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Introducing PHARMAC

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 that can be used in DHB hospitals and is a separate publication.

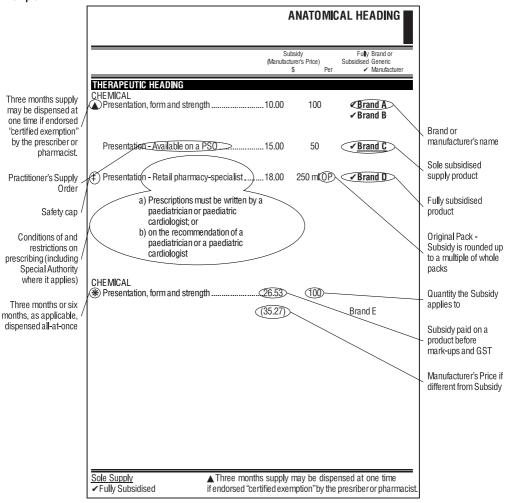
The Pharmaceuticals in this book are listed by therapeutic group, which is based on the WHO Anatomical Therapeutic Chemical (ATC) system. The listings are displayed alphabetically under each heading.

The index lists both chemical entities and product brand names.

Explaining pharmaceutical entries

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

Example



Glossary

Units of Measure

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

BSO Bulk Supply Order. CBS Cost Brand Source.

ECP Extemporaneously Compounded Preparation.

ΩP 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.

S29 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, Private Bag 3015, WANGANUI 4540 Fax: (06) 349 1983 or free fax 0800 100 131

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 whole-salers 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 2018 and is to be referred to as the Pharmaceutical Schedule Volume 25 Number 0, 2018. Distribution will be from 20 March 2018. This Schedule comes into force on 1 March 2018.

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 initialled 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 Prescriber. 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 Prescriber 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 Prescriber.
- "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 Prescriber which is either:
 - i) endorsed with the words "recommended by [name of specialist and year of authorisation]" and signed by the Prescriber, 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 Prescriber of the name of the Specialist and date of recommendation, with the words "recommended by [name of specialist and date of authorisation], confirmed by [Prescriber]". 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 Prescriber or any of the following: Quitcard Provider, a Pharmacist, or a Vaccinator as those terms are defined in the Pharmaceutical Schedule.
- "Practitioner's Supply Order", means a written order made by a Prescriber on a form supplied by the Ministry of Health, or approved by the Ministry of Health, for the supply of Community Pharmaceuticals to the Prescriber, which the Prescriber 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.
- "Prescriber", means a Doctor, a Dentist, a Dietitian, a Midwife, a Nurse Practitioner, a Registered Nurse Prescriber, an Optometrist, or a Pharmacist Prescriber as those terms are defined in the Pharmaceutical Schedule.
- "Prescription", means a quantity of a Community Pharmaceutical prescribed for a named person on a document signed by a Prescriber.
- "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 Prescriber, 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 Prescriber of the name of the Specialist and date of recommendation, with the words "recommended by [name of specialist and year of authorisation], confirmed by [Prescriber]". 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 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;
 - 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. Prescribers of 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.

"Vaccinator", means either:

- a) a pharmacist who has successfully completed a vaccinator training course approved by the Ministry of Health and who is complying with the immunisation standards of the Ministry of Health; or
- b) any other person who is authorised by the Director-General of Health or a Medical Officer of Health to administer vaccines in accordance with this Section 44A of the Medicines Regulations 1984.
- 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
 - 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 Prescribers Prescriptions and provision of pharmaceuticals by other Practitioners (other than oral contraceptives)

The following provisions apply to all Prescriptions, other than those for an oral contraceptive, written by a Prescriber and provision of pharmaceuticals by other Practitioners 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 Prescriber and 3.1.7 for an Optometrist, where a Prescriber 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:
 - the Prescriber endorses the Community Pharmaceutical on the Prescription with the words "certified exemption" written in the Prescriber's own handwriting, or signed or initialled by the Prescriber; and
 - 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 eliqible for Subsidy.
- 3.1.7 If a Community Pharmaceutical:
 - a) is stable for a limited period only, and the Prescriber 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 Prescriber for an oral contraceptive:

3.2.1 The 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 eliqible 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 Prescriber 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
 - 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
 - an unapproved medicine supplied under Section 29 of the Medicines Act 1981, but excluding any medicine listed as Cost, Brand, Source of Supply, or
 - any other pharmaceutical that PHARMAC determines, from time to time and notes in the Pharmaceutical Schedule

and it is prescribed or ordered by a Prescriber 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 Prescriber 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 or ordered by the Prescriber is less than 10% (eq; 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 or ordered by the Prescriber.

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 Non-prescribing Practitioners

- 3.6.1 Dispensing on the authority of a Quitcard will only be subsidised where it is:
 - a) for any of the following Community Pharmaceuticals: nicotine patches, nicotine lozenges or nicotine gum;
 and
 - b) written on a Quitcard.
- 3.6.2 Provision of vaccines by Vaccinators

Vaccines will only be valid for subsidy in accordance with an agreement between the Contractor and the DHB, and only for direct administration of a vaccine to a patient.

3.6.3 Provision of a Community Pharmaceutical by a Pharmacist Except where pursuant to a prescription, Quitcard or supply order, provision of a community pharmaceutical by a pharmacist will only be subsidised where specifically indicated in Section B of the Pharmaceutical Schedule.

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
 - 28 days' supply for any other Community Pharmaceutical (except under conditions outlined in 4.3 (Trial periods) below; and
- b) the Prescriber 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 Prescriber 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 page 15; 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 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 Prescriber 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 Prescriber may order such Community Pharmaceuticals as he or she expects to be required for personal administration to patients under the Prescriber's care if:
 - a) the Prescriber's normal practice is in the specified areas listed in Section E Part II of the Schedule, or if the Prescriber is a locum for a Prescriber 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 Prescriber 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 Prescriber; and
- ii) sets out the Prescriber'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 Prescriber 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 Prescriber 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 lig 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 Prescriber 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. Prescribers of 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 Prescribers obtain written consent); and
 - 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 Prescribers of unapproved Pharmaceuticals

Prescribers 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
- not explicitly preclude Government funded access to a Pharmaceutical when it is used for an Unapproved Indication:

Accordingly, if Prescribers are planning on prescribing an unapproved Pharmaceutical or a Pharmaceutical for an Unapproved Indication, Prescribers 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 Prescribers obtain written consent); and
- 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.

Prescribers 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 Prescriber 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
- 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 R. ALIMENTARY TRACT AND METAROLISM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
Antacids and Antiflatulants				
Antacids and Reflux Barrier Agents				
LGINIC ACID Sodium alginate 225 mg and magnesium alginate 87.5 mg po sachet		30	,	Gaviscon Infant
CODIUM ALGINATE Tab 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg - peppermint flavour	1.80 (8.60)	60		Gaviscon Double Strength
F Oral liq 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml		500 m	I	Acidex
Phosphate Binding Agents				
ALUMINIUM HYDROXIDE Tab 600 mg	12.56	100	•	Alu-Tab
Oral liq 1,250 mg per 5 ml (500 mg elemental per 5 ml) — Subsidy by endorsementOnly when prescribed for children under 12 years of age endorsed accordingly.		500 m ate bir		Roxane nt and the prescription is
Antidiarrhoeals				
Agents Which Reduce Motility				
OPERAMIDE HYDROCHLORIDE – Up to 30 cap available on a * Tab 2 mg * Cap 2 mg	10.75	400 400		Nodia Diamide Relief
Rectal and Colonic Anti-inflammatories				
BUDESONIDE Cap 3 mg - Special Authority see SA1155 below - Retail pharmacy	166.50	90	•	Entocort CIR

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

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

continued...

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

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

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

Note: Indication marked with * is an Unapproved Indication.

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

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

HYDROCORTISONE ACETATE

Rectal foam 10%, CFC-Free (14 applications)	26.55	21.1 g OP	✓ Colifoam
MESALAZINE			
Tab 400 mg	49.50	100	✓ Asacol
Tab EC 500 mg	49.50	100	✓ Asamax
Tab long-acting 500 mg		100	✓ Pentasa
Tab 800 mg	85.50	90	✓ Asacol
Modified release granules, 1 g	141.72	120 OP	✓ Pentasa
Enema 1 g per 100 ml		7	✓ Pentasa
Suppos 500 mg		20	✓ Asacol
Suppos 1 g		30	✓ Pentasa
OLSALAZINE			
Tab 500 mg	93.37	100	✓ Dipentum
Cap 250 mg		100	✓ Dipentum
SODIUM CROMOGLICATE			
Cap 100 mg	92.91	100	✓ Nalcrom
SULPHASALAZINE			
* Tab 500 mg - For sulphasalazine oral liquid formulation	n refer,		
page 227	14.00	100	✓ Salazopyrin
* Tab EC 500 mg	13.50	100	✓ Salazopyrin EN

Local preparations for Anal and Rectal Disorders

Antihaemorrhoidal Preparations

FLUOCORTOLONE CAPROATE WITH FLUOCORTOLONE PIVALATE AND CINCHOCA	INE
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Oint 950 mcg, with fluocortolone pivalate 920 mcg, and cinchocaine hydrochloride 5 mg per g	30 g OP	✓ Ultraproct
Suppos 630 mcg, with fluocortolone pivalate 610 mcg, and cinchocaine hydrochloride 1 mg2.66	12	✓ Ultraproct
HYDROCORTISONE WITH CINCHOCAINE		
Oint 5 mg with cinchocaine hydrochloride 5 mg per g15.00	30 g OP	✓ Proctosedyl
Suppos 5 mg with cinchocaine hydrochloride 5 mg per g9.90		✓ Proctosedyl

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Manufacturer Management of Anal Fissures GLYCERYL TRINITRATE - Special Authority see SA1329 below - Retail pharmacy 30 q OP ✓ Rectogesic ⇒SA1329 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has a chronic anal fissure that has persisted for longer than three weeks. Antispasmodics and Other Agents Altering Gut Motility **GLYCOPYRRONIUM BROMIDE** Inj 200 mcg per ml, 1 ml ampoule - Up to 10 inj available on a PSO.......17.14 10 ✓ Max Health HYOSCINE BUTYLBROMIDE * Tab 10 mg8.75 100 ✓ Buscopan * Inj 20 mg, 1 ml - Up to 5 inj available on a PSO......9.57 5 ✓ Buscopan MEBEVERINE HYDROCHLORIDE 90 ✓ Colofac **Antiulcerants** Antisecretory and Cytoprotective **MISOPROSTOL** 120 ✓ Cytotec Helicobacter Pylori Eradication CLARITHROMYCIN

Tab 500 mg - Subsidy by endorsement......10.40

14

✓ Apo-Clarithromycin

- a) Maximum of 14 tab per prescription
- b) Subsidised only if prescribed for helicobacter pylori eradication and prescription is endorsed accordingly.

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

H2 Antagonists

RA	NITIDINE – Only on a prescription			
*	Tab 150 mg	12.91	500	Ranitidine Relief
*	Tab 300 mg	18.21	500	✓ Ranitidine Relief
	Oral lig 150 mg per 10 ml		300 ml	✓ Peptisoothe
*	Inj 25 mg per ml, 2 ml	8.75	5	✓ Zantac

Proton Pump Inhibitors

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
DMEPRAZOLE	<u> </u>			
For omeprazole suspension refer Standard Formulae, page 2 Cap 10 mg		90	•	Omeprazole actavis
	(2.23)			Omezol Relief
Omeprazole actavis 10 to be Sole Supply on 1 June 2018 Cap 20 mg	3	90	✓	Omeprazole actavis
Omeprazole actavis 20 to be Sole Supply on 1 June 2018	(2.91)			20 Omezol Relief
Cap 40 mg		90	✓	Omeprazole actavis
	(4.42)			Omezol Relief
Omeprazole actavis 40 to be Sole Supply on 1 June 2018 Powder – Only in combination Only in extemporaneously compounded omeprazole susp	42.50	5 g	✓	Midwest
Finj 40 mg ampoule with diluent		5	✓	<u>Dr Reddy's</u> <u>Omeprazole</u>
Omezol Relief Cap 10 mg to be delisted 1 June 2018) Omezol Relief Cap 20 mg to be delisted 1 June 2018) Omezol Relief Cap 40 mg to be delisted 1 June 2018) ANTOPRAZOLE				
₹ Tab EC 20 mg		100 100		Panzop Relief Panzop Relief
Site Protective Agents				
COLLOIDAL BISMUTH SUBCITRATE Tab 120 mg	14.51	50	•	Gastrodenol S29
SUCRALFATE Tab 1 g	35.50 (48.28)	120		Carafate
Bile and Liver Therapy				
IFAXIMIN - Special Authority see SA1461 below - Retail pharm Tab 550 mg Special Authority for Subsidy		56	1	<u>Xifaxan</u>

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.

	Subsidy (Manufacturer's P \$	rice) Subs Per	Fully sidised	Brand or Generic Manufacturer
Diabetes				
Hyperglycaemic Agents				
DIAZOXIDE – Special Authority see SA1320 below – Retail ph Cap 25 mg Cap 100 mg Oral liq 50 mg per ml SA1320 Special Authority for Subsidy nitial application from any relevant practitioner. Approvals va nypoglycaemia caused by hyperinsulinism. Renewal from any relevant practitioner. Approvals valid withous ppropriate and the patient is benefiting from treatment.			✓ P ✓ P	
GLUCAGON HYDROCHLORIDE Inj 1 mg syringe kit – Up to 5 kit available on a PSO	32.00	1	√ G	lucagen Hypokit
Insulin - Short-acting Preparations				
NSULIN NEUTRAL ▲ Inj human 100 u per ml		10 ml OP		ctrapid umulin R
Inj human 100 u per ml, 3 ml	42.66	5		ctrapid Penfill umulin R
Insulin - Intermediate-acting Preparations				
NSULIN ASPART WITH INSULIN ASPART PROTAMINE Inj 100 iu per ml, 3 ml prefilled pen NSULIN ISOPHANE	52.15	5	✓ N	ovoMix 30 FlexPen
Inj human 100 u per ml	17.68	10 ml OP		umulin NPH rotaphane
▲ Inj human 100 u per ml, 3 ml	29.86	5	✓ H	umulin NPH rotaphane Penfill
NSULIN ISOPHANE WITH INSULIN NEUTRAL Inj human with neutral insulin 100 u per ml	25.26	10 ml OP		umulin 30/70 ixtard 30
Inj human with neutral insulin 100 u per ml, 3 ml	42.66	5	✓ H ✓ P ✓ P	ixtaru 30 umulin 30/70 enMix 30 enMix 40 enMix 50
NSULIN LISPRO WITH INSULIN LISPRO PROTAMINE Inj lispro 25% with insulin lispro protamine 75% 100 u per n 3 ml		5	√ H	umalog Mix 25
▲ Inj lispro 50% with insulin lispro protamine 50% 100 u per n		5		umalog Mix 50

	Subsidy (Manufacturer's Price \$	e) Sub: Per	Fully sidised	Brand or Generic Manufacturer
Insulin - Long-acting Preparations				
INSULIN GLARGINE				
▲ Inj 100 u per ml, 10 ml	63.00	1	√ L	antus
▲ Inj 100 u per ml, 3 ml		5	√ L	antus
▲ Inj 100 u per ml, 3 ml disposable pen	94.50	5	√ L	antus SoloStar
Insulin - Rapid Acting Preparations				
NSULIN ASPART				
▲ Inj 100 u per ml, 3 ml syringe	51.19	5	✓ N	lovoRapid FlexPen
▲ Inj 100 u per ml, 3 ml	51.19	5	✓ N	lovoRapid Penfill
▲ Inj 100 u per ml, 10 ml	30.03	1	✓ N	lovoRapid
NSULIN GLULISINE				
▲ Inj 100 u per ml, 10 ml	27.03	1	✓ A	pidra
Inj 100 u per ml, 3 ml	46.07	5	✓ A	pidra
Inj 100 u per ml, 3 ml disposable pen	46.07	5	✓ A	pidra SoloStar
NSULIN LISPRO				
Inj 100 u per ml, 10 ml	34.92	10 ml OP	√ H	lumalog
Inj 100 u per ml, 3 ml	59.52	5	✓ H	lumalog
Alpha Glucosidase Inhibitors				
ACARBOSE				
* Tab 50 mg	4.28	90	√ <u>G</u>	ilucobay
* Tab 100 mg	7.78	90	√ <u>G</u>	ilucobay
Oral Hypoglycaemic Agents				
GLIBENCLAMIDE				
₭ Tab 5 mg	5.00	100	√ D	aonil
GLICLAZIDE				
★ Tab 80 mg	10.29	500	√ <u>G</u>	<u>ilizide</u>
GLIPIZIDE				
★ Tab 5 mg	2.85	100	✓ <u>N</u>	<u>linidiab</u>
METFORMIN HYDROCHLORIDE				
★ Tab immediate-release 500 mg	9.59	1,000	✓ N	letchek
* Tab immediate-release 850 mg		500	✓ <u>N</u>	letformin Mylan
PIOGLITAZONE				
* Tab 15 mg	3.47	90	✓ V	exazone
* Tab 30 mg	5.06	90	✓ V	exazone
* Tab 45 mg	7.10	90	✓ V	exazone

[‡] safety cap

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

Diabetes Management

Ketone Testing

BLOOD KETONE DIAGNOSTIC TEST STRIP - Subsidy by endorsement

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

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

Neo

(Freestyle Optium Neo Meter to be delisted 1 August 2018)

KETONE BLOOD BETA-KETONE ELECTRODES

- a) Maximum of 20 strip per prescription
- b) Up to 10 strip available on a PSO

(Freestyle Optium Ketone Test strip to be delisted 1 August 2018)

SODIUM NITROPRUSSIDE - Maximum of 50 strip per prescription

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

Dual Blood Glucose and Blood Ketone Testing

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

- a) Maximum of 1 pack per prescription
- b) Up to 1 pack available on a PSO
- c) Note: may be provided by a pharmacist under the non-prescribing Practitioners provisions in Part III of Section A.
- d) A dual blood glucose and blood ketone diagnostic test meter is subsidised for a patient who has:
 - 1) type 1 diabetes; or
 - 2) permanent neonatal diabetes; or
 - 3) undergone a pancreatectomy; or
 - 4) cystic fibrosis-related diabetes, or
 - 5) metabolic disease or epilepsy under the care of a paediatrician, neurologist or metabolic specialist.

The prescription must be endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of insulin or sulphonylureas.

Only 1 meter per patient will be subsidised (no repeat prescriptions).

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

From 1 February 2018 – 31 July 2018 patients who have used a CareSens II blood glucose diagnostic meter and associated strips, as their only blood glucose diagnostic testing meter and strips, are eligible for a new CareSens meter provided they meet the funding criteria.

Meter with 50 lancets, a lancing device and 10 blood glucose

- a) Brand switch fee payable (Pharmacode 2535890) see page 224 for details
- b) No patient co-payment payable

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

Blood Glucose Testing

BLOOD GLUCOSE DIAGNOSTIC TEST METER - Subsidy by endorsement

- a) Maximum of 1 pack per prescription
- b) Up to 1 pack available on a PSO
- c) Note: may be provided by a pharmacist under the non-prescribing Practitioners provisions in Part III of Section A.
- d) A diagnostic blood glucose test meter is subsidised for a patient who:
 - 1) is receiving insulin or sulphonylurea therapy; or
 - 2) is pregnant with diabetes; or
 - 3) is on home TPN at risk of hypoglycaemia or hyperglycaemia; or
 - 4) has a genetic or an acquired disorder of glucose homeostasis, excluding type 1 or type 2 diabetes and metabolic syndrome.

The prescription must be endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of insulin or sulphonylureas.

Only one CareSens meter per patient will be subsidised (no repeat prescriptions).

Patients already using the CareSens N POP meter and CareSens N meter are not eligible for a new meter, unless they meet the criteria for a dual blood glucose and blood ketone diagnostic test meter.

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

From 1 February 2018 – 31 July 2018 patients who have used a CareSens II blood glucose diagnostic meter and associated strips, as their only blood glucose diagnostic testing meter and strips, are eligible for a new CareSens meter provided they meet the funding criteria.

b) CareSens N POP brand: Brand switch fee payable (Pharmacode 2423154) - see page 224 for details

c) CareSens N Premier brand: Brand switch fee payable (Pharmacode 2535882) - see page 224 for details

d) Note: Only 1 meter available per PSO

Meter with $50 \times$ lancets, $10 \times$ diagnostic test strips and a

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

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
- 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.

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

(CareSens Test strips to be delisted 1 August 2018)

(Accu-Chek Performa Test strips to be delisted 1 August 2018)

(Freestyle Optium Test strips to be delisted 1 August 2018)

⇒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: <u>bgstrips@pharmac.govt.nz</u>

BLOOD GLUCOSE TEST STRIPS (VISUALLY IMPAIRED)

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
- 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.

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

Insulin Syringes and Needles

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

INSULIN PEN NEEDLES	 Maximum of 100 dev per prescription

IIVO	ocin fen needles – maximum of 100 dev per prescript	lion		
*	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
*			100	✓ B-D Micro-Fine
INS	SULIN SYRINGES, DISPOSABLE WITH ATTACHED NEED	LE - Maximum of 1	00 dev per p	orescription
*	Syringe 0.3 ml with 29 g x 12.7 mm needle	13.00	100	B-D Ultra Fine
		1.30	10	
		(1.99)		B-D Ultra Fine
*	Syringe 0.3 ml with 31 g × 8 mm needle	13.00	100	B-D Ultra Fine II
		1.30	10	
		(1.99)		B-D Ultra Fine II
*	Syringe 0.5 ml with 29 g x 12.7 mm needle	13.00	100	B-D Ultra Fine
		1.30	10	
		(1.99)		B-D Ultra Fine
*	Syringe 0.5 ml with 31 g × 8 mm needle	13.00	100	B-D Ultra Fine II
		1.30	10	
		(1.99)		B-D Ultra Fine II
*	Syringe 1 ml with 29 g x 12.7 mm needle	13.00	100	B-D Ultra Fine
		1.30	10	
		(1.99)		B-D Ultra Fine
*	Syringe 1 ml with 31 g × 8 mm needle	13.00	100	B-D Ultra Fine II
		1.30	10	
		(1.99)		B-D Ultra Fine II

Insulin Pumps

INSULIN PUMP - Special Authority see SA1603 on the next page - 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	ar 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		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

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

⇒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 Fither:
 - 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 Fither:
 - 4.1 Applicant is a relevant specialist; or
 - 4.2 Applicant is a nurse practitioner working within their vocational scope.

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

All of the following:

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

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

All of the following:

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

Subsidy	Fi	ılly	Brand or
(Manufacturer's Price)	Subsidis	sed	Generic
\$	Per	/	Manufacturer

continued...

- 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:

- 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 Fither:
 - 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

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

continued...

- 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 Fither:
 - 4.1 It has been at least 4 years since the last insulin pump was received by the patient; or
 - 4.2 The pump is due for replacement; and
- 5 Either:
 - 5.1 Applicant is a relevant specialist; or
 - 5.2 Applicant is a nurse practitioner working within their vocational scope.

Insulin Pump Consumables

⇒SA1604 Special Authority for Subsidy

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

All of the following:

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

			
	Subsidy	Fully	Brand or
	(Manufacturer's Price)	Subsidised	Generic
	\$	Por 🗸	Manufacturer

continued...

- 2 Has undertaken carbohydrate counting education (either a carbohydrate counting course or direct education from an appropriate health professional); and
- 3 Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care; and
- 4 Has adhered to an intensive MDI regimen using analogue insulins for at least six months; and
- 5 Has 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
 - 3.2 Applicant is a nurse practitioner working within their vocational scope.

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

All of the following:

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

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

All of the following:

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

Subsidy	Fu	lly Brand or	
(Manufacturer's Price)	Subsidis	ed Generic	
\$	Per	 Manufactur 	er

continued...

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:

- 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 Fither:
 - 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 33 - 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	y Ca	р
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Subsidy Fully Brand or
(Manufacturer's Price) Subsidised Generic
\$ Per ✓ Manufacturer

INSULIN PUMP INFUSION SET (STEEL CANNULA) - Special Authority see SA1604 on page 33 - 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

c) Maximum of 13 infusion sets will be funded per year.			
10 mm steel needle; 29 G; manual insertion; 60 cm tubing x			
10 with 10 needles	130.00	1 OP	✓ Paradigm Sure-T MMT-884
10 mm steel needle; 29 G; manual insertion; 60 cm tubing \times			
10 with 10 needles; luer lock	130.00	1 OP	✓ Sure-T MMT-883
10 mm steel needle; 29 G; manual insertion; 80 cm tubing x			
10 with 10 needles	130.00	1 OP	Paradigm Sure-T
			MMT-886
10 mm steel needle; 29 G; manual insertion; 80 cm tubing \times			
10 with 10 needles; luer lock	130.00	1 OP	✓ Sure-T MMT-885
6 mm steel cannula; straight insertion; 60 cm grey line \times 10 with	า		
10 needles	130.00	1 OP	✓ Contact-D
6 mm steel needle; 29 G; manual insertion; 60 cm tubing x			
10 with 10 needles	130.00	1 OP	✓ Paradigm Sure-T
			MMT-864
6 mm steel needle; 29 G; manual insertion; 60 cm tubing ×			
10 with 10 needles; luer lock	130.00	1 OP	✓ Sure-T MMT-863
6 mm steel needle; 29 G; manual insertion; 80 cm tubing ×			
10 with 10 needles	130.00	1 OP	✓ Paradigm Sure-T
			MMT-866
6 mm steel needle; 29 G; manual insertion; 80 cm tubing x			
10 with 10 needles; luer lock	130.00	1 OP	✓ Sure-T MMT-865
8 mm steel cannula; straight insertion; 110 cm grey line x			
10 with 10 needles	130.00	1 OP	✓ Contact-D
8 mm steel cannula; straight insertion; 60 cm grey line × 10 with	า		
10 needles		1 OP	✓ Contact-D
8 mm steel needle; 29 G; manual insertion; 60 cm tubing ×			
10 with 10 needles	130.00	1 OP	✓ Paradigm Sure-T
			MMT-874
8 mm steel needle; 29 G; manual insertion; 60 cm tubing x			
10 with 10 needles; luer lock	130.00	1 OP	✓ Sure-T MMT-873
8 mm steel needle; 29 G; manual insertion; 80 cm tubing ×			
10 with 10 needles	130.00	1 OP	✓ Paradigm Sure-T
			MMT-876
8 mm steel needle; 29 G; manual insertion; 80 cm tubing ×			
10 with 10 needles; luer lock	130.00	1 OP	✓ Sure-T MMT-875

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

INSULIN PUMP INFUSION SET (TEFLON CANNULA, ANGLE INSERTION WITH INSERTION DEVICE) - Special Authority see SA1604 on page 33 - 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

c) Maximum of 13 iniusion 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

(Inset 30 13 mm teflon cannula; angle insertion; insertion device; 60 cm blue line x 10 with 10 needles to be delisted 1 May 2018) (Inset 30 13 mm teflon cannula; angle insertion; insertion device; 60 cm pink line x 10 with 10 needles to be delisted 1 May 2018)

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

INSULIN PUMP INFUSION SET (TEFLON CANNULA, ANGLE INSERTION) - Special Authority see SA1604 on page 33 - 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.

c) Maximum of 13 infusion sets will be funded per year.			
13 mm teflon cannula; angel insertion; 60 cm grey line $\times5$ with			
10 needles	120.00	1 OP	Comfort Short
13 mm teflon cannula; angle insertion; 120 cm line \times 10 with			
10 needles	130.00	1 OP	Paradigm Silhouette
			MMT-382
13 mm teflon cannula; angle insertion; 45 cm line × 10 with			4.5 11 6 111 11
10 needles	130.00	1 OP	✓ Paradigm Silhouette MMT-368
40 mans toffers according and a inscribing CO and line at 40 with			WIWI 1-308
13 mm teflon cannula; angle insertion; 60 cm line × 10 with 10 needles	120.00	1 OP	✓ Paradigm Silhouette
TO Fleedies	130.00	1 01	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 \times 10 with			_
10 needles	130.00	1 OP	✓ Paradigm Silhouette
47			MMT-377
17 mm teflon cannula; angle insertion; 110 cm line × 10 with	100.00	1 OP	✓ Silhouette MMT-371
10 needles; luer lock	130.00	TOP	Simouette wiw 1-371
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	120.00	1 01	Common
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 \times 10 with			
10 needles	130.00	1 OP	Paradigm Silhouette

(Comfort Short 13 mm teflon cannula; angel insertion; 60 cm grey line × 5 with 10 needles to be delisted 1 May 2018) (Comfort 17 mm teflon cannula; angle insertion; 110 cm grey line × 5 with 10 needles to be delisted 1 May 2018) (Comfort 17 mm teflon cannula; angle insertion; 60 cm grey line × 5 with 10 needles to be delisted 1 May 2018)

1 OP

1 OP

Paradigm Mio

MMT-921

Inset II

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

INSULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIGHT INSERTION WITH INSERTION DEVICE) - Special Authority see SA1604 on page 33 - Retail pharmacy

۵١	Maximum	~f 0	00+0		prescription
aı	Maximum	ળાડ	seis	ber	prescribition

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			

grey line × 10 with 10 needles......140.00

6 mm teflon cannula; straight insertion; insertion device; 60 cm

6 mm teflon cannula: straight insertion: insertion device: 60 cm

6 mm toflan cannula: atraight incortion; incortion davice: 90 cm

a mm toflan cannula: etraight incertion; incertion devices

			MM1-941
6 mm teflon cannula; straight insertion; insertion device; 45 ca	m		
pink tubing × 10 with 10 needles	130.00	1 OP	✓ Paradigm Mio

6 mm teflon cannula; straight insertion; insertion device; 60 cm blue line × 10 with 10 needles	40.00	1 OP	✓ Inset II
6 mm teflon cannula; straight insertion; insertion device; 60 cm			
blue tubing × 10 with 10 needles1	30.00	1 OP	✓ Paradigm Mid MMT-943

pink line x 10 with 10 needles	140.00	1 OP	✓ Inset II
6 mm teflon cannula; straight insertion; insertion device; 60 cm			_
pink tubing x 10 with 10 needles	130.00	1 OP	✓ Paradigm Mic MMT-923

blue tubing × 10 with 10 needles		1 OP	✓ Paradigm Mio MMT-945
6 mm teflon cannula; straight insertion; insertion device; 80 c	m		

clear tubing × 10 with 10 needles130.00	1 OP	✓ Paradigm Mio MMT-965
6 mm toflon cannula: straight insertion; insertion device: 80 cm		

o mini tenori camula, straigni insertion, insertion device, c	OU CITI		
pink tubing × 10 with 10 needles	130.00	1 OP	Paradigm Mio
			MMT-925

9 min tenon camula, straight insertion, insertion device,			
110 cm grey line × 10 with 10 needles	.140.00	1 OP	✓ Inset II
9 mm teflon cannula; straight insertion; insertion device; 60 cm			
blue line x 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 needles140.00	100	✓ Inset II
9 mm teflon cannula; straight insertion; insertion device; 60 cm		
pink line × 10 with 10 needles140.00	1 OP	✓ Inset II

pink line × 10 with 10 needles140.00	0 1 OP	✓ Inset II
9 mm teflon cannula; straight insertion; insertion device; 80 cm		
clear tubing × 10 with 10 needles130.00	0 1 OP	Paradigm Mio

(Inset II 6 mm teflon cannula; straight insertion; insertion device; 60 cm blue line x 10 with 10 needles to be delisted 1 May 2018) (Inset II 6 mm teflon cannula; straight insertion; insertion device; 60 cm pink line x 10 with 10 needles to be delisted 1 May 2018) (Inset II 9 mm teflon cannula; straight insertion; insertion device; 60 cm blue line x 10 with 10 needles to be delisted 1 May 2018) (Inset II 9 mm teflon cannula; straight insertion; insertion device; 60 cm pink line x 10 with 10 needles to be delisted 1 May 2018)

MMT-975

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

INSULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIGHT INSERTION) - Special Authority see SA1604 on page 33 - 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.

of maximum of to imacion colo will be funded per year.			
6 mm teflon cannula; straight insertion; 110 cm tubing \times 10 with			
10 needles	130.00	1 OP	✓ Paradigm Quick-Set MMT-398
6 mm teflon cannula; straight insertion; 110 cm tubing \times 10 with			
10 needles; luer lock	130.00	1 OP	✓ Quick-Set MMT-391
6 mm teflon cannula; straight insertion; 60 cm tubing \times 10 with			
10 needles	130.00	1 OP	✓ Paradigm Quick-Set MMT-399
6 mm teflon cannula; straight insertion; 60 cm tubing × 10 with			
10 needles; luer lock	130.00	1 OP	Quick-Set MMT-393
6 mm teflon cannula; straight insertion; 80 cm tubing \times 10 with			
10 needles	130.00	1 OP	✓ Paradigm Quick-Set MMT-387
9 mm teflon cannula; straight insertion; 106 cm tubing × 10 with			
10 needles	130.00	1 OP	✓ Paradigm Quick-Set MMT-396
9 mm teflon cannula; straight insertion; 110 cm tubing × 10 with			
10 needles; luer lock	130.00	1 OP	✓ Quick-Set MMT-390
9 mm teflon cannula; straight insertion; 60 cm tubing × 10 with			
10 needles	130.00	1 OP	✓ Paradigm Quick-Set MMT-397
9 mm teflon cannula; straight insertion; 60 cm tubing × 10 with			
10 needles; luer lock	130.00	1 OP	✓ Quick-Set MMT-392
9 mm teflon cannula; straight insertion; 80 cm tubing × 10 with			
10 needles	130.00	1 OP	✓ Paradigm Quick-Set MMT-386
SULIN PUMP RESERVOIR - Special Authority see SA1604 on pa	ige 33 – Reta	ail pharmacy	
a) Maximum of 3 sets per prescription	.9000	a p	
b) Only on a prescription			
c) Maximum of 13 packs of reservoir sets will be funded per year	r.		
10 × luer lock conversion cartridges 1.8 ml for Paradigm pumps.		1 OP	✓ ADR Cartridge 1.8
Cartridge 200 U, luer lock × 10		1 OP	✓ Animas Cartridge
			, <u> </u>

10 × luer lock conversion cartridges 1.8 ml for Paradigm pumps50.00 Cartridge 200 U, luer lock × 1050.00 Cartridge for 5 and 7 series pump; 1.8 ml × 1050.00	1 OP
Cartridge for 7 series pump; 3.0 ml × 1050.00	1 OP

Syringe and cartridge for 50X pump, 3.0 ml \times 10......50.00

- ✓ Animas Cartridge✓ Paradigm
- 1.8 Reservoir

 ✓ Paradigm
 3.0 Reservoir
- 3.0 Reservoir ✓ 50X 3.0 Reservoir

1 OP

100

100

Creon 25000

Ursosan

	Subsidy (Manufacturer's Price) \$	S 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) Cap pancreatin (175 mg (25,000 U lipase, 22,500 U amylase		100	✓ <u>C</u> ı	reon 10000
1,250 U protease)) Cap pancreatin 300 mg (amylase 18,000 Ph Eur U, lipase	94.40	100	✓ Pa	anzytrat

⇒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:

Fither:

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

Cap 250 mg - For ursodeoxycholic acid oral liquid formulation

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

25,000 Ph Eur U, total protease 1,000 Ph Eur U)94.38

URSODEOXYCHOLIC ACID - Special Authority see SA1383 below - Retail pharmacy

refer, page 22737.95

- 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 allogenic stem cell or bone marrow transplantation; and
- 2 Treatment for up to 13 weeks.

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

Both:

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

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

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

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

continued...

appropriate and the patient is benefiting from treatment.

ISPAGHULA (PSYLLIUM) HUSK - Only on a prescription

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

	500 g 5.	✓ Konsyl-D
MUCILAGINOUS LAXATIVES WITH STIMULANTS		
* Dry6.02	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	3.13	100 100 100 ml OP	✓ <u>Coloxyl</u> ✓ <u>Coloxyl</u> ✓ Coloxyl
	CUSATE SODIUM WITH SENNOSIDES Tab 50 mg with sennosides 8 mg	4.40	200	✓ Laxsol
РО	LOXAMER – Only on a prescription Not funded for use in the ear.			
*	Oral drops 10%	3.78	30 ml OP	✓ Coloxyl

Opioid Receptor Antagonists - Peripheral

METHYLNALTREXONE BROMIDE - Sp	pecial Authority see SA1691 below – I	Retail pharmacy	
Inj 12 mg per 0.6 ml vial	36.00	1	✓ Relistor
	246.00	7	✓ Relistor

⇒SA1691 Special Authority for Subsidy

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

Both:

- 1 The patient is receiving palliative care; and
- 2 Fither:
 - 2.1 Oral and rectal treatments for opioid induced constipation are ineffective; or
 - 2.2 Oral and rectal treatments for opioid induced constipation are unable to be tolerated.

✓ Bonvit

500 a OP

	Subsidy (Manufacturer's Price \$) Sı Per	Fully bsidised	Brand or Generic Manufacturer
Osmotic Laxatives				
GLYCEROL				
* Suppos 3.6 g - Only on a prescription	6.50	20	✓ P	<u>SM</u>
LACTULOSE - Only on a prescription				
* Oral liq 10 g per 15 ml	3.18	500 ml	✓ <u>L</u> a	<u>aevolac</u>
MACROGOL 3350 WITH POTASSIUM CHLORIDE, SODIUM BI	CARBONATE AND	SODIUM	CHLORIE	DE
Powder for oral soln 13.125 g with potassium chloride 46.6 m	ng,			
sodium bicarbonate 178.5 mg and sodium chloride 350.7	7 mg6.78 (7.65)	30		lolaxole ax-Sachets
Molaxole to be Sole Supply on 1 May 2018	,			
(Lax-Sachets Powder for oral soln 13.125 g with potassium chlor 350.7 mg to be delisted 1 May 2018)	ide 46.6 mg, sodium	bicarbor	nate 178.5	mg and sodium chloride
SODIUM ACID PHOSPHATE - Only on a prescription				
Enema 16% with sodium phosphate 8%	2.50	1		leet Phosphate Enema
SODIUM CITRATE WITH SODIUM LAURYL SULPHOACETATE	- Only on a prescr	ription		
Enema 90 mg with sodium lauryl sulphoacetate 9 mg per ml,	, ,			
5 ml		50	✓ M	licolette
Stimulant Laxatives				
BISACODYL - Only on a prescription				
* Tab 5 mg	5.99	200	✓ <u>L</u> a	ax-Tab
* Suppos 10 mg	3.78	10	✓ <u>L</u> a	ax-Suppositories
SENNA - Only on a prescription				
* Tab, standardised		100		
	(6.84)	00	S	enokot
	0.43 (1.72)	20	e.	enokot
	(1./2)		3	CHUNUL

Metabolic Disorder Agents

ALGLUCOSIDASE ALFA - Special Authority see SA1622 below - Retail pharmacy 1 ✓ Myozyme

⇒SA1622 Special Authority for Subsidy

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

- 1 The patient is aged up to 24 months at the time of initial application and has been diagnosed with infantile Pompe disease; and
- 2 Any of the following:
 - 2.1 Diagnosis confirmed by documented deficiency of acid alpha-glucosidase by prenatal diagnosis using chorionic villus biopsies and/or cultured amniotic cells; or
 - 2.2 Documented deficiency of acid alpha-glucosidase, and urinary tetrasaccharide testing indicating a diagnostic elevation of glucose tetrasaccharides; or
 - 2.3 Documented deficiency of acid alpha-glucosidase, and documented molecular genetic testing indicating a disease-causing mutation in the acid alpha-glucosidase gene (GAA gene); or

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

continued...

- 2.4 Documented urinary tetrasaccharide testing indicating a diagnostic elevation of glucose tetrasaccharides, and molecular genetic testing indicating a disease-causing mutation in the GAA gene; and
- 3 Patient has not required long-term invasive ventilation for respiratory failure prior to starting enzyme replacement therapy (ERT): and
- 4 Patient does not have another life-threatening or severe disease where the prognosis is unlikely to be influenced by ERT or might be reasonably expected to compromise a response to ERT; and
- 5 Alglucosidase alfa to be administered at doses no greater than 20 mg/kg every 2 weeks.

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

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

GALSULFASE - Special Authority see SA1593 below - Retail pharmacy

Inj 1 mg per ml, 5 ml vial.......2,234.00 1 ✓ <u>Naglazyme</u>

⇒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

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 FRT.

IDURSULFASE - Special Authority see SA1623 below - Retail pharmacy

⇒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

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

continued...

- 2 Either:
 - 2.1 Diagnosis confirmed by demonstration of iduronate 2-sulfatase deficiency in white blood cells by either enzyme assav in cultured skin fibroblasts: or
 - 2.2 Detection of a disease causing mutation in the iduronate 2-sulfatase gene; and
- 3 Patient is going to proceed with a haematopoietic stem cell transplant (HSCT) within the next 3 months and treatment with idursulfase would be bridging treatment to transplant; and
- 4 Patient has not required long-term invasive ventilation for respiratory failure prior to starting Enzyme Replacement Therapy (ERT): and
- 5 Idursulfase to be administered for a total of 24 weeks (equivalent to 12 weeks pre- and 12 weeks post-HSCT) at doses no greater than 0.5 mg/kg every week.

LARONIDASE - Special Authority see SA1695 below - Retail pharmacy ✓ Aldurazyme

⇒SA1695 Special Authority for Subsidy

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

- 1 The patient has been diagnosed with Hurler Syndrome (mucopolysacchardosis I-H); and
- 2 Fither:
 - 2.1 Diagnosis confirmed by demonstration of alpha-L-iduronidase deficiency in white blood cells by either enzyme assay in cultured skin fibroblasts; or
 - 2.2 Detection of two disease causing mutations in the alpha-L-iduronidase gene and patient has a sibling who is known to have Hurler syndrome; and
- 3 Patient is going to proceed with a haematopoietic stem cell transplant (HSCT) within the next 3 months and treatment with laronidase would be bridging treatment to transplant; and
- 4 Patient has not required long-term invasive ventilation for respiratory failure prior to starting Enzyme Replacement Therapy (ERT): and
- 5 Laronidase to be administered for a total of 24 weeks (equivalent to 12 weeks pre- and 12 post-HSCT) at doses no greater than 100 units/kg every week.

SODIUM BENZOATE - Special Authority see SA1599 below - Retail pharmacy Soln 100 mg per mlCBS 100 ml ✓ Amzoate S29

⇒SA1599 Special Authority for Subsidy

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

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

SODIUM PHENYLBUTYRATE - Special Authority see SA1598 below - Retail pharmacy 174 a 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

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

		e SA0473 on the next page – Retail pharmac	IMIGLUCERASE – Special Authority see SA047
Cerezyme	1	1,072.00	Inj 40 iu per ml, 200 iu vial
✓ Cerezyme	1	2,144.00	Inj 40 iu per ml, 400 iu vial

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

⇒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 Facsimile: (04) 916 7571

PHARMAC, PO Box 10 254

Wellington

Email: gaucherpanel@pharmac.govt.nz

Mouth and Throat

Agents Used in Mouth Ulceration

RENZYD/	LVDDO	

Soln 0.15%	- Higher subs	idy of up to \$	17.01 g	per 500 ml with

	II VVILII		
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.

CARMELLOSE SODILIM WITH GELATIN AND PECTIN

ON INCLESCE CODION WITH GEEN INVIND I COTIV				
Paste	17.20	56 g OP	Stomahesive	
	4.55	15 g OP		
	(7.90)	ŭ	Orabase	
	1.52	5 g OP		
	(3.60)	_	Orabase	
Powder	8.48	28 g OP		
	(10.95)	-	Stomahesive	
CHLORHEXIDINE GLUCONATE				
Mouthwash 0.2%	2.57	200 ml OP	✓ <u>healthE</u>	
CHOLINE SALICYLATE WITH CETALKONIUM CHLORIDE				
* Adhesive gel 8.7% with cetalkonium chloride 0.01%	2.06	15 g OP		
•	(6.00)	-	Bonjela	
TRIAMCINOLONE ACETONIDE				

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	1.95	24 ml OP	✓ Nilstat

Other Oral Agents

For folinic mouthwash, pilocarpine oral liquid or saliva substitute formula refer Standard Formulae, page 230

HYDROGEN PEROXIDE

✓ Pharmacy Health 100 ml

5 a OP

✓ Kenalog in Orabase

	7.5.111.5.17.1		AND INICIADOLION
	Subsidy (Manufacturer's Pri \$	ice) Subsi Per	Fully Brand or idised Generic ✓ Manufacturer
THYMOL GLYCERIN * Compound, BPC	9.15	500 ml	✓ <u>PSM</u>
Vitamins			
Vitamin A			
VITAMIN A WITH VITAMINS D AND C * Soln 1000 u with Vitamin D 400 u and ascorbic acid 30 mg pe 10 drops		10 ml OP	✓ Vitadol C
Vitamin B			
HYDROXOCOBALAMIN # Inj 1 mg per ml, 1 ml ampoule – Up to 6 inj available on a PS PYRIDOXINE HYDROCHLORIDE a) No more than 100 mg per dose b) Only on a prescription	O2.31	3	✓ <u>Neo-B12</u>
Tab 25 mg — No patient co-payment payable Tab 50 mg THIAMINE HYDROCHLORIDE — Only on a prescription		90 500	✓ <u>Vitamin B6 25</u> ✓ <u>Apo-Pyridoxine</u>
* Tab 50 mg VITAMIN B COMPLEX * Tab, strong, BPC		100	✓ Apo-Thiamine
Vitamin C	7.15	500	✓ <u>Bplex</u>
ASCORBIC ACID a) No more than 100 mg per dose b) Only on a prescription * Tab 100 mg	8.10	500	✓ <u>Cvite</u>
Vitamin D			
ALFACALCIDOL * Cap 0.25 mcg * Cap 1 mcg * Oral drops 2 mcg per ml	87.98	100 100 20 ml OP	✓ One-Alpha ✓ One-Alpha ✓ One-Alpha
CALCITRIOL * Cap 0.25 mcg * Cap 0.5 mcg		100 100	✓ <u>Calcitriol-AFT</u> ✓ <u>Calcitriol-AFT</u>
COLECALCIFEROL * Cap 1.25 mg (50,000 iu) – Maximum of 12 cap per prescripti	on2.50	12	✓ <u>Vit.D3</u>
Multivitamin Preparations			
MULTIVITAMIN RENAL - Special Authority see SA1546 on the r * Cap		l pharmacy 30	✓ Clinicians Renal Vit

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

⇒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 m² body surface area (BSA).

MULTIVITAMINS - Special Authority see SA1036 below - Retail pharmacy

200 a 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		

o (fat soluble vitamins A, D, E, K) — Special Authority see SA1002 below – Retail pharmacy23.40 ✓ Vitabdeck

⇒SA1002 Special Authority for Subsidy

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

Fither:

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

Minerals

(,0	cium

Calcium		
CALCIUM CARBONATE ★ Tab eff 1.75 g (1 g elemental)	10 250	✓ Calsource ✓ Arrow-Calcium
CALCIUM GLUCONATE * Inj 10%, 10 ml ampoule34.24	10	✓ Hospira
Fluoride		
SODIUM FLUORIDE * Tab 1.1 mg (0.5 mg elemental)5.00	100	✓ PSM
lodine		
POTASSIUM IODATE * Tab 253 mcg (150 mcg elemental iodine)	90	✓ NeuroTabs
Iron		
FERRIC CARBOXYMALTOSE - Special Authority see SA1675 on the next page -	Retail pharm	acy

[HP4] refer page 4

✓ Ferinject

Subsidy	F	ully	Brand or
(Manufacturer's Price)	Subsid	ised	Generic
\$	Per	1	Manufacturer

⇒SA1675 Special Authority for Subsidy

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

Both:

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

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

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

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

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

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

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

FERROUS FUMARATE * Tab 200 mg (65 mg elemental)	2.89	100	✓ <u>Ferro-tab</u>
FERROUS FUMARATE WITH FOLIC ACID	4.75	00	/ Farma E Taba
* Tab 310 mg (100 mg elemental) with folic acid 350 mcg FERROUS SULPHATE	4./5	60	✓ Ferro-F-Tabs
* Tab long-acting 325 mg (105 mg elemental)		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	30	
	(4.29)		Ferrograd F
(Ferrograd F Tab long-acting 325 mg (105 mg elemental) with folic	acid 350 mcg t	o be delisted	1 September 2018)
IRON POLYMALTOSE			
* Inj 50 mg per ml, 2 ml ampoule	15.22	5	✓ Ferrum H

49

	Subsidy (Manufacturer's Price) \$	F Subsidi Per	ully sed	Brand or Generic Manufacturer
Magnesium				
For magnesium hydroxide mixture refer Standard Formulae, page MAGNESIUM SULPHATE * Inj 2 mmol per ml, 5 ml ampoule		10	✓ <u>D</u>	<u>BL</u>
Zinc				

ZINC SULPHATE

* Cap 137.4 mg (50 mg elemental)......11.00 100 ✓ Zincaps

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

Antianaemics

Hypoplastic and Haemolytic

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

Note: 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 ju per week.

Note: Indication marked with * is an Unapproved Indication

	Subsidy (Manufactured Price)		Fully	
	(Manufacturer's Price) \$	Per	Subsidised	Generic Manufacturer
EPOETIN ALFA [ERYTHROPOIETIN ALFA] - Special Authority	see SA1469 on the p	revio	us 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	1	Eprex
Inj 5,000 iu in 0.5 ml, syringe	243.26	6	1	Eprex
Inj 6,000 iu in 0.6 ml, syringe	291.92	6	1	Eprex
Inj 8,000 iu in 0.8 ml, syringe		6	✓	Eprex
Inj 10,000 iu in 1 ml, syringe		6	1	Eprex
Inj 40,000 iu in 1 ml, syringe		1	•	Eprex

Megaloblastic

FO	LIC ACID			
*	Tab 0.8 mg	20.60	1,000	✓ Apo-Folic Acid
*	Tab 5 mg	10.92	500	✓ Apo-Folic Acid
	Oral lia 50 mag par ml	24.00	25 ml OD	√ Diamed

Antifibrinolytics, Haemostatics and Local Sclerosants

ELTROMBOPAG - Special Authority see SA1418 below - Retail pharmacy

wastage claimable – see rule 3.3.2 on page 13	5		
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);
- 3 Any of the following:
 - 3.1 Patient has a platelet count of 20,000 to 30,000 platelets per microlitre and has evidence of significant mucocutaneous bleeding; or
 - 3.2 Patient has a platelet count of less than or equal to 20,000 platelets per microlitre and has evidence of active bleeding; or
 - 3.3 Patient has a platelet count of less than or equal to 10,000 platelets per microlitre.

