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Introducing PHARMAC

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

PHARMAC's role:

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

New Zealand Public Health and Disability Act 2000

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

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

Purpose of the Pharmaceutical Schedule

The purpose of the Schedule is to list:

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

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

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

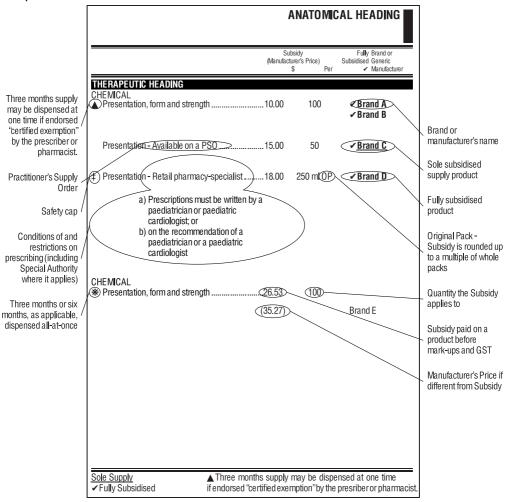
The Pharmaceuticals in this book are listed by therapeutic group, which is based on the WHO Anatomical Therapeutic Chemical (ATC) system. The listings are displayed alphabetically under each heading.

The index lists both chemical entities and product brand names.

Explaining pharmaceutical entries

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

Example



Glossary

Units of Measure

gram g kilogram kg international unit iu	microgrammcg milligrammg millilitreml	millimolemmol unitu
Abbreviations		
Ampoule Amp	GelatinousGel	SolutionSoln
CapsuleCap	GranulesGran	SuppositorySupp
CreamCrm	InfusionInf	TabletTab
Device	InjectionInj	TinctureTinc
DispersibleDisp	LiquidLiq	Trans Dermal Delivery
Effervescent Eff	Long ActingLA	SystemTDDS
Emulsion Emul	OintmentOint	,
Enteric CoatedEC	Sachet Sach	
BSO Bulk Supply Order		

BSO Bulk Supply Order.

CBS Cost Brand Source.

ECP Extemporaneously Compounded Preparation.

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

PSO Practitioner's Supply Order.

Sole Subsidised

Supplier Only brand of this medicine subsidised.

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

- Three months supply may be dispensed at one time if the exempted medicine is endorsed 'certified exemption' by the practitioner or pharmacist.
- * Three months dispensed all-at-once or, in the case of oral contraceptives, six months dispensed all-at-once, unless the medicine meets the Dispensing Frequency Rule criteria.
- ‡ Safety cap required for oral liquid formulations, including extemporaneously compounded preparations.
- Fully subsidised brand of a given medicine. Brands without the tick are not fully subsidised and may cost the patient a manufacturer's surcharge.
- 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 \checkmark in the product's Schedule listing.

Patient costs

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

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

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

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

Special Authority Applications

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

Subsidy

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

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

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

Criteria

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

Making a Special Authority application

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

Ministry of Health Sector Services, Fax: (06) 349 1983 or free fax 0800 100 131

Private Bag 3015, WANGANUI 4540

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

Named Patient Pharmaceutical Assessment policy

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

For more information on NPPA, or to apply, visit the PHARMAC website at

http://www.pharmac.govt.nz/nppa. or call the Panel Coordinators at 0800 660 050 Option 2.

INTRODUCTION

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

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

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

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

This Schedule is dated 1 September 2016 and is to be referred to as the Pharmaceutical Schedule Volume 23 Number 2, 2016. Distribution will be from 20 September 2016. This Schedule comes into force on 1 September 2016.

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.

"Diabetes Nurse Prescriber", means a nurse who is a Designated Prescriber—Registered Nurses Practising in Diabetes Health as determined by the Nursing Council of New Zealand to practice in diabetes health and has authority to prescribe specified diabetes medicines in accordance with regulations made under the Medicines Act 1981.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"National Contract Pharmaceutical", means a Hospital Pharmaceutical for which PHARMAC has negotiated a

national contract and the Price.

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

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

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

"Nurse Prescriber", means a person who is a nurse practitioner in terms of the Medicines Act 1981, or a Diabetes Nurse Prescriber

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

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

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

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

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

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

"PHARMAC", means the Pharmaceutical Management Agency established by Section 46 of the Act (PHARMAC). "Pharmaceutical", means a medicine, therapeutic medical device, or related product or related thing listed in Sections B to I of the Schedule.

"Pharmaceutical Benefits", means the right of:

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

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

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

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

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

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

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

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

"Prescription Medicine", means any Pharmaceutical listed in Part I of Schedule 1 of the Medicines Regulations

1984.

- "Private Hospital", means a hospital certified under the Health and Disability Services (Safety) Act 2001 that is not owned or operated by a DHB.
- "Quitcard Provider", means a person registered with the Ministry of Health as a Quitcard Provider.
- "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:
 - endorsed with the words "recommended by [name of Specialist and year of authorisation]" and signed by the Practitioner, or
 - ii) endorsed with the word 'protocol' which means "initiated in accordance with DHB hospital approved protocol".
 - iii) Annotated by the dispensing pharmacist, following verbal confirmation from the Practitioner of the name of the Specialist and date of recommendation, with the words "recommended by [name of specialist and year of authorisation], confirmed by [practitioner]". Where the Contractor has an electronic record of such an Endorsement or Annotation from a previous prescription for the same Community Pharmaceutical written by a prescriber for the same patient, they may annotate the prescription accordingly.

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

- a) i) follows a substantive consultation with an appropriate Specialist;
 - ii) the consultation to relate to the Patient for whom the Prescription is written;
 - iii) consultation to mean communication by referral, telephone, letter, facsimile or email;
 - iv) except in emergencies consultation to precede annotation of the Prescription; and
 - v) both the Specialist and the General Practitioner must keep a written record of consultation; or
- 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 who holds a current annual practising certificate and who satisfies the criteria set out in paragraphs (a) or (b) or (c) or (d) below:
 - a) the doctor is vocationally registered in accordance with the criteria set out by the Medical Council of New Zealand and the HPCA Act 2003 and who has written the Prescription in the course of practising in that area of medicine: or
 - b) the doctor is recognised by the Ministry of Health as a specialist for the purposes of this Schedule and receives remuneration from a DHB at a level which that DHB considers appropriate for specialists and who has written that prescription in the course of practising in that area of competency; or
 - 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 writes the prescription on DHB stationery and is appropriately authorised by the relevant DHB to do so.

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

"Supply Order", means a Bulk Supply Order or a Practitioner's Supply Order.

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

"Unlisted Pharmaceutical", means a Pharmaceutical that is within the scope of a Hospital Pharmaceutical but is not listed in Section H part II

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

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

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

PART II COMMUNITY PHARMACEUTICALS SUBSIDY

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

PART III PERIOD AND QUANTITY OF SUPPLY

3.1 Doctors', Dentists', Dietitians', Midwives', Nurse Prescribers', Optometrists and Pharmacist Prescribers' Prescriptions (other than oral contraceptives) The following provisions apply to all Prescriptions, other than those for an oral contraceptive, written by a Doctor, Dentist, Dietitian, Midwife, Nurse Prescriber, an Optometrist, or a Pharmacist Prescriber unless specifically excluded:

- 3.1.1 For a Community Pharmaceutical other than a Class B Controlled Drug, only a quantity sufficient to provide treatment for a period not exceeding three Months will be subsidised.
- 3.1.2 For methylphenidate hydrochloride and dexamphetamine 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 dexamphetamine sulphate, only a quantity:
 - i) sufficient to provide treatment for a period not exceeding 10 days; and
 - which has been dispensed pursuant to a Prescription sufficient to provide treatment for a period not exceeding one Month, will be subsidised.
 - b) for a Dentist prescription only such quantity as is necessary to provide treatment for a period not exceeding five days will be subsidised.
- 3.1.4 Subject to clauses 3.1.3 and 3.1.7, for a Doctor, Dentist, Dietitian, Midwife or Nurse Prescriber and 3.1.7 for an Optometrist, where a practitioner has prescribed a quantity of a Community Pharmaceutical sufficient to provide treatment for:
 - A) one Month or less than one Month, but dispensed by the Contractor in quantities smaller than the quantity prescribed, the Community Pharmaceutical will only be subsidised as if that Community Pharmaceutical had been dispensed in a Monthly Lot:
 - B) more than one Month, the Community Pharmaceutical will be subsidised only if it is dispensed:
 - i) in a 90 Day Lot, where the Community Pharmaceutical is a Pharmaceutical covered by Section F Part I of the Pharmaceutical Schedule; or
 - ii) if the Community Pharmaceutical is not a Pharmaceutical referred to in Section F Part I of the Pharmaceutical Schedule, in Monthly Lots, unless:
 - a) the eligible person or his/her nominated representative endorses the back of the Prescription form with a statement identifying which Access Exemption Criterion (Criteria) applies and signs that statement to this effect: or
 - b) both
 - the Practitioner endorses the Community Pharmaceutical on the Prescription with the words "certified exemption" written in the Practitioner's own handwriting, or signed or initialled by the Practitioner; and
 - 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
- 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
 - in any other case, one Month from the date the Community Pharmaceutical was first dispensed. Only
 that part of any Prescription that is dispensed within the time frames specified above is eligible for
 Subsidy.
- 3.1.7 If a Community Pharmaceutical:
 - a) is stable for a limited period only, and the Practitioner has endorsed the Prescription with the words "unstable medicine" and has specified the maximum quantity that may be dispensed at any one time; or
 - is stable for a limited period only, and the Contractor has endorsed the Prescription with the words "unstable medicine" and has specified the maximum quantity that should be dispensed at any one time in all the circumstances of the particular case; or
 - c) is under the Dispensing Frequency Rule,

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

3.2 Oral Contraceptives

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

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

3.3 Original Packs, Certain Antibiotics and Unapproved Medicines

- 3.3.1 Notwithstanding clauses 3.1 and 3.3 of the Schedule, if a Practitioner prescribes or orders a Community Pharmaceutical that is identified as an Original Pack (OP) on the Pharmaceutical Schedule and is packed in a container from which it is not practicable to dispense lesser amounts, every reference in those clauses to an amount or quantity eligible for Subsidy, is deemed to be a reference:
 - a) where an amount by weight or volume of the Community Pharmaceutical is specified in the Prescription, to the smallest container of the Community Pharmaceutical, or the smallest number of containers of the Community Pharmaceutical, sufficient to provide that amount; and
 - b) in every other case, to the amount contained in the smallest container of the Community Pharmaceutical that is manufactured in, or imported into, New Zealand.

3.3.2 If a Community Pharmaceutical is either:

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

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

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

3.4 Pharmacist Prescribers' Prescriptions

The following apply to every prescription written by a Pharmacist Prescriber

- 3.4.1 Prescriptions written by a Pharmacist Prescriber for a Community Pharmaceutical will only be subsidised where they are for either:
 - a) a Community Pharmaceutical classified as a Prescription Medicine and which a Pharmacist Prescriber is permitted under regulations to prescribe; or

- 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 Diabetes Nurse Prescribers' Prescriptions

The following provisions apply to every Prescription written by a Diabetes Nurse Prescriber:

- 3.5.1 Prescriptions written by a Diabetes Nurse Prescriber for a Community Pharmaceutical will only be subsidised where they are for either:
 - a) a Community Pharmaceutical classified as a Prescription Medicine or a Restricted Medicine and which a Diabetes Nurse Prescribers is permitted under regulations to prescribe; or
 - any other Community Pharmaceutical listed below:
 aspirin, blood glucose diagnostic test meter, blood glucose diagnostic test strip, blood ketone diagnostic
 test meter, glucagon hydrochloride inj 1 mg syringe kit, insulin pen needles, insulin syringes disposable
 with attached needle, insulin pump accessories, insulin pump infusion set, insulin pump reservoir,
 ketone blood beta-ketone electrodes test strip, nicotine, sodium nitroprusside test strip.
- 3.5.2 Any Diabetes Nurse Prescribers' prescription 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).

3.6 Quitcard Providers' Prescriptions

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

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

PART IV DISPENSING FREQUENCY RULE

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

For the purposes of this Dispensing Frequency Rule:

"Frequent Dispensing" means:

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

"Safety Medicine"

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

The Dispensing Frequency Rule covers 5 different circumstances where Frequent Dispensing for patients may be clinically or otherwise appropriate. These are:

- 1) Long Term Condition (LTC) patients and Core patients, or
- 2) Persons in residential care, or
- 3) Trial periods, or

- 4) Safety and co-prescribed medicines, or
- 5) Pharmaceutical Supply Management.

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

If a Pharmacist considers Frequent Dispensing is required, then:

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

4.2 Frequent Dispensings for persons in residential care

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

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

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

4.3 Frequent Dispensings for Trial Periods

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

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

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

4.4 Frequent Dispensing for Safety and co-prescribed medicines

- 4.4.1 For a Safety Medicine to be dispensed via Frequent Dispensing, both of the following conditions must be met:
 - a) The patient is not a resident in a Penal Institution, or one of the residential placements or facilities referenced in 4.2 on the previous page; and
 - b) The prescribing Practitioner has:
 - i) Assessed clinical risk and determined the patient requires increased Frequent Dispensing; and
 - ii) Specified the maximum quantity or period of supply to be dispensed for each Safety Medicine at each dispensing.
- 4.4.2 A Community Pharmaceutical that is co-prescribed with a Safety Medicine, which can be dispensed in accordance with rule 4.4.1 above, may be dispensed at the same frequency as the Safety Medicine if the dispensing pharmacist has:
 - Assessed clinical risk and determined the patient requires Frequent Dispensing of their co-dispensed medicines; and
 - Annotated the Prescription with the amended dispensing quantity and frequency.

4.5 Frequent Dispensing for Pharmaceutical Supply Management

- 4.5.1 Frequent Dispensing may be required from time to time to manage stock supply issues or emergency situations. Pharmacists may dispense more frequently than the Schedule would otherwise allow when all of the following conditions are met:
 - a) PHARMAC has approved and notified pharmacists to annotate Prescriptions for a specified Community Pharmaceutical(s) "out of stock" without prescriber endorsement for a specified time; and
 - b) the dispensing pharmacist has:
 - clearly annotated each of the approved Community Pharmaceuticals that appear on the Prescription with the words "out of stock" or "OOS"; and
 - ii) initialled the annotation in their own handwriting; and
 - iii) has complied with maximum quantity or period of supply to be dispensed at any one time, as specified by PHARMAC at the time of notification.

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

PART V

MISCELLANEOUS PROVISIONS

5.1 Bulk Supply Orders

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

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

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

5.2 Practitioner's Supply Orders

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

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

5.3 Retail Pharmacy and Hospital Pharmacy-Specialist Restriction

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

5.3.1 Record Keeping

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

5.3.2 **Expiry**

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

- 5.3.3 The circulation by Specialists of the circumstances under which they are prepared to recommend a particular Community Pharmaceutical is acceptable as a guide. It must however be followed up by the procedure in subclauses 5.3.1 and 5.3.2. for the individual Patient.
- 5.3.4 The use of preprinted forms and named lists of Specialists (as circulated by some pharmaceutical companies) is regarded as inappropriate.
- 5.3.5 The Rules for Retail Pharmacy-Specialist and Hospital Pharmacy-Specialist will be audited as part of the Ministry of Health's routine auditing procedures.

5.4 Pharmaceutical Cancer Treatments

- 5.4.1 DHBs must provide access to Pharmaceutical Cancer Treatments for the treatment of cancers in their DHB hospitals, and/or in association with Outpatient services provided in their DHB hospitals.
- 5.4.2 DHBs must only provide access to Pharmaceuticals for the treatment of cancer that are listed as Pharmaceutical Cancer Treatments in Sections A to G of the Schedule, provided that DHBs may provide access to an unlisted pharmaceutical for the treatment of cancer where that unlisted pharmaceutical:
 - a) has Named Patient Pharmaceutical Assessment (NPPA) approval;
 - b) is being used as part of a bona fide clinical trial which has Ethics Committee approval;
 - c) is being used and funded as part of a paediatric oncology service; or
 - d) was being used to treat the patient in question prior to 1 July 2005.
- 5.4.3 A DHB hospital pharmacy that holds a claiming agreement for Pharmaceutical Cancer Treatements with the Funder may claim a Subsidy for a Pharmaceutical Cancer Treatment marked as "PCT" or "PCT only" in Sections A to G of this Schedule subject to that Pharmaceutical Cancer Treatment being dispensed in accordance with:
 - a) Part 1:
 - b) clauses 2.1 to 2.2;
 - c) clauses 3.1 to 3.4: and
 - d) clause 5.4.
 - of Section A of the Schedule
- 5.4.4 A Contractor (other than a DHB hospital pharmacy) may only claim a Subsidy for a Pharmaceutical Cancer Treatment marked as "PCT" in Sections A to G of the Schedule subject to that Pharmaceutical Cancer Treatment being dispensed in accordance with the rules applying to Sections A to G of the Schedule.
- 5.4.5 Some indications for Pharmaceutical Cancer Treatments listed in the Schedule are Unapproved Indications. Some of these formed part of the October 2001 decision by the Minister of Health as to pharmaceuticals and indications for which DHBs must provide access. As far as reasonably practicable, these Unapproved Indications are marked in the Schedule. However, PHARMAC makes no representation and gives no guarantee as to the accuracy of this information. Practitioners prescribing Pharmaceutical Cancer Treatments for such Unapproved Indications should:
 - a) be aware of and comply with their obligations under sections 25 and 29 of the Medicines Act 1981, as applicable, and otherwise under that act and the Medicines Regulations 1984;
 - b) be aware of and comply with their obligations under the Health and Disability Commissioner's Code of Consumer Rights, including the requirement to obtain informed consent from the patient (PHARMAC recommends that Practitioners obtain written consent); and
 - exercise their own skill, judgement, expertise and discretion, and make their own prescribing decisions with respect to the use of an unapproved Pharmaceutical Cancer Treatment or a Pharmaceutical Cancer Treatment for an Unapproved Indication.
- 5.4.6 Applications to add pharmaceuticals, and add or amend indications for Pharmaceutical Cancer Treatments, may be made in writing by pharmaceutical suppliers and/or clinicians to PHARMAC. Applications should follow the Guidelines for Funding Applications to PHARMAC 2010 and Recommended methods to derive clinical inputs for proposals to PHARMAC, copies of which are available from PHARMAC or PHARMAC's website.

5.5 Practitioners prescribing unapproved Pharmaceuticals

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

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

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

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

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

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

5.6 Substitution

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

- a) there is a clinical reason why substitution should not occur; or
- b) the prescriber has marked the prescription with a statement such as 'no brand substitution permitted' Such an Authority to Substitute is valid whether or not there is a financial implication for the Pharmaceutical Budget. When dispensing a subsidised alternative brand, the Contractor must annotate and sign the prescription and inform the patient of the brand change.

5.7 Alteration to Presentation of Pharmaceutical Dispensed

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

5.8 Other DHB Funding

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

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

5.9 Conflict in Provisions

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

SECTION B: ALIMENTARY TRACT AND METABOLISM

(Manufacturer's Price) Subsidised Generic Per Manufacturer **Antacids and Antiflatulants** Antacids and Reflux Barrier Agents ALGINIC ACID Sodium alginate 225 mg and magnesium alginate 87.5 mg 30 ✓ Gaviscon Infant SIMETHICONE Oral liq aluminium hydroxide 200 mg with magnesium hydrox-500 ml Mylanta P (Mylanta P Oral liq aluminium hydroxide 200 mg with magnesium hydroxide 200 mg and activated simethicone 20 mg per 5 ml to be delisted 1 December 2016) SODIUM ALGINATE * Tab 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg - peppermint flavour1.80 60 Gaviscon Double (8.60)Strenath Oral lig 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml1.50 500 ml Acidex **Phosphate Binding Agents** ALUMINIUM HYDROXIDE ✔ Alu-Tab 100 CALCIUM CARBONATE Oral liq 1,250 mg per 5 ml (500 mg elemental per 5 ml) -Subsidy by endorsement......39.00 ✔ Roxane 500 ml Only when prescribed for children under 12 years of age for use as a phosphate binding agent and the prescription is endorsed accordingly. **Antidiarrhoeals Agents Which Reduce Motility** LOPERAMIDE HYDROCHLORIDE - Up to 30 cap available on a PSO Tab 2 mg10.75 400 ✔ Nodia Nodia to be Sole Supply on 1 November 2016 ✓ Diamide Relief 400 Diamide Relief to be Sole Supply on 1 October 2016 Rectal and Colonic Anti-inflammatories BUDESONIDE Cap 3 mg - Special Authority see SA1155 on the next page

Subsidy

Fully

Brand or

90

✓ Entocort CIR

- Retail pharmacy166.50

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

⇒SA1155 Special Authority for Subsidy

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

Both:

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

HYDROCORTISONE ACETATE

- 2.1 Diabetes: or
- 2.2 Cushingoid habitus: or
- 2.3 Osteoporosis where there is significant risk of fracture; or
- 2.4 Severe acne following treatment with conventional corticosteroid therapy: or
- 2.5 History of severe psychiatric problems associated with corticosteroid treatment; or
- 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	00.55	04.4 00	40 "
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	59.05	100	✓ Pentasa
Tab 800 mg	85.55	90	Asacol
Modified release granules, 1 g	141.72	120 OP	✓ Pentasa
Enema 1 g per 100 ml	41.30	7	✓ Pentasa
Suppos 500 mg	22.80	20	✓ Asacol
Suppos 1 g	54.60	30	✓ Pentasa
OLSALAZINE			
Tab 500 mg	59.86	100	✓ Dipentum
Cap 250 mg		100	✓ Dipentum
SODIUM CROMOGLYCATE			·
Cap 100 mg	92 91	100	✓ Nalcrom
		100	Maicroin
SULPHASALAZINE			
* Tab 500 mg – For sulphasalazine oral liquid formulation refer,			
page 221	14.00	100	Salazopyrin
Salazopyrin to be Sole Supply on 1 November 2016			4
* Tab EC 500 mg	13.50	100	Salazopyrin EN
Salazopyrin EN to be Sole Supply on 1 November 2016			

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Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per Manufacturer Local preparations for Anal and Rectal Disorders Antihaemorrhoidal Preparations FLUOCORTOLONE CAPROATE WITH FLUOCORTOLONE PIVALATE AND CINCHOCAINE Oint 950 mcg, with fluocortolone pivalate 920 mcg, and cinchocaine hydrochloride 5 mg per g6.35 30 a OP ✓ Ultraproct Suppos 630 mcg, with fluocortolone pivalate 610 mcg, and 12 Ultraproct HYDROCORTISONE WITH CINCHOCAINE 30 q OP ✔ Proctosedvl Suppos 5 mg with cinchocaine hydrochloride 5 mg per g9.90 12 ✔ Proctosedvl Management of Anal Fissures GLYCERYL TRINITRATE - Special Authority see SA1329 below - Retail pharmacy 30 g OP ✔ Rectogesic ⇒SA1329 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has a chronic anal fissure that has persisted for longer than three weeks. Antispasmodics and Other Agents Altering Gut Motility **GLYCOPYRRONIUM BROMIDE** Inj 200 mcg per ml, 1 ml ampoule - Up to 10 inj available on ✓ Max Health HYOSCINE N-BUTYL BROMIDE ✓ Gastrosoothe 20 Inj 20 mg, 1 ml - Up to 5 inj available on a PSO9.57 ✓ Buscopan MEBEVERINE HYDROCHLORIDE 90 ✓ Colofac **Antiulcerants**

Antisecretory and Cytoprotective

MIS	SOPRO	SIOL
N/	Tab 00	مر مر

★ Tab 200 mcg41.50 120 ✓ Cytotec

Helicobacter Pylori Eradication

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

	Subsidy (Manufacturer's F \$	Price) Sub Per	Fully Brand or osidised Generic Manufacturer
H2 Antagonists			
RANITIDINE - Only on a prescription			
* Tab 150 mg		500	Ranitidine Relief
* Tab 300 mg		500	Ranitidine Relie
* Oral liq 150 mg per 10 ml		300 ml	Peptisoothe
* Inj 25 mg per ml, 2 ml	8.75	5	✓ Zantac
Proton Pump Inhibitors			
ANSOPRAZOLE			
* Cap 15 mg	5.08	100	✓ Lanzol Relief
← Cap 30 mg	5.93	100	✓ Lanzol Relief
DMEPRAZOLE			
For omeprazole suspension refer Standard Formulae, pag			40 15 11 4
* Cap 10 mg		90	Omezol Relief
★ Cap 20 mg ★ Cap 40 mg		90 90	✓ Omezol Relief ✓ Omezol Relief
€ Powder – Only in combination			✓ Midwest
Only in extemporaneously compounded omeprazole su		5 g	₩ Iviiuwest
Inj 40 mg ampoule with diluent	•	5	✓ Dr Reddy's Omeprazole
Dr Reddy's Omeprazole to be Sole Supply on 1 Octobe	r 2016		
PANTOPRAZOLE			
← Tab EC 20 mg	2.68	100	✓ Pantoprazole
·			Actavis 20
★ Tab EC 40 mg	3.54	100	Pantoprazole
			Actavis 40
Site Protective Agents			
SISMUTH TRIOXIDE			
Tab 120 mg	32.50	112	✓ De Nol S29
De Nol S29 Tab 120 mg to be delisted 1 January 2017)			
COLLOIDAL BISMUTH SUBCITRATE			
	1/151	50	✓ Gastrodenol \$29
Tab 120 mg	14.31	50	₩ Gastrouerior 529
SUCRALFATE	05.50	100	
Tab 1 g		120	Carafata
	(48.28)		Carafate
Bile and Liver Therapy			
RIFAXIMIN - Special Authority see SA1461 below - Retail ph	armacy		
Tab 550 mg	•	56	✓ Xifaxan
PACA1461 Chaniel Authority for Cuboidy			

■SA1461 Special Authority for Subsidy

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

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

_	Subsidy (Manufacturer's		sidised G	and or eneric
Diabetes	\$	Per	✓ Mi	anufacturer
Hyperglycaemic Agents				
DIAZOXIDE - Special Authority see SA1320 below - Retail phan	macv			
Cap 25 mg	-	100	✓ Prog	licem \$29
Cap 100 mg	280.00	100	✔ Prog	licem S29
Oral liq 50 mg per ml	620.00	30 ml OP	✔ Prog	lycem S29
■ SA1320 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals valid glycaemia caused by hyperinsulinism. Renewal from any relevant practitioner. Approvals valid without fu priate and the patient is benefiting from treatment. GLUCAGON HYDROCHLORIDE	rther renewal ur	nless notified w	here the tre	atment remains appro
Inj 1 mg syringe kit – Up to 5 kit available on a PSO Insulin - Short-acting Preparations	32.00	1	∨ Gluc	agen Hypokit
insum - Short-acting Preparations				
INSULIN NEUTRAL Inj human 100 u per ml	25.26	10 ml OP	✓ Actra	•
▲ Inj human 100 u per ml, 3 ml	42.66	5		pid Penfill
Insulin - Intermediate-acting Preparations				
INSULIN ASPART WITH INSULIN ASPART PROTAMINE				
▲ Inj 100 iu per ml, 3 ml prefilled pen	52.15	5	✓ Novo	Mix 30 FlexPen
INSULIN ISOPHANE				
▲ Inj human 100 u per ml	17.68	10 ml OP		ulin NPH
A lai human 100 u nan ml 0 ml	00.00	-	✓ Prota	P
▲ Inj human 100 u per ml, 3 ml	29.86	5		ulin NPH phane Penfill
INOLII IN LOODI LANE WITH INOLII IN NEUTDAL			FIOL	ipilalie Pellilli
INSULIN ISOPHANE WITH INSULIN NEUTRAL Inj human with neutral insulin 100 u per ml	25.26	10 ml OP	4.∕ Humi	ulin 30/70
a inj numan with neutral insulin 100 u per mi	25.20	10 IIII OF	✓ Mixta	
▲ Inj human with neutral insulin 100 u per ml, 3 ml	42.66	5		ulin 30/70
,			✓ PenM	1ix 30
			✓ PenN	
			✓ PenN	lix 50
INSULIN LISPRO WITH INSULIN LISPRO PROTAMINE				
\blacktriangle Inj lispro 25% with insulin lispro protamine 75% 100 u per ml,				
3 ml	42.66	5	✓ Hum	alog Mix 25
▲ Inj lispro 50% with insulin lispro protamine 50% 100 u per ml,	40.00	-		ala a Mia 50
3 ml	42.66	5	✓ Huma	alog Mix 50
				-

(I	Subsidy Manufacturer's Pric \$	e) Sub	Fully Brand or sidised Generic Manufacturer	
nsulin - Long-acting Preparations	Ψ	rei	V Ivial luiacturei	
ISULIN GLARGINE ▶ Inj 100 u per ml, 10 ml	63.00	1	✓ Lantus	
Inj 100 u per ml, 3 ml		5	✓ Lantus	
Inj 100 u per ml, 3 ml disposable pen		5	✓ Lantus SoloStar	
nsulin - Rapid Acting Preparations				
ISULIN ASPART	F1 10	-	A Nava David Flav Dav	_
Inj 100 u per ml, 3 ml syringe		5	NovoRapid FlexPer	Л
Inj 100 u per ml, 3 ml		5 1	NovoRapid Penfill	
Inj 100 u per ml, 10 ml	30.03	ı	✓ NovoRapid	
ISULIN GLULISINE				
. Inj 100 u per ml, 10 ml		1	✓ Apidra	
Inj 100 u per ml, 3 ml		5	✓ Apidra	
Inj 100 u per ml, 3 ml disposable pen	46.07	5	Apidra SoloStar	
ISULIN LISPRO				
Inj 100 u per ml, 10 ml	34.92	10 ml OP	✓ Humalog	
. Inj 100 u per ml, 3 ml		5	✓ Humalog	
Alpha Glucosidase Inhibitors				
CARBOSE				
- Tab 50 mg	4.20	90	✓ Glucobay	
Tab 100 mg		90	✓ Glucobay ✓ Glucobay	
Oral Hypoglycaemic Agents		30	Gladobay	
LIBENCLAMIDE			4	
- Tab 5 mg	5.00	100	✓ Daonil	
LICLAZIDE				
Tab 80 mg	11.50	500	✓ Glizide	
LIPIZIDE			•	
Tab 5 mg	2.85	100	✓ Minidiab	
-	2.00	100	· immalab	
ETFORMIN HYDROCHLORIDE	0.50	4 000	4	
Tab immediate-release 500 mg		1,000	<u>✓ Metchek</u>	
Tab immediate-release 850 mg	7.82	500	Metformin Mylan	
OGLITAZONE				
Tab 15 mg		90	✓ <u>Vexazone</u>	
Tab 30 mg	5.06	90	✓ <u>Vexazone</u>	
Tab 45 mg	7.10	90	✓ <u>Vexazone</u>	
Diabetes Management				
Ketone Testing				
•				
LOOD KETONE DIAGNOSTIC TEST METER - Up to 1 meter ava				
Meter funded for the purposes of blood ketone diagnostics only			•	
at risk of future episodes or patient is on an insulin pump. Only			•	

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✔ Freestyle Optium

Neo

	(Manufacturer's \$	Price) Sub Per	sidised	Generic Manufacturer
KETONE BLOOD BETA-KETONE ELECTRODES a) Maximum of 20 strip per prescription b) Up to 10 strip available on a PSO Test strip – Not on a BSO	15.50	10 strip OP		reestyle Optium Ketone
SODIUM NITROPRUSSIDE – Maximum of 50 strip per prescripti	on			
* Test strip - Not on a BSO	6.00	50 strip OP		ccu-Chek Ketur-Test
	14.14		✓ K	etostix

Subsidy

Fully

Brand or

Blood Glucose Testing

BLOOD GLUCOSE DIAGNOSTIC TEST METER - Subsidy by endorsement

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

Meter with 50 lancets, a lancing device and 10 diagnostic test

strips	1 OP	CareSens II
		CareSens N
		✓ CareSone N POP

Note: Only 1 meter available per PSO

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

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

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

Blood glucose test strips - Note differing brand requirements

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

Brand or

Generic

Manufacturer

Subsidy Fully (Manufacturer's Price) Subsidised \$

■ SA1294 Special Authority for Subsidy

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

PHARMAC

PO Box 10 254 Facsimile: (04) 974 4788

Wellington Email: bgstrips@pharmac.govt.nz

⇒SA1291 Special Authority for Subsidy

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

PHARMAC

PO Box 10 254 Facsimile: (04) 974 4788

Wellington Email: bgstrips@pharmac.govt.nz
BLOOD GLUCOSE TEST STRIPS (VISUALLY IMPAIRED)

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

- 1) Prescribed for a patient on insulin or a sulphonylurea and endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of insulin or sulphonylurea; or
- 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.

