffin 3.63 3.5 g OP ✓ **Refresh Night Time**

‡ safety cap

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

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

SENSORY ORGANS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PARAFFIN LIQUID WITH WOOL FAT				
* Eye oint 3% with wool fat 3%	3.63	3.5 g OP	✓	Poly-Visc
RETINOL PALMITATE				
Eye oint 138 mcg per g	3.80	5 g OP	✓	VitA-POS

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

PHARMACY SERVICES

May only be claimed once per patient.

* Brand switch fee	4.50	1 fee	✓ BSF Lorstat ✓ BSF Sulprix
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a) The Pharmacode for BSF Lorstat is 2514206 - see also page 64

b) The Pharmacode for BSF Sulprix is 2514192 - see also page 145

(BSF Lorstat Brand switch fee to be delisted 1 May 2017)

(BSF Sulprix Brand switch fee to be delisted 1 May 2017)

Agents Used in the Treatment of Poisonings

Antidotes

ACETYLCYSTEINE – Retail pharmacy-Specialist

Inj 200 mg per ml, 10 ml ampoule	78.34	10	✓ DBL Acetylcysteine
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NALOXONE HYDROCHLORIDE

a) Up to 5 inj available on a PSO

b) Only on a PSO

* Inj 400 mcg per ml, 1 ml ampoule	48.84	5	✓ Hospira
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Removal and Elimination

CHARCOAL

* Oral liq 50 g per 250 ml	43.50	250 ml OP	✓ Carbosorb-X
a) Up to 250 ml available on a PSO			
b) Only on a PSO			

DEFERASIROX – Special Authority see SA1492 below – Retail pharmacy

Wastage claimable – see rule 3.3.2 on page 13

Tab 125 mg dispersible	276.00	28	✓ Exjade
Tab 250 mg dispersible	552.00	28	✓ Exjade
Tab 500 mg dispersible	1,105.00	28	✓ Exjade

SA1492 Special Authority for Subsidy

Initial application only from a haematologist. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia; and
- 2 Deferasirox is to be given at a daily dose not exceeding 40 mg/kg/day; and
- 3 Any of the following:
 - 3.1 Treatment with maximum tolerated doses of deferiprone monotherapy or deferiprone and desferrioxamine combination therapy have proven ineffective as measured by serum ferritin levels, liver or cardiac MRI T2*; or
 - 3.2 Treatment with deferiprone has resulted in severe persistent vomiting or diarrhoea; or
 - 3.3 Treatment with deferiprone has resulted in arthritis; or
 - 3.4 Treatment with deferiprone is contraindicated due to a history of agranulocytosis (defined as an absolute neutrophil count (ANC) of < 0.5 cells per μ L) or recurrent episodes (greater than 2 episodes) of moderate neutropenia (ANC 0.5 - 1.0 cells per μ L).

Renewal only from a haematologist. Approvals valid for 2 years for applications meeting the following criteria:

Either:

continued...

‡ safety cap

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

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

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

- 1 For the first renewal following 2 years of therapy, the treatment has been tolerated and has resulted in clinical improvement in all three parameters namely serum ferritin, cardiac MRI T2* and liver MRI T2* levels; or
- 2 For subsequent renewals, the treatment has been tolerated and has resulted in clinical stability or continued improvement in all three parameters namely serum ferritin, cardiac MRI T2* and liver MRI T2* levels.

DEFERIPRONE – Special Authority see SA1480 below – Retail pharmacy

Tab 500 mg	533.17	100	✓ Feriprox
Oral liq 100 mg per 1 ml	266.59	250 ml OP	✓ Feriprox

►SA1480 Special Authority for Subsidy

Initial application only from a haematologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia; or
- 2 The patient has been diagnosed with chronic iron overload due to acquired red cell aplasia.

DEFERRIOXAMINE MESILATE

* Inj 500 mg vial	51.52	10	✓ Desferal
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SODIUM CALCIUM EDETATE

* Inj 200 mg per ml, 5 ml	53.31 (156.71)	6	Calcium Disodium Versenate
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INTRODUCTION

The following extemporaneously compounded products are eligible for subsidy:

- The “Standard Formulae”.
- Oral liquid mixtures for patients unable to swallow subsidised solid dose oral formulations.
- The preparation of syringe drivers when prescribed by a general practitioner.
- Dermatological preparations
 - a) One or more subsidised dermatological galenical(s) in a subsidised dermatological base.
 - b) Dilution of proprietary Topical Corticosteroid-Plain preparations with a dermatological base (Retail pharmacy-Specialist).

Glossary

Dermatological base: The products listed in the Barrier creams and Emollients section and the Topical Corticosteroids-Plain section of the Pharmaceutical Schedule are classified as dermatological bases for the purposes of extemporaneous compounding and are the bases to which the dermatological galenicals can be added. Also the dermatological bases in the Barrier Creams and Emollients section of the Pharmaceutical Schedule can be used for diluting proprietary Topical Corticosteroid-Plain preparations. The following products are dermatological bases:

- Aqueous cream
- Cetomacrogol cream BP
- Collodion flexible
- Emulsifying ointment BP
- Hydrocortisone with wool fat and mineral oil lotion
- Oil in water emulsion
- Urea cream 10%
- White soft paraffin
- Wool fat with mineral oil lotion
- Zinc and castor oil ointment BP
- Proprietary Topical Corticosteroid-Plain preparations

Dermatological galenical: Dermatological galenicals will only be subsidised when added to a dermatological base. More than one dermatological galenical can be added to a dermatological base.

The following are dermatological galenicals:

- Coal tar solution - up to 10%
- Hydrocortisone powder - up to 5%
- Menthol crystals
- Salicylic acid powder
- Sulphur precipitated powder

Standard formulae: Standard formulae are a list of formulae for ECPs that are subsidised. Their ingredients are listed under the appropriate therapeutic heading in Section B of the Pharmaceutical Schedule and also in Section C.

Explanatory notes

Oral liquid mixtures

Oral liquid mixtures are subsidised for patients unable to swallow subsidised solid oral dose forms where no suitable alternative proprietary formulation is subsidised. Suitable alternatives include dispersible and sublingual formulations, oral liquid formulations or rectal formulations. Before extemporaneously compounding an oral liquid mixture, other alternatives such as dispersing the solid dose form (if appropriate) or crushing the solid dose form in jam, honey or soft foods such as yoghurt should be explored.

The Emixt website www.pharminfotech.co.nz has evidence-based formulations which are intended to standardise compounded oral liquids within New Zealand.

Pharmaceuticals with standardised formula for compounding in Ora products

Acetazolamide 25 mg/ml	Flecainide 20 mg/ml	Rifabutin 20 mg/ml
Allopurinol 20 mg/ml	Gabapentin 100 mg/ml	Sildenafil 2 mg/ml
Amlodipine 1 mg/ml	Hydrocortisone 1 mg/ml	Sotalol 5 mg/ml
Azathioprine 50 mg/ml	Labetalol 10 mg/ml	Sulphasalazine 100 mg/ml
Baclofen 10 mg/ml	Levetiracetam 100 mg/ml	Tacrolimus 1 mg/ml
Carvedilol 1 mg/ml	Levodopa with carbidopa (5 mg levodopa + 1.25 mg carbidopa)/ml	Terbinafine 25 mg/ml
Clopidogrel 5 mg/ml	Metoclopramide 1 mg/ml	Tramadol 10 mg/ml
Diltiazem hydrochloride 12 mg/ml	Metoprolol tartrate 10 mg/ml	Ursodeoxycholic acid 50 mg/ml
Dipyridamol 10 mg/ml	Nitrofurantoin 10 mg/ml	Valganciclovir 60 mg/ml*
Domperidone 1 mg/ml	Pyrazinamide 100 mg/ml	Verapamil hydrochloride 50 mg/ml
Enalapril 1 mg/ml		

*Note this is a DCS formulation

PHARMAC endorses the recommendations of the Emixt website and encourages New Zealand pharmacists to use these formulations when compounding is appropriate. The Emixt website also provides stability and expiry data for compounded products. For the majority of products compounded with Ora-Blend, Ora-Blend SF, Ora-Plus, Ora-Sweet or Ora-Sweet SF a four week expiry is appropriate.

Please note that no oral liquid mixture will be eligible for Subsidy unless all the requirements of Section B and C of the Schedule applicable to that pharmaceutical are met.

Some community pharmacies may not have appropriate equipment to compound all of the listed products, please use appropriate clinical judgement.

Subsidy for extemporaneously compounded oral liquid mixtures is based on:

Solid dose form	qs
Preservative	qs
Suspending agent	qs
Water	to 100%

or

Solid dose form	qs
Ora-Blend, Ora-Blend SF, Ora-Plus, Ora-Sweet and/or Ora-Sweet SF	to 100%

Prescribers may prescribe or pharmacists may add extra non-subsidised ingredients such as flavouring and colouring agents, but these extra ingredients will not be reimbursed. The subsidised ingredients in the formula will be reimbursed and a compounding fee paid.

The majority of extemporaneously compounded oral liquid mixtures should contain a preservative and suspending agent.

- Ora-Blend, Ora-Blend SF, Ora-Plus, Ora-Sweet and Ora-Sweet SF when used correctly are an appropriate preservative and suspending agent.
- Methylcellulose 3% is considered a suitable suspending agent and compound hydroxybenzoate solution or methyl hydroxybenzoate 10% solution are considered to be suitable preservatives. Usually 1 ml of these preservative solutions is added to 100 ml of oral liquid mixture.

Some solid oral dose forms are not appropriate for compounding into oral liquid mixtures and should therefore not be used/considered for extemporaneously compounded oral liquid mixtures. This includes long-acting solid dose formulations, enteric coated tablets or capsules, sugar coated tablets, hard gelatin capsules and chemotherapeutic agents.

The following practices will not be subsidised:

- Where a Standard Formula exists in the Pharmaceutical Schedule for a solid dose form, compounding the solid dose form in Ora-Blend, Ora-Blend SF, Ora-Plus, Ora-Sweet and/or Ora-Sweet SF.
- Mixing one or more proprietary oral liquids (eg an antihistamine with pholcodine linctus).
- Extemporaneously compounding an oral liquid with more than one solid dose chemical.
- Mixing more than one extemporaneously compounded oral liquid mixture.
- Mixing one or more extemporaneously compounded oral liquid mixtures with one or more proprietary oral liquids.
- The addition of a chemical/powder/agent/solution to a proprietary oral liquid or extemporaneously compounded oral mixture.

Standard formulae

A list of standard formulae is contained in this section. All ingredients associated with a standard formula will be subsidised and an appropriate compounding fee paid.

Prescribers may prescribe or pharmacists may add extra non-subsidised ingredients, but these extra ingredients will not be reimbursed. The subsidised ingredients in the formula will be reimbursed and a compounding fee paid.

Dermatological Preparations

Proprietary topical corticosteroid preparations may be diluted with a dermatological base (see page 223) from the Barrier Creams and Emollients section of the Pharmaceutical Schedule (Retail pharmacy-Specialist). Dilution of proprietary topical corticosteroid preparations should only be prescribed for withdrawing patients off higher strength proprietary topical corticosteroid products where there is no suitable proprietary product of a lower strength available or an extemporaneously compounded product with up to 5% hydrocortisone is not appropriate. (In general proprietary topical corticosteroid preparations should not be diluted because dilution effects can be unpredictable and may not be linear, and usually there is no stability data available for diluted products).