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

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

	2			
	Subsidy (Manufacturer's Price)		Fully Subsidised	
	(Manufacturer's Price) \$	Per		
ACTOR EIGHT INHIBITOR BYPASSING FRACTION -	[Xpharm]			
For patients with haemophilia, whose funded treatmer		philia	Treaters	Group in conjunction wit
the National Haemophilia Management Group.	• •			. ,
Inj 500 U	1,450.00	1	1	FEIBA NF
Inj 1,000 U	2,900.00	1	1	FEIBA NF
lnj 2,500 U	7,250.00	1	✓	FEIBA NF
OROCTOCOG ALFA [RECOMBINANT FACTOR VIII] -	- [Xpharm]			
Preferred Brand of recombinant factor VIII for patients				
to funded treatment is managed by the Haemophilia T	reaters Group in conjunction	n with	the Natio	nal Haemophilia
Management Group.				
Inj 250 iu prefilled syringe		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
ONACOG ALFA [RECOMBINANT FACTOR IX] - [Xpha	ırm]			
For patients with haemophilia, whose funded treatmer	nt is managed by the Haemo	philia	Treaters	Group in conjunction with
the National Haemophilia Management Group.	Ŭ ,			, ,
Inj 250 iu vial	310.00	1	✓	BeneFIX
Inj 500 iu vial		1	/	BeneFIX
Inj 1,000 iu vial	1,240.00	1	/	BeneFIX
Inj 2,000 iu vial	2,480.00	1	1	BeneFIX
Inj 3,000 iu vial	3,720.00	1	✓	BeneFIX
ONACOG GAMMA, [RECOMBINANT FACTOR IX] - [X	(pharm)			
For patients with haemophilia, whose funded treatmer		philia	Treaters	Group in conjunction wit
the National Haemophilia Management Group.	it to managed by the macine	p		on out in our junious.
Inj 250 iu vial	287.50	1	1	RIXUBIS
Inj 500 iu vial		1	1	RIXUBIS
Inj 1,000 iu vial		1	1	RIXUBIS
Inj 2,000 iu vial	2,300.00	1	✓	RIXUBIS
Inj 3,000 iu vial	3,450.00	1	✓	RIXUBIS
CTOCOG ALFA [RECOMBINANT FACTOR VIII] (ADVA				
Rare Clinical Circumstances Brand of recombinant fac		mont	nilia from 1	March 2016 until
28 February 2019. Access to funded treatment by ap				
be obtained from PHARMAC's website http://www.pha		1104	unonto i a	noi. Application dotalio
			•	
The Co-ordinator, Haemophilia Treatments Panel	Phone: 0800 023 588 O	puon	12	
PHARMAC PO Box 10 254	Facsimile: (04) 974 4881			
Wellington	Email: haemophilia@phai	mac.	govt.nz	
Inj 250 iu vial	287.50	1	1	Advate
Inj 500 iu vial		1		Advate
Inj 1,000 iu vial		1		Advate
Ini 1 500 in viol	•			Advete

1

1

✓ Advate

✓ Advate

✓ Advate

Inj 2,000 iu vial......2,300.00

Inj 3,000 iu vial......3,450.00

	Subsidy (Manufacturer's Price) \$	Su Per	Fully bsidised	Brand or Generic Manufacturer	
OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (KOGE Second Brand of recombinant factor VIII for patients w funded treatment by application to the Haemophilia Tre PHARMAC's website http://www.pharmac.govt.nz or:	ith haemophilia from 1 Marc				Access to
The Co-ordinator, Haemophilia Treatments Panel PHARMAC PO Box 10 254	Phone: 0800 023 588 C Facsimile: (04) 974 4881	ption 2			
Wellington	Email: haemophilia@pha	mac.go	<u>vt.nz</u>		
Inj 250 iu vial Inj 500 iu vial Inj 1,000 iu vial Inj 2,000 iu vial Inj 3,000 iu vial	475.00 950.00 1,900.00	1 1 1 1	✔ K ✔ K ✔ K	ogenate FS ogenate FS ogenate FS ogenate FS	
SODIUM TETRADECYL SULPHATE * Inj 3% 2 ml TRANEXAMIC ACID	·	5		ibro-vein	
Tab 500 mg	20.67	100	√ <u>C</u>	yklokapron	
Vitamin K					
PHYTOMENADIONE Inj 2 mg per 0.2 ml - Up to 5 inj available on a PSO Inj 10 mg per ml, 1 ml - Up to 5 inj available on a PSO		5 5		Onakion MM Onakion MM	
Antithrombotic Agents					
Antiplatelet Agents					
ASPIRIN * Tab 100 mg CLOPIDOGREL * Tab 75 mg Fax alonidageal avail liquid formulation relations and the control of		990	√ <u>E</u>	thics Aspirin E	<u>EC</u>
Tab 75 mg – For clopidogrel oral liquid formulation ref page 227 DIPYRIDAMOLE		84	✓ <u>A</u>	rrow - Clopid	

Cubaidu

Eully.

Drand or

⇒SA1201 Special Authority for Subsidy

PRASUGREL - Special Authority see SA1201 below - Retail pharmacy

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

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

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

Renewal — (coronary angioplasty and bare metal stent) from any relevant practitioner. Approvals valid for 6 months where

continued...

60

28

28

Pytazen SR

✓ Effient

✓ Effient

Subsidy (Manufacturer's Price)	Ful Subsidise	,	
\$	Per •	 Manufacturer 	

continued...

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

⇒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		10	✓ Fragmin
Inj 12,500 iu per 0.5 ml prefilled syringe		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		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
- 5 To be used in association with cardioversion of atrial fibrillation.

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

continued...

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

Either:

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

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

ENOXAPARIN SODIUM - Special Authority see SA1646 below - Retail pharmacy

Inj 20 mg in 0.2 ml syringe	27.93	10	Clexane
Inj 40 mg in 0.4 ml syringe		10	Clexane
Inj 60 mg in 0.6 ml syringe		10	Clexane
Inj 80 mg in 0.8 ml syringe		10	✓ Clexane
Inj 100 mg in 1 ml syringe		10	✓ Clexane
Inj 120 mg in 0.8 ml syringe		10	✓ Clexane
Inj 150 mg in 1 ml syringe	133.20	10	Clexane

⇒SA1646 Special Authority for Subsidy

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

Any of the following:

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

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

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

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

Any of the following:

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

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

HEPARIN SODIUM

A A III OODIOW			
Inj 1,000 iu per ml, 35 ml vial	17.76	1	Hospira
Inj 1,000 iu per ml, 5 ml	13.36	10	✓ Hospira
	61.04	50	✓ Pfizer
	66.80		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		Fully	Brand or
	(Manufacturer's Price)		Subsidised	Generic
	\$	Per		Manufacturer
EPARINISED SALINE				
Inj 10 iu per ml, 5 ml	39.00	50	√ F	fizer
, ps, c		•••		
Oral Anticoagulants				
Oral Anticoagulants				
DABIGATRAN				
Cap 75 mg - No more than 2 cap per day	76.36	60	✓ F	radaxa
Cap 110 mg		60	√ F	radaxa
Cap 150 mg		60	√ □	radaxa
, ,		00		Iuuunu
RIVAROXABAN – Special Authority see SA1066 below – R	etail pharmacy			
Tab 10 mg	153.00	15	✓ X	(arelto

⇒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		100	Marevan
	Tab 5 mg		50	Coumadin
	-	11.75	100	✓ Marevan

Blood Colony-stimulating Factors

FILGRASTIM - Special Authority see SA1259 below - Retail phar	rmacy		
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 greater than or equal to 20%*); or
- 2 Peripheral blood stem cell mobilisation in patients undergoing haematological transplantation; or
- 3 Peripheral blood stem cell mobilisation or bone marrow donation from healthy donors for transplantation; or
- 4 Treatment of severe chronic neutropenia (ANC < 0.5 ×10⁹/L); or
- 5 Treatment of drug-induced prolonged neutropenia (ANC $< 0.5 \times 10^9$ /L).

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

PEGFILGRASTIM - Special Authority see SA1384 on the next page - Retail pharmacy

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

⇒SA1384 Special Authority for Subsidy

Initial application only from a relevant specialist, vocationally registered general practitioner or medical practitioner on the recommendation of a relevant specialist. Approvals valid without further renewal unless notified where used for prevention of neutropenia in patients undergoing high risk chemotherapy for cancer (febrile neutropenia risk greater than or equal to 20%*). Note: *Febrile neutropenia risk greater than or equal to 20% after taking into account other risk factors as defined by the European Organisation for Research and Treatment of Cancer (EORTC) guidelines.

Fluids and Electrolytes

Intravenous Administration

b) Not in combination

GLUCOSE [DEXTROSE]			
* Inj 50%, 10 ml ampoule - Up to 5 inj available on a PSO	29.50	5	✓ Biomed
* Inj 50%, 90 ml bottle - Up to 5 inj available on a PSO	14.50	1	✓ Biomed
POTASSIUM CHLORIDE			
* Inj 75 mg per ml, 10 ml	55.00	50	✓ AstraZeneca
SODIUM BICARBONATE			
Inj 8.4%, 50 ml	19.95	1	✓ Biomed
a) Up to 5 inj available on a PSO			
b) Not in combination			
Inj 8.4%, 100 ml	20.50	1	Biomed
a) Up to 5 inj available on a PSO			

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

errity or post-ria	tai cale ili ilit	e nome of the patient, t
33.00	5	✓ Biomed
	230	
7.00	50	✓ InterPharma
		✓ Multichem
6.63	50	✓ Pfizer
5.00	20	✓ Multichem
7.50	30	✓ InterPharma
ecialist		
	1 OP	✓ TPN
	33.00 d Formulae, page 7.00 6.63 5.00	d Formulae, page 230 7.00 50 6.63 50 5.00 20 7.50 30 ecialist

WATER

- 1) On a prescription or Practitioner's Supply Order only when on the same form as an injection listed in the Pharmaceutical Schedule requiring a solvent or diluent; or
- 2) On a bulk supply order; or
- 3) When used in the extemporaneous compounding of eye drops; or
- 4) When used for the dilution of sodium chloride soln 7% for cystic fibrosis patients only.

Inj 5 ml ampoule - Up to 5 inj available on a PSO	7.00	50	✓ InterPharma
Inj 10 ml ampoule - Up to 5 inj available on a PSO	6.63	50	✓ Pfizer
Inj 20 ml ampoule - Up to 5 inj available on a PSO	5.00	20	Multichem
7	7.50	30	✓ InterPharma

	Subsidy (Manufacturer's F \$	Price) Subsi	Fully Brand or idised 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)	, ,	200	✓ Span-K
Cap 840 mg	8.52	100	✓ Sodibic✓ Sodibic
SODIUM POLYSTYRENE SULPHONATE			
Powder	84.65	454 g OP	✓ Resonium-A

	Subsidy	`	Fully	Brand or
	(Manufacturer's Price \$	e) Per	Subsidised <	Generic Manufacturer
Alpha Adrenoceptor Blockers				
DOXAZOSIN * Tab 2 mg	6.75	500	1	Apo-Doxazosin
* Tab 4 mg		500		Apo-Doxazosin
PHENOXYBENZAMINE HYDROCHLORIDE				
* Cap 10 mg	65.00	30	✓	BNM S29
PRAZOSIN				
* Tab 1 mg		100		Apo-Prazosin
* Tab 2 mg * Tab 5 mg		100 100		Apo-Prazosin Apo-Prazosin
TERAZOSIN				
* Tab 1 mg	0.59	28	1	Actavis
* Tab 2 mg		500		Apo-Terazosin
* Tab 5 mg	10.90	500	•	Apo-Terazosin
Agents Affecting the Renin-Angiotensin System	n			
ACE Inhibitors				
ACL IIIIIbitors				
CAPTOPRIL	04.00	05 1 0	ND .	0
*‡ Oral liq 5 mg per ml Oral liquid restricted to children under 12 years of age.	94.99	95 ml C)P •	Capoten
CILAZAPRIL				
* Tab 0.5 mg	2.00	90	1	Zapril
* Tab 2.5 mg		200		Apo-Cilazapril
* Tab 5 mg	12.00	200	•	Apo-Cilazapril
ENALAPRIL MALEATE	0.06	100	./	Ethica Englantil
* Tab 5 mg * Tab 10 mg		100		Ethics Enalapril Ethics Enalapril
* Tab 20 mg - For enalapril maleate oral liquid formulation re				
page 227	1.78	100	✓	Ethics Enalapril
LISINOPRIL				
* Tab 5 mg		90	_	Ethics Lisinopril
* Tab 10 mg * Tab 20 mg		90 90		Ethics Lisinopril Ethics Lisinopril
PERINDOPRIL		00	•	<u> </u>
* Tab 2 mg	3.75	30	1	Apo-Perindopril
* Tab 4 mg	4.80	30		Apo-Perindopril
QUINAPRIL				
* Tab 5 mg		90		Arrow-Quinapril 5
* Tab 10 mg * Tab 20 mg		90 90		Arrow-Quinapril 10 Arrow-Quinapril 20
		30	•	on Gamapin 20
ACE Inhibitors with Diuretics				
CILAZAPRIL WITH HYDROCHLOROTHIAZIDE			=	
* Tab 5 mg with hydrochlorothiazide 12.5 mg	10.18	100		Apo-Cilazapril/ Hydrochlorothiazide
				<u>rryurociniorotinaziue</u>

		-AUDIO //	ASCULAN STSTEW
	Subsidy (Manufacturer's Price)	F Subsid Per	Fully Brand or ised Generic Manufacturer
WITH HYDROCHLOROTHIAZIDE Tab 10 mg with hydrochlorothiazide 12.5 mg Tab 20 mg with hydrochlorothiazide 12.5 mg		30 30	✓ Accuretic 10 ✓ Accuretic 20
Angiotensin II Antagonists			
CANDESARTAN CILEXETIL - Special Authority see SA1223 be		•	
* Tab 4 mg * Tab 8 mg		90 90	✓ <u>Candestar</u> ✓ Candestar
* Tab 6 mg		90	✓ Candestar
* Tab 32 mg		90	✓ Candestar
Initial application — (ACE inhibitor intolerance) from any relenotified for applications meeting the following criteria: Either: 1 Patient has persistent ACE inhibitor induced cough that is inhibitor); or 2 Patient has a history of angioedema. Initial application — (Unsatisfactory response to ACE inhibitor further renewal unless notified where patient is not adequately collaboration. LOSARTAN POTASSIUM * Tab 12.5 mg	not resolved by ACE or) from any relevan ntrolled on maximum1.39	t practitione tolerated do	rial (same or new ACE r. Approvals valid without ose of an ACE inhibitor. ✓ Losartan Actavis
* Tab 25 mg		84	Losartan Actavis
* Tab 50 mg Tab 100 mg		84 84	✓ Losartan Actavis ✓ Losartan Actavis
Angiotensin II Antagonists with Diuretics LOSARTAN POTASSIUM WITH HYDROCHLOROTHIAZIDE Tab 50 mg with hydrochlorothiazide 12.5 mg	15 25	30	✓ Arrow-Losartan &
Tab oo ng man nyaroonoo anabao 12.6 mg	10.20		Hydrochlorothiazide
Antiarrhythmics			
For lignocaine hydrochloride refer to NERVOUS SYSTEM, Anaes	sthetics, Local, page	136	
AMIODARONE HYDROCHLORIDE			
▲ Tab 100 mg - Retail pharmacy-Specialist		30	✓ Cordarone-X
Tab 200 mg - Retail pharmacy-Specialist		30 5	✓ <u>Cordarone-X</u> ✓ Lodi
Inj 50 mg per ml, 3 ml ampoule – Up to 5 inj available on a F ATROPINE SULPHATE	JU 3.30	J	LOUI
* Inj 600 mcg per ml, 1 ml ampoule – Up to 5 inj available on a		50	✓ AstraZeneca
PSO DIGOXIN	71.00	50	AStrazeneca
* 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		240	Lanoxin
*‡ Oral liq 50 mcg per ml	16.60	60 ml	✓ Lanoxin
DISORVE AMIDE DUOSPUATE			✓ Lanoxin S29 S29
DISOPYRAMIDE PHOSPHATE A Cap 100 mg	15.00	100	
— -	(23.87)	. • •	Rythmodan

[‡] safety cap

[▲] Three months supply may be dispensed at one time

(N	Subsidy fanufacturer's Price) \$	Per	Fully Subsidised	I Generic
FLECAINIDE ACETATE - Retail pharmacy-Specialist	-			
▲ Tab 50 mg	38.95	60	1	Tambocor
▲ Cap long-acting 100 mg		30	1	Tambocor CR
▲ Cap long-acting 200 mg		30	1	Tambocor CR
Inj 10 mg per ml, 15 ml ampoule		5	1	Tambocor
MEXILETINE HYDROCHLORIDE				
▲ Cap 150 mg	162.00	100	✓	Mexiletine Hydrochloride USP \$29
▲ Cap 250 mg	202.00	100	•	Mexiletine Hydrochloride USP \$29
PROPAFENONE HYDROCHLORIDE – Retail pharmacy-Specialist				
▲ Tab 150 mg		50	✓	Rytmonorm
Antihypotensives				
MIDODRINE - Special Authority see SA1474 below - Retail pharm	•		_	_
Tab 2.5 mg		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 mg4.61	500	✓ Mylan Atenolol
* Tab 100 mg7.67	500	✓ Mylan Atenolol
* Oral liq 25 mg per 5 ml21.25	300 ml OP	✓ Atenolol AFT
Restricted to children under 12 years of age.		
BISOPROLOL FUMARATE		
* Tab 2.5 mg3.53	90	✓ Bosvate
* Tab 5 mg5.15	90	✓ Bosvate
* Tab 10 mg9.40	90	✓ Bosvate
CARVEDILOL		
* Tab 6.25 mg	60	✓ Carvedilol Sandoz
* Tab 12.5 mg2.30	60	✓ Carvedilol Sandoz
* Tab 25 mg - For carvedilol oral liquid formulation refer, page 227 2.95	60	✓ Carvedilol Sandoz
CELIPROLOL		
* Tab 200 mg21.40	180	✓ Celol

	Subsidy (Manufacturer's Price) \$	Per	Fully Brand or Subsidised Generic Manufacturer
ABETALOL			
k Tab 50 mg	8.99	100	✓ Hybloc
★ Tab 100 mg - For labetalol oral liquid formulation refer,			
page 227	11.36	100	✓ Hybloc
★ Tab 200 mg	29.74	100	✓ Hybloc
k Inj 5 mg per ml, 20 ml ampoule	59.06	5	
	(88.60)		Trandate
METOPROLOL SUCCINATE			
★ Tab long-acting 23.75 mg	1.03	30	✓ Betaloc CR
₹ Tab long-acting 47.5 mg		30	✓ Betaloc CR
F Tab long-acting 95 mg		30	✓ Betaloc CR
₭ Tab long-acting 190 mg		30	✓ Betaloc CR
METOPROLOL TARTRATE			
* Tab 50 mg – For metoprolol tartrate oral liquid formulation	4.64	100	✓ Apo-Metoprolol
refer, page 227		60	✓ Apo-Metoproloi ✓ Apo-Metoproloi
K Tab long acting 200 mg		28	✓ Apo-Metoproloi ✓ Slow-Lopresor
★ Tab long-acting 200 mg ★ Ini 1 mg per ml. 5 ml vial		5	✓ Slow-Lopresor ✓ Lopresor
, 31	24.00	5	Lopiesoi
IADOLOL			
€ Tab 40 mg		100	
€ Tab 80 mg	24.70	100	✓ Apo-Nadolol
INDOLOL			
₹ Tab 5 mg	9.72	100	Apo-Pindolol
€ Tab 10 mg	15.62	100	
F Tab 15 mg	23.46	100	Apo-Pindolol
ROPRANOLOL			
€ Tab 10 mg	3.65	100	✓ Apo-Propranolol
			✓ Apo-Propranolol
			S29 §29
€ Tab 40 mg	4.65	100	
1 ab 40 mg		100	✓ Apo-Propranolol
			S29 S29
Con long pating 100 mg	40.47	400	
Cap long-acting 160 mg		100	✓ Cardinol LA
€ Oral liq 4 mg per ml − Special Authority see SA1327 below			
Retail pharmacy	CBS	500 m	nl V Roxane \$29

⇒SA1327 Special Authority for Subsidy

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

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

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
SOTALOL				
Tab 80 mg – For sotalol oral liquid formulation refer, page 22	27 39.53	500	✓	<u>Mylan</u>
₭ Tab 160 mg	12.48	100	1	Mylan
Inj 10 mg per ml, 4 ml ampoule	65.39	5	1	Sotacor
Sotacor Inj 10 mg per ml, 4 ml ampoule to be delisted 1 August 2				
IMOLOL	,			
MOLOL € Tab 10 mg	10 FF	100	./	Ana Timal
* Tab To Hig	10.55	100	•	Apo-Timol
Calcium Channel Blockers				
Dihydropyridine Calcium Channel Blockers				
MLODIPINE				
k Tab 2.5 mg	1 72	100	1	Apo-Amlodipine
★ Tab 5 mg — For amlodipine oral liquid formulation refer, page		250		Apo-Amlodipine
Tab 3 mg = For amiodipline oral liquid formulation relei, page		250		Apo-Amiodipine
•	4.40	250	•	Apo-Amiouipine
ELODIPINE			_	
Fab long-acting 2.5 mg		30		Plendil ER
★ Tab long-acting 5 mg		30		Plendil ER
Fab long-acting 10 mg	2.30	30	/	Plendil ER
SRADIPINE				
★ Cap long-acting 2.5 mg	7.50	30	✓	Dynacirc-SRO
Cap long-acting 5 mg		30		Dynacirc-SRO
IIFEDIPINE				,
NFEDIFINE ├ Tab long-acting 10 mg	10.62	60	./	Adalat 10
r ab long-acting to mg	10.03	00		
* T.I.I	0.50	400		Adefin \$29
* Tab long-acting 20 mg		100		Nyefax Retard
* Tab long-acting 30 mg		30		Adalat Oros
* Tab long-acting 60 mg	5.67	30	•	Adalat Oros
Other Calcium Channel Blockers				
DILTIAZEM HYDROCHLORIDE				
★ Tab 30 mg	4.60	100	✓	Dilzem
★ Tab 60 mg – For diltiazem hydrochloride oral liquid formulati				
refer, page 227	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	1	Apo-Diltiazem CD
Cap long-acting 240 mg	10.22	30	1	Cardizem CD
	63.58	500	1	Apo-Diltiazem CD
ERHEXILINE MALEATE				
← Tab 100 mg	62 90	100	ſ	Pexsig
• 1ab 100 mg		100	•	LevelA

	Subsidy		Fully	Brand or
	(Manufacturer's Price)		Subsidised	
	\$	Per		Manufacturer
VERAPAMIL HYDROCHLORIDE				
* Tab 40 mg	7.01	100	•	Isoptin
* Tab 80 mg - For verapamil hydrochloride oral liquid				
formulation refer, page 227		100		Isoptin
* Tab long-acting 120 mg		250		Verpamil SR
* Tab long-acting 240 mg		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				
Containy Acting Agents				
CLONIDINE			_	
* Patch 2.5 mg, 100 mcg per day – Only on a prescription		4		Mylan
* Patch 5 mg, 200 mcg per day – Only on a prescription		4		Mylan
* Patch 7.5 mg, 300 mcg per day - Only on a prescription	12.34	4	•	<u>Mylan</u>
CLONIDINE HYDROCHLORIDE			_	
* Tab 25 mcg		112		Clonidine BNM
* Tab 150 mcg		100		Catapres
* Inj 150 mcg per ml, 1 ml ampoule	16.07	5	•	Catapres
METHYLDOPA				
* Tab 250 mg	15.10	100	•	Methyldopa Mylan
Diuratica				
Diuretics				
Loop Diuretics				
BUMETANIDE				
* Tab 1 mg	16.36	100	1	Burinex
* Inj 500 mcg per ml, 4 ml vial		5		Burinex
FUROSEMIDE [FRUSEMIDE]				
* Tab 40 mg - Up to 30 tab available on a PSO	8.00	1.000	· •	Diurin 40
* Tab 500 mg		50		Urex Forte
*‡ Oral liq 10 mg per ml		00 10 ml 0		Lasix
* Inj 10 mg per ml, 25 ml ampoule		6		Lasix
* Inj 10 mg per ml, 2 ml ampoule – Up to 5 inj available on a		5		Frusemide-Claris
, , , , , , , , , , , , , , , , , , , ,				
Potassium Sparing Diuretics				
AMILORIDE HYDROCHLORIDE				
* Tab 5 mg	15.00	100	1	Apo-Amiloride
t Oral liq 1 mg per ml		.5 ml (Biomed
(Apo-Amiloride Tab 5 mg to be delisted 1 January 2019)				
METOLAZONE - Special Authority see SA1678 below - Retail	pharmacy			
Tab 5 mg		1	1	Metolazone S29
1 40 0 mg		50		Zaroxolyn S29
TO CA1670 Chaolal Authority for Cubaidy		00	•	=u.v.viyii

⇒SA1678 Special Authority for Subsidy

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

	Subsidy (Manufacturer's Pri	ce) Subs	Fully sidised	Brand or Generic Manufacturer
ontinued Either:				
Patient has refractory heart failure and is intolerant or ha therapy; or Paediatric patient has oedema secondary to nephrotic sy	•	·		·
SPIRONOLACTONE				
₭ Tab 25 mg		100 100		Spiractin Spiractin
Fab 100 mg		25 ml OP		Biomed
Potassium Sparing Combination Diuretics				
MILORIDE HYDROCHLORIDE WITH FUROSEMIDE				
* Tab 5 mg with furosemide 40 mg		28	✓ F	rumil
MILORIDE HYDROCHLORIDE WITH HYDROCHLOROTHIAZ Tab 5 mg with hydrochlorothiazide 50 mg		50	✓ N	/loduretic
Thiazide and Related Diuretics				
ENDROFLUMETHIAZIDE [BENDROFLUAZIDE]				
€ Tab 2.5 mg — Up to 150 tab available on a PSO	12.50	500	✓	Arrow- Bendrofluazide
a) May be supplied on a PSO for reasons other than e b) Arrow-Bendrofluazide to be Sole Supply on 1 April 2				
₹ Tab 5 mg		500	√	Arrow- Bendrofluazide
Arrow-Bendrofluazide to be Sole Supply on 1 April 2018	3			
HLOROTHIAZIDE				
Oral liq 50 mg per ml	26.00	25 ml OP	✓ E	Biomed
:HLORTALIDONE [CHLORTHALIDONE] ≰ Tab 25 mg	9.00	50	./ L	lygroton
NDAPAMIDE		50	• 1	iygiololi
€ Tab 2.5 mg	2.60	90	√ [Dapa-Tabs
Lipid-Modifying Agents				
Fibrates				
BEZAFIBRATE			_	
Tab 200 mg		90 30	_	<u>Bezalip</u> Bezalip Retard
₹ Tab long-acting 400 mg SEMFIBROZIL	0./0	30	• [ezalip netalu
F Tab 600 mg	19.56	60	✓ <u>L</u>	<u>ipazil</u>
Other Lipid-Modifying Agents				
CIPIMOX	10.75	00		
Con DEO mag	10.75	20	.,,	Title ed e see

30

✓ Olbetam

		ANDIO	VASC	JULAN STSTEW
(Subsidy Manufacturer's Price)	Subs	Fully sidised	Brand or Generic Manufacturer
NICOTINIC ACID * Tab 50 mg * Tab 500 mg		100 100		Apo-Nicotinic Acid Apo-Nicotinic Acid
Resins				
CHOLESTYRAMINE Powder for oral liq 4 g	19.25 (52.68)	50	(Questran-Lite
COLESTIPOL HYDROCHLORIDE Grans for oral liq 5 g	28.60	30	✓ (Colestid
HMG CoA Reductase Inhibitors (Statins)				
Prescribing Guidelines Treatment with HMG CoA Reductase Inhibitors (statins) is recomme cardiovascular risk of 15% or greater. ATORVASTATIN – See prescribing guideline above	ended for patients	with dyslip	idaemi	ia and an absolute 5 ye
★ Tab 10 mg	9.29	500	✓ [Lorstat
★ Tab 20 mg		500	✓ [_orstat
← Tab 40 mg	21.23	500	✓ [_orstat
★ Tab 80 mg		500	✓ [_orstat
PRAVASTATIN - See prescribing guideline above				
★ Tab 20 mg	4.72	100	✓	Apo-Pravastatin
•	1.42	30		•
	(3.45)		(Cholvastin
And Drawantsting to be Cala Completed 4 June 2010				
Apo-Pravastatin to be Sole Supply on 1 June 2018				

2.42

		(6.36)		
	Apo-Pravastatin to be Sole Supply on 1 June 2018			
,	nolvastin Tab 20 mg to be delisted 1 June 2018)			
(Cr	olvastin Tab 40 mg to be delisted 1 June 2018)			
SIN	IVASTATIN - See prescribing guideline above			
*	Tab 10 mg	0.95	90	•
				•
	Simvastatin Mylan to be Sole Supply on 1 June 2018			
*	Tab 20 mg	1.52	90	•
		(1.61)		
	Simvastatin Mylan to be Sole Supply on 1 June 2018			
*	Tab 40 mg		90	•
		(2.83)		
	Simvastatin Mylan to be Sole Supply on 1 June 2018			
*	Tab 80 mg		90	•
		(7.91)		

[✓] Arrow-Simva 10mg ✓ Simvastatin Mylan

Cholvastin

[✓] Simvastatin Mylan Arrow-Simva 20mg

,	Simvastatin	Mylan
-		
	Arrow-Simva	40mg

✓	Simvastatin	Mylan
	Arrow-Simva	80mg

Simvastatin Mylan to be Sole Supply on 1 June 2018 (Arrow-Simva 10mg Tab 10 mg to be delisted 1 June 2018) (Arrow-Simva 20mg Tab 20 mg to be delisted 1 June 2018) (Arrow-Simva 40mg Tab 40 mg to be delisted 1 June 2018) (Arrow-Simva 80mg Tab 80 mg to be delisted 1 June 2018)

Subsidy	Fully	Brand or
(Manufacturer's Price)	Subsidised	Generic
\$	Por 🗸	Manufacturer

Selective Cholesterol Absorption Inhibitors

EZETIMIBE - Special Authority see SA1045 below - Retail pharm	acy		
Tab 10 mg	2.00	30	Ezetimibe Sandoz
	(3.35)		Ezemibe

Ezetimibe Sandoz to be Sole Supply on 1 June 2018 (Ezemibe Tab 10 mg to be delisted 1 June 2018)

⇒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 x 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 atoryastatin.

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

Other treatment options including fibrates, resins and nicotinic acid should be considered after failure of statin therapy. If a patient's LDL cholesterol cannot be calculated because the triglyceride level is too high then a repeat test should be performed and if the LDL cholesterol again cannot be calculated then it can be considered that the LDL cholesterol is greater than 2.0 mmol/litre.

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

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

Tab 10 mg with simvastatin 10 mg	5.15	30	✓ Zimybe
Tab 10 mg with simvastatin 20 mg		30	✓ Zimybe
Tab 10 mg with simvastatin 40 mg		30	✓ Zimybe
Tab 10 mg with simvastatin 80 mg		30	✓ Zimvbe

⇒SA1046 Special Authority for Subsidy

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

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

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

Other treatment options including fibrates, resins and nicotinic acid should be considered after failure of statin therapy. If a patient's LDL cholesterol cannot be calculated because the triglyceride level is too high then a repeat test should be performed and if the LDL cholesterol again cannot be calculated then it can be considered that the LDL cholesterol is greater than 2.0 mmol/litre.

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

_				
		Subsidy	D:) 01.	Fully Brand or
		(Manufacturer's	Price) Subsi	dised Generic ✓ Manufacturer
=		Ψ	1 01	- Mandidotator
Ν	itrates			
	VOEDVI TRINITRATE			
	YCERYL TRINITRATE Tab 600 mcg - Up to 100 tab available on a PSO	9.00	100 OP	✓ Lycinate
*	Oral pump spray, 400 mcg per dose — Up to 250 dose	8.00	100 OP	Lycinate
*	available on a PSO	4.45	250 dose OP	✓ Nitrolingual Pump
	available on a r oo		250 0030 01	Spray
*	Oral spray, 400 mcg per dose - Up to 250 dose available on	а		- P,
	PSO		250 dose OP	✓ Glytrin
*	Patch 25 mg, 5 mg per day	15.73	30	✓ Nitroderm TTS
*	Patch 50 mg, 10 mg per day	18.62	30	✓ Nitroderm TTS
ISC	SORBIDE MONONITRATE			
*	Tab 20 mg	18.80	100	✓ Ismo 20
*	Tab long-acting 40 mg		30	✓ Ismo 40 Retard
*	Tab long-acting 60 mg	8.29	90	✓ <u>Duride</u>
0	annual the antique the c			
5	ympathomimetics			
AD	RENALINE			
	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 PS	SO27.00	5	✓ Hospira
		49.00	10	Aspen Adrenaline
ISC	PRENALINE			
*	Inj 200 mcg per ml, 1 ml ampoule	36.80	25	
		(164.20)		Isuprel
v	asodilators			
٧	asounators			
	YL NITRITE			
*	Liq 98% in 0.3 ml cap	62.92	12	
		(73.40)		Baxter
ΗY	DRALAZINE HYDROCHLORIDE			
*	Tab 25 mg - Special Authority see SA1321 below - Retail			
	pharmacy	CBS	1	Hydralazine
			56	✓ Onelink S29
			84	✓ AMDIPHARM S29
*	Inj 20 mg ampoule	25.90	5	✓ Apresoline
	SA1321 Special Authority for Subsidy			
	ial application from any relevant practitioner. Approvals valid	without furthe	r renewal unless	notified for applications meeting
	following criteria:			
Eith				
	1 For the treatment of refractory hypertension; or			-t b t
	2 For the treatment of heart failure in combination with a nitral inhibitors and/or angiotensin receptor blockers.	ate, in patients	wno are intoleral	nt or have not responded to ACE
	IOXIDIL	70.00	100	./ Lanitan
	Tab 10 mg	/ 0.00	100	✓ Loniten
NIC	CORANDIL	07.05		∠ Hermal
A	Tab 10 mg		60 60	✓ Ikorel
•	Tab 20 mg	33.28	60	✓ Ikorel

[‡] safety cap

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
PAPAVERINE HYDROCHLORIDE * Inj 12 mg per ml, 10 ml ampoule PENTOXIFYLLINE [OXPENTIFYLLINE]	217.90	5	√ }	lospira
Tab 400 mg	42.26	50	√ 1	Frental 400
Endothelin Recentor Antagonists				

Endothelin Receptor Antagonists

AMBRISENTAN - Special Authority see SA1702 below - Retail pharmacy		
Tab 5 mg4,585.00	30	✓ Volibris
Tab 10 mg4,585.00	30	✓ Volibris

⇒SA1702 Special Authority for Subsidy

Special Authority approved by the Pulmonary Arterial Hypertension Panel

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

The Coordinator, PAH Panel

PHARMAC, PO Box 10-254, WELLINGTON

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

BOSENTAN - Special Authority see SA1712 below - Retail pharmacy

OSENTAN - Special Authority See SATT 12 below - 11	ciali priarriacy		
Tab 62.5 mg	375.00	56	✓ Mylan-Bosentan
· ·	401.79	60	✓ Bosentan-Mylan
Tab 125 mg	375.00	56	✓ Mylan-Bosentan
•	401.79	60	✓ Bosentan-Mylan

(Mylan-Bosentan Tab 62.5 mg to be delisted 1 July 2018) (Mylan-Bosentan Tab 125 mg to be delisted 1 July 2018)

⇒SA1712 Special Authority for Subsidy

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

All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH)*; and
- 2 PAH is in Group 1, 4 or 5 of the WHO (Venice) clinical classifications; and
- 3 PAH is at NYHA/WHO functional class II, III, or IV; and
- 4 Any of the following:
 - 4.1 Both:
 - 4.1.1 Bosentan is to be used as PAH monotherapy; and
 - 4.1.2 Either:
 - 4.1.2.1 Patient is intolerant or contraindicated to sildenafil; or
 - 4.1.2.2 Patient is a child with idiopathic PAH or PAH secondary to congenital heart disease; or
 - 4.2 Both:
 - 4.2.1 Bosentan is to be used as PAH dual therapy; and
 - 4.2.2 Either:
 - 4.2.2.1 Patient has tried a PAH monotherapy for at least three months and failed to respond; or
 - 4.2.2.2 Patient deteriorated while on a PAH monotherapy; or
 - 4.3 Both:
 - 4.3.1 Bosentan is to be used as PAH triple therapy; and
 - 4.3.2 Any of the following:
 - 4.3.2.1 Patient is on the lung transplant list; or
 - 4.3.2.2 Patient is presenting acutely with idiopathic pulmonary arterial hypertension (IPAH) in New York Heart Association/World Health Organization (NYHA/WHO) Functional Class IV; or

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

continued...

- 4.3.2.3 Patient is deteriorating rapidly to NYHA/WHO Functional Class IV who may be lung transplant recipients in the future, if their disease is stabilised; or
- 4.3.2.4 Patient has PAH associated with the scleroderma spectrum of diseases (APAHSSD) who have no major morbidities and are deteriorating despite combination therapy.

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

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

Phosphodiesterase Type 5 Inhibitors

SILDENAFIL – Special Authority see SA1704 below – Retail pharmacy		
Tab 25 mg	4	✓ Vedafil
Tab 50 mg	4	✓ Vedafil
Tab 100 mg - For sildenafil oral liquid formulation refer, page 2272.75	4	✓ Vedafil

⇒SA1704 Special Authority for Subsidy

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

All of the following:

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

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

All of the following:

- 1 Patient has pulmonary arterial hypertension (PAH)*; and
- 2 Any of the following:
 - 2.1 PAH is in Group 1 of the WHO (Venice) clinical classifications; or

Subsidy	Fully	Brand or
(Manufacturer's Price)	Subsidised	Generic
· • '	Por 🗸	Manufacturer

continued...

- 2.2 PAH is in Group 4 of the WHO (Venice) clinical classifications; or
- 2.3 PAH is in Group 5 of the WHO (Venice) clinical classifications; and
- 3 Any of the following:
 - 3.1 PAH is in NYHA/WHO functional class II: or
 - 3.2 PAH is in NYHA/WHO functional class III: or
 - 3.3 PAH is in NYHA/WHO functional class IV: and
- 4 Patient has a pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg; and
- 5 Either:
 - 5.1 Patient has a mean pulmonary artery pressure (PAPm) > 25 mmHg; or
 - 5.2 Patient is peri Fontan repair; and
- 6 Patient has a pulmonary vascular resistance (PVR) of at least 3 Wood Units or at least 240 International Units (dvn s

Note: Indications marked with * are Unapproved Indications.

Prostacyclin Analogues

EPOPROSTENOL - Special Authority see SA1696 below - F	Retail pharmacy		
Inj 500 mcg vial	36.61	1	✓ Veletri
Inj 1.5 mg vial	73.21	1	✓ Veletri
⇒SA1696 Special Authority for Subsidy			

Special Authority approved by the Pulmonary Arterial Hypertension Panel

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

The Coordinator, PAH Panel

PHARMAC, PO Box 10-254, WELLINGTON

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

ILOPROST – Special Authority see SA1705 below – Retail pharmacy 30 ✓ Ventavis

⇒SA1705 Special Authority for Subsidy

Special Authority approved by the Pulmonary Arterial Hypertension Panel

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

The Coordinator, PAH Panel

PHARMAC. PO Box 10-254. WELLINGTON

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

DERMATOLOGICALS

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

Antiacne Preparations

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 102

ADAPALENE

a) Maximum of 30 g per prescription

b)	Only on	a prescription
<u> </u>	0 40/	

Crm 0.1%	22.89	30 g OP	Differin
Gel 0.1%	22.89	30 g OP	✓ Differin
ISOTRETINOIN - Special Authority see SA1475 belo	w – Retail pharmacy		
Cap 10 mg	12.47	100	✓ Isotane 10
, -	14.96	120	Oratane
Cap 20 mg	19.27	100	✓ Isotane 20
	23.12	120	✓ Oratane

⇒SA1475 Special Authority for Subsidy

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

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

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

TRETINOIN

✓ ReTrieve 50 g OP

Antibacterials Topical

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 102

HYDROGEN PEROXIDE

15 g OP Crystaderm

DERMATOLOGICALS

	Subsidy (Manufacturer's F	Price) Subs	Fully Brand or sidised Generic
	\$	Per	✓ Manufacturer
MUPIROCIN			
Oint 2%	6.60	15 g OP	
	(9.26)	Ü	Bactroban
a) Only on a prescription	,		
b) Not in combination			
SODIUM FUSIDATE [FUSIDIC ACID]			
Crm 2%	2.52	15 g OP	✓ DP Fusidic Acid
OIII 2 /0	2.32	13 g O1	Cream
a) Maximum of 15 a per prescription			Oleani
a) Maximum of 15 g per prescription b) Only on a prescription			
b) Only on a prescriptionc) Not in combination			
,	2.45	15 a OB	√ Eahan
Oint 2%	3.40	15 g OP	✓ Foban
Maximum of 15 g per prescription			
b) Only on a prescription			
c) Not in combination			
SULFADIAZINE SILVER			
Crm 1%	10.80	50 g OP	✓ Flamazine
 a) Up to 250 g available on a PSO 			
b) Not in combination			
Antifungals Topical			
For systemic antifungals, refer to INFECTIONS, Antifung	gals, page 109		
AMOROLFINE			
a) Only on a prescription			
b) Not in combination			
Nail soln 5%	15.95	5 ml OP	✓ MycoNail
CICLOPIROX OLAMINE			
a) Only on a prescription b) Not in combination			
Nail-soln 8%	6.50	7 ml OP	✓ Apo-Ciclopirox
	0.30	7 IIII OP	* Apo-Ciciopitox
CLOTRIMAZOLE	0.70	00 . 05	/ Olama
* Crm 1%	0.70	20 g OP	✓ Clomazol
a) Only on a prescription			
b) Not in combination			
* Soln 1%		20 ml OP	_
	(7.55)		Canesten
 a) Only on a prescription 			
b) Not in combination			
ECONAZOLE NITRATE			
Crm 1%	1.00	20 g OP	
- ,	(7.48)	3	Pevaryl
a) Only on a prescription	(0)		, .
b) Not in combination			
Foaming soln 1%, 10 ml sachets	0.80	3	
1 Jaminy 30111 1 /0, 10 1111 30011013	(17.23)	3	Pevaryl
a) Only on a propertial	(17.23)		revalyi
a) Only on a prescription Net in combination			
b) Not in combination			

	Subsidy		Fully	
	(Manufacturer's Pi	rice) Per	Subsidised	
MICONAZOLENITRATE	Ψ	1 01		Manadator
MICONAZOLE NITRATE * Crm 2%	0.74	15 a C	ND ./	Multichem
	0.74	15 g C)P •	Multichem
a) Only on a prescriptionb) Not in combination				
* Lotn 2%	4.36	30 ml ()P	
- LOUI Z /V	(10.03)	00 1111 0	J.	Daktarin
a) Only on a prescription	(13133)			
b) Not in combination				
* Tinct 2%	4.36	30 ml (OP	
	(12.10)			Daktarin
a) Only on a prescription				
b) Not in combination				
NYSTATIN				
Crm 100,000 u per g	1.00	15 g C)P	
	(7.90)			Mycostatin
a) Only on a prescription				
b) Not in combination				
Antipruritic Preparations				
Antiprunitic Freparations				
CALAMINE				
a) Only on a prescription				
b) Not in combination			_	
Crm, aqueous, BP		100 (•	Pharmacy Health
Lotn, BP	12.94	2,000	ml 🗸	<u>PSM</u>
CROTAMITON				
a) Only on a prescription				
b) Not in combination	2.27	00 0		
Crm 10%	3.37	20 g C)P •	Itch-Soothe
MENTHOL – Only in combination				
 Only in combination with a dermatological base or prop 	rietary Topical Co	orticoster	iod – Plain	, refer dermatological base,
page 226				
2) With or without other dermatological galenicals.				
Crystals	6.50	25 g	1	PSM
Orystais	6.92	20 y		MidWest
	29.60	100 (_	MidWest
Corticosteroids Topical				
For systemic corticosteroids, refer to CORTICOSTEROIDS AND	RELATED AGEN	NTS, pag	e 91	
Corticosteroids - Plain				

:TAMETHASONE 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

[‡] safety cap

	Subsidy (Manufacturer's P	Price) Suba	Fully	
	(Wandacturer's F	Per	iuiseu •	Manufacturer
BETAMETHASONE VALERATE				
* Crm 0.1%	3.15	50 g OP	1	Beta Cream
* Oint 0.1%		50 g OP		Beta Ointment
* Lotn 0.1%		50 ml OP		Betnovate
				20014.0
CLOBETASOL PROPIONATE	0.00	00 - 00	,	D
* Crm 0.05%		30 g OP		Dermol
* Oint 0.05%	2.20	30 g OP	•	<u>Dermol</u>
CLOBETASONE BUTYRATE				
Crm 0.05%	5.38	30 g OP		
	(7.09)			Eumovate
DIFLUCORTOLONE VALERATE				
Crm 0.1%	8 97	50 g OP		
0111 011 /011	(15.86)	00 g 0.		Nerisone
Fatty oint 0.1%		50 g OP		1101100110
ratty on to 0.170	(15.86)	30 g Oi		Nerisone
W/DD000DT100VF	(13.00)			NCHOOLC
HYDROCORTISONE				
* Crm 1% – Only on a prescription		30 g OP		DermAssist
	16.25	500 g		Pharmacy Health
♣ Powder – Only in combination Up to 5% in a dermatological base (not proprietary Topic		25 g		<u>ABM</u>
HYDROCORTISONE AND PARAFFIN LIQUID AND LANOLIN				
HYDROCORTISONE AND PARAFFIN LIQUID AND LANOLIN Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% — Only o a prescription		250 ml	•	DP Lotn HC
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% - Only o a prescription		250 ml	1	DP Lotn HC
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% - Only o a prescription	10.57			
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% - Only o a prescription	10.57	30 g OP	/	Locoid Lipocream
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% - Only o a prescription	10.57 2.30 6.85	30 g OP 100 g OP	1	
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% - Only o a prescription		30 g OP 100 g OP 100 g OP	✓✓	Locoid Lipocream Locoid Lipocream Locoid
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% - Only o a prescription		30 g OP 100 g OP	✓✓	Locoid Lipocream
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% — Only o a prescription		30 g OP 100 g OP 100 g OP 100 ml OP	V V V	Locoid Lipocream Locoid Lipocream Locoid Locoid Crelo
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% — Only o a prescription		30 g OP 100 g OP 100 g OP 100 ml OP	\ \ \ \ \ \ \	Locoid Lipocream Locoid Lipocream Locoid Locoid Crelo
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% — Only o a prescription		30 g OP 100 g OP 100 g OP 100 ml OP	\ \ \ \ \ \ \	Locoid Lipocream Locoid Lipocream Locoid Locoid Crelo
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% — Only o a prescription		30 g OP 100 g OP 100 g OP 100 ml OP 15 g OP 15 g OP	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Locoid Lipocream Locoid Lipocream Locoid Locoid Crelo Advantan Advantan
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% — Only o a prescription		30 g OP 100 g OP 100 g OP 100 ml OP 15 g OP 15 g OP		Locoid Lipocream Locoid Lipocream Locoid Locoid Crelo Advantan Advantan Elocon Alcohol Free
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% — Only o a prescription HYDROCORTISONE BUTYRATE Lipocream 0.1%		30 g OP 100 g OP 100 g OP 100 ml OP 15 g OP 15 g OP 15 g OP 50 g OP	1111 11 11	Locoid Lipocream Locoid Lipocream Locoid Locoid Crelo Advantan Advantan Elocon Alcohol Free Elocon Alcohol Free
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% — Only o a prescription		30 g OP 100 g OP 100 g OP 100 ml OP 15 g OP 15 g OP 50 g OP 15 g OP	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	Locoid Lipocream Locoid Lipocream Locoid Locoid Crelo Advantan Advantan Elocon Alcohol Free Elocon Alcohol Free Elocon
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% — Only o a prescription HYDROCORTISONE BUTYRATE Lipocream 0.1%		30 g OP 100 g OP 100 g OP 100 ml OP 15 g OP 15 g OP 50 g OP 50 g OP 50 g OP	1111 11 1111	Locoid Lipocream Locoid Lipocream Locoid Crelo Advantan Advantan Elocon Alcohol Free Elocon Alcohol Free Elocon
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% — Only o a prescription		30 g OP 100 g OP 100 g OP 100 ml OP 15 g OP 15 g OP 50 g OP 15 g OP	1111 11 1111	Locoid Lipocream Locoid Lipocream Locoid Crelo Advantan Advantan Elocon Alcohol Free Elocon Alcohol Free Elocon
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% — Only of a prescription ————————————————————————————————————		30 g OP 100 g OP 100 g OP 100 ml OP 15 g OP 15 g OP 50 g OP 50 g OP 30 ml OP		Locoid Lipocream Locoid Lipocream Locoid Crelo Advantan Advantan Elocon Alcohol Free Elocon Alcohol Free Elocon Elocon Elocon
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% — Only o a prescription HYDROCORTISONE BUTYRATE Lipocream 0.1%		30 g OP 100 g OP 100 g OP 100 ml OP 15 g OP 15 g OP 50 g OP 50 g OP 30 ml OP		Locoid Lipocream Locoid Lipocream Locoid Crelo Advantan Advantan Elocon Alcohol Free Elocon Alcohol Free Elocon Elocon Elocon Aristocort
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% — Only of a prescription		30 g OP 100 g OP 100 g OP 100 ml OP 15 g OP 15 g OP 50 g OP 50 g OP 30 ml OP		Locoid Lipocream Locoid Lipocream Locoid Crelo Advantan Advantan Elocon Alcohol Free Elocon Alcohol Free Elocon Elocon Elocon
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% — Only of a prescription ————————————————————————————————————		30 g OP 100 g OP 100 g OP 100 ml OP 15 g OP 15 g OP 50 g OP 50 g OP 30 ml OP		Locoid Lipocream Locoid Lipocream Locoid Crelo Advantan Advantan Elocon Alcohol Free Elocon Alcohol Free Elocon Elocon Elocon Aristocort
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% — Only of a prescription		30 g OP 100 g OP 100 g OP 100 ml OP 15 g OP 15 g OP 50 g OP 50 g OP 50 g OP 30 ml OP 100 g OP 100 g OP		Locoid Lipocream Locoid Lipocream Locoid Crelo Advantan Advantan Elocon Alcohol Free Elocon Alcohol Free Elocon Elocon Elocon Aristocort
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% — Only of a prescription		30 g OP 100 g OP 100 g OP 100 ml OP 15 g OP 15 g OP 50 g OP 50 g OP 30 ml OP		Locoid Lipocream Locoid Lipocream Locoid Crelo Advantan Advantan Elocon Alcohol Free Elocon Alcohol Free Elocon Elocon Elocon Aristocort

(Manu	Subsidy facturer's Prio \$	ce) Subsi Per	Fully dised	Brand or Generic Manufacturer
BETAMETHASONE VALERATE WITH SODIUM FUSIDATE [FUSIDIC Crm 0.1% with sodium fusidate (fusidic acid) 2%		15 g OP	F	ucicort
a) Maximum of 15 g per prescriptionb) Only on a prescription				
HYDROCORTISONE WITH MICONAZOLE – Only on a prescription * Crm 1% with miconazole nitrate 2%	2.00	15 g OP	✓ <u>N</u>	licreme H
HYDROCORTISONE WITH NATAMYCIN AND NEOMYCIN — Only on Crm 1% with natamycin 1% and neomycin sulphate 0.5% Oint 1% with natamycin 1% and neomycin sulphate 0.5%	2.79	on 15 g OP 15 g OP		imafucort imafucort
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCIN AND 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	٧	'iaderm 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 er # Handrub 1% with ethanol 70% # Soln 4% wash TRICLOSAN – Subsidy by endorsement a) Maximum of 500 ml per prescription	4.29	ordingly. 500 ml 500 ml	_	ealthE ealthE
a) Only if prescribed for a patient identified with Methicillin-re surgery in hospital and the prescription is endorsed accord b) Only if prescribed for a patient with recurrent Staphylococa accordingly	lingly; or	•	,	, .
Soln 1%	5.90	500 ml OP	√ h	ealthE
Barrier Creams and Emollients				
Barrier Creams				
DIMETHICONE * Crm 5% pump bottle	4.59	500 ml OP	✓ <u>h</u>	ealthE Dimethicone 5%
* Crm 10% pump bottle	4.90	500 ml OP	✓ <u>h</u>	ealthE Dimethicone 10%
ZINC AND CASTOR OIL * Oint	5.95	500 g	✓ N	1 ultichem
Emollients				
AQUEOUS CREAM * Crm	1.99	500 g	✓ A	IFT SLS-free
CETOMACROGOL * Crm BP	2.74	500 g	√ <u>h</u>	ealthE

[‡] safety cap

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DERMATOLOGICALS

	Subsidy		Fully Brand or	
	(Manufacturer's		idised Generic	
	\$	Per	✓ Manufac	turer
CETOMACROGOL WITH GLYCEROL				
Crm 90% with glycerol 10%	2.82	500 ml OP	✓ Pharmacy	
			Sorbole	
			Glycerin	<u>!</u>
	3.87	1,000 ml OP	✓ Pharmacy	
			Sorbole	
			Glycerin	!
EMULSIFYING OINTMENT				
* Oint BP	3.59	500 g	✓ <u>AFT</u>	
OIL IN WATER EMULSION				
* Crm	2.25	500 g	✓ O/W Fatty	Emulsion
			Cream	
UREA				
* Crm 10%	1.37	100 g OP	✓ healthE Ui	rea Cream
WOOL FAT WITH MINERAL OIL - Only on a prescription		· ·		
* Lotn hydrous 3% with mineral oil	5.60	1,000 ml		
, ,	(11.95)	,	DP Lotion	
	` 1.40 [′]	250 ml OP		
	(4.53)		DP Lotion	
	5.60	1,000 ml		
	(20.53)		Alpha-Keri	Lotion
	(23.91)		BK Lotion	
	1.40	250 ml OP		
	(7.73)		BK Lotion	
Other Dermetalegical Pages				
Other Dermatological Bases				
PARAFFIN				
White soft - Only in combination	20.20	2,500 g	✓ IPW	
•	3 58	500 a		

, , , , , , , , , , , , , , , , , , , ,			
White soft - Only in combination20	0.20	2,500 g	IPW
	3.58	500 g	
(7	7.78)		IPW
3)	8.69)		PSM

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

Brand or

Fully

	(Manufacturer's Price	ce) Sub	sidised	Generic
	\$	Per	1	Manufacturer
Minor Skin Infections				
POVIDONE IODINE				
Oint 10%	3.27	25 g OP	✓ B	etadine
 a) Maximum of 100 g per prescription 				
b) Only on a prescription				
Antiseptic soln 10%	6.20	500 ml	_	etadine
			✓ R	iodine
	1.28	100 ml	_	
	(4.20)			iodine
	(13.27)		В	etadine
	0.19	15 ml	_	
	(7.41)			etadine
Skin preparation, povidone iodine 10% with 30% alcohol		500 ml	✓ B	etadine Skin Prep
	1.63	100 ml	_	
01: 12 14 15 16 16 17 17 17 17 17 17 17 17 17 17 17 17 17	(3.48)	500 I	В	etadine Skin Prep
Skin preparation, povidone iodine 10% with 70% alcohol		500 ml	•	
	(18.63)	400 1	O	rion
	1.63	100 ml	_	
	(6.04)		O	rion
Parasiticidal Preparations				

Subsidy

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:

DIMETHICONE

- 2.1 Both:
 - 2.1.1 The patient is in the community; and

Lotn 4% 4.98

IVERMECTIN - Special Authority see SA1225 below - Retail pharmacy Tab 3 mg - Up to 100 tab available on a PSO.......17.20

- 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

continued...