Insulin Syringes and Needles

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

INSULIN PEN NEEDLES - Maximum of 100 dev per prescription

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

		Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
INS	SULIN SYRINGES, DISPOSABLE WITH ATTACHED NEEDLE	– Maximum of 100 of	dev pe	r prescriptio	on
*	Syringe 0.3 ml with 29 g \times 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 \times 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 \times 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 \times 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 \times 12.7 mm needle	13.00	100	✓ B	-D Ultra Fine
		1.30	10		
		(1.99)		B-	-D Ultra Fine
*	Syringe 1 ml with 31 g × 8 mm needle	13.00	100	✓ B	-D Ultra Fine II
		1.30	10		
		(1.99)		B-	-D Ultra Fine II

Insulin Pumps

INSULIN PUMP - Special Authority see SA1603 below - Retail pharmacy

- a) Maximum of 1 dev per prescription
- b) Only on a prescription
- c) Maximum of 1 insulin pump per patient each four year period.

Min basal rate 0.025 U/h; black colour	4,500.00	1	Animas Vibe
Min basal rate 0.025 U/h; blue colour	4,500.00	1	Animas Vibe
Min basal rate 0.025 U/h; green colour	4,500.00	1	Animas Vibe
Min basal rate 0.025 U/h; pink colour	4,500.00	1	Animas Vibe
Min basal rate 0.025 U/h; silver colour	4,500.00	1	Animas Vibe
Min basal rate 0.05 U/h; blue colour	4,400.00	1	Paradigm 522
			Paradigm 722
Min basal rate 0.05 U/h; clear colour	4,400.00	1	✓ Paradigm 522
			Paradigm 722
Min basal rate 0.05 U/h; pink colour	4,400.00	1	Paradigm 522
			Paradigm 722
Min basal rate 0.05 U/h; purple colour	4,400.00	1	✓ Paradigm 522
			Paradigm 722
Min basal rate 0.05 U/h; smoke colour	4,400.00	1	Paradigm 522
			Paradigm 722

⇒SA1603 Special Authority for Subsidy

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

All of the following:

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

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

continued...

- 5 Applicant is part of a multidisciplinary team experienced in the management of type 1 diabetes care; and
- 6 Either:
 - 6.1 Applicant is a relevant specialist; or
 - 6.2 Applicant is a nurse practitioner working within their vocational scope.

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

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

All of the following:

1 Patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and

Subsidy (Manufacturer's Price)

Fully Subsidised

Per

Brand or Generic Manufacturer

continued...

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

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

All of the following:

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

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

continued...

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

All of the following:

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

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 Fither:
 - 3.1 Applicant is a relevant specialist; or
 - 3.2 Applicant is a nurse practitioner working within their vocational scope.

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

All of the following:

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

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

continued...

- 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 Fither:
 - 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
- 8 Has been evaluated by the multidisciplinary team for their suitability for insulin pump therapy; and
- 9 Fither:
 - 9.1 Applicant is a relevant specialist; or
 - 9.2 Applicant is a nurse practitioner working within their vocational scope.

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

All of the following:

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

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

All of the following:

1 Patient has type 1 diabetes or has undergone a pancreatectomy or has cystic fibrosis-related diabetes; and

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

continued...

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

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

- a) Maximum of 1 cap per prescription
- b) Only on a prescription
- c) Maximum of 1 prescription per 180 days.

Battery cap32.00 1 ✓ Animas Battery Cap

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

INSULIN PUMP INFUSION SET (STEEL CANNULA) - Special Authority see SA1604 on page 31 - Retail pharmacy

a'	Maximum	of :	3 sets	ner	prescription
a	i iviaxiiiiuiii	UI V	ノンロい	וסט	DIESCHDUID

 a) Maximum of 3 sets per prescription b) Only on a prescription c) Maximum of 13 infusion sets will be funded per year. 10 mm steel needle; 29 G; manual insertion; 60 cm tubing × 			
10 with 10 needles	130.00	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 \times 10 with 10 needles	130.00	1 OP	✓ Paradigm Sure-T
10 mm steel needle; 29 G; manual insertion; 80 cm tubing × 10 with 10 needles; luer lock	130.00	1 OP	MMT-886 ✓ Sure-T MMT-885
6 mm steel cannula; straight insertion; 60 cm grey line × 10 with 10 needles		1 OP	✓ Contact-D
6 mm steel needle; 29 G; manual insertion; 60 cm tubing \times 10 with 10 needles	130.00	1 OP	✓ Paradigm Sure-T
6 mm steel needle; 29 G; manual insertion; 60 cm tubing × 10 with 10 needles; luer lock	130.00	1 OP	MMT-864 ✓ Sure-T MMT-863
6 mm steel needle; 29 G; manual insertion; 80 cm tubing × 10 with 10 needles		1 OP	✓ Paradigm Sure-T
6 mm steel needle; 29 G; manual insertion; 80 cm tubing \times			MMT-866
10 with 10 needles; luer lock		1 OP	Sure-T MMT-865
10 with 10 needles		1 OP	✓ Contact-D
8 mm steel needle; 29 G; manual insertion; 60 cm tubing × 10 with 10 needles		1 OP	✓ Paradigm Sure-T
8 mm steel needle; 29 G; manual insertion; 60 cm tubing \times			MMT-874
10 with 10 needles; luer lock		1 OP	✓ Sure-T MMT-873
10 with 10 needles	130.00	1 OP	✓ Paradigm Sure-T MMT-876
o min steel needle, 23 d, manda msertion, 60 cm tubing x			4.4

1 OP

✓ Sure-T MMT-875

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

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

- a) Maximum of 3 sets per prescription
- b) Only on a prescription
- c) Maximum of 13 infusion sets will be funded per year.
- 13 mm teflon cannula: angle insertion: insertion device: 110 cm grey line × 10 with 10 needles140.00
- 13 mm teflon cannula: angle insertion: insertion device:
- 13 mm teflon cannula: angle insertion: insertion device:
- 60 cm grey line × 10 with 10 needles140.00 13 mm teflon cannula; angle insertion; insertion device:
- 60 cm pink line × 10 with 10 needles140.00 1 OP

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

- a) Maximum of 3 sets per prescription
- b) Only on a prescription
- c) Maximum of 13 infusion sets will be funded per year.
- 13 mm teflon cannula: angel insertion: 60 cm grev line ×
- 13 mm teflon cannula; angle insertion; 120 cm line \times 10 with 1 OP
- 13 mm teflon cannula; angle insertion; 45 cm line \times 10 with

- 13 mm teflon cannula; angle insertion; 60 cm line \times 10 with
- 13 mm teflon cannula; angle insertion; 80 cm line \times 10 with
- 17 mm teflon cannula; angle insertion; 110 cm grey line \times
- 17 mm teflon cannula; angle insertion; 110 cm line × 10 with
- 17 mm teflon cannula; angle insertion; 110 cm line × 10 with
- 17 mm teflon cannula; angle insertion; 60 cm grey line \times 17 mm teflon cannula; angle insertion; 60 cm line \times 10 with
- 17 mm teflon cannula; angle insertion; 60 cm line × 10 with
- 17 mm teflon cannula; angle insertion; 80 cm line \times 10 with

- 1 OP ✓ Inset 30
- 1 OP ✓ Inset 30
- 1 OP ✓ Inset 30
- ✓ Inset 30

1 OP

- - Comfort Short
 - ✔ Paradigm Silhouette
 - MMT-382
 - ✔ Paradigm Silhouette MMT-368
 - ✔ Paradigm Silhouette MMT-381
 - ✔ Paradigm Silhouette MMT-383
 - ✓ Comfort
 - ✔ Paradigm Silhouette MMT-377
 - ✓ Silhouette MMT-371
 - ✓ Comfort
 - ✔ Paradigm Silhouette MMT-378
 - ✓ Silhouette MMT-373
 - ✔ Paradigm Silhouette MMT-384

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

Brand or Generic Manufacturer

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

Maximum			

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 needles140.00 1 OP ✓ Ins	set II
The string by mile X to that to he calco millionism the control of the string to the s	
6 mm teflon cannula; straight insertion; insertion device;	
45 cm blue tubing × 10 with 10 needles130.00 1 OP ✓ Pa	aradigm Mio MMT-941
, ,	aradigm Mio MMT-921
· ·	aradigm Mio MMT-943
, •	aradigm Mio MMT-923
· ·	aradigm Mio MMT-945
	aradigm Mio MMT-965
, •	aradigm Mio MMT-925
6 mm teflon cannula; straight insertionl insertion device; 60 cm blue line × 10 with 10 needles140.00 1 OP ✓ Insertion device;	set II
60 cm grey line × 10 with 10 needles140.00 1 OP ✓ Ins	set II
6 mm teflon cannula; straight insertionl insertion device; 60 cm pink line × 10 with 10 needles140.00 1 OP ✓ Ins 9 mm teflon cannula; straight insertion; insertion device;	set II
60 cm blue line × 10 with 10 needles140.00 1 OP ✓ Ins	set II
9 mm teflon cannula; straight insertion; insertion device; 60 cm grey line × 10 with 10 needles140.00 1 OP ✓ Ins	set II
9 mm teflon cannula; straight insertion; insertion device; 60 cm pink line × 10 with 10 needles140.00 1 OP ✓ Ins	set II
v	aradigm Mio MMT-975
9 mm teflon cannula; straight insertionl insertion device;	
110 cm grey line × 10 with 10 needles140.00 1 OP ✓ Ins	set II

Fully Subsidy Brand or (Manufacturer's Price) Subsidised Generic Por \$ Manufacturer INSULIN PUMP INFUSION SET (TEFLON CANNULA, STRAIGHT INSERTION) - Special Authority see SA1604 on page 31 -Retail pharmacy a) Maximum of 3 sets per prescription b) Only on a prescription c) Maximum of 13 infusion sets will be funded per year. 6 mm teflon cannula: straight insertion: 110 cm tubing × 1 OP ✓ Paradigm Quick-Set MMT-398 6 mm teflon cannula; straight insertion; 110 cm tubing \times Quick-Set MMT-391 1 OP 6 mm teflon cannula; straight insertion; 60 cm tubina \times 1 OP ✔ Paradigm Quick-Set MMT-399 6 mm teflon cannula; straight insertion; 60 cm tubing \times 1 OP Quick-Set MMT-393 6 mm teflon cannula; straight insertion; 80 cm tubing \times 1 OP ✔ Paradigm Quick-Set MMT-387 9 mm teflon cannula; straight insertion; 106 cm tubing × ✓ Paradigm Quick-Set 1 OP MMT-396 9 mm teflon cannula; straight insertion; 110 cm tubing \times ✓ Quick-Set MMT-390 1 OP 9 mm teflon cannula; straight insertion: 60 cm tubing \times 1 OP ✔ Paradigm Quick-Set MMT-397 9 mm teflon cannula; straight insertion; 60 cm tubing \times 1 OP ✓ Quick-Set MMT-392 9 mm teflon cannula; straight insertion: 80 cm tubing \times 1 OP ✔ Paradigm Quick-Set MMT-386 INSULIN PUMP RESERVOIR - Special Authority see SA1604 on page 31 - Retail pharmacy a) Maximum of 3 sets per prescription b) Only on a prescription c) Maximum of 13 packs of reservoir sets will be funded per year. 10 × luer lock conversion cartridges 1.8 ml for Paradigm 1 OP ✓ ADR Cartridge 1.8 Cartridge 200 U, luer lock × 1050.00 1 OP ✓ Animas Cartridge

1 OP

1 OP

1 OP

✔ Paradiam 1.8 Reservoir

✓ Paradigm 3.0 Reservoir

✓ 50X 3.0 Reservoir

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Cartridge for 5 and 7 series pump: 1.8 ml \times 1050.00

Cartridge for 7 series pump; 3.0 ml × 1050.00

Syringe and cartridge for 50X pump, 3.0 ml \times 1050.00

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

Digestives Including Enzymes

PANCREATIC ENZYME

TATOLE AND ENERTIME			
Cap EC 10,000 BP u lipase, 9,000 BP u amylase and 210 BP u protease	34.93	100	✓ Creon 10000
Cap EC 25,000 BP u lipase, 18,000 BP u amylase, 1,000 BP u protease	94.38	100	✓ Creon 25000
Cap EC 25,000 BP u lipase, 22,500 BP u amylase, 1,250 BP u protease	94.40	100	✓ Panzytrat
URSODEOXYCHOLIC ACID – Special Authority see SA1383 below Cap 250 mg – For ursodeoxycholic acid oral liquid formula-	ı – Retail pharı	macy	
tion refer, page 221	53.40	100	✓ <u>Ursosan</u>

⇒SA1383 Special Authority for Subsidy

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

Either:

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

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

All of the following:

- 1 Patient has chronic severe drug induced cholestatic liver injury; and
- 2 Cholestatic liver injury not due to Total Parenteral Nutrition (TPN) use in adults: and
- 3 Treatment with ursodeoxycholic acid may prevent hospital admission or reduce duration of stay.

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

Both:

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

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

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

Both:

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

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

Both:

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

continued...

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

continued...

Laxatives

Bulk-forming Agents

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

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

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

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

- u				
ISPAGHULA (PSYLLIUM) HUSK – Only on a prescription * Powder for oral soln	5.51	500 g OP	✓ Konsyl-D	
MUCILAGINOUS LAXATIVES WITH STIMULANTS				
* Dry	6.02	500 g OP		
	(17.32)		Normacol Plus	
	2.41	200 g OP		
	(8.72)		Normacol Plus	
Faecal Softeners				

Faecai Sotteners		
DOCUSATE SODIUM – Only on a prescription * Tab 50 mg 2.31 * Tab 120 mg 3.13	100 100	✓ <u>Coloxyl</u> ✓ <u>Coloxyl</u>
* Enema conc 18%	100 ml OP	✓ Coloxyl ✓ Laxsol
* Tab 50 mg with sennosides 8 mg	200	₩ Laxsol
* Oral drops 10%	30 ml OP	✓ Coloxyl

* Oral drops 10%	3.78 30 ml OP	✓ <u>Coloxyl</u>
Osmotic Laxatives		
GLYCEROL * Suppos 3.6 g – Only on a prescription6 LACTULOSE – Only on a prescription	5.50 20	✓ <u>PSM</u>
* Oral liq 10 g per 15 ml Laevolac to be Sole Supply on 1 October 2016	3.18 500 ml	✓ Laevolac
MACROGOL 3350 WITH POTASSIUM CHLORIDE, SODIUM BICARBON.	ATE AND SODIUM	CHLORIDE - Specia

ial Authority see SA1473 on the next page - Retail pharmacy

Powder for oral soln 13.125 g with potassium chloride 46.6 mg, sodium bicarbonate 178.5 mg and sodium chlo-30 ✓ Lax-Sachets

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

⇒SA1473 Special Authority for Subsidy

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

- 1 The patient has problematic constipation despite an adequate trial of other oral pharmacotherapies including lactulose where lactulose is not contraindicated; and
- 2 The patient would otherwise require a per rectal preparation.

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

SODIUM ACID PHOSPHATE – Only on a prescription Enema 16% with sodium phosphate 8%	2.50	1	✓ Fleet Phosphate Enema
SODIUM CITRATE WITH SODIUM LAURYL SULPHOACETATE – Enema 90 mg with sodium lauryl sulphoacetate 9 mg per ml, 5 ml	, ,	eription 50	✓ Micolette
Stimulant Laxatives			
BISACODYL – Only on a prescription * Tab 5 mg	5 99	200	✓ Lax-Tab
* Suppos 10 mg		10	✓ <u>Lax-Tub</u> Lax-Suppositories
SENNA – Only on a prescription			
* Tab, standardised	2.17	100	
	(6.84)		Senokot
	0.43	20	
	(1.72)		Senokot

Metabolic Disorder Agents

GALSULFASE - Special Authority see SA1593 below - Retail pharmacy Inj 1 mg per ml, 5 ml vial2,234.00 ✓ Naglazyme

⇒SA1593 Special Authority for Subsidy

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

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

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

All of the following:

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

SODIUM BENZOATE - Special Authority see SA1599 on the next page - Retail pharmacy Soln 100 mg per mlCBS 100 ml ✓ Amzoate S29

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

⇒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 synthetase.

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

Gaucher's Disease

		ty see SA0473 below – Retail pharmacy	IMIGLUCERASE – Special Authority see S
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

⇒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

BENIZ'	$\nabla D\Delta$	MINE	HYDROCI	HI OBIDE
DEINE	IUA		IIIDOOG	ILUNIUL

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

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

CARMELLOSE SODIUM WITH GELATIN AND PECTIN

CANWELLOSE SODIOW WITH GELATIN AND FECTIN			
Paste	17.20	56 g OP	Stomahesive
	4.55	15 g OP	
	(7.90)	•	Orabase
	1.52	5 g OP	
	(3.60)	Ü	Orabase
Powder	8.48	28 g OP	
	(10.95)	Ü	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)

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Bonjela

	Subsidy (Manufacturer's I	Price) Sub	Fully Brand or osidised Generic
	\$	Per	✓ Manufacturer
TRIAMCINOLONE ACETONIDE	T 00	5 m OD	A Kanalan in Orahaaa
Paste 0.1%	5.33	5 g OP	✓ Kenalog in Orabase
Oropharyngeal Anti-infectives			
AMPHOTERICIN B Lozenges 10 mg	5.86	20	✓ Fungilin
VICONAZOLE		20	• Tungiini
Oral gel 20 mg per g	4.79	40 g OP	✓ Decozol
NYSTATIN Oral lig 100,000 u per ml	2 55	24 ml OP	✓ m-Nystatin
Other Oral Agents	2.00	241111 01	THI TY STATE OF
For folinic mouthwash, pilocarpine oral liquid or saliva substitute for	ormula refer Sta	ndard Formula	e nage 224
HYDROGEN PEROXIDE	ormala relei ola	naara r omiala	c, page 224
* Soln 3% (10 vol) – Maximum of 200 ml per prescription	1.40	100 ml	✓ Pharmacy Health
THYMOL GLYCERIN * Compound, BPC	0.15	500 ml	✓ PSM
•	9.10	300 1111	<u>F3W</u>
Vitamins			
Vitamin A			
VITAMIN A WITH VITAMINS D AND C			
* Soln 1000 u with Vitamin D 400 u and ascorbic acid 30 mg			4100 110
per 10 drops	4.50	10 ml OP	✓ Vitadol C
Vitamin B			
HYDROXOCOBALAMIN		_	4
* Inj 1 mg per ml, 1 ml ampoule – Up to 6 inj available on a PS	SO2.31	3	✓ Neo-B12
PYRIDOXINE HYDROCHLORIDE a) No more than 100 mg per dose			
b) Only on a prescription			
 ★ Tab 25 mg - No patient co-payment payable ★ Tab 50 mg 		90 500	✓ <u>Vitamin B6 25</u> ✓ Apo-Pyridoxine
★ Tab 50 mg	11.00	500	Apo-Pyridoxine
* Tab 50 mg	5.62	100	✓ Apo-Thiamine
/ITAMIN B COMPLEX			
* Tab, strong, BPC	4.30	500	✓ Bplex
Vitamin C			
ASCORBIC ACID			
a) No more than 100 mg per dose			
b) Only on a prescription * Tab 100 mg	7.00	500	✓ Cvite
•			

26.32	100	✓ One	e-Alpha
87.98	100	✓ One	e-Alpha
60.68	20 ml OP	One	e-Alpha
9.95	100	Cal	citriol-AFT
2.99	30		
(3.03)		Airf	low
	100	Cal	citriol-AFT
	30		
(5.62)		Airf	low
otion3.85	12	✓ Vit.	D3
	00		nicians Renal Vit

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

1.000 ✓ Mvite Cap (fat soluble vitamins A, D, E, K) - Special Authority see 60 ✓ 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 out syndrome.

	(Manufacturer's Price)) Sul Per	bsidised	Generic Manufacturer
Minerals				
Calcium				
CALCIUM CARBONATE * Tab eff 1.75 g (1 g elemental) * Tab 1.25 g (500 mg elemental) CALCIUM GLUCONATE * Inj 10%, 10 ml ampoule	5.38	30 250		alsource row-Calcium
Fluoride		10	• 110	уорни
SODIUM FLUORIDE * Tab 1.1 mg (0.5 mg elemental)	5.00	100	✓ PS	SM
lodine				
POTASSIUM IODATE * Tab 253 mcg (150 mcg elemental iodine)	3.65	90	✓ Ne	euroTabs
Iron				
FERROUS FUMARATE * Tab 200 mg (65 mg elemental)	2.89	100	✓ <u>Fe</u>	rro-tab
FERROUS FUMARATE WITH FOLIC ACID * Tab 310 mg (100 mg elemental) with folic acid 350 mcg	4.75	60	✓ Fe	rro-F-Tabs
### Tab long-acting 325 mg (105 mg elemental) ### Oral liq 30 mg (6 mg elemental) per 1 ml Ferodan to be Sole Supply on 1 November 2016		30 500 ml		rrograd rodan
FERROUS SULPHATE WITH FOLIC ACID * Tab long-acting 325 mg (105 mg elemental) with folic acid 350 mcg	1.80	30		-
IRON POLYMALTOSE * Inj 50 mg per ml, 2 ml ampoule	(4.29)	5		rrograd F
Magnesium	10.22	<u> </u>	<u> 10</u>	irum ri
For magnesium hydroxide mixture refer Standard Formulae, page MAGNESIUM SULPHATE * Inj 2 mmol per ml, 5 ml ampoule		10	✓ DE	BL
Zinc				
ZINC SULPHATE * Cap 137.4 mg (50 mg elemental)	11.00	100	✓ <u>Zir</u>	ncaps

Subsidy

Fully

Brand or

Fully Subsidy Brand or (Manufacturer's Price) Subsidised Generic \$ Per 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 ≤ 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 < 30ml/min: or
 - 3.2 Both:
 - 3.2.1 Patient has diabetes mellitus: and
 - 3.2.2 Glomerular filtration rate < 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

45

	Subsidy (Manufacturer's Price) \$	Subs Per	Fully idised	Brand or Generic Manufacturer
EPOETIN ALFA [ERYTHROPOIETIN ALFA] - Special Authority	see SA1469 on the p	revious pag	e – Re	etail pharmacy
Wastage claimable – see rule 3.3.2 on page 13	·	, •		
Inj 1,000 iu in 0.5 ml, syringe	48.68	6	√ E	prex
Inj 2,000 iu in 0.5 ml, syringe		6		prex
Inj 3,000 iu in 0.3 ml, syringe	166.87	6	✓ E	prex
Inj 4,000 iu in 0.4 ml, syringe	193.13	6	√ <u>E</u>	prex
Inj 5,000 iu in 0.5 ml, syringe	243.26	6	✓ <u>E</u>	prex
Inj 6,000 iu in 0.6 ml, syringe	291.92	6	✓ <u>E</u>	prex
Inj 8,000 iu in 0.8 ml, syringe	352.69	6	✓ <u>E</u>	prex
Inj 10,000 iu in 1 ml, syringe	395.18	6	✓ <u>E</u>	prex
Inj 40,000 iu in 1 ml, syringe	263.45	1	V E	prex
Megaloblastic				
FOLIC ACID				
* Tab 0.8 mg	20.60	1,000	✓ A	po-Folic Acid
* Tab 5 mg		500	✓ A	po-Folic Acid
Oral liq 50 mcg per ml	24.00 25	5 ml OP	✓ B	liomed
Antifibrinolytics, Haemostatics and Local Sclero	osants			
ELTROMBOPAG – Special Authority see SA1418 below – Retail Wastage claimable – see rule 3.3.2 on page 13	pharmacy			
Tab 25 mg	1,771.00	28	✓ R	levolade

⇒SA1418 Special Authority for Subsidy

Initial application — (idiopathic thrombocytopenic purpura - post-splenectomy) only from a haematologist. Approvals valid for 6 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient has had a splenectomy; and
- 2 Two immunosuppressive therapies have been trialled and failed after therapy of 3 months each (or 1 month for rituximab); and
- 3 Any of the following:

✓ fully subsidised

[HP4] refer page 4

- 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 ≤ 20,000 platelets per microlitre and has evidence of active bleeding; or
- 3.3 Patient has a platelet count of $\leq 10,000$ platelets per microlitre.

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

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

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

EPTACOG ALFA [RECOMBINANT FACTOR VIIA] - [Xpharm]

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

1,178.30 1 V NovoSeven RT
2,356.60 1 V NovoSeven RT
5,891.50 1 V NovoSeven RT
9,426.40 1 V NovoSeven RT
5,891.50 1 NovoSeven RT

✔ Revolade

Subsidy (Manufacturer's Price)	F Subsidis	ully	Brand or Generic	
\$	Per	√	Manufacturer	

FACTOR EIGHT INHIBITOR BYPASSING FRACTION - [Xpharm]

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

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

MOROCTOCOG ALFA [RECOMBINANT FACTOR VIII] - [Xpharm]

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

210.00	1	Xyntha
420.00	1	Xyntha
840.00	1	Xyntha
	1	Xyntha
	1	Xyntha
	210.00 420.00 840.00 1,680.00 2,520.00	420.00 1840.00 11,680.00 1

NONACOG ALFA [RECOMBINANT FACTOR IX] - [Xpharm]

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

rtational riadinopillia management en dapi			
Inj 250 iu vial	310.00	1	✓ BeneFIX
Inj 500 iu vial		1	✓ BeneFIX
Inj 1,000 iu vial		1	✓ BeneFIX
Inj 2,000 iu vial		1	✓ BeneFIX
Ini 3.000 iu vial	· · · · · · · · · · · · · · · · · · ·	1	✓ BeneFIX

NONACOG GAMMA. [RECOMBINANT FACTOR IX] - [Xpharm]

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

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

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

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

The Co-ordinator, Haemophilia Treatments Panel	Phone: 0800 023 588 Option 2		
PHARMAC PO Box 10 254	Facsimile: (04) 974 4881		
Wellington	Email: haemophilia@p	harmac.go	vt.nz
Inj 250 iu vial	287.50	1	✓ Advate
Inj 500 iu vial	575.00	1	Advate
Inj 1,000 iu vial	1,150.00	1	Advate
Inj 1,500 iu vial	1,725.00	1	Advate
Inj 2,000 iu vial	2,300.00	1	Advate
Ini 3.000 iu vial	3.450.00	1	✓ Advate

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

OCTOCOG ALFA [RECOMBINANT FACTOR VIII] (KOGENATE FS) - [Xpharm]

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

website http://www.priarriac.govt.nz or.					
The Co-ordinator, Haemophilia Treatments Panel	nel Phone: 0800 023 588 Option 2				
PHARMAC PO Box 10 254	Facsimile: (04) 974 4881				
Wellington	Email: haemophilia@p	harmac.gov	rt.nz		
Inj 250 iu vial	237.50	1	✓ Kogenate FS		
Inj 500 iu vial	475.00	1	✓ Kogenate FS		
Inj 1,000 iu vial	950.00	1	✓ Kogenate FS		
Inj 2,000 iu vial	1,900.00	1	✓ Kogenate FS		
Inj 3,000 iu vial	2,850.00	1	Kogenate FS		
SODIUM TETRADECYL SULPHATE					
* Inj 3% 2 ml	28.50	5			
.,	(73.00)	•	Fibro-vein		
TRANEXAMIC ACID	(* 5.55)				
	20.67	100	A Cuklakanyan		
Tab 500 mg Cyklokapron to be Sole Supply on 1 October 2016		100	Cyklokapron		
)				
Vitamin K					
PHYTOMENADIONE					
Inj 2 mg per 0.2 ml – Up to 5 inj available on a PSO	8.00	5	✓ Konakion MM		
Inj 10 mg per ml, 1 ml – Up to 5 inj available on a PS		5	✓ Konakion MM		
		•			
Antithrombotic Agents					
Antiplatelet Agents					
Antiplatolot Agonto					
ASPIRIN					
* Tab 100 mg	10.50	990	Ethics Aspirin EC		
CLOPIDOGREL					
* Tab 75 mg – For clopidogrel oral liquid formulation re	fer nage				
221	71 0	84	✓ Arrow - Clopid		
		0.	o Amon Giopia		
DIPYRIDAMOLE	11.50	00	A Putanan CD		
* Tab long-acting 150 mg		60	✓ Pytazen SR		
Pytazen SR to be Sole Supply on 1 October 2016					
PRASUGREL – Special Authority see SA1201 below – F	, ,		4 =		
Tab 5 mg		28	✓ Effient		
Tab 10 mg	120.00	28	✓ Effient		

⇒SA1201 Special Authority for Subsidy

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

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

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

continued...

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

continued...

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

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.

TIC	CAGRELOR - Special Authority see SA1382 below - Retail pharmacy		
*	Tab 90 mg90.00	56	Brilinta

⇒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

DALI EPARIN SODIUM – Special Authority see SA1270 below	w – Retail pharmacy		
Inj 2,500 iu per 0.2 ml prefilled syringe	19.97	10	Fragmin
Inj 5,000 iu per 0.2 ml prefilled syringe	39.94	10	✓ Fragmin
Inj 7,500 iu per 0.75 ml graduated syringe	60.03	10	✓ Fragmin
Inj 10,000 iu per 1 ml graduated syringe	77.55	10	✓ Fragmin
Inj 12,500 iu per 0.5 ml prefilled syringe	99.96	10	✓ Fragmin
Inj 15,000 iu per 0.6 ml prefilled syringe	120.05	10	✓ Fragmin
Inj 18,000 iu per 0.72 ml prefilled syringe		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:

Fither:

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

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

Any of the following:

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

continued...

Subsidy		Fully	Brand or
(Manufacturer's Price)	Sı	bsidised	Generic
\$	Per	~	Manufacturer

continued...

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

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

Either:

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

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

ENOXAPARIN SODIUM - Special Authority see SA1174 below - Retail pharmacy

Inj 20 mg in 0.2 ml syringe	30.91	10	Clexane
Inj 40 mg in 0.4 ml syringe		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		10	Clexane

⇒SA1174 Special Authority for Subsidy

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

Either:

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

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

Any of the following:

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

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

Either:

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

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

HEPARIN SODIUM

Inj 1,000 iu per ml, 5 ml	10	Hospira
61.04	50	✔ Pfizer
66.80		Hospira
Inj 1,000 iu per ml, 35 ml vial17.76	1	✓ Hospira
Inj 5,000 iu per ml, 1 ml14.20	5	✓ Hospira
Inj 5,000 iu per ml, 5 ml236.60	50	✔ Pfizer
Inj 25,000 iu per ml, 0.2 ml9.50	5	Hospira

	Subsidy		Fully	Brand or
	(Manufacturer's Price)		Subsidised	Generic
	\$	Per		Manufacturer
HEPARINISED SALINE				
Inj 10 iu per ml, 5 ml	23.40	30	✓ B	ecton Dickinson
				PosiFlush S29
	39.00	50	✓ P	fizer
PROTAMINE SULPHATE				
* Inj 10 mg per ml, 5 ml	22.40	10		
, ,	(119.23)		А	ırtex
Oral Anticoagulants				
Ordi Antioodguidino				
DABIGATRAN				
Cap 75 mg - No more than 2 cap per day	76.36	60	✓ P	radaxa
Cap 110 mg		60	✓ P	radaxa
Cap 150 mg		60	✓ P	radaxa
RIVAROXABAN - Special Authority see SA1066 below - Retail ph				
Tab 10 mg		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	50	Coumadin
	6.86	100	✓ Marevan
*	Tab 2 mg4.31	50	Coumadin
*	Tab 3 mg9.70	100	Marevan
*	Tab 5 mg5.93	50	Coumadin
	11.75	100	✓ Marevan

Blood Colony-stimulating Factors

FILGRASTIM - Special Authority see SA1259 below - Retail ph	armacy		
Inj 300 mcg per 0.5 ml prefilled syringe	270.00	5	Zarzio
Inj 480 mcg per 0.5 ml prefilled syringe	432.00	5	Zarzio

⇒SA1259 Special Authority for Subsidy

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

Any of the following:

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

continued...

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

continued...