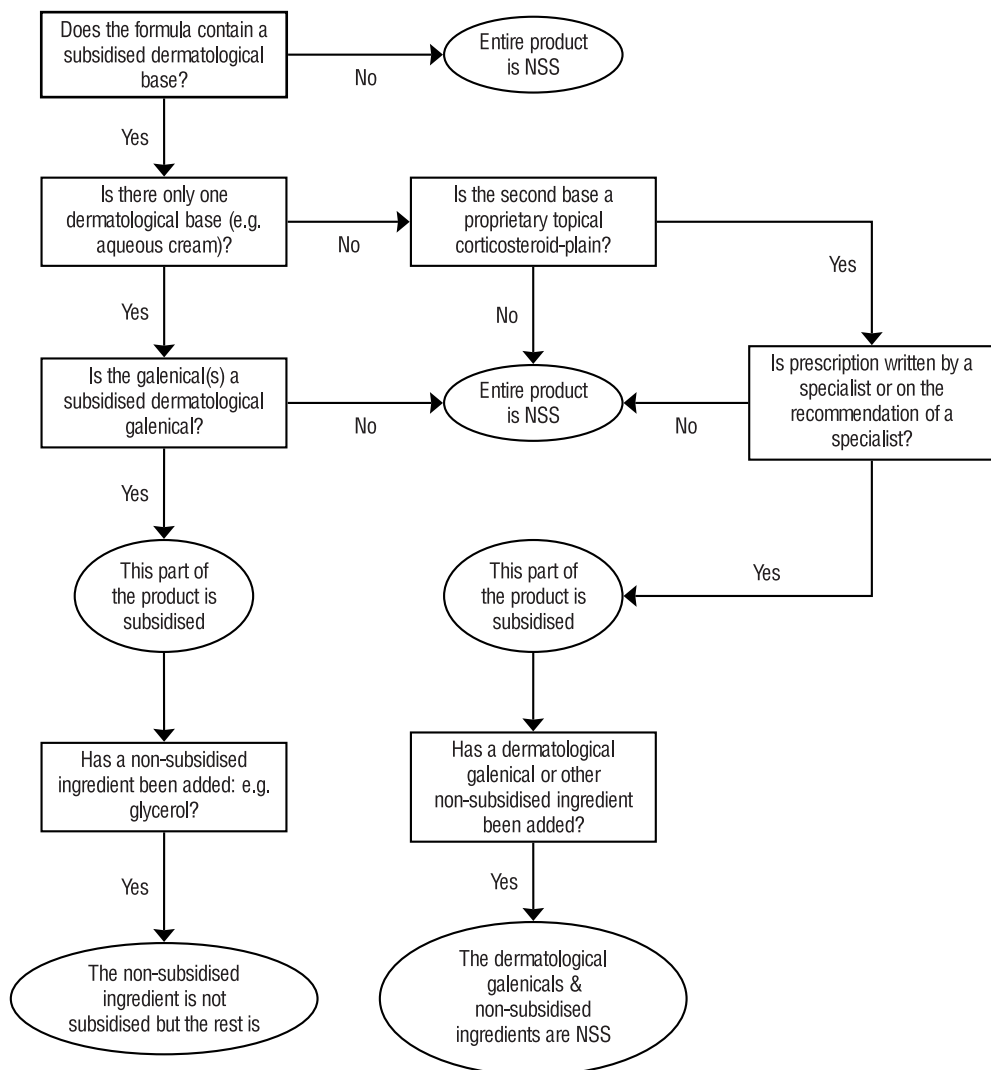
One or more dermatological galenicals may be added to a dermatological base (including proprietary topical corticosteroid preparations). Prescribers may prescribe or pharmacists may add extra non-subsidised ingredients, but these extra ingredients will not be reimbursed. The subsidised ingredients in the formula will be reimbursed and a compounding fee paid.

The addition of dermatological galenicals to diluted proprietary Topical Corticosteroids-Plain will not be subsidised.

The flow diagram on the next page may assist you in deciding whether or not a dermatological ECP is subsidised.

Dermatological ECPs

Is it subsidised?



Standard Formulae

ACETYLCYSTEINE EYE DROPS

Acetylcysteine inj 200 mg per ml, 10 ml	qs
Suitable eye drop base	qs

ASPIRIN AND CHLOROFORM APPLICATION

Aspirin Soluble tabs 300 mg	12 tabs
Chloroform	to 100 ml

CODEINE LINCTUS PAEDIATRIC (3 mg per 5 ml)

Codeine phosphate	60 mg
Glycerol	40 ml
Preservative	qs
Water	to 100 ml

CODEINE LINCTUS DIABETIC (15 mg per 5 ml)

Codeine phosphate	300 mg
Glycerol	40 ml
Preservative	qs
Water	to 100 ml

FOLINIC MOUTHWASH

Calcium folinate 15 mg tab	1 tab
Preservative	qs
Water	to 500 ml

(Preservative should be used if quantity supplied is for more than 5 days. Maximum 500 ml per prescription.)

MAGNESIUM HYDROXIDE 8% MIXTURE

Magnesium hydroxide paste 29%	275 g
Methyl hydroxybenzoate	1.5 g
Water	to 1,000 ml

METHADONE MIXTURE

Methadone powder	qs
Glycerol	qs
Water	to 100 ml

METHYL HYDROXYBENZOATE 10% SOLUTION

Methyl hydroxybenzoate	10 g
Propylene glycol	to 100 ml

(Use 1 ml of the 10% solution per 100 ml of oral liquid mixture)

OMEPRAZOLE SUSPENSION

Omeprazole capsules or powder	qs
Sodium bicarbonate powder BP	8.4 g
Water	to 100 ml

PHENOBARBITONE ORAL LIQUID

Phenobarbitone Sodium	1 g
Glycerol BP	70 ml
Water	to 100 ml

PHENOBARBITONE SODIUM PAEDIATRIC ORAL LIQUID (10 mg per ml)

Phenobarbitone Sodium	400 mg
Glycerol BP	4 ml
Water	to 40 ml

PILOCARPINE ORAL LIQUID

Pilocarpine 4% eye drops	qs
Preservative	qs
Water	to 500 ml

(Preservative should be used if quantity supplied is for more than 5 days.)

SALIVA SUBSTITUTE FORMULA

Methylcellulose	5 g
Preservative	qs
Water	to 500 ml

(Preservative should be used if quantity supplied is for more than 5 days. Maximum 500 ml per prescription.)

SODIUM CHLORIDE ORAL LIQUID

Sodium chloride inj 23.4%, 20 ml	qs
Water	qs

(Only funded if prescribed for treatment of hyponatraemia)

VANCOMYCIN ORAL SOLUTION (50 mg per ml)

Vancomycin 500 mg injection	10 vials
Glycerol BP	40 ml
Water	to 100 ml

(Only funded if prescribed for treatment of Clostridium difficile following metronidazole failure)

VOSOL EAR DROPS

WITH HYDROCORTISONE POWDER 1%

Hydrocortisone powder	1%
Vosol Ear Drops	to 35 ml

EXTEMPORANEOUSLY COMPOUNDED PREPARATIONS AND GALENICALS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Extemporaneously Compounded Preparations and Galenicals				
BENZOIN				
Tincture compound BP	24.42 (39.90)	500 ml		Pharmacy Health
	2.44 (5.10)	50 ml		Pharmacy Health
CHLOROFORM – Only in combination Only in aspirin and chloroform application.				
Chloroform BP	25.50	500 ml	✓ PSM	
CODEINE PHOSPHATE – Safety medicine; prescriber may determine dispensing frequency				
Powder – Only in combination	63.09 (90.09)	25 g		Douglas
	12.62 (25.46)	5 g		Douglas
a) Only in extemporaneously compounded codeine linctus diabetic or codeine linctus paediatric.				
b) ‡ Safety cap for extemporaneously compounded oral liquid preparations.				
COLLODION FLEXIBLE				
Collodion flexible	19.30	100 ml	✓ PSM	
COMPOUND HYDROXYBENZOATE – Only in combination Only in extemporaneously compounded oral mixtures.				
Soln	30.00 34.18	100 ml	✓ Midwest ✓ David Craig	
GLYCERIN WITH SODIUM SACCHARIN – Only in combination Only in combination with Ora-Plus.				
Suspension	32.50	473 ml	✓ Ora-Sweet SF	
GLYCERIN WITH SUCROSE – Only in combination Only in combination with Ora-Plus.				
Suspension	32.50	473 ml	✓ Ora-Sweet	
GLYCEROL				
* Liquid – Only in combination	3.71	500 ml	✓ <u>healthE Glycerol BP</u>	
Only in extemporaneously compounded oral liquid preparations.				
MAGNESIUM HYDROXIDE				
Paste 29%	22.61	500 g	✓ PSM	
METHADONE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
d) Extemporaneously compounded methadone will only be reimbursed at the rate of the cheapest form available (methadone powder, not methadone tablets).				
Powder	7.84	1 g	✓ AFT	
‡ Safety cap for extemporaneously compounded oral liquid preparations.				
METHYL HYDROXYBENZOATE				
Powder	8.00 8.98	25 g	✓ PSM ✓ Midwest	
METHYLCELLULOSE				
Powder	36.95	100 g	✓ MidWest	
Suspension – Only in combination	32.50	473 ml	✓ Ora-Plus	

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
METHYLCELLULOSE WITH GLYCERIN AND SODIUM SACCHARIN – Only in combination				
Suspension32.50	473 ml	✓ Ora-Blend SF		
METHYLCELLULOSE WITH GLYCERIN AND SUCROSE – Only in combination				
Suspension32.50	473 ml	✓ Ora-Blend		
PHENOBARBITONE SODIUM				
Powder – Only in combination52.50	10 g	✓ MidWest		
	325.00	100 g	✓ MidWest	
a) Only in children up to 12 years				
b) ‡ Safety cap for extemporaneously compounded oral liquid preparations.				
PROPYLENE GLYCOL				
Only in extemporaneously compounded methyl hydroxybenzoate 10% solution.				
Liq11.25	500 ml	✓ Midwest		
SODIUM BICARBONATE				
Powder BP – Only in combination8.95	500 g	✓ Midwest		
	9.80			
	(29.50)			David Craig
Only in extemporaneously compounded omeprazole and lansoprazole suspension.				
SYRUP (PHARMACEUTICAL GRADE) – Only in combination				
Only in extemporaneously compounded oral liquid preparations.				
Liq21.75	2,000 ml	✓ Midwest		
WATER				
Tap – Only in combination0.00	1 ml	✓ Tap water		

EXPLANATORY NOTES

The list of special foods to which Subsidies apply is contained in this section. The list of available products, guidelines for use, subsidies and charges is reviewed as required. Applications for new listings and changes to subsidies and access criteria will be considered by the special foods sub-committee of PTAC which meets as and when required. In all cases, subsidies are available by Special Authority only. This means that, unless a patient has a valid Special Authority number for their special food requirements, they must pay the full cost of the products themselves.

Eligibility for Special Authority

Special Authorities will be approved for patients meeting conditions specified under the *Conditions and Guidelines* for each product. In some cases there are also limits to how products can be prescribed (for example quantity, use or duration). Only those brands, presentations and flavours of special foods listed in this section are subsidised.

Who can apply for Special Authority?

Initial Applications: Only from a dietitian, relevant specialist or a vocationally registered general practitioner.

Reapplications: Only from a dietitian, relevant specialist or a vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or a vocationally registered general practitioner. Other general practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.

All applications must be made on an official form available from the PHARMAC website www.pharmac.govt.nz. All applications must include specific details as requested on the form relating to the application. Applications must be forwarded to:

Ministry of Health Sector Services
Private Bag 3015
WHANGANUI 4540
Freefax 0800 100 131

Subsidies and manufacturer's surcharges

The Subsidies for some special foods are based on the lowest priced product within each group. Where this is so, or where special foods are otherwise not fully subsidised, a manufacturer's surcharge may be payable by the patient. The manufacturer's surcharge is the difference between the price of the product and the subsidy attached to it and may be subject to mark-ups applied at a pharmacy level. As a result the manufacturer's surcharge may vary. Fully subsidised alternatives are available in most cases (as indicated by a tick in the left hand column). Patients should only have to pay a co-payment on these products.

Where are special foods available from?

Distribution arrangements for special foods vary from region to region. Special foods are available from hospital pharmacies providing an outpatient dispensing service as well as retail pharmacies in the Northern, Midland and Central (including Nelson and Blenheim) regions.

Definitions

<i>Failure to thrive</i>	An inability to gain or maintain weight resulting in physiological impairment.
<i>Growth deficiency</i>	Where the weight of the child is less than the fifth or possibly third percentile for their age, with evidence of malnutrition

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

Nutrient Modules

Carbohydrate

►SA1522 Special Authority for Subsidy

Initial application — (Cystic fibrosis or kidney disease) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Either:

- 1 cystic fibrosis; or
- 2 chronic kidney disease.

Initial application — (Indications other than cystic fibrosis or renal failure) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 cancer in children; or
- 2 cancers affecting alimentary tract where there are malabsorption problems in patients over the age of 20 years; or
- 3 faltering growth in an infant/child; or
- 4 bronchopulmonary dysplasia; or
- 5 premature and post premature infant; or
- 6 inborn errors of metabolism; or
- 7 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula.

Renewal — (Cystic fibrosis or renal failure) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis or renal failure) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

CARBOHYDRATE SUPPLEMENT – Special Authority see SA1522 above – Hospital pharmacy [HP3]

Powder 5.29 400 g OP ✓ Polycal

Carbohydrate And Fat

►SA1376 Special Authority for Subsidy

Initial application — (Cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 Infant or child aged four years or under; and
- 2 cystic fibrosis.

continued...