200 ml OP

✓ healthE

✓ Stromectol

Dimethicone 4% Lotion

DERMATOLOGICALS

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

continued...

- 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;
 - 2.2.3 Any of the following:
 - 2.2.3.1 Patient has a severe scables hyperinfestation (Crusted/ Norwegian scables); 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.

PEI		

Crm 5%	.4.95	30 g OP	✓ Lyderm
Lotn 5%	.3.69	30 ml OP	✓ A-Scabies

	Subsidy (Manufacturer's Price) \$	Subsid Per	Fully dised	Brand or Generic Manufacturer
DUENICTURN				

PHFNOTHRIN

Psoriasis and Eczema Preparations

ACITRETIN – Special Authority see SA1476 below – Retail pharmacy		
Cap 10 mg17.86	60	✓ Novatretin
Cap 25 mg41.36	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: Fither:

- 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 W	ITH CALCIPOTRIOL
------------------------------	------------------

Gel 500 mcg with calcipotriol 50 mcg per g Oint 500 mcg with calcipotriol 50 mcg per g		30 g OP 30 g OP	✓ <u>Daivobet</u> ✓ <u>Daivobet</u>
CALCIPOTRIOL Oint 50 mcg per g	45.00	100 g OP	✓ <u>Daivonex</u>
COAL TAR Soln BP - Only in combination	32.95	200 ml	✓ Midwest

- Up to 10% only in combination with a dermatological base or proprietary Topical Corticosteriod Plain, refer dermatological base, page 226
- 2) With or without other dermatological galenicals.

COAL TAR WITH ALLANTOIN, MENTHOL, PHENOL AND SULPHUR

Soln 5% with sulphur 0.5%, menthol 0.75%, phenol 0.5% and			
allantoin crm 2.5%	6.59	75 g OP	
	(8.00)		Egopsoryl TA
	3.43	30 g OP	
	(4.35)		Egopsoryl TA
COAL TAR WITH SALICYLIC ACID AND SULPHUR			
Soln 12% with salicylic acid 2% and sulphur 4% oint	7.95	40 g OP	✓ Coco-Scalp
PINE TAR WITH TROLAMINE LAURILSULFATE AND FLUORESC	EIN - Only or	n a prescription	
* Soln 2.3% with trolamine laurilsulfate and fluorescein sodium	3.86	500 ml	✓ Pinetarsol

DERMATOLOGICALS

DERMATOLOGICALS			
	Subsidy (Manufacturer's F \$	Price) Subs	Fully Brand or idised Generic Manufacturer
SALICYLIC ACID			
Powder – Only in combination		250 g	✓ PSM
 Only in combination with a dermatological base refer dermatological base, page 226 With or without other dermatological galenicals. 	or proprietary Topic	cal Corticostero	id – Plain or collodion flexible,
SULPHUR			
Precipitated – Only in combination	6.35	100 g	✓ Midwest
Only in combination with a dermatological base		ū	
base, page 226	or proprietary ropic	ai Corticostero	iu – i iaili, lelei delilialological
2) With or without other dermatological galenicals.			
Scala Dronovations			
Scalp Preparations			
BETAMETHASONE VALERATE	7.75	100 == 100	✓ Data Coal:
* Scalp app 0.1%	7.75	100 ml OP	✓ Beta Scalp
CLOBETASOL PROPIONATE	0.00	00 100	4. D
* Scalp app 0.05%	6.96	30 ml OP	✓ Dermol
HYDROCORTISONE BUTYRATE	0.05	400 ···· I OD	Z Landa
Scalp lotn 0.1%	3.65	100 ml OP	✓ Locoid
KETOCONAZOLE	2.22	100 100	40111
Shampoo 2%	2.99	100 ml OP	✓ <u>Sebizole</u>
a) Maximum of 100 ml per prescriptionb) Only on a prescription			
Sunscreens			
SUNSCREENS, PROPRIETARY – Subsidy by endorsement			
Only if prescribed for a patient with severe photosensitivity	y secondary to a de	fined clinical co	ondition and the prescription is
endorsed accordingly.		00	
Crm		100 g OP	Llamilton Cuncaraan
Lotn,	(5.89)	100 g OP	Hamilton Sunscreen ✓ Marine Blue Lotion
Loui,		100 g O1	SPF 50+
	5.10	200 g OP	✓ Marine Blue Lotion
		ŭ	SPF 50+
Wart Preparations			
For salicylic acid preparations refer to PSORIASIS AND ECZE	MA DREDADATIO	NS page 91	
		ivo, page or	
IMIQUIMOD Crm 5%, 250 mg sachet	17 00	12	✓ Apo-Imiquimod
Onn 5 /6, 250 mg sacriet	17.30	14	Cream 5%
PODOPHYLLOTOXIN			
Soln 0.5%	33.60	3.5 ml OP	✓ Condyline
a) Maximum of 3.5 ml per prescription		3.0 1111 01	- Januajimo
b) Only on a prescription			
, , , ,			

DERMATOLOGICALS

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

Other Skin Preparations

Antineoplastics

FLUOROURACIL SODIUM

20 g OP ✓ Efudix Crm 5%......8.95

Contraceptives - Non-hormonal

Condoms

CO		

*	49 mm - Up to 144 dev available on a PSO13.36	144	✓ Shield 49
*	53 mm - Up to 144 dev available on a PSO	12	✓ Gold Knight
			✓ Shield Blue
	13.36	144	✓ Shield Blue
*	53 mm (chocolate) - Up to 144 dev available on a PSO1.11	12	✓ Gold Knight
	13.36	144	✓ Gold Knight
*	53 mm (strawberry) - Up to 144 dev available on a PSO1.11	12	✓ Gold Knight
	13.36	144	✓ Gold Knight
*	56 mm - Up to 144 dev available on a PSO1.11	12	✓ Gold Knight
	13.36	144	✓ Durex Extra Safe
			✓ Gold Knight
*	56 mm, shaped - Up to 144 dev available on a PSO1.11	12	✓ Durex Confidence
	13.36	144	✓ Durex Confidence
*	60 mm - Up to 144 dev available on a PSO	144	✓ Shield XL

Contraceptive Devices

INTRA-UTERINE DEVICE

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

- TT380 Standard

✓ Choice

✓ Choice Load 375

✓ Choice TT380 Short

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 Fither:
 - 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: Fither:

- 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

		GENITO-URI	NARY SYSTEM
	Subsidy (Manufacturer's Price)	Fully Subsidised Per	Brand or Generic Manufacturer
continued The additional subsidy will fund Mercilon and Marvelon up to the rithe Schedule at 1 November 1999. Special Authorities approved before 1 November 1999 remain vali 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 N combined oral contraceptives and progestogen-only contraceptive ETHINYLOESTRADIOL WITH DESOGESTREL			
 * Tab 20 mcg with desogestrel 150 mcg and 7 inert tab a) Higher subsidy of \$13.80 per 84 tab with Special Auth 	(19.80)		Mercilon 28 ge
b) Up to 84 tab available on a PSO * Tab 30 mcg with desogestrel 150 mcg and 7 inert tab	6.62 (19.80)	84 N	Marvelon 28
 a) Higher subsidy of \$13.80 per 84 tab with Special Auth b) Up to 84 tab available on a PSO ETHINYLOESTRADIOL WITH LEVONORGESTREL 	ority see SA0500 or	n the previous paç	ge
* Tab 20 mcg with levonorgestrel 100 mcg and 7 inert tablets - Up to 84 tab available on a PSO			Microgynon 20 ED Ava 20 ED
Microgynon 20 ED to be Sole Supply on 1 April 2018 * Tab 50 mcg with levonorgestrel 125 mcg and 7 inert tab – Up to 84 tab available on a PSO	9.45		/licrogynon 50 ED
 Tab 30 mcg with levonorgestrel 150 mcg a) Higher subsidy of \$15.00 per 63 tab with Special Auth 	(16.50)		/licrogynon 30 ge
b) Up to 63 tab available on a PSO * Tab 30 mcg with levonorgestrel 150 mcg and 7 inert tablets - Up to 84 tab available on a PSO			.evlen ED Ava 30 ED
Levlen ED to be Sole Supply on 1 April 2018 (Ava 20 ED Tab 20 mcg with levonorgestrel 100 mcg and 7 inert to (Ava 30 ED Tab 30 mcg with levonorgestrel 150 mcg and 7 inert to	ablets to be delisted ablets to be delisted	1 April 2018) 1 1 April 2018)	
ETHINYLOESTRADIOL WITH NORETHISTERONE * Tab 35 mcg with norethisterone 1 mg - Up to 63 tab available	е		

‡ safety cap

63

84

63

84 tab available on a PSO......6.62

to 84 tab available on a PSO.......6.62

Tab 35 mcg with norethisterone 1 mg and 7 inert tab - Up to

* Tab 35 mcg with norethisterone 500 mcg and 7 inert tab - Up

* Tab 35 mcg with norethisterone 500 mcg - Up to 63 tab

✓ Brevinor 1/21

✓ Brevinor 1/28

✓ Brevinor 21

✓ Norimin

Subsidy (Manufacturer's Price)	Subsi	Fully dised	Brand or Generic
 \$	Per	•	Manufacturer

Progestogen-only Contraceptives

⇒SA0500 Special Authority for Alternate Subsidy

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

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

* Tab 30 mcg 6.62

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: Fither:

- 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

IF۱	/ON	36	FQ"	ΓR	F	

	(16.50)	٠.	Microlut
a) Higher subsidy of \$13.80 per 84 tab with Special Authorityb) Up to 84 tab available on a PSO	see SA0500 al	oove	
* Subdermal implant (2 x 75 mg rods) – Up to 3 pack available	100.00		4 1 1 11
on a PSO Jadelle to be Sole Supply on 1 April 2018	. 106.92	1	✓ Jadelle
MEDROXYPROGESTERONE ACETATE			
* Inj 150 mg per ml, 1 ml syringe – Up to 5 inj available on a PSO.	7.25	1	✓ <u>Depo-Provera</u>
NORETHISTERONE * Tab 350 mcg - Up to 84 tab available on a PSO	6.25	84	✓ Noriday 28
Emergency Contraceptives			
LEVONORGESTREL			

ᄔ	۷OI	AC.	7	IGLOTINEL
	_			_

*	Tab 1.5 mg4.95	1	✓ Postinor-1
---	----------------	---	--------------

- a) Maximum of 2 tab per prescription
- b) Up to 5 tab available on a PSO
- c) Note: may be provided by a pharmacist under the non-prescribing Practitioners provisions in Part III of Section A.

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

Antiandrogen Oral Contraceptives

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

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

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

CYPROTERONE ACETATE WITH ETHINYLOESTRADIOL

* Tab 2 mg with ethinyloestradiol 35 mcg and 7 inert tabs - Up to 168 tab available on a PSO......4.67 168 ✓ Ginet

Gv	naeco	logica	I Δnti-in	fectives
\sim	Hucoo	logiou		

ACETIC ACID WITH HYDROXYQUINOLINE AND RICINOLEIC ACID			
Jelly with glacial acetic acid 0.94%, hydroxyquinoline sulphate			
0.025%, glycerol 5% and ricinoleic acid 0.75% with applicator	8.43	100 g OP	
(2:	4.00)		Aci-Jel
CLOTRIMAZOLE			
* Vaginal crm 1% with applicators	1.60	35 g OP	✓ Clomazol
* Vaginal crm 2% with applicators		20 g OP	✓ Clomazol
MICONAZOLE NITRATE			
* Vaginal crm 2% with applicator	3.88	40 g OP	✓ <u>Micreme</u>
NYSTATIN			
Vaginal crm 100,000 u per 5 g with applicator(s)	4.45	75 a OP	✓ Nilstat

Myometrial and Vaginal Hormone Preparations

LINGOWETTINE WALLATE			
Inj 500 mcg per ml, 1 ml ampoule – Up to 5 inj available on a PSO		5	✓ DBL Ergometrine
OESTRIOL			
* Crm 1 mg per g with applicator	6.62	15 g OP	 Ovestin
* Pessaries 500 mcg	6.86	15	✓ Ovestin
OXYTOCIN - Up to 5 inj available on a PSO			
Inj 5 iu per ml, 1 ml ampoule	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 availa	able on a PSO		
Inj 5 iu with ergometrine maleate 500 mcg per ml, 1 ml	11.13	5	✓ Syntometrine

Pregnancy Tests - hCG Urine

PREGNANCY	TESTS -	HCG	URINE

- a) Up to 200 test available on a PSO
- b) Only on a PSO

ERCOMETRINE MAI FATE

40 test OP ✓ EasvCheck

Subsidy	Fully	Brand or	
(Manufacturer's Price)	Subsidised	Generic	
` <u>^</u>	Dox /	Manufacturer	

Urinary Agents

For urinary tract Infections refer to INFECTIONS, Antibacterials, page 123

5-Alpha Reductase Inhibitors

FINASTERIDE – Special Authority see SA0928 below – Retail pharmacy

* Tab 5 mg4.81 100

⇒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

⇒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	1.77	100	✓ Ditropan S29
ů	8.85	500	✓ Apo-Oxybutynin
* Oral liq 5 mg per 5 ml	60.40	473 ml	✓ Apo-Oxybutynin
(Ditropan S29 Tab 5 mg to be delisted 1 July 2018)			
POTASSIUM CITRATE			
Oral liq 3 mmol per ml - Special Authority see SA1083 below -			
Retail pharmacy	30.00	200 ml OP	✓ Biomed
- CA1000 Chaniel Authority for Cubaidy			

SA1083 Special Authority for Subsidy

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

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

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

SODIUM CITRO-TARTRATE

	Subsidy		Fully	
	(Manufacturer's Price) \$	Per	Subsidised	
SOLIFENACIN SUCCINATE - Special Authority see SA0998 be	low – Retail pharmac	;y		
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 overactive bladder and a documented intolerance of, or is non-re			ınless notif	ied where the patient has
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				

■ 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
	(8.25)		петнаѕих
TETRABROMOPHENOL			
* Blue diagnostic strips	7.02	100 test OP	
	(13.92)		Albustix

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

Calcium Homeostasis

CALCITONIN

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

⇒SA1618 Special Authority for Subsidy

Initial application only from a nephrologist or endocrinologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 All of the following:
 - 1.1 The patient has been diagnosed with a parathyroid carcinoma (see Note); and
 - 1.2 The patient has persistent hypercalcaemia (serum calcium greater than or equal to 3 mmol/L) despite previous first-line treatments including sodium thiosulfate (where appropriate) and bisphosphonates; and
 - 1.3 The patient is symptomatic; or
- 2 All of the following:
 - 2.1 The patient has been diagnosed with calciphylaxis (calcific uraemic arteriolopathy); and
 - 2.2 The patient has symptomatic (e.g. painful skin ulcers) hypercalcaemia (serum calcium greater than or equal to mmol/L); and
 - 2.3 The patient's condition has not responded to previous first-line treatments including bisphosphonates and sodium thiosulfate.

Renewal only from a nephrologist or endocrinologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 The patient's serum calcium level has fallen to < 3mmol/L; and
- 2 The patient has experienced clinically significant symptom improvement.

Note: This does not include parathyroid adenomas unless these have become malignant.

ZOLEDRONIC ACID

Inj 4 mg per 5 ml, vial − Special Authority see SA1687 below −
Retail pharmacy......84.50 1 ✓ Zoledronic acid
Mylan

550.00 ✓ Zometa

⇒SA1687 Special Authority for Subsidy

Initial application — (bone metastases) only from an oncologist, haematologist or palliative care specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 Patient has hypercalcaemia of malignancy; or
- 2 Both:
 - 2.1 Patient has bone metastases or involvement; and
 - 2.2 Patient has severe bone pain resistant to standard first-line treatments; or
- 3 Both:
 - 3.1 Patient has bone metastases or involvement: and
 - 3.2 Patient is at risk of skeletal-related events pathological fracture, spinal cord compression, radiation to bone or surgery to bone).

Initial application — **(early breast cancer)** only from an oncologist or medical practitioner on the recommendation of a oncologist. Approvals valid for 2 years for applications meeting the following criteria:

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

continued...

All of the following:

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

Corticosteroids and Related Agents for Systemic Use

# Inj 3.9 mg with betamethasone acetate 3 mg per ml, 1 ml	BETAMETHASONE SODIUM PHOSPHATE WITH BETAMETHASO	NE ACETATE		
DEXAMETHASONE * Tab 0.5 mg - Retail pharmacy-Specialist	* Inj 3.9 mg with betamethasone acetate 3 mg per ml, 1 ml	19.20	5	
DEXAMETHASONE		(36.96)		Celestone
* Tab 0.5 mg — Retail pharmacy-Specialist				Chronodose
Up to 60 tab available on a PSO # Tab 4 mg − Retail pharmacy-Specialist	DEXAMETHASONE			
Up to 60 tab available on a PSO ** Tab 4 mg - Retail pharmacy-Specialist		0.88	30	✓ Dexmethsone
# Tab 4 mg - Retail pharmacy-Specialist				
Up to 30 tab available on a PSO Oral liq 1 mg per ml - Retail pharmacy-Specialist		1.84	30	✓ Dexmethsone
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				
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	Oral liq 1 mg per ml - Retail pharmacy-Specialist	45.00	25 ml OP	✓ Biomed
DEXAMETHASONE PHOSPHATE Dexamethasone phosphate injection will not be funded for oral use. * Inj 4 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO	Oral liq prescriptions:			
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 PSO14.19 10	 Must be written by a Paediatrician or Paediatric Cardio 	ologist; or		
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 PSO14.19 10	2) On the recommendation of a Paediatrician or Paediatr	ic Cardiologis	t.	
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 PSO14.19 10				
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 PSO14.19 10	DEXAMETHASONE PHOSPHATE			
★ Inj 4 mg per ml, 1 ml ampoule - Up to 5 inj available on a PSO14.19 10 ✓ Max Health ★ Inj 4 mg per ml, 2 ml ampoule - Up to 5 inj available on a PSO25.18 10 ✓ Max Health FLUDROCORTISONE ACETATE ★ Tab 100 mcg		ise.		
* Inj 4 mg per ml, 2 ml ampoule — Up to 5 inj available on a PSO25.18 10			10	✓ Max Health
## Tab 100 mcg			10	✓ Max Health
# Tab 100 mcg				
HYDROCORTISONE * Tab 5 mg		14.32	100	✓ Florinef
** Tab 5 mg 8.10 100 ✓ Douglas ** Tab 20 mg − For hydrocortisone oral liquid formulation refer, page 227 20.32 100 ✓ Douglas ** Inj 100 mg vial 5.30 1 ✓ Solu-Cortef a) Up to 5 inj available on a PSO b) Only on a PSO Volume Volume Volume METHYLPREDNISOLONE − Retail pharmacy-Specialist 100 ✓ Medrol ✓ Medrol ** Tab 100 mg 180.00 20 ✓ Medrol METHYLPREDNISOLONE (AS SODIUM SUCCINATE) − Retail pharmacy-Specialist Volume Volume Inj 40 mg vial 10.50 1 ✓ Solu-Medrol Inj 500 mg vial 9.00 1 ✓ Solu-Medrol Inj 1 g vial 16.00 1 ✓ Solu-Medrol METHYLPREDNISOLONE ACETATE 40.00 5 ✓ Depo-Medrol METHYLPREDNISOLONE ACETATE 40.00 5 ✓ Depo-Medrol METHYLPREDNISOLONE ACETATE WITH LIDOCAINE [LIGNOCAINE] 1 mj 40 mg per ml with lidocaine [lignocaine] 1 ml vial 9.25 1 ✓ Depo-Medrol with	C .	14.02	100	· Home
** Tab 20 mg − For hydrocortisone oral liquid formulation refer, page 227		0.10	100	√ Deugles
page 227		8.10	100	Douglas
** Inj 100 mg vial 5.30 1 ✓ Solu-Cortef a) Up to 5 inj available on a PSO b) Only on a PSO METHYLPREDNISOLONE – Retail pharmacy-Specialist 80.00 100 ✓ Medrol ** Tab 4 mg 80.00 20 ✓ Medrol ** Tab 100 mg 180.00 20 ✓ Medrol METHYLPREDNISOLONE (AS SODIUM SUCCINATE) – Retail pharmacy-Specialist Inj 40 mg vial 10.50 1 ✓ Solu-Medrol Inj 125 mg vial 22.25 1 ✓ Solu-Medrol Inj 500 mg vial 9.00 1 ✓ Solu-Medrol Inj 1 g vial 16.00 1 ✓ Solu-Medrol METHYLPREDNISOLONE ACETATE 40.00 5 ✓ Depo-Medrol METHYLPREDNISOLONE ACETATE WITH LIDOCAINE [LIGNOCAINE] 1 ml vial 40.00 5 ✓ Depo-Medrol with		00.00	100	/ Davidas
a) Up to 5 inj available on a PSO b) Only on a PSO METHYLPREDNISOLONE - Retail pharmacy-Specialist * Tab 4 mg				
b) Only on a PSO METHYLPREDNISOLONE - Retail pharmacy-Specialist * Tab 4 mg	•	5.30	ı	Solu-Cortei
METHYLPREDNISOLONE - Retail pharmacy-Specialist 80.00 100 ✓ Medrol ** Tab 4 mg				
** Tab 4 mg 80.00 100 ✓ Medrol ** Tab 100 mg .180.00 20 ✓ Medrol METHYLPREDNISOLONE (AS SODIUM SUCCINATE) – Retail pharmacy-Specialist Inj 40 mg vial 10.50 1 ✓ Solu-Medrol Inj 125 mg vial .22.25 1 ✓ Solu-Medrol Inj 500 mg vial .9.00 1 ✓ Solu-Medrol Inj 1 g vial .16.00 1 ✓ Solu-Medrol METHYLPREDNISOLONE ACETATE Inj 40 mg per ml, 1 ml vial .40.00 5 ✓ Depo-Medrol METHYLPREDNISOLONE ACETATE WITH LIDOCAINE [LIGNOCAINE] Inj 40 mg per ml with lidocaine [lignocaine] 1 ml vial .9.25 1 ✓ Depo-Medrol with	•			
★ Tab 100 mg 180.00 20 ✓ Medrol METHYLPREDNISOLONE (AS SODIUM SUCCINATE) – Retail pharmacy-Specialist 10.50 1 ✓ Solu-Medrol Inj 40 mg vial 10.50 1 ✓ Solu-Medrol Inj 125 mg vial 22.25 1 ✓ Solu-Medrol Inj 500 mg vial 9.00 1 ✓ Solu-Medrol Inj 1 g vial 16.00 1 ✓ Solu-Medrol METHYLPREDNISOLONE ACETATE 40.00 5 ✓ Depo-Medrol METHYLPREDNISOLONE ACETATE WITH LIDOCAINE [LIGNOCAINE] 1 ml vial 9.25 1 ✓ Depo-Medrol with	• • • • • • • • • • • • • • • • • • • •			
METHYLPREDNISOLONE (AS SODIUM SUCCINATE) − Retail pharmacy-Specialist Inj 40 mg vial	· · · · · · · · · · · · · · · · · · ·			
Inj 40 mg vial	· ·			▼ <u>Medrol</u>
Inj 125 mg vial 22.25 1 ✓ Solu-Medrol Inj 500 mg vial 9.00 1 ✓ Solu-Medrol Inj 1 g vial 16.00 1 ✓ Solu-Medrol METHYLPREDNISOLONE ACETATE Inj 40 mg per ml, 1 ml vial 40.00 5 ✓ Depo-Medrol METHYLPREDNISOLONE ACETATE WITH LIDOCAINE [LIGNOCAINE] Inj 40 mg per ml with lidocaine [lignocaine] 1 ml vial 9.25 1 ✓ Depo-Medrol with				
Inj 500 mg vial			· -	
Inj 1 g vial			•	
METHYLPREDNISOLONE ACETATE Inj 40 mg per ml, 1 ml vial			· ·	
Inj 40 mg per ml, 1 ml vial	· · ·	16.00	1	Solu-Medrol
METHYLPREDNISOLONE ACETATE WITH LIDOCAINE [LIGNOCAINE] Inj 40 mg per ml with lidocaine [lignocaine] 1 ml vial9.25 1 ✓ Depo-Medrol with				
Inj 40 mg per ml with lidocaine [lignocaine] 1 ml vial9.25 1 ✓ Depo-Medrol with	Inj 40 mg per ml, 1 ml vial	40.00	5	✓ Depo-Medrol
Inj 40 mg per ml with lidocaine [lignocaine] 1 ml vial9.25 1 ✓ Depo-Medrol with	METHYLPREDNISOLONE ACETATE WITH LIDOCAINE [LIGNOCA	AINE]		
Lidocaine			1	✓ Depo-Medrol with
				Lidocaine

	Subsidy		Fully	Brand or
	(Manufacturer's P	rice) Subs	idised	Generic
	\$	Per	1	Manufacturer
PREDNISOLONE				
* Oral liq 5 mg per ml – Up to 30 ml available on a PSO Restricted to children under 12 years of age.	7.50	30 ml OP	•	Redipred
PREDNISONE				
* Tab 1 mg	10.68	500	1	Apo-Prednisone
* Tab 2.5 mg		500	1	Apo-Prednisone
* Tab 5 mg - Up to 30 tab available on a PSO		500	1	Apo-Prednisone
* Tab 20 mg		500	1	Apo-Prednisone
TETRACOSACTRIN				
* Inj 250 mcg per ml, 1 ml ampoule	75.00	1	1	Synacthen
* Inj 1 mg per ml, 1 ml ampoule		1	1	Synacthen Depot
TRIAMCINOLONE ACETONIDE				
Inj 10 mg per ml, 1 ml ampoule	20.80	5	1	Kenacort-A 10
Inj 40 mg per ml, 1 ml ampoule		5	1	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		50	✓ Procur
TESTOSTERONE	22.22	22	
Patch 5 mg per day	80.00	30	✓ Androderm
TESTOSTERONE CIPIONATE - Retail pharmacy-Specialist Inj 100 mg per ml, 10 ml vial	76.50	1	✓ <u>Depo-Testosterone</u>
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".

	Subsidy (Manufacturer's Price \$) Per	Fully Subsidised	Brand or Generic Manufacturer
Oestrogens				
DESTRADIOL - See prescribing guideline on the previous page				
★ Tab 1 mg		28 OF)	
· · · · · · · · · · · · · · · · · · ·	(11.10)			Estrofem
米 Tab 2 mg	, ,	28 OF		
	(11.10)			Estrofem
▶ Patch 25 mcg per day		8	_	Estradot
a) No more than 2 patch per week				
b) Only on a prescription				
Patch 50 mcg per day	7 04	8	1	Estradot 50 mcg
a) No more than 2 patch per week	7.04	U	•	Lottadot oo meg
, , ,				
b) Only on a prescription	7.01	8	./	Estradat
Patch 75 mcg per day	1.91	ō	•	<u>Estradot</u>
a) No more than 2 patch per week				
b) Only on a prescription	7.04	•	,	
Patch 100 mcg per day	7.91	8	•	<u>Estradot</u>
a) No more than 2 patch per week				
b) Only on a prescription				
ESTRADIOL VALERATE - See prescribing guideline on the pr	evious page			
€ Tab 1 mg		84	✓	Progynova
€ Tab 2 mg	12.36	84		Progynova
DESTROGENS - See prescribing guideline on the previous pag				
Conjugated, equine tab 300 mcg		28		
Conjugated, equine tab 500 meg	(11.48)	20		Premarin
Conjugated, equine tab 625 mcg		28		i ieilialili
Conjugated, equine tab 025 mog	(11.48)	20		Premarin
Duamantamana	(11.40)			T Terriariii
Progestogens				
MEDROXYPROGESTERONE ACETATE - See prescribing guid				Пислено
Fab 2.5 mg		30		Provera
	7.00	56		Provera S29 S29
F Tab 5 mg		100	_	<u>Provera</u>
Fab 10 mg		30	•	<u>Provera</u>
Provera S29 S29 Tab 2.5 mg to be delisted 1 September 2018)				
Progestogen and Oestrogen Combined Prepara	tions			
ESTRADIOL WITH NORETHISTERONE - See prescribing gui	ideline on the previo	us pad	ie	
Tab 1 mg with 0.5 mg norethisterone acetate		28 OF		
	(18.10)			Kliovance
Fab 2 mg with 1 mg norethisterone acetate	, ,	28 OF		
	(18.10)			Kliogest
Tab 2 mg with 1 mg norethisterone acetate (10), and 2 mg	(10.10)			i iiiogoot
oestradiol tab (12) and 1 mg oestradiol tab (6)	5.40	28 OF)	
oestiauloi lab (12) aliu 1 my destiauloi lab (0)		20 UF		Tricoguana
	(18.10)			Trisequens

		Subsidy (Manufacturer's Price) \$	Subs Per	Fully sidised	Brand or Generic Manufacturer
OE	STROGENS WITH MEDROXYPROGESTERONE - See pre	scribing guideline on	page 92		
*	Tab 625 mcg conjugated equine with 2.5 mg				
	medroxyprogesterone acetate tab (28)	5.40	28 OP		
		(22.96)		Р	remia
					2.5 Continuous
*	Tab 625 mcg conjugated equine with 5 mg				
	medroxyprogesterone acetate tab (28)	5.40	28 OP		
		(22.96)		Р	remia 5 Continuous

(Premia 2.5 Continuous Tab 625 mcg conjugated equine with 2.5 mg medroxyprogesterone acetate tab (28) to be delisted 1 June 2018)

(Premia 5 Continuous Tab 625 mcg conjugated equine with 5 mg medroxyprogesterone acetate tab (28) to be delisted 1 June 2018)

Other Oestrogen Preparations

# Tab 10 mcg	17.60	100	✓ <u>NZ Medical and</u> <u>Scientific</u>
OESTRIOL W. Tab Oman	7.00	00	/ Overalin
* Tab 2 mg	7.00	30	Ovestin

Other Progestogen Preparations

LEVONORGESTREL

⇒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	✓ Provera HD
NORETHISTERONE			
* Tab 5 mg - Up to 30 tab available on a PSO	18.29	100	Primolut N

	Subsidy (Manufacturer's Price) \$	Sı Per	Fully ubsidised	Brand or Generic Manufacturer
PROGESTERONE				
Cap 100 mg - Special Authority see SA1609 below - Retail pharmacy		30	√ <u>U</u>	trogestan

⇒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 ©29 ✓ Neo-Mercazole
LEVOTHYROXINE			
* Tab 25 mcg	3.89	90	✓ Synthroid
‡ Safety cap for extemporaneously compounded oral liquid p			•
* Tab 50 mcg	1.71	28	✓ Mercury Pharma
·	4.05	90	✓ Synthroid
	64.28	1,000	✓ Eltroxin
‡ Safety cap for extemporaneously compounded oral liquid p	reparations.		
* Tab 100 mcg		28	✓ Mercury Pharma
-	4.21	90	✓ Synthroid
	66.78	1,000	✓ Eltroxin
‡ Safety cap for extemporaneously compounded oral liquid p	reparations.		
PROPYLTHIOURACIL - Special Authority see SA1199 below - Re	tail pharmacy		
Propylthiouracil is not recommended for patients under the age treatments are contraindicated.	of 18 years ur	nless the patie	ent is pregnant and other
Tab 50 mg	35.00	100	✓ PTU S29
SA1100 Special Authority for Subsidy			

⇒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		Fully	Brand or
(Manufacturer's Price)	S	Subsidised	Generic
\$	Per	/	Manufacturer

Trophic Hormones

Growth Hormones

	rmacy	E) - Special Authority see SA1629 below - Retail pha	MATROPIN (OMNITROPE)	SO
Omnitrope	ĺ	109.50	Inj 5 mg cartridge	*
✓ Omnitrope	1	219.00	Inj 10 mg cartridge	*
✓ Omnitrope	1	328.50	Inj 15 mg cartridge	*

⇒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</p>
- 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</p>
 - 2.2 A current bone age is < 14 years (female patients) or < 16 years (male patients); and
 - 2.3 Peak growth hormone value of < 5.0 mcg per litre in response to two different growth hormone stimulation tests. In children who are 5 years or older, GH testing with sex steroid priming is required; and
 - 2.4 If the patient has been treated for a malignancy, they should be disease free for at least one year based upon follow-up laboratory and radiological imaging appropriate for the malignancy, unless there are strong medical reasons why this is either not necessary or appropriate; and
 - 2.5 Appropriate imaging of the pituitary gland has been obtained.

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

All of the following:

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

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

All of the following:

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

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

All of the following:

- 1 Height velocity is greater than or equal to 50th percentile for age (while on growth hormone calculated over 6 to 12 months using the Ranke's Turner Syndrome growth velocity charts); and
- 2 Height velocity is greater than or equal to 2 cm per year, calculated over six months; and

Subsidy (Manufacturer's Price)	Full Subsidise		
 \$	Per 🗸	Manufacturer	

continued...

- 3 A current bone age is 14 years or under; and
- 4 No serious adverse effect that the specialist considers is likely to be attributable to growth hormone treatment has occurred; and
- 5 No malignancy has developed since starting growth hormone.

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

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

continued...

- 3 A current bone age is 14 years or under (female patients) or 16 years or under (male patients); and
- 4 No serious adverse effect that the patients specialist considers is likely to be attributable to growth hormone has occurred; and
- 5 No malignancy has developed after growth hormone therapy was commenced; and
- 6 The patient has not experienced significant biochemical or metabolic deterioration confirmed by diagnostic results; and
- 7 The patient has not received renal transplantation since starting growth hormone treatment; and
- 8 If the patient requires transplantation, growth hormone prescription should cease before transplantation and a new application should be made after transplantation based on the above criteria.

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

All of the following:

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

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

All of the following:

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

Initial application — (adults and adolescents) only from a paediatric endocrinologist or endocrinologist. Approvals valid for 9 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®).

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

continued...

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

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

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

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

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

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

Either:

- 1 All of the following:
 - 1.1 The patient has been treated with somatropin for < 12 months; and
 - 1.2 There has been an improvement in Quality of Life defined as a reduction of at least 8 points on the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA®) score from baseline; and
 - 1.3 Serum IGF-I levels have been increased within ±1SD of the mean of the normal range for age and sex; and
 - 1.4 The dose of somatropin has not exceeded 0.7 mg per day for male patients, or 1 mg per day for female patients; or
- 2 All of the following:
 - 2.1 The patient has been treated with somatropin for more than 12 months; and
 - 2.2 The patient has not had a deterioration in Quality of Life defined as a 6 point or greater increase from their lowest QoL-AGHDA® score on treatment (other than due to obvious external factors such as external stressors); and
 - 2.3 Serum IGF-I levels have continued to be maintained within ±1SD of the mean of the normal range for age and sex (other than for obvious external factors); and
 - 2.4 The dose of somatropin has not exceeded 0.7 mg per day for male patients or 1 mg per day for female patients.

GnRH Analogues

GOSERELIN			
Implant 3.6 mg, syringe	66.48	1	✓ Zoladex
Implant 10.8 mg, syringe	177.50	1	✓ Zoladex
LEUPRORELIN			
Additional subsidy by endorsement where the patient i goserelin and the prescription is endorsed accordingly Inj 3.75 mg prefilled dual chamber syringe – Higher su		nd is unable	to tolerate administration of
\$221.60 per 1 inj with Endorsement	66.48	1	
	(221.60)		Lucrin Depot 1-month
Inj 11.25 mg prefilled dual chamber syringe - Higher	subsidy		
of \$591.68 per 1 inj with Endorsement	177.50	1	
• •	(591.68)		Lucrin Depot 3-month

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

Vasopressin Agonists

DECI			LAIOC	A /	$\neg \neg$	- ^ -	
DESI	אנאוו	HE	עווכיכ	Аι	<i>,</i> Γ I	А	16

Tab 100 mcg - Special Authority see SA1401 below - Retail pharmacy	25.00	30	✓ Minirin
Tab 200 mcg - Special Authority see SA1401 below - Retail pharmacy	54.45 39.03	30 2.5 ml OP 6 ml OP	✓ Minirin ✓ Minirin ✓ Desmopressin- PH&T

Inj 4 mcg per ml, 1 ml − Special Authority see SA1401 below −

Retail pharmacy.......67.18 10 ✓ Minirin

⇒SA1401 Special Authority for Subsidy

Initial application — (Desmopressin tablets for Nocturnal enuresis) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has primary nocturnal enuresis: and
- 2 The nasal forms of desmopressin are contraindicated; and
- 3 An enuresis alarm is contraindicated.

Initial application — (Desmopressin tablets for Diabetes insipidus) from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

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

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

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

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

Other Endocrine Agents

CABERGOLINE

Tab 0.5 mg - Maximum of 2 tab per prescription; can be		
waived by Special Authority see SA1370 below4.75	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.

	Subsidy (Manufacturer's Price)	Sub	Fully sidised	Brand or Generic
	\$	Per	•	Manufacturer
CLOMIFENE CITRATE				
Tab 50 mg	29.84	10	✓ N	Mylan
•				Clomiphen S29
			√ 9	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	✓ N	Metopirone

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

Anthelmintics

ALBENDAZOLE	 Special Authority see SA1318 below – Retail pharmacy 		
Tab 400 mg	469.20	60	✓ Eskazole S29

⇒SA1318 Special Authority for Subsidy

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

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

MEBENDAZOLE - Only on a prescription

Tab 100 mg	24.19	24	De-Worm
Oral liq 100 mg per 5 ml		15 ml	
	(7.17)		Vermox
PRAZIQUANTEL			
Tah 600 mg	68.00	8	✓ Riltricida

Antibacterials

- a) For topical antibacterials, refer to DERMATOLOGICALS, page 73
- b) For anti-infective eye preparations, refer to SENSORY ORGANS, page 219

Cephalosporins and Cephamycins

CEFACLOR MONOHYDRATE Cap 250 mg	24.70	100	✓ Ranbaxy-Cefaclor
Grans for oral liq 125 mg per 5 ml – Wastage claimable – serule 3.3.2 on page 13		100 ml	✓ Ranbaxy-Cefaclor
CEFALEXIN			
Cap 250 mg	3.50	20	✓ Cephalexin ABM
Cap 500 mg		20	✓ Cephalexin ABM
Grans for oral liq 25 mg per ml - Wastage claimable - see	rule		
3.3.2 on page 13	8.00	100 ml	✓ Cefalexin Sandoz
Note: Cefalexin grans for oral liq will not be funded in a	mounts more that	n 14 days trea	atment per dispensing.
Grans for oral liq 50 mg per ml - Wastage claimable - see	rule		
3.3.2 on page 13			Cefalexin Sandoz
Note: Cefalexin grans for oral liq will not be funded in a	mounts more thai	n 14 days trea	atment per dispensing.
CEFAZOLIN - Subsidy by endorsement			
Only if prescribed for dialysis or cellulitis in accordance with	a DHB approved	protocol and	the prescription is endorsed
accordingly.			
Inj 500 mg vial	3.39	5	✓ <u>AFT</u>
lnj 1 g vial	3.29	5	✓ <u>AFT</u>
CEFTRIAXONE - 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	✓ DEVA
Inj 1 g vial	0.84	1	✓ DEVA

	Subsidy (Manufacturer's Price)	Subsid	Fully lised	Brand or Generic	
	\$	Per	✓	Manufacturer	
CEFUROXIME AXETIL – Subsidy by endorsement					_
Only if prescribed for prophylaxis of endocarditis and the pres	scription is endorsed	accordingly			
Tah 250 mg	29 40	50	√ 7	innat	

Macrolides

AZITHROMYCIN – Maximum of 5 days treatment per prescription; can be waived by Special Authority see SA1683 below
A maximum of 24 months of azithromycin treatment for non-cystic fibrosis bronchiectasis will be subsidised on Special

Authority. Tab 250 mg9.00	30	✓ Apo-Azithromycin
Tab 500 mg - Up to 8 tab available on a PSO1.05	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 1312.50	15 ml	✓ Zithromax

⇒SA1683 Special Authority for Waiver of Rule

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

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

Note: Indications marked with * are Unapproved Indications.

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

All of the following:

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

Note: Indications marked with * are Unapproved Indications.

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

All of the following:

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

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

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

CLARITHROMYCIN – Maximum of 500 mg per prescription; can	i be waived by Spe	ecial Authority	see SA1131 on the next page
Tab 250 mg	3.98	14	✓ Apo-Clarithromycin
Grans for oral liq 250 mg per 5 ml - Wastage claimable - se	е		
rule 3.3.2 on page 13	23.12	50 ml	✓ Klacid

Subsidy		Fully	Brand or
(Manufacturer's Price)	Su	bsidised	Generic
\$	Per	/	Manufacturer

⇒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 pa	ge 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 pa	ge 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	100	
	(22.29)		ERA
Tab 500 mg	29.90	100	
ů	(44.58)		ERA
ROXITHROMYCIN	, ,		
Tab disp 50 mg	7.19	10	✓ Rulide D
Restricted to children under 12 years of age.	•		
Tab 150 mg	7.48	50	✓ Arrow-
ů			Roxithromycin
Tab 300 mg	14.40	50	Arrow- Roxithromycin

	Subsidy (Manufacturer's Price \$) Per	Fully Subsidised	
Penicillins				
AMOXICILLIN Cap 250 mg a) Up to 30 cap available on a PSO		500	•	Apo-Amoxi
b) Up to 10 x the maximum PSO quantity for RFPP – se Cap 500 mg	16.75	500	•	Apo-Amoxi
b) Up to 10 x the maximum PSO quantity for RFPP – se Grans for oral liq 125 mg per 5 ml		17 100 m	✓	Amoxicillin Actavis Alphamox 125 Ospamox
a) Up to 200 ml available on a PSO b) Wastage claimable – see rule 3.3.2 on page 13 c) Alphamox 125 to be Sole Supply on 1 May 2018 Grans for oral lig 250 mg per 5 ml	0.97	100 m	ı /	Amoxicillin Actavis
a) Up to 300 ml available on a PSO	1.31 2.00			Alphamox 250 Ospamox
 b) Up to 10 x the maximum PSO quantity for RFPP – se c) Wastage claimable – see rule 3.3.2 on page 13 d) Alphamox 250 to be Sole Supply on 1 May 2018 	ee rule 5.2.6 on page	e 17		
Inj 250 mg vial Inj 500 mg vial Inj 1 g vial – Up to 5 inj available on a PSO	12.41	10 10 10	1	Ibiamox Ibiamox Ibiamox
(Amoxicillin Actavis Grans for oral liq 125 mg per 5 ml to be delis (Ospamox Grans for oral liq 125 mg per 5 ml to be delisted 1 Ma (Amoxicillin Actavis Grans for oral liq 250 mg per 5 ml to be delis (Ospamox Grans for oral liq 250 mg per 5 ml to be delisted 1 Ma	y 2018) ted 1 May 2018)			
AMOXICILLIN WITH CLAVULANIC ACID Tab 500 mg with clavulanic acid 125 mg — Up to 30 tab available on a PSO		20	,	Augmentin
per ml	3.83	100 m	l •	Augmentin
per ml – Up to 200 ml available on a PSO		00 ml (OP ✓	Curam
available on a PSO BENZYLPENICILLIN SODIUM [PENICILLIN G]		10		Bicillin LA
Inj 600 mg (1 million units) vial – Up to 5 inj available on a P	SU 10.35	10	•	Sandoz

	Subsidy (Manufacturer's P		Fully sidised	Brand or Generic
	\$	Per	✓	Manufacturer
LUCLOXACILLIN				
Cap 250 mg – Up to 30 cap available on a PSO		250		<u>Staphlex</u>
Cap 500 mg		500		Staphlex AFT
Grans for oral liq 25 mg per ml	2.29	100 ml	•	<u>AFT</u>
 a) Up to 200 ml available on a PSO b) Wastage claimable – see rule 3.3.2 on page 13 				
Grans for oral lig 50 mg per ml	3.08	100 ml	1	AFT
a) Up to 200 ml available on a PSO		100 1111		<u>n</u>
b) Wastage claimable – see rule 3.3.2 on page 13				
Inj 250 mg vial	9.00	10	1	Flucloxin
Inj 500 mg vial		10	1	Flucloxin
Inj 1 g vial - Up to 5 inj available on a PSO	5.22	5	1	Flucil
PHENOXYMETHYLPENICILLIN (PENICILLIN V)				
Cap 250 mg - Up to 30 cap available on a PSO	2.88	50	1	Cilicaine VK
Cap 500 mg	4.73	50	1	Cilicaine VK
 a) Up to 20 cap available on a PSO 				
b) Up to 2 x the maximum PSO quantity for RFPP – s	•	•		
Grans for oral liq 125 mg per 5 ml	1.48	100 ml	•	<u>AFT</u>
a) Up to 200 ml available on a PSO				
b) Wastage claimable – see rule 3.3.2 on page 13	1 50	100 ml	./	AET
Grans for oral liq 250 mg per 5 ml	1.36	100 1111	•	<u>AFT</u>
b) Up to 2 x the maximum PSO quantity for RFPP – si	ee rule 5.2.6 on pa	ige 17		
c) Wastage claimable – see rule 3.3.2 on page 13		3		
BULAINE PENIUITIN				
	123.50	5	1	Cilicaine
Inj 1.5 g in 3.4 ml syringe — Up to 5 inj available on a PSO.	123.50	5	•	Cilicaine
Inj 1.5 g in 3.4 ml syringe – Up to 5 inj available on a PSO.	123.50	5	•	<u>Cilicaine</u>
PROCAINE PENICILLIN Inj 1.5 g in 3.4 ml syringe – Up to 5 inj available on a PSO. Tetracyclines DOXYCYCLINE	123.50	5	✓	Cilicaine
Inj 1.5 g in 3.4 ml syringe – Up to 5 inj available on a PSO. Tetracyclines OXYCYCLINE		5	•	Cilicaine
Inj 1.5 g in 3.4 ml syringe – Up to 5 inj available on a PSO. Tetracyclines OXYCYCLINE Tab 50 mg – Up to 30 tab available on a PSO	2.90 (6.00)			Cilicaine Doxy-50
Inj 1.5 g in 3.4 ml syringe – Up to 5 inj available on a PSO. Tetracyclines OXYCYCLINE	2.90 (6.00)			
Inj 1.5 g in 3.4 ml syringe – Up to 5 inj available on a PSO. Tetracyclines OXYCYCLINE Tab 50 mg – Up to 30 tab available on a PSO	2.90 (6.00)	30		Doxy-50
Inj 1.5 g in 3.4 ml syringe – Up to 5 inj available on a PSO. Tetracyclines OXYCYCLINE K Tab 50 mg – Up to 30 tab available on a PSO	2.90 (6.00)	30		Doxy-50
Inj 1.5 g in 3.4 ml syringe – Up to 5 inj available on a PSO. Tetracyclines OXYCYCLINE * Tab 50 mg – Up to 30 tab available on a PSO	2.90 (6.00) 6.75	30		Doxy-50
Inj 1.5 g in 3.4 ml syringe — Up to 5 inj available on a PSO. Tetracyclines DOXYCYCLINE Tab 50 mg — Up to 30 tab available on a PSO	2.90 (6.00) 6.75	30 250 60	•	Doxy-50
Inj 1.5 g in 3.4 ml syringe – Up to 5 inj available on a PSO. Tetracyclines OXYCYCLINE Tab 50 mg – Up to 30 tab available on a PSO	2.90 (6.00) 6.75 5.79 (12.05) 19.32	30 250	•	Doxy-50 Doxine Mino-tabs
Inj 1.5 g in 3.4 ml syringe – Up to 5 inj available on a PSO. Tetracyclines OXYCYCLINE Tab 50 mg – Up to 30 tab available on a PSO	2.90 (6.00) 6.75	30 250 60	•	Doxy-50 Doxine
Inj 1.5 g in 3.4 ml syringe — Up to 5 inj available on a PSO. Tetracyclines OXYCYCLINE K Tab 50 mg — Up to 30 tab available on a PSO		30 250 60 100	•	Doxy-50 Doxine Mino-tabs Minomycin
Inj 1.5 g in 3.4 ml syringe — Up to 5 inj available on a PSO. Tetracyclines OXYCYCLINE K Tab 50 mg — Up to 30 tab available on a PSO		30 250 60 100	•	Doxy-50 Doxine Mino-tabs Minomycin
Inj 1.5 g in 3.4 ml syringe — Up to 5 inj available on a PSO. Tetracyclines DOXYCYCLINE Tab 50 mg — Up to 30 tab available on a PSO	2.90 (6.00)5.79 (12.05)19.32 (52.04) lid without further	30 250 60 100	•	Doxy-50 Doxine Mino-tabs Minomycin
Inj 1.5 g in 3.4 ml syringe — Up to 5 inj available on a PSO. Tetracyclines OXYCYCLINE K Tab 50 mg — Up to 30 tab available on a PSO		30 250 60 100	√ s notifi	Doxy-50 Doxine Mino-tabs Minomycin

⇒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.