5 Treatment of drug-induced prolonged neutropenia (ANC < 0.5×10^9 /L).

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

PEGFILGRASTIM - Special Authority see SA1384 below - Retail pharmacy

⇒SA1384 Special Authority for Subsidy

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

Note: *Febrile neutropenia risk ≥ 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

GLUCOSE IDEXTROSEI

Intravenous Administration

* Ini 50%, 10 ml amp	=] oule – Up to 5 inj available on a PSO	27 50	5	✓ Biomed	
	e – Up to 5 inj available on a PSO		1	✓ Biomed	
POTASSIUM CHLORIDI	' '				
	D ml	55.00	50	✓ AstraZeneca	
SODIUM BICARBONAT					
		19.95	1	✓ Biomed	
a) Up to 5 inj ava			•	v Biolilou	
b) Not in combina					
Inj 8.4%, 100 ml		20.50	1	✓ Biomed	
a) Up to 5 inj ava	uilable on a PSO				
b) Not in combina	ation				
SODIUM CHLORIDE					
Not funded for use a	as a nasal drop. Only funded for nebulis	ser use when in cor	njunction with a	an antibiotic intended for nebuliser	
use.					
Inj 0.9%, bag - Up	to 2000 ml available on a PSO			✓ Baxter	
		1.26	1,000 ml	✓ Baxter	
, , ,	bed on a prescription for renal dialysis,	maternity or post-na	atal care in the	home of the patient, or on a PSO	i
0 ,	se. (500 ml and 1,000 ml packs)				
	Sole Supply on 1 October 2016	00.00	-	. C Diamad	
	ml), 20 ml ampoule		5	✓ Biomed	
,	nloride oral liquid formulation refer Stand Sole Supply on 1 November 2016	dard Formulae, pag	je 224		
,	to 5 inj available on a PSO	10.85	50	✓ Multichem	
iiij 0.570, 5 iiii - Op	to 5 mg available on a 1 50	15.50	30	✓ Pfizer	
Ini 0.9%. 10 ml – U	Ip to 5 inj available on a PSO		50	✓ Multichem	
, ,	, ,	15.50		✔ Pfizer	
Inj 0.9%, 20 ml		4.72	6	✔ Pharmacia	
•		8.41	20	✓ Multichem	
		11.79	30	✓ Pharmacia	
TOTAL PARENTERAL N	NUTRITION (TPN) - Retail pharmacy-S	Specialist			
Infusion		CBS	1 OP	✓ TPN	

100

454 g OP

✓ Sodibic

✔ Resonium-A

			_	
	Subsidy (Manufacturer's Pi \$	rice) Sub Per	Fully sidised	Brand or Generic Manufacturer
VATER				
 On a prescription or Practitioner's Supply Order only when Schedule requiring a solvent or diluent; or On a bulk supply order; or When used in the extemporaneous compounding of eye d 		orm as an inje	ction list	ed in the Pharmaceut
Purified for inj, 5 ml - Up to 5 inj available on a PSO	10.25	50	✓ Mu	ultichem
Purified for inj, 10 ml - Up to 5 inj available on a PSO		50		ultichem
Purified for inj, 20 ml – Up to 5 inj available on a PSO	6.50	20	✓ Mu	ultichem
Oral Administration				
CALCIUM POLYSTYRENE SULPHONATE Powder	169.85	300 g OP	✓ Ca	Ilcium Resonium
COMPOUND ELECTROLYTES Powder for oral soln — Up to 10 sach available on a PSO	1.80	10	✓ En	erlyte
DEXTROSE WITH ELECTROLYTES				
Soln with electrolytes	6.55	1,000 ml OP		dialyte - Bubblegum (\$29)
Soln with electrolytes (2 × 500 ml)	6.55	1,000 ml OP		dialyte - Bubblegum
Pedialyte - Bubblegum S29 Soln with electrolytes to be delisted 1	December 201	6)		· ·
PHOSPHORUS				
Tab eff 500 mg (16 mmol)	82.50	100	✓ Ph	osphate-Sandoz
POTASSIUM CHLORIDE				
* Tab eff 548 mg (14 m eq) with chloride 285 mg (8 m eq)	5.26 (11.85)	60	Ch	llorvescent
Tab long-acting 600 mg (8 mmol)	, ,	200	✓ Sp	an-K

SODIUM BICARBONATE

SODIUM POLYSTYRENE SULPHONATE

Cap 840 mg8.52

Powder84.65

	(Manufacturer's P	rica) Sub	Fully Brand or sidised Generic
	\$	Per	✓ Manufacturer
Alpha Adranagator Blockers			
Alpha Adrenoceptor Blockers			
DOXAZOSIN			
* Tab 2 mg		500	Apo-Doxazosin
* Tab 4 mg	9.67	500	✓ Apo-Doxazosin
PHENOXYBENZAMINE HYDROCHLORIDE			
* Cap 10 mg	65.00	30	✓ BNM \$29
PRAZOSIN			4
* Tab 1 mg		100	✓ Apo-Prazosin
* Tab 2 mg		100	✓ Apo-Prazosin
* Tab 5 mg	11.70	100	✓ Apo-Prazosin
TERAZOSIN	0.50	00	. A A atauria
* Tab 1 mg Actavis to be Sole Supply on 1 October 2016	0.59	28	✓ Actavis
* Tab 2 mg	0.45	28	✓ Arrow
* Tab 5 mg		28	✓ Arrow
Agents Affecting the Renin-Angiotensin System			
Agents Affecting the Herrin-Affgloterism System			
ACE Inhibitors			
OA PTOPPII			
CAPTOPRIL * # * * * * * * * * * * *	04 00	95 ml OP	✓ Capoten
Oral liquid restricted to children under 12 years of age.	94.99	33 IIII OI	• Capoten
CILAZAPRIL			
* Tab 0.5 mg	2.00	90	✓ Zapril
* Tab 2.5 mg		90	✓ Zapril
* Tab 5 mg	6.98	90	✓ Zapril
ENALAPRIL MALEATE			
* Tab 5 mg	0.96	100	Ethics Enalapril
* Tab 10 mg	1.24	100	Ethics Enalapril
* Tab 20 mg - For enalapril maleate oral liquid formulation re-			4
fer, page 221	1.78	100	Ethics Enalapril
LISINOPRIL			
* Tab 5 mg		90	Ethics Lisinopril
* Tab 10 mg		90	✓ Ethics Lisinopril ✓ Ethics Lisinopril
* Tab 20 mg	2./0	90	Ethics Lisinophi
PERINDOPRIL	0.75	00	. / Ama Davindamuil
* Tab 2 mg * Tab 4 mg		30 30	✓ Apo-Perindopril ✓ Apo-Perindopril
· ·	4.00	30	Apo-remilaopini
QUINAPRIL * Tab 5 mg	/ 21	90	✓ Arrow-Quinapril 5
* Tab 10 mg		90	✓ Arrow-Quinaprii 5 ✓ Arrow-Quinaprii 10
* Tab 20 mg		90	✓ Arrow-Quinapril 20
•			

Subsidy

Fully

Brand or

	Subsidy (Manufacturer's Price \$) Per	Fully Subsidised	Generic
ACE Inhibitors with Diuretics				
CILAZAPRIL WITH HYDROCHLOROTHIAZIDE * Tab 5 mg with hydrochlorothiazide 12.5 mg	10.18	100	V	Apo- Cilazapril/Hydrochloroth
Apo-Cilazapril/Hydrochlorothiazide to be Sole Supply on	1 October 2016			Chazaphi/hydrochloroth
QUINAPRIL WITH HYDROCHLOROTHIAZIDE * Tab 10 mg with hydrochlorothiazide 12.5 mg	3.65	30	~	Accuretic 10
* Tab 20 mg with hydrochlorothiazide 12.5 mg		30		Accuretic 20
Angiotensin II Antagonists				
CANDESARTAN CILEXETIL - Special Authority see SA1223 b	elow – Retail pharma	су		
* Tab 4 mg	2.50	90		<u>Candestar</u>
* Tab 8 mg		90		<u>Candestar</u>
* Tab 16 mg		90		Candestar Candestar
* Tab 32 mg SA1223 Special Authority for Subsidy * Tab 32 mg SPSA1223 Special Authority for Subsidy	10.66	90		<u>Candestar</u>
				provals valid without further
renewal unless notified where patient is not adequately controlle LOSARTAN POTASSIUM * Tab 12.5 mg	ed on maximum tolera	ted dos 84	se of an AC	CE inhibitor. Losartan Actavis
renewal unless notified where patient is not adequately controlle LOSARTAN POTASSIUM Tab 12.5 mg Tab 25 mg	ed on maximum tolera 1.55 1.90	84 84	se of an AC	CE inhibitor. Losartan Actavis Losartan Actavis
renewal unless notified where patient is not adequately controlle LOSARTAN POTASSIUM Tab 12.5 mg Tab 25 mg	ed on maximum tolera 1.55 1.90 2.25	ted dos 84	se of an AC	CE inhibitor. Losartan Actavis
renewal unless notified where patient is not adequately controlle LOSARTAN POTASSIUM Tab 12.5 mg Tab 25 mg Tab 50 mg	ed on maximum tolera 1.55 1.90 2.25	84 84 84 84	se of an AC	CE inhibitor. Losartan Actavis Losartan Actavis Losartan Actavis
renewal unless notified where patient is not adequately controlle LOSARTAN POTASSIUM Tab 12.5 mg Tab 25 mg Tab 50 mg Tab 100 mg	ed on maximum tolera 1.55 1.90 2.25	84 84 84 84	se of an AC	CE inhibitor. Losartan Actavis Losartan Actavis Losartan Actavis
renewal unless notified where patient is not adequately controlle LOSARTAN POTASSIUM Tab 12.5 mg Tab 25 mg Tab 50 mg Tab 100 mg Angiotensin II Antagonists with Diuretics	ed on maximum tolera 1.55 1.90 2.25 2.60	84 84 84 84	ee of an AC	CE inhibitor. Losartan Actavis Losartan Actavis Losartan Actavis
enewal unless notified where patient is not adequately controlle OSARTAN POTASSIUM Tab 12.5 mg Tab 25 mg Tab 50 mg Tab 100 mg Angiotensin II Antagonists with Diuretics OSARTAN POTASSIUM WITH HYDROCHLOROTHIAZIDE	ed on maximum tolera 1.55 1.90 2.25 2.60	84 84 84 84 84	ee of an AC	CE inhibitor. Losartan Actavis Losartan Actavis Losartan Actavis Losartan Actavis Arrow-Losartan &
enewal unless notified where patient is not adequately controlle OSARTAN POTASSIUM * Tab 12.5 mg	ed on maximum tolera1.551.902.252.60	84 84 84 84 84	ee of an AC	CE inhibitor. Losartan Actavis Losartan Actavis Losartan Actavis Losartan Actavis Arrow-Losartan &
enewal unless notified where patient is not adequately controlle OSARTAN POTASSIUM Tab 12.5 mg	ed on maximum tolera1.551.902.252.60	84 84 84 84 84	ee of an AC	CE inhibitor. Losartan Actavis Losartan Actavis Losartan Actavis Losartan Actavis Arrow-Losartan &
enewal unless notified where patient is not adequately controlle OSARTAN POTASSIUM Tab 12.5 mg	ed on maximum tolera	84 84 84 84 84	ee of an AC	CE inhibitor. Losartan Actavis Losartan Actavis Losartan Actavis Losartan Actavis Arrow-Losartan &
enewal unless notified where patient is not adequately controlle OSARTAN POTASSIUM * Tab 12.5 mg	ed on maximum tolera	84 84 84 84 30	ee of an AC	CE inhibitor. Losartan Actavis Losartan Actavis Losartan Actavis Losartan Actavis Arrow-Losartan & Hydrochlorothiazide
renewal unless notified where patient is not adequately controlle LOSARTAN POTASSIUM * Tab 12.5 mg * Tab 25 mg * Tab 50 mg * Tab 100 mg Angiotensin II Antagonists with Diuretics LOSARTAN POTASSIUM WITH HYDROCHLOROTHIAZIDE Tab 50 mg with hydrochlorothiazide 12.5 mg	ed on maximum tolera	84 84 84 84 30	ee of an AC	CE inhibitor. Losartan Actavis Losartan Actavis Losartan Actavis Losartan Actavis Arrow-Losartan & Hydrochlorothiazide Cordarone-X Aratac Cordarone-X
renewal unless notified where patient is not adequately controlle LOSARTAN POTASSIUM * Tab 12.5 mg	ed on maximum tolera	84 84 84 84 30	ee of an AC	CE inhibitor. Losartan Actavis Losartan Actavis Losartan Actavis Losartan Actavis Arrow-Losartan & Hydrochlorothiazide Cordarone-X Aratac
renewal unless notified where patient is not adequately controlle LOSARTAN POTASSIUM * Tab 12.5 mg	ed on maximum tolera	84 84 84 84 30	ee of an ACC	CE inhibitor. Losartan Actavis Losartan Actavis Losartan Actavis Losartan Actavis Arrow-Losartan & Hydrochlorothiazide Cordarone-X Aratac Cordarone-X
renewal unless notified where patient is not adequately controlle LOSARTAN POTASSIUM * Tab 12.5 mg	ed on maximum tolera	84 84 84 84 84 30 30 30	ee of an ACC	CE inhibitor. Losartan Actavis Losartan Actavis Losartan Actavis Losartan Actavis Losartan Actavis Arrow-Losartan & Hydrochlorothiazide Cordarone-X Aratac Cordarone-X Aratac
renewal unless notified where patient is not adequately controlle LOSARTAN POTASSIUM * Tab 12.5 mg	ed on maximum tolera	84 84 84 84 84 30 30 30	ee of an ACC	CE inhibitor. Losartan Actavis Losartan Actavis Losartan Actavis Losartan Actavis Losartan Actavis Arrow-Losartan & Hydrochlorothiazide Cordarone-X Aratac Cordarone-X Aratac
enewal unless notified where patient is not adequately controlle OSARTAN POTASSIUM Tab 12.5 mg Tab 25 mg Tab 50 mg Angiotensin II Antagonists with Diuretics OSARTAN POTASSIUM WITH HYDROCHLOROTHIAZIDE Tab 50 mg with hydrochlorothiazide 12.5 mg Antiarrhythmics For lignocaine hydrochloride refer to NERVOUS SYSTEM, Anae MIODARONE HYDROCHLORIDE Tab 100 mg — Retail pharmacy-Specialist Tab 200 mg — Retail pharmacy-Specialist Inj 50 mg per ml, 3 ml ampoule — Up to 6 inj available on PSO	ed on maximum tolera	84 84 84 84 84 30 30 30	ee of an AC	CE inhibitor. Losartan Actavis Losartan Actavis Losartan Actavis Losartan Actavis Losartan Actavis Arrow-Losartan & Hydrochlorothiazide Cordarone-X Aratac Cordarone-X Aratac

[†] safety car

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

	Subsidy (Manufacturer's Price) \$) Per	Fully Subsidised	Brand or Generic Manufacturer
DIGOXIN				
* Tab 62.5 mcg - Up to 30 tab available on a PSO		240	√ <u>L</u>	anoxin PG
* Tab 250 mcg - Up to 30 tab available on a PSO		240	_	<u>anoxin</u>
*‡ Oral liq 50 mcg per ml	16.60	60 ml	√ L	anoxin
DISOPYRAMIDE PHOSPHATE				
▲ Cap 100 mg	15.00	100		
	(23.87)			lythmodan
▲ Cap 150 mg	26.21	100	✓ R	lythmodan
FLECAINIDE ACETATE - Retail pharmacy-Specialist				
▲ Tab 50 mg	38.95	60	✓ T	ambocor
▲ Cap long-acting 100 mg		30	✓ T	ambocor CR
▲ Cap long-acting 200 mg	68.78	30	✓ T	ambocor CR
Inj 10 mg per ml, 15 ml ampoule	52.45	5	✓ T	ambocor
MEXILETINE HYDROCHLORIDE				
▲ Cap 150 mg	162.00	100	✓ N	lexiletine Hydrochloride USP 829
▲ Cap 250 mg	202.00	100	✓ M	lexiletine Hydrochloride USP 829
PROPAFENONE HYDROCHLORIDE - Retail pharmacy-Specialis	st			
▲ Tab 150 mg	40.90	50	✓ R	lytmonorm
Antihypotensives				
MIDODRINE – Special Authority see SA1474 below – Retail phar Tab 2.5 mg Tab 5 mg	53.00	100 100		autron autron

⇒SA1474 Special Authority for Subsidy

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

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

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

Beta Adrenoceptor Blockers

ATENOLOL * Tab 50 mg * Tab 100 mg * Oral liq 25 mg per 5 ml Restricted to children under 12 years of age.	7.67	500 500 300 ml OP	✓ Mylan Atenolol ✓ Mylan Atenolol ✓ Atenolol AFT
BISOPROLOL FUMARATE			
Tab 2.5 mg	2.40	30	✓ Bosvate
Tab 5 mg	3.50	30	Bosvate
Tab 10 mg	6.40	30	✓ Bosvate

	Cubaidu		rll	. Drand av
	Subsidy (Manufacturer's Price)		Full: Subsidise	
	\$	Per		Manufacturer
CARVEDILOL				
* Tab 6.25 mg	3.90	60	~	Dicarz
* Tab 12.5 mg	5.10	60	~	<u>Dicarz</u>
* Tab 25 mg - For carvedilol oral liquid formulation refer, page				
221	6.30	60	~	Dicarz
CELIPROLOL				
* Tab 200 mg	21.40	180	~	Celol
LABETALOL				
* Tab 50 mg	8.99	100	~	Hybloc
* Tab 100 mg - For labetalol oral liquid formulation refer, page				•
221	11.36	100	~	Hybloc
* Tab 200 mg	29.74	100	~	Hybloc
* Inj 5 mg per ml, 20 ml ampoule		5		
	(88.60)			Trandate
METOPROLOL SUCCINATE				
Tab long-acting 23.75 mg		90		Metoprolol - AFT CR
	20.11	100	~	Actavis-Metoprolol
Metoprolol - AFT CR to be Sole Supply on 1 January 2017				
Tab long-acting 47.5 mg		90		Metoprolol - AFT CR Betaloc CR
Metoprolol - AFT CR to be Sole Supply on 1 January 2017	7.50	30	•	Detaioc Ch
Tab long-acting 95 mg		90	V	Metoprolol - AFT CR
Tab long doing so mg	7.50	30		Betaloc CR
	31.18	100	_	Actavis-Metoprolol
Metoprolol - AFT CR to be Sole Supply on 1 January 2017				·
Tab long-acting 190 mg	3.85	30	~	Myloc CR
	11.54	90	~	Metoprolol - AFT CR
Metoprolol - AFT CR to be Sole Supply on 1 January 2017				
(Actavis-Metoprolol Tab long-acting 23.75 mg to be delisted 1 Oct				
(Betaloc CR Tab long-acting 47.5 mg to be delisted 1 January 2017	,			
(Betaloc CR Tab long-acting 95 mg to be delisted 1 January 2017, (Actavis-Metoprolol Tab long-acting 95 mg to be delisted 1 Octobe				
(Myloc CR Tab long-acting 190 mg to be delisted 1 January 2017)	,			
METOPROLOL TARTRATE				
* Tab 50 mg - For metoprolol tartrate oral liquid formulation refer, page 221	4.64	100	V	Apo-Metoprolol
10101, pago 221	(16.00)	100	•	Lopresor
Apo-Metoprolol to be Sole Supply on 1 November 2016	(1000)			
* Tab 100 mg	6.09	60	~	Apo-Metoprolol
•	(21.00)			Lopresor
Apo-Metoprolol to be Sole Supply on 1 November 2016				
* Tab long-acting 200 mg		28		Slow-Lopresor
* Inj 1 mg per ml, 5 ml vial	24.00	5	•	Lopresor
(Lopresor Tab 50 mg to be delisted 1 November 2016) (Lopresor Tab 100 mg to be delisted 1 November 2016)				
NADOLOL Vis. Tab. 40 mg	10.05	100		Ama Nadalal
* Tab 40 mg * Tab 80 mg		100 100	_	Apo-Nadolol Apo-Nadolol
* Iau 00 IIIg	24.70	100	•	Apo-Nauoloi

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

		Subsidy (Manufacturer's Pri	ce) Per	Fully Subsidised	Brand or Generic Manufacturer
PIN	IDOLOL				
*	Tab 5 mg	9.72	100	✓ A	po-Pindolol
*	Tab 10 mg	15.62	100	✓ A	po-Pindolol
*	Tab 15 mg	23.46	100	✓ A	po-Pindolol
PR	OPRANOLOL				
*	Tab 10 mg	3.65	100	✓ A	po-
	•				Propranolol S29
*	Tab 40 mg	4.65	100	✓ A	00-
					Propranolol S29
*	Cap long-acting 160 mg	18.17	100	✓ C	ardinol LA
*	Oral lig 4 mg per ml - Special Authority see SA1327 below -				
	Retail pharmacy	CBS	500 ml	✓ R	oxane S29
	SA1337 Special Authority for Subsidy				

⇒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

0.01

2 For the treatment of a child under 12 years with cardiac arrthymias or congenital cardiac abnormalities.

SOTALOL

*	Tab 80 mg - For sotalol oral liquid formulation refer, page 221	39.53	500	✓ Mylan
	Mylan to be Sole Supply on 1 November 2016			•
*	Tab 160 mg	12.48	100	Mylan
	Mylan to be Sole Supply on 1 November 2016			-
*	Inj 10 mg per ml, 4 ml ampoule	65.39	5	✓ Sotacor
	10LOL			
*	Tab 10 mg	10.55	100	Apo-Timol

Calcium Channel Blockers

Dihydropyridine Calcium Channel Blockers

AIVI	LOD	IHIN	۱E
110	Tala	0 5	

木	1ab 2.5 mg	2.21	100	Apo-Amiogipine
*	Tab 5 mg - For amlodipine oral liquid formulation refer, page			
	221	5.04	250	✓ Apo-Amlodipine
*	Tab 10 mg	7.21	250	✓ Apo-Amlodipine
FE	LODIPINE			
*	Tab long-acting 2.5 mg	1.45	30	✓ Plendil ER
	Tab long-acting 5 mg		30	✓ Plendil ER
	Tab long-acting 10 mg		30	✓ Plendil ER

_					
		Subsidy (Manufacturer's Price)		Fully	
		(Manufacturer's Price) \$	Per	Subsidised	
195	ADIPINE				
*	Cap long-acting 2.5 mg	7 50	30	V	Dynacirc-SRO
*	Cap long-acting 5 mg		30		Dynacirc-SRO
•	, , ,		50	•	2,
	EDIPINE	17.70	60		Adolet 10
*	Tab long-acting 10 mg		60		Adalat 10
* *	Tab long-acting 20 mg		100		Nyefax Retard
*	Tab long-acting 30 mg Tab long-acting 60 mg		30 30		Adefin XL Adefin XL
			30		AUCIIII AL
O	ther Calcium Channel Blockers				
DIL	TIAZEM HYDROCHLORIDE				
*	Tab 30 mg	4.60	100	~	Dilzem
*	Tab 60 mg - For diltiazem hydrochloride oral liquid formula-				
	tion refer, page 221	8.50	100	~	Dilzem
*	Cap long-acting 120 mg	1.91	30	~	Cardizem CD
		31.83	500	~	Apo-Diltiazem CD
*	Cap long-acting 180 mg	7.56	30	~	Cardizem CD
		47.67	500	~	Apo-Diltiazem CD
*	Cap long-acting 240 mg	10.22	30	~	Cardizem CD
		63.58	500	~	Apo-Diltiazem CD
PEI	RHEXILINE MALEATE				
*	Tab 100 mg	62.90	100	~	Pexsig
\/ = 1	RAPAMIL HYDROCHLORIDE				
*	Tab 40 mg	7.01	100		Isoptin
	3	7.01	100		ізорин
*	Tab 80 mg – For verapamil hydrochloride oral liquid formula-	11 74	100	.,	loontin
*	tion refer, page 221		100 250		Isoptin Verpamil SR
不 米	Tab long-acting 120 mg Tab long-acting 240 mg		250		Verpamil SR
*	Inj 2.5 mg per ml, 2 ml ampoule – Up to 5 inj available on a	25.00	250	•	verpailiii 3n
不	PSO	25.00	5	J	Isoptin
^		25.00	J		ізорині —
C	entrally-Acting Agents				
CLO	ONIDINE				
*	Patch 2.5 mg, 100 mcg per day - Only on a prescription	12.80	4	~	Catapres-TTS-1
*	Patch 5 mg, 200 mcg per day - Only on a prescription	18.04	4	~	Catapres-TTS-2
*	Patch 7.5 mg, 300 mcg per day - Only on a prescription	22.68	4	~	Catapres-TTS-3
CLO	ONIDINE HYDROCHLORIDE				
*	Tab 25 mcg	10.53	112	~	Clonidine BNM
*	Tab 150 mcg		100		Catapres
*	Inj 150 mcg per ml, 1 ml ampoule		5		Catapres
	THYLDOPA				•
\ \ \	Tab 125 mg	1/1 25	100	./	Prodona
*	Tab 250 mg		100		Prodopa Prodopa
*	Tab 500 mg		100		Prodopa Prodopa
*	1ab 500 mg	20.10	100	•	riouopa

	Subsidy			Brand or
	(Manufacturer's	Price) Su Per	bsidised	Generic Manufacturer
	Ψ	1 61		ivianulaciurei
Diuretics				
Loop Diuretics				
BUMETANIDE				
* Tab 1 mg	16.36	100	🗸 Bu	rinex
* Inj 500 mcg per ml, 4 ml vial	7.95	5	🗸 Bu	rinex
FUROSEMIDE [FRUSEMIDE]				
* Tab 40 mg - Up to 30 tab available on a PSO	8.00	1,000	✓ <u>Di</u> u	<u>ırin 40</u>
* Tab 500 mg		50		ex Forte
*‡ Oral liq 10 mg per ml		30 ml OP	✓ Las	
* Inj 10 mg per ml, 25 ml ampoule		6	✓ Las	SiX
* Inj 10 mg per ml, 2 ml ampoule – Up to 5 inj available on		_	4-	
PSO	1.20	5	✓ Fru	usemide-Claris
Potassium Sparing Diuretics				
AMILORIDE HYDROCHLORIDE				
* Tab 5 mg	15.00	100	✓ Ap	o-Amiloride
‡ Oral liq 1 mg per ml	30.00	25 ml OP	✓ Bio	omed
METOLAZONE - Special Authority see SA1349 below - Retail	pharmacy			
Tab 5 mg		1	✓ Me	tolazone S29
		50		roxolyn S29
Initial application from any relevant practitioner. Approvals val ment of patients with refractory heart failure who are intolerant conation therapy. SPIRONOLACTONE				
* Tab 25 mg Spiractin to be Sole Supply on 1 November 2016	4.38	100	✓ Sp	iractin
* Tab 100 mg	11.80	100	✓ Sp	iractin
‡ Oral liq 5 mg per ml	30.00	25 ml OP	✓ Bio	omed
Potassium Sparing Combination Diuretics				
AMILORIDE HYDROCHLORIDE WITH FUROSEMIDE				
* Tab 5 mg with furosemide 40 mg	8.63	28	✓ Fru	ımil
AMILORIDE HYDROCHLORIDE WITH HYDROCHLOROTHIAZ	IDE			
* Tab 5 mg with hydrochlorothiazide 50 mg	5.00	50	✓ Mo	duretic
Thiazide and Related Diuretics				
BENDROFLUMETHIAZIDE [BENDROFLUAZIDE]				
* Tab 2.5 mg - Up to 150 tab available on a PSO	5.48	500	✓ Arr	row-
			<u> </u>	Bendrofluazide
May be supplied on a PSO for reasons other than emerg	•			
* Tab 5 mg	8.95	500	✓ Arr	
OUI OPOTUAZIDE			<u> </u>	<u>Bendrofluazide</u>
CHLOROTHIAZIDE † Oral lig 50 mg per ml	26.00	25 ml OD	✓ Bio	amad
‡ Oral liq 50 mg per ml	20.00	25 ml OP	₽ DIC	nneu

	Subsidy (Manufacturer's Price) \$	Per	Fully Brand or Subsidised Generic Manufacturer
CHLORTALIDONE [CHLORTHALIDONE]			
* Tab 25 mg	8.00	50	Hygroton
INDAPAMIDE			
* Tab 2.5 mg	2.60	90	✓ Dapa-Tabs
Lipid-Modifying Agents			
Fibrates			
BEZAFIBRATE			
* Tab 200 mg	9.05	90	✓ Bezalip
* Tab long-acting 400 mg	6.78	30	Bezalip Retard
GEMFIBROZIL			
* Tab 600 mg	17.60	60	Lipazil
Other Lipid-Modifying Agents			
ACIPIMOX			
* Cap 250 mg	18.75	30	✓ Olbetam
NICOTINIC ACID			
* Tab 50 mg	3.96	100	✓ Apo-Nicotinic Acid
* Tab 500 mg	17.37	100	Apo-Nicotinic Acid
Resins			
CHOLESTYRAMINE			
Powder for oral liq 4 g	19.25	50	
	(52.68)		Questran-Lite
COLESTIPOL HYDROCHLORIDE			
Grans for oral liq 5 g	22.00	30	✓ Colestid
HMG CoA Reductase Inhibitors (Statins)			
Prescribing Guidelines Treatment with HMG CoA Reductase Inhibitors (statins) is reco cardiovascular risk of 15% or greater.	ommended for patients	with o	dyslipidaemia and an absolute 5 yea
ATORVASTATIN – See prescribing guideline above			
* Tab 10 mg	2 52	90	✓ Zarator
- Ido IV IIIg	9.29	500	✓ Lorstat
* Tab 20 mg		90	✓ Zarator
-	13.32	500	✓ Lorstat
* Tab 40 mg		90	✓ Zarator
W Tob 00 mg	21.23	500	✓ Lorstat
* Tab 80 mg	16.23	90 500	✓ Zarator✓ Lorstat
DDAMACTATINI Coo massacibile e e i dell'e e e becce	00.20	500	♥ Loisiai
PRAVASTATIN – See prescribing guideline above * Tab 20 mg	3.45	30	✓ Cholvastin
* Tab 40 mg		30	✓ Cholvastin
		50	- dilottuotiii

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
SIMVASTATIN – See prescribing guideline on the previous page				
* Tab 10 mg	0.95	90	V A	rrow-Simva 10mg
* Tab 20 mg	1.61	90	VA	rrow-Simva 20mg
* Tab 40 mg		90	VA	rrow-Simva 40mg
* Tab 80 mg	7.91	90	VA	rrow-Simva 80mg
Selective Cholesterol Absorption Inhibitors				
EZETIMIBE - Special Authority see SA1045 below - Retail phar	rmacy			

■ SA1045 Special Authority for Subsidy

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

- 1 Patient has a calculated absolute risk of cardiovascular disease of at least 15% over 5 years; and
- 2 Patient's LDL cholesterol is 2.0 mmol/litre or greater; and

- 3 Any of the following:
 - 3.1 The patient has rhabdomyolysis (defined as muscle aches and creatine kinase more than $10 \times \text{normal}$) when treated with one statin; or

30

Ezemibe

- 3.2 The patient is intolerant to both simvastatin and atorvastatin; or
- 3.3 The patient has not reduced their LDL cholesterol to less than 2.0 mmol/litre with the use of the maximal tolerated dose of atorvastatin.

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

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

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

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

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

Tab 10 mg with simvastatin 10 mg	5.15 30	✓ Zimybe
Tab 10 mg with simvastatin 20 mg	6.15 30	✓ Zimybe
Tab 10 mg with simvastatin 40 mg	7.15 30	✓ Zimybe
Tab 10 mg with simvastatin 80 mg	8.15 30	✓ Zimybe

⇒SA1046 Special Authority for Subsidy

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

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

Notes: A patient who has failed to reduce their LDL cholesterol to ≤ 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.