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

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 infant or child aged four years or under; and
- 2 Any of the following:
 - 2.1 cancer in children; or
 - 2.2 faltering growth; or
 - 2.3 bronchopulmonary dysplasia; or
 - 2.4 premature and post premature infants.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

CARBOHYDRATE AND FAT SUPPLEMENT – Special Authority see SA1376 on the previous page – Hospital pharmacy [HP3]

Powder (neutral)	60.31	400 g OP	✓ Duocal Super Soluble Powder
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Fat

►SA1523 Special Authority for Subsidy

Initial application — (Inborn errors of metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient has inborn errors of metabolism.

Initial application — (Indications other than inborn errors of metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 faltering growth in an infant/child; or
- 2 bronchopulmonary dysplasia; or
- 3 fat malabsorption; or
- 4 lymphangiectasia; or
- 5 short bowel syndrome; or
- 6 infants with necrotising enterocolitis; or
- 7 biliary atresia; or
- 8 for use in a ketogenic diet; or
- 9 chyle leak; or
- 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.

continued...

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

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula.

Renewal — (Inborn errors of metabolism) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner.

Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than inborn errors of metabolism) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

FAT SUPPLEMENT – Special Authority see SA1523 on the previous page – Hospital pharmacy [HP3]

Emulsion (neutral)	12.30	200 ml OP	✓ Calogen
	30.75	500 ml OP	✓ Calogen
Emulsion (strawberry)	12.30	200 ml OP	✓ Calogen
Oil	30.00	500 ml OP	✓ MCT oil (Nutricia)
Oil, 250 ml	114.92	4 OP	✓ Liquigen

Protein

►SA1524 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 protein losing enteropathy; or
- 2 high protein needs; or
- 3 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

PROTEIN SUPPLEMENT – Special Authority see SA1524 above – Hospital pharmacy [HP3]

Powder	7.90	225 g OP	✓ Protifar
	8.95	227 g OP	✓ Resource Beneprotein
Powder (vanilla)	12.90	275 g OP	✓ Promod

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

Oral Supplements/Complete Diet (Nasogastric/Gastrostomy Tube Feed)

Respiratory Products

►SA1094 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient has CORD and hypercapnia, defined as a CO₂ value exceeding 55 mmHg.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

CORD ORAL FEED 1.5KCAL/ML – Special Authority see SA1094 above – Hospital pharmacy [HP3]

Liquid	1.66	237 ml OP	✓ Pulmocare
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Diabetic Products

►SA1095 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient is a type I or and II diabetic who is suffering weight loss and malnutrition that requires nutritional support.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

DIABETIC ENTERAL FEED 1KCAL/ML – Special Authority see SA1095 above – Hospital pharmacy [HP3]

Liquid	7.50	1,000 ml OP	✓ Diason RTH
			✓ Glucerna Select RTH

DIABETIC ORAL FEED 1KCAL/ML – Special Authority see SA1095 above – Hospital pharmacy [HP3]

Liquid (strawberry)	1.50	200 ml OP	✓ Diasip
Liquid (vanilla)	1.50	200 ml OP	✓ Diasip
	1.88	250 ml OP	✓ Glucerna Select
	1.78	237 ml OP	
	(2.10)		Resource Diabetic
	(2.10)		Sustagen Diabetic

Fat Modified Products

►SA1525 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 Patient has metabolic disorders of fat metabolism; or
- 2 Patient has a chyle leak; or

continued...

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

- 3 Modified as a modular feed, made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule, for adults.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

FAT MODIFIED FEED – Special Authority see SA1525 on the previous page – Hospital pharmacy [HP3]

Powder 60.48 400 g OP ✓ **Monogen**

Paediatric Products For Children Awaiting Liver Transplant

►SA1098 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient is a child (up to 18 years) who requires a liver transplant.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL FEED 1KCAL/ML – Special Authority see SA1098 above – Hospital pharmacy [HP3]

Powder (unflavoured) 78.97 400 g OP ✓ **Heparon Junior**

Paediatric Products For Children With Chronic Renal Failure

►SA1099 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient is a child (up to 18 years) with acute or chronic kidney disease.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL FEED 1KCAL/ML – Special Authority see SA1099 above – Hospital pharmacy [HP3]

Liquid 54.00 400 g OP ✓ **Kindergen**

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

►SA1379 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 Child is aged one to ten years; and
- 2 Any of the following:
 - 2.1 the child is being fed via a tube or a tube is to be inserted for the purposes of feeding; or
 - 2.2 any condition causing malabsorption; or
 - 2.3 faltering growth in an infant/child; or
 - 2.4 increased nutritional requirements; or
 - 2.5 the child is being transitioned from TPN or tube feeding to oral feeding.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

PAEDIATRIC ENTERAL FEED 1.5KCAL/ML – Special Authority see SA1379 above – Hospital pharmacy [HP3]

Liquid	6.00	500 ml OP	✓ Nutrini Energy RTH
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PAEDIATRIC ENTERAL FEED 1KCAL/ML – Special Authority see SA1379 above – Hospital pharmacy [HP3]

Liquid	2.68	500 ml OP	✓ Nutrini RTH ✓ Pediasure RTH
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PAEDIATRIC ENTERAL FEED WITH FIBRE 1.5KCAL/ML – Special Authority see SA1379 above – Hospital pharmacy [HP3]

Liquid	6.00	500 ml OP	✓ Nutrini Energy Multi Fibre
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PAEDIATRIC ORAL FEED – Special Authority see SA1379 above – Hospital pharmacy [HP3]

Powder (vanilla)	28.00	850 g OP	✓ Pediasure
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PAEDIATRIC ORAL FEED 1.5KCAL/ML – Special Authority see SA1379 above – Hospital pharmacy [HP3]

Liquid (strawberry)	1.60	200 ml OP	✓ Fortini
Liquid (vanilla)	1.60	200 ml OP	✓ Fortini

PAEDIATRIC ORAL FEED 1KCAL/ML – Special Authority see SA1379 above – Hospital pharmacy [HP3]

Liquid (chocolate)	1.07	200 ml OP	✓ Pediasure
Liquid (strawberry)	1.07	200 ml OP	✓ Pediasure
Liquid (vanilla)	1.07	200 ml OP	✓ Pediasure
	1.34	250 ml OP	✓ Pediasure

PAEDIATRIC ORAL FEED WITH FIBRE 1.5KCAL/ML – Special Authority see SA1379 above – Hospital pharmacy [HP3]

Liquid (chocolate)	1.60	200 ml OP	✓ Fortini Multi Fibre
Liquid (strawberry)	1.60	200 ml OP	✓ Fortini Multi Fibre
Liquid (vanilla)	1.60	200 ml OP	✓ Fortini Multi Fibre

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

▶▶SA1101 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient has acute or chronic kidney disease.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

- Both:
- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
 - 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

RENAL ENTERAL FEED 1.8 KCAL/ML – Special Authority see SA1101 above – Hospital pharmacy [HP3]

Liquid	6.08	500 ml OP	✓ Nepro HP RTH
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RENAL ORAL FEED 1.8 KCAL/ML – Special Authority see SA1101 above – Hospital pharmacy [HP3]

Liquid	2.67	220 ml OP	✓ Nepro HP (strawberry) ✓ Nepro HP (vanilla)
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RENAL ORAL FEED 2 KCAL/ML – Special Authority see SA1101 above – Hospital pharmacy [HP3]

Liquid	2.88	237 ml OP	
	(3.31)		NovaSource Renal
Liquid (apricot) 125 ml	11.52	4 OP	✓ Renilon 7.5
Liquid (caramel) 125 ml	11.52	4 OP	✓ Renilon 7.5

Specialised And Elemental Products

▶▶SA1377 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 malabsorption; or
- 2 short bowel syndrome; or
- 3 enterocutaneous fistulas; or
- 4 eosinophilic oesophagitis; or
- 5 inflammatory bowel disease; or
- 6 patients with multiple food allergies requiring enteral feeding.

Notes: Each of these products is highly specialised and would be prescribed only by an expert for a specific disorder. The alternative is hospitalisation.

Elemental 028 Extra is more expensive than other products listed in this section and should only be used where the alternatives have been tried first and/or are unsuitable.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

- Both:
- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
 - 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL ELEMENTAL FEED 1KCAL/ML – Special Authority see SA1377 above – Hospital pharmacy [HP3]

Powder	7.50	76 g OP	✓ Alitraq
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(Alitraq Powder to be delisted 1 September 2017)

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
ENTERAL/ORAL SEMI-ELEMENTAL FEED 1.5KCAL/ML – Special Authority see SA1377 on the previous page – Hospital pharmacy [HP3]			
Liquid	18.06	1,000 ml OP	✓ Vital
ORAL ELEMENTAL FEED 0.8KCAL/ML – Special Authority see SA1377 on the previous page – Hospital pharmacy [HP3]			
Liquid (grapefruit), 250 ml carton	171.00	18 OP	✓ Elemental 028 Extra
Liquid (pineapple & orange), 250 ml carton	171.00	18 OP	✓ Elemental 028 Extra
Liquid (summer fruits), 250 ml carton	171.00	18 OP	✓ Elemental 028 Extra
ORAL ELEMENTAL FEED 1KCAL/ML – Special Authority see SA1377 on the previous page – Hospital pharmacy [HP3]			
Powder (unflavoured)	4.50	80 g OP	✓ Vivonex TEN
SEMI-ELEMENTAL ENTERAL FEED 1KCAL/ML – Special Authority see SA1377 on the previous page – Hospital pharmacy [HP3]			
Liquid	12.04	1,000 ml OP	✓ Peptisorb

Paediatric Products For Children With Low Energy Requirements

►SA1196 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 Child aged one to eight years; and
- 2 The child has a low energy requirement but normal protein and micronutrient requirements.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

PAEDIATRIC ENTERAL FEED WITH FIBRE 0.76 KCAL/ML – Special Authority see SA1196 above – Hospital pharmacy [HP3]

Liquid	4.00	500 ml OP	✓ Nutrini Low Energy Multi Fibre
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Standard Supplements

►SA1554 Special Authority for Subsidy

Initial application — (Children - indications other than exclusive enteral nutrition for Crohn's disease) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 The patient is under 18 years of age; and
- 2 Any of the following:
 - 2.1 The patient has a condition causing malabsorption; or
 - 2.2 The patient has failure to thrive; or
 - 2.3 The patient has increased nutritional requirements; and
- 3 Nutrition goal has been set (eg reach a specific weight or BMI).

Renewal — (Children - indications other than exclusive enteral nutrition for Crohn's disease) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

continued...

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

- 1 The patient is under 18 years of age; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment; and
- 3 A nutrition goal has been set (eg reach a specific weight or BMI).

Initial application — (Children - exclusive enteral nutrition for Crohn's disease) only from a gastroenterologist or dietitian on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 The patient is under 18 years of age; and
- 2 It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease; and
- 3 Dietitians must include the name of the gastroenterologist recommending treatment and the date the gastroenterologist was contacted.

Renewal — (Children - exclusive enteral nutrition for Crohn's disease) only from a gastroenterologist, dietitian on the recommendation of a gastroenterologist or vocationally registered general practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 The patient is under 18 years of age; and
- 2 It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease; and
- 3 General Practitioners and dietitians must include the name of the gastroenterologist recommending treatment and the date the gastroenterologist was contacted.

Initial application — (Adults) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
Patient is Malnourished
 - 1.1 Patient has a body mass index (BMI) of less than 18.5 kg/m²; or
 - 1.2 Patient has unintentional weight loss greater than 10% within the last 3-6 months; or
 - 1.3 Patient has a BMI of less than 20 kg/m² and unintentional weight loss greater than 5% within the last 3-6 months; and
- 2 Any of the following:
Patient has not responded to first-line dietary measures over a 4 week period by:
 - 2.1 Increasing their food intake frequency (eg snacks between meals); or
 - 2.2 Using high-energy foods (e.g. milkshakes, full fat milk, butter, cream, cheese, sugar etc); or
 - 2.3 Using over the counter supplements (e.g. Complan); and
- 3 A nutrition goal has been set (e.g. to reach a specific weight or BMI).

Renewal — (Adults) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 A nutrition goal has been set (eg reach a specific weight or BMI); and
- 2 Any of the following:
Patient is Malnourished
 - 2.1 Patient has a body mass index (BMI) of less than 18.5 kg/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) 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:

continued...

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

- 1 Is being fed via a nasogastric tube or a nasogastric tube is to be inserted for feeding; or
- 2 Malignancy and is considered likely to develop malnutrition as a result; or
- 3 Is undergoing a bone marrow transplant; or
- 4 Tempomandibular surgery or glossectomy; or
- 5 Both:
 - 5.1 Pregnant; and
 - 5.2 Any of the following:
 - 5.2.1 Patient is in early pregnancy (<13 weeks) and has severe clinical hyperemesis gravidarum requiring admission to hospital and is unlikely to meet her nutritional requirements due to continuing hyperemesis gravidarum; or
 - 5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or
 - 5.2.3 Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met.