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Cipflox

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per Manufacturer Other Antibiotics For topical antibiotics, refer to DERMATOLOGICALS, page 73 **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 500 mg - Up to 5 tab available on a PSO	1 99	28	✓ Cipflox
Tab 750 mg		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
Inj phosphate 150 mg per ml, 4 ml ampoule – Retail pharmacy-Specialist	65.00	10	✓ <u>Dalacin C</u>
COLISTIN SULPHOMETHATE - Retail pharmacy-Specialist -	Subsidy by endors	ement	
Only if prescribed for dialysis or cystic fibrosis patient and the	ne prescription is e	ndorsed acc	ordingly.
Inj 150 mg		1	✓ Colistin-Link
GENTAMICIN SULPHATE			
Ini 10 mg per ml. 1 ml. – Subsidy by endorsement	8.56	5	✓ Hospira

-1	NTAMIOIN SOLI HATE				
	Inj 10 mg per ml, 1 ml - Subsidy by endorsement	8.56	5	1	Hospira
	Only if prescribed for a dialysis or cystic fibrosis patient or co	mplicated urinary	tract infec	ction	and the prescription is
	endorsed accordingly.				
	Ini 10 mg per ml. 2 ml - Subsidy by endorsement	175.10	25	1	APP

Pharmaceuticals \$29

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 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 below - Retail pharmacy

No patient co-payment payable

Tab 400 mg52.00 5 ✓ Avelox

⇒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

	Subsidy (Manufacturer's Price) \$	Sul Per	Fully osidised	Brand or Generic Manufacturer
continued				
1.2.3 Impaired visual acuity (considered to preclute 1.2.4 Significant pre-existing liver disease or hepathements.1.2.5 Significant documented intolerance and/or sometimes.	atotoxicity from tubero side effects following	culosis m a reason	able trial	of first-line medications;
2 Mycobacterium avium-intracellulare complex not respondir Note: Indications marked with * are Unapproved Indications (refe Renewal only from a respiratory specialist or infectious disease s remains appropriate and the patient is benefiting from treatment. Initial application — (Mycoplasma genitalium) from any releva meeting the following criteria: All of the following:	r to Interpretations as pecialist. Approvals	nd Defini valid for	tions). 1 year w	here the treatment
 1 Has nucleic acid amplification test (NAAT) confirmed Mycc 2 Has tried and failed to clear infection using azithromycin; a 3 Treatment is only for 7 days. 		and		
Initial application — (Penetrating eye injury) only from an ophrequires prophylaxis following a penetrating eye injury and treatm. Note: Indications marked with * are Unapproved Indications (refe	ent is for 5 days only			onth where the patient
PAROMOMYCIN - Special Authority see SA1689 below - Retail	pharmacy			
Cap 250 mg	126.00	16	✓ H	lumatin \$29
■ SA1689 Special Authority for Subsidy Initial application only from an infectious disease specialist, clinimonth for applications meeting the following criteria: Either: 1 Patient has confirmed cryptosporidium infection; or 2 For the eradication of Entamoeba histolyica carriage. Renewal only from an infectious disease specialist, clinical microlapplications meeting the following criteria:			Ū	
Either:				
 Patient has confirmed cryptosporidium infection; or For the eradication of Entamoeba histolyica carriage. 				
PYRIMETHAMINE - Special Authority see SA1328 below - Reta	il pharmacy			
Tab 25 mg		30		araprim (\$29)
■ SA1328 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid the following criteria: Any of the following:	36.95 I without further rene	50 wal unle		laraprim \$290 d for applications meeting
 For the treatment of toxoplasmosis in patients with HIV for For pregnant patients for the term of the pregnancy; or For infants with congenital toxoplasmosis until 12 months of 	·	s; or		
SODIUM FUSIDATE [FUSIDIC ACID] Tab 250 mg - Retail pharmacy-Specialist Prescriptions must be written by, or on the recommendat		12 lisease p	_	ucidin or a clinical microbiologi
SULFADIAZINE SODIUM – Special Authority see SA1331 on the	e next page – Retail p	harmac	/	

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✓ Wockhardt S29

Subsid	dy Fi	ılly Brand or
(Manufacture	er's Price) Subsidis	ed Generic
\$	Per	 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

JDHAW I CIN			
Inj 40 mg per ml, 2 ml vial - Subsidy by endorsement	15.00	5	✓ Tobramycin Mylan
Only if prescribed for dialysis or cystic fibrosis patient ar	nd the prescriptio	n is endorsed a	accordingly.
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	e prescription is e	ndorsed accord	dingly.
RIMETHOPRIM			
Tob 200 mg. Up to 20 tob quallable on a DCO	15.00	EO	✓ TMD

b) Only if prescribed for a cystic fibrosis patient and the pres	scription is er	ndorsed accor	dingly.
TRIMETHOPRIM			
* Tab 300 mg - Up to 30 tab available on a PSO	15.00	50	✓ <u>TMP</u>
TRIMETHOPRIM WITH SULPHAMETHOXAZOLE [CO-TRIMOXAZO	DLE]		
* Tab trimethoprim 80 mg and sulphamethoxazole 400 mg - Up			
to 30 tab available on a PSO	22.90	500	✓ Trisul
★ Oral liq 8 mg sulphamethoxazole 40 mg per ml - Up to 200 ml			
available on a PSO	2.97	100 ml	✓ Deprim
VANCOMYCIN - Subsidy by endorsement			
Only if prescribed for a dialysis or cystic fibrosis patient or for pro	phylaxis of e	ndocarditis or	for treatment of Clostridium

difficile following metronidazole failure and the prescription is endorsed accordingly.

Inj 500 mg vial2.37 Mylan

Antifungals

- a) For topical antifungals refer to DERMATOLOGICALS, page 74
- b) For topical antifungals refer to GENITO URINARY, page 87

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	Subsidy		Fully	Brand or
	(Manufacturer's Price)	Per	Subsidised	Generic Manufacturer
FLUCONAZOLE				
Cap 50 mg - Retail pharmacy-Specialist	2.09	28		Mylan Ozole
Mylan to be Sole Supply on 1 May 2018				
Cap 150 mg - Subsidy by endorsement	0.33	1		Mylan Ozole
 a) Maximum of 1 cap per prescription; can be waived by b) Patient has vaginal candida albicans and the practition of recommended and the prescription is endorsed a Specialist. 	oner considers that a	topica	al imidazole	e (used intra-vaginally) is
c) Mylan to be Sole Supply on 1 May 2018 Cap 200 mg - Retail pharmacy-Specialist	5.08	28		Mylan Ozole
Mylan to be Sole Supply on 1 May 2018 Powder for oral suspension 10 mg per ml - Special Authority	V			02010
see SA1359 below – Retail pharmacy	,	35 ml		Diflucan S29 S29 Diflucan
Wastage claimable – see rule 3.3.2 on page 13				
(Ozole Cap 50 mg to be delisted 1 May 2018)				

(Ozole Cap 150 mg to be delisted 1 May 2018)

(Ozole Cap 200 mg to be delisted 1 May 2018)

⇒SA1359 Special Authority for Subsidy

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

Both:

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

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

All of the following:

- 1 Patient is immunocompromised; and
- 2 Patient is at moderate to high risk of invasive fungal infection; and
- 3 Patient is unable to swallow capsules.

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

Both:

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

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

All of the following:

- 1 Patient remains immunocompromised: and
- 2 Patient remains at moderate to high risk of invasive fungal infection; and
- 3 Patient is unable to swallow capsules.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
ITRACONAZOLE				
Cap 100 mg — Subsidy by endorsement		15		razole

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 -

⇒SA1322 Special Authority for Subsidy

Initial application only from an infectious disease specialist, clinical microbiologist, clinical immunologist or any relevant practitioner on the recommendation of a infectious disease physician, clinical microbiologist or clinical immunologist. Approvals valid for 6 months where the patient has a congenital immune deficiency.

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

KETOCONAZOLE

Tab 200 mg - PCT - Retail pharmacy-Specialist - Subsidy by endorsement	CBS	30	✓ Link Healthcare S29
			✓ Nizoral S29
Prescriptions must be written by, or on the recommendation	of an oncolog	jist	
NYSTATIN			
Tab 500,000 u	14.16	50	
	(17.09)		Nilstat
Cap 500,000 u	12.81	50	
	(15.47)		Nilstat
POSACONAZOLE - Special Authority see SA1285 below - Retail ph	narmacy		
Tab modified-release 100 mg	869.86	24	✓ Noxafil
Oral liq 40 mg per ml	761.13	105 ml OP	✓ Noxafil

SA1285 Special Authority for Subsidy

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

Fither:

- 1 Patient has acute myeloid leukaemia and is to be treated with high dose remission induction, re-induction or consolidation chemotherapy; or
- 2 Patient has received a stem cell transplant and has graft versus host disease and is on significant immunosuppressive therapy*.

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

Either:

- 1 Patient has acute myeloid leukaemia and is to be treated with high dose remission induction, re-induction or consolidation therapy; or
- 2 Patient has received a stem cell transplant and has graft versus host disease and is on significant immunosuppression* and requires on going posaconazole treatment.

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
TERBINAFINE				
* Tab 250 mg - For terbinafine oral liquid formulation refer,				
page 227		14		Deolate
	(1.50)		[Dr Reddy's Terbinafine
Deolate to be Sole Supply on 1 April 2018				
(Dr Reddy's Terbinafine Tab 250 mg to be delisted 1 April 2018)				
VORICONAZOLE - Special Authority see SA1273 below - Retain	il pharmacy			
Tab 50 mg	130.00	56	✓ \	Vttack
Tab 200 mg	500.00	56	✓ 1	Vttack
Powder for oral suspension 40 mg per ml - Wastage claimal	ble			
- see rule 3.3.2 on page 13	876.00	70 ml	1	Vfend
m SA1273 Special Authority for Subsidy				

⇒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 asperallus 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 SA1684 below - Retail pharmacy					
Tab 7.5 mg	117.00	56	✓ Primacin S29		
- CA4CO4 Consist Authority for Cubaids					

⇒SA1684 Special Authority for Subsidy

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

Both:

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

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

Both:

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

	INFECTIONS -	AGENTS	FOR SYSTEMIC USE
	Subsidy (Manufacturer's Pri \$	ce) Sub	Fully Brand or osidised Generic Manufacturer
Antiparasitics			
Antiprotozoals			
QUININE SULPHATE * Tab 300 mg ‡ Safety cap for extemporaneously compounded oral		500	✓ Q 300
Antitrichomonal Agents			
METRONIDAZOLE Tab 200 mg — Up to 30 tab available on a PSO Tab 400 mg Oral liq benzoate 200 mg per 5 ml Suppos 500 mg ORNIDAZOLE	18.15 25.00	100 100 100 ml 10	✓ Trichozole ✓ Trichozole ✓ Flagyl-S ✓ Flagyl
Tab 500 mg	23.00	10	✓ <u>Arrow-Ornidazole</u>
Antituberculotics and Antileprotics Note: There is no co-payment charge for all pharmaceutical immigration status. CLOFAZIMINE – Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recomme dermatologist. ** Cap 50 mg	ndation of, an infectiou		
b) Prescriptions must be written by, or on the recomme respiratory physician.	ndation of, an infectiou	s disease pl	nysician, clinical microbiologist or
Cap 250 mg	ndation of, an infectiou	100 s disease ph 100 100	✓ King S29 nysician, clinical microbiologist or ✓ Dapsone ✓ Dapsone
ETHAMBUTOL HYDROCHLORIDE – Retail pharmacy-Spe a) No patient co-payment payable b) Prescriptions must be written by, or on the recomme respiratory physician		s disease pl	nysician, clinical microbiologist or
Tab 100 mg Tab 400 mg		56 56	✓ Myambutol S29✓ Myambutol S29
ISONIAZID – Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recomme microbiologist, dermatologist or public health physici		medicine ph	ysician, paediatrician, clinical
* Tab 100 mg * Tab 100 mg with rifampicin 150 mg * Tab 150 mg with rifampicin 300 mg	20.00 85.54	100 100 100	✓ <u>PSM</u> ✓ <u>Rifinah</u> ✓ <u>Rifinah</u>

[‡] safety cap

	INFECTIONS - AGENTS FOR SYSTEMIC USI	E			
		Subsidy (Manufacturer's Price)	Sub Per	Fully sidised	Brand or Generic Manufacturer
PA	RA-AMINO SALICYLIC ACID — Retail pharmacy-Specialist a) No patient co-payment payable b) Specialist must be an infectious disease specialist, clinica Grans for oral liq 4 g sachet		spiratory		it. aser §29
PR	OTIONAMIDE – Retail pharmacy-Specialist a) No patient co-payment payable b) Specialist must be an infectious disease specialist, clinica Tab 250 mg		spiratory		it. eteha §29
	RAZINAMIDE – Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation respiratory physician	on of, an infectious di	sease ph		
*	Tab 500 mg — For pyrazinamide oral liquid formulation refer, page 227		100		FT-Pyrazinamide FT-Pyrazinamide S29 ^{S29}
	ABUTIN – Retail pharmacy-Specialist a) No patient co-payment payable b) Prescriptions must be written by, or on the recommendation gastroenterologist Cap 150 mg – For rifabutin oral liquid formulation refer, page 227		sease ph		respiratory physician or
RIF	AMPICIN – Subsidy by endorsement a) No patient co-payment payable b) For confirmed recurrent Staphylococcus aureus infection antimicrobial based on susceptibilities and the prescription Retail pharmacy - Specialist. Specialist must be an interr paediatrician, or public health physician.	n is endorsed accordi	ngly; car	be waiv	red by endorsement -
*	Cap 150 mg	116.25	100 100 60 ml	✓ R	<u>ifadin</u> ifadin ifadin
A	ntivirals				
For	eye preparations refer to Eye Preparations, Anti-Infective Pre	parations, page 219			
Н	epatitis B Treatment				
≫ : Init	EFOVIR DIPIVOXIL – Special Authority see SA0829 below – Tab 10 mg	670.00	30 rovals va		lepsera year for applications
	 Patient has confirmed Hepatitis B infection (HBsAg+); and Documented resistance to lamivudine, defined as: Patient has raised serum ALT (> 1 x ULN); and Patient has HBV DNA greater than 100,000 copies per mL 		or highe	r over na	idir; and

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

continued...

- 4 Detection of M204I or M204V mutation; and
- 5 Fither:
 - 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 x ULN); and
- ii) HBV DNA greater than 100,000 copies per mL, or viral load 10 fold or higher over nadir; and
- iii) Detection of N236T or A181T/V mutation.

Adefovir dipivoxil should be stopped 6 months following HBeAg seroconversion for patients who were HBeAg+ prior to commencing adefovir dipivoxil.

The recommended dose of adefovir dipivoxil is no more than 10mg daily.

In patients with renal insufficiency adefovir dipivoxil dose should be reduced in accordance with the datasheet guidelines.

Adefovir dipivoxil should be avoided in pregnant women and children.

ENTECAVIR - Special Authority see SA1361 below - Retail pharmacy 30 ✓ Baraclude

⇒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-naive; 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 a minimum of 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.

	Subsidy (Manufacturer's Price \$) Subs	Fully sidised	Brand or Generic Manufacturer
LAMIVUDINE – Special Authority see SA1685 below – Retail ph	6.00	28 40 ml OD	✓ Z	******
Oral liq 5 mg per ml	270.00 2	40 ml OP	✓ Z	effix

⇒SA1685 Special Authority for Subsidy

Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 1 year where used for the treatment or prevention of hepatitis B.

Renewal from any relevant practitioner. Approvals valid for 2 years where used for the treatment or prevention of hepatitis B.

Herpesvirus Treatments

ı,	\sim 1	\sim	1	IR

* Tab dispersible 200 mg	1.60	25	✓ Lovir
* Tab dispersible 400 mg	5.38	56	Lovir
* Tab dispersible 800 mg	5.98	35	✓ Lovir
VALACICLOVIR			
Tab 500 mg	6.42	30	✓ Vaclovir
Tab 1,000 mg		30	✓ Vaclovir
VALGANCICLOVIR - Special Authority see SA1404 below - R	etail pharmacy		
Tab 450 mg	1,050.00	60	✓ Valcyte

⇒SA1404 Special Authority for Subsidy

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

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

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

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

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

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

Initial application — (Lung transplant cytomegalovirus prophylaxis) only from a relevant specialist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has undergone a lung transplant; and
- 2 Either:
 - 2.1 The donor was cytomegalovirus positive and the patient is cytomegalovirus negative; or
 - 2.2 The recipient is cytomegalovirus positive.

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

Both:

1 Patient is immunocompromised; and

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

continued...

- 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 SA1690 below Endorsement for treatment of HIV: Prescription is deemed to be endorsed if tenofovir disoproxil furnarate is co-prescribed with another antiretroviral subsidised under Special Authority SA1651 and the prescription is annotated accordingly by the Pharmacist or endorsed by the prescriber.

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 SA1651, page 120

✓ Viread Tab 300 mg531.00

⇒SA1690 Special Authority for Subsidy

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: 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 or higher 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.

Initial application — (Women of child bearing age with active hepatitis B) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 2 years for applications meeting the following criteria: All of the following:

- 1 Patient is HBsAg positive; and
- 2 Either:
 - 2.1 HBV DNA > 20,000 IU/mL and ALT > ULN; or
 - 2.2 HBV DNA > 20 million IU/mL and ALT normal; and
- 3 Any of the following:

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

continued...

- 3.1 Patient is of child bearing potential and has not yet completed a family; or
- 3.2 Patient is pregnant; or
- 3.3 Patient is breastfeeding.

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 or higher 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 — (Women of child bearing age with active hepatitis B) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 Patient is HBsAg positive; and
- 2 Either:
 - 2.1 HBV DNA > 20,000 IU/mL and ALT > ULN: or
 - 2.2 HBV DNA > 20 million IU/mL and ALT normal: and
- 3 Any of the following:
 - 3.1 Patient is of child bearing potential and has not yet completed a family; or
 - 3.2 Patient is pregnant; or
 - 3.3 Patient is breastfeeding.

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 furnarate 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

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

No patient co-payment payable

⇒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

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

PARITAPREVIR, 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),

1 OP

✓ Viekira Pak

PARITAPREVIR, 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

1 OP

✓ Viekira Pak-RBV

HIV Prophylaxis and Treatment

EMTRICITABINE WITH TENOFOVIR DISOPROXIL FUMARATE - Subsidy by endorsement; can be waived by Special Authority see SA1714 below

Endorsement for treatment of HIV: Prescription is deemed to be endorsed if emtricitabine with tenofovir disoproxil fumarate is co-prescribed with another antiretroviral subsidised under Special Authority SA1651 and the prescription is annotated accordingly by the Pharmacist or endorsed by the prescriber.

Emtricitabine with tenofovir disoproxil fumarate prescribed under endorsement for the treatment of HIV is included in the count of up to 4 subsidised antiretrovirals, and counts as two antiretroviral medications, for the purposes of Special Authority SA1651., page 120

There is an approval process to become a named specialist to prescribe antiretroviral therapy in New Zealand. Further information is available on the PHARMAC website.

Tab 200 mg with tenofovir disoproxil fumarate 300 mg......838.20

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✓ Truvada

⇒SA1714 Special Authority for Waiver of Rule

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

- 1 Patient has tested HIV negative; and
- 2 Fither:
 - 2.1 All of the following:
 - 2.1.1 Patient is male or transgender; and
 - 2.1.2 Patient has sex with men: and
 - 2.1.3 Patient is likely to have multiple episodes of condomless anal intercourse in the next 3 months; and
 - 2.1.4 Any of the following:
 - 2.1.4.1 Patient has had at least one episode of condomless receptive anal intercourse with one or more casual male partners in the last 3 months; or
 - 2.1.4.2 A diagnosis of rectal chlamydia, rectal gonorrhoea, or infectious syphilis within the last 3 months; or
 - 2.1.4.3 Patient has used methamphetamine in the last three months; or
 - 2.2 All of the following:
 - 2.2.1 Patient has a regular partner who has HIV infection; and
 - 2.2.2 Partner is either not on treatment or has a detectable viral load; and
 - 2.2.3 Condoms have not been consistently used.

Renewal from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria: All of the following:

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

continued...

- 1 Applicant has an up to date knowledge of the safety issues and is competent to prescribe pre-exposure prophylaxis; and
- 2 Patient has undergone testing for HIV, syphilis, and a full STI screen in the previous two weeks; and
- 3 Patient has had renal function testing (creatinine, phosphate and urine protein/creatinine ratio) within the last 12 months;
- 4 Patient has received advice regarding the reduction of risk of HIV and sexually transmitted infections and how to reduce those risks; and
- 5 Patient has tested HIV negative; and
- 6 Either:
 - 6.1 All of the following:
 - 6.1.1 Patient is male or transgender; and
 - 6.1.2 Patient has sex with men; and
 - 6.1.3 Patient is likely to have multiple episodes of condomless anal intercourse in the next 3 months; and
 - 6.1.4 Any of the following:
 - 6.1.4.1 Patient has had at least one episode of condomless receptive anal intercourse with one or more casual male partners in the last 3 months; or
 - 6.1.4.2 A diagnosis of rectal chlamydia, rectal gonorrhoea, or infectious syphilis within the last 3 months; or
 - 6.1.4.3 Patient has used methamphetamine in the last three months; or
 - 6.2 All of the following:
 - 6.2.1 Patient has a regular partner who has HIV infection; and
 - 6.2.2 Partner is either not on treatment or has a detectable viral load; and
 - 6.2.3 Condoms have not been consistently used.

Antiretrovirals

⇒SA1651 Special Authority for Subsidy

Initial application — (Confirmed HIV) only from a named specialist. Approvals valid without further renewal unless notified where the patient has confirmed HIV infection.

Notes: Tenofovir disoproxil fumarate prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals.

Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.

Renewal — (Confirmed HIV) only from a named specialist. Approvals valid without further renewal unless notified where the treatment remains appropriate and the patient is benefiting from treatment.

Initial application — (**Prevention of maternal transmission**) only from a named specialist. Approvals valid for 1 year for applications meeting the following criteria:

Either:

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

Notes: Tenofovir disoproxil fumarate prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals.

Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.

Some antiretrovirals are unapproved or contraindicated for this indication. Practitioners prescribing these medications should exercise their own skill, judgement, expertise and discretion, and make their own prescribing decisions with respect to the use of

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

continued...

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 apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.

Renewal — (second or subsequent post-exposure prophylaxis) only from a named specialist. Approvals valid for 4 weeks for applications meeting the following criteria:

Both:

- 1 Treatment course to be initiated within 72 hours post exposure; and
- 2 Any of the following:
 - 2.1 Patient has had unprotected receptive anal intercourse with a known HIV positive person; or
 - 2.2 Patient has shared intravenous injecting equipment with a known HIV positive person; or
 - 2.3 Patient has had non-consensual intercourse and the clinician considers that the risk assessment indicates prophylaxis is required.

Initial application — (Percutaneous exposure) only from a named specialist. Approvals valid for 6 weeks where the patient has percutaneous exposure to blood known to be HIV positive.

Notes: Tenofovir disoproxil fumarate prescribed under endorsement for HIV is included in the count of up to 4 subsidised antiretrovirals.

Subsidies apply for a combination of up to four antiretroviral medications. The combination of a protease inhibitor and low-dose ritonavir given as a booster (either as part of a combination product or separately) will be counted as one protease inhibitor for the purpose of accessing funding to antiretrovirals.

Renewal — (Second or subsequent percutaneous exposure) only from a named specialist. Approvals valid for 6 weeks where the patient has percutaneous exposure to blood known to be HIV positive.

Non-nucleosides Reverse Transcriptase Inhibitors

EFAVIRENZ – Special Authority see SA1651 on the pr	evious page – Retail phar	macy	
Tab 50 mg	63.38	30	✓ Stocrin S29
Tab 200 mg	190.15	90	✓ Stocrin
Tab 600 mg	63.38	30	✓ Stocrin
Oral liq 30 mg per ml	145.79	180 ml OP	✓ Stocrin S29
ETRAVIRINE - Special Authority see SA1651 on the p	revious page - Retail pha	rmacy	
Tab 200 mg	770.00	60	✓ Intelence
NEVIRAPINE - Special Authority see SA1651 on the p	revious page - Retail pha	rmacy	
Tab 200 mg	65.00	60	✓ <u>Nevirapine</u> Alphapharm
Oral suspension 10 mg per ml	203.55	240 ml	✓ Viramune Suspension

	Subsidy (Manufacturer's Pric		Fully dised	Brand or Generic Manufacturer
Nucleosides Reverse Transcriptase Inhibitors				
ABACAVIR SULPHATE – Special Authority see SA1651 on page Tab 300 mg Oral liq 20 mg per ml	229.00	macy 60 240 ml OP	_	liagen liagen
ABACAVIR SULPHATE WITH LAMIVUDINE — Special Authority Note: abacavir with lamivudine (combination tablets) counts anti-retroviral Special Authority.	as two anti-retrovir		s for t	
Tab 600 mg with lamivudine 300 mg EFAVIRENZ WITH EMTRICITABINE AND TENOFOVIR DISOPF page 120 – Retail pharmacy Note: Efavirenz with emtricitabine and tenofovir disoproxil fu purposes of the anti-retroviral Special Authority Tab 600 mg with emtricitabine 200 mg and tenofovir disoprox	ROXIL FUMARATE marate counts as t	- Special A	uthorit	y see SA1651 on
fumarate 300 mg EMTRICITABINE – Special Authority see SA1651 on page 120 – Cap 200 mg	- Retail pharmacy	30 30	_	Atripla Emtriva
LAMIVUDINE – Special Authority see SA1651 on page 120 – Re Tab 150 mg	etail pharmacy 52.50	60	√ L	amivudine Alphapharm
Oral liq 10 mg per ml	0 – Retail pharmac 152.25	240 ml OP cy 100 200 ml OP		TC Retrovir Retrovir
ZIDOVUDINE [AZT] WITH LAMIVUDINE – Special Authority see Note: zidovudine [AZT] with lamivudine (combination tablets the anti-retroviral Special Authority. Tab 300 mg with lamivudine 150 mg	SA1651 on page) counts as two and	120 – Retail p	harma edicati	acy
Protease Inhibitors			_	
ATAZANAVIR SULPHATE – Special Authority see SA1651 on page 200 mg	568.34 757.79 tail pharmacy	60 60	√ F	Reyataz Reyataz
Tab 400 mg Tab 600 mg LOPINAVIR WITH RITONAVIR – Special Authority see SA1651	476.00	60 60 ail pharmacy	_	Prezista Prezista
Tab 100 mg with ritonavir 25 mg	183.75 463.00 735.00	60 120 300 ml OP	✓ <u>K</u>	Caletra Caletra Caletra
Tab 100 mg Oral liq 80 mg per ml	43.31	30 90 ml OP		lorvir Iorvir
Strand Transfer Inhibitors				
DOLUTEGRAVIR – Special Authority see SA1651 on page 120 - Tab 50 mg		30	✓ T	ivicay

	Subsidy (Manufacturer's Price)		Fully idised	Brand or Generic	
	\$	Per	1	Manufacturer	
RALTEGRAVIR POTASSIUM - Special Authority see SA1651 of	n page 120 – Retail p	harmacy			
Tab 400 mg	1,090.00	60	✓ Is	sentress	

Immune Modulators

Guidelines for the use of interferon in the treatment of hepatitis C:

Physicians considering treatment of patients with hepatitis C should discuss cases with a gastroenterologist or an infectious disease physician. All subjects undergoing treatment require careful monitoring for side effects. Patients should be otherwise fit.

Hepatocellular carcinoma should be excluded by ultrasound examination and alpha-fetoprotein level.

Criteria for Treatment

- 1) Diagnosis
 - Anti-HCV positive on at least two occasions with a positive PCR for HCV-RNA and preferably confirmed by a supplementary RIBA test: or
 - PCR-RNA positive for HCV on at least 2 occasions if antibody negative; or
 - Anti-HCV positive on at least two occasions with a positive supplementary RIBA test with a negative PCR for HCV RNA but with a liver biopsy consistent with 2(b) following.

Exclusion Criteria

- 1) Autoimmune liver disease. (Interferon may exacerbate autoimmune liver disease as well as other autoimmune diseases such as thyroid disease).
- 2) Pregnancy.
- 3) Neutropenia (< 2.0 × 10⁹) and/or thrombocytopenia.
- 4) Continuing alcohol abuse and/or continuing intravenous drug users.

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

Exit Criteria

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

INTERFERON ALFA-2A - PCT - Retail pharmacy-Specialist

- a) See prescribing guideline above
- b) Prescriptions must be written by, or on the recommendation of, an internal medicine physician or ophthalmologist
- ✓ Roferon-A Inj 3 m iu prefilled syringe......31.32

INTERFERON ALFA-2B - PCT - Retail pharmacy-Specialist

- a) See prescribing guideline above
- b) Prescriptions must be written by, or on the recommendation of, an internal medicine physician or ophthalmologist
- ✓ Intron-A 1 1 ✓ Intron-A
- 1 ✓ Intron-A

123

	Subsidy (Manufacturer's Price) \$	Sı Per	Fully ubsidised	Brand or Generic Manufacturer
PEGYLATED INTERFERON ALFA-2A — Special Authority see	SA1400 below – Retai	l pharm	асу	
See prescribing guideline on the previous page Inj 180 mcg prefilled syringe	500.00	4	√ <u>P</u>	egasys
Inj 135 mcg prefilled syringe × 4 with ribavirin tab 200 mg × 168	1,975.00	1 OP	√ P	egasys RBV Combination Pack
Inj 180 mcg prefilled syringe × 4 with ribavirin tab 200 mg × 112	1,159.84	1 OP	√ P	egasys RBV Combination Pack
Inj 180 mcg prefilled syringe × 4 with ribavirin tab 200 mg × 168	1,290.00	1 OP	✓ P	egasys 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:

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

Notes:

- Consider stopping treatment if there is absence of a virological response (defined as at least a 2-log reduction in viral load) following 12 weeks of treatment since this is predictive of treatment failure.
- Consider reducing treatment to 24 weeks if serum HCV RNA level at Week 4 is undetectable by sensitive PCR assay (less than 50IU/ml) AND Baseline serum HCV RNA is less than 400.000IU/ml

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

All of the following:

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

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

All of the following:

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

	Subsidy	Fully	Brand or
	acturer's Price) Subsi	dised	Generic
,	\$ Per	1	Manufacturer

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

Both:

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

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

All of the following:

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

Notes:

- · Approved dose is 180 mcg once weekly.
- The recommended dose of Pegylated Interferon alfa-2a is 180 mcg once weekly.
- In patients with renal insufficiency (calculated creatinine clearance less than 50ml/min), Pegylated Interferon-alfa 2a dose should be reduced to 135 mcg once weekly.
- In patients with neutropaenia and thrombocytopaenia, dose should be reduced in accordance with the datasheet guidelines.
- Pegylated Interferon-alfa 2a is not approved for use in children.

Urinary Tract Infections

HEXAMINE HIPPURATE			
* Tab 1 g	18.40	100	
·	(40.01)		Hiprex
NITROFURANTOIN			
* Tab 50 mg - For nitrofurantoin oral liquid formulation refer,			
page 227	22.20	100	✓ Nifuran
* Tab 100 mg	37.50	100	✓ Nifuran
NORFLOXACIN			
Tab 400 mg - Subsidy by endorsement		100	✓ Arrow-Norfloxacin

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

	Subsidy		Fully	Brand or
	(Manufacturer's Price)	Subsidised	
	\$	Per	1	Manufacturer
Anticholinesterases				
NEOSTIGMINE METILSULFATE				
Inj 2.5 mg per ml, 1 ml ampoule	98.00	50	/	AstraZeneca
PYRIDOSTIGMINE BROMIDE				
▲ Tab 60 mg	42.79	100	1	Mestinon
· ·				
Non-Steroidal Anti-Inflammatory Drugs				
DICLOFENAC SODIUM				
* Tab EC 25 mg	1.30	50		Diclofenac Sandoz
* Tab 50 mg dispersible	1.50	20	•	Voltaren D
* Tab EC 50 mg	1.00	50		Diclofenac Sandoz
* Tab long-acting 75 mg	15.20	500	1	Apo-Diclo SR
* Tab long-acting 100 mg		500		Apo-Diclo SR
★ Inj 25 mg per ml, 3 ml ampoule – Up to 5 inj available on a F		5		Voltaren
★ Suppos 12.5 mg	2.04	10	✓	Voltaren
* Suppos 25 mg	2.44	10	✓	Voltaren
★ Suppos 50 mg – Up to 10 supp available on a PSO	4.22	10	✓	Voltaren
★ Suppos 100 mg	7.00	10	✓	Voltaren
BUPROFEN				
★ Tab 200 mg	9.45	1,000	/	Ibugesic
v	11.71		✓	Relieve
Relieve to be Sole Supply on 1 May 2018				
₭ Tab long-acting 800 mg	7.99	30	1	Brufen SR
k‡ Oral liq 20 mg per ml		200 m	_	Fenpaed
Ibugesic Tab 200 mg to be delisted 1 May 2018)				•
(ETOPROFEN				
Cap long-acting 200 mg	12.07	28	1	Oruvail SR
	12.01	20	•	Oldvall Oll
MEFENAMIC ACID	4.05			
€ Cap 250 mg	4	50		Danielan
	(9.16)	00		Ponstan
	0.50	20		Danielan
	(5.60)			Ponstan
IAPROXEN ├ Tab 250 mg	18.06	500	1	Noflam 250
k Tab 500 mg		250		Noflam 500
		28		Naprosyn SR 750
		28		Naprosyn SR 1000
* Tab long-acting 1 g	0.33	20	•	Naprosyll on 1000
SULINDAC				
₭ Tab 100 mg		50	_	Aclin
★ Tab 200 mg	15.10	50	•	Aclin
ENOXICAM				
★ Tab 20 mg	10.95	100	1	Tilcotil
₭ Inj 20 mg vial	9.95	1	/	AFT
NSAIDs Other				
CELECOXIB				
Cap 100 mg	3.63	60	/	Celecoxib Pfizer
Cap 200 mg		30		Celecoxib Pfizer
•				

	(Manufacturer's Price)	Sul Per	osidised ✓	Generic Manufacturer	
MELOXICAM – Special Authority see SA1034 below – Retail pt	,	30	✓ A	rrow-Meloxicam	_

⇒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		✓ Zostrix

⇒SA1289 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has osteoarthritis that is not responsive to paracetamol and oral non-steroidal anti-inflammatories are contraindicated.

Antirheumatoid Agents

HYDROXYCHLOROQUINE * Tab 200 mg10.50	100	✓ <u>Plaquenil</u>
LEFLUNOMIDE		
Tab 10 mg2.90	30	✓ Apo-Leflunomide
Tab 20 mg2.90	30	✓ Apo-Leflunomide
PENICILLAMINE		
Tab 125 mg67.23	100	D-Penamine
Tab 250 mg110.12	100	D-Penamine
SODIUM AUROTHIOMALATE		
Inj 10 mg in 0.5 ml ampoule76.87	10	✓ Myocrisin
Inj 20 mg in 0.5 ml ampoule113.17	10	✓ Myocrisin
Inj 50 mg in 0.5 ml ampoule217.23	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)) greater than or equal to 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or

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

continued...

equal to -2.5) (see Note); or

- 2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
- 3 History of two significant osteoporotic fractures demonstrated radiologically; or
- 4 Documented T-Score less than or equal to -3.0 (see Note); or
- 5 A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or
- 6 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:

- 1 The patient is receiving systemic glucocorticosteriod therapy (greater than or egual to 5 mg per day prednisone equivalents) and has already received or is expected to receive therapy for at least three months; and
- 2 Any of the following:
 - 2.1 The patient has documented BMD greater than or equal to 1.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -1.5) (see Note); or
 - 2.2 The patient has a history of one significant osteoporotic fracture demonstrated radiologically; or
 - 2.3 The patient has had a Special Authority approval for 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 glucocorticosteriod therapy (greater than or equal to 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:

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

- a) BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.
- b) Evidence suggests patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score less than or equal to -2.5 and, therefore, do not require BMD measurement for treatment with bisphosphonates.
- c) Osteoporotic fractures are the incident events for severe (established) osteoporosis, and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical

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

continued...

forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less.

d) 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.

ALENDRONATE SODIUM - Special Authority see SA1039 on page	127 - Retail ph	armacy	
* Tab 70 mg	4.82	4	✓ Fosamax
ALENDRONATE SODIUM WITH COLECALCIFEROL - Special Aut	hority see SA10	39 on page	e 127 – Retail pharmacy
* Tab 70 mg with colecalciferol 5,600 iu	4.82	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.

benefiting from treatment.		
ALENDRONATE SODIUM	- Special Authority see SA0949 above - Retail pharmacy	

Other Treatments

ETIDRONATE DISODIUM - See prescribing guideline b	elow		
* Tab 200 mg	13.50	100	✓ Arrow-Etidronate

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.

E 00

PAMIDRONATE DISODIUM

	iiij 5 iiig pei iiii, 10 iiii viai		ı	• Faiiiisoi
	Inj 6 mg per ml, 10 ml vial	15.02	1	✓ Pamisol
	Inj 9 mg per ml, 10 ml vial		1	✓ Pamisol
RA	LOXIFENE HYDROCHLORIDE - Special Authority see SA1138 I	below – Retail	l pharmacy	
*	Tab 60 mg	53.76	28	Evista

⇒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:

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✓ Fosamax

/ Daminal

(Mar	Subsidy nufacturer's Price)	Sub	Fully sidised	Brand or Generic
	\$	Per	1	Manufacturer

continued...

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

Notes:

- a) BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA).
 Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.
- b) Evidence suggests that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score less than or equal to -2.5 and, therefore, do not require BMD measurement for raloxifene funding.
- c) Osteoporotic fractures are the incident events for severe (established) osteoporosis, and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less.
- d) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

RISEDRONATE SODIUM			
Tab 35 mg	3.80	4	✓ Risedronate Sandoz
TERIPARATIDE – Special Authority see SA1139 on the next pag	e – Retail pharma	асу	
Inj 250 mcg per ml, 2.4 ml	490.00	1	✓ Forteo

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

⇒SA1139 Special Authority for Subsidy

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

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

Notes:

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

ZOLEDRONIC ACID

Inj 0.05 mg per ml, 100 ml, vial - Special Authority see

⇒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) greater than or equal to 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -2.5) (see Note); or
 - 1.2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
 - 1.3 History of two significant osteoporotic fractures demonstrated radiologically; or
 - 1.4 Documented T-Score less than or equal to -3.0 (see Note); or

	Subsidy		Fully	Brand or
(Manuf	acturer's Price)	Subsic	dised	Generic
	\$	Per	1	Manufacturer

continued...

- 1.5 A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or
- 1.6 Patient has had a Special Authority approval for alendronate (Underlying cause Osteoporosis) 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 (greater than or equal to 5 mg per day prednisone equivalents) and has already received or is expected to receive therapy for at least three months; and
- 2 Any of the following:
 - 2.1 The patient has documented BMD greater than or equal to 1.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -1.5) (see Note); or
 - 2.2 The patient has a history of one significant osteoporotic fracture demonstrated radiologically; or
 - 2.3 The patient has had a Special Authority approval for alendronate (Underlying cause glucocorticosteroid therapy) 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
- 2 The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period.

The patient must not have had more than 1 prior approval in the last 12 months.

Renewal — (Underlying cause was, and remains, glucocorticosteroid therapy) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The patient is continuing systemic glucocorticosteriod therapy (greater than or equal to 5 mg per day prednisone equivalents); and
- 2 The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period.

The patient must not have had more than 1 prior approval in the last 12 months.

Renewal — (Underlying cause was glucocorticosteroid therapy but patient now meets the 'Underlying cause - osteoporosis' criteria) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 Any of the following:
 - 1.1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) greater than or equal to 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score less than or equal to -2.5) (see Note); or
 - 1.2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
 - 1.3 History of two significant osteoporotic fractures demonstrated radiologically; or
 - 1.4 Documented T-Score less than or equal to -3.0 (see Note); or
 - 1.5 A 10-year risk of hip fracture greater than or equal to 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or

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

continued...

- 1.6 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
- 2 The patient will not be prescribed more than 5 mg of zoledronic acid in a 12-month period.

Notes:

- a) BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA).
 Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.
- b) Evidence suggests that patients aged 75 years and over who have a history of significant osteoporotic fracture demonstrated radiologically are very likely to have a T-Score less than or equal to -2.5 and, therefore, do not require BMD measurement for treatment with bisphosphonates.
- c) Osteoporotic fractures are the incident events for severe (established) osteoporosis and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less.
- d) A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

Hyperuricaemia and Antigout

4.54	500	DP-Allopurinol
9.08	1,000	
(15.11)		Allopurinol-Apotex
, ,		
10.35	500	✓ DP-Allopurinol
(15.91)		Allopurinol-Apotex
etail pharmacy		
45.00	100	✓ Benzbromaron AL
		100 \$29
	(15.11)	9.08 1,000 (15.11) 500 (15.91)

⇒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

Subsidy (Manufacturer's	Price) Sub	Fully	Brand or Generic	
\$	Per	1	Manufacturer	

continued...

- 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
FEBUXOSTAT - Special Authority see SA1538 below - Re	tail pharmacy		
Tab 80 mg	39.50	28	✓ Adenuric
Tab 120 mg	39.50	28	Adenuric

⇒SA1538 Special Authority for Subsidy

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

- 1 Patient has been diagnosed with gout; and
- 2 Any of the following:
 - 2.1 The patient has a serum urate level greater than 0.36 mmol/l despite treatment with allopurinol at doses of at least 600 mg/day and addition of probenecid at doses of up to 2 g per day or maximum tolerated dose; or
 - 2.2 The patient has experienced intolerable side effects from allopurinol such that treatment discontinuation is required and serum urate remains greater than 0.36 mmol/l despite use of probenecid at doses of up to 2 g per day or maximum tolerated dose; or
 - 2.3 The patient has renal impairment such that probenecid is contraindicated or likely to be ineffective and serum urate remains greater than 0.36 mmol/l despite optimal treatment with allopurinol (see Note).

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

Note: In chronic renal insufficiency, particularly when the glomerular filtration rate is 30 ml/minute or less, probenecid may not be effective. The efficacy and safety of febuxostat have not been fully evaluated in patients with severe renal impairment (creatinine clearance less than 30 ml/minute). No dosage adjustment of febuxostat is necessary in patients with mild or moderate renal impairment. Optimal treatment with allopurinol in patients with renal impairment is defined as treatment to the creatinine clearance-adjusted dose of allopurinol then, if serum urate remains greater than 0.36 mmol/l, a gradual increase of the dose of allopurinol to 600 mg or the maximum tolerated dose.

PROBENECID

*	Tab 500 mg	55.00	100	✓ Probenecid-AFT
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Subsidy		Fully	Brand or
(Manufacturer's Price)	Subs	sidised	Generic
\$	Per	/	Manufacturer

Muscle Relaxants

BA	\sim 1	\cap		NI
DA	UL	UI.	ᅚ	IN

*	Tab 10 mg - For bacloten oral liquid formulation refer, page 2273.85	100	✓ Pacifen
	Inj 0.05 mg per ml, 1 ml ampoule - Subsidy by endorsement11.55	1	✓ Lioresal Intrathecal
	Subsidised only for use in a programmable pump in patients where oral a	antispastic a	agents have been ineffective or have
	caused intolerable side effects and the prescription is endorsed accordin	ıgly.	
	Ini 2 mg nor ml E ml amnoula Cubaidy by andersoment 200.20	- 1	/ Lierocal Introthecal

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.

DANTROI ENF

DANTROLENE			
Cap 25 mg	65.00	100	Dantrium
Cap 50 mg	77.00	100	Dantrium
ORPHENADRINE CITRATE			
Tah 100 mg	18 54	100	✓ Norflex

Subsidy (Manufacturer's Price) Fully Subsidised Per

Brand or Generic Manufacturer

Agents for Parkinsonism and Related Disorders

Dopamine Agonists and Related Agents
AMANUTA DINIE UN (DDOOUII ODIDE

AMANTADINE HYDROCHLORIDE	60	Cummatual
▲ Cap 100 mg38.24	00	✓ Symmetrel
APOMORPHINE HYDROCHLORIDE	5	√ Moyono
▲ Inj 10 mg per ml, 2 ml ampoule119.00	3	✓ Movapo
BROMOCRIPTINE MESYLATE		
* Tab 2.5 mg32.08	100	Apo-Bromocriptine
ENTACAPONE		
▲ Tab 200 mg28.00	100	✓ Entapone
LEVODOPA WITH BENSERAZIDE		
* Tab dispersible 50 mg with benserazide 12.5 mg10.00	100	Madopar Rapid
* Cap 50 mg with benserazide 12.5 mg8.00	100	✓ Madopar 62.5
* Cap 100 mg with benserazide 25 mg12.50	100	Madopar 125
* Cap long-acting 100 mg with benserazide 25 mg17.00	100	Madopar HBS
* Cap 200 mg with benserazide 50 mg25.00	100	Madopar 250
LEVODOPA WITH CARBIDOPA		
* Tab 100 mg with carbidopa 25 mg - For levodopa with		
carbidopa oral liquid formulation refer, page 22717.97	100	✓ Kinson
		✓ Sinemet
Sinemet to be Sole Supply on 1 May 2018		
* Tab long-acting 200 mg with carbidopa 50 mg37.15	100	✓ Sinemet CR
* Tab 250 mg with carbidopa 25 mg32.67	100	✓ Sinemet
(Kinson Tab 100 mg with carbidopa 25 mg to be delisted 1 May 2018)		
PRAMIPEXOLE HYDROCHLORIDE		
▲ Tab 0.25 mg	100	✓ Ramipex
▲ Tab 1 mg24.39	100	✓ Ramipex
ROPINIROLE HYDROCHLORIDE		
▲ Tab 0.25 mg2.78	100	✓ Apo-Ropinirole
▲ Tab 1 mg5.00	100	✓ Apo-Ropinirole
▲ Tab 2 mg7.72	100	✓ Apo-Ropinirole
▲ Tab 5 mg16.51	100	✓ Apo-Ropinirole
SELEGILINE HYDROCHLORIDE		
* Tab 5 mg22.00	100	✓ Apo-Selegiline

Anticholinergics

TOLCAPONE

BENZATROPINE I	MESYLATE
----------------	----------

Tab 2 mg	7.99	60	✓ Benztrop
Inj 1 mg per ml, 2 ml	95.00	5	✓ Cogentir
,	190.00	10	✓ Omega

a) Up to 10 inj available on a PSO

▲ Tab 100 mg132.50

b) Only on a PSO

100

S29 S29

✓ Tasmar

NERVOUS SYSTEM

			NERVOUS STSTEN	'
	Subsidy (Manufacturer's Price) \$	Sub Per	Fully Brand or bisidised Generic Manufacturer	
PROCYCLIDINE HYDROCHLORIDE Tab 5 mg	7.40	100	✓ Kemadrin	
Agents for Essential Tremor, Chorea and Re	ated Disorders			
RILUZOLE – Special Authority see SA1403 below – Retail pl Wastage claimable – see rule 3.3.2 on page 13 Tab 50 mg	•	56	✓ Rilutek	
■ SA1403 Special Authority for Subsidy Initial application only from a neurologist or respiratory specifollowing criteria: All of the following: 1 The patient has amyotrophic lateral sclerosis with disection 2 The patient has at least 60 percent of predicted forced 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 use upper limbs; or 5.3 The patient is able to swallow. Renewal from any relevant practitioner. Approvals valid for 1 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	ase duration of 5 years of vital capacity within 2 md	or less; ar onths pri	nd or to the initial application; ar	
3.2 The patient is able to use upper limbs; or 3.3 The patient is able to swallow. TETRABENAZINE	01.10	110	/ Madadia	
3.3 The patient is able to swallow.	91.10	112	✓ <u>Motetis</u>	

Anaesthetics

Local

LIDOCAINE [LIGNOCAINE]

Gel 2%, tube - Subsidy by endorsement14.50 30 ml ✓ Xylocaine 2% Jelly

a) Up to 150 ml available on a PSO

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

Gel 2%, 10 ml urethral syringe - Subsidy by endorsement......81.50 10 ✓ Pfizer ✓ Cathejell 212.50 25

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.

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	Subsidy		Fully	
	(Manufacturer's Price \$) Subs Per	idised •	Generic Manufacturer
LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE				
Oral (gel) soln 2%	38.00	200 ml	1	Mucosoothe
Inj 1%, 5 ml ampoule - Up to 25 inj available on a PSO	8.75	25	1	Lidocaine-Claris
	17.50	50		
	(35.00)			Xylocaine
Inj 2%, 5 ml ampoule - Up to 5 inj available on a PSO	6.90	25	1	Lidocaine-Claris
Inj 1%, 20 ml ampoule - Up to 5 inj available on a PSO	2.40	1	1	Lidocaine-Claris
	12.00	5		
	(20.00)			Xylocaine
Inj 1%, 20 ml vial - Up to 5 inj available on a PSO	12.00	5	1	Lidocaine-Claris
Inj 2%, 20 ml ampoule - Up to 5 inj available on a PSO	2.40	1	1	Lidocaine-Claris
Inj 2%, 20 ml vial - Up to 5 inj available on a PSO	12.00	5	1	Lidocaine-Claris
LIDOCAINE [LIGNOCAINE] WITH CHLORHEXIDINE				
Gel 2% with chlorhexidine 0.05%, 10 ml urethral syringes –				
Subsidy by endorsement	81.50	10	1	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 se	ee SA0906 above – Retail pharr	nacy	
Crm 4%	5.40	5 g OP	✓ LMX4
	27.00	30 g OP	✓ LMX4
LIDOCAINE [LIGNOCAINE] WITH PRILOCAINE -	- Special Authority see SA0906	above - Reta	ail pharmacy
Crm 2.5% with prilocaine 2.5%	45.00	30 g OP	✓ EMLA
Crm 2.5% with prilocaine 2.5% (5 g tubes)	45.00	5	EMLA

Analgesics

For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, page 126

Non-opioid Analgesics

For aspirin & chloroform application refer Standard Formulae, page 230

* Tab dispersible 300 mg - Up to 30 tab available on a PSO

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The disposition of the section at a section in the		<u> </u>
CAPSAICIN – Subsidy by endorsement		
Subsidised only if prescribed for post-herpetic neuralgia or diabetic peripheral n	europathy and	d the prescription is endorsed
accordingly.		