Brand or

Fully

	Subsidy		Fully Brand or
	(Manufacturer's	Per Subs	sidised Generic Manufacturer
	Ψ	1 (1	• Manadatarer
Nitrates			
GLYCERYL TRINITRATE	0.00	400 OD	. A Localisada
* Tab 600 mcg – Up to 100 tab available on a PSO		100 OP	✓ Lycinate
* Oral pump spray, 400 mcg per dose – Up to 250 dose avail-		050 dasa 0D	A Nitralia aval Duman
able on a PSO	4.45	250 dose OP	✓ Nitrolingual Pump
W Oval anyon 400 mag new door . Up to 050 door quallable on			Spray
Oral spray, 400 mcg per dose – Up to 250 dose available on a PSO		250 dose OP	✓ Glytrin
* Patch 25 mg, 5 mg per day		30 dose or	✓ Nitroderm TTS
* Patch 50 mg, 10 mg per day		30	✓ Nitroderm TTS
* *, *	10.02	00	Miliodellii 115
SOSORBIDE MONONITRATE	17.10	400	. 4 I 00
* Tab 20 mg		100	✓ Ismo 20
Tab long-acting 40 mg Tab long-acting 60 mg		30 90	✓ Ismo 40 Retard ✓ Duride
	0.49	90	Duride
Sympathomimetics			
ADRENALINE	4.00	-	A Assess Advancelles
Inj 1 in 1,000, 1 ml ampoule - Up to 5 inj available on a PSO		5	✓ Aspen Adrenaline
Let 4 be 40,000, 40 and according to the fact of well-the con-	5.25		✓ Hospira
Inj 1 in 10,000, 10 ml ampoule – Up to 5 inj available on a		-	. / Haanina
PSO	49.00	5 10	✓ Hospira✓ Aspen Adrenaline
	49.00	10	Aspen Autenanne
SOPRENALINE			
* Inj 200 mcg per ml, 1 ml ampoule		25	Invested
	(164.20)		Isuprel
Vasodilators			
AMYL NITRITE			
★ Liq 98% in 0.3 ml cap		12	Deviter
	(73.40)		Baxter
HYDRALAZINE HYDROCHLORIDE			
* Tab 25 mg - Special Authority see SA1321 below - Retail			
pharmacy	CBS	1	Hydralazine
		56	✓ Onelink S29
* Inj 20 mg ampoule	25.90	5	✓ Apresoline
▶SA1321 Special Authority for Subsidy			
nitial application from any relevant practitioner. Approvals valid	d without furthe	er renewal unless	s notified for applications meetin
he following criteria:			
Either:			
1 For the treatment of refractory hypertension; or			
2 For the treatment of heart failure in combination with a nit	rate, in patients	s who are intolera	ant or have not responded to AC
inhibitors and/or angiotensin receptor blockers.	, ,		,
VINOXIDIL - Special Authority see SA1271 below - Retail pharn	nacv		
MINOXIDIE — Special Additionty see SA1271 below — Netali priami	•	100	✓ Loniten
- 'av 'v'''g		100	

Initial application only from a relevant specialist. Approvals valid without further renewal unless notified where patient has severe

Subsidy

± safety cap

refractory hypertension which has failed to respond to extensive multiple therapies.

⇒SA1271 | Special Authority for Subsidy

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

	Subsidy (Manufacturer's Price)	Per	Full Subsidise	d Generic
NICORANDIL				
▲ Tab 10 mg	27.95	60	~	Ikorel
▲ Tab 20 mg	33.28	60	~	Ikorel
PAPAVERINE HYDROCHLORIDE * Inj 12 mg per ml, 10 ml ampoule	217.90	5	~	Hospira
PENTOXIFYLLINE [OXPENTIFYLLINE]				
Tab 400 mg	36.94	50		
	(42.26)			Trental 400

Endothelin Receptor Antagonists

⇒SA0967 Special Authority for Subsidy

Special Authority approved by the Pulmonary Arterial Hypertension Panel

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

The Coordinator, PAH Panel

PHARMAC. PO Box 10-254. WELLINGTON

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

AMBRISENTAN - Special Authority see SA0967 ab	ove – Retail pharmacy		
Tab 5 mg	4,585.00	30	✓ Volibris
Tab 10 mg	4,585.00	30	✓ Volibris
BOSENTAN - Special Authority see SA0967 above	- Retail pharmacy		
Tab 62.5 mg	375.00	56	✓ Mylan-Bosentan
Tab 125 mg	375.00	56	✓ Mylan-Bosentan

Phosphodiesterase Type 5 Inhibitors

■ SA1293 Special Authority for Subsidy

initial application — (Raynaud's Phenomenon* - for Pulmonary Arterial Hypertension see note below) from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria: All of the following:

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

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

Application details may be obtained from:

The Coordinator, PAH Panel

PHARMAC, PO Box 10 254, Wellington

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

Indications marked with * are Unapproved Indications.

SILDENAFIL – Special Authority see SA1293 above – Retail pharmacy		
Tab 25 mg	4	✓ Vedafil
Tab 50 mg	4	✓ Vedafil
Tab 100 mg - For sildenafil oral liquid formulation refer, page		
2212.75	4	✓ Vedafil

Subsidy (Manufacturer's Price) \$

Fully Subsidised Per

Brand or Generic Manufacturer

Prostacyclin Analogues

⇒SA0969 | Special Authority for Subsidy

Special Authority approved by the Pulmonary Arterial Hypertension Panel

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

The Coordinator, PAH Panel

PHARMAC, PO Box 10-254, WELLINGTON

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

ILOPROST - Special Authority see SA0969 above - Retail pharmacy

Nebuliser soln 10 mcg per ml, 2 ml1,185.00 30 Ventavis

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

Antiacne Preparations

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 95

ADAPAI FNF

a) Maximum of 30 g per prescription

b) Only on a prescription

Crm 0.1%		22.89	30 g OP	Differin
Gel 0.1%		22.89	30 g OP	Differin
ATDETINOIN Consist Author	rity and CA147E balance	Datail pharmanu		

SOTRETINOIN - Special Authority see SA1475 below -	- 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 Either:
 - 3.1 Patient is female and has been counselled and understands the risk of teratogenicity if isotretinoin is used during pregnancy and the applicant has ensured that the possibility of pregnancy has been excluded prior to the commencement of the treatment and that the patient is informed that she must not become pregnant during treatment and for a period of one month after the completion of the treatment; or
 - 3.2 Patient is male.

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

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

Either:

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

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

TRFTINOIN

50 q OP ✔ ReTrieve

	Subsidy (Manufacturer's l \$	Price) Sub Per	Fully Brand or osidised Generic Manufacturer
Antibacterials Topical			
For systemic antibacterials, refer to INFECTIONS, Antibacterial	s, page 95		
FUSIDIC ACID			
Crm 2%	2.52	15 g OP	✓ DP Fusidic Acid
a) Maximum of 15 a new processistion			Cream
a) Maximum of 15 g per prescription b) Only on a prescription			
c) Not in combination			
Oint 2%	3.45	15 g OP	✓ Foban
a) Maximum of 15 g per prescription		·	
b) Only on a prescription			
c) Not in combination			
HYDROGEN PEROXIDE			
* Crm 1%	8.56	15 g OP	✓ Crystaderm
MUPIROCIN			
Oint 2%		15 g OP	5
a) Only an a managinting	(9.26)		Bactroban
a) Only on a prescription b) Not in combination			
SILVER SULPHADIAZINE			
Crm 1%	12.30	50 g OP	✓ Flamazine
a) Up to 250 g available on a PSO	12.00	00 g O1	• Hamazine
b) Not in combination			
Antifungals Topical			
For systemic antifungals, refer to INFECTIONS, Antifungals, pa	ne 102		
AMOROLFINE	gc 102		
a) Only on a prescription			
b) Not in combination			
Nail soln 5%	19.95	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
CLOTRIMAZOLE			
* Crm 1%	0.52	20 g OP	✓ Clomazol
a) Only on a prescription			
b) Not in combination * Soln 1%	4.26	20 ml OP	
本 JUII 170	4.36 (7.55)	20 IIII UP	Canesten
a) Only on a prescription	(7.55)		Ouriodoll
1) 11 11 11 11 11			

b) Not in combination

DERMATOLOGICALS

	Subsidy (Manufacturer's \$		Fu Subsidis er	
ECONAZOLE NITRATE				
Crm 1%		20 g (OP	Pevaryl
a) Only on a prescription	(7.48)			revaryi
b) Not in combination				
Foaming soln 1%, 10 ml sachets	9.89 (17.23)	3		Pevaryl
a) Only on a prescription				•
b) Not in combination				
MICONAZOLE NITRATE				
* Crm 2%	0.55	15 g (OP 🗸	<u>Multichem</u>
a) Only on a prescription b) Not in combination				
* Lotn 2%	4.36	30 ml	OP	
2501 270	(10.03)	00 1111	0.	Daktarin
a) Only on a prescription	(/			
b) Not in combination				
* Tinct 2%		30 ml	OP	5
a) Only on a preservintion	(12.10)			Daktarin
a) Only on a prescription b) Not in combination				
NYSTATIN				
Crm 100,000 u per g	1 00	15 g (ΩP	
51111 160,000 a por g	(7.90)	10 9	0.	Mycostatin
a) Only on a prescription b) Not in combination	, ,			,
Antipruritic Preparations				
CALAMINE				
a) Only on a prescription				
b) Not in combination				4 m
Crm, aqueous, BP Lotn. BP		100 2.000	-	Pharmacy Health
	12.94	2,000	·	' <u>PSM</u>
CROTAMITON				
a) Only on a prescription b) Not in combination				
Crm 10%	3.37	20 g (OP 🗸	Itch-Soothe
MENTHOL – Only in combination		- 3	-	
Only in combination with a dermatological base or propage 220	orietary Topical C	Corticoste	eriod – Pla	in, refer dermatological base
With or without other dermatological galenicals.				
Crystals		25 (_	PSM
	6.92	400		MidWest
	29.60	100	g 🗸	MidWest

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

Corticosteroids Topical

For systemic corticosteroids, refer to CORTICOSTEROIDS AND RELATED AGENTS, page 84

Corticosteroids - Plain

BETAMETHASONE DIPROPIONATE			
Crm 0.05%	2.96	15 g OP	✓ Diprosone
	8.97	50 g OP	✓ Diprosone
Crm 0.05% in propylene glycol base	4.33	30 g OP	✓ Diprosone OV
Oint 0.05%	2.96	15 g OP	✓ Diprosone
	8.97	50 g OP	✓ Diprosone
Oint 0.05% in propylene glycol base	4.33	30 g OP	✓ Diprosone OV
BETAMETHASONE VALERATE			
* Crm 0.1%	3.15	50 g OP	✓ Beta Cream
* Oint 0.1%		50 g OP	✓ Beta Ointment
* Lotn 0.1%		50 ml OP	✓ Betnovate
CLOBETASOL PROPIONATE			
* Crm 0.05%	2.20	30 g OP	✓ Dermol
* CIII 0.05%	3.20	30 g OF	✓ Clobetasol BNM
* Oint 0.05%		30 g OP	✓ Dermol
* OIII 0.05 /0	3.20	30 g OF	✓ Clobetasol BNM
	3.20		Clobetasol Bivivi
CLOBETASONE BUTYRATE			
Crm 0.05%		30 g OP	_
	(7.09)		Eumovate
DIFLUCORTOLONE VALERATE			
Crm 0.1%	8.97	50 g OP	
	(15.86)		Nerisone
Fatty oint 0.1%	8.97	50 g OP	
	(15.86)		Nerisone
HYDROCORTISONE			
* Crm 1% – Only on a prescription	3.75	100 g	✓ Pharmacy Health
The contract of the contract o	14.00	500 g	✓ Pharmacy Health
* Powder – Only in combination		25 g	✓ ABM
Up to 5% in a dermatological base (not proprietary Topica galenicals. Refer, page 220			or without other dermatological
HYDROCORTISONE AND PARAFFIN LIQUID AND LANOLIN			
Lotn 1% with paraffin liquid 15.9% and lanolin 0.6% – Only			
on a prescription	10.57	250 ml	✓ DP Lotn HC
·	10.57	250 1111	<u>DF LOUITIC</u>
HYDROCORTISONE BUTYRATE			4
Lipocream 0.1%		30 g OP	✓ Locoid Lipocream
0: 10.40/	6.85	100 g OP	✓ Locoid Lipocream
Oint 0.1%		100 g OP	✓ Locoid
Milky emul 0.1%	6.85	100 ml OP	✓ Locoid Crelo
METHYLPREDNISOLONE ACEPONATE			
Crm 0.1%	4.95	15 g OP	✓ Advantan
Oint 0.1%	4.95	15 g OP	✓ Advantan

DERMATOLOGICALS

	Subsidy (Manufacturer's F \$	Price) Sub Per	Fully Brand or osidised Generic Manufacturer
MOMETASONE FUROATE			
Crm 0.1%	1.51	15 g OP	✓ Elocon Alcohol Free
2 1.12.14	2.90	50 g OP	Elocon Alcohol Free
Oint 0.1%	1.51 2.90	15 g OP 50 g OP	✓ <u>Elocon</u> ✓ Elocon
Lotn 0.1%		30 g Oi	✓ Elocon
TRIAMCINOLONE ACETONIDE			
Crm 0.02%	6.30	100 g OP	✓ Aristocort
Oint 0.02%	6.35	100 g OP	✓ Aristocort
Corticosteroids - Combination			
BETAMETHASONE VALERATE WITH CLIOQUINOL - Only on a	prescription		
Crm 0.1% with clioquinol 3%		15 g OP	
	(4.90)		Betnovate-C
BETAMETHASONE VALERATE WITH FUSIDIC ACID	2.40	15 ~ OD	
Crm 0.1% with fusidic acid 2%	(10.45)	15 g OP	Fucicort
a) Maximum of 15 g per prescriptionb) Only on a prescription	(10.10)		, doloon
HYDROCORTISONE WITH MICONAZOLE - Only on a prescript	tion		
* Crm 1% with miconazole nitrate 2%		15 g OP	✓ Micreme H
HYDROCORTISONE WITH NATAMYCIN AND NEOMYCIN - Or	, , ,		
Crm 1% with natamycin 1% and neomycin sulphate 0.5%		15 g OP	✓ Pimafucort✓ Pimafucort
Oint 1% with natamycin 1% and neomycin sulphate 0.5%		15 g OP	Pimaiucort
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCII Crm 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg		N	
and gramicidin 250 mcg per g - Only on a prescription		15 g OP	
	(6.60)	3 -	Viaderm KC
Disinfecting and Cleansing Agents			
CHLORHEXIDINE GLUCONATE – Subsidy by endorsement			
a) No more than 500 ml per month			
b) Only if prescribed for a dialysis patient and the prescription			. A beautif
* Handrub 1% with ethanol 70%* Soln 4% wash		500 ml 500 ml	✓ <u>healthE</u>✓ healthE
TRICLOSAN – Subsidy by endorsement		000 1111	· IIOUIUIE
a) Maximum of 500 ml per prescription			
b)			
a) Only if prescribed for a patient identified with Methicillin-r in boarded and the prescribed is a reduced according to the prescribed and the prescribed in the prescribed and t		ococcus aureu	s (MRSA) prior to elective surgery
in hospital and the prescription is endorsed accordingly; of b) Only if prescribed for a patient with recurrent Staphylococ		tion and the or	escription is endorsed accordingly
Soln 1%		500 ml OP	✓ Pharmacy Health
	5.90		✓ healthE
(Pharmacy Health Soln 1% to be delisted 1 December 2016)			

Subsidy (Manufacturer's Price) \$

Fully Subsidised Per

Brand or Generic Manufacturer

Barrier Creams and Emollients			
	Daniel au	O	
	Barrier		III-lanks

Barrier Creams		
DIMETHICONE		
* Crm 5% pump bottle	500 ml OP	✓ healthE Dimethicone 5%
healthE Dimethicone 5% to be Sole Supply on 1 October 2016	500 LOD	41 111 =
* Crm 10% pump bottle	500 ml OP	✓ <u>healthE</u> <u>Dimethicone 10%</u>
ZINC AND CASTOR OIL		4
* Oint BP	500 g	✓ Multichem
Emollients		
AQUEOUS CREAM		
* Crm	500 g	✓ AFT SLS-free
CETOMACROGOL * Crm BP	500 g	✓ healthE
CETOMACROGOL WITH GLYCEROL	300 g	<u>licatuiL</u>
Crm 90% with glycerol 10%2.82	500 ml OP	✓ Pharmacy Health
3,000		Sorbolene with
3.87	1,000 ml OP	Glycerin ✓ Pharmacy Health
3.07	1,000 1111 01	Sorbolene with
		Glycerin
EMULSIFYING OINTMENT		4
* Oint BP2.73	500 g	✓ <u>AFT</u>
OIL IN WATER EMULSION	500	. A OAM Fatter Francisco
* Crm2.25	500 g	✓ O/W Fatty Emulsion Cream
UREA		<u>oroum</u>
* Crm 10%1.37	100 g OP	✓ healthE Urea Cream
healthE Urea Cream to be Sole Supply on 1 October 2016		
WOOL FAT WITH MINERAL OIL – Only on a prescription		
* Lotn hydrous 3% with mineral oil5.60	1,000 ml	DD Lation
(11.95) 1.40	250 ml OP	DP Lotion
(4.53)	200 1111 01	DP Lotion
5.60	1,000 ml	
(20.53)		Alpha-Keri Lotion
(23.91)		BK Lotion
1.40	250 ml OP	DIC Latina

(7.73)

BK Lotion

DERMATOLOGICALS

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

Other Dermatological Bases

PARAFFIN

✓ IPW White soft - Only in combination 20.20 2.500 a 3.58 500 g (7.78)**IPW** (8.69)**PSM**

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

Minor Skin Infections

POVIDONE IODINE		
Oint 10%	25 g OP	Betadine
a) Maximum of 100 g per prescription b) Only on a prescription		
Antiseptic soln 10%	500 ml	✓ Betadine
·		✓ Riodine
1.28	100 ml	
(4.20)		Riodine
(8.25)		Betadine
0.19	15 ml	
(4.45)		Betadine
Skin preparation, povidone iodine 10% with 30% alcohol10.00	500 ml	Betadine Skin Prep
1.63	100 ml	•
(3.65)		Betadine Skin Prep
Skin preparation, povidone iodine 10% with 70% alcohol8.13	500 ml	·
(18.63)		Orion
1.63	100 ml	
(6.04)		Orion

Parasiticidal Preparations

IVERMECTIN - Special Authority see SA1225 below - Retail pharmacy

Tab 3 mg - Up to 100 tab available on a PSO......17.20 Stromectol

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

⇒SA1225 Special Authority for Subsidy

Initial application — (Scables) 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

continued...

DERMATOLOGICALS

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

continued...

- 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;
 - 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;
 - 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
- Strongyloidiasis.

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

- 1 Applying clinician has discussed the diagnosis of scables 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;
 - 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.

DERMATOLOGICALS

	Subsidy (Manufacturer's Price)) Subsi	Fully idised	Brand or Generic Manufacturer
MALATHION WITH PERMETHRIN AND PIPERONYL BUTOXIDE Spray 0.25% with permethrin 0.5% and piperonyl butoxide 2% (Para Plus Spray 0.25% with permethrin 0.5% and piperonyl butox		- 9		ra Plus
PERMETHRIN Crm 5% Lotn 5%		30 g OP 0 ml OP		<u>derm</u> Scabies
PHENOTHRIN Shampoo 0.5%		00 ml OP 00 ml OP		rasidose rasidose

Psoriasis and Eczema Preparations

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

⇒SA1476 Special Authority for Subsidy

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

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

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

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

BETAMETHASONE DIPROPIONATE WITH CALCIPOTRIOL Gel 500 mcg with calcipotriol 50 mcg per g26.12 Oint 500 mcg with calcipotriol 50 mcg per g26.12	30 g OP 30 g OP	✓ <u>Daivobet</u> ✓ <u>Daivobet</u>
CALCIPOTRIOL		
Crm 50 mcg per g16.00	30 g OP	Daivonex
45.00	100 g OP	Daivonex
Oint 50 mcg per g45.00	100 g OP	Daivonex
Soln 50 mcg per ml16.00	30 ml OP	Daivonex
COAL TAR		
Soln - Only in combination12.55		✓ Midwest

- Up to 10% only in combination with a dermatological base or proprietary Topical Corticosteriod Plain, refer dermatological base, page 220
- 2) With or without other dermatological galenicals.

	Subsidy (Manufacturer's I \$	Price) Subs	Fully sidised	Brand or Generic Manufacturer
COAL TAR WITH ALLANTOIN, MENTHOL, PHENOL AND SULPI Soln 5% with sulphur 0.5%, menthol 0.75%, phenol 0.5% and	HUR			
allantoin crm 2.5%	(8.00) 3.43	75 g OP 30 g OP		gopsoryl TA
COAL TAR WITH SALICYLIC ACID AND SULPHUR Soln 12% with salicylic acid 2% and sulphur 4% oint	(4.35)	40 g OP		gopsoryl TA
PINE TAR WITH TROLAMINE LAURILSULFATE AND FLUORES(* Soln 2.3% with trolamine laurilsulfate and fluorescein sodium	CEIN - Only or	ŭ		netarsol
SALICYLIC ACID Powder – Only in combination 1) Only in combination with a dermatological base or prop dermatological base, page 220 2) With or without other dermatological galenicals.		250 g Corticosteroid -	√ P 9 - Plain	
SULPHUR Precipitated – Only in combination		100 g Corticosteroid –		idwest efer dermatological base,
Scalp Preparations				
BETAMETHASONE VALERATE * Scalp app 0.1%	7.75	100 ml OP	✓ B	eta Scalp
CLOBETASOL PROPIONATE * Scalp app 0.05%	6.96	30 ml OP	✓ D	ermol
HYDROCORTISONE BUTYRATE Scalp lotn 0.1%	3.65	100 ml OP	✓ Lo	ocoid
KETOCONAZOLE Shampoo 2%	2.99	100 ml OP	✓ <u>S</u>	<u>ebizole</u>
Sunscreens				
SUNSCREENS, PROPRIETARY – Subsidy by endorsement Only if prescribed for a patient with severe photosensitivity sendorsed accordingly.	secondary to a	defined clinical	conditi	on and the prescription is
Crm		100 g OP	Į I.	amilton Sunscreen
Lotn,	(5.89) 3.30	100 g OP	✓ M	amilton Sunscreen arine Blue Lotion SPF 50+
	5.10	200 g OP		arine Blue Lotion SPF 50+
Lotn	4.13	125 ml OP		

Aquasun 30+

(6.94)

DERMATOLOGICALS

Subsidy (Manufacturer's Price) \$ Per

Fully Subsidised

Brand or Generic Manufacturer

Cream 5%

Wart Preparations

For salicylic acid preparations refer to PSORIASIS AND ECZEMA PREPARATIONS, page 74

IMIQUIMOD

PODOPHYLLOTOXIN

a) Maximum of 3.5 ml per prescription

b) Only on a prescription

Other Skin Preparations

Antineoplastics

FLUOROURACIL SODIUM

Crm 5%8.95

20 g OP

✓ Efudix

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

Contraceptives - Non-hormonal

Condoms CONDOMO

CC	DNDOMS			
*	49 mm - Up to 144 dev available on a PSO	. 13.36	144	✓ MarquisTantiliza
				✓ Shield 49
*	52 mm - Up to 144 dev available on a PSO	13.36	144	✓ Marquis Selecta
*	52 mm extra strength - Up to 144 dev available on a PSO	13.36	144	✓ Marquis Protecta
*	53 mm - Up to 144 dev available on a PSO	1.11	12	✓ Gold Knight
				✓ Shield Blue
		13.36	144	✓ Marquis Black
				✓ Shield Blue
*	53 mm (chocolate) - Up to 144 dev available on a PSO	1.11	12	Gold Knight
		13.36	144	✓ Gold Knight
*	53 mm (strawberry) - Up to 144 dev available on a PSO	1.11	12	✓ Gold Knight
		13.36	144	✓ Gold Knight
*	54 mm, shaped - Up to 144 dev available on a PSO	1.12	12	
		(1.24)		Lifestyles Flared
		13.36	144	
		(14.84)		Lifestyles Flared
*	55 mm - Up to 144 dev available on a PSO	13.36	144	✓ Marquis Conforma
*	56 mm - Up to 144 dev available on a PSO	1.11	12	✓ Gold Knight
		13.36	144	Durex Extra Safe
				Gold Knight
*	56 mm, shaped - Up to 144 dev available on a PSO	1.11	12	Durex Confidence
		13.36	144	Durex Confidence
*	60 mm - Up to 144 dev available on a PSO	13.36	144	Shield XL
(Li	festyles Flared 54 mm, shaped to be delisted 1 November 2016)			

Contraceptive Devices

DIAPHRAGM - Up to 1 dev available on a PSO One of each size is permitted on a PSO.

(Lifestyles Flared 54 mm, shaped to be delisted 1 November 2016)

*	65 mm42.90	1	Ortho All-flex
*	70 mm42.90	1	Ortho All-flex
*	75 mm42.90	1	Ortho All-flex
*	80 mm42.90	1	Ortho All-flex
IN	FRA-UTERINE DEVICE		
	a) Up to 40 dev available on a PSO		
	b) Only on a PSO		
*	IUD 29.1 mm length × 23.2 mm width31.60	1	✓ Choice TT380 Short
*	IUD 33.6 mm length × 29.9 mm width31.60	1	✓ Choice
			TT380 Standard
*	IUD 35.5 mm length × 19.6 mm width31.60	1	✓ Choice Load 375

Subsidy (Manufacturer's Price)

Fully Subsidised Per

Brand or Generic Manufacturer

Contraceptives - Hormonal

Combined Oral Contraceptives

⇒SA0500 Special Authority for Alternate Subsidy

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

- 1 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.

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

(19.80)

ETHINYLOESTRADIOL WITH DESOGESTREL

a) Higher subsidy of \$13.80 per 84 tab with Special Authority b) Up to 84 tab available on a PSO	see SA0500 a	above	
Tab 30 mcg with desogestrel 150 mcg and 7 inert tab	6.62	84	
	(19.80)		Marvelon 28
a) Higher subsidy of \$13.80 per 84 tab with Special Authorityb) Up to 84 tab available on a PSO	see SA0500 a	above	
HINYLOESTRADIOL WITH LEVONORGESTREL			
Tab 20 mcg with levonorgestrel 100 mcg and 7 inert tab - Up			
to 84 tab available on a PSO	2.65	84	✓ Ava 20 ED
Tab 50 mcg with levonorgestrel 125 mcg and 7 inert tab - Up			
to 84 tab available on a PSO	9.45	84	Microgynon 50 ED
Tab 30 mcg with levonorgestrel 150 mcg	6.62	63	
	(16.50)		Microgynon 30
a) Higher subsidy of \$15.00 per 63 tab with Special Authority	see SA0500 a	above	
b) Up to 63 tab available on a PSO			
Tab 30 mcg with levonorgestrel 150 mcg and 7 inert tab - Up			
to 84 tab available on a PSO	2.30	84	✓ Ava 30 ED
	b) Up to 84 tab available on a PSO Tab 30 mcg with desogestrel 150 mcg and 7 inert tab	b) Up to 84 tab available on a PSO Tab 30 mcg with desogestrel 150 mcg and 7 inert tab	Tab 30 mcg with desogestrel 150 mcg and 7 inert tab

84

Mercilon 28

	Subsidy (Manufacturer's Price)	Per	Fully Subsidised	Brand or Generic Manufacturer	
ETHINYLOESTRADIOL WITH NORETHISTERONE					
* Tab 35 mcg with norethisterone 1 mg - Up to 63 tab available on a PSO		63	✓ B	revinor 1/21	
* Tab 35 mcg with norethisterone 1 mg and 7 inert tab – Up to 84 tab available on a PSO		84	✓ B	revinor 1/28	
* Tab 35 mcg with norethisterone 500 mcg - Up to 63 tab available on a PSO		63	✓ B	revinor 21	
* Tab 35 mcg with norethisterone 500 mcg and 7 inert tab — Up to 84 tab available on a PSO		84	✓ N	lorimin	

Progestogen-only Contraceptives

■ SA0500 Special Authority for Alternate Subsidy

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

- 1 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.

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

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

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

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

LEVONORGESTREL Tab 20 mag

*	Iab 30 mcg	6.62	84	
	ů	(16.50)		Microlut
	 a) Higher subsidy of \$13.80 per 84 tab with Special Authority b) Up to 84 tab available on a PSO 	see SA0500 abov	/e	
*	Subdermal implant (2 × 75 mg rods)	133.65	1	✓ <u>Jadelle</u>
ME	DROXYPROGESTERONE ACETATE			
*	Inj 150 mg per ml, 1 ml syringe – Up to 5 inj available on a PSO Depo-Provera to be Sole Supply on 1 November 2016	7.25	1	✓ Depo-Provera
NO	RETHISTERONE			
*	Tab 350 mcg - Up to 84 tab available on a PSO	6.25	84	✓ Noriday 28

79

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

Aci-Jel

Emergency Contraceptives

LEVONORGESTREL

- ✔ Postinor-1
 - a) Maximum of 2 tab per prescription
 - b) Up to 5 tab available on a PSO

Antiandrogen Oral Contraceptives

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

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

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

CYPROTERONE ACETATE WITH ETHINYLOESTRADIOL

* Tab 2 mg with ethinyloestradiol 35 mcg and 7 inert tabs - Up

168 ✓ Ginet

Gynaecological Anti-infectives

Jelly with glacial acetic acid 0.94%, hydroxyguinoline sulphate 0.025%, glycerol 5% and ricinoleic acid 0.75% with

applicator8.43 100 g OP (24.00)

CLOTRIMAZOLE

✔ Clomazol 35 q OP Clomazol to be Sole Supply on 1 December 2016

Vaginal crm 2% with applicators2.10 ✓ Clomazol 20 a OP Clomazol to be Sole Supply on 1 December 2016

MICONAZOLE NITRATE

40 a OP ✓ Micreme NYSTATIN

✓ Nilstat Vaginal crm 100,000 u per 5 g with applicator(s)4.71 75 q OP

Myometrial and Vaginal Hormone Preparations

ERGOMETRINE MALEATE

Ini 500 mcg per ml, 1 ml ampoule - Up to 5 inj available on a PSO 94.70 5 ✓ DBL Ergometrine

OESTRIOL

* Crm 1 mg per g with applicator6.30 15 q OP Ovestin 15 ✓ Ovestin

OXYTOCIN - Up to 5 inj available on a PSO

Inj 5 iu per ml, 1 ml ampoule4.03 Oxvtocin BNM ✓ Oxytocin BNM 5

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

Ini 5 iu with ergometrine maleate 500 mcg per ml. 1 ml11.13 Syntometrine

GENITO-URINARY SYSTEM

Subsidy (Manufacturer's Price) \$

Fully Subsidised Per

Brand or Generic Manufacturer

Pregnancy Tests - hCG Urine

PREGNANCY TESTS - HCG URINE

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

Cassette 40 test OP ✓ EasyCheck

Urinary Agents

For urinary tract Infections refer to INFECTIONS, Antibacterials, page 116

5-Alpha Reductase Inhibitors

FINASTERIDE - Special Authority see SA0928 below - Retail pharmacy

30 ' Finpro

⇒SA0928 Special Authority for Subsidy

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

Both:

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

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

Alpha-1A Adrenoreceptor Blockers

TAMSULOSIN HYDROCHLORIDE - Special Authority see SA1032 below - Retail pharmacy

✓ Tamsulosin-Rex

■SA1032 Special Authority for Subsidy

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

Both:

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

Other Urinary Agents

OXYBUTYNIN

*	Tab 5 mg8.85	500	Apo-Oxybutynin
	Apo-Oxybutynin to be Sole Supply on 1 October 2016		
*	Oral liq 5 mg per 5 ml60.40	473 ml	Apo-Oxybutynin

Apo-Oxybutynin to be Sole Supply on 1 October 2016

POTASSIUM CITRATE

Oral lig 3 mmol per ml - Special Authority see SA1083 on 200 ml OP Biomed

GENITO-URINARY SYSTEM

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

⇒SA1083 Special Authority for Subsidy

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

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

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

SODIUM CITRO-TARTRATE			
* Grans eff 4 g sachets	2.93	28	✓ <u>Ural</u>
SOLIFENACIN SUCCINATE - Special Authority see S	SA0998 below – Retail pharm	acy	
Tab 5 mg	37.50	30	✓ Vesicare
Tab 10 mg	37.50	30	✓ Vesicare

⇒SA0998 Special Authority for Subsidy

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

TOLTERODINE – Special Authority see SA1272 below – Retail pharmacy					
Tab 1 mg	14.56	56	Arrow-Tolterodine		
Tab 2 mg	14.56	56	Arrow-Tolterodine		

⇒SA1272 Special Authority for Subsidy

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

Detection of Substances in Urine

ORTHO-TOLIDINE * Compound diagnostic sticks	7.50	50 test OP	
	(8.25)	00 1001 01	Hemastix
TETRABROMOPHENOL			
* Blue diagnostic strips	7.02	100 test OP	
-	(13.92)		Albustix

Subsidy

(Manufacturer's Price)

Fully

Subsidised

Brand or

Generic

·	\$	Per	✓ Manufacturer
Calcium Homeostasis			
CALCITONIN * Inj 100 iu per ml, 1 ml ampoule121.	.00	5	✓ <u>Miacalcic</u>
CINACALCET – Special Authority see SA1594 below – Retail pharmacy Tab 30 mg – Wastage claimable – see rule 3.3.2 on page 13403.	.70	28	✓ Sensipar

⇒SA1594 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 > 3 mmol/L) despite previous first-line treatments including bisphosphonates and sodium thiosulfate; 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 ≥ 3 mmol/L); and
 - 2.3 The patient's condition has not responded to previous first-line treatments including bisphosphonates and sodium thiosulfate.