Renewal — (Short-term medical condition) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 Is being fed via a nasogastric tube; or
- 2 Malignancy and is considered likely to develop malnutrition as a result; or
- 3 Has undergone a bone marrow transplant; or
- 4 Tempomandibular surgery or glossectomy; or
- 5 Both:
 - 5.1 Pregnant; and
 - 5.2 Any of the following:
 - 5.2.1 Patient is in early pregnancy (<13 weeks) and has severe clinical hyperemesis gravidarum requiring admission to hospital and is unlikely to meet her nutritional requirements due to continuing hyperemesis gravidarum; or
 - 5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or
 - 5.2.3 Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met.

Initial application — (Long-term medical condition) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube - refer to specific medical condition criteria); or
- 2 Cystic Fibrosis; or
- 3 Liver disease; or
- 4 Chronic Renal failure; or
- 5 Inflammatory bowel disease; or
- 6 Chronic obstructive pulmonary disease with hypercapnia; or
- 7 Short bowel syndrome; or
- 8 Bowel fistula; or
- 9 Severe chronic neurological conditions; or

continued...

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

- 10 Epidermolysis bullosa; or
- 11 AIDS (CD4 count < 200 cells/mm³); or
- 12 Chronic pancreatitis.

Renewal — (Chronic disease OR tube feeding for patients who have previously been funded under Special Authority forms SA0702 or SA0583) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube - refer to specific medical condition criteria); or
- 2 Cystic Fibrosis; or
- 3 Liver disease; or
- 4 Chronic Renal failure; or
- 5 Inflammatory bowel disease; or
- 6 Chronic obstructive pulmonary disease with hypercapnia; or
- 7 Short bowel syndrome; or
- 8 Bowel fistula; or
- 9 Severe chronic neurological conditions.

ENTERAL FEED 1.5KCAL/ML – Special Authority see SA1554 on page 238 – Hospital pharmacy [HP3]

Liquid	7.00	1,000 ml OP	✓ Nutrison Energy
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ENTERAL FEED 1KCAL/ML – Special Authority see SA1554 on page 238 – Hospital pharmacy [HP3]

Liquid	1.24	250 ml OP	✓ Isosource Standard
	5.29	1,000 ml OP	✓ Isosource Standard RTH
			✓ Nutrison Standard RTH
			✓ Osmolite RTH

ENTERAL FEED WITH FIBRE 0.83 KCAL/ML – Special Authority see SA1554 on page 238 – Hospital pharmacy [HP3]

Liquid	5.29	1,000 ml OP	✓ Nutrison 800 Complete Multi Fibre
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ENTERAL FEED WITH FIBRE 1 KCAL/ML – Special Authority see SA1554 on page 238 – Hospital pharmacy [HP3]

Liquid	1.32	237 ml OP	✓ Jevity
	5.29	1,000 ml OP	✓ Jevity RTH
			✓ Nutrison Multi Fibre

(Jevity Liquid to be delisted 1 June 2017)

ENTERAL FEED WITH FIBRE 1.5KCAL/ML – Special Authority see SA1554 on page 238 – Hospital pharmacy [HP3]

Liquid	1.75	250 ml OP	✓ Ensure Plus HN
	7.00	1,000 ml OP	✓ Ensure Plus RTH
			✓ Jevity HiCal RTH
			✓ Nutrison Energy Multi Fibre

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ORAL FEED (POWDER) – Special Authority see SA1554 on page 238 – Hospital pharmacy [HP3]				
Note: Higher subsidy for Sustagen Hospital Formula will only be reimbursed for patients with both a valid Special Authority number and an appropriately endorsed prescription.				
Powder (chocolate) – Higher subsidy of up to \$26.00 per 850 g				
g with Endorsement.....	26.00	850 g OP	✓ Ensure	
	9.54	840 g OP		
	(14.90)			Sustagen Hospital Formula
Additional subsidy by endorsement is available for patients with fat malabsorption, fat intolerance or chyle leak. The prescription must be endorsed accordingly.				
Powder (vanilla) – Higher subsidy of up to \$26.00 per 850 g				
with Endorsement.....	3.67	350 g OP	✓ Fortisip	
	26.00	850 g OP	✓ Ensure	
	9.54	840 g OP		
	(14.90)			Sustagen Hospital Formula
Additional subsidy by endorsement is available for patients with fat malabsorption, fat intolerance or chyle leak. The prescription must be endorsed accordingly.				
ORAL FEED 1.5KCAL/ML – Special Authority see SA1554 on page 238 – Hospital pharmacy [HP3]				
Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, who have severe epidermolysis bullosa, or as exclusive enteral nutrition in children under the age of 18 years for the treatment of Crohn's disease. The prescription must be endorsed accordingly.				
Liquid (banana) – Higher subsidy of \$1.26 per 200 ml with				
Endorsement	0.72	200 ml OP		
	(1.26)			Ensure Plus
	(1.26)			Fortisip
Liquid (chocolate) – Higher subsidy of \$1.26 per 200 ml with				
Endorsement	0.72	200 ml OP		
	(1.26)			Ensure Plus
	(1.26)			Fortisip
Liquid (fruit of the forest) – Higher subsidy of \$1.26 per 200 ml with				
Endorsement	0.72	200 ml OP		
	(1.26)			Ensure Plus
Liquid (strawberry) – Higher subsidy of \$1.26 per 200 ml with				
Endorsement	0.72	200 ml OP		
	(1.26)			Ensure Plus
	(1.26)			Fortisip
Liquid (vanilla) – Higher subsidy of up to \$1.33 per 237 ml				
with Endorsement.....	0.85	237 ml OP		
	(1.33)			Ensure Plus
	0.72	200 ml OP		
	(1.26)			Ensure Plus
	(1.26)			Fortisip

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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ORAL FEED WITH FIBRE 1.5 KCAL/ML – Special Authority see SA1554 on page 238 – Hospital pharmacy [HP3]

Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, or who have severe epidermolysis bullosa. The prescription must be endorsed accordingly.

Liquid (chocolate) – Higher subsidy of \$1.26 per 200 ml with

Endorsement	0.72	200 ml OP	
	(1.26)		Fortisip Multi Fibre

Liquid (strawberry) – Higher subsidy of \$1.26 per 200 ml with

Endorsement	0.72	200 ml OP	
	(1.26)		Fortisip Multi Fibre

Liquid (vanilla) – Higher subsidy of \$1.26 per 200 ml with

Endorsement	0.72	200 ml OP	
	(1.26)		Fortisip Multi Fibre

High Calorie Products

►SA1195 Special Authority for Subsidy

Initial application — (Cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner.

Approvals valid for 3 years for applications meeting the following criteria:

All of the following:

- 1 Cystic fibrosis; and
- 2 other lower calorie products have been tried; and
- 3 patient has substantially increased metabolic requirements.

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
 - 1.1 any condition causing malabsorption; or
 - 1.2 faltering growth in an infant/child; or
 - 1.3 increased nutritional requirements; or
 - 1.4 fluid restricted; and
- 2 other lower calorie products have been tried; and
- 3 patient has substantially increased metabolic requirements or is fluid restricted.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ENTERAL FEED 2 KCAL/ML – Special Authority see SA1195 on the previous page – Hospital pharmacy [HP3]				
Liquid	5.50	500 ml OP	✓	Nutrison Concentrated
	11.00	1,000 ml OP	✓	Two Cal HN RTH
ORAL FEED 2 KCAL/ML – Special Authority see SA1195 on the previous page – Hospital pharmacy [HP3]				
Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, or who have severe epidermolysis bullosa. The prescription must be endorsed accordingly.				
Liquid (vanilla) – Higher subsidy of \$1.90 per 200 ml with				
Endorsement	0.96	200 ml OP		
	(1.90)			Two Cal HN

Food Thickeners

►SA1106 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient has motor neurone disease with swallowing disorder.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

FOOD THICKENER – Special Authority see SA1106 above – Hospital pharmacy [HP3]

Powder	6.53	300 g OP	✓	Nutrilis
	7.25	380 g OP	✓	Feed Thickener Karicare Aptamil

Gluten Free Foods

The funding of gluten free foods is no longer being actively managed by PHARMAC from 1 April 2011. This means that we are no longer considering the listing of new products, or making subsidy, or other changes to the existing listings. As a result we anticipate that the range of funded items will reduce over time. Management of Coeliac disease with a gluten free diet is necessary for good outcomes. A range of gluten free options are available through retail outlets.

►SA1107 Special Authority for Subsidy

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

Either:

- 1 Gluten enteropathy has been diagnosed by biopsy; or
- 2 Patient suffers from dermatitis herpetiformis.

GLUTEN FREE BAKING MIX – Special Authority see SA1107 above – Hospital pharmacy [HP3]

Powder	2.81	1,000 g OP		
	(5.15)			Healtheries Simple Baking Mix

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
GLUTEN FREE BREAD MIX – Special Authority see SA1107 on the previous page – Hospital pharmacy [HP3]				
Powder	3.93 (7.32)	1,000 g OP		NZB Low Gluten Bread Mix
	4.77 (8.71)			Bakels Gluten Free Health Bread Mix
	3.51 (10.87)			Horleys Bread Mix
<i>(Bakels Gluten Free Health Bread Mix Powder to be delisted 1 April 2017)</i>				
GLUTEN FREE FLOUR – Special Authority see SA1107 on the previous page – Hospital pharmacy [HP3]				
Powder	5.62 (18.10)	2,000 g OP		Horleys Flour
GLUTEN FREE PASTA – Special Authority see SA1107 on the previous page – Hospital pharmacy [HP3]				
Buckwheat Spirals	2.00 (3.11)	250 g OP		Orgran
Corn and Vegetable Shells	2.00 (2.92)	250 g OP		Orgran
Corn and Vegetable Spirals	2.00 (2.92)	250 g OP		Orgran
Rice and Corn Lasagne Sheets	1.60 (3.82)	200 g OP		Orgran
Rice and Corn Macaroni	2.00 (2.92)	250 g OP		Orgran
Rice and Corn Penne	2.00 (2.92)	250 g OP		Orgran
Rice and Maize Pasta Spirals	2.00 (2.92)	250 g OP		Orgran
Rice and Millet Spirals	2.00 (3.11)	250 g OP		Orgran
Rice and corn spaghetti noodles	2.00 (2.92)	375 g OP		Orgran
Vegetable and Rice Spirals	2.00 (2.92)	250 g OP		Orgran
Italian long style spaghetti	2.00 (3.11)	220 g OP		Orgran

Foods And Supplements For Inborn Errors Of Metabolism

►SA1108 | Special Authority for Subsidy

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

Any of the following:

- 1 Dietary management of homocystinuria; or
- 2 Dietary management of maple syrup urine disease; or
- 3 Dietary management of phenylketonuria (PKU); or
- 4 For use as a supplement to the Ketogenic diet in patients diagnosed with epilepsy.