3.90

100

✓ Fthics Aspirin

Crm 0.075%......12.50 45 g OP ✓ Zostrix HP

NEFOPAM HYDROCHLORIDE

90 ✓ Acupan

	Subsidy		Fully	Brand or
	(Manufacturer's Pri		sidised	Generic
	\$	Per		Manufacturer
PARACETAMOL				
* Tab 500 mg - blister pack - Up to 30 tab available on a PS0	O7.12	1,000	✓	Pharmacare
* Tab 500 mg - bottle pack	6.32	1,000	✓	Pharmacare
*‡ Oral lig 120 mg per 5 ml	5.35	1,000 ml	✓	Paracare
a) Up to 200 ml available on a PSO			_	<u> </u>
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		10	1	Gacet
* Suppos 500 mg	12.60	50	✓	Paracare
Opioid Analgesics				
CODEINE PHOSPHATE - Safety medicine; prescriber may det	ermine dispensina	frequency		
Tab 15 mg		100	✓	PSM
Tab 30 mg		100	-	PSM
Tab 60 mg		100	-	PSM
DIHYDROCODEINE TARTRATE			-	
Tab long-acting 60 mg	0.55	60	/ I	OHC Continus
0 0		00	• !	orio conunus
FENTANYL				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing fr		10		Davidson and Millin
Inj 50 mcg per ml, 2 ml ampoule		10	_	Boucher and Muir
Inj 50 mcg per ml, 10 ml ampoule		10	-	Boucher and Muir
Patch 12.5 mcg per hour		5 5		Fentanyl Sandoz
Patch 25 mcg per hour		5 5	-	Fentanyl Sandoz
Patch 50 mcg per hourPatch 75 mcg per hour		5 5	-	Fentanyl Sandoz Fentanyl Sandoz
01		5 5	-	Fentanyi Sandoz
Patch 100 mcg per hour	11.40	3	• !	remanyi Sandoz
METHADONE HYDROCHLORIDE				
 a) Only on a controlled drug form 				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing fr				
d) Extemporaneously compounded methadone will only be	reimbursed at the	rate of the ch	neapest	form available
(methadone powder, not methadone tablets).				
e) For methadone hydrochloride oral liquid refer Standard F				
Tab 5 mg		10	-	<u>Methatabs</u>
‡ Oral liq 2 mg per ml		200 ml	_	Biodone
‡ Oral liq 5 mg per ml		200 ml	-	Biodone Forte
‡ Oral liq 10 mg per ml		200 ml	-	Biodone Extra Forte
Inj 10 mg per ml, 1 ml	61.00	10	•	AFT

		Subsidy (Manufacturer's Price	e) Sı	Fully ubsidised	
_		\$	Per	1	Manufacturer
MC	RPHINE HYDROCHLORIDE				
	a) Only on a controlled drug form				
	b) No patient co-payment payable				
	c) Safety medicine; prescriber may determine dispensing free	quency			
‡	Oral liq 1 mg per ml	8.84	200 ml		RA-Morph
‡	Oral liq 2 mg per ml	14.00	200 ml	/	RA-Morph
‡	Oral liq 5 mg per ml	18.00	200 ml	/	RA-Morph
‡	Oral liq 10 mg per ml	26.00	200 ml	/	RA-Morph
MC	RPHINE SULPHATE				
	a) Only on a controlled drug form				
	b) No patient co-payment payable				
	c) Safety medicine; prescriber may determine dispensing fred	uencv			
	Tab immediate-release 10 mg		10	1	Sevredol
	Tab long-acting 10 mg		10		Arrow-Morphine LA
	Tab immediate-release 20 mg		10		Sevredol
	Tab long-acting 30 mg		10		Arrow-Morphine LA
	Tab long-acting 60 mg		10		Arrow-Morphine LA
	Tab long-acting 100 mg		10	1	Arrow-Morphine LA
	Cap long-acting 10 mg		10	1	m-Eslon
	Cap long-acting 30 mg	2.50	10	1	m-Eslon
	Cap long-acting 60 mg	5.40	10	1	m-Eslon
	Cap long-acting 100 mg	6.38	10	/	m-Eslon
	Inj 5 mg per ml, 1 ml ampoule - Up to 5 inj available on a PSO	O6.27	5	/	DBL Morphine
					Sulphate
	Inj 10 mg per ml, 1 ml ampoule - Up to 5 inj available on a PS	SO4.47	5	1	DBL Morphine
					Sulphate
	Inj 15 mg per ml, 1 ml ampoule - Up to 5 inj available on a PS	SO4.76	5	/	DBL Morphine
	,g p, ap.ap,				Sulphate
	Inj 30 mg per ml, 1 ml ampoule - Up to 5 inj available on a PS	SO 6.19	5	/	DBL Morphine
	ing or mg per mi, i mi ampeare to pite of mg aramazio en a re		Ū		Sulphate
M	RPHINE TARTRATE				p
IVIC					
	a) Only on a controlled drug form				
	b) No patient co-payment payable				
	c) Safety medicine; prescriber may determine dispensing fred		-		DDI Marahina
	Inj 80 mg per ml, 1.5 ml ampoule	42.72	5	•	DBL Morphine

Tartrate

_					
		Subsidy		Fully	Brand or
				Subsidised	
		(Manufacturer's Price)	Per	Subsidised	
_		\$	Per		Manufacturer
OX	YCODONE HYDROCHLORIDE				
٠,٠					
	a) Only on a controlled drug form				
	b) No patient co-payment payable				
	c) Safety medicine; prescriber may determine dispensing fre	quency			
	Tab controlled-release 5 mg		20	1	BNM
	•				
	Tab controlled-release 10 mg		20		BNM
	Tab controlled-release 20 mg	4.72	20	•	BNM
	Tab controlled-release 40 mg	7.69	20	✓	BNM
	Tab controlled-release 80 mg	14.11	20	1	BNM
	Cap immediate-release 5 mg		20		OxyNorm
	Cap immediate-release 10 mg		20	_	<u>OxyNorm</u>
	Cap immediate-release 20 mg	6.84	20	/	<u>OxyNorm</u>
‡	Oral lig 5 mg per 5 ml	11.20 2	50 m	/	OxyNorm
•	Inj 10 mg per ml, 1 ml ampoule		5		OxyNorm
	, , ,		-		
	Inj 10 mg per ml, 2 ml ampoule		5		<u>OxyNorm</u>
	Inj 50 mg per ml, 1 ml ampoule	51.00	5	•	<u>OxyNorm</u>
DΔ	RACETAMOL WITH CODEINE - Safety medicine; prescriber	may datarmina diena	nein	r fraguanc	V
不	Tab paracetamol 500 mg with codeine phosphate 8 mg	10.21	1,000	V	Paracetamol +
					Codeine (Relieve)
DE.	THIDINE HYDROCHLORIDE				
1 -					
	a) Only on a controlled drug form				
	b) No patient co-payment payable				
	c) Safety medicine; prescriber may determine dispensing fre	guency			
	Tab 50 mg		10	1	PSM
	•				
	Tab 100 mg		10		<u>PSM</u>
	Inj 50 mg per ml, 1 ml ampoule - Up to 5 inj available on a P	SO4.98	5	•	DBL Pethidine
					Hydrochloride
	Inj 50 mg per ml, 2 ml ampoule - Up to 5 inj available on a P	SO 5.12	5	1	DBL Pethidine
	inj 50 mg per mi, 2 mi ampodie – Op to 5 mj avaliable on a 1	00	J	•	
					<u>Hydrochloride</u>
TR	AMADOL HYDROCHLORIDE				
	Tab sustained-release 100 mg	1 55	20	1	Tramal SR 100
	•				
	Tab sustained-release 150 mg		20		Tramal SR 150
	Tab sustained-release 200 mg	2.75	20	•	Tramal SR 200
	Cap 50 mg - For tramadol hydrochloride oral liquid formulation	on			
	refer, page 227		100	1	Arrow-Tramadol
	Telei, page 227	2.20	100	•	Allow-Hailladol
Α	ntidepressants				
	•				
^	yclic and Related Agents				
C	yolio aliu nelaleu Agelilo				
	ITDIDTVI INF. O-feb				
AIVI	ITRIPTYLINE – Safety medicine; prescriber may determine di				
	Tab 10 mg	1.96	100	•	Arrow-Amitriptyline
	Arrow-Amitriptyline to be Sole Supply on 1 May 2018				
		1.52	100	✓	Arrow-Amitriptyline
	Arrow-Amitriptyline to be Sole Supply on 1 May 2018			-	
		0.54	100	,	Annana Amaltulastulias
	Tab 50 mg	2.51	100	•	Arrow-Amitriptyline
	Arrow-Amitriptyline to be Sole Supply on 1 May 2018				
٠.					

100

100

CLOMIPRAMINE HYDROCHLORIDE - Safety medicine; prescriber may determine dispensing frequency

Tab 25 mg8.68

✓ <u>Apo-Clomipramine</u>
✓ <u>Apo-Clomipramine</u>

	Subsidy		Fully	
	(Manufacturer's Price) \$	Per	Subsidised	
OOSULEPIN [DOTHIEPIN] HYDROCHLORIDE - Safety medic	ne; prescriber may de	termi	ine dispen	sing frequency
Tab 75 mg		100	✓	Dopress
Cap 25 mg	6.45	100	✓	Dopress
OXEPIN HYDROCHLORIDE - Safety medicine; prescriber ma	av determine dispensi	na fre	auencv	
Cap 10 mg		100		Anten
Cap 25 mg	6.86	100	✓	Anten
Cap 50 mg	8.55	100	✓	Anten
MIPRAMINE HYDROCHLORIDE - Safety medicine; prescriber	may determine dispe	nsina	requenc	V
Tab 10 mg		50		Tofranil
·	6.58	60	/	Tofranil s29 S29
	10.96	100		Tofranil
Tab 25 mg	8.80	50	1	Tofranil
MAPROTILINE HYDROCHLORIDE - Safety medicine; prescrib		nensii	na freatier	nev
Tab 25 mg		30		Ludiomil
·	12.53	50		Ludiomil
	25.06	100		Ludiomil
Tab 75 mg	14.01	20	✓	Ludiomil
Ç	21.01	30	✓	Ludiomil
NORTRIPTYLINE HYDROCHLORIDE - Safety medicine; presc	riber may determine o	lisper	nsina freai	iency
Tab 10 mg		100		Norpress
Tab 25 mg		180		Norpress
PHENELZINE SULPHATE Tab 15 mg TRANYLCYPROMINE SULPHATE		100		Nardil
₭ Tab 10 mg	22.94	50	•	Parnate
Monoamine-Oxidase Type A Inhibitors				
Monoamine-Oxidase Type A Inhibitors				
MOCLOBEMIDE	85.10	500	•	Apo-Moclobemide
MOCLOBEMIDE ★ Tab 150 mg		500 100		Apo-Moclobemide Apo-Moclobemide
MOCLOBEMIDE * Tab 150 mg * Tab 300 mg				
MOCLOBEMIDE * Tab 150 mg * Tab 300 mg Selective Serotonin Reuptake Inhibitors				
MOCLOBEMIDE K Tab 150 mg K Tab 300 mg Selective Serotonin Reuptake Inhibitors CITALOPRAM HYDROBROMIDE	30.70	100	•	Apo-Moclobemide
MOCLOBEMIDE Tab 150 mg Tab 300 mg Selective Serotonin Reuptake Inhibitors CITALOPRAM HYDROBROMIDE Tab 20 mg	30.70		•	
MOCLOBEMIDE K Tab 150 mg K Tab 300 mg Selective Serotonin Reuptake Inhibitors CITALOPRAM HYDROBROMIDE K Tab 20 mg SSCITALOPRAM	1.79	100	•	Apo-Moclobemide PSM Citalopram
MOCLOBEMIDE F Tab 150 mg F Tab 300 mg Selective Serotonin Reuptake Inhibitors EITALOPRAM HYDROBROMIDE F Tab 20 mg SCITALOPRAM F Tab 10 mg	1.79	100 84 28	<i>y</i>	Apo-Moclobemide PSM Citalopram Apo-Escitalopram
MOCLOBEMIDE F Tab 150 mg Tab 300 mg Selective Serotonin Reuptake Inhibitors EITALOPRAM HYDROBROMIDE F Tab 20 mg SCITALOPRAM Tab 10 mg Tab 20 mg	1.79	100	<i>y</i>	Apo-Moclobemide PSM Citalopram
COCLOBEMIDE F Tab 150 mg Tab 300 mg Selective Serotonin Reuptake Inhibitors ETALOPRAM HYDROBROMIDE F Tab 20 mg SCITALOPRAM Tab 10 mg Tab 20 mg LUOXETINE HYDROCHLORIDE	1.79	100 84 28 28	\tag{\tau}	PSM Citalopram Apo-Escitalopram Apo-Escitalopram
COCLOBEMIDE F Tab 150 mg Tab 300 mg Selective Serotonin Reuptake Inhibitors ETALOPRAM HYDROBROMIDE F Tab 20 mg SCITALOPRAM Tab 10 mg Tab 20 mg LUOXETINE HYDROCHLORIDE	1.79	100 84 28	<i>y</i>	Apo-Moclobemide PSM Citalopram Apo-Escitalopram
MOCLOBEMIDE # Tab 150 mg # Tab 300 mg Selective Serotonin Reuptake Inhibitors CITALOPRAM HYDROBROMIDE # Tab 20 mg ESCITALOPRAM # Tab 10 mg # Tab 20 mg # Tab 20 mg # Tab 20 mg # Tab 30 mg # Tab 30 mg	1.791.111.902.47	100 84 28 28 30	<i>*</i>	PSM Citalopram Apo-Escitalopram Apo-Escitalopram Arrow-Fluoxetine
MOCLOBEMIDE * Tab 150 mg * Tab 300 mg Selective Serotonin Reuptake Inhibitors CITALOPRAM HYDROBROMIDE * Tab 20 mg ESCITALOPRAM * Tab 10 mg * Tab 20 mg * Tab 20 mg * Tab 20 mg * Tab 30 mg		84 28 28 30 sules	and the prescri	PSM Citalopram Apo-Escitalopram Apo-Escitalopram Arrow-Fluoxetine rescription is endorsed ription is deemed to be

	Subsidy (Manufacturer's Price)		Fully Subsidised	
	\$	Per		Manufacturer
PAROXETINE				
* Tab 20 mg	4.02	90	•	Apo-Paroxetine
SERTRALINE	0.05	00		Awaru Cautualina
* Tab 50 mg * Tab 100 mg		90 90		Arrow-Sertraline Arrow-Sertraline
Other Antidepressants				
MIRTAZAPINE				
Tab 30 mg	2.55	30	1	Apo-Mirtazapine
Tab 45 mg	3.25	30	✓	Apo-Mirtazapine
VENLAFAXINE				
* Cap 37.5 mg		84		Enlafax XR
* Cap 75 mg		84		Enlafax XR
* Cap 150 mg	11.16	84		Enlafax XR
Antiepilepsy Drugs				
Agents for Control of Status Epilepticus				
CLONAZEPAM - Safety medicine; prescriber may determine di	spensing frequency			
Inj 1 mg per ml, 1 ml	19.00	5	•	Rivotril
DIAZEPAM – Safety medicine; prescriber may determine disper		_		
Inj 5 mg per ml, 2 ml ampoule – Subsidy by endorsement a) Up to 5 inj available on a PSO	11.83	5	•	Hospira
b) Only on a PSOc) PSO must be endorsed "not for anaesthetic procedu	ree"			
Rectal tubes 5 mg - Up to 5 tube available on a PSO		5	/	Stesolid
Rectal tubes 10 mg - Up to 5 tube available on a PSO		5		Stesolid
PARALDEHYDE				
* Inj 5 ml	1,500.00	5	1	AFT S29
PHENYTOIN SODIUM				
* Inj 50 mg per ml, 2 ml ampoule – Up to 5 inj available on a l	PSO 88.63	5	1	Hospira
* Inj 50 mg per ml, 5 ml ampoule - Up to 5 inj available on a				
PSO	133.92	5	✓	<u>Hospira</u>
Control of Epilepsy				
CARBAMAZEPINE				
* Tab 200 mg		100		Tegretol
* Tab long-acting 200 mg		100		Tegretol CR
* Tab 400 mg		100		Tegretol CD
* Tab long-acting 400 mg* † Oral lig 20 mg per ml		100 250 m	_	Tegretol CR Tegretol
CLOBAZAM – Safety medicine; prescriber may determine dispe		_UU 11	•	rogrotor
Tab 10 mg		50	1	Frisium
‡ Safety cap for extemporaneously compounded oral liqu		50	•	1 Holulii
CLONAZEPAM - Safety medicine; prescriber may determine di				
Oral drops 2.5 mg per ml		0 ml 0	OP 🗸	Rivotril
· · · · · · · · · · · · · · · · · · ·	,			

[‡] safety cap

NERVOUS SYSTEM

	Subsidy	-) (Fully	
	(Manufacturer's Price	Per	Subsidised •	Generic Manufacturer
ETHOSUXIMIDE				
Cap 250 mg	16.45	100	✓	Zarontin
•	32.90	200	1	Zarontin
‡ Oral liq 250 mg per 5 ml	13.60	200 ml	1	Zarontin
GABAPENTIN - Special Authority see SA1477 below - Retail p	oharmacy			
▲ Cap 100 mg	7.16	100	1	Arrow-Gabapentin Neurontin Nupentin
▲ Cap 300 mg − For gabapentin oral liquid formulation refer,			-	таропш
page 227	11.00	100		Arrow-Gabapentin Neurontin
▲ Cap 400 mg	13.75	100		Nupentin 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
- 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:

Fither:

- 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.

	Subsidy (Manufacturer's Price)	Sı	Fully ubsidised	Brand or Generic
	\$	Per	1	Manufacturer
ACOSAMIDE - Special Authority see SA11	25 below – Retail pharmacy			
▲ Tab 50 mg	. ,	14	✓ V	/impat
•				•
▲ Tab 100 mg	50.06	14	✓ ∨	/impat
▲ Tab 100 mg	50.06 200.24	14 56		/impat /impat
▲ Tab 100 mg	200.24		✓ V	
5	200.24	56	✓ V ✓ V	/impat

⇒SA1125 Special Authority for Subsidy

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

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

Note: "Optimal treatment" is defined as treatment which is indicated and clinically appropriate for the patient, given in adequate doses for the patient's age, weight and other features affecting the pharmacokinetics of the drug with good evidence of compliance. Women of childbearing age are not required to have a trial of sodium valproate.

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

Note: As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anticonvulsant therapy and have assessed quality of life from the patient's perspective.

LAMOTRIGINE

▲ Tab dispersible 2 mg	6.74	30	✓ Lamictal
▲ Tab dispersible 5 mg	9.64	30	✓ Lamictal
·	15.00	56	✓ Arrow-Lamotrigine
▲ Tab dispersible 25 mg	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
(Motrig Tab dispersible 25 mg to be delisted 1 April 2018) (Motrig Tab dispersible 50 mg to be delisted 1 April 2018) (Motrig Tab dispersible 100 mg to be delisted 1 April 2018)			
LEVETIRACETAM			
Tab 250 mg	24.03	60	✓ Everet
Tab 500 mg		60	✓ Everet
Tab 750 mg		60	✓ Everet
Tab 1,000 mg		60	✓ Everet
Oral liq 100 mg per ml		300 ml OP	✓ Levetiracetam-AFT
PHENOBARBITONE			
For phenobarbitone oral liquid refer Standard Formulae, pa	age 230		
* Tab 15 mg	30.00	500	✓ <u>PSM</u>
* Tab 30 mg	31.00	500	✓ PSM

[‡] safety cap

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

[▲] Three months supply may be dispensed at one time

	Subsidy		Fully	Brand or
	(Manufacturer's Pr	,	sidised	
	\$	Per		Manufacturer
PHENYTOIN SODIUM				
* Tab 50 mg	50.51	200	1	Dilantin Infatab
Cap 30 mg	22.00	200	1	Dilantin
Cap 100 mg	19.79	200	1	Dilantin
*‡ Oral liq 30 mg per 5 ml	22.03	500 ml	1	Dilantin
PRIMIDONE				
* Tab 250 mg	17.25	100	1	Apo-Primidone
SODIUM VALPROATE				
Tab 100 mg	13.65	100	✓	Epilim Crushable
Tab 200 mg EC	27.44	100	✓	Epilim
Tab 500 mg EC		100	1	Epilim
* Oral liq 200 mg per 5 ml		300 ml	1	Epilim S/F Liquid
			1	Epilim Syrup
* Inj 100 mg per ml, 4 ml	41.50	1	1	Epilim IV
STIRIPENTOL - Special Authority see SA1330 below - Retail p	harmacy			
Cap 250 mg	509.29	60	1	Diacomit S29
Powder for oral liq 250 mg sachet	509.29	60	•	Diacomit S29

⇒SA1330 Special Authority for Subsidy

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

Both:

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

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

OPIRAMATE ■ Tab 25 mg	11.07	60	✓ Arrow-Topiramate
<u> </u>			✓ Topiramate Actavis
	26.04		✓ Topamax
▲ Tab 50 mg	18.81	60	✓ Arrow-Topiramate
· ·			✓ Topiramate Actavis
	44.26		✓ Topamax
▲ Tab 100 mg	31.99	60	✓ Arrow-Topiramate
•			✓ Topiramate Actavis
	75.25		✓ Topamax
Tab 200 mg	55.19	60	✓ Arrow-Topiramate
•			✓ Topiramate Actavis
	129.85		✓ Topamax
Sprinkle cap 15 mg	20.84	60	✓ Topamax
Sprinkle cap 25 mg	26.04	60	✓ Topamax
/IGABATRIN - 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:

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

continued...

- 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.

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 126

Acute Migraine Treatment

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

Prophylaxis of Migraine

For Beta Adrenoceptor Blockers refer to CARDIOVASCULAR SYSTEM, page 62

PIZOTIFEN

★ Tab 500 mcg......23.21 100 ✓ Sandomigran

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

Antinausea and Vertigo Agents

For Antispasmodics refer to ALIMENTARY TRACT, page	ie 22
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APREPITANT - Special Authority see SA0987 below - Reta	il pharmacy		
Cap 2 × 80 mg and 1 × 125 mg	100.00	3 OP	✓ Emend Tri-Pack
Cap 40 mg	71.43	5 OP	✓ Emend

⇒SA0987 Special Authority for Subsidy

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

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

BETAHISTINE DIHYDROCHLORIDE

*	Tab 16 mg	2.89	84	✓ Vergo 16
CYC	CLIZINE HYDROCHLORIDE			
	Tab 50 mg	0.59	20	✓ Nauzene
CYC	CLIZINE LACTATE			
	Inj 50 mg per ml, 1 ml	14.95	5	✓ Nausicalm
DOI	MPERIDONE			
*	Tab 10 mg - For domperidone oral liquid formulation refer,			
	page 227	3.20	100	✓ Prokinex
HYC	DSCINE HYDROBROMIDE			
*	Inj 400 mcg per ml, 1 ml ampoule	46.50	5	✓ Hospira
		93.00	10	✓ Martindale S29
	Patch 1.5 mg - Special Authority see SA1387 below - Retail			
	pharmacy	11.95	2	✓ Scopoderm TTS

⇒SA1387 Special Authority for Subsidy

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

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

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

METOCLOPRAMIDE HYDROCHLORIDE

*	Tab 10 mg - For metoclopramide hydrochloride oral liquid		
	formulation refer, page 227	100	Metoclopramide Actavis 10
	(1.82)		Metamide
	Metoclopramide Actavis 10 to be Sole Supply on 1 April 2018		
*	Inj 5 mg per ml, 2 ml ampoule - Up to 5 inj available on a PSO4.50	10	✓ Pfizer
(M	etamide Tab 10 mg to be delisted 1 April 2018)		

(N	Subsidy lanufacturer's Price) \$	Per	Fully Subsidised	I Generic
ONDANSETRON				
★ Tab 4 mg	3.36	50	✓	Apo-Ondansetron
* Tab disp 4 mg	0.95	10	•	Ondansetron ODT-ORLA
Ondansetron ODT-ORLA to be Sole Supply on 1 May 2018				
★ Tab 8 mg	4.77	50	✓	Apo-Ondansetron
F Tab disp 8 mg	1.43	10	•	Ondansetron ODT-DRLA
Ondansetron ODT-DRLA to be Sole Supply on 1 May 2018				
PROCHLORPERAZINE				
★ Tab 3 mg buccal	5 97	50		
- 1ab 5 mg 5abba	(15.00)	00		Buccastem
₹ Tab 5 mg - Up to 30 tab available on a PSO	` '	250	/	Nausafix
	9.75	500	/	Antinaus
Nausafix to be Sole Supply on 1 June 2018	00			
Inj 12.5 mg per ml, 1 ml – Up to 5 inj available on a PSO	25.81	10	✓	Stemetil
PROMETHAZINE THEOCLATE				
★ Tab 25 mg	1.20	10		
ř	(5.59)			Avomine

Antipsychotics

General

AMISULPRIDE - Safety medicine; prescriber may deter	rmine dispensing frequency	y	
Tab 100 mg	4.56	30	✓ Sulprix
Tab 200 mg	14.75	60	✓ Sulprix
Tab 400 mg	27.70	60	✓ Sulprix
Oral liq 100 mg per ml	65.53	60 ml	✓ Solian
ARIPIPRAZOLE – Special Authority see SA1539 below Safety medicine; prescriber may determine dispensi	, ,		
Tab 5 mg - No more than 1 tab per day	123.54	30	Abilify
Tab 10 mg	123.54	30	Abilify
Tab 15 mg	175.28	30	Abilify
Tab 20 mg	213.42	30	Abilify
Tab 30 mg	260.07	30	Abilify
Safety medicine; prescriber may determine dispensi Tab 5 mg – No more than 1 tab per day Tab 10 mg Tab 15 mg Tab 20 mg	ing frequency	30 30 30	✓ Abilify ✓ Abilify ✓ Abilify

⇒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



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

continued...

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

CHLORPROMAZINE HYDROCHLORIDE - Safety medicine; pre-	scriber may dete	ermine dispens	sing frequency
Tab 10 mg - Up to 30 tab available on a PSO		100	✓ Largactil
Tab 25 mg - Up to 30 tab available on a PSO		100	✓ Largactil
Tab 100 mg - Up to 30 tab available on a PSO		100	✓ Largactil
Inj 25 mg per ml, 2 ml - Up to 5 inj available on a PSO		10	✓ Largactil
CLOZAPINE - Hospital pharmacy [HP4]			•
Safety medicine; prescriber may determine dispensing freque	ncv		
Tab 25 mg		50	✓ Clozaril
	6.69		✓ Clopine
	11.36	100	✓ Clozaril
	13.37		✓ Clopine
Tab 50 mg		50	✓ Clopine
ů	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 dis	pensina freauen	icv	
Tab 500 mcg - Up to 30 tab available on a PSO		100	✓ Serenace
Tab 1.5 mg - Up to 30 tab available on a PSO		100	✓ Serenace
Tab 5 mg - Up to 30 tab available on a PSO		100	✓ Serenace
Oral lig 2 mg per ml - Up to 200 ml available on a PSO		100 ml	✓ Serenace
Inj 5 mg per ml, 1 ml ampoule - Up to 5 inj available on a PS	O21.55	10	✓ Serenace
LEVOMEPROMAZINE HYDROCHLORIDE - Safety medicine; pr	escriber may de	termine disne	nsing frequency
Inj 25 mg per ml, 1 ml ampoule		10	✓ Wockhardt
LEVOMEPROMAZINE MALEATE – Safety medicine; prescriber r			
	,	iisperisirig irec 100	√ Nozinan
Tab 25 mg		100	✓ Nozinan
Tab 100 mg			▼ NOZIIIaII
LITHIUM CARBONATE - Safety medicine; prescriber may determ			4 LULY 1 EQ
Tab 250 mg		500	Lithicarb FC
Tab 400 mg		100	✓ <u>Lithicarb FC</u>
Tab long-acting 400 mg		100	✓ Priadel
Cap 250 mg	9.42	100	Douglas

	Subsidy (Manufacturaria Price)		Fully	
	(Manufacturer's Price) \$	Per	Subsidised	
LANZAPINE – Safety medicine; prescriber may determine di	ispensing frequency			
Tab 2.5 mg		28	/	Zypine
Tab 5 mg		28		Zypine
Tab orodispersible 5 mg		28		Zypine ODT
Tab 10 mg		28		Zypine
Tab orodispersible 10 mg		28		Zypine ODT
ERICYAZINE – Safety medicine; prescriber may determine of		20	·	<u> </u>
Tab 2.5 mg	,	100	1	Neulactil
Tab 10 mg		100	/	Neulactil
UETIAPINE – Safety medicine; prescriber may determine dis				
Tab 25 mg		90	/	Quetapel
Tab 100 mg		90		Quetapel
Tab 200 mg		90		Quetapel
Tab 300 mg		90	_	Quetapel
ISPERIDONE - Safety medicine; prescriber may determine of		30	•	<u>Quetaper</u>
Tab 0.5 mg		60	/	Actavis
Tab 1 mg		60		Actavis
Tab 2 mg		60	_	Actavis
Tab 3 mg		60		Actavis
Tab 4 mg		60		Actavis
3		30 m		Risperon
Oral liq 1 mg per ml		30 111	•	nisperoii
PRASIDONE – Safety medicine; prescriber may determine of			_	
Cap 20 mg		60		Zusdone
Cap 40 mg		60		Zusdone
Cap 60 mg	33.87	60	_	Zusdone
Cap 80 mg	39.74	60	•	Zusdone
JCLOPENTHIXOL HYDROCHLORIDE - Safety medicine; p	rescriber may determin	e disp	ensing fro	equency
Tab 10 mg	31.45	100	•	Clopixol
Depot Injections				
	may determine dispens	ing fr	equency	
Inj 20 mg per ml, 1 ml - Up to 5 inj available on a PSO		5	1	Fluanxol
Inj 20 mg per ml, 2 ml - Up to 5 inj available on a PSO		5	•	Fluanxol
Inj 100 mg per ml, 1 ml - Up to 5 inj available on a PSO		5	1	Fluanxol
ALOPERIDOL DECANOATE - Safety medicine; prescriber r		na fre	allency	
Inj 50 mg per ml, 1 ml – Up to 5 inj available on a PSO	,	5	. ,	Haldol
Inj 100 mg per ml, 1 ml – Up to 5 inj available on a PSO		5		Haldol Concentrate
ing 100 mg por mi, 1 mi Op to 5 mg available on a 1 00		J		Haldol
			•	Decanoas \$29
	ne – Retail nharmacy			
LANZAPINE - Special Authority see SA1428 on the next page				
	• • •			
Safety medicine; prescriber may determine dispensing fred	quency	1	/	Zyprexa Relprevy
LANZAPINE – Special Authority see SA1428 on the next pag Safety medicine; prescriber may determine dispensing fred Inj 210 mg vial	quency 280.00	1		Zyprexa Relprevv Zyprexa Relprevv



Sub	osidy Fu	ly Brand or
(Manufactu	urer's Price) Subsidise	ed Generic
	\$ Per	Manufacturer

⇒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 f	requency		
Inj 25 mg syringe	194.25	1	✓ Invega Sustenna
Inj 50 mg syringe		1	✓ Invega Sustenna
Inj 75 mg syringe		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.

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

(Piportil Inj 50 mg per ml, 1 ml to be delisted 1 June 2019)

(Piportil Inj 50 mg per ml, 2 ml to be delisted 1 June 2019)

RISPERIDONE – Special Authority see SA1427 on the next page – Retail pharmacy

calcity medicine, presented may actermine dispense	ing iroquorioy		
Inj 25 mg vial	135.98	1	Risperdal Consta
Inj 37.5 mg vial	178.71	1	✓ Risperdal Consta
Inj 50 mg vial		1	✓ Risperdal Consta

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

⇒SA1427 Special Authority for Subsidy

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

- 1 The patient has had an initial Special Authority approval for paliperidone depot injection or olanzapine depot injection; or
- 2 All of the following:
 - 2.1 The patient has schizophrenia or other psychotic disorder; and
 - 2.2 Has tried but failed to comply with treatment using oral atypical antipsychotic agents; and
 - 2.3 Has been admitted to hospital or treated in respite care, or intensive outpatient or home-based treatment for 30 days or more in last 12 months.

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

Note: Risperidone depot injection should ideally be used as monotherapy (i.e. without concurrent use of any other antipsychotic medication). In some cases, it may be clinically appropriate to attempt to treat a patient with typical antipsychotic agents in depot injectable form before trialing risperidone depot injection.

ZUCLOPENTHIXOL DECANOATE - Safety medicine; prescriber may determine dispensing frequency

✓ Clopixol

Anx		

BUSPIRONE HYDROCHLORIDE			
* Tab 5 mg	.23.80	100	✓ Orion
* Tab 10 mg	.14.96	100	✓ Orion
CLONAZEPAM - Safety medicine; prescriber may determine dispensin	ng frequency		
Tab 500 mcg	7.53	100	✓ Paxam
Tab 2 mg		100	✓ Paxam
DIAZEPAM - Safety medicine; prescriber may determine dispensing from	equency		
Tab 2 mg	.15.05	500 •	✓ Arrow-Diazepam
a)‡ Safety cap for extemporaneously compounded oral liquid p			
b) Arrow-Diazepam to be Sole Supply on 1 April 2018			4
Tab 5 mg		500 •	Arrow-Diazepam
a)‡ Safety cap for extemporaneously compounded oral liquid pb) Arrow-Diazepam to be Sole Supply on 1 April 2018	reparations.		
LORAZEPAM - Safety medicine; prescriber may determine dispensing	frequency		
Tab 1 mg	.10.79	250	✓ <u>Ativan</u>
‡ Safety cap for extemporaneously compounded oral liquid prepare	arations.		
Tab 2.5 mg		100	/ Ativan
‡ Safety cap for extemporaneously compounded oral liquid prepare	arations.		
OXAZEPAM - Safety medicine; prescriber may determine dispensing f	requency		
Tab 10 mg		100	✓ <u>Ox-Pam</u>
‡ Safety cap for extemporaneously compounded oral liquid prepare			
Tab 15 mg	8.53	100 •	✓ Ox-Pam

Multiple Sclerosis Treatments

DIMETHYL FUMARATE - Special Authority see SA1559 on the next page - Retail pharmacy Wastage claimable - see rule 3.3.2 on page 13

‡ Safety cap for extemporaneously compounded oral liquid preparations.

Cap 120 mg	520.00	14	Tecfidera
Cap 240 mg	2,000.00	56	Tecfidera



Subsidy (Manufacturer's Price) Fully Subsidised Per

Brand or Generic Manufacturer

⇒SA1559 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

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

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

The coordinator Phone: 04 460 4990

Multiple Sclerosis Treatment Assessment Committee Facsimile: 04 916 7571

PHARMAC PO Box 10 254 Email: mstaccoordinator@pharmac.govt.nz

Wellington

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

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

Entry Criteria

- a) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
- b) patients must have Clinically Definite Relapsing Remitting MS with or without underlying progression; and
- c) patients must have:
 - a) EDSS score 0 4.0 and:
 - Experienced at least 1 significant relapse of MS in the previous 12 months or 2 significant relapses in the
 past 24 months; and
 - Evidence of new inflammatory activity on an MR scan within the past 24 months, any of the following:
 - i) a gadolinium enhancing lesion; or
 - ii) a Diffusion Weighted Imaging positive lesion; or
 - iii) a T2 lesion with associated local swelling; or
 - iv) a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse; or
 - v) new T2 lesions compared with a previous MR scan; and
- d) A significant relapse must:
 - a) be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
 - b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);
 - c) last at least one week:
 - d) start at least one month after the onset of a previous relapse;
 - e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least 1 point;
 - f) be distinguishable from the effects of general fatigue; and
 - g) not be associated with a fever (T> 37.5°C); and
- e) applications must be made by the patient's neurologist or general physician; and
- f) patients must have no previous history of lack of response to dimethyl fumarate; and
- g) patients must have not previously had intolerance to dimethyl fumarate; and
- h) patient must not be co-prescribed beta interferon or glatiramer acetate.

Stopping Criteria

Any of the following:

1) Confirmed progression of disability that is sustained for six months. Progression of disability is defined as progress by any of the following EDDSS points:

Subsidy (Manufacturer's Price) \$

Subsidised Per

Fully

Brand or Generic Manufacturer

continued...

- a) from starting at EDSS 0 increasing to (i.e. stopping on reaching) EDSS 3.0; or
- b) 1.0 to 3.0; or
- c) 1.5 to 3.5; or
- d) 2.0 to 4.0; or
- e) 2.5 to 4.5; or
- f) 3.0 to 4.5; or g) 3.5 to 4.5; or
- h) 4.0 to 4.5.
- 2) increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment)(see note); or
- 3) intolerance to dimethyl fumarate; or
- 4) 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 below - Retail pharmacy

Wastage claimable – see rule 3.3.2 on page 13

Cap 0.5 mg......2,650.00 28 **✓ Gilenya**

⇒SA1562 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

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

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

The coordinator Phone: 04 460 4990

Multiple Sclerosis Treatment Assessment Committee Facsimile: 04 916 7571

PHARMAC PO Box 10 254 Email: mstaccoordinator@pharmac.govt.nz

Wellington

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

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

Entry Criteria

- 1) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
- 2) patients must have Clinically Definite Relapsing Remitting MS with or without underlying progression; and
- 3) patients must have:
 - a) EDSS score 0 4.0 and:
 - Experienced at least 1 significant relapse of MS in the previous 12 months or 2 significant relapses in the
 past 24 months; and
 - Evidence of new inflammatory activity on an MR scan within the past 24 months, any of the following:
 - i) a gadolinium enhancing lesion; or
 - ii) a Diffusion Weighted Imaging positive lesion; or
 - iii) a T2 lesion with associated local swelling; or
 - iv) a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse; or
 - v) new T2 lesions compared with a previous MR scan; and



	Subsidy	Fully	Brand or
(Manu	facturer's Price)	Subsidised	Generic
	\$ Pe	er 🗸	Manufacturer

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- 4) A significant relapse must:
 - a) be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
 - b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);
 - c) last at least one week:
 - d) start at least one month after the onset of a previous relapse;
 - e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least 1 point;
 - f) be distinguishable from the effects of general fatigue; and
 - g) not be associated with a fever (T> 37.5°C); and
- 5) applications must be made by the patient's neurologist or general physician; and
- 6) patients must have no previous history of lack of response to fingolimod; and
- 7) patients must have not previously had intolerance to fingolimod; and
- 8) patient must not be co-prescribed beta interferon or glatiramer acetate.

Stopping Criteria

Any of the following:

- 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
 - a) 3.5 to 4.5; or
 - h) 4.0 to 4.5.
- 2) increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment)(see note); or
- 3) intolerance to fingolimod; or
- 4) non-compliance with treatment, including refusal to undergo annual assessment.

Note: Switching between natalizumab, fingolimod, dimethyl fumarate 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

⇒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:

Subsidy (Manufacturer's Price) \$

Subsidised Per 🗸

Fully

Brand or Generic Manufacturer

continued...

The coordinator Phone: 04 460 4990

Multiple Sclerosis Treatment Assessment Committee Facsimile: 04 916 7571

PHARMAC PO Box 10 254 Email: mstaccoordinator@pharmac.govt.nz

Wellington

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

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

Entry Criteria

- 1) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
- 2) patients must have Clinically Definite Relapsing Remitting MS with or without underlying progression; and
- 3) patients must have:
 - a) EDSS score 0 4.0 and:
 - Experienced at least 1 significant relapse of MS in the previous 12 months or 2 significant relapses in the
 past 24 months; and
 - Evidence of new inflammatory activity on an MR scan within the past 24 months, any of the following:
 - i) a gadolinium enhancing lesion; or
 - ii) a Diffusion Weighted Imaging positive lesion; or
 - iii) a T2 lesion with associated local swelling; or
 - iv) a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse; or
 - v) new T2 lesions compared with a previous MR scan; and
- 4) A significant relapse must:
 - a) be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria):
 - b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);
 - c) last at least one week;
 - d) start at least one month after the onset of a previous relapse;
 - e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least 1 point;
 - f) be distinguishable from the effects of general fatigue; and
 - g) not be associated with a fever (T> 37.5°C); and
- 5) applications must be made by the patient's neurologist or general physician; and
- 6) treatment must be initiated and supervised by a neurologist who is registered in the Tysabri Australasian Prescribing Programme operated by the supplier; and
- 7) patients must have no previous history of lack of response to natalizumab; and
- 8) patients must have not previously had intolerance to natalizumab; and
- 9) a) Patient is JC virus negative, or
 - Patient is JC virus positive and has given written informed consent acknowledging an understanding of the risk of progressive multifocal leucoencephalopathy (PML) associated with natalizumab
- 10) patient must not be co-prescribed beta interferon or glatiramer acetate.

Stopping Criteria

Any of the following:

- 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

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Per

Brand or Generic Manufacturer

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b) 1.0 to 3.0; or

c) 1.5 to 3.5; or

d) 2.0 to 4.0; or

e) 2.5 to 4.5: or

f) 3.0 to 4.5; or

g) 3.5 to 4.5; or

h) 4.0 to 4.5.

- 2) increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment)(see note); or
- 3) intolerance to natalizumab; or
- 4) non-compliance with treatment, including refusal to undergo annual assessment.

Note: Natalizumab can only be dispensed from a pharmacy registered in the Tysabri Australasian Prescribing Programme operated by the supplier.

Switching between natalizumab, fingolimod, dimethyl fumarate 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

⇒SA1560 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

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

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

The coordinator Phone: 04 460 4990

Multiple Sclerosis Treatment Assessment Committee Facsimile: 04 916 7571

PHARMAC PO Box 10 254 Email: mstaccoordinator@pharmac.govt.nz

Wellington

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

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

Entry Criteria

- 1) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
- 2) patients must have Clinically Definite Relapsing Remitting MS with or without underlying progression; and
- 3) patients must have:
 - a) EDSS score 0 4.0 and:
 - Experienced at least 1 significant relapse of MS in the previous 12 months or 2 significant relapses in the
 past 24 months; and
 - Evidence of new inflammatory activity on an MR scan within the past 24 months, any of the following:
 - i) a gadolinium enhancing lesion; or
 - ii) a Diffusion Weighted Imaging positive lesion; or
 - iii) a T2 lesion with associated local swelling; or
 - iv) a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse; or

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

continued...

- v) new T2 lesions compared with a previous MR scan; and
- 4) A significant relapse must:
 - a) be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
 - b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);
 - c) last at least one week:
 - d) start at least one month after the onset of a previous relapse;
 - e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least 1 point;
 - f) be distinguishable from the effects of general fatigue; and
 - g) not be associated with a fever (T> 37.5°C); and
- 5) applications must be made by the patient's neurologist or general physician; and
- 6) patients must have no previous history of lack of response to teriflunomide; and
- 7) patients must have not previously had intolerance to teriflunomide; and
- 8) patient must not be co-prescribed beta interferon or glatiramer acetate.

Stopping Criteria

Any of the following:

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

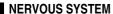
Note: Switching between natalizumab, fingolimod, dimethyl fumarate and teriflunomide is permitted provided the EDSS stopping criteria are not met. Switching to interferon or glatiramer acetate is only permitted provided the EDSS stopping criteria are not met and both fingolimod and natalizumab are either 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).



Subsidy (Manufacturer's Price) Fully Subsidised

Per

Brand or Generic Manufacturer

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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).

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

- 1) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis must include MRI confirmation; and
- 2) patients must have Clinically Definite Relapsing Remitting MS with or without underlying progression; and
- 3) patients must have:
 - a) EDSS score 0 4.0 and:
 - Experienced at least 1 significant relapse of MS in the previous 12 months or 2 significant relapses in the
 past 24 months; and
 - Evidence of new inflammatory activity on an MR scan within the past 24 months, any of the following:
 - i) a gadolinium enhancing lesion; or
 - ii) a Diffusion Weighted Imaging positive lesion; or
 - iii) a T2 lesion with associated local swelling; or
 - iv) a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse; or
 - v) new T2 lesions compared with a previous MR scan; and
- 4) A significant relapse must:
 - a) be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
 - b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s);
 - c) last at least one week;
 - d) start at least one month after the onset of a previous relapse;
 - e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least 1 point;
 - f) be distinguishable from the effects of general fatigue; and
 - g) not be associated with a fever (T> 37.5°C); and
- 5) applications must be made by the patient's neurologist; and
- 6) patients must have no previous history of lack of response to beta-interferon or glatiramer acetate; and
- 7) patients must have either:
 - a) intolerance to both natalizumab and fingolimod; or
 - b) treatment with both natalizumab and fingolimod is considered clinically inappropriate; and
- 8) patient will not be co-prescribed natalizumab or fingolimod.

Subsidy		Fully	Brand or	
(Manufacturer's Price)		Subsidised	Generic	
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Stopping Criteria

Any of the following:

- Confirmed progression of disability that is sustained for six months during a minimum of one year of treatment.
 Progression of disability is defined as progress by any of the following EDDSS Points:
 - a) from starting at EDSS 0 increasing to (i.e. stopping on reaching) EDSS 3.0; or
 - b) 1.0 to 3.0; or
 - c) 1.5 to 3.5; or
 - d) 2.0 to 4.0: or
 - e) 2.5 to 4.5; or
 - f) 3.0 to 4.5; or
 - g) 3.5 to 4.5; or
 - h) 4.0 to 4.5.
- 2) increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment)(see note); or
- 3) intolerance to interferon beta-1-alpha, and/or interferon beta-1-beta and/or glatiramer acetate; or
- 4) non-compliance with treatment, including refusal to undergo annual assessment.

Note: Treatment with interferon beta -1-beta, interferon beta-1-alpha and glatiramer acetate, is permitted only if treatment with both natalizumab and fingolimod is not tolerated or treatment with both would be clinically inappropriate. Beta-interferon or glatiramer acetate will not be funded as second line treatments if EDSS progression has occurred on treatment with natalizumab or fingolimod. Patients who have an increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment) and who do not meet the EDSS Stopping Criteria at annual review may switch from either of the beta-interferon 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 page 159 – [Xpharm	1]	
Inj 20 mg prefilled syringe	1,089.25	28	Copaxone
INTERFERON BETA-1-ALPHA - Special Authority see SA	1564 on page 159 – [X	pharm]	
Inj 6 million iu prefilled syringe	1,170.00	4	Avonex
Injection 6 million iu per 0.5 ml pen injector		4	Avonex Pen
INTERFERON BETA-1-BETA - Special Authority see SA15	564 on page 159 – [Xpl	narm]	
Inj 8 million iu per 1 ml	1,322.89	15	✓ Betaferon

Sedatives and Hypnotics

LORMETAZEPAM - Safety medicine; prescriber may determine di	spensing frequenc	У	
Tab 1 mg	3.11	30	
•	(23.50)		Noctamid
‡ Safety cap for extemporaneously compounded oral liquid p	preparations.		
MELATONIN - Special Authority see SA1666 below - Retail pharm	nacy		
Tab modified-release 2 mg - No more than 5 tab per day	28.22	30	Circadin

⇒SA1666 Special Authority for Subsidy

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



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All of the following:

- 1 Patient has been diagnosed with persistent and distressing insomnia secondary to a neurodevelopmental disorder (including, but not limited to, autism spectrum disorder or attention deficit hyperactivity disorder)*; and
- 2 Behavioural and environmental approaches have been tried and were unsuccessful, or are inappropriate; and
- 3 Funded modified-release melatonin is to be given at doses no greater than 10 mg per day; and
- 4 Patient is aged 18 years or under*.

Renewal only from a psychiatrist, paediatrician, neurologist, respiratory specialist or medical practitioner on the recommendation of a psychiatrist, paediatrician, neurologist or respiratory specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

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

Note: Indications marked with * are Unapproved Indications.

MIDAZOLAM – Safety medicine; prescriber may determine dispension in 1 mg per ml, 5 ml ampoule	0 , ,	10	✓ Midazolam-Claris
Inj 1 mg per ml, 5 ml plastic ampoule - Up to 10 inj available			4.70
on a PSO		10	✓ Pfizer
On a PSO for status epilepticus use only. PSO must be en	dorsed for statu	ıs epileptici	us use only.
Inj 5 mg per ml, 3 ml ampoule		5	✓ Midazolam-Claris
Inj 5 mg per ml, 3 ml plastic ampoule – Up to 5 inj available on	1		
a PSO	11.90	5	✓ Pfizer
On a PSO for status epilepticus use only. PSO must be en	idorsed for statu	ıs epilepticı	us use only.
NITRAZEPAM - Safety medicine; prescriber may determine disper	sing frequency		
Tab 5 mg	5.22	100	✓ Nitrados
‡ Safety cap for extemporaneously compounded oral liquid p	reparations.		
PHENOBARBITONE SODIUM - Special Authority see SA1386 bel	ow – Retail pha	rmacy	
Inj 200 mg per ml, 1 ml ampoule	46.20	10	✓ Martindale \$29
SA1386 Special Authority for Subsidy			

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 free Tab 10 mg		✓ Normison
‡ Safety cap for extemporaneously compounded oral liquid preparat		<u> </u>
TRIAZOLAM - Safety medicine; prescriber may determine dispensing freq	uency	
Tab 125 mcg5.	10 100	
(9.	35)	Hypam
‡ Safety cap for extemporaneously compounded oral liquid preparat	ions.	
Tab 250 mcg4.	10 100	
(11.:	20)	Hypam
‡ Safety cap for extemporaneously compounded oral liquid preparat	ions.	
ZOPICLONE - Safety medicine; prescriber may determine dispensing freq	uency	
Tab 7.5 mg8.	99 500	✓ Zopiclone Actav

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(Manufacturer's Price)	Subsidis	ed Generic	
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Stimulants/ADHD Treatments

ATOMOXETINE - Special Authority see SA1416 below	v – Retail pharmacy		
Cap 10 mg	, ,	28	✓ Strattera
Cap 18 mg		28	✓ Strattera
Cap 25 mg	107.03	28	✓ Strattera
Cap 40 mg	107.03	28	✓ Strattera
Cap 60 mg		28	Strattera
Cap 80 mg	139.11	28	Strattera
Cap 100 mg	139.11	28	✓ Strattera

⇒SA1416 Special Authority for Subsidy

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

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

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

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

DEXAMFETAMINE SULFATE - Special Authority see SA1149 below - Retail pharmacy

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

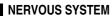
⇒SA1149 Special Authority for Subsidy

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



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

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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:

Roth:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 Either:
 - 2.1 Applicant is a paediatrician or psychiatrist; or
 - 2.2 Applicant is a medical practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing.

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

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

METHYLPHENIDATE HYDROCHLORIDE - Special Authority see SA1150 below - Retail pharmacy

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

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Tab immediate-release 5 mg	3.20	30	Rubifen
Tab immediate-release 10 mg		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 Fither:
 - 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:

Subsidy	F	ully	Brand or
(Manufacturer's Price)	Subsid	ised	Generic
\$	Per	✓	Manufacturer

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Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 Either:
 - 2.1 Applicant is a paediatrician or psychiatrist; or
 - 2.2 Applicant is a medical practitioner and confirms that a paediatrician or psychiatrist has been consulted within the last 2 years and has recommended treatment for the patient in writing.

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

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

METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE - Special Authority see SA1151 below - Retail pharmacy

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

z, caret, meanine, processes may actermine alepend			
Tab extended-release 18 mg	58.96	30	Concerta
Tab extended-release 27 mg	65.44	30	Concerta
Tab extended-release 36 mg		30	Concerta
Tab extended-release 54 mg	86.24	30	Concerta
Cap modified-release 10 mg		30	Ritalin LA
Cap modified-release 20 mg		30	Ritalin LA
Cap modified-release 30 mg		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 on the next page - Retail pharmacy

✓ Modaviqil 30



Subsidy		Fully	Brand or
(Manufacturer's Price)		Subsidised	Generic
<u> </u>	Per		Manufacturer

⇒SA1126 Special Authority for Subsidy

Initial application only from a neurologist or respiratory specialist. Approvals valid for 24 months for applications meeting the following criteria:

All of the following:

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

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

Treatments for Dementia

DONEPEZIL HYDROCHLORIDE			
* Tab 5 mg	4.34	90	✓ Donepezil-Rex
* Tab 10 mg	6.64	90	✓ Donepezil-Rex
RIVASTIGMINE - Special Authority see SA1488 below - F	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

Suboxone	28]57.40	rab sublingual 2 mg with haloxone 0.5 mg
Suboxone	28	166.00	Tab sublingual 8 mg with naloxone 2 mg

⇒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:

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

continued...