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

Both:

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

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

ZOLEDRONIC ACID

		Special Authority see SA1512 below	Inj 4 mg per 5 ml, vial -
Zoledronic acid	1	84.50	 Retail pharmacy
Mylan			
✓ Zometa		550.00	

■ SA1512 Special Authority for Subsidy

Initial application 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).

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

Corticosteroids and Related Agents for Systemic	Use		
BETAMETHASONE SODIUM PHOSPHATE WITH BETAMETHASO	NE ACETATE		
* Inj 3.9 mg with betamethasone acetate 3 mg per ml, 1 ml	19.20	5	
	(36.96)		Celestone
			Chronodose
DEXAMETHASONE			
* Tab 0.5 mg - Retail pharmacy-Specialist	0.88	30	✓ <u>Dexmethsone</u>
Up to 60 tab available on a PSO			
* Tab 4 mg - Retail pharmacy-Specialist	1.84	30	✓ <u>Dexmethsone</u>
Up to 30 tab available on a PSO			4.50
Oral liq 1 mg per ml – Retail pharmacy-Specialist	45.00	25 ml OP	✓ Biomed
Oral liq prescriptions:			
 Must be written by a Paediatrician or Paediatric Cardiologist On the recommendation of a Paediatrician or Paediatric Cardiologist 			
•	ulologist.		
DEXAMETHASONE PHOSPHATE Dexamethasone phosphate injection will not be funded for oral u	100		
* Inj 4 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSO		10	✓ Max Health
* Inj 4 mg per ml, 2 ml ampoule — Up to 5 inj available on a PSO		5	✓ Max Health
FLUDROCORTISONE ACETATE		Ŭ	· max riounii
* Tab 100 mcg	1/1 20	100	✓ Florinef
-	14.32	100	Fiorine
HYDROCORTISONE	0.40	400	. d Daniela
* Tab 5 mg	8.10	100	✓ <u>Douglas</u>
* Tab 20 mg – For hydrocortisone oral liquid formulation refer,	00.00	100	A Daumian
page 221* Inj 100 mg vial		100	✓ <u>Douglas</u> ✓ Solu-Cortef
a) Up to 5 inj available on a PSO		'	V Joiu-Corter
b) Only on a PSO			
c) Solu-Cortef to be Sole Supply on 1 November 2016			
METHYLPREDNISOLONE - Retail pharmacy-Specialist			
* Tab 4 mg	80.00	100	✓ Medrol
* Tab 100 mg	180.00	20	✓ <u>Medrol</u>
METHYLPREDNISOLONE (AS SODIUM SUCCINATE) - Retail pha	armacy-Speci	alist	
Inj 40 mg vial		1	✓ Solu-Medrol
Inj 125 mg vial		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 [LIGNOCA	INEI		
Inj 40 mg per ml with lidocaine [lignocaine] 1 ml vial		1	✓ Depo-Medrol with
			Lidocaine
PREDNISOLONE			
* Oral liq 5 mg per ml - Up to 30 ml available on a PSO	7.50	30 ml OP	✓ Redipred

Restricted to children under 12 years of age.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	d Generic
PREDNISONE				
* Tab 1 mg	2.13	100	~	Apo-Prednisone S29 S29
	10.68	500	~	Apo-Prednisone
* Tab 2.5 mg	12.09	500	~	Apo-Prednisone
* Tab 5 mg - Up to 30 tab available on a PSO	11.09	500	~	Apo-Prednisone
* Tab 20 mg		500	~	Apo-Prednisone
TETRACOSACTRIN				
* Inj 250 mcg per ml, 1 ml ampoule	75.00	1	~	Synacthen
* Inj 1 mg per ml, 1 ml ampoule		1		Synacthen Depot
TRIAMCINOLONE ACETONIDE				
Inj 10 mg per ml, 1 ml ampoule	20.80	5	~	Kenacort-A 10
Inj 40 mg per ml, 1 ml ampoule		5	-	Kenacort-A 40
Sex Hormones Non Contraceptive				

Androgen Agonists and Antagonists

CYPROTERONE ACETATE - Retail pharmacy-Specialist			
Tab 50 mg	. 15.87	50	✓ <u>Procur</u>
Tab 100 mg	.30.40	50	✓ Procur
TESTOSTERONE			
Transdermal patch, 2.5 mg per day	.80.00	60	✓ Androderm
TESTOSTERONE CYPIONATE - Retail pharmacy-Specialist			
Inj 100 mg per ml, 10 ml vial	.76.50	1	✓ <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

■ SA1018 Special Authority for Alternate Subsidy

Initial application from any relevant practitioner. Approvals valid for 5 years for applications meeting the following criteria: Any of the following:

- 1 acute or significant liver disease where oral oestrogens are contraindicated as determined by a gastroenterologist or general physician. The applicant must keep written confirmation from such a specialist with the patient's record; or
- 2 oestrogen induced hypertension requiring antihypertensive therapy documented evidence must be kept on file that raised blood pressure levels or inability to control blood pressure adequately occurred post oral oestrogens; or
- 3 hypertriglyceridaemia documented evidence must be kept on file that triglyceride levels increased to at least 2 × normal triglyceride levels post oral oestrogens; or
- 4 Somatropin co-therapy patient is being prescribed somatropin with subsidy provided under a valid approval issued under Special Authority.

Note: Prescriptions with a valid Special Authority (CHEM) number will be reimbursed at the level of the lowest priced TDDS product within the specified dose group.

Renewal from any relevant practitioner. Approvals valid for 5 years where the treatment remains appropriate and the patient is benefiting from treatment, or the patient remains on subsidised somatropin co-therapy.

85

Subsidy (Manufacturer's Price) \$

Fully Subsidised Per

Brand or Generic Manufacturer

Prescribing Guideline

HRT should be taken at the lowest dose for the shortest period of time necessary to control symptoms. Patients should be reviewed 6 monthly in line with the updated NZGG "Evidence-based Best Practice Guideline on Hormone Replacement Therapy March 2004".

Oestrogens

OE	STRADIOL - See prescribing guideline above			
*	Tab 1 mg	4.12	28 OP	
		(11.10)		Estrofem
*	Tab 2 mg	4.12	28 OP	
		(11.10)		Estrofem
*	Patch 25 mcg per day	6.12	8	Estradot
	a) No more than 2 patch per week			
	b) Only on a prescription			
	c) Estradot to be Sole Supply on 1 November 2016			
*	TDDS 3.9 mg (releases 50 mcg of oestradiol per day)	4.12	4	
		(13.18)		Climara 50
	a) Higher subsidy of \$13.18 per 4 patch with Special A	uthority see SA1018	on the previo	ous page
	b) No more than 1 patch per week	,	·	1 0
	c) Only on a prescription			
*	Patch 50 mcg per day	7.04	8	✓ Estradot 50 mcg
	a) No more than 2 patch per week			ŭ
	b) Only on a prescription			
*	TDDS 7.8 mg (releases 100 mcg of oestradiol per day) .	7.05	4	
		(16.14)		Climara 100
	a) Higher subsidy of \$16.14 per 4 patch with Special A	uthoritv see SA1018	on the previo	ous page
	b) No more than 1 patch per week	, , , , , , , , , , , , , , , , , , , ,		
	c) Only on a prescription			
*	Patch 100 mcg per day	7.91	8	✓ Estradot
•	a) No more than 2 patch per week		-	
	b) Only on a prescription			
∩ E	STRADIOL VALERATE - See prescribing guideline above			
*	Tab 1 mg		84	✓ Progynova
*	•		84	✓ Progynova
	Tab 2 mg	12.30	04	Progyriova
OE	STROGENS – See prescribing guideline above			
*	Conjugated, equine tab 300 mcg	3.01	28	
		(11.48)		Premarin
*	Conjugated, equine tab 625 mcg	4.12	28	
		(11.48)		Premarin

Progestogens

ME	DROXYPROGESTERONE ACETATE - See prescribing guideli	ne above		
*	Tab 2.5 mg	3.75	30	Provera
	Provera to be Sole Supply on 1 November 2016			
*	Tab 5 mg	14.00	100	Provera
	Provera to be Sole Supply on 1 November 2016			
*	Tab 10 mg	7.15	30	Provera
	Dravers to be Cale Cumply on 1 Nevember 2016			

Provera to be Sole Supply on 1 November 2016

	Subsidy (Manufacturer's Price) \$		Fully Brand or lised Generic Manufacturer
Progestogen and Oestrogen Combined Prepara	tions		
OESTRADIOL WITH NORETHISTERONE - See prescribing gui	ideline on the previou	s page	
* Tab 1 mg with 0.5 mg norethisterone acetate		28 OP	
ŭ	(18.10)		Kliovance
* Tab 2 mg with 1 mg norethisterone acetate	5.40 2	28 OP	
ů ů	(18.10)		Kliogest
* Tab 2 mg with 1 mg norethisterone acetate (10), and 2 mg	, , 		•
oestradiol tab (12) and 1 mg oestradiol tab (6)	5.40	28 OP	
. , , , , , , , , , , , , , , , , , , ,	(18.10)		Trisequens
OESTROGENS WITH MEDROXYPROGESTERONE - See pres	cribing guideline on t	he previous	page
* Tab 625 mcg conjugated equine with 2.5 mg medroxyproges-	0.0		v
terone acetate tab (28)		28 OP	
()	(22.96)		Premia
	, ,		2.5 Continuous
* Tab 625 mcg conjugated equine with 5 mg medroxyproges-	•		
terone acetate tab (28)		28 OP	
• •	(22.96)		Premia 5 Continuous
Other Oestrogen Preparations			

Other Destrogen Preparations

ETHINTLUESTRADIOL			
* Tab 10 mcg	17.60	100	NZ Medical and
· · · · · · · · · · · · · · · · · · ·			Scientific
			Ocientatio
OFSTRIOI			

* Tab 2 mg7.00
Other Progestogen Preparations

LEVONORGESTREL

ETHINIA OFOTOADIO

★ Intra-uterine system 20 mcg per day – Special Authority see SA1608 below – Retail pharmacy269.50
1
✓ Mirena

■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.

Ovestin

30

87

	Subsidy (Manufacturer's Price \$) Per	Fully Subsidised	Brand or Generic Manufacturer	
MEDROXYPROGESTERONE ACETATE * Tab 100 mg - Retail pharmacy-Specialist Provera HD to be Sole Supply on 1 November 2016	101.00	100	✓ Pi	rovera HD	
NORETHISTERONE * Tab 5 mg - Up to 30 tab available on a PSO	18.29	100	✓ <u>P</u> i	rimolut N	
PROGESTERONE Cap 100 mg - Special Authority see SA1609 below - Retail pharmacy	16.50	30	✓ <u>U</u>	<u>trogestan</u>	

■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** 100 ✓ Neo-Mercazole LEVOTHYROXINE 90 Synthroid ± Safety cap for extemporaneously compounded oral liquid preparations. ✓ Synthroid Tab 50 mcg4.05 90 1.000 ✓ Eltroxin ± Safety cap for extemporaneously compounded oral liquid preparations. * Tab 100 mcg4.21 90 Synthroid ✓ Eltroxin 1,000 ‡ Safety cap for extemporaneously compounded oral liquid preparations. LEVOTHYROXINE (MERCURY PHARMA) 28 ✓ Mercury Pharma ‡ Safety cap for extemporaneously compounded oral liquid preparations. 28 ✓ Mercury Pharma ‡ Safety cap for extemporaneously compounded oral liquid preparations. PROPYLTHIOURACIL - Special Authority see SA1199 on the next page - Retail pharmacy Propylthiouracil is not recommended for patients under the age of 18 years unless the patient is pregnant and other treatments are contraindicated. Tab 50 mg35.00 100 ✓ PTU S29

Cubaidy		Eully	Drand or
Subsidy	_	,	Brand or
(Manufacturer's Price)	Sı	ıbsidised	Generic
\$	Per	~	Manufacturer

⇒SA1199 | Special Authority for Subsidy

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

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

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

Trophic Hormones

Growth Hormones

SO	MATROPIN (OMNITROPE) - Special Authority see SA1451 below - Retail	pharmacy	
*	Inj 5 mg cartridge109.50	1	Omnitrope
*	Inj 10 mg cartridge219.00	1	✓ Omnitrope
*	Inj 15 mg cartridge328.50	1	✓ Omnitrope

⇒SA1451 | Special Authority for Subsidy

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

Fither:

- 1 Growth hormone deficiency causing symptomatic hypoglycaemia, or with other significant growth hormone deficient sequelae (e.g. cardiomyopathy, hepatic dysfunction) and diagnosed with GH < 5 mcg/l on at least two random blood samples in the first 2 weeks of life, or from samples during established hypoglycaemia (whole blood glucose < 2 mmol/l using a laboratory device); or
- 2 All of the following:
 - 2.1 Height velocity < 25th percentile for age adjusted for bone age/pubertal status if appropriate over 6 or 12 months using the standards of Tanner and Davies (1985); and
 - 2.2 A current bone age is < 14 years (female patients) or < 16 years (male patients); and
 - 2.3 Peak growth hormone value of < 5.0 mcg per litre in response to two different growth hormone stimulation tests. In children who are 5 years or older, GH testing with sex steroid priming is required; and
 - 2.4 If the patient has been treated for a malignancy, they should be disease free for at least one year based upon followup 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 \leq 14 years (female patients) or \leq 16 years (male patients); and
- 2 Height velocity is ≥ 25th percentile for age (adjusted for bone age/pubertal status if appropriate) while on growth hormone treatment, as calculated over six months using the standards of Tanner and Davis (1985); and
- 3 Height velocity is ≥ 2.0 cm per year, as calculated over 6 months; and
- 4 No serious adverse effect that the patients specialist considers is likely to be attributable to growth hormone treatment has occurred: and
- 5 No malignancy has developed since starting growth hormone.

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

All of the following:

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

Subsidy (Manufacturer's Price) \$

Fully Subsidised Per

Brand or Generic Manufacturer

continued...

3 A current bone age is < 14 years.

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

All of the following:

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

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

All of the following:

- 1 The patient's height is more than 3 standard deviations below the mean for age or for bone age if there is marked growth acceleration or delay; and
- 2 Height velocity is < 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 (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 ≥ 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 ≥ 2 cm per year as calculated over six months; and
- 3 A current bone age is \leq 14 years (female patients) or \leq 16 years (male patients); and
- 4 No serious adverse effect that the patient's specialist considers is likely to be attributable to growth hormone treatment has occurred.

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 \leq to 14 years (female patients) or \leq to 16 years (male patients); and
- 4 The patient is metabolically stable, has no evidence of metabolic bone disease and absence of any other severe chronic disease: and
- 5 The patient is under the supervision of a specialist with expertise in renal medicine; and
- 6 Fither:
 - 6.1 The patient has a GFR ≤ 30 ml/min/1.73m² as measured by the Schwartz method (Height(cm)/plasma creatinine $(umol/l) \times 40 = corrected GFR (ml/min/1.73m²) in a child who may or may not be receiving dialysis; or$
 - 6.2 The patient has received a renal transplant and has received < 5mg/m²/day of prednisone or equivalent for at least 6 months...

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

continued...

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 > 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 ≥ 2 cm per year as calculated over six months; and
- 3 A current bone age is < 14 years (female patients) or < 16 years (male patients); and
- 4 No serious adverse effect that the patients specialist considers is likely to be attributable to growth hormone has occurred;
- 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's 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 Fither:
 - 3.1 The patient is under two years of age and height velocity has been assessed over a minimum six month period from the age of 12 months, with at least three supine length measurements over this period demonstrating clear and consistent evidence of linear growth failure (with height velocity < 25th percentile); or
 - 3.2 The patient is aged two years or older; and
- 4 A current bone age is < 14 years (female patients) or < 16 years (male patients); and
- 5 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
- 6 There is no evidence of type II diabetes or uncontrolled obesity defined by BMI that has increased by ≥ 0.5 standard deviations in the preceding 12 months.

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 ≥ 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 ≥ 2 cm per year as calculated over six months; and
- 3 A current bone age is ≤ 14 years (female patients) or ≤ 16 years (male patients); and
- 4 No serious adverse effect that the patient's specialist considers is likely to be attributable to growth hormone treatment has occurred: 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 ≥ 0.5 standard deviations in the preceding 12 months.

Subsidy (Manufacturer's Price) \$

Fully Subsidised

Per

Brand or Generic Manufacturer

continued...

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

All of the following:

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

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

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

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

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

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

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

Fither:

- 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

✓ fully subsidised

[HP4] refer page 4

GOSERELIN ACETATE			
Inj 3.6 mg	166.20	1	Zoladex
Inj 10.8 mg	443.76	1	Zoladex

	Subsidy (Manufacturer's Price) \$	Sı Per	Fully ubsidised	Brand or Generic Manufacturer
LEUPRORELIN				
Inj 3.75 mg prefilled syringe	221.60	1	✓ Li	ucrin Depot PDS
Inj 7.5 mg		1	√ E	ligard .
Inj 11.25 mg prefilled syringe	591.68	1	✓ Li	ucrin Depot PDS
Inj 22.5 mg	443.76	1	√ E	ligard .
Inj 30 mg	591.68	1	✓ E	ligard
Inj 30 mg prefilled syringe		1	✓ Li	ucrin Depot PDS
Inj 45 mg		1	✓ E	ligard .
Vasopressin Agonists				
DECMODDECCIN ACCTATE				

	CETATE

	Tab 100 mcg - Special Authority see SA1401 below - Retail pharmacy	25.00	30	✓ Minirin
	Tab 200 mcg - Special Authority see SA1401 below - Retail pharmacy	54.45	30	✓ Minirin
	Nasal drops 100 mcg per ml - Retail pharmacy-Specialist	39.03	2.5 ml OP	Minirin
A	Nasal spray 10 mcg per dose - Retail pharmacy-Specialist	22.95	6 ml OP	✓ <u>Desmopressin-</u> <u>PH&T</u>
	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
2 ✓ Dostinex	2	waived by Special Authority see SA1370 on the next page4.75
8 Dostinex	8	19.00

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

⇒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:

Fither:

- 1 pathological hyperprolactinemia; or
- 2 acromegaly*.

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

Note: Indication marked with * is an Unapproved indication.

CLOMIPHENE CITRATE Tab 50 mg	29.84	10	✓ MylanClomiphen S29✓ Serophene
DANAZOL			
Cap 100 mg	68.33	100	✓ Azol
Cap 200 mg	97.83	100	✓ Azol
METYRAPONE			
Cap 250 mg - Retail pharmacy-Specialist	.520.00	50	✓ Metopirone

Subsidy		Fully	Brand or
(Manufacturer's Price)		Subsidised	Generic
· · · · · ·	Dor	./	Manufacturor

Anthelmintics

ALBENDAZOLE - Special Authority see SA1318 below - Retail pharmacy

60 ✓ Eskazole \$29

■ 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.

Tab 100 mg	24.19	24	De-Worm
Oral liq 100 mg per 5 ml	2.18	15 ml	
	(7.17)		Vermox

PRAZIQUANTFI

✓ Biltricide Tab 600 mg68.00

Antibacterials

- a) For topical antibacterials, refer to DERMATOLOGICALS, page 67
- b) For anti-infective eye preparations, refer to SENSORY ORGANS, page 213

Cephalosporins and Cephamycins

CEFACLOR MONOHYDRAI	E
Can DEO ma	

Oap 230 mg	24.70	100	Tranbaxy-Celacion
Ranbaxy-Cefaclor to be Sole Supply on 1 October 2016			
Grans for oral liq 125 mg per 5 ml - Wastage claimable - see	9		
rule 3.3.2 on page 13	3.53	100 ml	✔ Ranbaxy-Cefaclor
Ranbaxy-Cefaclor to be Sole Supply on 1 October 2016			
CEFALEXIN			

24.70

100

/ Panhavy Cafaalay

Cap 250 mg	5.50 20	Cephalexin ABM
Cap 500 mg		Cephalexin ABM
Cephalexin ABM to be Sole Supply on 1 November 2016		·
Grans for oral liq 25 mg per ml - Wastage claimable - see		
rule 3.3.2 on page 13	.00 100 ml	Cefalexin Sandoz

Note: Cefalexin grans for oral lig will not be funded in amounts more than 14 days treatment per dispensing.

Grans for oral lig 50 mg per ml - Wastage claimable - see

rule 3.3.2 on page 1311.00 100 ml ✓ Cefalexin Sandoz

Note: Cefalexin grans for oral lig will not be funded in amounts more than 14 days treatment 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 accordinaly

Inj 500 mg vial	99 5	✓ AFT
Inj 1 g vial	38 5	✓ <u>AFT</u>

	(Manufacturer's Price) \$	Per	Josiaisea 🗸	Manufacturer
CEFTRIAXONE – Subsidy by endorsement				
a) Up to 5 inj available on a PSO				
b) Subsidised only if prescribed for a dialysis or cystic fib	rosis patient, or the tre	atment	of gonori	rhoea, or the treatment of
pelvic inflammatory disease, or the treatment of suspected	I meningitis in patients v	who hav	e a know	n allergy to penicillin, and
the prescription or PSO is endorsed accordingly.	3			37
Inj 500 mg vial	1.20	1	✓ D	EVA
, ,	1.50		V C	eftriaxone-AFT
Inj 1 g vial	0.84	1	✓ D	EVA
. 0	5.22	5	✓ C	eftriaxone-AFT
CEFUROXIME AXETIL – Subsidy by endorsement				
Only if prescribed for prophylaxis of endocarditis and the pr	escription is endorsed a	ccordin	gly.	
Tab 250 mg	29.40	50	Ž 🗸 Zi	innat

Subsidy

Fully

Brand or

Macrolides

AZITHROMYCIN - Maximum of 5 days treatment per prescription: can be waived by endorsement

For Endorsement, patient has either:

- 1) Received a lung transplant and requires treatment or prophylaxis for bronchiolitis obliterans syndrome*; or
- 2) Cystic fibrosis and has chronic infection with Pseudomonas aeruginosa or Pseudomonas related gram negative organisms*.

indications marked with " are Unapproved Indications			
Tab 250 mg	9.00	30	✓ Apo-Azithromycin
Tab 500 mg - Up to 8 tab available on a PSO	1.05	2	✓ Apo-Azithromycin
Grans for oral lig 200 mg per 5 ml (40 mg per ml) - Wastage			
claimable – see rule 3.3.2 on page 13	12.50	15 ml	✓ Zithromax
CLARITHROMYCIN - Maximum of 500 mg per prescription; can b	e waived by Sr	ecial Authorit	y see SA1131 below
Tab 250 mg		14	✓ Apo-Clarithromycin
Grans for oral lig 125 mg per 5 ml - Wastage claimable -			
see rule 3.3.2 on page 13	23.12	70 ml	✓ Klacid
Grans for oral lig 250 mg per 5 ml - Wastage claimable - see			
rule 3.3.2 on page 13	23.12	50 ml	✓ Klacid
(Klacid Grans for oral liq 125 mg per 5 ml to be delisted 1 October 2	2016)		

⇒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.

	Subsidy		Fully	Brand or
	(Manufacturer's Pri \$	ce) Per	Subsidised <	Generic Manufacturer
RYTHROMYCIN ETHYL SUCCINATE				
Tab 400 mg	16.05	100	4 1	E-Mycin
a) Up to 20 tab available on a PSO	10.33	100	•	wyciii
, .	mula F O C an name :	17		
b) Up to 2 x the maximum PSO quantity for RFPP – see				- Music
Grans for oral liq 200 mg per 5 ml	5.00	100 ml	•	E-Mycin
a) Up to 300 ml available on a PSO	rulo E O C on nogo	17		
b) Up to 2 x the maximum PSO quantity for RFPP – see	rule 5.2.6 on page	17		
c) Wastage claimable – see rule 3.3.2 on page 13	0.77	100 1		Marain
Grans for oral liq 400 mg per 5 ml		100 ml	V 1	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		
Tab 200 mg Op to 00 tab available on a 1 00	(22.29)	100		ERA
Tab 500 mg		100		_i i/1
Tab 500 mg		100		ERA
	(44.58)			INA .
ROXITHROMYCIN				
Tab 150 mg	7.48	50	V 1	Arrow-
				Roxithromycin
Tab 300 mg	14.40	50	V 1	Arrow-
· ·				Roxithromycin
Penicillins				
AMOXICILLIN				
Cap 250 mg	14.97	500	V 1	Apo-Amoxi
a) Up to 30 cap available on a PSO				-
b) Up to 10 x the maximum PSO quantity for RFPP – se	e rule 5.2.6 on page	17		
c) Apo-Amoxi to be Sole Supply on 1 October 2016				
Cap 500 mg	16.75	500	V 1	Apo-Amoxi
a) Up to 30 cap available on a PSO				•
b) Up to 10 x the maximum PSO quantity for RFPP – se	e rule 5.2.6 on page	17		
c) Apo-Amoxi to be Sole Supply on 1 October 2016	o pago	-		
Grans for oral liq 125 mg per 5 ml	0.88	100 ml	V 1	Alphamox
Grand for Graning 120 mg por Gran		100 1111		Amoxicillin Actavis
				Ranmoxy
	2.00			Ospamox
a) Up to 200 ml available on a PSO	2.00		• (Jopaniox
b) Wastage claimable – see rule 3.3.2 on page 13				
	0.07	100 ml	./	Minhamov
Grans for oral liq 250 mg per 5 ml	0.97	100 1111		Alphamox Amoxicillin Actavis
	0.00			Ranmoxy
\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	2.00		•	Ospamox
a) Up to 300 ml available on a PSO		4-		
b) Up to 10 x the maximum PSO quantity for RFPP – se	e rule 5.2.6 on page	17		
c) Wastage claimable – see rule 3.3.2 on page 13				
Inj 250 mg vial		10	_	<u>biamox</u>
Inj 500 mg vial	12.41	10		<u>biamox</u>
Inj 1 g vial - Up to 5 inj available on a PSO		10		biamox

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

	Subsidy (Manufacturer's Price	<i>a)</i>	Fully Subsidised	Brand or Generic
	\$	Per	✓ ✓	Manufacturer
(Alphamox Grans for oral liq 125 mg per 5 ml to be delisted 1 Nov (Ranmoxy Grans for oral liq 125 mg per 5 ml to be delisted 1 Nov				
(Alphamox Grans for oral liq 250 mg per 5 ml to be delisted 1 Nov				
(Ranmoxy Grans for oral liq 250 mg per 5 ml to be delisted 1 Nove	ember 2016)			
AMOXICILLIN WITH CLAVULANIC ACID				
Tab 500 mg with clavulanic acid 125 mg - Up to 30 tab avail-				
able on a PSO		20	✓ <u>A</u>	ugmentin
Grans for oral liq amoxicillin 125 mg with clavulanic acid				
31.25 mg per 5 ml	3.83	100 ml	✓ A	ugmentin
a) Up to 200 ml available on a PSO b) Wastage claimable – see rule 3.3.2 on page 13				
Grans for oral liq amoxicillin 250 mg with clavulanic acid				
62.5 mg per 5 ml		100 ml	✓ A	ugmentin
a) Up to 200 ml available on a PSO				
b) Wastage claimable – see rule 3.3.2 on page 13				
BENZATHINE BENZYLPENICILLIN				
Inj 900 mg (1.2 million units) in 2.3 ml syringe - Up to 5 inj				
available on a PSO	315.00	10	✓ <u>B</u>	icillin LA
BENZYLPENICILLIN SODIUM (PENICILLIN G)				
Inj 600 mg (1 million units) vial - Up to 5 inj available on a				
PSO	10.35	10	✓ <u>S</u>	<u>andoz</u>
FLUCLOXACILLIN				
Cap 250 mg – Up to 30 cap available on a PSO		250		taphlex
Cap 500 mg		500	. –	taphlex
Grans for oral liq 25 mg per ml	2.29	100 ml	✓ <u>A</u>	<u>F1</u>
b) Wastage claimable – see rule 3.3.2 on page 13				
Grans for oral liq 50 mg per ml	3.08	100 ml	✓ A	FT
a) Up to 200 ml available on a PSO			_	
b) Wastage claimable – see rule 3.3.2 on page 13				
Inj 250 mg vial		10		lucloxin
Inj 500 mg vial		10	. —	lucloxin
Inj 1 g vial – Up to 10 inj available on a PSO	11.00	10	V <u>F</u>	<u>lucloxin</u>
PHENOXYMETHYLPENICILLIN (PENICILLIN V)	0.00			iliaaina VIV
Cap 250 mg - Up to 30 cap available on a PSO		50 50		ilicaine VK ilicaine VK
a) Up to 20 cap available on a PSO		50	• •	meanie VIX
b) Up to 2 x the maximum PSO quantity for RFPP – see ru	ile 5.2.6 on page 17			
Grans for oral liq 125 mg per 5 ml		100 ml	✓ A	FT
a) Up to 200 ml available on a PSO				
b) Wastage claimable – see rule 3.3.2 on page 13				
c) AFT to be Sole Supply on 1 October 2016	1 50	100 ml	✓ A	CT
Grans for oral liq 250 mg per 5 mla) Up to 300 ml available on a PSO	1.30	100 ml	VA	гі
b) Up to 2 x the maximum PSO quantity for RFPP – see ru	lle 5.2.6 on page 17			
c) Wastage claimable – see rule 3.3.2 on page 13	1.3			
d) AFT to be Sole Supply on 1 October 2016				
PROCAINE PENICILLIN				
Inj 1.5 g in 3.4 ml syringe – Up to 5 inj available on a PSO	123.50	5	✓ <u>C</u>	<u>ilicaine</u>

		Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
Te	etracyclines				
DO	XYCYCLINE				
*	Tab 50 mg - Up to 30 tab available on a PSO	2.90 (6.00)	30	1	Doxy-50
*	Tab 100 mg - Up to 30 tab available on a PSO	` '	250		<u>Doxine</u>
MIN	NOCYCLINE HYDROCHLORIDE				
*	Tab 50 mg - Additional subsidy by Special Authority see	Э			
	SA1355 below – Retail pharmacy		60		
		(12.05)		ı	Mino-tabs
*	Cap 100 mg		100		
		(52.04)			Minomycin
	SA1332 Special Authority for Subsidy ial application from any relevant practitioner. Approvals valid th:	for 3 months for appli	cation	ns meeting	the following criteria:
	1 For the eradication of helicobacter pylori following unsuc2 For use only in combination with bismuth as part of a qu			opriate firs	t-line therapy; and
0				opriate firs	t-line therapy; and
For	2 For use only in combination with bismuth as part of a questher Antibiotics topical antibiotics, refer to DERMATOLOGICALS, page 67 PROFLOXACIN Recommended for patients with any of the following: i) microbiologically confirmed and clinically significant pset ii) prostatitis; or iii) pyelonephritis; or iv) gonorrhoea.	adruple therapy regim	r		·
For	2 For use only in combination with bismuth as part of a questher Antibiotics topical antibiotics, refer to DERMATOLOGICALS, page 67 PROFLOXACIN Recommended for patients with any of the following: i) microbiologically confirmed and clinically significant pset ii) prostatitis; or iii) pyelonephritis; or	adruple therapy regimudomonas infection; o	en.	V	t-line therapy; and Cipflox Cipflox Cipflox Cipflox
For CIF	2 For use only in combination with bismuth as part of a questher Antibiotics topical antibiotics, refer to DERMATOLOGICALS, page 67 PROFLOXACIN Recommended for patients with any of the following: i) microbiologically confirmed and clinically significant pset ii) prostatitis; or iii) pyelonephritis; or iv) gonorrhoea. Tab 250 mg – Up to 5 tab available on a PSO	udomonas infection; o	r 28 28	V	Cipflox Cipflox

CO-TRIMOXAZOLE

16

10

500

100 ml

Clindamycin ABM

✓ Dalacin C

Trisul

✓ Deprim

tion; can be waived by endorsement - Retail pharmacy -

Clindamycin ABM to be Sole Supply on 1 October 2016 Inj phosphate 150 mg per ml, 4 ml ampoule – Retail

Tab trimethoprim 80 mg and sulphamethoxazole 400 mg -

Oral liq trimethoprim 40 mg and sulphamethoxazole 200 mg

Dalacin C to be Sole Supply on 1 October 2016

Specialist4.10

pharmacy-Specialist65.00

Up to 30 tab available on a PSO22.90

per 5 ml - Up to 200 ml available on a PSO......2.15

[±] safety cap

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

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per Manufacturer COLISTIN SULPHOMETHATE - Retail pharmacy-Specialist - Subsidy by endorsement Only if prescribed for dialysis or cystic fibrosis patient and the prescription is endorsed accordingly. ✓ Colistin-Link **FUSIDIC ACID** ✓ Fucidin Prescriptions must be written by, or on the recommendation of, an infectious disease physician or a clinical microbiologist GENTAMICIN SULPHATE ✔ Hospira Only if prescribed for a dialysis or cystic fibrosis patient or complicated urinary tract infection and the prescription is endorsed accordingly. Pharmaceuticals \$29

Only if prescribed for a dialysis or cystic fibrosis patient or complicated urinary tract infection and the prescription is endorsed accordingly.