Supplements For Homocystinuria

AMINOACID FORMULA WITHOUT METHIONINE – Special Authority see SA1108 above – Hospital pharmacy [HP3]

Powder 461.94 500 g OP ✓ **XMET Maxamum**

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

AMINOACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE – Special Authority see SA1108 on the previous page – Hospital pharmacy [HP3]

Powder	300.54	500 g OP	✓ MSUD Maxamaid
	437.22		✓ MSUD Maxamum

(MSUD Maxamaid Powder to be delisted 1 May 2017)

Supplements For PKU

AMINOACID FORMULA WITHOUT PHENYLALANINE – Special Authority see SA1108 on the previous page – Hospital pharmacy [HP3]

Tabs	99.00	75 OP	✓ Phlexy 10
Powder (unflavoured) 36 g sachets	393.00	30	✓ PKU Anamix Junior
Infant formula	174.72	400 g OP	✓ PKU Anamix Infant
Powder (orange)	221.00	500 g OP	✓ XP Maxamaid
	320.00		✓ XP Maxamum
Powder (unflavoured)	221.00	500 g OP	✓ XP Maxamaid
	320.00		✓ XP Maxamum
Liquid (berry)	13.10	125 ml OP	✓ PKU Anamix Junior LQ
Liquid (orange)	13.10	125 ml OP	✓ PKU Anamix Junior LQ
Liquid (unflavoured)	13.10	125 ml OP	✓ PKU Anamix Junior LQ
Liquid (forest berries), 250 ml carton	540.00	18 OP	✓ Easiphen Liquid
Liquid (juicy berries) 62.5 ml	939.00	60 OP	✓ PKU Lophlex LQ 10
Liquid (juicy citrus) 62.5 ml	939.00	60 OP	✓ PKU Lophlex LQ 10
Liquid (juicy orange) 62.5 ml	939.00	60 OP	✓ PKU Lophlex LQ 10
Liquid (juicy berries) 125 ml	936.00	30 OP	✓ PKU Lophlex LQ 20
Liquid (juicy citrus) 125 ml	936.00	30 OP	✓ PKU Lophlex LQ 20
Liquid (juicy orange) 125 ml	936.00	30 OP	✓ PKU Lophlex LQ 20

Foods

LOW PROTEIN BAKING MIX – Special Authority see SA1108 on the previous page – Hospital pharmacy [HP3]

Powder	8.22	500 g OP	✓ Loprofin Mix
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LOW PROTEIN PASTA – Special Authority see SA1108 on the previous page – Hospital pharmacy [HP3]

Animal shapes	11.91	500 g OP	✓ Loprofin
Lasagne	5.95	250 g OP	✓ Loprofin
Low protein rice pasta	11.91	500 g OP	✓ Loprofin
Macaroni	5.95	250 g OP	✓ Loprofin
Penne	11.91	500 g OP	✓ Loprofin
Spaghetti	11.91	500 g OP	✓ Loprofin
Spirals	11.91	500 g OP	✓ Loprofin

Infant Formulae

For Premature Infants

PRETERM POST-DISCHARGE INFANT FORMULA – Special Authority see SA1198 on the next page – Hospital pharmacy [HP3]

Powder	15.25	400 g OP	✓ S-26 Gold Premgro
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Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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▶▶SA1198 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:

Both:

- 1 The infant was born before 33 weeks gestation or weighed less than 1.5 kg at birth; and
- 2 Either:
 - 2.1 The infant has faltering growth (downward crossing of percentiles); or
 - 2.2 The infant is not maintaining, or is considered unlikely to maintain, adequate growth on standard infant formula.

For Williams Syndrome**▶▶SA1110 Special Authority for Subsidy**

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient is an infant suffering from Williams Syndrome and associated hypercalcaemia.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

LOW CALCIUM INFANT FORMULA – Special Authority see SA1110 above – Hospital pharmacy [HP3]

Powder	44.40	400 g OP	✓ Locasol
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Gastrointestinal and Other Malabsorptive Problems

AMINO ACID FORMULA – Special Authority see SA1219 below – Hospital pharmacy [HP3]

Powder	6.00	48.5 g OP	✓ Vivonex Pediatric
	43.60	400 g OP	✓ Alfamino Junior
	53.00		✓ Neocate LCP
Powder (unflavoured)	53.00	400 g OP	✓ Elecare
			✓ Elecare LCP
			✓ Neocate Advance
			✓ Neocate Gold
Powder (vanilla)	53.00	400 g OP	✓ Elecare
			✓ Neocate Advance

(Vivonex Pediatric Powder to be delisted 1 April 2017)

▶▶SA1219 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Any of the following:

- 1 Extensively hydrolysed formula has been reasonably trialled and is inappropriate due to documented severe intolerance or allergy or malabsorption; or
- 2 History of anaphylaxis to cows milk protein formula or dairy products; or
- 3 Eosinophilic oesophagitis.

continued...

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

Note: A reasonable trial is defined as a 2-4 week trial.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 An assessment as to whether the infant can be transitioned to a cows milk protein, soy, or extensively hydrolysed infant formula has been undertaken; and
- 2 The outcome of the assessment is that the infant continues to require an amino acid infant formula; and
- 3 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

EXTENSIVELY HYDROLYSED FORMULA – Special Authority see SA1557 below – Hospital pharmacy [HP3]

Powder 15.21 450 g OP ✓ **Aptamil Gold+ Pepti Junior**

►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 malabsorption; 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.

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

Ketogenic Diet

▶▶SA1197 Special Authority for Subsidy

Initial application only from a metabolic physician or paediatric neurologist. Approvals valid for 3 months where the patient has intractable epilepsy, pyruvate dehydrogenase deficiency or glucose transported type-1 deficiency and other conditions requiring a ketogenic diet.

Renewal only from a metabolic physician or paediatric neurologist. Approvals valid for 2 years where the patient is on a ketogenic diet and the patient is benefiting from the diet.

HIGH FAT LOW CARBOHYDRATE FORMULA – Special Authority see SA1197 above – Retail pharmacy

Powder (unflavoured)	35.50	300 g OP	✓ KetoCal 4:1
Powder (vanilla)	35.50	300 g OP	✓ Ketocal 3:1
			✓ KetoCal 4:1

SECTION E PART I

PRACTITIONER'S SUPPLY ORDERS

Pharmaceuticals and quantities that may be obtained on a Practitioner's Supply Order

ADRENALINE	
✓ Inj 1 in 1,000, 1 ml ampoule.....	5
✓ Inj 1 in 10,000, 10 ml ampoule.....	5
AMINOPHYLLINE	
✓ Inj 25 mg per ml, 10 ml ampoule	5
AMIODARONE HYDROCHLORIDE	
✓ Inj 50 mg per ml, 3 ml ampoule	6
AMOXICILLIN	
✓ Cap 250 mg	30
✓ Cap 500 mg	30
✓ Grans for oral liq 125 mg per 5 ml	200 ml
✓ Grans for oral liq 250 mg per 5 ml	300 ml
✓ Inj 1 g vial.....	5
AMOXICILLIN WITH CLAVULANIC ACID	
✓ Tab 500 mg with clavulanic acid 125 mg	30
✓ Grans for oral liq amoxicillin 125 mg with clavulanic acid 31.25 mg per 5 ml.....	200 ml
✓ Grans for oral liq amoxicillin 250 mg with clavulanic acid 62.5 mg per 5 ml	200 ml
ASPIRIN	
✓ Tab dispersible 300 mg.....	30
ATROPINE SULPHATE	
✓ Inj 600 mcg per ml, 1 ml ampoule.....	5
AZITHROMYCIN	
✓ Tab 500 mg – See note on page 98.....	8
BENDROFLUMETHIAZIDE [BENDROFLUAZIDE]	
✓ Tab 2.5 mg – See note on page 63.....	150
BENZATHINE BENZYL PENICILLIN	
✓ Inj 900 mg (1.2 million units) in 2.3 ml syringe.....	5
BENZTROPINE MESYLATE	
✓ Inj 1 mg per ml, 2 ml	10
BENZYL PENICILLIN SODIUM (PENICILLIN G)	
✓ Inj 600 mg (1 million units) vial	5
BLOOD GLUCOSE DIAGNOSTIC TEST METER	
✓ Meter with 50 lancets, a lancing device and 10 diagnostic test strips – Subsidy by endorsement – See note on page 26	1
BLOOD GLUCOSE DIAGNOSTIC TEST STRIP	
✓ Blood glucose test strips – See note on page 26	50 test
BLOOD KETONE DIAGNOSTIC TEST METER	
✓ Meter – See note on page 25	1
CEFTRIAXONE	
✓ Inj 500 mg vial – Subsidy by endorsement – See note on page 97	5
✓ Inj 1 g vial – Subsidy by endorsement – See note on page 97	5
CHARCOAL	
✓ Oral liq 50 g per 250 ml	250 ml
CHLORPROMAZINE HYDROCHLORIDE	
✓ Tab 10 mg.....	30
✓ Tab 25 mg.....	30
✓ Tab 100 mg.....	30
✓ Inj 25 mg per ml, 2 ml	5
CIPROFLOXACIN	
✓ Tab 250 mg – See note on page 101.....	5
✓ Tab 500 mg – See note on page 101.....	5
CO-TRIMOXAZOLE	
✓ Tab trimethoprim 80 mg and sulphamethoxazole 400 mg.....	30
✓ Oral liq trimethoprim 40 mg and sulphamethoxazole 200 mg per 5 ml.....	200 ml
COMPOUND ELECTROLYTES	
✓ Powder for oral soln	10
CONDOMS	
✓ 49 mm.....	144
✓ 52 mm.....	144
✓ 52 mm extra strength.....	144
✓ 53 mm.....	144
✓ 53 mm (chocolate).....	144
✓ 53 mm (strawberry).....	144
✓ 55 mm.....	144
✓ 56 mm.....	144
✓ 56 mm, shaped	144
✓ 60 mm.....	144
CYPROTERONE ACETATE WITH ETHINYL OESTRADIOL	
✓ Tab 2 mg with ethinyl oestradiol 35 mcg and 7 inert tabs.....	168
DEXAMETHASONE	
✓ Tab 0.5 mg – Retail pharmacy-Specialist	60
✓ Tab 4 mg – Retail pharmacy-Specialist	30
DEXAMETHASONE PHOSPHATE	
✓ Inj 4 mg per ml, 1 ml ampoule – See note on page 86	5

continued . .

(continued)

- ✓ Inj 4 mg per ml, 2 ml ampoule – See note on page 86 5

DIAPHRAGM

- ✓ 65 mm – See note on page 79 1
- ✓ 70 mm – See note on page 79 1
- ✓ 75 mm – See note on page 79 1
- ✓ 80 mm – See note on page 79 1

DIAZEPAM

- ✓ Inj 5 mg per ml, 2 ml ampoule – Subsidy by endorsement – See note on page 138 5
- ✓ Rectal tubes 5 mg 5
- ✓ Rectal tubes 10 mg 5

DICLOFENAC SODIUM

- ✓ Inj 25 mg per ml, 3 ml ampoule 5
- ✓ Suppos 50 mg 10

DIGOXIN

- ✓ Tab 62.5 mcg 30
- ✓ Tab 250 mcg 30

DOXYCYCLINE

- Tab 50 mg 30
- ✓ Tab 100 mg 30

ERGOMETRINE MALEATE

- ✓ Inj 500 mcg per ml, 1 ml ampoule 5

ERYTHROMYCIN ETHYL SUCCINATE

- ✓ Tab 400 mg 20
- ✓ Grans for oral liq 200 mg per 5 ml 300 ml
- ✓ Grans for oral liq 400 mg per 5 ml 200 ml

ERYTHROMYCIN STEARATE

- Tab 250 mg 30

ETHINYLLOESTRADIOL WITH DESOGESTREL

- Tab 20 mcg with desogestrel 150 mcg and 7 inert tab 84
- Tab 30 mcg with desogestrel 150 mcg and 7 inert tab 84

ETHINYLLOESTRADIOL WITH LEVONORGESTREL

- ✓ Tab 20 mcg with levonorgestrel 100 mcg and 7 inert tab 84
- ✓ Tab 50 mcg with levonorgestrel 125 mcg and 7 inert tab 84
- Tab 30 mcg with levonorgestrel 150 mcg 63
- ✓ Tab 30 mcg with levonorgestrel 150 mcg and 7 inert tab 84

ETHINYLLOESTRADIOL WITH NORETHISTERONE

- ✓ Tab 35 mcg with norethisterone 1 mg 63

- ✓ Tab 35 mcg with norethisterone 1 mg and 7 inert tab 84
- ✓ Tab 35 mcg with norethisterone 500 mcg 63
- ✓ Tab 35 mcg with norethisterone 500 mcg and 7 inert tab 84

FLUCLOXACILLIN

- ✓ Cap 250 mg 30
- ✓ Grans for oral liq 25 mg per ml 200 ml
- ✓ Grans for oral liq 50 mg per ml 200 ml
- ✓ Inj 1 g vial 10

FLUPENTHIXOL DECANOATE

- ✓ Inj 20 mg per ml, 1 ml 5
- ✓ Inj 20 mg per ml, 2 ml 5
- ✓ Inj 100 mg per ml, 1 ml 5

FLUPHENAZINE DECANOATE

- ✓ Inj 12.5 mg per 0.5 ml, 0.5 ml – Subsidy by endorsement – See note on page 148 5
- ✓ Inj 25 mg per ml, 1 ml – Subsidy by endorsement – See note on page 148 5
- ✓ Inj 25 mg per ml, 2 ml – Subsidy by endorsement – See note on page 148 5
- ✓ Inj 100 mg per ml, 1 ml – Subsidy by endorsement – See note on page 148 5

FUROSEMIDE [FRUSEMIDE]

- ✓ Tab 40 mg 30
- ✓ Inj 10 mg per ml, 2 ml ampoule 5

GLUCAGON HYDROCHLORIDE

- ✓ Inj 1 mg syringe kit 5

GLUCOSE [DEXTROSE]

- ✓ Inj 50%, 10 ml ampoule 5
- ✓ Inj 50%, 90 ml bottle 5

GLYCERYL TRINITRATE

- ✓ Tab 600 mcg 100
- ✓ Oral pump spray, 400 mcg per dose 250 dose
- ✓ Oral spray, 400 mcg per dose 250 dose

GLYCOPYRROLONIUM BROMIDE

- ✓ Inj 200 mcg per ml, 1 ml ampoule 10

HALOPERIDOL

- ✓ Tab 500 mcg 30
- ✓ Tab 1.5 mg 30
- ✓ Tab 5 mg 30
- ✓ Oral liq 2 mg per ml 200 ml
- ✓ Inj 5 mg per ml, 1 ml ampoule 5

HALOPERIDOL DECANOATE

- ✓ Inj 50 mg per ml, 1 ml 5
- ✓ Inj 100 mg per ml, 1 ml 5

continued..