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

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

BUPROPIO	ИН	/DF	ROCHLORIDE

Tab modified-release 150 mg	11.00	30	✓ Zyban
DISULFIRAM			
Tab 200 mg	44.30	100	Antabuse
NALTREXONE HYDROCHLORIDE - Special Authority see SA	A1408 below - Retai	il pharmacy	
Tab 50 mg	112.55	30	✓ Naltraccord

⇒SA1408 Special Authority for Subsidy

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

- 1 Patient is currently enrolled in a recognised comprehensive treatment programme for alcohol dependence; and
- 2 Applicant works in or with a community Alcohol and Drug Service contracted to one of the District Health Boards or accredited against the New Zealand Alcohol and Other Drug Sector Standard or the National Mental Health Sector

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

continued...

Standard.

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

- 1 Compliance with the medication (prescriber determined); and
- 2 Any of the following:
 - 2.1 Patient is still unstable and requires further treatment; or
 - 2.2 Patient achieved significant improvement but requires further treatment; or
 - 2.3 Patient is well controlled but requires maintenance therapy.

NICOTINE

COTINE			
a) Nicotine will not be funded under the Dispensing Frequency R	ule in amounts le	ess than 4 w	eeks of treatment.
b) Note: may be provided by a pharmacist under the non-prescr	ibing Practitioner	s provisions	in Part III of Section A.
Patch 7 mg - Up to 28 patch available on a PSO	16.00	28	✓ Habitrol
Habitrol to be Sole Supply on 1 April 2018			
Patch 7 mg for direct distribution only - [Xpharm]	3.94	7	✓ Habitrol
Habitrol to be Sole Supply on 1 April 2018			
Patch 14 mg - Up to 28 patch available on a PSO	17.59	28	✓ Habitrol
Habitrol to be Sole Supply on 1 April 2018			
Patch 14 mg for direct distribution only - [Xpharm]	4.52	7	✓ Habitrol
Habitrol to be Sole Supply on 1 April 2018			
Patch 21 mg - Up to 28 patch available on a PSO	20.16	28	✓ Habitrol
Habitrol to be Sole Supply on 1 April 2018			
Patch 21 mg for direct distribution only - [Xpharm]	5.18	7	✓ Habitrol
Habitrol to be Sole Supply on 1 April 2018			
Lozenge 1 mg - Up to 216 loz available on a PSO	16.61	216	✓ Habitrol
Habitrol to be Sole Supply on 1 April 2018			
Lozenge 1 mg for direct distribution only - [Xpharm]	3.20	36	✓ Habitrol
Habitrol to be Sole Supply on 1 April 2018			
Lozenge 2 mg - Up to 216 loz available on a PSO	18.20	216	✓ Habitrol
Habitrol to be Sole Supply on 1 April 2018			
Lozenge 2 mg for direct distribution only - [Xpharm]	3.24	36	✓ Habitrol
Habitrol to be Sole Supply on 1 April 2018			
Gum 2 mg (Fruit) – Up to 384 piece available on a PSO	33.69	384	✓ Habitrol
Habitrol to be Sole Supply on 1 April 2018			
Gum 2 mg (Fruit) for direct distribution only - [Xpharm]	8.64	96	✓ Habitrol
Habitrol to be Sole Supply on 1 April 2018			_
Gum 2 mg (Mint) - Up to 384 piece available on a PSO	33.69	384	✓ Habitrol
Habitrol to be Sole Supply on 1 April 2018			
Gum 2 mg (Mint) for direct distribution only – [Xpharm]	8.64	96	✓ Habitrol
Habitrol to be Sole Supply on 1 April 2018			4
Gum 4 mg (Fruit) – Up to 384 piece available on a PSO	38.95	384	✓ Habitrol
Habitrol to be Sole Supply on 1 April 2018			4
Gum 4 mg (Fruit) for direct distribution only – [Xpharm]	10.01	96	✓ Habitrol
Habitrol to be Sole Supply on 1 April 2018	00.05	004	✓ 11-1-141
Gum 4 mg (Mint) – Up to 384 piece available on a PSO	38.95	384	✓ Habitrol
Habitrol to be Sole Supply on 1 April 2018 Gum 4 mg (Mint) for direct distribution only – [Xpharm]	10.01	06	✓ Habitrol
	10.01	96	▼ ⊓abittoi
Habitrol to be Sole Supply on 1 April 2018			

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

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

✓ Champix	28	Tab 1 mg67.74
✓ Champix	56	135.48
✓ Champix	25 OP	Tab 0.5 mg x 11 and 1 mg x 14

⇒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:

- 1 Short-term therapy as an aid to achieving abstinence in a patient who has indicated that they are ready to cease smoking; and
- 2 The patient is part of, or is about to enrol in, a comprehensive support and counselling smoking cessation programme, which includes prescriber or nurse monitoring; and
- 3 Either:
 - 3.1 The patient has tried but failed to quit smoking after at least two separate trials of nicotine replacement therapy, at least one of which included the patient receiving comprehensive advice on the optimal use of nicotine replacement therapy; or
 - 3.2 The patient has tried but failed to quit smoking using bupropion or nortriptyline; and
- 4 The patient has not used funded varenicline in the last 12 months; and
- 5 Varenicline is not to be used in combination with other pharmacological smoking cessation treatments and the patient has agreed to this; and
- 6 The patient is not pregnant; and
- 7 The patient will not be prescribed more than 12 weeks' funded varenicline (see note).

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

- 1 Short-term therapy as an aid to achieving abstinence in a patient who has indicated that they are ready to cease smoking; and
- 2 The patient is part of, or is about to enrol in, a comprehensive support and counselling smoking cessation programme, which includes prescriber or nurse monitoring; and
- 3 The patient has not used funded varenicline in the last 12 months; and
- 4 Varenicline is not to be used in combination with other pharmacological smoking cessation treatments and the patient has agreed to this; and
- 5 The patient is not pregnant; and
- 6 The patient will not be prescribed more than 12 weeks' funded varenicline (see note).

The patient must not have had an approval in the past 12 months.

Notes: a maximum of 12 weeks' varenicline will be subsidised on each Special Authority approval.

This includes the 2-week 'starter' pack.

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

Chemotherapeutic Agents

Alkylating Agents

BENDAMUSTINE HYDROCHLORIDE - PCT only - Specialist - Special Authority see SA1667 below

Inj 25 mg vial	 	271.35	1	✓ Ribomustin
Inj 100 mg vial	 	1,085.38	1	✓ Ribomustin
Inj 1 mg for ECP	 	11.40	1 mg	✓ Baxter

⇒SA1667 Special Authority for Subsidy

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

All of the following:

- 1 The patient has Binet stage B or C, or progressive stage A chronic lymphocytic leukaemia requiring treatment; and
- 2 The patient is chemotherapy treatment naive; and
- 3 The patient is unable to tolerate toxicity of full-dose FCR; and
- 4 Patient has ECOG performance status 0-2; and
- 5 Patient has a Cumulative Illness Rating Scale (CIRS) score of < 6; and
- 6 Bendamustine is to be administered at a maximum dose of 100 mg/m² on days 1 and 2 every 4 weeks for a maximum of 6 cycles.

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

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

- 1 The patient has indolent low grade NHL requiring treatment; and
- 2 Patient has a WHO performance status of 0-2; and
- 3 Either:
 - 3.1 Both:
 - 3.1.1 Patient is treatment naive; and
 - 3.1.2 Bendamustine is to be administered for a maximum of 6 cycles (in combination with rituximab when CD20+); or
 - 3.2 All of the following:
 - 3.2.1 Patient has relapsed refractory disease following prior chemotherapy; and
 - 3.2.2 The patient has not received prior bendamustine therapy; and
 - 3.2.3 Fither:
 - 3.2.3.1 Both:
 - 3.2.3.1.1 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and
 - 3.2.3.1.2 Patient has had a rituximab treatment-free interval of 12 months or more: or
 - 3.2.3.2 Bendamustine is to be administered as a monotherapy for a maximum of 6 cycles in rituximab refractory patients.

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

Both:

- 1 Patients have not received a bendamustine regimen within the last 12 months; and
- 2 Either:
 - 2.1 Both:

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

- 2.1.1 Bendamustine is to be administered for a maximum of 6 cycles in relapsed patients (in combination with rituximab when CD20+); and
- 2.1.2 Patient has had a rituximab treatment-free interval of 12 months or more; or
- 2.2 Bendamustine is to be administered as a monotherapy for a maximum of 6 cycles in rituximab refractory patients. Note: 'indolent, low-grade lymphomas' includes follicular, mantle cell, marginal zone and lymphoplasmacytic/ Waldenstrom's macroglobulinaemia.

macroglobalinacinia.			
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 Ebew
Inj 10 mg per ml, 15 ml vial	14.05	1	✓ DBL Carboplatin
, ,	19.50		✓ Carbaccord
	22.50		✓ Carboplatin Ebeween
Inj 10 mg per ml, 45 ml vial	32.59	1	✓ DBL Carboplatin
	48.50		✓ Carbaccord
	50.00		✓ Carboplatin Ebeween
Inj 1 mg for ECP		1 mg	✓ Baxter
CARMUSTINE - PCT only - Specialist			
Inj 100 mg vial	532.00	1	✓ BiCNU
Inj 100 mg for ECP		100 mg OP	✓ Baxter
CHLORAMBUCIL - PCT - Retail pharmacy-Specialist		3 -	
Tab 2 mg	20.06	25	✓ Leukeran FC
<u> </u>	29.00	23	Leukeranii
CISPLATIN - PCT only - Specialist	10.00		A DDL Olambatic
Inj 1 mg per ml, 50 ml vial		1	✓ DBL Cisplatin
la: 4 are are al 400 articlet	15.00	4	✓ Cisplatin Ebewe
Inj 1 mg per ml, 100 ml vial		1	✓ Cisplatin Ebewe
Inj 1 mg for ECP	22.46	1 ma	✓ DBL Cisplatin✓ Baxter
, -	0.20	1 mg	▼ Daxter
CYCLOPHOSPHAMIDE			
Tab 50 mg - PCT - Retail pharmacy-Specialist	79.00	50	✓ Endoxan S29
	158.00	100	✓ Procytox S29
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		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		20	✓ CeeNU
MELPHALAN			
Tab 2 mg - PCT - Retail pharmacy-Specialist	40.70	25	✓ Alkeran
Inj 50 mg – PCT – Netali priarmacy-Specialist		25 1	✓ Alkeran
ing 50 mg - FOT only - Specialist	07.00	1	- AINCIAII

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
OXALIPLATIN - PCT only - Specialist				
Inj 5 mg per ml, 10 ml vial	13.32	1	1	Oxaliccord
Inj 50 mg vial		1	•	Oxaliplatin Actavis 50
	55.00		1	Oxaliplatin Ebewe
Inj 100 mg vial	25.01	1		Oxaliplatin Actavis 100
	110.00		1	Oxaliplatin Ebewe
Inj 5 mg per ml, 20 ml vial	16.00	1	✓	Oxaliccord
Inj 1 mg for ECP	0.18	1 mg	/	Baxter
THIOTEPA - PCT only - Specialist				
Inj 15 mg vial	CBS	1	1	Bedford S29
, 0			1	THIO-TEPA \$29
			1	Tepadina \$29
Inj 100 mg vial	CBS	1	_	Tepadina S29

Antimetabolites

AZACITIDINE - PCT only - Specialist - Special Authority se	e 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:

- 1 Any of the following:
 - 1.1 The patient has International Prognostic Scoring System (IPSS) intermediate-2 or high risk myelodysplastic syndrome; or
 - 1.2 The patient has chronic myelomonocytic leukaemia (10%-29% marrow blasts without myeloproliferative disorder); or
 - 1.3 The patient has acute myeloid leukaemia with 20-30% blasts and multi-lineage dysplasia, according to World Health Organisation Classification (WHO); and
- 2 The patient has performance status (WHO/ECOG) grade 0-2; and
- 3 The patient does not have secondary myelodysplastic syndrome resulting from chemical injury or prior treatment with chemotherapy and/or radiation for other diseases; and
- 4 The patient has an estimated life expectancy of at least 3 months.

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

Both:

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

	Subsidy	\	Fully	
	(Manufacturer's Prio	ce) Per	Subsidised <	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	1	Hospira
Inj 10 mg per ml, 5 ml vial - PCT - Retail pharmacy-Special	list4.55	1	/	Calcium Folinate Sandoz
Inj 50 mg - PCT - Retail pharmacy-Specialist	18.25	5	•	Calcium Folinate Ebewe
Inj 10 mg per ml, 10 ml vial - PCT only - Specialist	7.30	1	•	Calcium Folinate Sandoz
Inj 100 mg – PCT only – Specialist	7.33	1	•	Calcium Folinate Ebewe
Inj 300 mg - PCT only - Specialist	22.51	1	✓	Calcium Folinate Ebewe
Inj 10 mg per ml, 35 ml vial - PCT only - Specialist	20.95	1	•	Calcium Folinate Sandoz
Inj 1 g - PCT only - Specialist	67.51	1	✓	Calcium Folinate Ebewe
Inj 1 mg for ECP - PCT only - Specialist	0.06	1 mg	✓	Baxter
Tab 150 mg	11 15	60	/	Brinov
Tab 500 mg		120		Brinov
CLADRIBINE - PCT only - Specialist				
Inj 1 mg per ml, 10 ml	5,249.72	7	1	Leustatin
Inj 10 mg for ECP	749.96	10 mg C)P 🗸	Baxter
CYTARABINE				
Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Special		5		Pfizer
Inj 100 mg per ml, 10 ml vial – PCT – Retail pharmacy-Spec	cialist8.83	1	•	Pfizer
Inj 100 mg per ml, 20 ml vial – PCT – Retail pharmacy-Specialist	<i>1</i> 1.36	1	1	Pfizer
Inj 1 mg for ECP – PCT only – Specialist		10 mg		Baxter
Inj 100 mg intrathecal syringe for ECP – PCT only – Special		100 mg (Baxter
FLUDARABINE PHOSPHATE		ŭ		
Tab 10 mg - PCT - Retail pharmacy-Specialist	412.00	20	1	Fludara Oral
Inj 50 mg vial - PCT only - Specialist		5	1	Fludarabine Ebewe
Inj 50 mg for ECP - PCT only - Specialist	105.00	50 mg C)P 🗸	Baxter
FLUOROURACIL				
Inj 50 mg per ml, 20 ml vial - PCT only - Specialist		1		Fluorouracil Ebewe
Inj 50 mg per ml, 50 ml vial - PCT only - Specialist		1		Fluorouracil Ebewe
Inj 50 mg per ml, 100 ml vial – PCT only – Specialist		1	_	Fluorouracil Ebewe
Inj 1 mg for ECP – PCT only – Specialist	0.66	100 m	,	Baxter
GEMCITABINE HYDROCHLORIDE – PCT only – Specialist	00.75		_	DDI 0
Inj 1 g, 26.3 ml vial		1		DBL Gemcitabine
lnj 1 g		1		Gemcitabine Ebewe
Inj 200 mg	349.20	1		Gemzar Gemcitabine Ebewe
111j 200 111g	78.00	ı		Gemcitabine Ebewe
	70.00		•	MOITIEUI

[‡] safety cap

	Subsidy (Manufacturer's Pric	e) Per	Fully Subsidised	Brand or Generic Manufacturer
RINOTECAN 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	1	Baxter
IERCAPTOPURINE - PCT - Retail pharmacy-Specialist				
Tab 50 mg	49.41	25	•	Puri-nethol
IETHOTREXATE ← Tab 2.5 mg – PCT – Retail pharmacy-Specialist	3.18	30	1	Trexate
Tab 10 mg - PCT - Retail pharmacy-Specialist		50		Trexate
Inj 2.5 mg per ml, 2 ml - PCT - Retail pharmacy-Specialist	47.50	5	✓	Hospira
Inj 7.5 mg prefilled syringe	14.61	1	•	Methotrexate Sandoz
Inj 10 mg prefilled syringe	14.66	1	•	Methotrexate Sandoz
f Inj 15 mg prefilled syringe	14.77	1	•	Methotrexate Sandoz
f Inj 20 mg prefilled syringe	14.88	1	•	Methotrexate Sandoz
f Inj 25 mg prefilled syringe	14.99	1	•	Methotrexate Sandoz
f Inj 30 mg prefilled syringe	15.09	1	•	Methotrexate Sandoz
Finj 25 mg per ml, 2 ml vial - PCT - Retail pharmacy-Specia	alist30.00	5	•	DBL Methotrexate Onco-Vial
f Inj 25 mg per ml, 20 ml vial - PCT - Retail pharmacy-Spec	ialist45.00	1	•	DBL Methotrexate Onco-Vial
f Inj 100 mg per ml, 10 ml − PCT − Retail pharmacy-Special f Inj 100 mg per ml, 50 ml vial − PCT − Retail	ist25.00	1	•	Methotrexate Ebewe
pharmacy-Specialist	79.99	1	✓	Methotrexate Ebewe
Inj 1 mg for ECP - PCT only - Specialist	0.06	1 mg		Baxter
Inj 5 mg intrathecal syringe for ECP - PCT only - Specialis		5 mg O	P 🗸	Baxter
EMETREXED - PCT only - Specialist - Special Authority see			_	
Inj 100 mg vial		1		Juno Pemetrexed
Inj 500 mg vial		1		Juno Pemetrexed
Inj 1 mg for ECP	0.55	1 mg	•	Baxter

⇒SA1679 Special Authority for Subsidy

Initial application — (mesothelioma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria:

Both:

- 1 Patient has been diagnosed with mesothelioma; and
- 2 Pemetrexed to be administered at a dose of 500 mg/m² every 21 days in combination with cisplatin or carboplatin for a

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

continued...

maximum of 6 cycles.

Renewal — (mesothelioma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria:

All of the following:

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and the patient is benefitting from treatment; and
- 3 Pemetrexed to be administered at a dose of 500mg/m² every 21 days for a maximum of 6 cycles.

Initial application — (non-small cell lung carcinoma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria: Both:

- 1 Patient has locally advanced or metastatic non-squamous non-small cell lung carcinoma; and
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Patient has chemotherapy-naïve disease; and
 - 2.1.2 Pemetrexed is to be administered at a dose of 500 mg/m² every 21 days in combination with cisplatin or carboplatin for a maximum of 6 cycles; or
 - 2.2 All of the following:
 - 2.2.1 Patient has had first-line treatment with platinum based chemotherapy; and
 - 2.2.2 Patient has not received prior funded treatment with pemetrexed; and
 - 2.2.3 Pemetrexed is to be administered at a dose of 500 mg/m² every 21 days for a maximum of 6 cycles.

Renewal — (non-small cell lung carcinoma) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria:

All of the following:

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and the patient is benefitting from treatment; and
- 3 Pemetrexed is to be administered at a dose of 500mg/m² every 21 days.

THIOGUAININE - POT - 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 ampoule1,500.00	6	✓ Amsidine S29
Inj 75 mg1,250.00	5	✓ AmsaLyo S29
ANAGRELIDE HYDROCHLORIDE - PCT - Retail pharmacy-Specialist		
Cap 0.5 mgCBS	100	✓ Agrylin S29
		✓ Teva S29
ARSENIC TRIOXIDE - PCT only - Specialist		
Inj 10 mg4,817.00	10	✓ AFT S29
BLEOMYCIN SULPHATE - PCT only - Specialist		
Inj 15,000 iu, vial	1	 DBL Bleomycin Sulfate
Inj 1,000 iu for ECP11.64	1,000 iu	✓ Baxter
BORTEZOMIB - PCT only - Specialist - Special Authority see SA1576 on the nu	ext page	
Inj 3.5 mg vial1,892.50	1	✓ Velcade
Inj 1 mg for ECP594.77	1 mg	✓ Baxter

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

⇒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.

COLASPASE [L-ASPARAGINASE] - PCT only - Specialist

Renewal — (Relapsed/refractory multiple myeloma/amyloidosis) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 8 months for applications meeting the following criteria:

Both:

- 1 The patient's disease obtained at least a partial response from treatment with bortezomib at the completion of cycle 4; and
- 2 Maximum of 4 further treatment cycles (making a total maximum of 8 consecutive treatment cycles).

Notes: Responding relapsed/refractory multiple myeloma patients should receive no more than 2 additional cycles of treatment beyond the cycle at which a confirmed complete response was first achieved. A line of therapy is considered to comprise either:

- a) a known therapeutic chemotherapy regimen and supportive treatments; or
- b) a transplant induction chemotherapy regimen, stem cell transplantation and supportive treatments.

Refer to datasheet for recommended dosage and number of doses of bortezomib per treatment cycle.

Inj 10,000 iu	102.32	1	✓ Leunase
Inj 10,000 iu for ECP		10,000 iu OP	✓ Baxter
DACARBAZINE - PCT only - Specialist			
Inj 200 mg vial	58.06	1	 DBL Dacarbazine
	580.60	10	✓ Dacarbazine APP \$29
Inj 200 mg for ECP	58.06	200 mg OP	✓ Baxter
DACTINOMYCIN [ACTINOMYCIN D] - PCT only - Specialist			
Inj 0.5 mg vial	166.75	1	✓ Cosmegen
Inj 0.5 mg for ECP		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

	Subsidy		Fully	Brand or
	(Manufacturer's Price) \$	Per	Subsidised	Generic Manufacturer
OCETAXEL - PCT only - Specialist	· · · · · · · · · · · · · · · · · · ·			
Inj 10 mg per ml, 2 ml vial	12.40	1	✓ [OBL Docetaxel
Inj 20 mg		1		Oocetaxel Sandoz
Inj 10 mg per ml, 8 ml vial		1	√ [OBL Docetaxel
Inj 80 mg		1	✓ [Docetaxel Sandoz
Inj 1 mg for ECP		1 mg	✓ E	Baxter
OXORUBICIN 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		1	√ [Doxorubicin Ebewe
, 3, - , -	17.00		✓ /	Arrow-Doxorubicin
Inj 2 mg per ml, 50 ml vial	23.00	1	√ [Doxorubicin Ebewe
Inj 2 mg per ml, 100 ml vial		1	✓ [Doxorubicin Ebewe
, 01	65.00		✓	Arrow-Doxorubicin
Inj 1 mg for ECP	0.25	1 mg	✓ E	Baxter
PIRUBICIN HYDROCHLORIDE - PCT only - Specialist				
Inj 2 mg per ml, 5 ml vial	25.00	1	√ E	Epirubicin Ebewe
Inj 2 mg per ml, 25 ml vial		1		Epirubicin Ebewe
Inj 2 mg per ml, 50 ml vial		1		Epirubicin Ebewe
Inj 2 mg per ml, 100 ml vial		1		Epirubicin Ebewe
Inj 1 mg for ECP		1 mg		Baxter
OPOSIDE		9		
Cap 50 mg - PCT - Retail pharmacy-Specialist	340.73	20	✓ \	/epesid
Cap 100 mg - PCT - Retail pharmacy-Specialist		10		/epesid
Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Spec		1		Rex Medical
Inj 1 mg for ECP – PCT only – Specialist		1 mg	- =	Baxter
OPOSIDE PHOSPHATE - PCT only - Specialist		3		
Inj 100 mg (of etoposide base)	40.00	1	√ F	Etopophos
Inj 1 mg (of etoposide base) for ECP		1 mg	_	Baxter
, , , ,		i ilig	٠.	Jaktol
DROXYUREA – PCT – Retail pharmacy-Specialist	01.76	100	./ ۱	Juduaa
Cap 500 mg	31./0	100	V F	Hydrea
ARUBICIN HYDROCHLORIDE	405.00			
Inj 5 mg vial – PCT only – Specialist		1	_	Zavedos
Inj 10 mg vial – PCT only – Specialist		. 1	_	Zavedos
Inj 1 mg for ECP - PCT only - Specialist	27.75	1 mg	✓ E	Baxter
NALIDOMIDE – Retail pharmacy-Specialist – Special Authomatage claimable – see rule 3.3.2 on page 13	ority see SA1468 below	1		
Cap 10 mg	6,207.00	21	√ F	Revlimid
Cap 15 mg		21	√ F	Revlimid
Cap 25 mg		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:

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

continued...

- 2.2.1 Lenalidomide to be used as second line treatment for multiple myeloma; and
- 2.2.2 The patient has experienced severe (grade 3 or higher), dose limiting, peripheral neuropathy with either bortezomib or thalidomide that precludes further treatment with either of these treatments; and
- 3 Lenalidomide to be administered at a maximum dose of 25 mg/day in combination with dexamethasone.

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

Both:

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

Note: Indication marked with * is an Unapproved Indication (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.

MFSNA

Tab 400 mg - PCT - Retail pharmacy-Specialist273.00	50	✓ Uromitexan
Tab 600 mg - PCT - Retail pharmacy-Specialist407.50	50	✓ Uromitexan
Inj 100 mg per ml, 4 ml ampoule - PCT only - Specialist161.25	15	✓ Uromitexan
Inj 100 mg per ml, 10 ml ampoule - PCT only - Specialist370.35	15	✓ Uromitexan
Inj 1 mg for ECP - PCT only - Specialist2.69	100 mg	✓ Baxter
MITOMYCIN C - PCT only - Specialist	-	
Inj 5 mg vial204.08	1	✓ Arrow
Inj 1 mg for ECP42.04	1 mg	✓ Baxter
MITOZANTRONE - PCT only - Specialist	· ·	
Inj 2 mg per ml, 10 ml vial97.50	1	✓ Mitozantrone Ebewe
Inj 1 mg for ECP5.51	1 mg	✓ Baxter
PACLITAXEL - PCT only - Specialist	· ·	
Inj 30 mg47.30	5	✓ Paclitaxel Ebewe
Inj 100 mg20.00	1	✓ Paclitaxel Ebewe
91.67		✓ Paclitaxel Actavis
Inj 150 mg26.69	1	✓ Paclitaxel Ebewe
137.50		✓ Anzatax
		✓ Paclitaxel Actavis
Inj 300 mg35.35	1	✓ Paclitaxel Ebewe
275.00		✓ Anzatax
		✓ Paclitaxel Actavis
Inj 600 mg73.06	1	✓ Paclitaxel Ebewe
Inj 1 mg for ECP	1 mg	✓ Baxter
(Paclitaxel Ebewe Inj 600 mg to be delisted 1 April 2018)	3	
PEGASPARGASE – PCT only – Special Authority see SA1325 below		
Inj 3,750 IU per 5 ml3,005.00	1	✓ Oncaspar S29
		•

⇒SA1325 Special Authority for Subsidy

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

All of the following:

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

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

continued...

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 mgCBS	1	✓ Nipent S29
PROCARBAZINE HYDROCHLORIDE - PCT - Retail pharmacy-Specialist		
Cap 50 mg498.00	50	✓ Natulan S29
TEMOZOLOMIDE - Special Authority see SA1616 below - Retail pharmacy		
Cap 5 mg10.20	5	✓ Orion
		<u>Temozolomide</u>
Cap 20 mg18.30	5	✓ Orion
		<u>Temozolomide</u>
		✓ Temizole 20 S29
Cap 100 mg40.20	5	✓ <u>Orion</u>
		Temozolomide
Cap 140 mg56.00	5	✓ Orion
		Temozolomide
Cap 250 mg96.80	5	✓ Orion
		<u>Temozolomide</u>

⇒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:

Sut	bsidy F	ully Brand	lor
(Manufacti	turer's Price) Subsidis	sed Gene	ric
	\$ Per	✓ Manu	facturer

continued...

- 1.1 Patient has glioblastoma multiforme; and
- 1.2 The treatment remains appropriate and the patient is benefitting from treatment; or
- 2 All of the following:
 - 2.1 Patient has anaplastic astrocytoma*: and
 - 2.2 The treatment remains appropriate and the patient is benefitting from treatment; and
 - 2.3 Adjuvant temozolomide is to be used for a maximum of 24 months.

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

Both:

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

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

THALIDOMIDE - Retail pharmacy-Specialist - Special A	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:

Fither:

- 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-Specialist479.50	100	✓ Vesanoid
VINBLASTINE SULPHATE		
Inj 1 mg per ml, 10 ml vial - PCT - Retail pharmacy-Specialist37.29	1	✓ Vinblastina
		Teva S29
186.46	5	✓ Hospira
Inj 1 mg for ECP - PCT only - Specialist4.14	1 mg	✓ Baxter
VINCRISTINE SULPHATE		
Inj 1 mg per ml, 1 ml vial - PCT - Retail pharmacy-Specialist74.52	5	✓ DBL Vincristine Sulfate
Inj 1 mg per ml, 2 ml vial – PCT – Retail pharmacy-Specialist85.61	5	✓ DBL Vincristine
ing 1 mg per mi, 2 mi viai -1 01 - netaii phamacy-opeciaist	3	Sulfate
Inj 1 mg for ECP - PCT only - Specialist11.30	1 mg	✓ Baxter
VINORELBINE - PCT only - Specialist		
Inj 10 mg per ml, 1 ml vial8.00	1	✓ Navelbine
42.00		✓ Vinorelbine Ebewe
Inj 10 mg per ml, 5 ml vial40.00	1	✓ Navelbine
210.00		✓ Vinorelbine Ebewe
Inj 1 mg for ECP0.90	1 mg	✓ Baxter

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

Protein-tyrosine Kinase Inhibitors

DASATINIB - Special Authority see SA0976 below - [Xph	narm]		
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	· ·	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

- a) Funded for patients with diagnosis (confirmed by a haematologist) of a chronic myeloid leukaemia (CML) in blast crisis, accelerated phase, or in chronic phase.
- b) Maximum dose of 140 mg/day for accelerated or blast phase, and 100 mg/day for chronic phase CML.
- c) Subsidised for use as monotherapy only.
- d) Initial approvals valid seven months.
- e) 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

- a) 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 x 10⁹/L, platelets > 100 x 10⁹/L, absence of peripheral blood (PB) blasts, bone marrow (BM) blasts < 5% (or FISH Ph+ 0-35% metaphases), and absence of extramedullary disease); or
 - 2) no evidence of leukaemia (as characterised by an absolute neutrophil count (ANC) > 1.0×10^9 /L, platelets > 20×10^9 /L, absence of peripheral blood (PB) blasts, bone marrow (BM) blasts < 5% (or FISH Ph+ 0-35% metaphases), and absence of extramedullary disease); or
 - 3) 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).
- b) 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 SA1653 below		
Tab 100 mg	764.00	30	✓ Tarceva
Tab 150 mg	1,146.00	30	✓ Tarceva

⇒SA1653 Special Authority for Subsidy

Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist.

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

continued...

Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

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

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

GEFITINIB - Retail pharmacy-Specialist - Special Authority see SA1654 below

Tab 250 mg1,700.00 30 ✓ Iressa

⇒SA1654 Special Authority for Subsidy

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

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

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

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 below -

	[Xpharm]	2,400.00	60	✓ Glivec
*	Cap 100 mg		60	✓ Imatinib-AFT
*	Cap 400 mg	197.50	30	✓ Imatinib-AFT

⇒SA1460 Special Authority for Subsidy

Special Authority approved by the CML/GIST Co-ordinator

Notes: Application details may be obtained from PHARMAC's website http://www.pharmac.govt.nz, and prescriptions should be sent to:

The CML/GIST Co-ordinator Phone: (04) 460 4990 PHARMAC Facsimile: (04) 916 7571

PO Box 10 254 Email: cmlgistcoordinator@pharmac.govt.nz

Wellington

Special Authority criteria for GIST – access by application

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

continued...

Funded for patients:

- a) With a diagnosis (confirmed by an oncologist) of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST).
- b) Maximum dose of 400 mg/day.
- c) Applications to be made and subsequent prescriptions can be written by an oncologist.
- d) Initial and subsequent applications are valid for one year. The re-application criterion is an adequate clinical response to the treatment with imatinib (prescriber determined).

LAPATINIB DITOSYLATE − Special Authority see SA1191 below − Retail pharmacy
Tab 250 mg1,899.00 70 ✓ Tykerb

⇒SA1191 Special Authority for Subsidy

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

Either:

- 1 All of the following:
 - 1.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
 - 1.2 The patient has not previously received trastuzumab treatment for HER 2 positive metastatic breast cancer; and
 - 1.3 Lapatinib not to be given in combination with trastuzumab; and
 - 1.4 Lapatinib to be discontinued at disease progression; or
- 2 All of the following:
 - 2.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
 - 2.2 The patient started trastuzumab for metastatic breast cancer but discontinued trastuzumab within 3 months of starting treatment due to intolerance; and
 - 2.3 The cancer did not progress whilst on trastuzumab; and
 - 2.4 Lapatinib not to be given in combination with trastuzumab; and
 - 2.5 Lapatinib to be discontinued at disease progression.

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

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 The cancer has not progressed at any time point during the previous 12 months whilst on lapatinib; and
- 3 Lapatinib not to be given in combination with trastuzumab; and
- 4 Lapatinib to be discontinued at disease progression.

NILOTINIB - Special Authority see SA1489 below - 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

⇒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

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

continued...

- 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 less than or equal to 70; or
 - 5.6 2 or more sites of organ metastasis; and
- 6 Pazopanib to be used for a maximum of 3 months.

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

Both:

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

Notes: Pazopanib treatment should be stopped if disease progresses.

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

SUNITINIB - Special Authority see SA1266 on the next page - Retail pharmacy

Cap 12.5 mg2,315	5.38 28	✓ Sutent
Cap 25 mg4,630).77 28	✓ Sutent
Cap 50 mg	.54 28	✓ Sutent

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⇒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 less than or equal to 70; or
 - 5.6 2 or more sites of organ metastasis; and
- 6 Sunitinib to be used for a maximum of 2 cycles.

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

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

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

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

Notes: Sunitinib treatment should be stopped if disease progresses.

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

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

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

- 1 Any of the following:
 - 1.1 The patient has had a complete response (disappearance of all lesions and no new lesions); or

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	\$ Pe	er 🗸	Manufacturer

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

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

Endocrine Therapy

For GnRH ANALOGUES - refer to HORMONE PREPARATIONS, Trophic Hormones, page 96

ABIRATERONE ACETATE - Retail pharmacy-Specialist - Special Authority see SA1515 below

Wastage claimable – see rule 3.3.2 on page 13

Tab 250 mg4,276.19 120 **✓ 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:

- 1 Significant decrease in serum PSA from baseline; and
- 2 No evidence of clinical disease progression; and
- 3 No initiation of taxane chemotherapy with abiraterone; and
- 4 The treatment remains appropriate and the patient is benefiting from treatment.

BICALUTAMIDE

 Tab 50 mg
 3.80
 28
 ✓ Binarex

 (4.90)
 Bicalaccord

Binarex to be Sole Supply on 1 May 2018 (Bicalaccord Tab 50 mg to be delisted 1 May 2018)

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	I Generic
FLUTAMIDE - Retail pharmacy-Specialist Tab 250 mg		30		Flutamide Mylan S29
MEGESTROL ACETATE – Retail pharmacy-Specialist Tab 160 mg	55.00 54.30	100 30		Flutamin Apo-Megestrol
OCTREOTIDE Inj 50 mcg per ml, 1 ml vial Inj 100 mcg per ml, 1 ml vial	18.69	5	1	DBL Octreotide DBL Octreotide
Inj 500 mcg per ml, 1 ml ampoule	72.50	5 5		Octreotide MaxRx DBL Octreotide
OCTREOTIDE LAR (SOMATOSTATIN ANALOGUE) – Special Inj LAR 10 mg prefilled syringe	1,772.50 2,358.75	belo 1 1 1	1	pharmacy Sandostatin LAR Sandostatin LAR Sandostatin LAR

⇒SA1016 Special Authority for Subsidy

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

All of the following:

- 1 The patient has nausea* and vomiting* due to malignant bowel obstruction*; and
- 2 Treatment with antiemetics, rehydration, antimuscarinic agents, corticosteroids and analgesics for at least 48 hours has failed; and
- 3 Octreotide to be given at a maximum dose 1500 mcg daily for up to 4 weeks.

Note: Indications marked with * are Unapproved Indications.

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

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

Both:

- 1 The patient has acromegaly; and
- 2 Any of the following:
 - 2.1 Treatment with surgery, radiotherapy and a dopamine agonist has failed; or
 - 2.2 Treatment with octreotide is for an interim period while awaiting the effects of radiotherapy and a dopamine agonist has failed; or
 - 2.3 The patient is unwilling, or unable, to undergo surgery and/or radiotherapy.

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

Both:

- 1 IGF1 levels have decreased since starting octreotide; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

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

Initial application — (Other Indications) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

(manufacturer's Price) Subsidised Generic \$ Per ✓ Manufacturer		Subsidy (Manufacturer's Price) \$		Fully bsidised	Brand or Generic Manufacturer	
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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 Roth
 - 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 mg19	9.50	100	✓ Genox
	Tab 20 mg		30	✓ Genox
	11	2.50	100	✓ Genox

Aromatase Inhibitors

	5.04	30	✓ Rolin
	(26.55)		Aremed
	(26.55)		Arimidex
	(26.55)		DP-Anastrozole
be Sole Supply on 1 April 2018	, ,		
ng to be delisted 1 April 2018)			
	be Sole Supply on 1 April 2018 to be delisted 1 April 2018)		

(Arimidex Tab 1 mg to be delisted 1 April 2018)

(DP-Anastrozole Tab 1 mg to be delisted 1 April 2018)

EXEMESTANE

I FTROZOLF

Immunosuppressants

Cytotoxic Immunosuppressants

AZ	ATHIOPRINE – Retail pharmacy-Specialist		
*	Tab 25 mg	100	Imuran
*	Tab 50 mg - For azathioprine oral liquid formulation refer.		
	page 22710.58	100	✓ Imuran
*	Inj 50 mg vial60.00	1	✓ Imuran

	Subsidy (Manufacturer's Pi	rice) Subs	Fully idised	Brand or Generic Manufacturer
MYCOPHENOLATE MOFETIL Tab 500 mg	25.00	50		Cellcept
Cap 250 mg Powder for oral lig 1 g per 5 ml — Subsidy by endorsement	25.00	100 165 ml OP		Cellcept Cellcept
Mycophenolate powder for oral liquid is subsidised only the prescription is endorsed accordingly.				

Fusion Proteins

ETANERCEPT - Special Authority see SA1620 below - Retail p	harmacy		
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:

- 1.1 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 ioints: or
 - 2.5.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and
 - 2.5.2 Physician's global assessment indicating severe disease.

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

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for adalimumab for rheumatoid arthritis; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
 - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for rheumatoid arthritis; or
- 2 All of the following:

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- 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 Fither:
 - 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 Fither
 - 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 plague psoriasis; or
- 2 All of the following:
 - 2.1 Either:
 - 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 15, where lesions have been present for at least 6 months from the time of initial diagnosis; or
 - 2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
 - 2.2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin. or acitretin: and
 - 2.3 A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and

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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 sacroillitis demonstrated by plain radiographs, CT or MRI scan; and
 - 2.4 Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and
 - 2.5 Either:
 - 2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following Bath Ankylosing Spondylitis Metrology Index (BASMI) measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or
 - 2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender (see Notes); and
 - 2.6 A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 6 on a 0-10 scale.

Notes: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure must be no more than 1 month old at the time of initial application.

Average normal chest expansion corrected for age and gender:

18-24 years - Male: 7.0 cm; Female: 5.5 cm

25-34 years - Male: 7.5 cm: Female: 5.5 cm

35-44 years - Male: 6.5 cm; Female: 4.5 cm

45-54 years - Male: 6.0 cm; Female: 5.0 cm

55-64 years - Male: 5.5 cm: Female: 4.0 cm

65-74 years - Male: 4.0 cm; Female: 4.0 cm

75+ years - Male: 3.0 cm; Female: 2.5 cm

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

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for adalimumab for psoriatic arthritis; and
 - 1.2 Either
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or

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- 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:

Fither:

- 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 Fither:
 - 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:

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All of the following:

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

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

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

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

All of the following:

- 1 Either:
 - 1.1 Applicant is a dermatologist; or
 - 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 plague 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

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\$	Per	•	Manufacturer

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2.2.2.2 Following each prior etanercept treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; and

3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

Note: A treatment course is defined as a minimum of 12 weeks of etanercept treatment

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

All of the following:

- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 Following 12 weeks' initial treatment and for subsequent renewals, treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10 point scale, or an improvement in BASDAI of 50%, whichever is less; and
- 3 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and
- 4 Etanercept to be administered at doses no greater than 50 mg every 7 days.

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

All of the following:

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

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

	Subsidy (Manufacturer's Price) \$	Su Per	Fully bsidised	Brand or Generic Manufacturer
BACILLUS CALMETTE-GUERIN (BCG) VACCINE – PCT only – Subsidised only for bladder cancer. Inj 2-8 × 100 million CFU	•	1	√ Oı	ncoTICE

Monoclonal Antibodies

ADALIMUMAB – Special Authority see SA1621 below –	Retail pharmacy		
Inj 20 mg per 0.4 ml prefilled syringe	1,599.96	2	Humira
Inj 40 mg per 0.8 ml prefilled pen	1,599.96	2	✓ HumiraPen
Ini 40 mg per 0.8 ml prefilled syringe	1.599.96	2	✓ Humira

⇒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
- 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 hydroxychloroguine 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:

continued...

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

continued...

- 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:
 - 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

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continued...

- 2 All of the following:
 - 2.1 Patient has a confirmed diagnosis of ankylosing spondylitis for more than six months; and
 - 2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
 - 2.3 Patient has bilateral sacroiliitis demonstrated by plain radiographs, CT or MRI scan; and
 - 2.4 Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis; and
 - 2.5 Either:
 - 2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following Bath Ankylosing Spondylitis Metrology Index (BASMI) measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right); or
 - 2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the following average normal values corrected for age and gender (see Notes); and
 - 2.6 A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 6 on a 0-10 scale.

Notes: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure must be no more than 1 month old at the time of initial application.

Average normal chest expansion corrected for age and gender:

18-24 years - Male: 7.0 cm; Female: 5.5 cm 25-34 years - Male: 7.5 cm; Female: 5.5 cm 35-44 years - Male: 6.5 cm; Female: 4.5 cm 45-54 years - Male: 6.0 cm; Female: 5.0 cm 55-64 years - Male: 5.5 cm; Female: 4.0 cm 65-74 years - Male: 4.0 cm; Female: 4.0 cm 75+ years - Male: 3.0 cm; Female: 2.5 cm

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

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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:
 - 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 Fither:
 - 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).

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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 Fither:
 - 1.1.1 The patient has had an initial Special Authority approval for etanercept for adult-onset Still's disease
 - 1.1.2 The patient has been started on tocilizumab for AOSD in a DHB hospital in accordance with the HML rules: and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
 - 1.2.2 The patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab such that they do not meet the renewal criteria for AOSD: or
- 2 All of the following:
 - 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and
 - 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal anti-inflammatory drugs (NSAIDs) and methotrexate; and
 - 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

Renewal — (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 Fither:
 - 2.1 Fither:
 - 2.1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab;

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- 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 Fither:
 - 1.1 Applicant is a dermatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
 - 2.1.2 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

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

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- 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with 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 Fither:
 - 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 Fither:
 - 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 Fither:
 - 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.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
CETUXIMAB - PCT only - Specialist - Special Authority see SA	1697 below			
Inj 5 mg per ml, 20 ml vial	364.00	1	✓ E	Erbitux
Inj 5 mg per ml, 100 ml vial	1,820.00	1	✓ E	Erbitux
Inj 1 mg for ECP	3.82	1 mg	✓ E	Baxter

SA1697 Special Authority for Subsidy

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

All of the following:

- 1 Patient has locally advanced, non-metastatic, squamous cell cancer of the head and neck; and
- 2 Patient is contraindicated to, or is intolerant of, cisplatin; and
- 3 Patient has good performance status; and
- 4 To be administered in combination with radiation therapy.

OBINUTUZUMAB – PCT only – Specialist – Special A	Authority see SA1627 below
Ini 05 mg nor ml 40 ml viol	E 010 00

✓ Gazyva	1	Inj 25 mg per ml, 40 ml vial5,910.00
Baxter	1 mg	Inj 1 mg for ECP

⇒SA1627 Special Authority for Subsidy

Initial application — (chronic lymphocytic leukaemia) only from a haematologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has progressive Binet stage A, B or C CD20+ chronic lymphocytic leukaemia requiring treatment; and
- 2 The patient is obinutuzumab treatment naive; and
- 3 The patient is not eligible for full dose FCR due to comorbidities with a score > 6 on the Cumulative Illness Rating Scale (CIRS) or reduced renal function (creatinine clearance < 70mL/min); and</p>
- 4 Patient has adequate neutrophil and platelet counts* unless the cytopenias are a consequence of marrow infiltration by CLL; and
- 5 Patient has good performance status; and
- 6 Obinutuzumab to be administered at a maximum cumulative dose of 8,000 mg and in combination with chlorambucil for a maximum of 6 cycles.

Notes: Chronic lymphocytic leukaemia includes small lymphocytic lymphoma. Comorbidity refers only to illness/impairment other than CLL induced illness/impairment in the patient. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with obinutuzumab is expected to improve symptoms and improve ECOG score to < 2.

* Neutrophil greater than or equal to 1.5×10^9 /L and platelets greater than or equal to 75×10^9 /L.

OMALIZUMAB – Special Authority see SA1490 below – Retail pharmacy
Inj 150 mg vial500.00 1 ✓ Xolair

⇒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:

- 1 Patient is over the age of 6: and
- 2 Patient has a diagnosis of severe, life threatening asthma; and
- 3 Past or current evidence of atopy, documented by skin prick testing or RAST; and
- 4 Total serum human immunoglobulin E (IgE) between 76 IU/mL and 1300 IU/ml at baseline; and
- 5 Proven 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 eformoterol 12 micrograms bd) for at least 12 months, unless contraindicated or not tolerated; and
- 6 Patient has received courses of systemic corticosteroids equivalent to at least 28 days treatment in the past 12 months,

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unless contraindicated or not tolerated: and

- 7 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
- 8 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:

- 1 Hospital admissions have been reduced as a result of treatment; and
- 2 A reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 1.0 from baseline; and
- 3 A reduction in the maintenance oral corticosteroid dose of at least 50% from baseline.

PERTUZUMAB - PCT only - Specialist - Special Authorit	y 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:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 Either:
 - 2.1 Patient is chemotherapy treatment naïve; or
 - 2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer; and
- 3 The patient has good performance status (ECOG grade 0-1); and
- 4 Pertuzumab to be administered in combination with trastuzumab; and
- 5 Pertuzumab maximum first dose of 840 mg, followed by maximum of 420 mg every 3 weeks; and
- 6 Pertuzumab to be discontinued at disease progression.

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

Both:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 The cancer has not progressed at any time point during the previous 12 months whilst on pertuzumab and trastuzumab.

		B - PCT only - Specialist - Special Authority see SA1686 below	RITUXIMAB - PCT only - Spe
Mabthera	2) mg per 10 ml vial1,075.50	Inj 100 mg per 10 ml vial
Mabthera	1) mg per 50 ml vial2,688.30	Inj 500 mg per 50 ml vial
✓ Baxter	1 ma	ng for FCP 5.64	Ini 1 mg for FCP

⇒SA1686 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:

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(Manufacturer's Price	·) :	Subsidised	Generic	
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Fither:

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

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

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

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

- 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
- 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 an interval of 36 months or more since commencement of initial rituximab treatment; 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) or bendamustine: and
- 5 Rituximab to be administered in combination with fludarabine and cyclophosphamide or bendamustine 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
Ini 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 – Speci 	alist – Special Authorii	ty see SA1632	on the next page
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Inj 150 mg vial	1,350.00	✓	Herceptin
Inj 440 mg vial		✓	Herceptin
Inj 1 mg for ECP	9.36 1 r	ng 🗸	Baxter

Subsidy	y Full	/ Brand or
(Manufacturer's	s Price) Subsidise	d Generic
\$	Per 🗸	Manufacturer

⇒SA1632 Special Authority for Subsidy

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

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
 - 2 Either:
 - 2.1 The patient has not previously received lapatinib treatment for HER-2 positive metastatic breast cancer; or
 - 2.2 Both:
 - 2.2.1 The patient started lapatinib treatment for metastatic breast cancer but discontinued lapatinib within 3 months of starting treatment due to intolerance; and
 - 2.2.2 The cancer did not progress whilst on lapatinib; and
 - 3 Either:
 - 3.1 Trastuzumab will not be given in combination with pertuzumab; or
 - 3.2 All of the following:
 - 3.2.1 Trastuzumab to be administered in combination with pertuzumab; and
 - 3.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer: and
 - 3.2.3 The patient has good performance status (ECOG grade 0-1); and
 - 4 Trastuzumab not to be given in combination with lapatinib; and
 - 5 Trastuzumab to be discontinued at disease progression.

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

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
- 3 Trastuzumab not to be given in combination with lapatinib; and
- 4 Trastuzumab to be discontinued at disease progression.

Initial application — (early breast cancer) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 15 months for applications meeting the following criteria:

All of the following:

- 1 The patient has early breast cancer expressing HER 2 IHC 3+ or ISH + (including FISH or other current technology); and
- 2 Maximum cumulative dose of 106 mg/kg (12 months' treatment); and
- 3 Any of the following:
 - 3.1 9 weeks' concurrent treatment with adjuvant chemotherapy is planned; or
 - 3.2 12 months' concurrent treatment with adjuvant chemotherapy is planned; or
 - 3.3 12 months' sequential treatment following adjuvant chemotherapy is planned; or
 - 3.4 12 months' treatment with neoadjuvant and adjuvant chemotherapy is planned; or
 - 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

Subsidy (Manufacturer's Price)	Subs	Fully	Brand or Generic
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continued...

- 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 Fither:
 - 4.1 Trastuzumab will not be given in combination with pertuzumab; or
 - 4.2 All of the following:
 - 4.2.1 Trastuzumab to be administered in combination with pertuzumab; and
 - 4.2.2 Patient has not received prior treatment for their metastatic disease and has had a treatment-free interval of at least 12 months between prior (neo)adjuvant chemotherapy treatment and diagnosis of metastatic breast cancer: and
 - 4.2.3 The patient has good performance status (ECOG grade 0-1); and
- 5 Trastuzumab not to be given in combination with lapatinib; and
- 6 Trastuzumab to be discontinued at disease progression.

Note: * For patients with relapsed HER-2 positive disease who have previously received adjuvant trastuzumab for early breast cancer.

Programmed Cell Death-1 (PD-1) Inhibitors

		- PCT only - Specialist - Special Authority see SA1656 below	NIVOLUMAB - PCT only - Specia
Opdivo	1	per ml, 4 ml vial	Inj 10 mg per ml, 4 ml vial
✓ Opdivo	1	per ml, 10 ml vial2,629.96	Inj 10 mg per ml, 10 ml vial
✓ Baxter	1 mg	or ECP27.62	Inj 1 mg for ECP

⇒SA1656 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 The patient has ECOG performance score of 0-2; and
- 4 Either:
 - 4.1 Patient has not received funded pembrolizumab; or
 - 4.2 Both:
 - 4.2.1 Patient has received an initial Special Authority approval for pembrolizumab and has discontinued pembrolizumab within 12 weeks of starting treatment due to intolerance; and
 - 4.2.2 The cancer did not progress while the patient was on pembrolizumab; and
- 5 Nivolumab is to be used at a maximum dose of 3 mg/kg every 2 weeks for a maximum of 12 weeks (6 cycles); and
- 6 Baseline measurement of overall tumour burden is documented (see Note); and
- 7 Documentation confirming that the patient has been informed and acknowledges that the initial funded treatment period of nivolumab will not be continued beyond 12 weeks (6 cycles) if their disease progresses during this time.