10 ✔ Pfizer 30.00 50 ✔ Pfizer

Only if prescribed for a dialysis or cystic fibrosis patient or complicated urinary tract infection and the prescription is endorsed accordingly.

MOXIFLOXACIN - Special Authority see SA1358 below - Retail pharmacy

No patient co-payment payable

✓ 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:

Fither:

- 1 Both:
 - 1.1 Active tuberculosis*; and
 - 1.2 Any of the following:
 - 1.2.1 Documented resistance to one or more first-line medications: or
 - 1.2.2 Suspected resistance to one or more first-line medications (tuberculosis assumed to be contracted in an area with known resistance), as part of regimen containing other second-line agents; or
 - 1.2.3 Impaired visual acuity (considered to preclude ethambutol use); or
 - 1.2.4 Significant pre-existing liver disease or hepatotoxicity from tuberculosis medications; or
 - 1.2.5 Significant documented intolerance and/or side effects following a reasonable trial of first-line medications:
- 2 Mycobacterium avium-intracellulare complex not responding to other therapy or where such therapy is contraindicated.*.

Note: Indications marked with * are Unapproved Indications (refer to Interpretations and Definitions).

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

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

All of the following:

- 1 Has nucleic acid amplification test (NAAT) confirmed Mycoplasma genitalium*; and
- 2 Has tried and failed to clear infection using azithromycin; and
- 3 Treatment is only for 7 days.

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

Note: Indications marked with * are Unapproved Indications (refer to Interpretations and Definitions).

				Ш
	Subsidy (Manufacturer's Pric \$	e) Sub Per	Fully Brand or sidised Generic Manufacturer	
PAROMOMYCIN - Special Authority see SA1324 below - Retal Cap 250 mg		16	✓ Humatin \$29	
■► SA1324 Special Authority for Subsidy Initial application only from an infectious disease specialist or class confirmed cryptosporidium infection. Renewal only from an infectious disease specialist or clinical nation	ŭ		·	
PYRIMETHAMINE – Special Authority see SA1328 below – Ret Tab 25 mg	' '	30 50	✓ Daraprim \$29 ✓ Daraprim \$29	
■→SA1328 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals val the following criteria: Any of the following:	id without further re	newal unles	s notified for applications me	eeting
 For the treatment of toxoplasmosis in patients with HIV For pregnant patients for the term of the pregnancy; or For infants with congenital toxoplasmosis until 12 month 	·	iths; or		
SULFADIAZINE SODIUM - Special Authority see SA1331 below Tab 500 mg		56	✓ Wockhardt S29	
■ SA1331 Special Authority for Subsidy Initial application from any relevant practitioner. Approvals val the following criteria: Any of the following:	id without further re	newal unles	s notified for applications me	eeting
 For the treatment of toxoplasmosis in patients with HIV For pregnant patients for the term of the pregnancy; or For infants with congenital toxoplasmosis until 12 month 	·	nths; or		
TOBRAMYCIN Inj 40 mg per ml, 2 ml ampoule – Subsidy by endorsement Only if prescribed for dialysis or cystic fibrosis patient and Solution for inhalation 60 mg per ml, 5 ml – Subsidy by endorsement	I the prescription is e	5 endorsed ac 56 dose	✓ DBL Tobramycin cordingly.	
 a) Wastage claimable – see rule 3.3.2 on page 13 b) Only if prescribed for a cystic fibrosis patient and the p TRIMETHOPRIM 	rescription is endors	ed accordin	gly.	
* Tab 300 mg - Up to 30 tab available on a PSO	15.00	50	✓ <u>TMP</u>	
VANCOMYCIN – Subsidy by endorsement Only if prescribed for a dialysis or cystic fibrosis patient or fo following metronidazole failure and the prescription is endors	sed accordingly.			ifficile
Inj 500 mg	2.64	1	✓ <u>Mylan</u>	

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

Antifungals

a) For topical antifungals refer to DERMATOLOGICALS, page 67

b) For topical antifungals refer to GENITO URINARY, page 80

FLUCONAZOLE

Cap 50 mg - Retail pharmacy-Specialist3.49 28 ✓ Ozole Cap 150 mg - Subsidy by endorsement0.71 ✓ Ozole a) Maximum of 1 cap per prescription; can be waived by endorsement - Retail pharmacy - Specialist b) Patient has vaginal candida albicans and the practitioner considers that a topical imidazole (used intra-vaginally) is not recommended and the prescription is endorsed accordingly; can be waived by endorsement - Retail pharmacy - Specialist. Cap 200 mg - Retail pharmacy-Specialist9.69 ✓ Ozole

Powder for oral suspension 10 mg per ml - Special Authority

see SA1359 below - Retail pharmacy34.56 35 ml ✓ Diflucan S29 S29 ✓ Diflucan

Wastage claimable - see rule 3.3.2 on page 13

⇒SA1359 Special Authority for Subsidy

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

Both:

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

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

All of the following:

- 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.

ITRACONAZOI F

✓ Itrazole 15

a) Funded for tinea vesicolor where topical treatment has not been successful and diagnosis has been confirmed by mycology, or for tinea unquium 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.

b) Itrazole to be Sole Supply on 1 October 2016

Oral lig 10 mg per ml - Special Authority see SA1322 on the

next page – Retail pharmacy141.80 150 ml OP **Sporanox**

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

⇒SA1322 Special Authority for Subsidy

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

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

KFTOCONAZOI F

Tab 200 mg - PCT - Retail pharmacy-Specialist - Subsidy by endorsement	CBS	30	✓ Link Healthcare \$29 ✓ Nizoral \$29
Prescriptions must be written by, or on the recommendation	of an oncolog	ist	V MEGICI
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	oharmacy		
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:

Fither:

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

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

TERBINAFINE

* Tab 250 mg - For terbinafine oral liquid formulation page 221	,	14	✓ <u>Dr Reddy's</u> <u>Terbinafine</u>
VORICONAZOLE - Special Authority see SA1273 on the n	ext page – Retail pharn	nacy	
Tab 50 mg	130.00	56	✓ Vttack
Tab 200 mg	500.00	56	✓ Vttack
Powder for oral suspension 40 mg per ml - Wa	stage		
claimable – see rule 3.3.2 on page 13		70 ml	✓ Vfend

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

⇒SA1273 Special Authority for Subsidy

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

All of the following:

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

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

All of the following:

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

Antimalarials

PRIMAQUINE PHOSPHATE – Special Authority see SA1326 below – Retail pharmacy

⇒SA1326 Special Authority for Subsidy

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

Both:

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

Antiparasitics

Antiprotozoals

QUININE SULPHATE

‡ Safety cap for extemporaneously compounded oral liquid preparations.

Antitrichomonal Agents

METRONIDAZOLE

Tab 200 mg - Up to 30 tab available on a PSO	10.45	100	✓ Trichozole
Tab 400 mg	18.15	100	Trichozole
Oral liq benzoate 200 mg per 5 ml	25.00	100 ml	✓ Flagyl-S
Suppos 500 mg	24.48	10	✓ Flagyl
ORNIDAZOLE			
Tab 500 mg	23.00	10	✓ Arrow-Ornidazole

Arrow-Ornidazole to be Sole Supply on 1 November 2016

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

Antituberculotics and Antileprotics

Note: There is no co-payment charge for all pharmaceuticals listed in the Antituberculotics and Antileprotics group regardless of immigration status.

CLOFAZIMINE - Retail pharmacy-Specialist

- a) No patient co-payment payable
- b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or dermatologist.

CYCLOSERINE - Retail pharmacy-Specialist

- a) No patient co-payment payable
- b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or respiratory physician.

DAPSONE - Retail pharmacy-Specialist

- a) No patient co-payment payable
- b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or dermatologist

Tab 25 mg	95.00	100	✓ <u>Dapsone</u>
Tab 100 mg	110.00	100	✓ Dapsone

ETHAMBUTOL HYDROCHLORIDE - Retail pharmacy-Specialist

- a) No patient co-payment payable
- b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or respiratory physician

respiratory priyololari			
Tab 100 mg	48.01	56	Myambutol
Tab 400 mg	49.34	56	✓ Myambutol

ISONIAZID - Retail pharmacy-Specialist

- a) No patient co-payment payable
- b) Prescriptions must be written by, or on the recommendation of, an internal medicine physician, paediatrician, clinical microbiologist, dermatologist or public health physician

	biologist, derinatologist of public fleatili physician		
*	Tab 100 mg20.0	00 100	✓ PSM
	Tab 100 mg with rifampicin 150 mg85.5		✓ Rifinah
*	Tab 150 mg with rifampicin 300 mg170.6	0 100	✓ Rifinah

PARA-AMINO SALICYLIC ACID - Retail pharmacy-Specialist

- a) No patient co-payment payable
- b) Specialist must be an infectious disease specialist, clinical microbiologist or respiratory specialist.

PROTIONAMIDE - Retail pharmacy-Specialist

- a) No patient co-payment payable
- b) Specialist must be an infectious disease specialist, clinical microbiologist or respiratory specialist.

PYRAZINAMIDE - Retail pharmacy-Specialist

- a) No patient co-payment payable
- b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or respiratory physician
- * Tab 500 mg For pyrazinamide oral liquid formulation refer,

page 22159.00 100 **✔ AFT-Pyrazinamide**

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

RIFABUTIN - Retail pharmacy-Specialist

- a) No patient co-payment payable
- b) Prescriptions must be written by, or on the recommendation of, an infectious disease physician, respiratory physician or gastroenterologist
- Cap 150 mg For rifabutin oral liquid formulation refer, page

221275.00 30 Mycobutin

Mycobutin to be Sole Supply on 1 November 2016

RIFAMPICIN - Subsidy by endorsement

- a) No patient co-payment payable
- b) For confirmed recurrent Staphylococcus aureus infection in combination with other effective anti-staphylococcal antimicrobial based on susceptibilities and the prescription is endorsed accordingly; can be waived by endorsement - Retail pharmacy -Specialist. Specialist must be an internal medicine physician, clinical microbiologist, dermatologist, paediatrician, or public health physician.

*	Cap 150 mg55.75	100	✓ Rifadin
*	Cap 300 mg116.25	100	✓ Rifadin
*	Oral lig 100 mg per 5 ml	60 ml	✓ Rifadin

Antivirals

For eye preparations refer to Eye Preparations, Anti-Infective Preparations, page 213

Hepatitis B Treatment

ADEFOVIR DIPIVOXIL - Special Authority see SA0829 below - Retail pharmacy 30 ✓ Hepsera Tab 10 mg670.00

⇒SA0829 Special Authority for Subsidy

Initial application only from a gastroenterologist or infectious disease specialist. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 Patient has confirmed Hepatitis B infection (HBsAg+); and Documented resistance to lamivudine, defined as:
- 2 Patient has raised serum ALT (> 1 × ULN); and
- 3 Patient has HBV DNA greater than 100,000 copies per mL, or viral load ≥ 10 fold over nadir; and
- 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: Lamiyudine should be added to adefovir dipiyoxil if a patient develops documented resistance to adefovir dipiyoxil, defined as:

- i) raised serum ALT (> 1 \times ULN); and
- ii) HBV DNA greater than 100,000 copies per mL, or viral load ≥ 10 fold over nadir; and
- iii) Detection of N236T or A181T/V mutation.

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

continued...

Adefovir dipivoxil should be stopped 6 months following HBeAq seroconversion for patients who were HBeAq+ 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 / Raraclude Tab 0.5 mg400.00

■ 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 ≥ 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 HBeAq plus appearance of anti-HBe plus loss of serum HBV DNA) for patients who were HBeAq positive prior to commencing this agent. This period of consolidation therapy should be extended to 12 months in patients with advanced fibrosis (Metavir Stage F3 or F4).
- Entecavir should be taken on an empty stomach to improve absorption.

LAMIVUDINE - Special Authority see SA1360 below - Retail pharmacy

Tab 100 mg6.00 28 ✓ Zeffix 240 ml Zeffix

⇒SA1360 | Special Authority for Subsidy

Initial application only from a gastroenterologist, infectious disease specialist, paediatrician, general physician or medical practitioner on the recommendation of a gastroenterologist, infectious disease specialist, paediatrician or general physician. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 HBV DNA positive cirrhosis prior to liver transplantation; or
- 2 HBsAg positive and have had a liver, kidney, heart, lung or bone marrow transplant; or
- 3 Hepatitis B virus naive patient who has received a liver transplant from an anti-HBc (Hepatitis B core antibody) positive donor: or
- 4 Hepatitis B surface antigen (HbsAg) positive patient who is receiving chemotherapy for a malignancy, or high dose steroids (at least 20mg/day for at least 7 days), or who has received such treatment within the previous two months; or
- 5 Hepatitis B surface antigen positive patient who is receiving anti-tumour necrosis factor treatment; or

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Fully Subsidised Per

Brand or Generic Manufacturer

continued...

6 Hepatitis B core antibody (anti-HBc) positive patient who is receiving rituximab plus high dose steroids (e.g. R-CHOP).

Renewal only from a gastroenterologist, infectious disease specialist, paediatrician, general physician or medical practitioner on the recommendation of a gastroenterologist, infectious disease specialist, paediatrician or general physician. Approvals valid for 2 vears for applications meeting the following criteria:

Any of the following:

Renewal for patients who have maintained continuous treatment and response to lamivudine

- 1 All of the following:
 - 1.1 Have maintained continuous treatment with lamivudine; and
 - 1.2 Most recent test result shows continuing biochemical response (normal ALT); and
 - 1.3 HBV DNA <100,000 copies per ml by quantitative PCR at a reference laboratory; or

Renewal when given in combination with adefovir dipivoxil for patients with cirrhosis and resistance to lamivudine

- 2 All of the following:
 - 2.1 Lamiyudine to be used in combination with adefovir dipiyoxil; and
 - 2.2 Patient is cirrhotic: and
 - Documented resistance to lamivudine, defined as:
 - 2.3 Patient has raised serum ALT (> 1 × ULN); and
 - 2.4 Patient has HBV DNA greater than 100,000 copies per mL, or viral load = 10 fold over nadir; and
 - 2.5 Detection of M204I or M204V mutation; or

Renewal when given in combination with adefovir dipivoxil for patients with resistance to adefovir dipivoxil

- 3 All of the following:
 - 3.1 Lamivudine to be used in combination with adefovir dipivoxil; and Documented resistance to adefovir, defined as:
 - 3.2 Patient has raised serum ALT (> 1 \times ULN); and
 - 3.3 Patient has HBV DNA greater than 100,000 copies per mL, or viral load = 10 fold over nadir; and
 - 3.4 Detection of N236T or A181T/V mutation.

Herpesvirus Treatments

ACICLOVIR			
* Tab dispersible 200 mg	1.60	25	Lovir
Lovir to be Sole Supply on 1 October 2016	5		
* Tab dispersible 400 mg	5.38	56	Lovir
Lovir to be Sole Supply on 1 October 2016	5		
* Tab dispersible 800 mg	5.98	35	Lovir
Lovir to be Sole Supply on 1 October 2016	3		
VALACICLOVIR			
Tab 500 mg	6.42	30	✓ Vaclovir
Tab 1,000 mg	12.75	30	✓ Vaclovir
VALGANCICLOVIR - Special Authority see SA14	404 below – Retail pharmacy		
Tab 450 mg	1,050.00	60	✓ <u>Valcyte</u>

⇒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:

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

continued...

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

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

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

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

Hepatitis B/ HIV/AIDS Treatment

TENOFOVIR DISOPROXIL FUMARATE - Subsidy by endorsement; can be waived by Special Authority see SA1362 on the next page

Endorsement for treatment of HIV: Prescription is deemed to be endorsed if tenofovir disoproxil fumarate is co-prescribed with another anti-retroviral subsidised under Special Authority SA1364 and the prescription is annotated accordingly by the Pharmacist or endorsed by the prescriber.

Note: Tenofovir disoproxil fumarate prescribed under endorsement for the treatment of HIV is included in the count of up to 4 subsidised antiretrovirals for the purposes of Special Authority SA1364, page 112

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Subsidy (Manufacturer's Price) \$

Fully Subsidised

Per

Brand or Generic Manufacturer

⇒SA1362 Special Authority for Waiver of Rule

Initial application — (Chronic Hepatitis B) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid without further renewal unless notified for applications meeting the following criteria: Any of the following:

- 1 All of the following:
 - 1.1 Patient has confirmed Hepatitis B infection (HBsAg positive for more than 6 months); and
 - 1.2 Patient has had previous lamivudine, adefovir or entecavir therapy; and
 - 1.3 HBV DNA greater than 20,000 IU/mL or increased ≥ 10 fold over nadir; and
 - 1.4 Any of the following:
 - 1.4.1 Lamiyudine resistance detection of M204I/V mutation: or
 - 1.4.2 Adefovir resistance detection of A181T/V or N236T mutation; or
 - 1.4.3 Entecavir resistance detection of relevant mutations including I169T, L180M T184S/A/I/L/G/C/M, S202C/G/I, M204V or M250I/V mutation: or
- 2 Patient is either listed or has undergone liver transplantation for HBV; or
- 3 Patient has decompensated cirrhosis with a Mayo score >20.

Initial application — (Pregnant, Active hepatitis B) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 12 months for applications meeting the following criteria: Both:

- 1 Patient is HBsAg positive and pregnant; and
- 2 HBV DNA > 20,000 IU/mL and ALT > ULN.

Renewal — (Confirmed Hepatitis B following funded tenofovir treatment for pregnancy within the previous two years) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid without further renewal unless notified for applications meeting the following criteria: Either:

- 1 All of the following:
 - 1.1 Patient has confirmed Hepatitis B infection (HBsAg positive for more than 6 months); and
 - 1.2 Patient has had previous lamivudine, adefovir or entecavir therapy; and
 - 1.3 HBV DNA greater than 20,000 IU/mL or increased > 10 fold over nadir; and
 - 1.4 Any of the following:
 - 1.4.1 Lamivudine resistance detection of M204I/V mutation; or
 - 1.4.2 Adefovir resistance detection of A181T/V or N236T mutation; or
 - 1.4.3 Entecavir resistance detection of relevant mutations including I169T, L180M T184S/A/I/L/G/C/M, S202C/G/I. M204V or M250I/V mutation; or
- 2 Patient is either listed or has undergone liver transplantation for HBV.

Renewal — (Subsequent pregnancy or Breastfeeding, Active hepatitis B) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 12 months for applications meeting the following criteria: Both:

- 1 Patient is HBsAg positive and pregnant or breastfeeding; and
- 2 HBV DNA > 20,000 IU/mL and ALT > ULN.

Initial application — (Pregnant, prevention of vertical transmission) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 6 months for applications meeting the following criteria: Both:

- 1 Patient is HBsAg positive and pregnant; and
- 2 HBV DNA > 20 million IU/mL and ALT normal.

Renewal — (Subsequent pregnancy, prevention of vertical transmission) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 6 months for applications meeting the following criteria: Both:

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

continued...

- 1 Patient is HBsAq positive and pregnant; and
- 2 HBV DNA > 20 million IU/mL and ALT normal.

Notes:

- Tenofovir disoproxil fumarate should be stopped 6 months following HBeAg seroconversion for patients who were HBeAg positive prior to commencing this agent and 6 months following HBsAg seroconversion for patients who were HBeAg negative prior to commencing this agent.
- The recommended dose of Tenofovir disoproxil 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

BOCEPREVIR - Special Authority see SA1402 below - Retail pharmacy

Cap 200 mg - Wastage claimable - see rule 3.3.2 on page

Victrelis

⇒SA1402 Special Authority for Subsidy

Initial application — (chronic hepatitis C - genotype 1, first-line) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 18 months for applications meeting the following criteria: All of the following:

- 1 Patient has chronic hepatitis C, genotype 1; and
- 2 Patient has not received prior pegylated interferon treatment; and
- 3 Patient has IL-28B genotype CT or TT; and
- 4 Patient is to be treated in combination with pegylated interferon and ribavirin; and
- 5 Patient is hepatitis C protease inhibitor treatment-naive; and
- 6 Maximum of 44 weeks therapy.

Initial application — (chronic hepatitis C - genotype 1, second-line) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 18 months for applications meeting the following criteria: All of the following:

- 1 Patient has chronic hepatitis C, genotype 1; and
- 2 Patient has received pegylated interferon treatment; and
- 3 Any of the following:
 - 3.1 Patient was a responder relapser; or
 - 3.2 Patient was a partial responder; or
 - 3.3 Patient received pegylated interferon prior to 2004; and
- 4 Patient is to be treated in combination with pegylated interferon and ribavirin; and
- 5 Maximum of 44 weeks therapy.

Notes:

- Due to risk of severe sepsis boceprevir should not be initiated if either Platelet count < 100 x10⁹ /l or Albumin <35 g/l
- The wastage rule applies to boceprevir to allow dispensing to occur more frequently than monthly

LEDIPASVIR WITH SOFOSBUVIR - Special Authority see SA1605 on the next page - [Xpharm]

No patient co-payment payable

Tab 90 mg with sofosbuvir 400 mg24,363.46 28 ✔ Harvoni

111

Subsidy (Manufacturer's Price) \$

Fully Subsidised

Per

Brand or Generic Manufacturer

⇒SA1605 Special Authority for Subsidy

Special Authority approved by the Hepatitis C Treatment Panel (HepCTP)

Notes: By application to the Hepatitis C Treatment Panel (HepCTP).

Applications will be considered by HepCTP and approved subject to confirmation of eligibility.

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

The Coordinator, Hepatitis C Treatment Panel

PHARMAC, PO Box 10-254, WELLINGTON Tel: (04) 460 4990,

Email: hepcpanel@pharmac.govt.nz

PARITAPREVIR, RITONAVIR AND OMBITASVIR WITH DASABUVIR - [Xpharm]

- a) No patient co-payment payable
- b) Note From 1 July 2016 until 1 October 2016, PHARMAC will only process prescriptions received from an infectious disease specialist, a gastroenterologist or a hepatologist. PHARMAC may receive prescriptions from other prescribers prior to 1 October 2016: however they will not be processed until this date.
- c) 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

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 From 1 July 2016 until 1 October 2016. PHARMAC will only process prescriptions received from an infectious disease specialist, a gastroenterologist or a hepatologist. PHARMAC may receive prescriptions from other prescribers prior to 1 October 2016; however they will not be processed until this date.
- c) 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

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

Antiretrovirals

⇒SA1364 | Special Authority for Subsidy

Initial application — (Confirmed HIV) only from a named specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria: Both:

- 1 Confirmed HIV infection: and
- 2 Any of the following:
 - 2.1 Symptomatic patient; or
 - 2.2 Patient aged 12 months and under; or
 - 2.3 Both:
 - 2.3.1 Patient aged 1 to 5 years; and
 - 2.3.2 Any of the following:
 - 2.3.2.1 CD4 counts < 1000 cells/mm³; or
 - 2.3.2.2 CD4 counts < 0.25 × total lymphocyte count; or
 - 2.3.2.3 Viral load counts > 100000 copies per ml; or
 - 2.4 Both:
 - 2.4.1 Patient aged 6 years and over; and
 - 2.4.2 CD4 counts < 500 cells/mm³.

Subsidy (Manufacturer's Price) \$ Per

Fully Subsidised Brand or Generic Manufacturer

continued...

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

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

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

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

Either:

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

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

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

Some antiretrovirals are unapproved or contraindicated for this indication. Practitioners prescribing these medications should exercise their own skill, judgement, expertise and discretion, and make their own prescribing decisions with respect to the use of a Pharmaceutical for an indication for which it is not approved or contraindicated.

Initial application — (post-exposure prophylaxis following non-occupational exposure to HIV) only from a named specialist. Approvals valid for 4 weeks for applications meeting the following criteria:

Both:

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

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

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

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

Both:

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

Cap 400 mg368.16

EMTRICITABINE - Special Authority see SA1364 on page 112 - Retail pharmacy

Tab 600 mg with emtricitabine 200 mg and tenofovir disoproxil

INFECTIONS - AGENTS FOR SYSTEMIC US	E			
	Subsidy (Manufacturer's Pri	ce) Sub Per	Fully sidised	Brand or Generic Manufacturer
continued Initial application — (Percutaneous exposure) only from a na	amed specialist. Ap	orovals valid	for 6 we	eeks where the patient has
percutaneous exposure to blood known to be HIV positive. Notes: Tenofovir disoproxil fumarate prescribed under endorserr virals.	nent for HIV is includ	led in the cou	unt of up	o to 4 subsidised antiretro-
Subsidies for a combination of up to four antiretroviral medicatio given as a booster (either as part of a combination product or se of accessing funding to antiretrovirals.				
Renewal — (Second or subsequent percutaneous exposure the patient has percutaneous exposure to blood known to be HIV		d specialist.	Approva	als valid for 6 weeks where
Non-nucleosides Reverse Transcriptase Inhibit	ors			
EFAVIRENZ - Special Authority see SA1364 on page 112 - Re	tail pharmacy			
Tab 50 mg	63.38	30	_	tocrin S29
Tab 200 mg	190.15	90	✓ S	tocrin
Tab 600 mg	63.38	30	✓ <u>S</u>	tocrin_
Oral liq 30 mg per ml	145.79	180 ml OP	√ S	tocrin S29
ETRAVIRINE – Special Authority see SA1364 on page 112 – R		60	a./ In	itelence
Tab 200 mg		60	V III	itelefice
NEVIRAPINE - Special Authority see SA1364 on page 112 - R			4	
Tab 200 mg	65.00	60	✓ <u>N</u>	evirapine
0	000 55	040		Alphapharm iramune
Oral suspension 10 mg per ml	203.55	240 ml		Suspension
Nucleosides Reverse Transcriptase Inhibitors				
ABACAVIR SULPHATE - Special Authority see SA1364 on page	e 112 – Retail phar	macy		
Tab 300 mg	229.00	60	✓ Z	iagen
Oral liq 20 mg per ml	256.31	240 ml OP	✓ Z	iagen
ABACAVIR SULPHATE WITH LAMIVUDINE - Special Authority	see SA1364 on pa	ae 112 – Re	tail phai	rmacv
Note: abacavir with lamivudine (combination tablets) coun retroviral Special Authority.				
Tab 600 mg with lamivudine 300 mg	630.00	30	✓ K	ivexa
DIDANOSINE [DDI] - Special Authority see SA1364 on page 1		·V		
Cap 125 mg		,y 30	√ V	idex EC
Cap 200 mg		30		idex EC
Cap 250 mg		30		idex EC
			*	· · · · · · ·

EFAVIRENZ WITH EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE - Special Authority see SA1364 on page 112

Note: Efavirenz with emtricitabine and tenofovir disoproxil fumarate counts as three anti-retroviral medications for the purposes

\$29 Unapproved medicine supplied under Section 29 Sole Subsidised Supply

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✓ Videx EC

✓ Atripla

✓ Emtriva

- Retail pharmacy

of the anti-retroviral Special Authority

✓ fully subsidised

[HP4] refer page 4

	Subsidy (Manufacturer's \$	Price) Subs	Fully Brand or sidised Generic Manufacturer
EMTRICITABINE WITH TENOFOVIR DISOPROXIL FUMARATE Note: Emtricitabine with tenofovir disoproxil fumarate count retroviral Special Authority	•	•	
Tab 200 mg with tenofovir disoproxil fumarate 300 mg	838.20	30	✓ Truvada
AMIVUDINE - Special Authority see SA1364 on page 112 - Re	, ,	00	. A Laurebroodler
Tab 150 mg	52.50	60	✓ Lamivudine Alphapharm
Oral liq 10 mg per ml	102.50	240 ml OP	✓ 3TC
STAVUDINE [D4T] - Special Authority see SA1364 on page 112 Cap 40 mg	- Retail pharma	acy 60	✓ Zerit
Powder for oral soln 1 mg per ml		200 ml OP	✓ Zerit S29
ZIDOVUDINE [AZT] – Special Authority see SA1364 on page 11			
Cap 100 mg		100	✓ Retrovir
Oral liq 10 mg per ml	30.45	200 ml OP	✓ Retrovir
ZIDOVUDINE [AZT] WITH LAMIVUDINE — Special Authority see Note: zidovudine [AZT] with lamivudine (combination tablets anti-retroviral Special Authority. Tab 300 mg with lamivudine 150 mg	counts as two		,
Protease Inhibitors			
ATAZANAVIR SULPHATE - Special Authority see SA1364 on pa	ao 112 — Botail	nharmacy	
Cap 150 mg	•	60	✓ Reyataz
Cap 200 mg		60	✓ Reyataz
DARUNAVIR - Special Authority see SA1364 on page 112 - Re	ail pharmacy		
Tab 400 mg	837.50	60	✓ Prezista
Tab 600 mg	1,190.00	60	✓ Prezista
NDINAVIR - Special Authority see SA1364 on page 112 - Reta			
Cap 200 mg		360	✓ Crixivan
Cap 400 mg		180	✓ Crixivan
OPINAVIR WITH RITONAVIR – Special Authority see SA1364			
Tab 100 mg with ritonavir 25 mg		60	✓ Kaletra
Tab 200 mg with ritonavir 50 mg		120 300 ml OP	✓ Kaletra✓ Kaletra
Oral liq 80 mg with ritonavir 20 mg per ml		300 IIII OP	Naieua
RITONAVIR - Special Authority see SA1364 on page 112 - Reta Tab 100 mg	,	30	✓ Norvir
Oral liq 80 mg per ml		90 ml OP	✓ Norvir
Strand Transfer Inhibitors			
DALTECHAVID DOTACCILIM Consid Authority and CA4004 or	nogo 110 D-	toil phorman	
RALTEGRAVIR POTASSIUM – Special Authority see SA1364 or Tab 400 mg		60	✓ Isentress

Subsidy (Manufacturer's Price)

Fully Subsidised Per

Brand or Generic Manufacturer

Antiretrovirals - Additional Therapies

HIV Fusion Inhibitors

ENFUVIRTIDE - Special Authority see SA0845 below - Retail pharmacy

Powder for inj 90 mg per ml \times 602,380.00

1 ✓ Fuzeon

⇒SA0845 Special Authority for Subsidy

Initial application only from a named specialist. Approvals valid for 3 months for applications meeting the following criteria: All of the following:

- 1 Confirmed HIV infection: and
- 2 Enfuvirtide to be given in combination with optimized background therapy (including at least 1 other antiretroviral drug that the patient has never previously been exposed to) for treatment failure; and
- 3 Either:
 - 3.1 Patient has evidence of HIV replication, despite ongoing therapy; or
 - 3.2 Patient has treatment-limiting toxicity to previous antiretroviral agents; and
- 4 Previous treatment with 3 different antiretroviral regimens has failed; and
- 5 All of the following:
 - 5.1 Previous treatment with a non-nucleoside reverse transcriptase inhibitor has failed; and
 - 5.2 Previous treatment with a nucleoside reverse transcriptase inhibitor has failed; and
 - 5.3 Previous treatment with a protease inhibitor has failed.

Renewal only from a named specialist. Approvals valid for 1 year for applications meeting the following criteria: Both:

- 1 Evidence of at least a 10 fold reduction in viral load at 12: and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

Immune Modulators

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

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

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

Criteria for Treatment

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

Exclusion Criteria

- a) Autoimmune liver disease. (Interferon may exacerbate autoimmune liver disease as well as other autoimmune diseases such as thyroid disease).
- b) Pregnancy.
- c) Neutropenia ($<2.0 \times 10^9$) and/or thrombocytopenia.
- d) Continuing alcohol abuse and/or continuing intravenous drug users.