✓ fully subsidised brand available

Please refer to Section A for a definition, and conditions of supply, of Practitioner's Supply Orders.

(continued)

HYDROCORTISONE
✓ Inj 100 mg vial..... 5

HYDROXOCOBALAMIN
✓ Inj 1 mg per ml, 1 ml ampoule..... 6

HYOSCINE N-BUTYLBROMIDE
✓ Inj 20 mg, 1 ml..... 5

INTRA-UTERINE DEVICE
✓ IUD 29.1 mm length × 23.2 mm width..... 40
✓ IUD 33.6 mm length × 29.9 mm width..... 40
✓ IUD 35.5 mm length × 19.6 mm width..... 40

IPRATROPIUM BROMIDE
✓ Aerosol inhaler, 20 mcg per dose
CFC-free..... 400 dose
✓ Nebuliser soln, 250 mcg per ml, 1 ml ampoule..... 40
✓ Nebuliser soln, 250 mcg per ml, 2 ml ampoule..... 40

IVERMECTIN
✓ Tab 3 mg – See note on page 74..... 100

KETONE BLOOD BETA-KETONE ELECTRODES
✓ Test strip..... 10

LEVONORGESTREL
Tab 30 mcg..... 84
✓ Tab 1.5 mg..... 5
✓ Subdermal implant (2 × 75 mg rods)..... 3

LIDOCAINE [LIGNOCAINE]
✓ Gel 2%, 10 ml urethral syringe – Subsidy by
endorsement – See note on page 132..... 5

LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE
✓ Inj 1%, 5 ml ampoule..... 25
✓ Inj 2%, 5 ml ampoule..... 5
✓ Inj 1%, 20 ml ampoule..... 5
✓ Inj 1%, 20 ml vial..... 5
✓ Inj 2%, 20 ml ampoule..... 5
✓ Inj 2%, 20 ml vial..... 5

LIDOCAINE [LIGNOCAINE] WITH CHLORHEXIDINE
✓ Gel 2% with chlorhexidine 0.05%, 10 ml
urethral syringes – Subsidy by
endorsement – See note on page 133..... 5

LOPERAMIDE HYDROCHLORIDE
✓ Tab 2 mg..... 30
✓ Cap 2 mg..... 30

MASK FOR SPACER DEVICE
✓ Small – See note on page 215..... 20

MEDROXYPROGESTERONE ACETATE
✓ Inj 150 mg per ml, 1 ml syringe..... 5

METOCLOPRAMIDE HYDROCHLORIDE
✓ Inj 5 mg per ml, 2 ml ampoule..... 5

METRONIDAZOLE
✓ Tab 200 mg..... 30

MORPHINE SULPHATE
✓ Inj 5 mg per ml, 1 ml ampoule – Only on a
controlled drug form..... 5
✓ Inj 10 mg per ml, 1 ml ampoule – Only on a
controlled drug form..... 5
✓ Inj 15 mg per ml, 1 ml ampoule – Only on a
controlled drug form..... 5
✓ Inj 30 mg per ml, 1 ml ampoule – Only on a
controlled drug form..... 5

NALOXONE HYDROCHLORIDE
✓ Inj 400 mcg per ml, 1 ml ampoule..... 5

NICOTINE
✓ Patch 7 mg – See note on page 165..... 28
✓ Patch 14 mg – See note on page 165..... 28
✓ Patch 21 mg – See note on page 165..... 28
✓ Lozenge 1 mg – See note on page 165..... 216
✓ Lozenge 2 mg – See note on page 165..... 216
✓ Gum 2 mg (Fruit) – See note on page 165..... 384
✓ Gum 2 mg (Mint) – See note on page 165..... 384
✓ Gum 4 mg (Fruit) – See note on page 165..... 384
✓ Gum 4 mg (Mint) – See note on page 165..... 384

NORETHISTERONE
✓ Tab 350 mcg..... 84
✓ Tab 5 mg..... 30

OXYTOCIN
✓ Inj 5 iu per ml, 1 ml ampoule..... 5
✓ Inj 10 iu per ml, 1 ml ampoule..... 5

OXYTOCIN WITH ERGOMETRINE MALEATE
✓ Inj 5 iu with ergometrine maleate 500 mcg
per ml, 1 ml..... 5

PARACETAMOL
✓ Tab 500 mg..... 30
✓ Oral liq 120 mg per 5 ml..... 200 ml
✓ Oral liq 250 mg per 5 ml..... 100 ml

PEAK FLOW METER
✓ Low range..... 10
✓ Normal range..... 10

PETHIDINE HYDROCHLORIDE
✓ Inj 50 mg per ml, 1 ml – Only on a controlled
drug form..... 5
✓ Inj 50 mg per ml, 2 ml – Only on a controlled
drug form..... 5

continued...

(continued)

PHENOXYMETHYLPENICILLIN (PENICILLIN V)

- ✓ Cap 250 mg 30
- ✓ Cap 500 mg 20
- ✓ Grans for oral liq 125 mg per 5 ml 200 ml
- ✓ Grans for oral liq 250 mg per 5 ml 300 ml

PHENYTOIN SODIUM

- ✓ Inj 50 mg per ml, 2 ml ampoule 5
- ✓ Inj 50 mg per ml, 5 ml ampoule 5

PHYTOMENADIONE

- ✓ Inj 2 mg per 0.2 ml 5
- ✓ Inj 10 mg per ml, 1 ml 5

PIPOTHIAZINE PALMITATE

- ✓ Inj 50 mg per ml, 1 ml – Subsidy by
endorsement – See note on page 150 5
- ✓ Inj 50 mg per ml, 2 ml – Subsidy by
endorsement – See note on page 150 5

PREDNISOLONE

- ✓ Oral liq 5 mg per ml – See note on page
86 30 ml

PREDNISONE

- ✓ Tab 5 mg 30

PREGNANCY TESTS - HCG URINE

- ✓ Cassette 200 test

PROCAINE PENICILLIN

- ✓ Inj 1.5 g in 3.4 ml syringe 5

PROCHLORPERAZINE

- ✓ Tab 5 mg 30
- ✓ Inj 12.5 mg per ml, 1 ml 5

PROMETHAZINE HYDROCHLORIDE

- ✓ Inj 25 mg per ml, 2 ml ampoule 5

SALBUTAMOL

- ✓ Inj 500 mcg per ml, 1 ml 5

- ✓ Aerosol inhaler, 100 mcg per dose CFC
free 1000 dose
- ✓ Nebuliser soln, 1 mg per ml, 2.5 ml ampoule 30
- ✓ Nebuliser soln, 2 mg per ml, 2.5 ml ampoule 30

SALBUTAMOL WITH IPRATROPIUM BROMIDE

- ✓ Nebuliser soln, 2.5 mg with ipratropium
bromide 0.5 mg per vial, 2.5 ml ampoule 20

SILVER SULPHADIAZINE

- ✓ Crm 1% 250 g

SODIUM BICARBONATE

- ✓ Inj 8.4%, 50 ml 5
- ✓ Inj 8.4%, 100 ml 5

SODIUM CHLORIDE

- ✓ Inj 0.9%, bag – See note on page
55 2000 ml
- ✓ Inj 0.9%, 5 ml ampoule – See note on page 55 5
- ✓ Inj 0.9%, 10 ml ampoule – See note on page 55 5

SPACER DEVICE

- ✓ 220 ml (single patient) 20
- ✓ 510 ml (single patient) 20
- ✓ 800 ml 20

TRIMETHOPRIM

- ✓ Tab 300 mg 30

VERAPAMIL HYDROCHLORIDE

- ✓ Inj 2.5 mg per ml, 2 ml ampoule 5

WATER

- ✓ Inj 5 ml ampoule – See note on page 55 5
- ✓ Inj 10 ml ampoule – See note on page 55 5
- ✓ Inj 20 ml ampoule – See note on page 55 5

ZUCLOPENTHIXOL DECANOATE

- ✓ Inj 200 mg per ml, 1 ml 5

Rural Areas for Practitioner's Supply Orders
NORTH ISLAND
Northland DHB

Dargaville
Hikurangi
Kaeo
Kaikohe
Kaitiaki
Kawakawa
Kerikeri
Mangonui
Maungaturoto
Moerewa
Ngunguru
Paihia
Rawene
Ruakaka
Russell
Tutukaka
Waipu
Whangaroa

Waitemata DHB

Helensville
Huapai
Kumeu
Snells Beach
Waimauku
Warkworth
Wellsford

Auckland DHB

Great Barrier Island
Oneroa
Ostend

Counties Manukau DHB

Tuakau
Waiuku

Waikato DHB

Coromandel
Huntly
Kawhia
Matamata
Morrinsville
Ngatea
Otorohanga
Paeroa
Pauanui Beach
Putaruru
Raglan

Tairua
Taumarunui
Te Aroha
Te Kauwhata
Te Kuiti
Tokoroa
Waihi
Whangamata
Whitianga

Bay of Plenty DHB

Edgecumbe
Katikati
Kawerau
Murupara
Opotiki
Taneatua
Te Kaha
Waihi Beach
Whakatane

Lakes DHB

Mangakino
Turangi

Tairāwhiti DHB

Ruatoria
Te Araroa
Te Karaka
Te Puia Springs
Tikitiki
Tokomaru Bay
Tolaga Bay

Taranaki DHB

Eltham
Inglewood
Manaia
Oakura
Okato
Opunake
Patea
Stratford
Waverley

Hawkes Bay DHB

Waipawa
Waipukurau
Wairoa

Whanganui DHB

Bulls

Marton
Ohakune
Raetihi
Taihape
Waiouru

MidCentral DHB

Dannevirke
Foxton
Levin
Otaki
Pahiatua
Shannon
Woodville

Wairarapa DHB

Carterton
Featherston
Greytown
Martinborough

SOUTH ISLAND
Nelson/Marlborough DHB

Havelock
Mapua
Motueka
Murchison
Picton
Takaka
Wakefield

West Coast DHB

Dobson
Greymouth
Hokitika
Karamea
Reefton
South Westland
Westport
Whataroa

Canterbury DHB

Akaroa
Amberley
Amuri
Chatham Islands
Cheviot
Darfield
Diamond Harbour
Hammer Springs

Kaikoura
Leeston
Lincoln
Methven
Oxford
Rakaia
Rolleston
Rotherham
Templeton
Waikari

South Canterbury DHB

Fairlie
Geraldine
Pleasant Point
Temuka
Twizel
Waimate

Southern DHB

Alexandra
Balclutha
Cromwell
Gore
Kuwrow
Lawrence
Lumsden
Mataura
Milton
Oamaru
Oban
Otautau
Outram
Owaka
Palmerston
Queenstown
Ranfurly
Riverton
Roxburgh
Tapanui
Te Anau
Tokonui
Tuatapere
Wanaka
Winton

SECTION F: PART I

A Community Pharmaceutical identified with a * within the other sections of the Pharmaceutical Schedule:

- a) is exempt from any requirement to dispense in Monthly Lots;
- b) will only be subsidised if it is dispensed in a 90 Day Lot unless it is under the Dispensing Frequency Rule.

A Community Pharmaceutical that is an oral contraceptive and that is identified with a * within the other sections of the Pharmaceutical Schedule:

- a) is exempt from any requirement to dispense in Monthly Lots;
- b) will only be subsidised if it is dispensed in a 180 Day Lot unless it is under the Dispensing Frequency Rule.

SECTION F: PART II: CERTIFIED EXEMPTIONS AND ACCESS EXEMPTIONS TO MONTHLY DISPENSING

A Community Pharmaceutical, other than a Community Pharmaceutical identified with a * within the other sections of the Pharmaceutical Schedule, may be dispensed in a 90 Day Lot if:

- a) the Community Pharmaceutical is identified with a ▲ within the other sections of the Pharmaceutical Schedule and the prescriber/pharmacist has endorsed/annotated the Prescription item(s) on the Prescription to which the exemption applies "certified exemption".