Renewal — (unresectable or metastatic melanoma) only from a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

1 Any of the following:

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

continued...

- 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:

- 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 SA1657 below
Inj 50 mg vial2,340.00 1 ✓ Keytruda
Inj 1 mg for ECP49.14 1 mg ✓ Baxter

⇒SA1657 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 The patient has ECOG performance score of 0-2; and
- 4 Fither:
 - 4.1 Patient has not received funded nivolumab; or
 - 4.2 Both:
 - 4.2.1 Patient has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance; and
 - 4.2.2 The cancer did not progress while the patient was on nivolumab; and
- 5 Pembrolizumab is to be used at a maximum dose of 2 mg/kg every 3 weeks for a maximum of 12 weeks (4 cycles); and
- 6 Baseline measurement of overall tumour burden is documented (see Note); and
- 7 Documentation confirming that the patient has been informed and acknowledges that the initial funded treatment period of pembrolizumab will not be continued beyond 12 weeks (4 cycles) if their disease progresses during this time.

Renewal — (unresectable or metastatic melanoma) only from a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

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

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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).

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		50	✓ Neoral
Cap 100 mg		50	✓ Neoral
Oral liq 100 mg per ml		50 ml OP	✓ Neoral
EVEROLIMUS - Special Authority see SA1491 below - Retail	pharmacy		
Wastage claimable – see rule 3.3.2 on page 13			
Tab 10 mg	6,512.29	30	Afinitor
Tab 5 mg	4,555.76	30	Afinitor

⇒SA1491 Special Authority for Subsidy

Initial application only from a neurologist or oncologist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 Patient has tuberous sclerosis: and
- 2 Patient has progressively enlarging sub-ependymal giant cell astrocytomas (SEGAs) that require treatment.

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

Subsidy	Fully		Brand or
(Manufacturer's Price)	Subsidised		Generic
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- 1 Documented evidence of SEGA reduction or stabilisation by MRI within the last 3 months; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment; and
- 3 Everolimus to be discontinued at progression of SEGAs.

Note: MRI should be performed at minimum once every 12 months, more frequent scanning should be performed with new onset of symptoms such as headaches, visual complaints, nausea or vomiting, or increase in seizure activity.

SIROLIMUS - Special Authority see SA0866 below - Retail pharmacy

Tab 1 mg	749.99	100	Rapamune
Tab 2 mg	1,499.99	100	✓ Rapamune
Oral liq 1 mg per ml	449.99	60 ml OP	Rapamune

⇒SA0866 Special Authority for Subsidy

Initial application from any medical practitioner. Approvals valid without further renewal unless notified where the drug is to be used for rescue therapy for an organ transplant recipient.

Notes: Rescue therapy defined as unresponsive to calcineurin inhibitor treatment as defined by refractory rejection; or intolerant to calcineurin inhibitor treatment due to any of the following:

- GFR< 30 ml/min: or
- Rapidly progressive transplant vasculopathy; or
- Rapidly progressive obstructive bronchiolitis; or
- . HUS or TTP; or
- · Leukoencepthalopathy; or
- · Significant malignant disease

TACROLIMUS - Special Authority see SA1540 below - Retail pharmacy

Cap 0.5 mg	85.60	100	Tacrolimus Sandoz
Cap 1 mg	171.20	100	✓ Tacrolimus Sandoz
Cap 5 mg - For tacrolimus oral liquid formulation refer,			
page 227	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 Fully Brand or (Manufacturer's Price) Subsidised Generic Manufacturer

Antiallergy Preparations

Allergic Emergencies

ICATIBANT – Special Authority see SA1558 below – Retail pharmacy
Inj 10 mg per ml, 3 ml prefilled syringe.......2,668.00 1 ✓ Firazyr

⇒SA1558 Special Authority for Subsidy

Initial application only from a clinical immunologist or relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Supply for anticipated emergency treatment of laryngeal/oro-pharyngeal or severe abdominal attacks of acute hereditary angioedema (HAE) for patients with confirmed diagnosis of C1-esterase inhibitor deficiency; and
- 2 The patient has undergone product training and has agreed upon an action plan for self-administration.

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

Allergy Desensitisation

⇒SA1367 Special Authority for Subsidy

Initial application only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria: Both:

- 1 RAST or skin test positive; and
- 2 Patient has had severe generalised reaction to the sensitising agent.

Maintenance kit - 6 vials 120 mcg freeze dried venom, with

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

diluent	285.00	1 OP	✓ Venomil S29
Treatment kit - 1 vial 550 mcg freeze dried venom, 1 diluent 9 ml, 3 diluent 1.8 ml	305.00	1 OP	✓ Albey
WASP VENOM ALLERGY TREATMENT - Special Authority see S	A1367 above	- Retail pharr	nacy
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 S29
Treatment kit (Yellow jacket venom) - 1 vial 550 mcg freeze dried vespula venom, 1 diluent 9 ml, 1 diluent 1.8 ml	305.00	1 OP	✓ Albey
Treatment kit (Yellow jacket venom) - 6 vials 120 mcg freeze dried venom, with diluent	305.00	1 OP	✓ Venomil S29

Antihistamines

CETIRIZINE HYDROCHLORIDE			
* Tab 10 mg	1.01	100	✓ Zista
*‡ Oral liq 1 mg per ml		200 ml	✓ Histaclear
CHLORPHENIRAMINE MALEATE			
* Oral lig 2 mg per 5 ml	8.06	500 ml	Histafen

	Subsidy		Fully Brand or
	(Manufacturer's Pri		ubsidised Generic
	\$	Per	✓ Manufacturer
DEXTROCHLORPHENIRAMINE MALEATE			
★ Tab 2 mg	2.02	40	
· ·	(8.40)		Polaramine
	1.01	20	
	(5.99)		Polaramine
*‡ Oral liq 2 mg per 5 ml		100 ml	
- 1 01	(10.29)		Polaramine
EXOFENADINE HYDROCHLORIDE	,		
	4.24	20	
≮ Tab 60 mg		20	Telfast
لا حمد المراجع	(8.23)	10	Tellast
★ Tab 120 mg		10	Talfact
	(8.23)	00	Telfast
	14.22	30	T-161
	(26.44)		Telfast
ORATADINE			
* Tab 10 mg	1.28	100	✓ Lorafix
* Oral liq 1 mg per ml	2.15	120 ml	✓ Lorfast
PROMETHAZINE HYDROCHLORIDE			
* Tab 10 mg	1 78	50	✓ Allersoothe
* Tab 25 mg		50	✓ Allersoothe
k‡ Oral lig 1 mg per 1 ml		100 ml	✓ Allersoothe
★ Unit of this per till ★ Inj 25 mg per ml, 2 ml ampoule – Up to 5 inj available on		5	✓ Hospira
	a F30 13.34	3	• nospira
FRIMEPRAZINE TARTRATE			
Pral liq 30 mg per 5 ml	2.79	100 ml OF	
	(8.06)		Vallergan Forte
Inhaled Corticosteroids			
BECLOMETHASONE DIPROPIONATE			
Aerosol inhaler, 50 mcg per dose		200 dose O	
Aerosol inhaler, 50 mcg per dose CFC-free	8.54 2	200 dose O	P ✓ Beclazone 50
Aerosol inhaler, 50 mcg per dose CFC-free	8.54 2	200 dose O 200 dose O	P
Aerosol inhaler, 50 mcg per dose CFC-free	8.54 2	200 dose O	OP
Aerosol inhaler, 50 mcg per dose CFC-free	8.54 2 15.50 2 12.50 2	200 dose O 200 dose O	OP
Aerosol inhaler, 50 mcg per dose CFC-free Aerosol inhaler, 100 mcg per dose Aerosol inhaler, 100 mcg per dose CFC-free	8.54 2 15.50 2 12.50 2	200 dose O 200 dose O 200 dose O	OP
Aerosol inhaler, 50 mcg per dose CFC-free	8.54 2 15.50 2 12.50 2 22.67 2	200 dose O 200 dose O 200 dose O 200 dose O	OP
Aerosol inhaler, 50 mcg per dose CFC-free	8.54 2 15.50 2 12.50 2 22.67 2	200 dose O 200 dose O 200 dose O	P P Beclazone 50 P V Qvar P Beclazone 100 P Beclazone 250 P P Pulmicort
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose O 200 dose O 200 dose O 200 dose O 200 dose O	P Seclazone 50 P Qvar P Beclazone 100 P Beclazone 250 P Pulmicort Turbuhaler
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose O 200 dose O 200 dose O 200 dose O	DP
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 200 dose O	OP
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose O 200 dose O 200 dose O 200 dose O 200 dose O	OP
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 200 dose O	OP
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 200 dose O	DP
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 200 dose O	OP
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 120 dose O 120 dose O 120 dose O	DP
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose O 200 dose O	DP
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 120 dose O 120 dose O 120 dose O	DP
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 120 dose O 120 dose O 60 dose Ol	DP
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 120 dose O 120 dose O 60 dose O 60 dose O 60 dose O	DP
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 120 dose O 120 dose O 60 dose O 120 dose O 120 dose O 120 dose O 120 dose O	DP
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 200 dose O 120 dose O 60 dose O 60 dose O 120 dose O 120 dose O 120 dose O 120 dose O 120 dose O 120 dose O	DP

Fully

Brand or

Subsidy

	(Manufacturer's		
	\$	Per	✓ Manufacturer
Inhaled Long-acting Beta-adrenoceptor Agoni	sts		
EFORMOTEROL FUMARATE			
Powder for inhalation, 6 mcg per dose, breath activated		60 dose OP	
Davidantaniah olation 10 mas nan dasa and manadasa da	(16.90)	CO dasa	Oxis Turbuhaler
Powder for inhalation, 12 mcg per dose, and monodose de	(35.80)	60 dose	Foradil
INDACATEROL	(66.66)		rordan
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		120 dose OP	✓ Serevent
Aerosol inhaler 25 mcg per dosePowder for inhalation, 50 mcg per dose, breath activated		120 dose OP 60 dose OP	✓ Meterol✓ Serevent Accuhaler
Powder for initialation, 50 flicg per dose, breath activated	25.00	60 dose OF	• Serevent Accumaler
Inhaled Corticosteroids with Long-Acting Beta	a-Adrenocept	or Agonists	
BUDESONIDE WITH EFORMOTEROL			
Aerosol inhaler 100 mcg with eformoterol fumarate 6 mcg.		120 dose OP	✓ Vannair
Powder for inhalation 100 mcg with eformoterol fumarate 6	mcg33.74	120 dose OP	✓ Symbicort Turbuhaler 100/6
Aerosol inhaler 200 mcg with eformoterol fumarate 6 mcg.		120 dose OP	✓ Vannair
Powder for inhalation 200 mcg with eformoterol fumarate 6	mcg 44.08	120 dose OP	✓ Symbicort Turbuhaler 200/6
Powder for inhalation 400 mcg with eformoterol fumarate			
12 mcg - No more than 2 dose per day	44.08	60 dose OP	✓ Symbicort Turbuhaler 400/12
FLUTICASONE FUROATE WITH VILANTEROL			
Powder for inhalation 100 mcg with vilanterol 25 mcg	44.08	30 dose OP	✓ Breo Ellipta
FLUTICASONE WITH SALMETEROL	44.50	400 de e OD	/ Davids
Aerosol inhaler 50 mcg with salmeterol 25 mcg	14.58	120 dose OP	✓ RexAir✓ Seretide
Aerosol inhaler 125 mcg with salmeterol 25 mcg		120 dose OP	✓ RexAir
	44.08		✓ Seretide
Powder for inhalation 100 mcg with salmeterol 50 mcg - N			
more than 2 dose per day		60 dose OP	Seretide Accuhaler
Powder for inhalation 250 mcg with salmeterol 50 mcg – N more than 2 dose per day		60 dose OP	✓ Seretide Accuhaler
more than 2 dose per day	44.00	60 dose OF	Serende Accumaler
Beta-Adrenoceptor Agonists			
SALBUTAMOL			
Oral liq 400 mcg per ml		150 ml	✓ Ventolin
Infusion 1 mg per ml, 5 ml		10	Ventalin
Inj 500 mcg per ml, 1 ml - Up to 5 inj available on a PSO.	(130.21) 12.90	5	Ventolin ✓ Ventolin
ing ood may per mi, i mi op to a mig available on a r oo.	12.00	3	- TORIONII

	Subsidy		Fully Brand or
	(Manufacturer's F \$	Price) Sul Per	bsidised Generic ✓ Manufacturer
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 Of	1 3
	(6.00)		✓ SalAir Ventolin
Nebuliser soln, 1 mg per ml, 2.5 ml ampoule - Up to 30 neb	, ,		VOIROIIII
available on a PSO	3.19	20	✓ <u>Asthalin</u>
Nebuliser soln, 2 mg per ml, 2.5 ml ampoule – Up to 30 neb			
available on a PSO	3.29	20	✓ <u>Asthalin</u>
TERBUTALINE SULPHATE Powder for inhalation, 250 mcg per dose, breath activated	22.00	200 dose Of	✓ Bricanyl Turbuhaler
Fowder for infralation, 250 mcg per dose, breath activated	22.00	200 dose Or	▼ Bricarryi Turbunaler
Anticholinergic Agents			
IPRATROPIUM BROMIDE			
Aerosol inhaler, 20 mcg per dose CFC-free – Up to 400 dos	е		
available on a PSO	16.20	200 dose Of	○ ✓ Atrovent
Nebuliser soln, 250 mcg per ml, 1 ml ampoule – Up to 40 ne		20	4 11 1
available on a PSO Nebuliser soln, 250 mcg per ml, 2 ml ampoule – Up to 40 ne		20	✓ <u>Univent</u>
available on a PSO		20	✓ Univent
Inhaled Beta-Adrenoceptor Agonists with Antic	nolinergic A	gents	
SALBUTAMOL WITH IPRATROPIUM BROMIDE			
Aerosol inhaler, 100 mcg with ipratropium bromide, 20 mcg p		000 dese 01	O A Booklin LIEA
dose CFC-free	12.19	200 dose Of	○ ✓ Duolin HFA
vial, 2.5 ml ampoule — Up to 20 neb available on a PSC	3.59	20	✓ Duolin
Long-Acting Muscarinic Antagonists			
GLYCOPYRRONIUM – Subsidy by endorsement			
a) Inhaled glycopyrronium treatment will not be subsidised i	f patient is also r	eceiving treat	ment with subsidised tiotropium or
umeclidinium. b) Glycopyrronium powder for inhalation 50 mcg per dose is	e cubeidiead anly	for nationts v	uho haya haan diagnosad as
having COPD using spirometry, and the prescription is e			viio nave been diagnosed as
Powder for inhalation 50 mcg per dose		30 dose OP	✓ Seebri Breezhaler
TIOTROPIUM BROMIDE - Special Authority see SA1568 below			
Tiotropium treatment will not be subsidised if patient is also r	receiving treatme	ent with subsid	dised inhaled glycopyrronium or
umeclidinium. Powder for inhalation, 18 mcg per dose	50.37	30 dose	✓ Spiriva
Soln for inhalation 2.5 mcg per dose	50.37	60 dose OP	

Initial application only from a general practitioner or relevant specialist. Approvals valid for 2 years for applications meeting the

continued...

⇒SA1568 Special Authority for Subsidy

following criteria:

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

continued...

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 a.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 FEV, (litres); and
- 4.2 Predicted FEV, (litres); and
- 4.3 Actual FEV, as a % of predicted (must be below 60%); and
- 5 Fither:
 - 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 dose......61.50 30 dose OP ✓ Incruse Ellipta

Long-Acting Muscarinic Antagonists with Long-Acting Beta-Adrenoceptor Agonists

Combination long acting muscarinic antagonist and long acting beta-2 agonist will not be subsidised if patient is also receiving treatment with a combination inhaled corticosteroid and long acting beta-2 agonist.

⇒SA1584 Special Authority for Subsidy

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

- 1 Patient has been stabilised on a long acting muscarinic antagonist; and
- 2 The prescriber considers that the patient would receive additional benefit from switching to a combination product.

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

- 1 Patient is compliant with the medication; and
- 2 Patient has experienced improved COPD symptom control (prescriber determined).

GLYCOPYRRONIUM WITH INDACATEROL - Special Authority see SA1584 at	oove – 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

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

Antifibrotics

PIRFENIDONE - Retail pharmacy-Specialist - Special Authority see SA1628 below

Cap 267 mg - Wastage claimable - see rule 3.3.2 on

⇒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.

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 mg5.25	28	✓ Apo-Montelukast
Tab 5 mg5.50	28	✓ Apo-Montelukast
Tab 10 mg	28	✓ Apo-Montelukast

⇒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:

RESPIRATORY SYSTEM AND ALLERGIES

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

continued...

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

NIE	= רחר	\mathcal{C}_{F}	סכו	мп

SODIUM CROMOGLICATE

Methylxanthines

AMINOPHYLLINE

THEOPHYLLINE

 * Tab long-acting 250 mg
 21.51
 100
 ✓ Nuelin-SR

 *‡ Oral lig 80 mg per 15 ml
 15.50
 500 ml
 ✓ Nuelin

Mucolytics

DORNASE ALFA - Special Authority see SA0611 below - Retail pharmacy

⇒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.

Nasal Preparations

Allergy Prophylactics

BECLOMETHASONE DIPROPIONATE

Metered aqueous nasal spray, 50 mcg per dose	2.35	200 dose OP	
	(5.26)		Alanase
Metered aqueous nasal spray, 100 mcg per dose	2.46	200 dose OP	

(6.00) Alanase

RESPIRATORY SYSTEM AND ALLERGIES

	Subsidy (Manufacturer's \$	Price) Subsi	Fully Brand or idised Generic Manufacturer
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	, ,	200 dose OP	Butacort Aqueous
FLUTICASONE PROPIONATE	,		'
Metered aqueous nasal spray, 50 mcg per dose	2.18	120 dose OP	✓ Flixonase Hayfever & Allergy
PRATROPIUM BROMIDE			
Aqueous nasal spray, 0.03%	4.61	15 ml OP	✓ <u>Univent</u>
Respiratory Devices			
MASK FOR SPACER DEVICE			
a) Up to 50 dev available on a PSO			
b) Only on a PSO			
c) Only for children aged six years and under			
Small	2.20	1	✓ e-chamber Mask
PEAK FLOW METER			
a) Up to 25 dev available on a PSO			
b) Only on a PSO			
Low range	9.54	1	✓ Mini-Wright AFS
.			Low Range
Normal range	9.54	1	✓ Mini-Wright
•			Standard
SPACER DEVICE			
a) Up to 50 dev available on a PSO			
b) Only on a PSO			
220 ml (single patient)	2.95	1	✓ e-chamber Turbo
510 ml (single patient)		1	✓ e-chamber La
			Grande
800 ml	6.50	1	✓ Volumatic
Respiratory Stimulants			
CAFFEINE CITRATE			
,			

Oral liq 20 mg per ml (10 mg base per ml)......14.85 25 ml OP

✓ Biomed

			SENSC	ORY ORGANS
	Subsidy (Manufacturer's Prio \$	ce) Subs Per	idised (Brand or Generic Manufacturer
Ear Preparations				
ACETIC ACID WITH 1, 2- PROPANEDIOL DIACETATE AND BE For Vosol ear drops with hydrocortisone powder refer Standa Ear drops 2% with 1, 2-Propanediol diacetate 3% and benzethonium chloride 0.02%	ard Formulae, page	e 230 35 ml OP	√ Vos	ol
FLUMETASONE PIVALATE Ear drops 0.02% with clioquinol 1%		7.5 ml OP	✓ Loc	acorten-Viaform D's orten-Vioform
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCI Ear drops 1 mg with nystatin 100,000 u, neomycin sulphate		7.5 ml OP	. Va	acomb
2.5 mg and gramicidin 250 mcg per g Ear/Eye Preparations	5.10	7.5 IIII OP	▼ Ker	acomb
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	Sofi	radex
FRAMYCETIN SULPHATE Ear/Eye drops 0.5%	4.13 (8.65)	8 ml OP	Sofi	ramycin
Eye Preparations				
Eye preparations are only funded for use in the eye, unless explicit	citly stated otherwi	se.		
Anti-Infective Preparations				
ACICLOVIR * Eye oint 3% CHLORAMPHENICOL	14.92	4.5 g OP	✓ <u>Viru</u>	<u>IPOS</u>
Eye oint 1% Eye drops 0.5% Funded for use in the ear*. Indications marked with * are Unapproved Indications.		4 g OP 10 ml OP	✓ <u>Chl</u> ✓ <u>Chl</u>	orsig orafast
CIPROFLOXACIN Eye Drops 0.3% – Subsidy by endorsement When prescribed for the treatment of bacterial keratitis o for the second line treatment of chronic suppurative otitis Note: Indication marked with a * is an Unapproved Indication of the second line treatment of chronic suppurative otitis note: Indication marked with a * is an Unapproved Indication of the second line in the secon	or severe bacterial media (CSOM)*;	5 ml OP conjunctivitis and the preso	✓ Cilc resistant cription is	to chloramphenicol; or

GENTAMICIN SULPHATE

PROPAMIDINE ISETHIONATE

SODIUM FUSIDATE [FUSIDIC ACID]

5 ml OP

10 ml OP

5 g OP

(14.55)

✓ Genoptic

Brolene

✓ Fucithalmic

	Subsidy (Manufacturer's I	Price)	Fully Subsidised	
	\$	Per	•	Manufacturer
TOBRAMYCIN				
Eye oint 0.3%	10.45	3.5 g C	P 🗸	Tobrex
Eye drops 0.3%	11.48	5 ml O	P 🗸	Tobrex
Corticosteroids and Other Anti-Inflammatory Pre	eparations			
DEXAMETHASONE				
* Eye oint 0.1%	5.86	3.5 g C	P 🗸	Maxidex
* Eye drops 0.1%	4.50	5 ml O	P 🗸	Maxidex
Ocular implant 700 mcg - Special Authority see SA1680 belo)W			

⇒SA1680 Special Authority for Subsidy

Initial application — (Diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

1 Patient has diabetic macular oedema with pseudophakic lens; and

- 2 Patient has reduced visual acuity of between 6/9 6/48 with functional awareness of reduction in vision; and
- 3 Fither
 - 3.1 Patient's disease has progressed despite 3 injections with bevacizumab; or
 - 3.2 Patient is unsuitable or contraindicated to treatment with anti-VEGF agents; and
- 4 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

Renewal — (Diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 Patient's vision is stable or has improved (prescriber determined); and
- 2 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

Initial application — (Women of child bearing age with diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has diabetic macular oedema; and
- 2 Patient has reduced visual acuity of between 6/9 6/48 with functional awareness of reduction in vision; and
- 3 Patient is of child bearing potential and has not yet completed a family; and
- 4 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

Renewal — (Women of child bearing age with diabetic macular oedema) only from an ophthalmologist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient's vision is stable or has improved (prescriber determined); and
- 2 Patient is of child bearing potential and has not vet completed a family; and
- 3 Dexamethasone implants are to be administered not more frequently than once every 4 months into each eye, and up to a maximum of 3 implants per eye per year.

DEXAMETHASONE WITH NEOMYCIN SULPHATE AND POLYMYXIN B SULPHATE

*	sulphate 6,000 u per g	5.39	3.5 g OP	✓ Maxitrol
*	Eye drops 0.1% with neomycin sulphate 0.35% and polymyxin b sulphate 6,000 u per ml	4.50	5 ml OP	✓ Maxitrol
	CLOFENAC SODIUM Eye drops 0.1%1	3.80	5 ml OP	✓ Voltaren Ophtha

✓ Ozurdex

	Subsidy		Fully	Brand or
	(Manufacturer's Pr	rice) Subs	idised	Generic
	\$	Per	•	Manufacturer
FLUOROMETHOLONE				
* Eye drops 0.1%	3.09	5 ml OP	√ F	ML_
LEVOCABASTINE				
Eye drops 0.5 mg per ml	8.71	4 ml OP		
• •	(10.34)		Li	vostin
LODOXAMIDE				
Eye drops 0.1%	8.71	10 ml OP	✓ L	omide
PREDNISOLONE ACETATE				
Eye drops 1%	3.93	10 ml OP	√ P	rednisolone-AFT
•	7.00	5 ml OP	√ P	red Forte
PREDNISOLONE SODIUM PHOSPHATE - Special Authority so	ee SA1715 below	- Retail pharn	nacy	
Eye drops 0.5%, single dose (preservative free)	38.50	20 dose	🗸 M	linims
- · · · · · · · · · · · · · · · · · · ·				Prednisolone

⇒SA1715 Special Authority for Subsidy

Initial application only from an ophthalmologist or optometrist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has severe inflammation; and
- 2 Patient has a confirmed allergic reaction to preservative in eye drops.

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

SODIUM CROMOGLICATE

Eve drops 2%	0.85	5 ml OP	✓ Rexacrom
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Glaucoma Preparat	ions - Beta	Blockers
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BETAXOLOL			
* Eye drops 0.25%	11.80	5 ml OP	✓ Betoptic S
* Eye drops 0.5%		5 ml OP	✓ Betoptic
LEVOBUNOLOL			
* Eye drops 0.5%	7.00	5 ml OP	Betagan
TIMOLOL			
* Eye drops 0.25%	1.43	5 ml OP	✓ Arrow-Timolol
* Eye drops 0.25%, gel forming	3.30	2.5 ml OP	✓ Timoptol XE
* Eye drops 0.5%	1.43	5 ml OP	✓ Arrow-Timolol
* Eye drops 0.5%, gel forming	3.78	2.5 ml OP	✓ Timoptol XE

Glaucoma Preparations - Carbonic Anhydrase Inhibitors

* Tab 250 mg - For acetazolamide oral liquid formulation refer,

ACETAZOLAMIDE

page 227	17.03	100	✓ Diamox
BRINZOLAMIDE			
* Eye drops 1%	9.77	5 ml OP	✓ Azopt
DORZOLAMIDE HYDROCHLORIDE			
* Eye drops 2%	9.77	5 ml OP	
	(17.44)		Trusopt
DORZOLAMIDE WITH TIMOLOL			
* Eye drops 2% with timolol 0.5%	3.45	5 ml OP	✓ Arrow-Dortim

[‡] safety cap

	Subsidy		Fully	Brand or
	(Manufacturer's P		idised	Generic
	\$	Per		Manufacturer
Glaucoma Preparations - Prostaglandin Analog	gues			
BIMATOPROST				
* Eye drops 0.03%	3.65	3 ml OP	✓ Bir	natoprost Actavis
LATANOPROST				
* Eye drops 0.005%	1.50	2.5 ml OP	✓ Hy	site
TRAVOPROST			_	
* Eye drops 0.004%	7.30	5 ml OP	✓ Trans	vont
	3.65	2.5 ml OP	•••	
	(19.50)		Tra	vatan
Travopt to be Sole Supply on 1 April 2018	(/			
(Travatan Eye drops 0.004% to be delisted 1 April 2018)				
Glaucoma Preparations - Other				
BRIMONIDINE TARTRATE				
* Eye drops 0.2%	A 20	5 ml OP	✓ Ar	row-Brimonidine
•	4.23	3 1111 01	V AII	OW-DI IIIIOIIIGIIIE
BRIMONIDINE TARTRATE WITH TIMOLOL MALEATE	10.50	5 ml OD		h!
* Eye drops 0.2% with timolol maleate 0.5%	18.50	5 ml OP	V C0	mbigan
PILOCARPINE HYDROCHLORIDE				
* Eye drops 1%		15 ml OP		pto Carpine
* Eye drops 2%		15 ml OP		pto Carpine
* Eye drops 4%		15 ml OP	V ISC	pto Carpine
Subsidised for oral use pursuant to the Standard Formu	liae.			
* Eye drops 2% single dose – Special Authority see SA0895	04.05	00 daaa	Z 14:	olma Dilanamina
below – Retail pharmacy	31.95	20 dose	V IVIII	nims Pilocarpine
⇒SA0895 Special Authority for Subsidy				
Initial application from any relevant practitioner. Approvals val	id for 2 years for a	ipplications me	eeting the	e following criteria:
Either:				
1 Patient has to use an unpreserved solution due to an alle	ergy to the preserv	ative; or		
2 Patient wears soft contact lenses.				
Note: Minims for a general practice are considered to be "tools				
Renewal from any relevant practitioner. Approvals valid for 2 ye benefiting from treatment.	ears where the tre	atment remain	s approp	riate and the patient is
benefiting from treatment.				
Mydriatics and Cycloplegics				
ATROPINE SULPHATE				
* Eye drops 1%	17.36	15 ml OP	✓ <u>Atı</u>	opt
CYCLOPENTOLATE HYDROCHLORIDE				
* Eye drops 1%	8.76	15 ml OP	✓ Cy	clogyl
TROPICAMIDE				
* Eye drops 0.5%	7.15	15 ml OP	✓ Mv	driacyl
* Eye drops 1%		15 ml OP		driacyl
Preparations for Tear Deficiency			•	•
Preparations for real Deliciency				
For acetylcysteine eye drops refer Standard Formulae, page 230)			
HYPROMELLOSE				
* Eye drops 0.5%	2.00	15 ml OP		
A 14. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1.	(3.92)		Me	thopt
	()			r. ·

	Subsidy (Manufacturer's Pri \$	ce) Subs	Fully sidised	Brand or Generic Manufacturer
HYPROMELLOSE WITH DEXTRAN * Eye drops 0.3% with dextran 0.1%	2.30	15 ml OP	√ P	oly-Tears
POLYVINYL ALCOHOL * Eye drops 1.4% * Eye drops 3%		15 ml OP 15 ml OP	_	istil istil 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.

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%13.60	5 ml OP	✓ Patanol
PARAFFIN LIQUID WITH SOFT WHITE PARAFFIN * Eye oint with soft white paraffin3.63	3.5 g OP	✓ Refresh Night Time
PARAFFIN LIQUID WITH WOOL FAT * Eye oint 3% with wool fat 3%	3.5 g OP	✓ Poly-Visc
RETINOL PALMITATE Eve oint 138 mgg per g	5 a OP	✓ VitA-POS



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

Various

PHARMACY SERVICES

May only be claimed once per patient.

* Brand switch fee4.50

✓ BSF CareSens Dual

✓ BSF CareSens N

1 fee

✓ BSF CareSens N
POP

✓ BSF CareSens N
Premier

- a) The Pharmacode for BSF CareSens N is 2423138 see also page 28
- b) The Pharmacode for BSF CareSens N POP is 2423154 see also page 28
- c) The Pharmacode for BSF CareSens N Premier is 2535882 see also page 28
- d) The Pharmacode for BSF CareSens Dual is 2535890 see also page 27

(BSF CareSens Dual Brand switch fee to be delisted 1 August 2018)

(BSF CareSens N Brand switch fee to be delisted 1 August 2018)

(BSF CareSens N POP Brand switch fee to be delisted 1 August 2018)

(BSF CareSens N Premier Brand switch fee to be delisted 1 August 2018)

Agents Used in the Treatment of Poisonings

Antidotes

ACETYLCYSTEINE - Retail pharmacy-Specialist			
Inj 200 mg per ml, 10 ml ampoule	78.34	10	✓ <u>DBL Acetylcysteine</u>

NALOXONE HYDROCHLORIDE

- a) Up to 5 inj available on a PSO
- b) Only on a PSO

Removal and Elimination

CHARCOAL

*	Oral lig 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		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



(M	Subsidy	F	-ully	Brand or
	lanufacturer's Price)	Subsid	ised	Generic
	\$	Per	1	Manufacturer

combination therapy have proven ineffective as measured by serum ferritin levels, liver or cardiac MRI T2*; or

- 3.2 Treatment with deferiprone has resulted in severe persistent vomiting or diarrhoea; or
- 3.3 Treatment with deferiprone has resulted in arthritis: or
- 3.4 Treatment with deferiprone is contraindicated due to a history of agranulocytosis (defined as an absolute neutrophil count (ANC) of < 0.5 cells per μL) or recurrent episodes (greater than 2 episodes) of moderate neutropenia (ANC 0.5 1.0 cells per μL).</p>

Renewal only from a haematologist. Approvals valid for 2 years for applications meeting the following criteria: Either:

- 1 For the first renewal following 2 years of therapy, the treatment has been tolerated and has resulted in clinical improvement in all three parameters namely serum ferritin, cardiac MRI T2* and liver MRI T2* levels; or
- 2 For subsequent renewals, the treatment has been tolerated and has resulted in clinical stability or continued improvement in all three parameters namely serum ferritin, cardiac MRI T2* and liver MRI T2* levels.

DEFERIPRONE - Special Authority see SA1480 below - F	Retail pharmacy		
Tab 500 mg	533.17	100	✓ Ferriprox
Oral lig 100 mg per 1 ml	266.59	250 ml OP	✓ Ferriprox

⇒SA1480 Special Authority for Subsidy

Initial application only from a haematologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia; or
- 2 The patient has been diagnosed with chronic iron overload due to acquired red cell aplasia.

* Inj 500 mg vial	51.52	10	✓ <u>Desferal</u>
SODIUM CALCIUM EDETATE			
* Inj 200 mg per ml, 5 ml	53.31	6	
	(156.71)		Calcium Disodium Versenate

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SECTION C: EXTEMPORANEOUSLY COMPOUNDED PRODUCTS AND GALENICALS

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.
 - 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
- Hvdrocortisone 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 fomulae 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 Allopurinol 20 mg/ml Amlodipine 1 mg/ml Azathioprine 50 mg/ml Baclofen 10 mg/ml Carvedilol 1 mg/ml Clopidogrel 5 mg/ml Diltiazem hydrochloride 12 mg/ml

Dipyridamole 10 mg/ml Domperidone 1 mg/ml Enalapril 1 mg/ml Flecainide 20 mg/ml Gabapentin 100 mg/ml Hydrocortisone 1 mg/ml Labetolol 10 mg/ml

Levodopa with carbidopa (5 mg levodopa + 1.25 mg carbidopa)/ml Metoclopramide 1 mg/ml Metoprolol tartrate 10 mg/ml Nitrofurantoin 10 mg/ml Pyrazinamide 100 mg/ml Rifabutin 20 mg/ml Sildenafil 2 mg/ml Sotalol 5 mg/ml

Sulphasalazine 100 mg/ml Tacrolimus 1 mg/ml Terbinafine 25 mg/ml Tramadol 10 mg/ml

Ursodeoxycholic acid 50 mg/ml Valganciclovir 60 mg/ml*

Verapamil hydrochloride 50 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.



EXTEMPORANEOUSLY COMPOUNDED PRODUCTS AND GALENICALS

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 pholoodine 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.

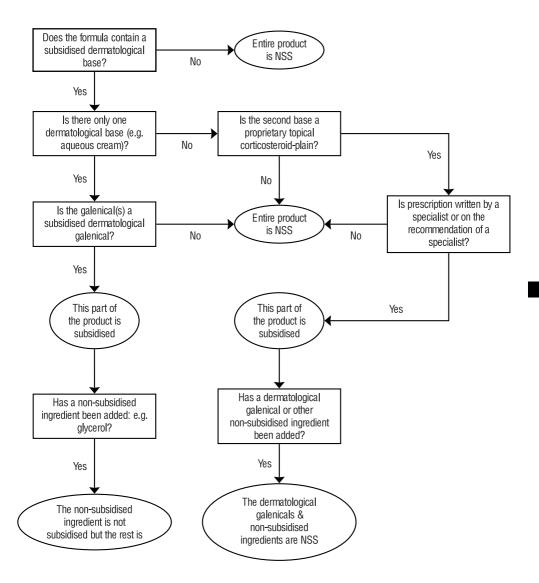
Prescribers may prescribe or pharmacists may add extra non-subsidised ingredients, but these extra ingredients will not be reimbursed. The subsidised ingredients in the formula will be reimbursed and a compounding fee paid.

Dermatological Preparations

Proprietary topical corticosteroid preparations may be diluted with a dermatological base (see page 226) 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?



EXTEMPORANEOUSLY COMPOUNDED PRODUCTS AND GALENICALS

Standard Formulae			
ACETYLCYSTEINE EYE DROPS Acetylcysteine inj 200 mg per ml, 10 ml Suitable eye drop base	qs qs	PHENOBARBITONE ORAL LIQUID Phenobarbitone Sodium Glycerol BP Water	1 g 70 ml to 100 ml
ASPIRIN AND CHLOROFORM APPLICATION Aspirin Soluble tabs 300 mg Chloroform	12 tabs to 100 ml	PHENOBARBITONE SODIUM PAEDIATRIC ORAL mg per ml)	LIQUID (10
CODEINE LINCTUS PAEDIATRIC (3 mg per 5 ml) Codeine phosphate Glycerol Preservative Water	60 mg 40 ml qs to 100 ml	Phenobarbitone Sodium Glycerol BP Water PILOCARPINE ORAL LIQUID Pilocarpine 4% eye drops	400 mg 4 ml to 40 ml
CODEINE LINCTUS DIABETIC (15 mg per 5 ml) Codeine phosphate Glycerol Preservative	300 mg 40 ml qs	Preservative Water (Preservative should be used if quantity supplied is than 5 days.)	qs qs to 500 ml for more
Water FOLINIC MOUTHWASH	to 100 ml	SALIVA SUBSTITUTE FORMULA Methylcellulose Preservative	5 g qs
Calcium folinate 15 mg tab Preservative Water (Preservative should be used if quantity supplied is	1 tab qs to 500 ml for more	Water (Preservative should be used if quantity supplied is than 5 days. Maximum 500 ml per prescription.) SODIUM CHLORIDE ORAL LIQUID	to 500 ml for more
than 5 days. Maximum 500 ml per prescription.) MAGNESIUM HYDROXIDE 8% MIXTURE Magnesium hydroxide paste 29% Methyl hydroxybenzoate	275 g 1.5 g	Sodium chloride inj 23.4%, 20 ml Water (Only funded if prescribed for treatment of hyponatra	qs qs aemia)
Water METHADONE MIXTURE Methadone powder Glycerol	to 1,000 m	I VANCOMYCIN ORAL SOLUTION (50 mg per ml) Vancomycin 500 mg injection Glycerol BP Water (Only funded if prescribed for treatment of Clostridiu	10 vials 40 ml to 100 ml
Water METHYL HYDROXYBENZOATE 10% SOLUTION	to 100 ml	following metronidazole failure) VOSOL EAR DROPS	in dinicile
Methyl hydroxybenzoate Propylene glycol (Use 1 ml of the 10% solution per 100 ml of oral liqu	10 g to 100 ml iid mixture)	WITH HYDROCORTISONE POWDER 1% Hydrocortisone powder Vosol Ear Drops	1% to 35 ml
OMEPRAZOLE SUSPENSION Omeprazole capules or powder Sodium bicarbonate powder BP Water	qs 8.4 g to 100 ml		

EXTEMPORANEOUSLY COMPOUNDED PREPARATIONS AND GALENICALS

Subsidy

(Manufacturer's Price)

Fully

Subsidised

Per

Brand or

Generic

Manufacturer

Extemporaneously Compounded Preparations and Galenicals BENZOIN Tincture compound BP......24.42 500 ml (39.90)Pharmacy Health 2.44 50 ml (5.10)Pharmacy Health CHLOROFORM - Only in combination Only in aspirin and chloroform application. 500 ml ✓ PSM CODEINE PHOSPHATE - Safety medicine; prescriber may determine dispensing frequency Powder - Only in combination......63.09 (90.09)Douglas a) Only in extemporaneously compounded codeine linctus diabetic or codeine linctus paediatric. b) \$\preceq\$ Safety cap for extemporaneously compounded oral liquid preparations. COLLODION FLEXIBLE Collodion flexible19.30 100 ml ✓ PSM COMPOUND HYDROXYBENZOATE - Only in combination Only in extemporaneously compounded oral mixtures. ✓ Midwest 100 ml 34.18 David Craig GLYCERIN WITH SODIUM SACCHARIN - Only in combination Only in combination with Ora-Plus. 473 ml ✓ Ora-Sweet SF GLYCERIN WITH SUCROSE - Only in combination Only in combination with Ora-Plus. 473 ml ✓ Ora-Sweet GI YCFROI 500 ml ✓ healthE Glycerol BP Only in extemporaneously compounded oral liquid preparations. MAGNESIUM HYDROXIDE ✓ PSM 500 q METHADONE HYDROCHI ORIDE 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). 1 g ✓ AFT ‡ Safety cap for extemporaneously compounded oral liquid preparations. METHYL HYDROXYBENZOATE PSM 25 g ✓ Midwest **METHYLCELLULOSE** ✓ MidWest 100 g ✓ Ora-Plus 473 ml METHYLCELLULOSE WITH GLYCERIN AND SODIUM SACCHARIN - Only in combination 473 ml ✓ Ora-Blend SF

if endorsed "certified exemption" by the prescriber or pharmacist.

[‡] safety cap

EXTEMPORANEOUSLY COMPOUNDED PREPARATIONS AND GALENICALS

	Subsidy (Manufacturer's Price \$	e) Per	Fully Subsidised	
METHYLCELLULOSE WITH GLYCERIN AND SUCROSE - Onl	v in combination			
Suspension		473 m	/	Ora-Blend
PHENOBARBITONE SODIUM				
	50.50	40	,	B#1-D#7 4
Powder – Only in combination		10 g	_	MidWest
	325.00	100 g		MidWest
a) Only in children up to 12 years				
b)‡ Safety cap for extemporaneously compounded oral li	iquid preparations.			
PROPYLENE GLYCOL				
	anta 100/ natution			
Only in extemporaneously compounded methyl hydroxybenz				
Liq	11.25	500 m		Midwest
SODIUM BICARBONATE				
Powder BP - Only in combination	8.95	500 g	✓	Midwest
,	9.80	3		
	(29.50)			David Craig
Only in extemporaneously compounded omeprazole and	` ,	oncion		David Oralg
	i iai isopiazoie suspi	ension.		
SYRUP (PHARMACEUTICAL GRADE) – Only in combination				
Only in extemporaneously compounded oral liquid preparation	ons.			
Liq	21.75	2,000 r	nl 🗸	Midwest
WATER				
	0.00	1 ml	1	Tap water
Tap - Only in combination	0.00	1 1111	•	iap 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 charges 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.

Only from a dietitian, relevant specialist or a vocationally registered general Reapplications:

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

Failure to thrive An inability to gain or maintain weight resulting in physiological impairment. Growth deficiency

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:

Fither:

- 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 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:

0.1.1		F. !!	D 1	
Subsidy		Fully	Brand or	
(Manufacturer's Price)	Sı	ubsidised	Generic	
\$	Per	✓	Manufacturer	

- 1 Infant or child aged four years or under; and
- 2 cystic fibrosis.

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 infant or child aged four years or under; and
- 2 Any of the following:
 - 2.1 cancer in children; or
 - 2.2 faltering growth; or
 - 2.3 bronchopulmonary dysplasia; or
 - 2.4 premature and post premature infants.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

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



S	Subsidy	Fully	Brand or
(Manufac	cturer's Price) Subsid	lised	Generic
	\$ Per	1	Manufacturer

- 10 ascites: or
- 11 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula. **Renewal — (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:

- 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)	200 ml OP	✓ Calogen
30.75	500 ml OP	✓ Calogen
Emulsion (strawberry)12.30	200 ml OP	✓ Calogen
Oil	500 ml OP	✓ MCT oil (Nutricia)
Oil, 250 ml114.92	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 p 	narmacy [HP3]	
Powder	7.90	225 g OP	✓ Protifar
	8.95	227 g OP	✓ Resource
		•	Beneprotein

Subsidy (Manufacturer's Price) \$ Fully Subsidised Per

Brand or Generic Manufacturer

Sustagen Diabetic

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.

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 pharm 	nacy [HP3]
Liquid7.50	1,000 ml OP	Diason RTH
		✓ Glucerna Select RTH
DIABETIC ORAL FEED 1KCAL/ML - Special Authority see SA1095 above - Ho	ospital 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)



Subsidy (Manufacturer's Price) Fully Subsidised er Brand or Generic Manufacturer

Fat Modified Products

⇒SA1525 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 Patient has metabolic disorders of fat metabolism; or
- 2 Patient has a chyle leak; or
- 3 Modified as a modular feed, made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule, for adults.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula. **Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

FAT MODIFIED FEED – Special Authority see SA1525 above – Hospital pharmacy [HP3]

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:

Roth:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL FEED 1KCAL/ML - Special Authority see SA1098 above - Hospital pharmacy [HP3]

Paediatric Products For Children With Chronic Renal Failure

⇒SA1099 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient is a child (up to 18 years) with acute or chronic kidney disease.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Subsidy		Fully	Brand or
(Manufacturer's Pric	ce)	Subsidised	Generic
\$	Per	•	Manufacturer

ENTERAL/ORAL FEED 1KCAL/ML − Special Authority see SA1099 on the previous page − Hospital pharmacy [HP3] Liquid.......54.00 400 g OP ✓ Kindergen

Paediatric Products

⇒SA1379 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 Child is aged one to ten years: and
- 2 Any of the following:
 - 2.1 the child is being fed via a tube or a tube is to be inserted for the purposes of feeding; or
 - 2.2 any condition causing malabsorption; or
 - 2.3 faltering growth in an infant/child; or
 - 2.4 increased nutritional requirements; or
 - 2.5 the child is being transitioned from TPN or tube feeding to oral feeding.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

PAEDIATRIC ENTERAL FEED 1.5KCAL/ML - Special Authority see SA1379 at Liquid	500 ml OP Vutrini Energy RTH
PAEDIATRIC ENTERAL FEED WITH FIBRE 1.5KCAL/ML - Special Authority s Liquid6.00	
PAEDIATRIC ORAL FEED – Special Authority see SA1379 above – Hospital ph Powder (vanilla)28.00 (Pediasure Powder (vanilla) to be delisted 1 July 2018)	armacy [HP3] 850 g OP ✓ Pediasure
PAEDIATRIC ORAL FEED 1.5KCAL/ML – Special Authority see SA1379 above Liquid (strawberry)	 Hospital pharmacy [HP3] 200 ml OP ✓ Fortini 200 ml OP ✓ Fortini
PAEDIATRIC ORAL FEED 1KCAL/ML - Special Authority see SA1379 above - Liquid (chocolate)	Hospital pharmacy [HP3] 200 ml OP
PAEDIATRIC ORAL FEED WITH FIBRE 1.5KCAL/ML — Special Authority see S Liquid (chocolate)	A1379 above – Hospital pharmacy [HP3] 200 ml OP
PEPTIDE-BASED ORAL FEED – Special Authority see SA1379 above – Hospit Powder43.60	al pharmacy [HP3] 400 g OP ✓ Peptamen Junior



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

Renal Products

⇒SA1101 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient has acute or chronic kidney disease.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

RENAL ENTERAL FEED 1.8 KCAL/ML - Special Authority see Liquid			,
RENAL ORAL FEED 1.8 KCAL/ML – Special Authority see SA Liquid			[HP3] ✓ Nepro HP (strawberry) ✓ Nepro HP (vanilla)
RENAL ORAL FEED 2 KCAL/ML - Special Authority see SA11	01 above - Hospi	tal pharmacy [F	1P3]
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.

Brand or

Fully

	(Manufacturer's F	Price) Subsi Per	idised Generic Manufacturer
ENTERAL/ORAL SEMI-ELEMENTAL FEED 1.5KCAL/ML — Spe pharmacy [HP3] Liquid	•	e SA1377 on the	e previous page – Hospital Vital
ORAL ELEMENTAL FEED 0.8KCAL/ML - Special Authority see Liquid (grapefruit), 250 ml carton Liquid (pineapple & orange), 250 ml carton Liquid (summer fruits), 250 ml carton	171.00 171.00	previous page - 18 OP 18 OP 18 OP	- Hospital pharmacy [HP3] ✓ Elemental 028 Extra ✓ Elemental 028 Extra ✓ Elemental 028 Extra
ORAL ELEMENTAL FEED 1KCAL/ML - Special Authority see S Powder (unflavoured)		revious page – F 80 g OP	Hospital pharmacy [HP3] ✓ Vivonex TEN
SEMI-ELEMENTAL ENTERAL FEED 1KCAL/ML - Special Autr [HP3] Liquid	•	7 on the previou	us page – Hospital pharmacy ✓ Peptisorb
<u> </u>	12.07	1,000 1111 01	· r cptioorb

Subsidy

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.

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



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

continued...

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:

- 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.



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

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:

- 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



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

- 8 Bowel fistula; or
 - 9 Severe chronic neurological conditions; or
- 10 Epidermolysis bullosa; or
- 11 AIDS (CD4 count < 200 cells/mm3); or
- 12 Chronic pancreatitis.

Renewal — (Chronic disease OR tube feeding for patients who have previously been funded under Special Authority forms SA0702 or SA0583) 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 Liquid		lospital pharmacy 1,000 ml OP	/ [HP3] ✓ Nutrison Energy
ENTERAL FEED 1KCAL/ML - Special Authority see SA1554 or Liquid		spital pharmacy [250 ml OP 1,000 ml OP	
ENTERAL FEED WITH FIBRE 0.83 KCAL/ML – Special Authori Liquid	•	on page 241 – Ho 1,000 ml OP	ospital pharmacy [HP3] Nutrison 800 Complete Multi Fibre
ENTERAL FEED WITH FIBRE 1 KCAL/ML - Special Authority s Liquid		oage 241 – Hospi 1,000 ml OP	tal pharmacy [HP3] Jevity RTH Nutrison Multi Fibre
ENTERAL FEED WITH FIBRE 1.5KCAL/ML - Special Authority Liquid		page 241 – Hosp 250 ml OP 1,000 ml OP	oital pharmacy [HP3] ✓ Ensure Plus HN ✓ Ensure Plus RTH ✓ Jevity HiCal RTH ✓ Nutrison Energy Multi Fibre

Hospital

Formula

Ensure Plus Fortisip

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

ORAL FEED (POWDER) - Special Authority see SA1554 on page 241 - Hospital pharmacy [HP3]

Note: Higher subsidy for Sustagen Hospital Formula will only be reimbursed for patients with both a valid Special Authority number and an appropriately endorsed prescription.

Powder (chocolate) - Higher subsidy of up to \$26.00 per 850 g	
with Endorsoment	

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	8.54	857 g OP	✓ Fortisip
	26.00	850 g OP	✓ Ensure
	9.54	840 g OP	
	(14.90)	-	Sustagen

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 241 - 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)

(1.26)

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

ORAL FEED WITH FIBRE 1.5 KCAL/ML - Special Authority see SA1554 on page 241 - 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

Liquid (chocolate) — Higher Subsidy of \$1.20 per 200 fill with			
Endorsement	0.72	200 ml OP	
	(1.26)		Fortisip Multi Fibre
Liquid (strawberry) - Higher subsidy of \$1.26 per 200 ml with			
Endorsement	0.72	200 ml OP	
	(1.26)		Fortisip Multi Fibre
Liquid (vanilla) - Higher subsidy of \$1.26 per 200 ml with			
Endorsement	0.72	200 ml OP	

(1.26)

Fortisip Multi Fibre

High Calorie Products

⇒SA1195 Special Authority for Subsidy

Initial application — **(Cystic fibrosis)** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

All of the following:

- 1 Cystic fibrosis; and
- 2 other lower calorie products have been tried; and
- 3 patient has substantially increased metabolic requirements.