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(Manufacturer's Price)	Sı	ubsidised		
\$	Per	V	Manufacturer	

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Dosage

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

Exit Criteria

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

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

- a) See prescribing guideline on the previous page
- b) Prescriptions must be written by, or on the recommendation of, an internal medicine physician or ophthalmologist
- ✔ Roferon-A 1

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

- a) See prescribing guideline on the previous page
- b) Prescriptions must be written by, or on the recommendation of, an internal medicine physician or ophthalmologist

Inj 18 m iu, 1.2 ml multidose pen	206.71	1 .	✓ Intron-A
Inj 30 m iu, 1.2 ml multidose pen	344.52	1	✓ Intron-A
Inj 60 m iu, 1.2 ml multidose pen	689.04	1	✓ Intron-A

PEGYLATED INTERFERON ALFA-2A - Special Authority see SA1400 below - Retail pharmacy

arenies in en	11 100 001011	riotan pharmacy	
See prescribing guideline on the previous page			
Inj 135 mcg prefilled syringe	1,448.00	4	✓ Pegasys
Inj 180 mcg prefilled syringe	900.00	4	✓ Pegasys
Inj 135 mcg prefilled syringe \times 4 with ribavirin tab 200 mg \times			
112	1,799.68	1 OP	✓ Pegasys RBV
			Combination Pack
Inj 135 mcg prefilled syringe \times 4 with ribavirin tab 200 mg \times			
168	1,975.00	1 OP	✓ Pegasys RBV
			Combination Pack
Ini 180 mcg prefilled syringe × 4 with ribayirin tab 200 mg ×			

1121,159.84	1 OP

✔ Pegasys RBV **Combination Pack**

Inj 180 mcg prefilled syringe $ imes$ 4 with ribavirin tab 200 mg $ imes$	
168	0

✔ Pegasys RBV

1 OP

Combination Pack

(Pegasys Inj 135 mcg prefilled syringe to be delisted 1 November 2016)

(Pegasys RBV Combination Pack Inj 135 mcg prefilled syringe × 4 with ribavirin tab 200 mg × 112 to be delisted 1 November 2016)

⇒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.

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continued...

 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 Fither:
 - 3.1 Patient has responder relapsed; or
 - 3.2 Patient was a partial responder; and
- 4 Patient is to be treated in combination with boceprevir; and
- 5 Maximum of 48 weeks therapy.

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

All of the following:

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

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

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

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

All of the following:

- 1 Patient has confirmed Hepatitis B infection (HBsAg positive for more than 6 months); and
- 2 Patient is Hepatitis B treatment-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 ≥ 2,000 units/ml and significant fibrosis (≥ Metavir Stage F2 or moderate fibrosis); and
- 6 Compensated liver disease: and
- 7 No continuing alcohol abuse or intravenous drug use; and
- 8 Not co-infected with HCV. HIV or HDV: and
- 9 Neither ALT nor AST > 10 times upper limit of normal; and
- 10 No history of hypersensitivity or contraindications to pegylated interferon; and
- 11 Maximum of 48 weeks therapy.

Notes:

	Subsidy	Fu	lly	Brand or
(Ma	nufacturer's Price)	Subsidis	ed	Generic
	\$	Per	~	Manufacturer

continued...

- 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 quidelines.
- Pegylated Interferon-alfa 2a is not approved for use in children.

Urinary Tract Infections			
HEXAMINE HIPPURATE			
* Tab 1 g	18.40	100	
· ·	(38.10)		Hiprex
NITROFURANTOIN			
* Tab 50 mg - For nitrofurantoin oral liquid formulation refer,			
page 221	22.20	100	✓ Nifuran
* Tab 100 mg	37.50	100	✓ Nifuran

NORFLOXACIN

✓ Arrow-Norfloxacin 100

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		. ,	Brand or
	(Manufacturer's Price			Generic
	<u> </u>	Per		Manufacturer
Anticholinesterases				
NEOSTIGMINE METILSULFATE				
Inj 2.5 mg per ml, 1 ml ampoule	98.00	50	✓ Ast	raZeneca
PYRIDOSTIGMINE BROMIDE				
	40.70	100	✓ Me	otinon
Tab 60 mg	42.79	100	V IVIE	sunon
Mestinon to be Sole Supply on 1 December 2016				
Non-Steroidal Anti-Inflammatory Drugs				
DICLOFENAC SODIUM				
* Tab EC 25 mg	1.30	50	✓ Dic	lofenac Sandoz
* Tab 50 mg dispersible		20		taren D
* Tab EC 50 mg		50	✓ Dic	lofenac Sandoz
* Tab long-acting 75 mg		500		o-Diclo SR
* Tab long-acting 100 mg		500		o-Diclo SR
* Inj 25 mg per ml, 3 ml ampoule – Up to 5 inj available on				
PSO		5	✓ Vol	taren
* Suppos 12.5 mg		10	✓ Vol	
* Suppos 25 mg		10	✓ Vol	
* Suppos 50 mg - Up to 10 supp available on a PSO		10	✓ Vol	
* Suppos 100 mg		10	✓ Vol	taren
IBUPROFEN				
* Tab 200 mg	0.45	1,000	✓ Ibu	nocio
Tab long-acting 800 mg		30		ıfen SR
* Oral liq 20 mg per ml		200 ml		
	1.00	200 1111	V 101	ipacu
KETOPROFEN	40.07		4.0	".00
* Cap long-acting 200 mg	12.07	28	✓ Ort	ıvail SR
MEFENAMIC ACID				
* Cap 250 mg	1.25	50		
	(9.16)		Por	nstan
	0.50	20		
	(5.60)		Por	nstan
NAPROXEN				
* Tab 250 mg	18.06	500	✓ Not	flam 250
* Tab 500 mg		250	✓ Not	flam 500
* Tab long-acting 750 mg		90		prosyn SR 750
* Tab long-acting 1 g		90		prosyn SR 1000
SULINDAC				•
* Tab 100 mg	8 55	50	✓ Acl	in
* Tab 200 mg		50	✓ Aci	
v		00	₩ AU	
TENOXICAM	0.40		4.5	
* Tab 20 mg		20		utenox
Tileatil te ha Cala Complete of 4 December 2040	10.95	100	✓ Tild	OTII
Tilcotil to be Sole Supply on 1 December 2016	0.05		. / A ==	-
* Inj 20 mg vial	9.95	1	✓ AF	ı
(Reutenox Tab 20 mg to be delisted 1 December 2016)				

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

NSAIDs Other

ME	LOXICAM - Special Authority see SA1034 below - Retail pharmacy		
*	Tab 7.5 mg11.50	30	Arrow-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	45 a OP	✓ Zostrix

⇒SA1289 Special Authority for Subsidy

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

Antirheumatoid Agents

AURANOFIN			
Tab 3 mg	68.99	60	✓ Ridaura s29 S29
	114.98	100	✓ Ridaura s29 S29
HYDROXYCHLOROQUINE			
* Tab 200 mg	10.50	100	✓ Plaquenil
LEFLUNOMIDE			
Tab 10 mg	55.00	30	✓ Arava
Tab 20 mg	76.00	30	✓ Arava
PENICILLAMINE			
Tab 125 mg	67.23	100	✓ D-Penamine
Tab 250 mg		100	✓ D-Penamine
SODIUM AUROTHIOMALATE			
Inj 10 mg in 0.5 ml ampoule	76.87	10	✓ Myocrisin
Inj 20 mg in 0.5 ml ampoule		10	✓ Myocrisin
Ini 50 mg in 0.5 ml ampoule		10	✓ Myocrisin

Drugs Affecting Bone Metabolism

Alendronate for Osteoporosis

■ SA1039 | Special Authority for Subsidy

Subsidy (Manufacturer's Price) \$

Fully Subsidised

Per

Brand or Generic Manufacturer

continued...

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

Any of the following:

- 1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) ≥ 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score ≤ -2.5) (see Note); or
- 2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
- 3 History of two significant osteoporotic fractures demonstrated radiologically; or
- 4 Documented T-Score < -3.0 (see Note); or
- 5 A 10-year risk of hip fracture ≥ 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 (> 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 ≥ 1.5 standard deviations below the mean normal value in young adults (i.e. T-Score < -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 (> 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) ≥ 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score ≤ -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 ≤ -3.0 (see Note); or
- 5 A 10-year risk of hip fracture ≥ 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 ≤ -2.5 and, therefore, do not require BMD measurement for treatment with bisphosphonates.

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- 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) 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 121 - Retail pharmacy ✓ Fosamax ALENDRONATE SODIUM WITH COLECALCIFEROL - Special Authority see SA1039 on page 121 - Retail pharmacy ✓ Fosamax Plus

Alendronate for Paget's Disease

■SA0949 Special Authority for Subsidy

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

- 1 Paget's disease; and
- 2 Any of the following:
 - 2.1 Bone or articular pain; or
 - 2.2 Bone deformity; or
 - 2.3 Bone, articular or neurological complications; or
 - 2.4 Asymptomatic disease, but risk of complications due to site (base of skull, spine, long bones of lower limbs); or
 - 2.5 Preparation for orthopaedic surgery.

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

ALENDRONATE SODIUM - Special Authority see SA0949 above - Retail pharmacy 30 ✓ Fosamax

Other Treatments

ETIDRONATE DISODIUM - See prescribing guideline below	
* Tab 200 mg13.50	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.

PAMIDRONATE DISODIUM

Inj 3 mg per ml, 10 ml vial	6.80	1	✓ Pamisol
Inj 6 mg per ml, 10 ml vial	13.20	1	✓ Pamisol
Inj 9 mg per ml, 10 ml vial	19.20	1	✓ Pamisol

KA	LOXIFENE HYDROCHLORIDE — Special Authority see SATI38 of	ı tne next page -	– Hetali pri	armacy
*	Tab 60 mg	53.76	28	Evista

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⇒SA1138 Special Authority for Subsidy

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

Any of the following:

- 1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) > 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score < -2.5) (see Notes); or
- 2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
- 3 History of two significant osteoporotic fractures demonstrated radiologically; or
- 4 Documented T-Score < -3.0 (see Notes); or
- 5 A 10-year risk of hip fracture ≥ 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 ≤ -2.5 and, therefore, do not require BMD measurement for raloxifene fundina.
- 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 ✓ Risedronate Sandoz Tab 35 mg4.00 TERIPARATIDE - Special Authority see SA1139 below - Retail pharmacy ✔ Forteo

⇒SA1139 Special Authority for Subsidy

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

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

Notes:

a) The bone mineral density (BMD) measurement used to derive the T-score must be made using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable

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\$ Per ✔ Manufacturer

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- 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 below − Retail pharmacy600.00 100 ml OP ✓ Aclasta

⇒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) ≥ 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score ≤ -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 < -3.0 (see Note); or
 - 1.5 A 10-year risk of hip fracture ≥ 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 (≥ 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:

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Subsidy (Manufacturer's Price) \$

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Per

Brand or Generic Manufacturer

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- 2.1 The patient has documented BMD ≥ 1.5 standard deviations below the mean normal value in young adults (i.e. T-Score \leq -1.5) (see Note); or
- 2.2 The patient has a history of one significant osteoporotic fracture demonstrated radiologically; or
- 2.3 The patient has had a Special Authority approval for alendronate (Underlying cause glucocorticosteroid therapy) or raloxifene: and
- 3 The patient will not be prescribed more than 5 mg of zoledronic acid in the 12-month approval period.

Renewal — (Paget's disease) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria: Both:

- 1 Any of the following:
 - 1.1 The patient has relapsed (based on increases in serum alkaline phosphatase); or
 - 1.2 The patient's serum alkaline phosphatase has not normalised following previous treatment with zoledronic acid; or
 - 1.3 Symptomatic disease (prescriber determined); and
- 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 (≥ 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) ≥ 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score ≤ -2.5) (see Note);
 - 1.2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or density metry 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 ≤ -3.0 (see Note); or
 - 1.5 A 10-year risk of hip fracture ≥ 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 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 ≤ -2.5 and, therefore, do not require BMD measurement for treatment with bisphosphonates.

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ALL OPLIBINOL

- 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

	LOI OI III OL			
*	Tab 100 mg	15.11	1,000	✓ Apo-Allopurinol
*	Tab 300 mg - For allopurinol oral liquid formulation refer,			
	page 221	15.91	500	✓ Apo-Allopurinol
BE	NZBROMARONE - Special Authority see SA1537 below - Retail	pharmacy		
	Tab 100 mg	45.00	100	Benzbromaron AL
				100 \$29

⇒SA1537 Special Authority for Subsidy

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

- 1 Patient has been diagnosed with gout; and
- 2 Any of the following:
 - 2.1 The patient has a serum urate level greater than 0.36 mmol/l despite treatment with allopurinol at doses of at least 600 mg/day and addition of probenecid at doses of up to 2 g per day or maximum tolerated dose; or
 - 2.2 The patient has experienced intolerable side effects from allopurinol such that treatment discontinuation is required and serum urate remains greater than 0.36 mmol/l despite use of probenecid at doses of up to 2 g per day or maximum tolerated dose: or
 - 2.3 Both:
 - 2.3.1 The patient has renal impairment such that probenecid is contraindicated or likely to be ineffective and serum urate remains greater than 0.36 mmol/l despite optimal treatment with allopurinol (see Notes); and
 - 2.3.2 The patient has a rate of creatinine clearance greater than or equal to 20 ml/min; or
 - 2.4 All of the following:
 - 2.4.1 The patient is taking azathioprine and requires urate-lowering therapy; and
 - 2.4.2 Allopurinol is contraindicated; and
 - 2.4.3 Appropriate doses of probenecid are ineffective or probenecid cannot be used due to reduced renal function;
- 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: Roth:

- 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.

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Per

Brand or Generic Manufacturer

continued...

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/downloads/Benzbromarone-prescriber-information-NZRA-V2.pdf

COLCHICINE * Tab 500 mcg	10.08	100	✓ Colgout
FEBUXOSTAT - Special Authority see SA1538 below - Retail pharma	асу		
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 mg55.00 100 **✔ Probenecid-AFT**

Muscle Relaxants

BACLOFEN

* Tab 10 mg - For baclofen oral liquid formulation refer, page

caused intolerable side effects and the prescription is endorsed accordingly.

Inj 2 mg per ml, 5 ml ampoule – Subsidy by endorsement.......209.29

1
Lioresal Intrathecal

Subsidised only for use in a programmable pump in patients where oral antispastic agents have been ineffective or have caused intolerable side effects and the prescription is endorsed accordingly.

DANTROI FNF

Subsidy (Manufacturer's Price) \$

Fully Subsidised Per

Brand or Generic Manufacturer

Agents for Parkinsonism and Related Disorders

AMANTADINE HYDROCHLORIDE		
▲ Cap 100 mg	60	✓ Symmetrel
APOMORPHINE HYDROCHLORIDE		
▲ Inj 10 mg per ml, 2 ml ampoule119.00	5	Apomine
(Apomine Inj 10 mg per ml, 2 ml ampoule to be delisted 1 December 2016)		✓ Movapo
BROMOCRIPTINE MESYLATE	400	An Donner colutto
* Tab 2.5 mg32.08	100	✓ Apo-Bromocriptine
ENTACAPONE		4
▲ Tab 200 mg	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 mg	100	✓ Madopar 62.5
* Cap 100 mg with benserazide 25 mg	100	✓ Madopar 125
* Cap long-acting 100 mg with benserazide 25 mg	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 car-		•
bidopa oral liquid formulation refer, page 22120.00	100	Kinson
Nr. Tala languaging 000 mag with parkidana 50 mag	100	✓ Sinemet
* Tab long-acting 200 mg with carbidopa 50 mg	100 100	✓ Sinemet CR ✓ Sinemet
	100	Sinemet
PRAMIPEXOLE HYDROCHLORIDE	400	45.
Tab 0.25 mg	100	✓ Ramipex
Ramipex to be Sole Supply on 1 October 2016 Tab 1 mg24.39	100	✓ Ramipex
Ramipex to be Sole Supply on 1 October 2016	100	• Hampex
ROPINIROLE HYDROCHLORIDE		
▲ Tab 0.25 mg2.78	100	✓ Apo-Ropinirole
Apo-Ropinirole to be Sole Supply on 1 October 2016	100	• Apo Hophiniolo
▲ Tab 1 mg	100	✓ Apo-Ropinirole
Apo-Ropinirole to be Sole Supply on 1 October 2016		
▲ Tab 2 mg	100	Apo-Ropinirole
Apo-Ropinirole to be Sole Supply on 1 October 2016		
▲ Tab 5 mg	100	✓ Apo-Ropinirole
Apo-Ropinirole to be Sole Supply on 1 October 2016		
SELEGILINE HYDROCHLORIDE	400	44 01 111
* Tab 5 mg	100	✓ Apo-Selegiline
		✓ Apo-Selegiline
(Ana Calacilina Tab E may to be delicated 1 October 2016)		S29 S29
(Apo-Selegiline Tab 5 mg to be delisted 1 October 2016)		
TOLCAPONE		4-
▲ Tab 100 mg	100	✓ Tasmar

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	d Generic
Anticholinergics				
BENZTROPINE MESYLATE Tab 2 mg	95.00 190.00	60 5 10	<i>V</i>	Benztrop Cogentin Omega S29
Agents for Essential Tremor, Chorea and Related			•	
RILUZOLE - Special Authority see SA1403 below - Retail pharm Wastage claimable - see rule 3.3.2 on page 13 Tab 50 mg SA1403 Special Authority for Subsidy	nacy	56	V	Rilutek
Initial application only from a neurologist or respiratory special following criteria: All of the following: 1 The patient has amyotrophic lateral sclerosis with disease 2 The patient has at least 60 percent of predicted forced vit 3 The patient has not undergone a tracheostomy; and	e duration of 5 years	or les	s; 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 				

- 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

5.3 The patient is able to swallow.

- 3.2 The patient is able to use upper limbs; or
- 3.3 The patient is able to swallow.

TETRABENAZINE

All of the following:

Tab 25 mg91.10 112 ✓ Motetis Motetis to be Sole Supply on 1 October 2016

Renewal from any relevant practitioner. Approvals valid for 18 months for applications meeting the following criteria:

Anaesthetics

Local

LIDOCAINE [LIGNOCAINE]

Gel 2%, 10 ml urethral syringe – Subsidy by endorsement...............43.26 10 ✔ Pfizer

- a) Up to 5 each available on a PSO
- b) Subsidised only if prescribed for urethral or cervical administration and the prescription is endorsed accordingly.

	Subsidy (Manufacturer's Pric \$	ee) Sul Per	Fully bsidised	Brand or Generic Manufacturer
LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE				
Oral (viscous) soln 2%	55.00	200 ml	✓ X	ylocaine Viscous
Inj 1%, 5 ml ampoule - Up to 25 inj available on a PSO	8.75	25	✓ Li	docaine-Claris
	17.50	50		
	(35.00)		X	ylocaine
Inj 2%, 5 ml ampoule - Up to 5 inj available on a PSO	6.90	25	✓ Li	docaine-Claris
Inj 1%, 20 ml ampoule - Up to 5 inj available on a PSO		1	🗸 Li	docaine-Claris
	12.00	5		
	(20.00)		X	ylocaine
Inj 2%, 20 ml ampoule - Up to 5 inj available on a PSO	2.40	1	✓ Li	docaine-Claris
LIDOCAINE [LIGNOCAINE] WITH CHLORHEXIDINE				
Gel 2% with chlorhexidine 0.05%, 10 ml urethral syringes -				
Subsidy by endorsement	43.26	10	✓ P¹	fizer
a) Up to 5 each available on a PSO				
hà Calbatalla and a shall a san a saile and fan a san thank and a san dead and a	atatata da Rancia da Aria		. San and a	and the second contract of

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

⇒SA0906 Special Authority for Subsidy

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

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

LIDOCAINE [LIGNOCAINE] - Special Authority see SA0906 abo	ve – Retail pharı	macy	
Crm 4%	27.00	30 g OP	✓ LMX4
Crm 4% (5 g tubes)	27.00	5	✓ LMX4
LIDOCAINE [LIGNOCAINE] WITH PRILOCAINE - Special Author	rity see SA0906	above – Retai	l 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 120

Non-opioid Analgesics

For aspirin & chloroform application refer Standard Formulae, page 224

ASPIRIN

* Tab dispersible 300 mg - Up to 30 tab available on a PSO2.55 100 ✓ Ethics Aspirin

CAPSAICIN - Subsidy by endorsement

Subsidised only if prescribed for post-herpetic neuralgia or diabetic peripheral neuropathy and the prescription is endorsed accordingly.

45 q OP ✓ Zostrix HP

NEFOPAM HYDROCHLORIDE

90 ✓ Acupan

	0.1.11			D 1
	Subsidy (Manufacturer's F \$	Price) Sul Per	Fully bsidised	Brand or Generic Manufacturer
PARACETAMOL	<u> </u>			
* Tab 500 mg - Up to 30 tab available on a PSO	8.47	1,000	✓ P	narmacare
*‡ Oral liq 120 mg per 5 ml		1,000 ml	_	aracare
a) Up to 200 ml available on a PSO			_	
b) Not in combination				
*‡ Oral liq 250 mg per 5 ml	4.35	1,000 ml	✓ Pa	aracare Double
\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\				Strength
a) Up to 100 ml available on a PSO				
b) Not in combination	0.60	10		
* Suppos 125 mg		10	✓ <u>G</u> ✓ G	-
* Suppos 250 mg * Suppos 500 mg		10 50	· · · · ·	acet aracare
	12.00	50	<u> </u>	aracare
Opioid Analgesics				
CODEINE PHOSPHATE - Safety medicine; prescriber ma	y determine dispensing	g frequency		
Tab 15 mg	4.75	100	✓ P:	SM
Tab 30 mg	5.80	100	✓ P:	
Tab 60 mg	12.50	100	✓ P:	SM
DIHYDROCODEINE TARTRATE				
Tab long-acting 60 mg	9.55	60	✓ D	HC Continus
DHC Continus to be Sole Supply on 1 October 2016				
FENTANYL				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensi				
Inj 50 mcg per ml, 2 ml ampoule		10	_	oucher and Muir
Inj 50 mcg per ml, 10 ml ampoule		10	_	oucher and Muir
Patch 12.5 mcg per hour		5		entanyl Sandoz
Patch 25 mcg per hour		5		entanyl Sandoz
Patch 50 mcg per hour		5		entanyl Sandoz
Patch 75 mcg per hour		5 5		entanyl Sandoz
Patch 100 mcg per hour	11.29	5	VF	entanyl Sandoz
METHADONE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensi				9.11.7.11.1
d) Extemporaneously compounded methadone will on	y be reimbursed at the	e rate of the ch	eapest f	orm available (methado
powder, not methadone tablets).	and Formulae noss 00	4		
e) For methadone hydrochloride oral liquid refer Standa				ath ataba
Tab 5 mg		10	_	ethatabs
Cral lig 2 mg per ml		200 ml	_	iodone iodone Forte
† Oral liq 5 mg per ml † Oral liq 10 mg per ml		200 ml 200 ml		odone Forte odone Extra Forte
t Craring to mig per mir	0.00	200 1111	<u> </u>	

10

✓ AFT

Inj 10 mg per ml, 1 ml61.00

		Subsidy		Fully Brand or
		(Manufacturer's F	Price) Su Per	bsidised Generic Manufacturer
_		Ψ	FEI	- Ivianulacturei
MC	PRPHINE 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
МС	ORPHINE SULPHATE			
	a) Only on a controlled drug form			
	b) No patient co-payment payable			
	c) Safety medicine; prescriber may determine dispensing free	nuency		
	Tab immediate-release 10 mg		10	✓ Sevredol
	Tab long-acting 10 mg		10	✓ Arrow-Morphine LA
	Arrow-Morphine LA to be Sole Supply on 1 October 2016			v viii iiioi piiiiio Ex
	Tab immediate-release 20 mg	5 52	10	✓ Sevredol
	Tab long-acting 30 mg		10	✓ Arrow-Morphine LA
	Arrow-Morphine LA to be Sole Supply on 1 October 2016	2.00	10	• Anow morphine Ex
	Tab long-acting 60 mg	5.60	10	✓ Arrow-Morphine LA
	Arrow-Morphine LA to be Sole Supply on 1 October 2016		10	• Anow morphine Ex
	Tab long-acting 100 mg	6 10	10	✓ Arrow-Morphine LA
	Arrow-Morphine LA to be Sole Supply on 1 October 2016		10	₩ Anow-Morphine EA
	Cap long-acting 10 mg	1 70	10	✓ m-Eslon
	Cap long-acting 30 mg		10	✓ m-Eslon
	Cap long-acting 60 mg		10	✓ m-Esion
	Cap long-acting 100 mg		10	✓ m-Esion
	Inj 5 mg per ml, 1 ml ampoule – Up to 5 inj available on a PSC		5	✓ DBL Morphine
	injoing permit, i mi ampoule op to o injuvaliable on a roc	J	Ü	Sulphate
	Inj 10 mg per ml, 1 ml ampoule - Up to 5 inj available on a			<u>ouiphute</u>
	PSO		5	✓ DBL Morphine
	1 00		Ü	Sulphate
	Inj 15 mg per ml, 1 ml ampoule - Up to 5 inj available on a			<u>cuipitate</u>
	PSO		5	✓ DBL Morphine
	1 00		Ü	Sulphate
	Inj 30 mg per ml, 1 ml ampoule - Up to 5 inj available on a			<u>ouiphato</u>
	PSO		5	✓ DBL Morphine
			-	Sulphate
MC	ORPHINE TARTRATE			
IVIC	a) Only on a controlled drug form			
	b) No patient co-payment payable			
	c) Safety medicine; prescriber may determine dispensing free	THO DOV		
	Inj 80 mg per ml, 1.5 ml ampoule		5	✓ DBL Morphine
	iiij oo nig per iiii, 1.5 iiii ampoule	42.12	J	Tartrate
	DBL Morphine Tartrate to be Sole Supply on 1 November	2016		iai li ale
	Inj 80 mg per ml, 5 ml		5	✓ Hospira
	iij oo iiig poi iiii, o iiii	107.07	3	∓ ποσρπα

Subsidy

Fully

Brand or

✓ fully subsidised

[HP4] refer page 4

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	
(YCODONE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing				
Tab controlled-release 5 mg		20		BNM
	(7.51)		(OxyContin
BNM to be Sole Supply on 1 December 2016				
Tab controlled-release 10 mg		20		BNM
	(6.75)		(Oxycodone ControlledRelease Tablets(BNM)
BNM to be Sole Supply on 1 December 2016				140.010(2.111)
Tab controlled-release 20 mg	4.72	20	V	BNM
J	(11.50)		(Oxycodone ControlledRelease Tablets(BNM)
BNM to be Sole Supply on 1 December 2016				
Tab controlled-release 40 mg	7.69	20	/ 1	BNM
	(18.50)		(Oxycodone ControlledRelease Tablets(BNM)
BNM to be Sole Supply on 1 December 2016				
Tab controlled-release 80 mg	14.11	20	/	BNM
	(34.00)		(Oxycodone ControlledRelease Tablets(BNM)
BNM to be Sole Supply on 1 December 2016				
Cap immediate-release 5 mg		20		OxyNorm OxyNorm
Cap immediate-release 10 mg		20	_	OxyNorm
Cap immediate-release 20 mg		20 250 ml	_	<u>OxyNorm</u> OxyNorm
Oral liq 5 mg per 5 ml		5		OxyNorm
Inj 10 mg per ml, 2 ml ampoule		5		OxyNorm
Inj 50 mg per ml, 1 ml ampoule		5	_	OxyNorm
xyContin Tab controlled-release 5 mg to be delisted 1 Dece		J	• 1	- Ayriviiii
xycodone ControlledRelease Tablets(BNM) Tab controlled-r xycodone ControlledRelease Tablets(BNM) Tab controlled-r xycodone ControlledRelease Tablets(BNM) Tab controlled-r xycodone ControlledRelease Tablets(BNM) Tab controlled-r	elease 10 mg to be delis elease 20 mg to be delis elease 40 mg to be delis	sted 1 sted 1	December December	2016) 2016)
, ,	· ·			20.0)
NRACETAMOL WITH CODEINE – Safety medicine; prescrib		•		Dama a atau: -1
Tab paracetamol 500 mg with codeine phosphate 8 mg	21.06	1,000	V	Paracetamol +

Codeine (Relieve)

	Subsidy		Fully	Brand or
	(Manufacturer's Price)		Subsidised	
	\$	Per		Manufacturer
PETHIDINE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing fre-	quency			
Tab 50 mg		10		<u>PSM</u>
Tab 100 mg		10	_	PSM
Inj 50 mg per ml, 1 ml - Up to 5 inj available on a PSO	5.51	5	/ [DBL Pethidine
lai 50 ann ann an 10 an 1. Marta 5 ini available an a BCO	T 00	5		Hydrochloride
Inj 50 mg per ml, 2 ml – Up to 5 inj available on a PSO	5.83	5	V <u>I</u>	DBL Pethidine
				<u>Hydrochloride</u>
TRAMADOL HYDROCHLORIDE	0.00		, .	
Tab sustained-release 100 mg		20		Framal SR 100
Tab sustained-release 150 mg		20	-	Tramal SR 150
Tab sustained-release 200 mg		20	'	Tramal SR 200
Cap 50 mg – For tramadol hydrochloride oral liquid formula		100		A Tuanaa dal
tion refer, page 221	2.50	100	<i>V</i> <u>!</u>	Arrow-Tramadol
Antidepressants				
Cyclic and Related Agents				
AMITRIPTYLINE - Safety medicine; prescriber may determine of	lienansina fraguancy			
Tab 10 mg		100	1	Arrow-Amitriptyline
Tab 25 mg		100	_	Arrow-Amitriptyline
Tab 50 mg		100	-	Arrow-Amitriptyline
CLOMIPRAMINE HYDROCHLORIDE – Safety medicine; prescr		enanci	na fragua	nov
Tab 10 mg		100		Apo-Clomipramine
Tab 25 mg		100	-	Apo-Clomipramine
DOTHIEPIN HYDROCHLORIDE – Safety medicine; prescriber n			-	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Tab 75 mg		100		Dopress
Cap 25 mg		100	_	Dopress
				20pi caa
DOXEPIN HYDROCHLORIDE - Safety medicine; prescriber ma	•			A 4
Cap 10 mg		100		Anten
Cap 25 mg		100 100		Anten Anten
Cap 50 mg				Anten
IMIPRAMINE HYDROCHLORIDE – Safety medicine; prescriber		•		
Tab 10 mg		50		Tofranil
	6.58	60	-	Tofranil s29 S29
	10.96	100	-	Tofranil
Tab 25 mg	8.80	50	7	Tofranil
MAPROTILINE HYDROCHLORIDE - Safety medicine; prescribe	er may determine disp	ensing	frequenc	у
Tab 25 mg	7.52	30	/ I	Ludiomil
	12.53	50	/ I	Ludiomil

100

20

30

✓ Ludiomil

✓ Ludiomil

✓ Ludiomil

25.06

21.01

Tab 75 mg14.01

	Subsidy (Manufacturer's Price) \$	Per	Ful Subsidise	
NORTRIPTYLINE HYDROCHLORIDE – Safety medicine; presc	•	dispens 100		uency Norpress
Norpress to be Sole Supply on 1 October 2016 Tab 25 mg Norpress to be Sole Supply on 1 October 2016	7.08	180	~	Norpress
Monoamine-Oxidase Inhibitors (MAOIs) - Non S	elective			
PHENELZINE SULPHATE * Tab 15 mg TRANYLCYPROMINE SULPHATE	95.00	100	V	Nardil
* Tab 10 mg	22.94	50	~	Parnate
Monoamine-Oxidase Type A Inhibitors				
MOCLOBEMIDE * Tab 150 mg	85.10	500	~	Apo-Moclobemide
* Tab 300 mg	30.70	100	~	Apo-Moclobemide
Selective Serotonin Reuptake Inhibitors				
CITALOPRAM HYDROBROMIDE * Tab 20 mg	1.79	84	~	PSM Citalopram
ESCITALOPRAM	4.40	00		
* Tab 10 mg * Tab 20 mg		28 28	-	Air Flow Products Air Flow Products
FLUOXETINE HYDROCHLORIDE				
* Tab dispersible 20 mg, scored – Subsidy by endorsement a) Subsidised by endorsement		30	•	Arrow-Fluoxetine
When prescribed for a patient who cannot swallow whole or	e tablets or capsules a	and the	prescrip	tion is endorsed accordingl
When prescribed in a daily dose that is not a multiple of Note: Tablets should be combined with capsules to facilib) Arrow-Fluoxetine to be Sole Supply on 1 November 20	itate incremental 10 m			n is deemed to be endorsed
* Cap 20 mg	1.99	90	~	Arrow-Fluoxetine
PAROXETINE HYDROCHLORIDE	4 22	90	./	Loxamine
* Tab 20 mg	4.32	90	•	LOAGIIIIIG
Tab 50 mg	3.05 1.02	90 30	•	Arrow-Sertraline
	(1.21)			Sertraline Actavis S29
Arrow-Sertraline to be Sole Supply on 1 December 2016 Tab 100 mg	5.25	90	/	Arrow-Sertraline
Arrow-Sertraline to be Sole Supply on 1 December 2016 (Sertraline Actavis \$29 Tab 50 mg to be delisted 1 December 2	016)			

	(Manufacturer's Price)	Per	Subsidised	Generic Manufacturer
Other Antidepressants				
MIRTAZAPINE				
Tab 30 mg	2.55	30	V	Apo-Mirtazapine
Tab 45 mg		30	V	Apo-Mirtazapine
VENLAFAXINE				
Tab 37.5 mg	5.06	28	✓ A	Arrow-Venlafaxine XR
Tab 75 mg	6.44	28	✓ A	Arrow-Venlafaxine XR
Tab 150 mg	8.86	28	✓ A	Arrow-Venlafaxine XR
Tab 225 mg	14.34	28	✓ A	Arrow-Venlafaxine XR
Cap 37.5 mg - Special Authority see SA1061 below - Retail				
pharmacy	5.69	28	✓ E	fexor XR
Cap 75 mg - Special Authority see SA1061 below - Retail				
pharmacy	11.40	28	✓ E	fexor XR
Cap 150 mg - Special Authority see SA1061 below - Retail			_	
pharmacy	13.98	28	✓ E	fexor XR

Subsidy

Fully

Brand or

⇒SA1061 Special Authority for Subsidy

Initial application only from a relevant specialist or vocationally registered general practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 The patient has 'treatment-resistant' depression; and
- 2 Either:
 - 2.1 The patient must have had a trial of two different antidepressants and have had an inadequate response from an adequate dose over an adequate period of time (usually at least four weeks); or
 - 2.2 Both:
 - 2.2.1 The patient is currently a hospital in-patient as a result of an acute depressive episode; and
 - 2.2.2 The patient must have had a trial of one other antidepressant and have had an inadequate response from an adequate dose over an adequate period of time.