In endorsing/annotating the Prescription items for a certified exemption, the prescriber/pharmacist is certifying that:

- i) the patient wished to have the medicine dispensed in a quantity greater than a Monthly Lot; and
 - ii) the patient has been stabilised on the same medicine for a reasonable period of time; and
 - iii) the prescriber/pharmacist has reason to believe the patient will continue on the medicine and is compliant.
- b) a patient, who has difficulty getting to and from a pharmacy, signs the back of the Prescription to qualify for an Access Exemption. In signing the Prescription, the patient or his or her nominated representative must also certify which of the following criteria they meet:
 - i) have limited physical mobility;
 - ii) live and work more than 30 minutes from the nearest pharmacy by their normal form of transport;
 - iii) are relocating to another area;
 - iv) are travelling extensively and will be out of town when the repeat prescriptions are due.

SECTION F: PART III: FLEXIBLE AND VARIABLE DISPENSING PERIODS FOR PHARMACY

A Community Pharmaceutical, other than a Community Pharmaceutical identified with a * within the other sections of the Pharmaceutical Schedule, may be dispensed in variable dispensing periods under the following conditions:

- a) for stock management where the original pack(s) result in dispensing greater than 30 days supply,
- b) to synchronise a patient's medication where multiple medicines result in uneven supply periods, note if dispensing a medicine other than a Pharmaceutical identified with a * please refer to Section F: Part II

Note – the total quantity and dispensing period can not exceed the total quantity and period prescribed on the prescription.

SECTION F

The following Community Pharmaceuticals are identified with a ▲ within the other sections of the Pharmaceutical Schedule and may be dispensed in a 90 Day Lot if endorsed as a certified exemption in accordance with paragraph (a) in Section F Part II above.

ALIMENTARY TRACT AND METABOLISM

INSULIN ASPART

INSULIN ASPART WITH INSULIN ASPART PROTAMINE

INSULIN GLARGINE

INSULIN GLULISINE

INSULIN ISOPHANE

INSULIN ISOPHANE WITH INSULIN NEUTRAL

INSULIN LISPRO

INSULIN LISPRO WITH INSULIN LISPRO PROTAMINE

INSULIN NEUTRAL

CARDIOVASCULAR SYSTEM

AMIODARONE HYDROCHLORIDE

Tab 100 mg	Cordarone-X
Tab 200 mg	Cordarone-X

DISOPYRAMIDE PHOSPHATE

FLECAINIDE ACETATE

Tab 50 mg	Tambocor
Cap long-acting 100 mg	Tambocor CR
Cap long-acting 200 mg	Tambocor CR

MEXILETINE HYDROCHLORIDE

MINOXIDIL

NICORANDIL

PROPAFENONE HYDROCHLORIDE

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

DESMOPRESSIN ACETATE

Nasal drops 100 mcg Minirin
per ml

Nasal spray 10 mcg per Dosemopressin-PH&T
dose

MUSCULOSKELETAL SYSTEM

PYRIDOSTIGMINE BROMIDE

NERVOUS SYSTEM

AMANTADINE HYDROCHLORIDE

APOMORPHINE HYDROCHLORIDE

ENTACAPONE

GABAPENTIN

LACOSAMIDE

LAMOTRIGINE

PRAMIPEXOLE HYDROCHLORIDE

ROPINIROLE HYDROCHLORIDE

TOLCAPONE

TOPIRAMATE

VIGABATRIN

Pharmacists are required, under the Code of Ethics of the Pharmacy Council of New Zealand, to endeavour to use safety caps when dispensing any of the medicines listed in Section G in an oral liquid formulation pursuant to a prescription or Practitioner's Supply Order. This includes all proprietary and extemporaneously compounded oral liquid preparations of those pharmaceuticals listed in Section G of the Pharmaceutical Schedule. These medicines will be identified throughout Section B of the Pharmaceutical Schedule with the symbol '†'.

Exemptions

Oral liquid preparations of the pharmaceuticals listed in Section G of the Pharmaceutical Schedule will be dispensed in a container with a safety cap unless:

- the practitioner has endorsed the Prescription or Practitioner's Supply Order, stating that, the Pharmaceutical is not to be dispensed in a container with a safety cap; or
- the Contractor has annotated the Prescription or Practitioner's Supply Order stating that, because of infirmity of the particular person, the Pharmaceutical to be used by that person should not be dispensed in a container with a safety cap; or
- the Pharmaceutical is packaged in an Original Pack so designed that on the professional judgement of the Contractor, transfer to a container with a safety cap would be inadvisable or a retrograde procedure.

Reimbursement

Pharmacists will be reimbursed according to their agreement. Where an additional fee is paid on safety caps it will be paid on all dispensings of oral liquid preparations for those pharmaceuticals listed in Section G of the Pharmaceutical Schedule unless the practitioner has endorsed or the contractor has annotated the Prescription or Practitioner's Supply Order that a safety cap has not been supplied.

Safety Caps (NZS 5825:1991)

20 mm.....	<i>Clic-Loc</i> , United Closures & Plastics PLC, England <i>Kerr</i> , Cormack Packaging, Sydney, under licence to Kerr USA
24 mm.....	<i>Clic-Loc</i> , United Closures & Plastics PLC, England <i>Clic-Loc</i> , ACI Closures under license to Owens-Illinois <i>Kerr</i> , Cormack Packaging, Sydney, under licence to Kerr USA
28 mm.....	<i>Clic-Loc</i> , United Closures & Plastics PLC, England <i>Clic-Loc</i> , ACI Closures under license to Owens-Illinois <i>Kerr</i> , Cormack Packaging, Sydney, under licence to Kerr USA <i>PDL Squeezlok</i> <i>PDL FG</i>

ALIMENTARY TRACT AND METABOLISM
FERROUS SULPHATE

Oral liq 30 mg (6 mg elemental) per 1 ml Ferodan

CARDIOVASCULAR SYSTEM
AMILORIDE HYDROCHLORIDE

Oral liq 1 mg per ml Biomed

CAPTOPRIL

Oral liq 5 mg per ml Capoten

CHLOROTHIAZIDE

Oral liq 50 mg per ml Biomed

DIGOXIN

Oral liq 50 mcg per ml Lanoxin

FUROSEMIDE [FRUSEMIDE]

Oral liq 10 mg per ml Lasix

SPIRONOLACTONE

Oral liq 5 mg per ml Biomed

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES
LEVOTHYROXINE

Tab 25 mcg Synthroid

Tab 50 mcg Eltroxin

Tab 100 mcg Synthroid

Tab 100 mcg Eltroxin

Tab 100 mcg Synthroid

(Extemporaneously compounded oral liquid preparations)

LEVOTHYROXINE (MERCURY PHARMA)

Tab 50 mcg Mercury Pharma

Tab 100 mcg Mercury Pharma

(Extemporaneously compounded oral liquid preparations)

INFECTIONS - AGENTS FOR SYSTEMIC USE
QUININE SULPHATE

Tab 300 mg Q 300

(Extemporaneously compounded oral liquid preparations)

MUSCULOSKELETAL SYSTEM
IBUPROFEN

Oral liq 20 mg per ml Fenpaed

NERVOUS SYSTEM
ALPRAZOLAM

Tab 250 mcg Xanax

Tab 500 mcg Xanax

Tab 1 mg Xanax

(Extemporaneously compounded oral liquid preparations)

CARBAMAZEPINE

Oral liq 20 mg per ml Tegretol

CLOBAZAM

Tab 10 mg Frisium

(Extemporaneously compounded oral liquid preparations)

CLONAZEPAM

Oral drops 2.5 mg per ml Rivotril

DIAZEPAM

Tab 2 mg

Tab 5 mg Arrow-Diazepam

Arrow-Diazepam

(Extemporaneously compounded oral liquid preparations)

ETHOSUXIMIDE

Oral liq 250 mg per 5 ml Zarontin

LORAZEPAM

Tab 1 mg

Tab 2.5 mg Ativan

Ativan

(Extemporaneously compounded oral liquid preparations)

LORMETAZEPAM

Tab 1 mg

Tab 1 mg Noctamid

(Extemporaneously compounded oral liquid preparations)

METHADONE HYDROCHLORIDE

Oral liq 2 mg per ml Biodone

Oral liq 5 mg per ml Biodone Forte

Oral liq 10 mg per ml Biodone Extra Forte

MORPHINE HYDROCHLORIDE

Oral liq 1 mg per ml RA-Morph

Oral liq 2 mg per ml RA-Morph

Oral liq 5 mg per ml RA-Morph

Oral liq 10 mg per ml RA-Morph

NITRAZEPAM

Tab 5 mg

Tab 5 mg Nitrados

(Extemporaneously compounded oral liquid preparations)

OXAZEPAM

Tab 10 mg

Tab 15 mg Ox-Pam

Ox-Pam

(Extemporaneously compounded oral liquid preparations)

OXYCODONE HYDROCHLORIDE

Oral liq 5 mg per 5 ml OxyNorm

PARACETAMOL

Oral liq 120 mg per 5 ml Paracare

Oral liq 250 mg per 5 ml Paracare Double Strength

PHENYTOIN SODIUM

Oral liq 30 mg per 5 ml Dilantin

SODIUM VALPROATEOral liq 200 mg per 5 ml Epilim S/F Liquid
Epilim Syrup**TEMAZEPAM**

Tab 10 mg Normison

*(Extemporaneously compounded oral liquid preparations)***TRIAZOLAM**

Tab 125 mcg Hypam

Tab 250 mcg Hypam

*(Extemporaneously compounded oral liquid preparations)***SALBUTAMOL**

Oral liq 400 mcg per ml Ventolin

THEOPHYLLINE

Oral liq 80 mg per 15 ml Nuelin

TRIMEPAZINE TARTRATE

Oral liq 30 mg per 5 ml Vallergran Forte

**EXTEMPORANEOUSLY COMPOUNDED
PREPARATIONS AND GALENICALS****CODEINE PHOSPHATE**

Powder Douglas

*(Extemporaneously compounded oral liquid preparations)***METHADONE HYDROCHLORIDE**

Powder AFT

*(Extemporaneously compounded oral liquid preparations)***PHENOBARBITONE SODIUM**

Powder MidWest

*(Extemporaneously compounded oral liquid preparations)***RESPIRATORY SYSTEM AND ALLERGIES****CETIRIZINE HYDROCHLORIDE**

Oral liq 1 mg per ml Histaclear

CHLORPHENIRAMINE MALEATE

Oral liq 2 mg per 5 ml Histafen

DEXTROCHLORPHENIRAMINE MALEATE

Oral liq 2 mg per 5 ml Polaramine

PROMETHAZINE HYDROCHLORIDE

Oral liq 1 mg per 1 ml Allersoothe

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
Vaccinations			
ADULT DIPHTHERIA AND TETANUS VACCINE – [Xpharm]			
Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid in 0.5 ml	0.00	5	✓ ADT Booster
		1	✓ ADT Booster
Any of the following:			
1) For vaccination of patients aged 45 and 65 years old; or			
2) For vaccination of previously unimmunised or partially immunised patients; or			
3) For revaccination following immunosuppression; or			
4) For boosting of patients with tetanus-prone wounds; or			
5) For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.			
Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.			
BACILLUS CALMETTE-GUERIN VACCINE – [Xpharm]			
For infants at increased risk of tuberculosis. Increased risk is defined as:			
1) living in a house or family with a person with current or past history of TB; or			
2) having one or more household members or carers who within the last 5 years lived in a country with a rate of TB > or equal to 40 per 100,000 for 6 months or longer; or			
3) during their first 5 years will be living 3 months or longer in a country with a rate of TB > or equal to 40 per 100,000			
Note a list of countries with high rates of TB are available at www.health.govt.nz/tuberculosis (search for downloads) or www.bcgatlas.org/index.php .			
Inj Mycobacterium bovis BCG (Bacillus Calmette-Guerin),			
Danish strain 1331, live attenuated, vial with diluent	0.00	10	✓ BCG Vaccine
DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE – [Xpharm]			
Funded for any of the following criteria:			
1) A single vaccine for pregnant woman between gestational weeks 28 and 38; or			
2) A course of up to four vaccines is funded for children from age 7 up to the age of 18 years inclusive to complete full primary immunisation; or			
3) An additional four doses (as appropriate) are funded for (re-)immunisation for patients post haematopoietic stem cell transplantation or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens.			
Notes: Tdap is not registered for patients aged less than 10 years. Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.			
Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid, 8 mcg pertussis toxoid, 8 mcg pertussis filamentous haemagglutinin			
and 2.5 mcg pertactin in 0.5 ml syringe	0.00	10	✓ Boostrix
		1	✓ Boostrix

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

DIPHTHERIA, TETANUS, PERTUSSIS AND POLIO VACCINE – [Xpharm]

Funded for any of the following:

- 1) A single dose for children up to the age of 7 who have completed primary immunisation; or
- 2) A course of four vaccines is funded for catch up programmes for children (to the age of 10 years) to complete full primary immunisation; or
- 3) An additional four doses (as appropriate) are funded for (re-)immunisation for patients post HSCT, or chemotherapy; pre- or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens; or
- 4) Five doses will be funded for children requiring solid organ transplantation.