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
 - 1.1 any condition causing malabsorption; or
 - 1.2 faltering growth in an infant/child; or
 - 1.3 increased nutritional requirements; or
 - 1.4 fluid restricted: and
- 2 other lower calorie products have been tried; and
- 3 patient has substantially increased metabolic requirements or is fluid restricted.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL FEED 2 KCAL/ML - Special Authority see SA1195 above	e – Hospital	pharmacy [HP3]	
Liquid	5.50	500 ml OP	✓ Nutrison
·			Concentrated
	11.00	1,000 ml OP	✓ Two Cal HN RTH

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

ORAL FEED 2 KCAL/ML - Special Authority see SA1195 on the previous page - Hospital pharmacy [HP3]

Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, or who have severe epidermolysis bullosa. The prescription must be endorsed accordingly.

Liquid (vanilla) - Higher subsidy of \$1.90 per 200 ml with

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.

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:

Fither:

- 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
GLUTEN FREE BREAD MIX - Special Authority see SA1107	above – Hospital pharmacy	[HP3]
Powder	3.93 1,000 g	OP
	(7.32)	NZB Low Gluten Bread Mix
	3.51	
	(10.87)	Horleys Bread Mix
GLUTEN FREE FLOUR - Special Authority see SA1107 above	e – Hospital pharmacy [HP3	3]
Powder	5.62 2,000 g	OP
	(18.10)	Horleys Flour

	Subsidy		Fully	Brand or
	(Manufacturer's Pric	e) Su Per	ıbsidised •	Generic Manufacturer
GLUTEN FREE PASTA - Special Authority see SA1107 on the	previous page – Ho	ospital pha	rmacy [H	P3]
Buckwheat Spirals	2.00	250 g OP		
	(3.11)		C	Orgran
Corn and Vegetable Shells	2.00	250 g OP		
	(2.92)		C	Orgran
Corn and Vegetable Spirals	2.00	250 g OP		
	(2.92)		C	Orgran
Rice and Corn Lasagne Sheets	1.60	200 g OP		
	(3.82)		C	Orgran
Rice and Corn Macaroni	2.00	250 g OP		
	(2.92)		C	Orgran
Rice and Corn Penne	2.00	250 g OP		
	(2.92)		C	Orgran
Rice and Maize Pasta Spirals	2.00	250 g OP		
	(2.92)		C	Orgran
Rice and Millet Spirals	2.00	250 g OP		
	(3.11)		C	Orgran
Rice and corn spaghetti noodles	2.00	375 g OP		
	(2.92)		C	Orgran
Vegetable and Rice Spirals	2.00	250 g OP		
	(2.92)		C	Orgran
Italian long style spaghetti	2.00	220 g OP		
	(3.11)		C	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

Supplements For MSUD

AMINOACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE - Special Authority see SA1108 above - Hospital pharmacy [HP3]

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

Supplements For PKU

AMINOACID FORMULA WITHOUT PHENYLALANINE - Special Authority see SA1108 on the previous page - Hospital pharmacy [HP3]

Tabs	99.00	75 OP	✓ Phlexy 10
Powder (unflavoured) 36 g sachets	393.00	30	✓ PKU Anamix Junior
Infant formula		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
4 (3-)			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		60 OP	✓ PKU Lophlex LQ 10
Liquid (juicy orange) 62.5 ml		60 OP	✓ PKU Lophlex LQ 10
Liquid (juicy berries) 125 ml		30 OP	✓ PKU Lophlex LQ 20
Liquid (juicy citrus) 125 ml		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] 500 g OP ✓ Loprofin Mix LOW PROTEIN PASTA - Special Authority see SA1108 on the previous page - Hospital pharmacy [HP3] Animal shapes......11.91 500 q OP ✓ Loprofin ✓ Loprofin Lasagne 5.95 250 q OP ✓ Loprofin 500 a OP ✓ Loprofin 250 q OP Penne 11.91 500 a OP ✓ Loprofin 500 g OP ✓ Loprofin 500 g OP ✓ Loprofin

Infant Formulae

For Premature Infants

PRETERM POST-DISCHARGE INFANT FORMULA - Special Authority see SA1198 below - Hospital pharmacy [HP3] 400 g OP ✓ S-26 Gold Premgro (S-26 Gold Premgro Powder to be delisted 1 July 2018)

⇒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:



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

- 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.

Gastrointestinal and Other Malabsorptive Problems

AMINO ACID FORMULA – Special Authority see SA1219 below – Ho Powder		400 g OP	✓ Alfamino Junior
	53.00	•	✓ Neocate LCP
Powder (unflavoured)	53.00	400 g OP	✓ Elecare
,			✓ Elecare LCP
			✓ Neocate Advance
			✓ Neocate Gold
			Neocate Junior Unflavoured
Powder (vanilla)	53.00	400 g OP	✓ Elecare
		-	✓ Neocate Advance
			Neocate Junior Vanilla

(Neocate Advance Powder (unflavoured) to be delisted 1 May 2018) (Neocate Advance Powder (vanilla) to be delisted 1 May 2018)

⇒SA1219 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Any of the following:

- 1 Extensively hydrolysed formula has been reasonably trialled and is inappropriate due to documented severe intolerance or allergy or malabsorption; or
- 2 History of anaphylaxis to cows milk protein formula or dairy products; or
- 3 Eosinophilic oesophagitis.

Note: A reasonable trial is defined as a 2-4 week trial.



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

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.

⇒SA1557 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Any of the following:

- 1 Both:
 - 1.1 Cows milk formula is inappropriate due to severe intolerance or allergy to its protein content; and
 - 1.2 Either:
 - 1.2.1 Soy milk formula has been reasonably trialled without resolution of symptoms; or
 - 1.2.2 Soy milk formula is considered clinically inappropriate or contraindicated; or
- 2 Severe malabsorption; or
- 3 Short bowel syndrome; or
- 4 Intractable diarrhoea; or
- 5 Biliary atresia; or
- 6 Cholestatic liver diseases causing malsorption; or
- 7 Cystic fibrosis; or
- 8 Proven fat malabsorption: or
- 9 Severe intestinal motility disorders causing significant malabsorption; or
- 10 Intestinal failure: or
- 11 All of the following:
 - 11.1 For step down from Amino Acid Formula; and
 - 11.2 The infant is currently receiving funded amino acid formula; and
 - 11.3 The infant is to be trialled on, or transitioned to, an extensively hydrolysed formula; and
 - 11.4 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.

Note: A reasonable trial is defined as a 2-4 week trial, or signs of an immediate IgE mediated allergic reaction.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 An assessment as to whether the infant can be transitioned to a cows milk protein or soy infant formula has been undertaken; and
- 2 The outcome of the assessment is that the infant continues to require an extensively hydrolysed infant formula; and
- 3 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.



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

Fluid Restricted

PAEDIATRIC ORAL/ENTERAL FEED 1 KCAL/ML - Special Authority see SA1698 below - Hospital pharmacy [HP3] Liquid.......2.35 125 ml OP ✓ Infatrini

⇒SA1698 Special Authority for Subsidy

Initial application only from a paediatrician, dietitian or general practitioner on the recommendation of a paediatrician or dietitian. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient is fluid restricted or volume intolerant and has been diagnosed with faltering growth; and
- 2 Patient is under the care of a paediatrician or dietitian who has recommended treatment with a high energy infant formula; and
- 3 Patient is under 18 months of age or weighs less than 8 kg.

Note: "Volume intolerant" patients are those who are unable to tolerate an adequate volume of infant formula to achieve expected growth rate. These patients should have first trialled appropriate clinical alternative treatments, such as concentrating, fortifying and adjusting the frequency of feeding.

Renewal only from a paediatrician, dietitian or general practitioner on the recommendation of a paediatrician or dietitian.

Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient continues to be fluid restricted or volume intolerant and has faltering growth; and
- 2 Patient is under the care of a hospital paediatrician or dietitian who has recommended treatment with a high energy infant formula; and
- 3 Patient is under 18 months of age or weighs less than 8 kg.

Note: 'Volume intolerant' patients are those who are unable to tolerate an adequate volume of infant formula to achieve expected growth rate. These patients should have first trialled appropriate clinical alternative treatments, such as concentrating, fortifying and adjusting the frequency of feeding.

Ketogenic Diet

⇒SA1197 Special Authority for Subsidy

Initial application only from a metabolic physician or paediatric neurologist. Approvals valid for 3 months where the patient has intractable epilepsy, pyruvate dehydrogenase deficiency or glucose transported type-1 deficiency and other conditions requiring a ketogenic diet.

Renewal only from a metabolic physician or paediatric neurologist. Approvals valid for 2 years where the patient is on a ketogenic diet and the patient is benefiting from the diet.

HIGH FAT LOW CARBOHYDRATE FORMULA - Special Authority see SA1197 above - Retail pharmacy

Powder (unflavoured)35.50	300 g OP	✓ KetoCal 4:1
		✓ Ketocal 3:1
Powder (vanilla)35.50	300 g OP	✓ KetoCal 4:1

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	
AMINOPHYLLINE	
✓ Inj 25 mg per ml, 10 ml ampoule	5
AMIODARONE HYDROCHLORIDE	
✓ Inj 50 mg per ml, 3 ml ampoule	5
AMOXICILLIN	
	20
✓ Cap 250 mg ✓ Cap 500 mg	
✓ Grans for oral liq 125 mg per 5 ml	
✓ Grans for oral liq 250 mg per 5 ml	300 ml
✓ Inj 1 g vial	
AMOXICILLIN WITH CLAVULANIC ACID	
✓ Tab 500 mg with clavulanic acid 125 mg	30
✓ Grans for oral lig amoxicillin 25 mg with clavulanic	00
acid 6.25 mg per ml	200 ml
✓ Grans for oral liq amoxicillin 50 mg with clavulanic	200 1111
acid 12.5 mg per 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 103	0
BENDROFLUMETHIAZIDE [BENDROFLUAZIDE]	450
✓ Tab 2.5 mg – See note on page 66	150
BENZATHINE BENZYLPENICILLIN	_
✓ Inj 900 mg (1.2 million units) in 2.3 ml syringe	5
BENZATROPINE MESYLATE	
✓ Inj 1 mg per ml, 2 ml	10
BENZYLPENICILLIN SODIUM [PENICILLIN G]	
✓ Inj 600 mg (1 million units) vial	5
BLOOD KETONE DIAGNOSTIC TEST STRIP	
✓ Test strips – Subsidy by endorsement – See note	
on page 26	10
BLOOD GLUCOSE DIAGNOSTIC TEST METER	
✓ Meter with 50 lancets, a lancing device and	
10 diagnostic test strips – Subsidy by	
endorsement - See note on page 28	1
✓ Meter with 50 x lancets, 10 x diagnostic test	
strips and a lancing device - Subsidy by	
endorsement – See note on page 28	1
BLOOD GLUCOSE DIAGNOSTIC TEST STRIP	
✓ Test strips – See note on page 29	50 test
BLOOD KETONE DIAGNOSTIC TEST METER	

inieu on a Fractitioner's Supply Order	
CEFTRIAXONE	
✓ Inj 500 mg vial – Subsidy by endorsement – See note on page 102	5
✓ Inj 1 g vial – Subsidy by endorsement – See note on page 102	
CHARCOAL	
✓ Oral liq 50 g per 250 ml	0 m
CHLORPROMAZINE HYDROCHLORIDE	
✓ Tab 10 mg	30
✓ Tab 25 mg	30
✓ Tab 100 mg	
✓ Inj 25 mg per ml, 2 ml	5
CIPROFLOXACIN	
✓ Tab 250 mg – See note on page 107	
✓ Tab 500 mg – See note on page 107	5
COMPOUND ELECTROLYTES	
✓ Powder for oral soln	10
CONDOMS	
✓ 49 mm	
✓ 53 mm	
✓ 53 mm (chocolate)	
✓ 53 mm (strawberry)	
✓ 56 mm, shaped	
✓ 60 mm	
CYPROTERONE ACETATE WITH ETHINYLOESTRADIO	
✓ Tab 2 mg with ethinyloestradiol 35 mcg and	_
7 inert tabs	.168
DEXAMETHASONE	
✓ Tab 0.5 mg – Retail pharmacy-Specialist	60
✓ Tab 4 mg – Retail pharmacy-Specialist	
DEXAMETHASONE PHOSPHATE	
✓ Inj 4 mg per ml, 1 ml ampoule – See note on page 91	5
✓ Inj 4 mg per ml, 2 ml ampoule – See note on page 91	

rab + mg Tietaii phamiacy opecialist
DEXAMETHASONE PHOSPHATE
✓ Inj 4 mg per ml, 1 ml ampoule – See note on page 915
✓ Inj 4 mg per ml, 2 ml ampoule – See note on page 915
DIAZEPAM
✓ Inj 5 mg per ml, 2 ml ampoule – Subsidy by
endorsement – See note on page 1435

Rectal tubes 5 mg	
✓ Rectal tubes 10 mg	
DICLOFENAC SODIUM	
✓ Inj 25 mg per ml, 3 ml ampoule	
✓ Suppos 50 mg1	ı

DIGOXIN	
✓ Tab 62.5 mcg	30
✓ Tab 250 mcg	
DOXYCYCLINE	
Tab 50 mg	30

✓ Tab 100 mg......30

continued...

✓ Meter – See note on page 26......1

PRACTITIONER'S SUPPLY ORDERS

(continued)		
DUAL BLOOD GLUCOSE AND BLOOD KETONE		GLYCOPYRRONIUM BROMIDE
DIAGNOSTIC TEST METER		✓ Inj 200 mcg per ml, 1 ml ampoule
✓ Meter with 50 lancets, a lancing device and		HALOPERIDOL
10 blood glucose diagnostic test strips –		✓ Tab 500 mcg
Subsidy by endorsement – See note on pag	e 271	✓ Tab 1.5 mg
ERGOMETRINE MALEATE		✓ Tab 5 mg
✓ Inj 500 mcg per ml, 1 ml ampoule	5	✓ Oral liq 2 mg per ml
ERYTHROMYCIN ETHYL SUCCINATE		✓ Inj 5 mg per ml, 1 ml ampoule
✓ Tab 400 mg	20	HALOPERIDOL DECANOATE
✓ Grans for oral liq 200 mg per 5 ml		✓ Inj 50 mg per ml, 1 ml
✓ Grans for oral liq 400 mg per 5 ml	200 ml	✓ Inj 100 mg per ml, 1 ml
ERYTHROMYCIN STEARATE		HYDROCORTISONE
Tab 250 mg	30	✓ Inj 100 mg vial
ETHINYLOESTRADIOL WITH DESOGESTREL		HYDROXOCOBALAMIN
Tab 20 mcg with desogestrel 150 mcg and 7 inert	tab 84	✓ Inj 1 mg per ml, 1 ml ampoule
Tab 30 mcg with desogestrel 150 mcg and 7 inert		
ETHINYLOESTRADIOL WITH LEVONORGESTREL		HYOSCINE BUTYLBROMIDE
✓ Tab 20 mcg with levonorgestrel 100 mcg and		✓ Inj 20 mg, 1 ml
7 inert tablets	84	INTRA-UTERINE DEVICE
✓ Tab 50 mcg with levonorgestrel 125 mcg and		✓ IUD 29.1 mm length × 23.2 mm width
7 inert tab	QΛ	✓ IUD 33.6 mm length × 29.9 mm width
		✓ IUD 35.5 mm length x 19.6 mm width
Tab 30 mcg with levonorgestrel 150 mcg	03	IPRATROPIUM BROMIDE
✓ Tab 30 mcg with levonorgestrel 150 mcg and	0.4	✓ Aerosol inhaler, 20 mcg per dose CF
7 inert tablets		✓ Nebuliser soln, 250 mcg per ml, 1 ml
ETHINYLOESTRADIOL WITH NORETHISTERONE		✓ Nebuliser soln, 250 mcg per ml, 2 ml
✓ Tab 35 mcg with norethisterone 1 mg		IVERMECTIN
✓ Tab 35 mcg with norethisterone 1 mg and 7 inert		✓ Tab 3 mg – See note on page 79
✓ Tab 35 mcg with norethisterone 500 mcg	63	KETONE BLOOD BETA-KETONE ELEC
✓ Tab 35 mcg with norethisterone 500 mcg and		✓ Test strip
7 inert tab	84	LEVONORGESTREL
FLUCLOXACILLIN		
✓ Cap 250 mg	30	Tab 30 mcg
✓ Grans for oral liq 25 mg per ml		Tab 1.5 mg – See note on page 86
✓ Grans for oral liq 50 mg per ml	200 ml	✓ Subdermal implant (2 x 75 mg rods)
✓ Inj 1 g vial	5	LIDOCAINE [LIGNOCAINE]
FLUPENTHIXOL DECANOATE		✓ Gel 2%, tube – Subsidy by endorsem
✓ Inj 20 mg per ml, 1 ml	5	note on page 137
✓ Inj 20 mg per ml, 2 ml		✓ Gel 2%, 10 ml urethral syringe – Subs
✓ Inj 100 mg per ml, 1 ml		endorsement – See note on pag
FUROSEMIDE [FRUSEMIDE]		LIDOCAINE [LIGNOCAINE] HYDROCH
✓ Tab 40 mg	30	✓ Inj 1%, 5 ml ampoule
✓ Inj 10 mg per ml, 2 ml ampoule		✓ Inj 2%, 5 ml ampoule
GLUCAGON HYDROCHLORIDE		✓ Inj 1%, 20 ml ampoule
✓ Inj 1 mg syringe kit	5	✓ Inj 1%, 20 ml vial
GLUCOSE [DEXTROSE]		✓ Inj 2%, 20 ml ampoule
✓ Inj 50%, 10 ml ampoule	5	✓ Inj 2%, 20 ml vial
		LIDOCAINE [LIGNOCAINE] WITH CHL
✓ Inj 50%, 90 ml bottle	ວ	✓ Gel 2% with chlorhexidine 0.05%, 10
GLYCERYL TRINITRATE	400	
✓ Tab 600 mcg	100	syringes – Subsidy by endorser
✓ Oral pump spray, 400 mcg per dose		note on page 138
✓ Oral spray, 400 mcg per dose	. 250 dose	

HALOPERIDOL	
✓ Tab 500 mcg	30
✓ Tab 1.5 mg	30
✓ Tab 5 mg	30
Oral liq 2 mg per 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	
HYDROCORTISONE	
Inj 100 mg vial	5
HYDROXOCOBALAMIN	
Inj 1 mg per ml, 1 ml ampoule	6
HYOSCINE BUTYLBROMIDE	
/ Inj 20 mg, 1 ml	5
NTRA-UTERINE DEVICE	
	40
✓ IUD 29.1 mm length × 23.2 mm width ✓ IUD 33.6 mm length × 29.9 mm width	
✓ IUD 35.5 mm length × 19.6 mm width	
	40
PRATROPIUM BROMIDE	400 -1
Aerosol inhaler, 20 mcg per dose CFC-free	
Nebuliser soln, 250 mcg per ml, 1 ml ampoule	40
Nebuliser soln, 250 mcg per ml, 2 ml ampoule	40
VERMECTIN	400
Tab 3 mg – See note on page 79	100
KETONE BLOOD BETA-KETONE ELECTRODES	
Test strip	10
LEVONORGESTREL	
Tab 30 mcg	84
Tab 1.5 mg - See note on page 86	5
Subdermal implant (2 × 75 mg rods)	3
LIDOCAINE [LIGNOCAINE]	
✓ Gel 2%, tube – Subsidy by endorsement – See	
note on page 137	150 ml
Gel 2%, 10 ml urethral syringe – Subsidy by	
endorsement – See note on page 137	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	
✓ Inj 2%, 20 ml vial	5
LIDOCAINE [LIGNOCAINE] WITH CHLORHEXIDIN	Ε
Gel 2% with chlorhexidine 0.05%, 10 ml urethral	
syringes – Subsidy by endorsement – See	
note on page 138	5
CI	ontinued

(continued)			
LOPERAMIDE HYDROCHLORIDE		PEAK FLOW METER	
✓ Tab 2 mg	30	✓ Low range	
✓ Cap 2 mg	30	✓ Normal range	25
MASK FOR SPACER DEVICE		PETHIDINE HYDROCHLORIDE	
✓ Small – See note on page 218	50	✓ Inj 50 mg per ml, 1 ml ampoule – Only on a	_
MEDROXYPROGESTERONE ACETATE		controlled drug form	5
✓ Inj 150 mg per ml, 1 ml syringe	5	✓ Inj 50 mg per ml, 2 ml ampoule – Only on a	_
METOCLOPRAMIDE HYDROCHLORIDE		controlled drug form	5
✓ Inj 5 mg per ml, 2 ml ampoule	5	PHENOXYMETHYLPENICILLIN (PENICILLIN V)	
METRONIDAZOLE		✓ Cap 250 mg	
✓ Tab 200 mg	30	✓ Cap 500 mg	
MIDAZOLAM		✓ Grans for oral liq 125 mg per 5 ml	
✓ Inj 1 mg per ml, 5 ml plastic ampoule – See note		✓ Grans for oral liq 250 mg per 5 ml) MI
on page 162	10	PHENYTOIN SODIUM	_
✓ Inj 5 mg per ml, 3 ml plastic ampoule – See note		✓ Inj 50 mg per ml, 2 ml ampoule	
on page 162	5	✓ Inj 50 mg per ml, 5 ml ampoule	5
MORPHINE SULPHATE		PHYTOMENADIONE	_
✓ Inj 5 mg per ml, 1 ml ampoule – Only on a		✓ Inj 2 mg per 0.2 ml	
controlled drug form	5	✓ Inj 10 mg per ml, 1 ml	5
✓ Inj 10 mg per ml, 1 ml ampoule – Only on a		PIPOTHIAZINE PALMITATE	
controlled drug form	5	✓ Inj 50 mg per ml, 1 ml – Subsidy by endorsement – See note on page 152	5
✓ Inj 15 mg per ml, 1 ml ampoule – Only on a		✓ Inj 50 mg per ml, 2 ml – Subsidy by endorsement	0
controlled drug form	5	- See note on page 152	5
✓ Inj 30 mg per ml, 1 ml ampoule – Only on a		PREDNISOLONE	0
controlled drug form	5	✓ Oral lig 5 mg per ml – See note on page 92	n ml
NALOXONE HYDROCHLORIDE		PREDNISONE	<i>J</i> 1111
✓ Inj 400 mcg per ml, 1 ml ampoule	5	✓ Tab 5 mg	30
NICOTINE		PREGNANCY TESTS - HCG URINE	
✓ Patch 7 mg – See note on page 168	28	✓ Cassette	test
✓ Patch 14 mg – See note on page 168		PROCAINE PENICILLIN	
✓ Patch 21 mg – See note on page 168		✓ Inj 1.5 g in 3.4 ml syringe	5
✓ Lozenge 1 mg – See note on page 168		PROCHLORPERAZINE	
✓ Lozenge 2 mg – See note on page 168		✓ Tab 5 mg	30
✓ Gum 2 mg (Fruit) – See note on page 168	384	✓ Inj 12.5 mg per ml, 1 ml	
✓ Gum 2 mg (Mint) – See note on page 168		PROMETHAZINE HYDROCHLORIDE	
✓ Gum 4 mg (Fruit) – See note on page 168	384	✓ Inj 25 mg per ml, 2 ml ampoule	5
✓ Gum 4 mg (Mint) – See note on page 168	384	SALBUTAMOL	
NORETHISTERONE		✓ Inj 500 mcg per ml, 1 ml	5
✓ Tab 350 mcg	84	✓ Aerosol inhaler, 100 mcg per dose CFC	
✓ Tab 5 mg	30	free1000 d	lose
OXYTOCIN		✓ Nebuliser soln, 1 mg per ml, 2.5 ml ampoule	
✓ Inj 5 iu per ml, 1 ml ampoule	5	✓ Nebuliser soln, 2 mg per ml, 2.5 ml ampoule	
✓ Inj 10 iu per ml, 1 ml ampoule	5	SALBUTAMOL WITH IPRATROPIUM BROMIDE	
OXYTOCIN WITH ERGOMETRINE MALEATE		✓ Nebuliser soln, 2.5 mg with ipratropium bromide	
✓ Inj 5 iu with ergometrine maleate 500 mcg per ml, 1	ml5	0.5 mg per vial, 2.5 ml ampoule	20
PARACETAMOL		SODIUM BICARBONATE	
✓ Tab 500 mg - blister pack	30	✓ Inj 8.4%, 50 ml	5
✓ Oral lig 120 mg per 5 ml		✓ Inj 8.4%, 100 ml	
✓ Oral liq 250 mg per 5 ml		continue	
1 - 91			

PRACTITIONER'S SUPPLY ORDERS

(continued)		
SODIUM CHLORIDE		
✓ Inj 0.9%, bag – See note on page 582000 ml ✓ Inj 0.9%, 5 ml ampoule – See note on page 585	TRIMETHOPRIM WITH SULPHAMETHOXAZOLE [CO-TRIMOXAZOLE]	
✓ Inj 0.9%, 10 ml ampoule – See note on page 585	✓ Tab trimethoprim 80 mg and sulphamethoxazole 400 mg	30
SPACER DEVICE	 Oral liq 8 mg sulphamethoxazole 40 mg per 	
✓ 220 ml (single patient)	ml2	200 ml
✓ 510 ml (single patient)50	VERAPAMIL HYDROCHLORIDE	
✓ 800 ml50	✓ Inj 2.5 mg per ml, 2 ml ampoule WATER	5
SULFADIAZINE SILVER	✓ Inj 5 ml ampoule – See note on page 58	5
✓ Crm 1%	✓ Inj 10 ml ampoule – See note on page 58	5
	✓ Inj 20 ml ampoule – See note on page 58	5
TRIMETHOPRIM ✓ Tab 300 mg30	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
Kaitaia
Kawakawa
Kerikeri

Mangonui Maungaturoto Moerewa Ngunguru Paihia Rawene Ruakaka Russell Tutukaka Waipu

Waitemata DHB Helensville Huapai Kumeu Snells Beach

Whangaroa

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

Tairawhiti DHB
Ruatoria
Te Araroa
Te Karaka
Te Puia Springs
Tikitiki
Tokomaru Bay
Tolaga Bay
Taranaki DHB

Taranaki DH 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 Carteron Featherston Greytown Martinborough

SOUTH ISLAND

Nelson/Marlborough DHB Havelock Mapua Motueka Murchison

Picton
Takaka
Wakefield
West Coast DHB
Dobson
Greymouth

Greymouth Hokitika Karamea Reefton South Westland Westport Whataroa

Canterbury DHB Akaroa Amberlev

Amuri Chatham Islands Cheviot

Darfield

Diamond Harbour Hanmer Springs Kaikoura Leeston Lincoln Methven Oxford Rakaia Rolleston Rotherham Templeton

South Canterbury DHB

Fairlie
Geraldine
Pleasant Point
Temuka
Twizel
Waimate
Southern DHB

Waikari

Alexandra Ralclutha Cromwell Gore Kurow Lawrence Lumsden Mataura Milton Oamaru Oban Otautau Outram Owaka Palmerston Queenstown Ranfurly Riverton Roxburah Tapanui Te Anau

Tokonui

Wanaka

Winton

Tuatapere

SECTION F: COMMUNITY PHARMACEUTICALS DISPENSING PERIOD EXEMPTIONS

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 patients 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.

COMMUNITY PHARMACEUTICALS DISPENSING PERIOD EXEMPTIONS

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 Tambocor CR

100 mg

Cap long-acting Tambocor CR

200 mg

MEXILETINE HYDROCHLORIDE

MINOXIDII

NICORANDIL

PROPAFENONE HYDROCHLORIDE

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

DESMOPRESSIN ACETATE
Nasal drops 100 mcg Minirin

per ml

Nasal spray 10 mcg

Desmopressin-PH&T

per dose

MUSCULOSKELETAL SYSTEM

PYRIDOSTIGMINE BROMIDE

NERVOUS SYSTEM

AMANTADINE HYDROCHLORIDE

APOMORPHINE HYDROCHLORIDE

ENTACAPONE

GABAPENTIN

LACOSAMIDE

LAMOTRIGINE

PRAMIPEXOLE HYDROCHLORIDE

ROPINIROLE HYDROCHLORIDE

TOLCAPONE

TOPIRAMATE

VIGABATRIN

SECTION G: SAFETY CAP MEDICINES

Pharmacists should 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	Clic-Loc, United Closures & Plastics PLC, England
	Kerr, Cormack Packaging, Sydney, under licence to Kerr USA
24 mm	Clic-Loc, United Closures & Plastics PLC, England
	Clic-Loc, ACI Closures under license to Owens-Illinois
	Kerr, Cormack Packaging, Sydney, under licence to Kerr USA
28 mm	Clic-Loc, United Closures & Plastics PLC, England
	Clic-Loc, ACI Closures under license to Owens-Illinois
	Kerr, Cormack Packaging, Sydney, under licence to Kerr USA
	PDL Squeezlok
	PDL FG

ALIMENTARY TRACT AND METABOLISM

FERROUS SULPHATE

Oral liq 30 mg (6 mg

Ferodan

CI OBAZAM Tab 10 mg

Frisium

(Extemporaneously compounded oral liquid preparations) elemental) per 1 ml

CLONAZEPAM

DIAZEPAM

Oral drops 2.5 mg per ml Rivotril

CARDIOVASCUL AR SYSTEM

AMILORIDE HYDROCHLORIDE

Oral liq 1 mg per ml Biomed Tab 2 mg

Arrow-Diazepam

Tab 5 mg Arrow-Diazepam (Extemporaneously compounded oral liquid preparations)

CAPTOPRIL

Oral lig 5 mg per ml Capoten

ETHOSUXIMIDE

7arontin Oral liq 250 mg per 5 ml

CHI OROTHIAZIDE

Oral lig 50 mg per ml Biomed

I EVETIRACETAM

Oral liq 100 mg per ml Levetiracetam-AFT

DIGOXIN

Oral lig 50 mcg per ml Lanoxin

Lanoxin S29

I ORAZEPAM

Ativan

FUROSEMIDE [FRUSEMIDE]

Oral lig 10 mg per ml Lasix

Tab 1 mg Tab 2.5 mg Ativan (Extemporaneously compounded oral liquid preparations)

I ORMETAZEPAM

SPIRONOLACTONE Oral lig 5 mg per ml **Biomed**

Tab 1 mg Noctamid

(Extemporaneously compounded oral liquid preparations)

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

LEVOTHYROXINE

Tab 25 mcg Synthroid Tab 50 mcg Eltroxin

Mercury Pharma

Synthroid

Eltroxin Tab 100 mcg

Mercury Pharma

Synthroid

(Extemporaneously compounded oral liquid preparations)

METHADONE HYDROCHLORIDE

Oral liq 2 mg per ml **Biodone** Oral lig 5 mg per ml Biodone Forte Oral lig 10 mg per ml Biodone Extra Forte

MORPHINE HYDROCHLORIDE

Oral lig 10 mg per ml

Oral liq 1 mg per ml RA-Morph Oral lig 2 mg per ml RA-Morph Oral lig 5 mg per ml RA-Morph

NITRAZEPAM

Tab 5 mg Nitrados

(Extemporaneously compounded oral liquid preparations)

INFECTIONS - AGENTS FOR SYSTEMIC USE

QUININE SULPHATE

Tab 300 mg Q 300

(Extemporaneously compounded oral liquid preparations)

OXAZEPAM

Tab 10 mg Ox-Pam Ox-Pam Tab 15 mg

(Extemporaneously compounded oral liquid preparations)

MUSCULOSKELETAL SYSTEM

IBUPROFEN

Oral liq 20 mg per ml Fenpaed OXYCODONE HYDROCHLORIDE

Oral lig 5 mg per 5 ml OxvNorm

PARACETAMOL

Oral lig 120 mg per 5 ml

Paracare

RA-Morph

Oral lig 250 mg per 5 ml Paracare Double

Strength

NERVOUS SYSTEM

CARBAMAZEPINE

Oral lig 20 mg per ml Tegretol

SAFETY CAP MEDICINES

PHENYTOIN SODIUM

Oral liq 30 mg per 5 ml Dilantin

SODIUM VAI PROATE

Oral lig 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)

RESPIRATORY SYSTEM AND ALLERGIES

CETIRIZINE HYDROCHLORIDE

Oral lig 1 mg per ml Histaclear

CHLORPHENIRAMINE MALEATE

Oral lig 2 mg per 5 ml Histafen

DEXTROCHLORPHENIRAMINE MALEATE

Oral liq 2 mg per 5 ml Polaramine

PROMETHAZINE HYDROCHI ORIDE

Oral liq 1 mg per 1 ml Allersoothe

SAI BUTAMOI

Oral lig 400 mcg per ml Ventolin

THEOPHYLLINE

Oral lig 80 mg per 15 ml Nuelin

TRIMEPRAZINE TARTRATE

Oral lig 30 mg per 5 ml Vallergan 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)

SECTION I: NATIONAL IMMUNISATION SCHEDULE

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

Vaccinations

ADULT DIPHTHERIA AND TETANUS VACCINE - [Xpharm]

Inj 2 IU diphtheria toxoid with 20 IU tetanus toxoid in 0.5 ml.................. **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 egual 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

haemagluttinin and 2.5 mcg pertactin in 0.5 ml syringe 0.00 10

Boostrix

Boostrix

263

	Subsidy (Manufacturer's Price) \$	Subsidi Per	ully sed	Brand or Generic Manufacturer
DIPHTHERIA, TETANUS, PERTUSSIS AND POLIO VACCINE -	- [Xpharm]			
Funded for any of the following:				
A single dose for children up to the age of 7 who have of 2) A course of four vaccines is funded for catch up program and a single single state.		,		rs) to complete full
primary immunisation; or 3) An additional four doses (as appropriate) are funded for pre- or post splenectomy; pre- or post solid organ transfergimens; or				
Five doses will be funded for children requiring solid org	gan transplantation.			
Note: Please refer to the Immunisation Handbook for approp Inj 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis toxoid, 25 mcg pertussis filamentous haemagluttinin, 8 mcg pertactin and 80 D-antigen units poliomyelitis virus in 0.5ml syringe		ch up progra		s. fanrix IPV
DIPHTHERIA, TETANUS, PERTUSSIS, POLIO, HEPATITIS B A	ND HAEMOPHILUS I	NFLUENZA	E TYF	PE 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	f 10 for primary immu	nication: or		
2) An additional four doses (as appropriate) are funded for 10 who are patients post haematopoietic stem cell trans post solid organ transplant, renal dialysis and other sev 3) Up to five doses for children up to and under the age of	r (re-)immunisation for splantation, or chemo- erely immunosuppres	r children up therapy; pre sive regime	or pos	st splenectomy; pre- or
Note: A course of up-to four vaccines is funded for catch up to complete full primary immunisation. Please refer to the Improgrammes.				
Inj 30IU diphtheriatoxoid with 40IU tetanustoxoid, 25mcg pertussistoxoid, 25mcg pertussisfilamentoushaemagluttinin, 8 mcgpertactin, 80 D-AgUpoliovirus, 10mcghepatitisBsurfaceantigen in 0.5ml syringe	0.00	10	√ Ini	fanrix-hexa
HAEMOPHILUS INFLUENZAE TYPE B VACCINE – [Xpharm]	0.00	10	<u> </u>	Idillix-liexa
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-)im transplantation, or chemotherapy; functional asplenic; p or post cochlear implants, renal dialysis and other seve 3) For use in testing for primary immunodeficiency disease paediatrician.	re or post splenecton rely immunosuppress	ny; pre- or po ive regimen	ost sol s; or	lid organ transplant, pre-
Haemophilus Influenzae type B polysaccharide 10 mcg conjugated to tetanus toxoid as carrier protein 20-40 mcg prefilled syringe plus vial 0.5 ml		1	✓ <u>Hi</u>	<u>berix</u>

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

HEPATITIS A VACCINE - [Xpharm]

Funded for patients meeting any of the following criteria:

- 1) Two vaccinations for use in transplant patients; or
- 2) Two vaccinations for use in children with chronic liver disease; or
- 3) One dose of vaccine for close contacts of known hepatitis A cases.

Inj 1440 ELISA units in 1 ml syringe	0.00	1	✓ Havrix
Inj 720 ELISA units in 0.5 ml syringe		1	✓ <u>Havrix Junior</u>

	Subsidy (Manufacturer's Price) \$	Per	Full Subsidise	d Generic
EPATITIS B RECOMBINANT VACCINE - [Xpharm]				
Inj 5 mcg per 0.5 ml vial	0.00	1	•	<u>HBvaxPRO</u>
Funded for patients meeting any of the following criteria	:			
1) for household or sexual contacts of known acute h				iers; or
for children born to mothers who are hepatitis B st	urface antigen (HBsAg) pos	itive; or	
for children up to and under the age of 18 years in	clusive who are consid	dered	I not to ha	ive achieved a positive
serology and require additional vaccination or requ	uire a primary course o	f vac	cination;	or
for HIV positive patients; or				
for hepatitis C positive patients; or				
for patients following non-consensual sexual interest	course; or			
for patients following immunosuppression; or				
for solid organ transplant patients; or				
for post-haematopoietic stem cell transplant (HSC	T) patients; or			
following needle stick injury.				
Inj 10 mcg per 1 ml vial	0.00	1	,	HBvaxPRO
Funded for patients meeting any of the following criteria		'	•	IIDVAXEIIO
		onot	itio D oor	ioro: or
 for household or sexual contacts of known acute h for children born to mothers who are hepatitis B si 				1615, 01
3) for children up to and under the age of 18 years in	0 1			wa achieved a pocitive
serology and require additional vaccination or requ				
for HIV positive patients; or	ulle a pilillary course o	ıı vac	Ciriation,	UI .
5) for hepatitis C positive patients; or				
6) for patients following non-consensual sexual interest	contred: or			
7) for patients following immunosuppression; or	course, or			
8) for solid organ transplant patients; or				
for post-haematopoietic stem cell transplant (HSC)	T) natients: or			
10) following needle stick injury.	i) pationio, oi			
Inj 20 mcg per 1 ml prefilled syringe		1	•	Engerix-B
Funded for patients meeting any of the following criteria				
for household or sexual contacts of known acute h				iers; or
2) for children born to mothers who are hepatitis B st				
3) for children up to and under the age of 18 years in				
serology and require additional vaccination or require	uire a primary course o	or vac	cination;	or
4) for HIV positive patients; or				
5) for hepatitis C positive patients; or				
6) for patients following non-consensual sexual interest	course; or			
7) for patients following immunosuppression; or				
8) for solid organ transplant patients; or	T)			
for post-haematopoietic stem cell transplant (HSC following poodle stick injury)	i) patients; or			
10) following needle stick injury.				
Inj 40 mcg per 1 ml vial	0.00	1	/	HBvaxPRO
Funded for any of the following criteria:		•	_	
,				
for dialysis patients; or for liver or kidney transplant patient.				

S29 Unapproved medicine supplied under Section 29

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

HUMAN PAPILLOMAVIRUS (6, 11, 16, 18, 31, 33, 45, 52 AND 58) VACCINE [HPV] - [Xpharm]

Any of the following:

- 1) Maximum of two doses for children aged 14 years and under; or
- 2) Maximum of three doses for patients meeting any of the following criteria:
 - 1) People aged 15 to 26 years inclusive; or
 - 2) Either:

People aged 9 to 26 years inclusive

- 1) Confirmed HIV infection; or
- 2) Transplant (including stem cell) patients: or
- 3) Maximum of four doses for people aged 9 to 26 years inclusive post chemotherapy

10 ✓ Gardasil 9

Subsidy (Manufacturer's Price)	Subsi Per	Fully dised	Brand or Generic Manufacturer
Ψ	1 01		- Iviarialactaroi

INFLUENZA VACCINE

Inj 60 mcg in 0.5 ml syringe (paediatric quadrivalent vaccine) -

[Xpharm]......9.00 1 ✓ Fluarix Tetra

A) INFLUENZA VACCINE - child aged 6 months to 36 months

is available each year for patients aged 6 months to 35 months who meet the following criteria, as set by PHARMAC:

- i) have any of the following cardiovascular diseases
 - a) ischaemic heart disease, or
 - b) congestive heart failure, or
 - c) rheumatic heart disease, or
 - d) congenital heart disease, or
 - e) cerebo-vascular disease; or
- ii) have either of the following chronic respiratory diseases:
 - a) asthma, if on a regular preventative therapy, or
 - b) other chronic respiratory disease with impaired lung function; or
- iii) have diabetes; or
- iv) have chronic renal disease; or
- v) have any cancer, excluding basal and squamous skin cancers if not invasive; or
- vi) have any of the following other conditions:
 - a) autoimmune disease, or
 - b) immune suppression or immune deficiency, or
 - c) HIV, or
 - d) transplant recipients, or
 - e) neuromuscular and CNS diseases/disorders, or
 - f) haemoglobinopathies, or
 - g) on long term aspirin, or
 - h) have a cochlear implant, or
 - i) errors of metabolism at risk of major metabolic decompensation, or
 - j) pre and post splenectomy, or
 - k) down syndrome, or
- vii) have been hospitalised for respiratory illness or have a history of significant respiratory illness:
- viii) are living in the Seddon/Ward and rural Eastern Marlborough region (within the Nelson Marlborough District Health Board) and Kaikoura and Hurunui areas (within the Canterbury District Health Board);
- ix) have been displaced from their homes in Edgecumbe and the surrounding region;

Unless meeting the criteria set out above, the following conditions are excluded from funding:

- a) asthma not requiring regular preventative therapy,
- b) hypertension and/or dyslipidaemia without evidence of end-organ disease.
- B) Doctors are the only Contractors entitled to claim payment from the Funder for the supply of influenza vaccine inj 60 mcg in 0.5 ml syringe (paediatric quadrivalent vaccine) to patients eligible under the above criteria for subsidised immunisation and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.

Inj 60 mcg in 0.5 ml syringe (quadrivalent vaccine)......90.00 10 ✓ Influvac Tetra

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

- a) Only on a prescription
- b) No patient co-payment payable

C)

A) INFLUENZA VACCINE - people 3 years and over

is available each year for patients aged 3 years and over who meet the following criteria, as set by PHARMAC:

- a) all people 65 years of age and over; or
- b) people under 65 years of age who:
 - i) have any of the following cardiovascular diseases:
 - a) ischaemic heart disease, or
 - b) congestive heart failure, or
 - c) rheumatic heart disease, or
 - d) congenital heart disease, or
 - e) cerebo-vascular disease; or
 - ii) have either of the following chronic respiratory diseases:
 - a) asthma, if on a regular preventative therapy, or
 - b) other chronic respiratory disease with impaired lung function; or
 - iii) have diabetes; or
 - iv) have chronic renal disease; or
 - v) have any cancer, excluding basal and squamous skin cancers if not invasive; or
 - vi) have any of the following other conditions:
 - a) autoimmune disease, or
 - b) immune suppression or immune deficiency, or
 - c) HIV, or
 - d) transplant recipients, or
 - e) neuromuscular and CNS diseases/disorders, or
 - f) haemoglobinopathies, or
 - g) are children on long term aspirin, or
 - h) have a cochlear implant, or
 - i) errors of metabolism at risk of major metabolic decompensation, or
 - j) pre and post splenectomy, or
 - k) down syndrome, or
 - vii) are pregnant; or
- c) children aged four years or less (but over three years) who have been hospitalised for respiratory illness or have a history of significant respiratory illness;
- d) people under 18 years of age living in the Seddon/Ward and rural Eastern Marlborough region (within the Nelson Marlborough District Health Board) and Kaikoura and Hurunui areas (within the Canterbury District Health Board):
- e) People under 18 years of age who have been displaced from their homes in Edgecumbe and the surrounding region;

Unless meeting the criteria set out above, the following conditions are excluded from funding:

- a) asthma not requiring regular preventative therapy.
- b) hypertension and/or dyslipidaemia without evidence of end-organ disease.
- B) Contractors will be entitled to claim payment from the Funder for the supply of influenza vaccine to patients eligible under the above criteria pursuant to their contract with their DHB for subsidised immunisation, and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.
- C) Contractors may only claim for patient populations within the criteria that are covered by their contract, which may be a sub-set of the population described in paragraph A above.

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Manufacturer 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. Injection, measles virus 1.000 CCID50, mumps virus 5,012 CCID50, Rubella virus 1,000 CCID50; prefilled 10 Priorix 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 Menactra MENINGOCOCCAL C CONJUGATE VACCINE - [Xpharm] Any of the following: 1) Up to three doses and a booster every five years for patients pre- and post splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre or post solid organ transplant; or 2) One dose for close contacts of meningococcal cases; or 3) A maximum of two doses for bone marrow transplant patients: or 4) A maximum of two doses for patients following immunosuppression*. Note: children under seven years of age require two doses 8 weeks apart, a booster dose three years after the primary series and then five yearly. *Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days. ✓ Neisvac-C PNEUMOCOCCAL (PCV10) CONJUGATE VACCINE - [Xpharm] Fither: 1) A primary course of four doses for previously unvaccinated individuals up to the age of 59 months inclusive; or 2) Up to three doses as appropriate to complete the primary course of immunisation for individuals under the age of 59 months who have received one to three doses of PCV13. Note: please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes Ini 1 mcg of pneumococcal polysaccharide serotypes 1, 5, 6B. 7F, 9V, 14 and 23F; 3 mcg of pneumococcal polysaccharide serotypes 4, 18C and 19F in 0.5 ml 10 Synflorix

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

PNEUMOCOCCAL (PCV13) CONJUGATE VACCINE - [Xpharm]

Any of the following:

- One dose is funded for high risk children (over the age of 17 months and under 18 years) who have previously received four doses of PCV10: or
- 2) Up to an additional four doses (as appropriate) are funded for high risk children aged under 5 years for (re-)immunisation of patients with any of the following:
 - a) on immunosuppressive therapy or radiation therapy, vaccinate when there is expected to be a sufficient immune response; or
 - b) with primary immune deficiencies; or
 - c) with HIV infection; or
 - d) with renal failure, or nephrotic syndrome; or
 - e) who are immune-suppressed following organ transplantation (including haematopoietic stem cell transplant); or
 - f) with cochlear implants or intracranial shunts; or
 - g) with cerebrospinal fluid leaks; or
 - h) receiving corticosteroid therapy for more than two weeks, and who are on an equivalent daily dosage of prednisone of 2 mg/kg per day or greater, or children who weigh more than 10 kg on a total daily dosage of 20 mg or greater; or
 - i) with chronic pulmonary disease (including asthma treated with high-dose corticosteroid therapy); or
 - j) pre term infants, born before 28 weeks gestation; or
 - k) with cardiac disease, with cyanosis or failure; or
 - I) with diabetes; or
 - m) with Down syndrome; or
 - n) who are pre-or post-splenectomy, or with functional asplenia; or
- 3) Up to an additional four doses (as appropriate) are funded for (re-)immunisation of patients 5 years and over with HIV, for patients pre or post haematopoietic stem cell transplantation, or chemotherapy; pre- or post splenectomy; functional asplenia, pre- or post- solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, or primary immunodeficiency; or
- 4) For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

svringe		0.00	10	✓ Prevenar 13
5, 6A, 6B, 7F, 9V	', 14, 18C, 19A, 19F and 23F in 0.5ml			
Inj 30.8 mcg of pneum	nococcal polysaccharide serotypes 1, 3, 4,			
Note: please refer to	the Immunisation Handbook for the appropriat	ie schedule foi	r catch up pr	ogrammes

Prevenar 13

	Subsidy (Manufacturer's Price) \$	Subs	Fully sidised	Brand or Generic Manufacturer
PNEUMOCOCCAL (PPV23) POLYSACCHARIDE VACCINE - Either:	- [Xpharm]			
Up to three doses (as appropriate) for patients with F chemotherapy; pre- or post-splenectomy or with function complement deficiency (acquired or inherited), cochless. All of the following:	tional asplenia, pre- or pear implants, or primary	oost-solid	organ t	ransplant, renal dialysis,
 a) Patient is a child under 18 years for (re-)immun b) Treatment is for a maximum of two doses; and c) Any of the following: 	isation; and			
i) on immunosuppressive therapy or radiation immune response; or ii) with primary immune deficiencies; or iii) with HIV infection; or iv) with renal failure, or nephrotic syndrome;	• • • • • • • • • • • • • • • • • • • •	nen there	is expe	cted to be a sufficient
v) who are immune-suppressed following or or	gan transplantation (incl	uding hae	ematopo	pietic stem cell transplant);
 vi) with cochlear implants or intracranial shur vii) with cerebrospinal fluid leaks; or viii) receiving corticosteroid therapy for more to prednisone of 2 mg/kg per day or greater, 	han two weeks, and wh			
20 mg or greater; or ix) with chronic pulmonary disease (including x) pre term infants, born before 28 weeks ge xi) with cardiac disease, with cyanosis or fail xii) with diabetes; or xiii) with Down syndrome; or xiv) who are pre-or post-splenectomy, or with	station; or ure; or	gh-dose c	orticoste	eroid therapy); or
Inj 575 mcg in 0.5 ml prefilled syringe (25 mcg of each 23 pneumococcal serotype)	ng:	1	√ <u>P</u>	neumovax 23
Note: Please refer to the Immunisation Handbook for app Inj 80D antigen units in 0.5 ml syringe	0.00 1 weeks of age; and	tch-up pro 1	ogramm ✓ <u>IF</u>	

Oral susp live attenuated human rotavirus

1,000,000 CCID50 per dose, prefilled oral applicator......0.00

10

✓ Rotarix

✓ Varilrix

10

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

VARICELLA VACCINE [CHICKENPOX VACCINE] - [Xpharm]

Either:

- 1) Maximum of one dose for primary vaccination for either:
 - a) Any infant born on or after 1 April 2016; or
 - For previously unvaccinated children turning 11 years old on or after 1 July 2017, who have not previously had a varicella infection (chickenpox), or
- 2) Maximum of two doses for any of the following:
 - a) Any of the following for non-immune patients:
 - i) with chronic liver disease who may in future be candidates for transplantation; or
 - ii) with deteriorating renal function before transplantation; or
 - iii) prior to solid organ transplant; or
 - iv) prior to any elective immunosuppression*, or
 - v) for post exposure prophylaxis who are immune competent inpatients.; or
 - b) For patients at least 2 years after bone marrow transplantation, on advice of their specialist, or
 - c) For patients at least 6 months after completion of chemotherapy, on advice of their specialist, or
 - d) For HIV positive non immune to varicella with mild or moderate immunosuppression on advice of HIV specialist, or
 - For patients with inborn errors of metabolism at risk of major metabolic decompensation, with no clinical history of varicella, or
 - f) For household contacts of paediatric patients who are immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella, or
 - g) For household contacts of adult patients who have no clinical history of varicella and who are severely immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella.

* immu	unosuppression due to	steroid or other imr	nunosuppressive th	herapy must be fo	or a treatment perio	od of greater than
28 day	'S					

28 days				
Inj 2000 PFU prefilled syringe plus vial	0.00	1	✓ Varilrix	

Diagnostic Agents

- Symbols -		Renin-Angiotensin System 60 Andriol Testocaps	9
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- •		·	

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Apo-Imiquimod Cream 5%		Arrow-Quinapril 5		Bactroban	
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AHOW-DEHUIDHUAZIUE		\(\frac{1}{2}\) \(\frac{1}2\) \(\frac{1}{2}\) \(\frac{1}2\) \(\frac{1}2\) \(\frac{1}2\) \(\frac{1}2\) \(\frac	143	Detailiethasone souluin phosphi	ii.

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