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

Inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagglutinin, 8 mcg pertactin and 80 D-antigen units poliomyelitis virus in 0.5ml syringe	0.00	1	✓ <u>Infanrix IPV</u>
		10	✓ <u>Infanrix IPV</u>

DIPHTHERIA, TETANUS, PERTUSSIS, POLIO, HEPATITIS B AND HAEMOPHILUS INFLUENZAE TYPE B VACCINE – [Xpharm]

Funded for patients meeting any of the following criteria:

- 1) Up to four doses for children up to and under the age of 10 for primary immunisation; or
- 2) An additional four doses (as appropriate) are funded for (re-)immunisation for children up to and under the age of 10 who are patients post haematopoietic stem cell transplantation, or chemotherapy; pre or post splenectomy; pre- or post solid organ transplant, renal dialysis and other severely immunosuppressive regimens; or
- 3) Up to five doses for children up to and under the age of 10 receiving solid organ transplantation.

Note: A course of up-to four vaccines is funded for catch up programmes for children (up to and under the age of 10 years) to complete full primary immunisation. Please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes.

Inj 30IU diphtheriattoxoid with 40IU tetanustoxoid, 25mcg per- tussistoxoid, 25mcg pertussisfilamentoushaemagglutinin, 8 mcg pertactin, 80 D-AgUpoliavirus, 10mcghepatitisB- surfaceantigen in 0.5ml syringe	0.00	10	✓ <u>Infanrix-hexa</u>
		1	✓ <u>Infanrix-hexa</u>

HAEMOPHILUS INFLUENZAE TYPE B VACCINE – [Xpharm]

One dose for patients meeting any of the following:

- 1) For primary vaccination in children; or
- 2) An additional dose (as appropriate) is funded for (re-)immunisation for patients post haematopoietic stem cell transplantation, or chemotherapy; functional asplenic; pre or post splenectomy; pre- or post solid organ transplant, pre- or post cochlear implants, renal dialysis and other severely immunosuppressive regimens; or
- 3) For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

Inj 10 mcg vial with diluent syringe	0.00	1	✓ <u>Act-HIB</u>
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HEPATITIS A VACCINE – [Xpharm]

Funded for patients meeting any of the following criteria:

- 1) Two vaccinations for use in transplant patients; or
- 2) Two vaccinations for use in children with chronic liver disease; or
- 3) One dose of vaccine for close contacts of known hepatitis A cases.

Inj 1440 ELISA units in 1 ml syringe	0.00	1	✓ <u>Havrix</u>
Inj 720 ELISA units in 0.5 ml syringe	0.00	1	✓ <u>Havrix Junior</u>

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
HEPATITIS B RECOMBINANT VACCINE – [Xpharm]				
Inj 5 mcg per 0.5 ml vial	0.00	1	✓	HBvaxPRO
Funded for patients meeting any of the following criteria:				
1) for household or sexual contacts of known acute hepatitis B patients or hepatitis B carriers; or				
2) for children born to mothers who are hepatitis B surface antigen (HBsAg) positive; or				
3) for children up to and under the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination; or				
4) for HIV positive patients; or				
5) for hepatitis C positive patients; or				
6) for patients following non-consensual sexual intercourse; or				
7) for patients following immunosuppression; or				
8) for transplant patients; or				
9) following needle stick injury.				
Inj 10 mcg per 1 ml vial	0.00	1	✓	HBvaxPRO
Funded for patients meeting any of the following criteria:				
1) for household or sexual contacts of known acute hepatitis B patients or hepatitis B carriers; or				
2) for children born to mothers who are hepatitis B surface antigen (HBsAg) positive; or				
3) for children up to and under the age of 18 years inclusive who are considered not to have achieved a positive serology and require additional vaccination; or				
4) for HIV positive patients; or				
5) for hepatitis C positive patients; or				
6) for patients following non-consensual sexual intercourse; or				
7) for patients following immunosuppression; or				
8) for transplant patients; or				
9) following needle stick injury.				
Inj 40 mcg per 1 ml vial	0.00	1	✓	HBvaxPRO
Funded for any of the following criteria:				
1) for dialysis patients; or				
2) for liver or kidney transplant patient.				
HUMAN PAPILLOMAVIRUS (6, 11, 16 AND 18) VACCINE [HPV] – [Xpharm]				
Funded for patient meeting either of the following criteria:				
1) Maximum of 3 doses for people aged 9 to 26 years inclusive; or				
2) Maximum of four doses for people aged 9 to 26 years inclusive, post chemotherapy.				
Inj 120 mcg in 0.5 ml syringe	0.00	10	✓	Gardasil
		1	✓	Gardasil
<i>(Gardasil Inj 120 mcg in 0.5 ml syringe to be delisted 1 October 2017)</i>				
<i>(Gardasil Inj 120 mcg in 0.5 ml syringe to be delisted 1 October 2017)</i>				
HUMAN PAPILLOMAVIRUS (6, 11, 16, 18, 31, 33, 45, 52 AND 58) VACCINE [HPV] – [Xpharm]				
Any of the following:				
1) Maximum of two doses for children aged 14 years and under; or				
2) Maximum of three doses for patients meeting any of the following criteria:				
a) People aged 15 to 26 years inclusive; or				
b) Either:				
People aged 9 to 26 years inclusive				
a) Confirmed HIV infection; or				
b) Transplant (including stem cell) patients: or				
3) Maximum of four doses for people aged 9 to 26 years inclusive post chemotherapy				
Inj 270 mcg in 0.5 ml syringe	0.00	10	✓	Gardasil 9

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

INFLUENZA VACCINE – [Xpharm]

A) 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) cerebro-vascular disease; or
 - ii) have either of the following chronic respiratory diseases:
 - a) asthma, if on a regular preventative therapy, or
 - b) other chronic respiratory disease with impaired lung function; or
 - iii) have diabetes; or
 - iv) have chronic renal disease; or
 - v) have any cancer, excluding basal and squamous skin cancers if not invasive; or
 - vi) have any of the following other conditions:
 - a) autoimmune disease, or
 - b) immune suppression or immune deficiency, or
 - c) HIV, or
 - d) transplant recipients, or
 - e) neuromuscular and CNS diseases/disorders, or
 - f) haemoglobinopathies, or
 - g) are children on long term aspirin, or
 - h) have a cochlear implant, or
 - i) errors of metabolism at risk of major metabolic decompensation, or
 - j) pre and post splenectomy, or
 - k) down syndrome, or
 - vii) are pregnant; or
- c) children aged four years and under who have been hospitalised for respiratory illness or have a history of significant respiratory illness;

Unless meeting the criteria set out above, the following conditions are excluded from funding:

- a) asthma not requiring regular preventative therapy,
- b) hypertension and/or dyslipidaemia without evidence of end-organ disease.

- B) Doctors are the only Contractors entitled to claim payment from the Funder for the supply of influenza vaccine to patients eligible under the above criteria for subsidised immunisation and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.
- C) Stock of the seasonal influenza vaccine is typically available from February until late July with suppliers being required to ensure supply until at least 30 June. Exact start and end dates for each season will be notified each year.

Inj 45 mcg in 0.5 ml syringe	90.00	10	✓ Influvac
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MEASLES, MUMPS AND RUBELLA VACCINE – [Xpharm]

A maximum of two doses for any patient meeting the following criteria:

- 1) For primary vaccination in children; or
- 2) For revaccination following immunosuppression; or
- 3) For any individual susceptible to measles, mumps or rubella; or
- 4) A maximum of three doses for children who have had their first dose prior to 12 months.

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

Inj 1000 TCID50 measles, 12500 TCID50 mumps and			
1000 TCID50 rubella vial with diluent 0.5 ml vial	0.00	10	✓ M-M-R II
		1	✓ M-M-R II

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
MENINGOCOCCAL (GROUPS A, C, Y AND W-135) CONJUGATE VACCINE – [Xpharm]				
Any of the following:				
1) Up to three doses and a booster every five years for patients pre- and post splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre or post solid organ transplant; or				
2) One dose for close contacts of meningococcal cases; or				
3) A maximum of two doses for bone marrow transplant patients; or				
4) A maximum of two doses for patients following immunosuppression*.				
Note: children under seven years of age require two doses 8 weeks apart, a booster dose three years after the primary series and then five yearly.				
*Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.				
Inj 4 mcg of each meningococcal polysaccharide conjugated to a total of approximately 48 mcg of diphtheria toxoid carrier per 0.5 ml vial	0.00	1	✓	Menactra
MENINGOCOCCAL C CONJUGATED VACCINE – [Xpharm]				
Any of the following:				
1) Up to three doses and a booster every five years for patients pre- and post splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre or post solid organ transplant; or				
2) One dose for close contacts of meningococcal cases; or				
3) A maximum of two doses for bone marrow transplant patients; or				
4) A maximum of two doses for patients following immunosuppression*.				
Note: children under seven years of age require two doses 8 weeks apart, a booster dose three years after the primary series and then five yearly.				
*Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.				
Inj 10 mcg in 0.5 ml syringe	0.00	1	✓	Neisvac-C
		10	✓	Neisvac-C
PNEUMOCOCCAL (PCV13) VACCINE – [Xpharm]				
Any of the following:				
1) A primary course of four doses for previously unvaccinated individuals up to the age of 59 months inclusive; or				
2) Up to three doses as appropriate to complete the primary course of immunisation for individuals under the age of 59 months who have received one to three doses of PCV10; or				
3) One dose is funded for high risk children (over the age of 17 months and up to the age of 18) who have previously received four doses of PCV10; or				
4) Up to an additional four doses (as appropriate) are funded for (re-)immunisation of patients with HIV, for patients post haematopoietic stem cell transplantation, or chemotherapy; pre- or post splenectomy; functional asplenia, pre- or post-solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, or primary immunodeficiency; or				
5) For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.				
Note: please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes				
Inj 30.8 mcg in 0.5 ml syringe	0.00	10	✓	Prevenar 13
		1	✓	Prevenar 13
PNEUMOCOCCAL (PPV23) POLYSACCHARIDE VACCINE – [Xpharm]				
Either:				
1) Up to three doses (as appropriate) for patients with HIV, for patients post haematopoietic stem cell transplant, or chemotherapy; pre- or post-splenectomy or with functional asplenia, pre- or post-solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, or primary immunodeficiency; or				
2) Up to two doses are funded for high risk children to the age of 18.				
Inj 575 mcg in 0.5 ml prefilled syringe (25 mcg of each 23 pneumococcal serotype)	0.00	1	✓	Pneumovax 23

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
POLIOMYELITIS VACCINE – [Xpharm]			
Up to three doses for patients meeting either of the following:			
1) For partially vaccinated or previously unvaccinated individuals; or			
2) For revaccination following immunosuppression.			
Note: Please refer to the Immunisation Handbook for appropriate schedule for catch-up programmes.			
Inj 80D antigen units in 0.5 ml syringe	0.00	1	✓ IPOL
ROTAVIRUS LIVE REASSORTANT ORAL VACCINE – [Xpharm]			
Maximum of three doses for patients meeting the following:			
1) first dose to be administered in infants aged under 15 weeks of age; and			
2) no vaccination being administered to children aged 8 months or over.			
Oral susp G1, G2, G3, G4, P1(8)11.5 million CCID50 units per 2 ml, tube	0.00	10	✓ RotaTeq
VARICELLA VACCINE [CHICKEN POX VACCINE] – [Xpharm]			
Maximum of two doses for any of the following:			
1) For non-immune patients:			
2) a) with chronic liver disease who may in future be candidates for transplantation; or			
b) with deteriorating renal function before transplantation; or			
c) prior to solid organ transplant; or			
d) prior to any elective immunosuppression*.			
3) For patients at least 2 years after bone marrow transplantation, on advice of their specialist.			
4) For patients at least 6 months after completion of chemotherapy, on advice of their specialist.			
5) For HIV positive non immune to varicella with mild or moderate immunosuppression on advice of HIV specialist.			
6) For patients with inborn errors of metabolism at risk of major metabolic decompensation, with no clinical history of varicella.			
7) 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.			
8) For household contacts of adult patients who have no clinical history of varicella and who are severely immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella.			
* immunosuppression due to steroid or other immunosuppressive therapy must be for a treatment period of greater than 28 days			
Inj 2000 PFU vial with diluent	0.00	1	✓ Varilrix

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