Renewal from any medical practitioner. Approvals valid for 2 years where the patient has a high risk of relapse (prescriber determined).

Antiepilepsy Drugs

Agents for Control of Status Epilepticus

CLONAZEPAM – Safety medicine; prescriber may determine dispensing frequency Inj 1 mg per ml, 1 ml19.00	/ 5	✓ Rivotril	
DIAZEPAM – Safety medicine; prescriber may determine dispensing frequency Inj 5 mg per ml, 2 ml ampoule – Subsidy by endorsement11.83 a) Up to 5 inj available on a PSO	5	✓ Hospira	
b) Only on a PSOc) PSO must be endorsed "not for anaesthetic procedures".			
Rectal tubes 5 mg - Up to 5 tube available on a PSO25.05	5	✓ Stesolid	
Rectal tubes 10 mg - Up to 5 tube available on a PSO30.50	5	✓ Stesolid	
PARALDEHYDE	-	AFT	
* Inj 5 ml	5	✓ AFT	

	Subsidy (Manufacturer's Pric	ce) Su Per	Fully bsidised	Brand or Generic Manufacturer
PHENYTOIN SODIUM				
* Inj 50 mg per ml, 2 ml ampoule - Up to 5 inj available on PSO		5	✓ <u>H</u>	<u>ospira</u>
# Inj 50 mg per ml, 5 ml ampoule – Up to 5 inj available on PSO		5	✓ <u>H</u>	<u>ospira</u>
Control of Epilepsy				
CARBAMAZEPINE				
* Tab 200 mg	16.98 34.58 39.17	100 100 100 100	V To V To	egretol egretol CR egretol egretol CR
*‡ Oral liq 20 mg per ml	26.37	250 ml	✓ To	egretol
CLOBAZAM — Safety medicine; prescriber may determine dispersable 10 mg	9.12	50	✓ F	risium
CLONAZEPAM - Safety medicine; prescriber may determine di				
‡ Oral drops 2.5 mg per ml	7.38	10 ml OP	∨ R	ivotril
ETHOSUXIMIDE Cap 250 mg ‡ Oral liq 250 mg per 5 ml	32.90 13.60	100 200 200 ml	✓ Z	arontin arontin arontin
GABAPENTIN – Special Authority see SA1477 below – Retail p Cap 100 mg	,	100	✓ N	rrow-Gabapentin eurontin upentin
▲ Cap 300 mg — For gabapentin oral liquid formulation refe page 221		100	✓ N	rrow-Gabapentin eurontin upentin
▲ Cap 400 mg	13.75	100	V A V N	rrow-Gabapentin eurontin upentin

⇒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

NERVOUS SYSTEM

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

continued...

- 2 Both:
 - 2.1 The patient has Chronic Kidney Disease Stage 5-associated pruritus* where no other cause for pruritus can be identified (e.g. scabies, allergy); and
 - 2.2 The patient has persistent pruritus not relieved with a trial of emollient/moisturising creams alone.

Renewal — (Epilepsy) from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life.

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

Renewal — (Neuropathic pain or Chronic Kidney Disease associated pruritus) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria: Either:

- 1 The patient has demonstrated a marked improvement in their control of pain or itch (prescriber determined); or
- 2 The patient has previously demonstrated clinical responsiveness to gabapentin and has now developed neuropathic pain in a new site.

Note: Indications marked with * are Unapproved Indications (see Interpretations and Definitions). Dosage adjustment of gabapentin is recommended for patients with renal impairment.

LA(COSAMIDE – Special Authority see SA1125 below – I	Retail pharmacy		
\blacktriangle	Tab 50 mg	25.04	14	Vimpat
\blacktriangle	Tab 100 mg	50.06	14	✓ Vimpat
	•	200.24	56	✓ Vimpat
\blacktriangle	Tab 150 mg	75.10	14	Vimpat
	· ·	300.40	56	✓ Vimpat
\blacktriangle	Tab 200 mg	400.55	56	✓ Vimpat

⇒SA1125 Special Authority for Subsidy

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

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

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

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

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

	Subsidy (Manufacturer's Price)		Fully Subsidised	d Generic
	\$	Per		Manufacturer
LAMOTRIGINE				
▲ Tab dispersible 2 mg	6.74	30		Lamictal
▲ Tab dispersible 5 mg	9.64	30		Lamictal
	15.00	56		Arrow-Lamotrigine
▲ Tab dispersible 25 mg		56		Motrig
	19.38			Logem
	20.40			Arrow-Lamotrigine
	29.09		-	Lamictal
▲ Tab dispersible 50 mg		56		Motrig
	32.97			Logem
	34.70			Arrow-Lamotrigine
	47.89			Lamictal
▲ Tab dispersible 100 mg		56		Motrig
	56.91			Logem
	59.90			Arrow-Lamotrigine
	79.16		~	Lamictal
LEVETIRACETAM				
Tab 250 mg	24.03	60	~	Everet
Tab 500 mg - For levetiracetam oral liquid formulation refer				
page 221		60	~	Everet
Tab 750 mg		60	1	Everet
Tab 1,000 mg		60	1	Everet
PHENOBARBITONE				
For phenobarbitone oral liquid refer Standard Formulae, pag	e 224			
* Tab 15 mg		500	~	PSM
* Tab 30 mg		500		PSM
· ·				
PHENYTOIN SODIUM	E0 E1	000		Dilantin Infatab
* Tab 50 mg		200	-	Dilantin Infatab Dilantin
Cap 30 mg		200	-	
Cap 100 mg		200		Dilantin Dilantin
*‡ Oral liq 30 mg per 5 ml	22.03	500 m	•	Dilantin
PRIMIDONE				
* Tab 250 mg	17.25	100	~	Apo-Primidone
SODIUM VALPROATE				
Tab 100 mg	13.65	100	~	Epilim Crushable
Tab 200 mg EC		100		Epilim
Tab 500 mg EC		100		Epilim
*‡ Oral liq 200 mg per 5 ml		300 m		Epilim S/F Liquid
7				Epilim Syrup
* Inj 100 mg per ml, 4 ml	41.50	1		Epilim IV
, , , ,		•	,	-p
STIRIPENTOL – Special Authority see SA1330 on the next page		0.5		D: 11
Cap 250 mg		60		Diacomit S29
Powder for oral liq 250 mg sachet	509.29	60	~	Diacomit S29

NERVOUS SYSTEM

Subsidy (Manufacturer's Price) \$

Fully Subsidised

Per

Brand or Generic Manufacturer

⇒SA1330 Special Authority for Subsidy

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

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

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

TOPIRAMATE

\blacksquare	Tab 25 mg11.07	60	Arrow-Topiramate
			✓ Topiramate Actavis
	26.04		✓ Topamax
\blacktriangle	Tab 50 mg18.81	60	✓ Arrow-Topiramate
	•		✓ Topiramate Actavis
	44.26		✓ Topamax
\blacktriangle	Tab 100 mg31.99	60	✓ Arrow-Topiramate
	•		✓ Topiramate Actavis
	75.25		✓ Topamax
\blacktriangle	Tab 200 mg55.19	60	✓ Arrow-Topiramate
			✓ Topiramate Actavis
	129.85		✓ Topamax
\blacktriangle	Sprinkle cap 15 mg20.84	60	✓ Topamax
\blacktriangle	Sprinkle cap 25 mg26.04	60	✓ Topamax
VIG	ABATRIN - Special Authority see SA1072 below - Retail pharmacy		
\blacktriangle	Tab 500 mg119.30	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 Fither:
 - 1.1 Patient has infantile spasms; or
 - 1.2 Both:
 - 1.2.1 Patient has epilepsy; and
 - 1.2.2 Fither:
 - 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 6monthly basis thereafter); or
 - 2.2 It is impractical or impossible (due to comorbid conditions) to monitor the patient's visual fields.

Subsidy (Manufacturer's Price)	Su	Fully ubsidised	Brand or Generic	
\$	Per	~	Manufacturer	

continued...

Notes: "Optimal treatment with other antiepilepsy agents" is defined as treatment with other antiepilepsy agents which are indicated and clinically appropriate for the patient, given in adequate doses for the patient's age, weight, and other features affecting the pharmacokinetics of the drug with good evidence of compliance.

Vigabatrin is associated with a risk of irreversible visual field defects, which may be asymptomatic in the early stages.

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

Both:

- 1 The patient has demonstrated a significant and sustained improvement in seizure rate or severity and or quality of life; and
- 2 Fither:
 - 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 120

Acute Migraine Treatment		
ERGOTAMINE TARTRATE WITH CAFFEINE Tab 1 mg with caffeine 100 mg31.00	100	✓ Cafergot✓ Cafergot S29 S29
RIZATRIPTAN Tab orodispersible 10 mg3.24 8.10	12 30	✓ <u>Rizamelt</u> ✓ Rizamelt
SUMATRIPTAN	00	THEUMORE.
Tab 50 mg	100 100	✓ Arrow-Sumatriptan✓ Arrow-Sumatriptan
prescription	2 OP	✓ Arrow-Sumatriptan
prescription13.80	2 OP	✓ Sun Pharma S29
Prophylaxis of Migraine		
For Beta Adrenoceptor Blockers refer to CARDIOVASCULAR SYSTEM, page 56 PIZOTIFEN		
* Tab 500 mcg23.21	100	✓ Sandomigran
Antinausea and Vertigo Agents		
For Antispasmodics refer to ALIMENTARY TRACT, page 22		
APREPITANT - Special Authority see SA0987 on the next page - Retail pharmacy		

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✓ Emend Tri-Pack

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

⇒SA0987 Special Authority for Subsidy

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

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

BETAHISTINE DIHYDROCHLORIDE * Tab 16 mg	84	✓ <u>Vergo 16</u>
CYCLIZINE HYDROCHLORIDE Tab 50 mg	20	✓ Nauzene
CYCLIZINE LACTATE Inj 50 mg per ml, 1 ml14.95	5	✓ Nausicalm
DOMPERIDONE		
* Tab 10 mg - For domperidone oral liquid formulation refer, page 221	100	✓ <u>Prokinex</u>
GRANISETRON		
* Tab 1 mg	50	✓ Granirex
HYOSCINE HYDROBROMIDE		
* Inj 400 mcg per ml, 1 ml ampoule46.50	5	Hospira
93.00	10	✓ Martindale S29
Patch 1.5 mg - Special Authority see SA1387 below - Retail pharmacy11.95	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 2211.82	100	✓ <u>Metamide</u>
*	Inj 5 mg per ml, 2 ml ampoule – Up to 5 inj available on a PSO4.50	10	✓ <u>Pfizer</u>
ON	DANSETRON		
*	Tab 4 mg5.51	50	Onrex
*	Tab disp 4 mg1.00	10	✓ Dr Reddy's
			Ondansetron
*	Tab 8 mg6.19	50	✓ Onrex
*	Tab disp 8 mg1.50	10	Ondansetron
			ODT-DRLA
PR	OCHLORPERAZINE		
*	Tab 3 mg buccal	50	
	(15.00)		Buccastem
*	Tab 5 mg - Up to 30 tab available on a PSO	500	✓ Antinaus
*	Inj 12.5 mg per ml, 1 ml - Up to 5 inj available on a PSO25.81	10	✓ Stemetil

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
PROMETHAZINE THEOCLATE				
* Tab 25 mg	1.20 (6.24)	10	Av	vomine
Antipsychotics				
General				
AMISULPRIDE - Safety medicine; prescriber may determine disp	pensing frequency			
Tab 100 mg		30	✓ Si	ulprix
	6.22		✓ So	olian
Tab 200 mg	14.75	60		ulprix
	21.92		✓ Sc	
Tab 400 mg	27.70	60		ulprix
	44.52		✓ Sc	
Oral liq 100 mg per ml	65.53	60 ml	✓ So	olian
Solian to be Sole Supply on 1 November 2016				
ARIPIPRAZOLE - Special Authority see SA1539 below - Retail p	pharmacy			
Safety medicine; prescriber may determine dispensing freque	ency			
Tab 5 mg - No more than 1 tab per day	123.54	30	✓ Al	bilify
Tab 10 mg	123.54	30	✓ Al	bilify
Tab 15 mg	175.28	30	✓ Al	bilify
Tab 20 mg	213.42	30	✓ Al	bilify

⇒SA1539 Special Authority for Subsidy

Initial application — (Schizophrenia or related psychoses) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:

Both:

1 Patient is suffering from schizophrenia or related psychoses; and

- 2 Either:
 - 2.1 An effective dose of risperidone or quetiapine has been trialled and has been discontinued, or is in the process of being discontinued, because of unacceptable side effects; or
 - 2.2 An effective dose of risperidone or quetiapine has been trialled and has been discontinued, or is in the process of being discontinued, because of inadequate clinical response.

Initial application — (Autism spectrum disorder*) only from a paediatrician or psychiatrist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has been diagnosed with an autism spectrum disorder* and has symptoms of severe irritability; and
- 2 An effective dose of risperidone has been trialled and has been discontinued because of unacceptable side effects or inadequate response; and
- 3 The patient is aged less than 18 years.

Renewal — (Schizophrenia or related psychoses) from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Renewal — (Autism spectrum disorder*) only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

Note: Indications marked with * are Unapproved Indications

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✓ Abilify

	Subsidy (Manufacturer's Price) \$ Per		Fully bsidised	Brand or Generic Manufacturer
	<u> </u>			
CHLORPROMAZINE HYDROCHLORIDE – Safety medicine; pro	•			•
Tab 10 mg - Up to 30 tab available on a PSO		100		argactil
Tab 25 mg — Up to 30 tab available on a PSO		100		argactil
Tab 100 mg – Up to 30 tab available on a PSO		100		argactil
Inj 25 mg per ml, 2 ml - Up to 5 inj available on a PSO	25.66	10	V L	argactil
CLOZAPINE – Hospital pharmacy [HP4]				
Safety medicine; prescriber may determine dispensing frequ	•			
Tab 25 mg		50		lozaril
	6.69			lopine
	11.36	100		lozaril
	13.37			lopine
Tab 50 mg		50		lopine
T1 100	17.33	100		lopine
Tab 100 mg		50		lozaril
	17.33	400		lopine
	29.45	100		lozaril
T 000	34.65			lopine
Tab 200 mg		50		lopine
C 50	69.30	100		lopine
Suspension 50 mg per ml		100 ml		lopine
HALOPERIDOL - Safety medicine; prescriber may determine di		у		
Tab 500 mcg - Up to 30 tab available on a PSO	6.23	100	√ S	erenace
Serenace to be Sole Supply on 1 November 2016				
Tab 1.5 mg - Up to 30 tab available on a PSO	9.43	100	√ S	erenace
Serenace to be Sole Supply on 1 November 2016				
Tab 5 mg - Up to 30 tab available on a PSO	29.72	100	√ S	erenace
Serenace to be Sole Supply on 1 November 2016				
Oral liq 2 mg per ml — Up to 200 ml available on a PSO	23.84	100 ml	V S	erenace
Serenace to be Sole Supply on 1 November 2016		40	4.0	
Inj 5 mg per ml, 1 ml ampoule – Up to 5 inj available on a PS	O21.55	10	V S	erenace
Serenace to be Sole Supply on 1 November 2016				
LEVOMEPROMAZINE HYDROCHLORIDE - Safety medicine; p				
Inj 25 mg per ml, 1 ml ampoule		10		ockhardt/
	(73.68)		N	ozinan
Wockhardt to be Sole Supply on 1 December 2016				
(Nozinan Inj 25 mg per ml, 1 ml ampoule to be delisted 1 Decem	ber 2016)			
LEVOMEPROMAZINE MALEATE - Safety medicine; prescriber	may determine dis	pensing fred	quency	
Tab 25 mg	16.93	100	✓ N	ozinan
Tab 100 mg	43.96	100	✓ N	ozinan
LITHIUM CARBONATE - Safety medicine; prescriber may deter	mine dispensing fr	eguency		
Tab 250 mg	, ,	500	V Li	ithicarb FC
Tab 400 mg		100		ithicarb FC
Tab long-acting 400 mg		100	_	riadel
Cap 250 mg		100		ouglas
1 0			-	

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
DLANZAPINE - Safety medicine; prescriber may determine disp	ensing frequency			
Tab 2.5 mg	0.75	28	√ <u>Z</u>	<u>ypine</u>
Tab 5 mg	1.65	28	√ <u>Z</u>	<u>ypine</u>
Tab orodispersible 5 mg	1.75	28	✓ <u>Z</u>	ypine ODT
Tab 10 mg	2.55	28	✓ Z	<u>ypine</u>
Tab orodispersible 10 mg	3.05	28	✓ <u>Z</u>	ypine ODT
PERICYAZINE - Safety medicine; prescriber may determine disp	ensing frequency			
Tab 2.5 mg	12.49	100	✓ N	leulactil
Tab 10 mg	44.45	100	✓ N	leulactil
QUETIAPINE - Safety medicine; prescriber may determine dispe	ensina frequency			
Tab 25 mg	. ,	90	√ 0	uetapel
Tab 100 mg		90		luetapel
Tab 200 mg		90		uetapel
Tab 300 mg		90	√ 0	luetapel
RISPERIDONE – Safety medicine; prescriber may determine dis	nensing frequency			
Tab orodispersible 0.5 mg — Special Authority see SA0927				
below – Retail pharmacy		28	✓ R	isperdal Quicklet
Tab 0.5 mg		60		ctavis
Tab 1 mg		60	_	ctavis
Tab orodispersible 1 mg - Special Authority see SA0927		•	· ·	
below – Retail pharmacy		28	✓ R	isperdal Quicklet
Tab 2 mg		60		ctavis
Tab orodispersible 2 mg - Special Authority see SA0927				
below – Retail pharmacy		28	✓ R	isperdal Quicklet
Tab 3 mg		60		ctavis
Tab 4 mg		60	_	ctavis
Oral lig 1 mg per ml		30 ml	_	lisperon
Risperdal Quicklet Tab orodispersible 0.5 mg to be delisted 1 Jur				_

⇒SA0927 Special Authority for Subsidy

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

Both:

- 1 For a non-adherent patient on oral therapy with standard risperidone tablets or risperidone oral liquid; and
- 2 The patient is under direct supervision for administration of medicine.

(Risperdal Quicklet Tab orodispersible 2 mg to be delisted 1 June 2017)

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

Both:

- 1 The patient is unable to take standard risperidone tablets or oral liquid, or once stabilized refuses to take risperidone tablets or oral liquid: and
- 2 The patient is under direct supervision for administration of medicine.

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

- 1 The patient is unable to take standard risperidone tablets or oral liquid, or once stabilized refuses to take risperidone tablets or oral liquid; and
- 2 The patient is under direct supervision for administration of medicine.

Note: Risperdal Quicklets cost significantly more than risperidone tablets and should only be used where necessary.

	Subsidy		Fully	
	(Manufacturer's Price) \$	Per	Subsidised	
	- Ψ	rei		Manuaciurei
TRIFLUOPERAZINE HYDROCHLORIDE - Safety medicine; pres	scriber may determin	e dispe	ensing fre	quency
Tab 1 mg	9.83	100	V :	Stelazine
Tab 2 mg	14.64	100	V :	Stelazine
Tab 5 mg	16.66	100	V :	Stelazine
ZIPRASIDONE – Safety medicine; prescriber may determine disp	ensing frequency			
Cap 20 mg	0 ,	60	V :	Zusdone
Cap 40 mg		60		Zusdone
Cap 60 mg		60	-	Zusdone
Cap 80 mg		60	-	Zusdone
		م مانمه م	naina fra	***************************************
ZUCLOPENTHIXOL HYDROCHLORIDE – Safety medicine; pres Tab 10 mg		auspe 100		quency Clopixol
, and the same of	31.43	100		Сюріхої
Depot Injections				
FLUPENTHIXOL DECANOATE - Safety medicine; prescriber ma	y determine dispens	ing free	quency	
Inj 20 mg per ml, 1 ml - Up to 5 inj available on a PSO	13.14	5	· /	Fluanxol
Inj 20 mg per ml, 2 ml - Up to 5 inj available on a PSO	20.90	5	/	Fluanxol
Inj 100 mg per ml, 1 ml - Up to 5 inj available on a PSO	40.87	5	/	Fluanxol
FLUPHENAZINE DECANOATE - Safety medicine; prescriber ma	v determine dispens	ina fre	guency	
Inj 12.5 mg per 0.5 ml, 0.5 ml – Up to 5 inj available on a PSC		5		Modecate
Inj 25 mg per ml, 1 ml – Up to 5 inj available on a PSO		5		Modecate
Inj 25 mg per ml, 2 ml – Up to 5 inj available on a PSO		5	V	Modecate S29
Inj 100 mg per ml, 1 ml – Up to 5 inj available on a PSO		5		Modecate
, , ,		-		
HALOPERIDOL DECANOATE – Safety medicine; prescriber may				Haldol
Inj 50 mg per ml, 1 ml – Up to 5 inj available on a PSO		5 5		naidoi Haldol Concentrate
Inj 100 mg per ml, 1 ml - Up to 5 inj available on a PSO	33.90	Э		Haldol Concentrate
			•	
				Decanoas S29
OLANZAPINE - Special Authority see SA1428 below - Retail pha	•			
Safety medicine; prescriber may determine dispensing freque	,			
Inj 210 mg vial		1		Zyprexa Relprevv
Inj 300 mg vial		1		Zyprexa Relprevv
Inj 405 mg vial	560.00	1	/ 7	Zyprexa Relprevv
SACA1428 Special Authority for Subsidy				

Subsidy

Fully

Brand or

⇒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.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
PALIPERIDONE - Special Authority see SA1429 be	elow – Retail pharmacy			
Safety medicine; prescriber may determine disp	ensing frequency			
Inj 25 mg syringe	194.25	1	✓ In	vega Sustenna
Inj 50 mg syringe	271.95	1	✓ In	vega Sustenna
Inj 75 mg syringe	357.42	1	✓ In	vega Sustenna
Inj 100 mg syringe	435.12	1	✓ In	vega Sustenna
Inj 150 mg syringe	435.12	1	🗸 In	vega Sustenna

⇒SA1429 Special Authority for Subsidy

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

- 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 atvoical 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. ✔ Pinortil

Inj 50 mg per ml, 2 ml - Up to 5 inj available on a PSO	353.32 10	✔ Piportil
RISPERIDONE - Special Authority see SA1427 on the next p	age - Retail pharmacy	
Safety medicine; prescriber may determine dispensing fre	quency	
Inj 25 mg vial	135.98 1	Risperdal Consta
Inj 37.5 mg vial	178.71 1	Risperdal Consta
lni 50 mg vial	217.56 1	✓ Risperdal Consta

Subsidy (Manufacturer's Price) \$

Fully Subsidised

Per

Brand or Generic 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

Inj 200 mg per ml, 1 ml - Up to 5 inj available on a PSO19.80 ✔ Clopixol

Anxiolytics

ALPRAZOLAM – Safety medicine; prescriber may determine dispensing frequency Tab 250 mcg2.50	50	✓ Xanax
‡ Safety cap for extemporaneously compounded oral liquid preparations.	50	Adilax
Tab 500 mcg	50	✓ Xanax
‡ Safety cap for extemporaneously compounded oral liquid preparations.		
Tab 1 mg5.00	50	✓ Xanax
‡ Safety cap for extemporaneously compounded oral liquid preparations.		
BUSPIRONE HYDROCHLORIDE		
* Tab 5 mg23.80	100	✔ Orion
		Pacific Buspirone
Orion to be Sole Supply on 1 October 2016		4.4.
* Tab 10 mg14.96	100	✓ Orion
Orien to he Cale Cumply on 1 October 2016		Pacific Buspirone
Orion to be Sole Supply on 1 October 2016 (Pacific Buspirone Tab 5 mg to be delisted 1 October 2016)		
(Pacific Buspirone Tab 10 mg to be delisted 1 October 2016)		
, , ,		
CLONAZEPAM – Safety medicine; prescriber may determine dispensing frequency Tab 500 mcg	100	✓ Paxam
Tab 2 mg	100	✓ Paxam
•	100	• Tuxuiii
DIAZEPAM – Safety medicine; prescriber may determine dispensing frequency Tab 2 mg11.44	500	✓ Arrow-Diazepam
‡ Safety cap for extemporaneously compounded oral liquid preparations.	300	W Allow-Diazepaili
Tab 5 mg	500	✓ Arrow-Diazepam
Safety cap for extemporaneously compounded oral liquid preparations.	000	V Allon Bidzopalii
LORAZEPAM - Safety medicine; prescriber may determine dispensing frequency		
Tab 1 mg	250	✓ Ativan
‡ Safety cap for extemporaneously compounded oral liquid preparations.		·
Tab 2.5 mg13.88	100	✓ Ativan
‡ Safety cap for extemporaneously compounded oral liquid preparations.		

	Subsidy (Manufacturer's Price)	Per	Fully Subsidised	Brand or Generic Manufacturer
OXAZEPAM – Safety medicine; prescriber may determine dispens	sing frequency			
Tab 10 mg	6.17	100	✓ <u>0</u> :	x-Pam
‡ Safety cap for extemporaneously compounded oral liquid	preparations.			
Tab 15 mg	8.53	100	✓ 0:	x-Pam
t Safety cap for extemporaneously compounded oral liquid	preparations.			

Multiple Sclerosis Treatments

⇒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

Subsidy (Manufacturer's Price) \$ Fully Subsidised

Per

Brand or Generic Manufacturer

continued...

- f) patients must have no previous history of lack of response to dimethyl fumarate; and
- g) patients must have not previously had intolerance to dimethyl fumarate; and
- h) patient must not be co-prescribed beta interferon or glatiramer acetate.

Stopping Criteria

Any of the following:

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

Note: Switching between natalizumab, fingolimod, dimethyl fumarate and teriflunomide is permitted provided the EDSS stopping criteria are not met. Switching to interferon or glatiramer acetate is only permitted provided the EDSS stopping criteria are not met and both fingolimod and natalizumab are either not tolerated or treatment with both agents would be clinically inappropriate. Continued relapses on treatment would be expected to lead to a switch of treatment provided the stopping criteria are not met. If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse for recovery to occur.

FINGOLIMOD - Special Authority see SA1562 below - Retail pharmacy

Wastage claimable - see rule 3.3.2 on page 13

⇒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 Facsimile: 04 916 7571

Multiple Sclerosis Treatment Assessment Committee 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

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

continued...

- ii) a Diffusion Weighted Imaging positive lesion; or
- iii) a T2 lesion with associated local swelling; or
- iv) a prominent T2 lesion that clearly is responsible for the clinical features of a recent relapse; or
- v) new T2 lesions compared with a previous MR scan; and
- d) A significant relapse must:
 - a) be confirmed by the applying neurologist or general physician (the patient may not necessarily have been seen by them during the relapse but the neurologist/physician must be satisfied that the clinical features were characteristic and met the specified criteria);
 - b) be associated with characteristic new symptom(s)/sign(s) or substantial worsening of previously experienced symptom(s)/sign(s):
 - c) last at least one week;
 - d) start at least one month after the onset of a previous relapse:
 - e) be severe enough to change either the EDSS or at least one of the Kurtzke Functional System scores by at least
 - 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 fingolimod; and
- g) patients must have not previously had intolerance to fingolimod; and
- h) patient must not be co-prescribed beta interferon or glatiramer acetate.

Stopping Criteria

Any of the following:

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

Note: Switching between natalizumab, fingolimod, dimethyl fumarate and teriflunomide is permitted provided the EDSS stopping criteria are not met. Switching to interferon or glatiramer acetate is only permitted provided the EDSS stopping criteria are not met and both fingolimod and natalizumab are either not tolerated or treatment with both agents would be clinically inappropriate. Continued relapses on treatment would be expected to lead to a switch of treatment provided the stopping criteria are not met. If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse for recovery to occur.

NATALIZUMAB - Special Authority see SA1563 on the next page - Retail pharmacy 1 Tysabri

Subsidy (Manufacturer's Price)

Fully Subsidised

Per

Brand or Generic Manufacturer

⇒SA1563 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

Notes: Special Authority approved by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (below). Application details may be obtained from PHARMAC's website http://www.pharmac.govt.nz or:

The coordinator Phone: 04 460 4990 Multiple Sclerosis Treatment Assessment Committee Facsimile: 04 916 7571

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

Wellington

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

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

Entry Criteria

- 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
 - 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) treatment must be initiated and supervised by a neurologist who is registered in the Tysabri Australasian Prescribing Programme operated by the supplier; and
- g) patients must have no previous history of lack of response to natalizumab; and
- h) patients must have not previously had intolerance to natalizumab; and
 - a) Patient is JC virus negative, or
 - b) Patient is JC virus positive and has given written informed consent acknowledging an understanding of the risk of progressive multifocal leucoencephalopathy (PML) associated with natalizumab
- i) patient must not be co-prescribed beta interferon or glatiramer acetate.

Stopping Criteria

Any of the following:

Subsidy (Manufacturer's Price) \$

Fully Subsidised Per

Brand or Generic Manufacturer

continued...

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

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

Switching between natalizumab, fingolimod, dimethyl fumarate and teriflunomide is permitted provided the EDSS stopping criteria are not met. Switching to interferon or glatiramer acetate is only permitted provided the EDSS stopping criteria are not met and both fingolimod and natalizumab are either not tolerated or treatment with both agents would be clinically inappropriate. Continued relapses on treatment would be expected to lead to a switch of treatment provided the stopping criteria are not met. If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse for recovery to occur.

TERIFLUNOMIDE - Special Authority see SA1560 below - Retail pharmacy

Wastage claimable - see rule 3.3.2 on page 13

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■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

- 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

Subsidy (Manufacturer's Price)

Fully Subsidised

Per

Brand or Generic Manufacturer

continued...

- 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
 - 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 teriflunomide; and
- g) patients must have not previously had intolerance to teriflunomide; and
- h) patient must not be co-prescribed beta interferon or glatiramer acetate.

Stopping Criteria

Any of the following:

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

Note: Switching between natalizumab, fingolimod, dimethyl fumarate and teriflunomide is permitted provided the EDSS stopping criteria are not met. Switching to interferon or glatiramer acetate is only permitted provided the EDSS stopping criteria are not met and both fingolimod and natalizumab are either not tolerated or treatment with both agents would be clinically inappropriate. Continued relapses on treatment would be expected to lead to a switch of treatment provided the stopping criteria are not met. If a relapse has resulted in an increased EDSS score that potentially may lead to discontinuation of treatment according to stopping criteria, a period of 6 months is allowed from the start of the relapse for recovery to occur.

Other Multiple Sclerosis Treatments

⇒SA1564 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

Notes: Special Authority approved by the Multiple Sclerosis Treatment Assessment Committee (MSTAC). Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (below). Application details may be obtained from PHARMAC's website http://www.pharmac.govt.nz or:



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

Brand or Generic Manufacturer

continued...

The coordinator

Multiple Sclerosis Treatment Assessment Committee

Phone: 04 460 4990 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

- 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; and
- f) patients must have no previous history of lack of response to beta-interferon or glatiramer acetate; and
- g) patients must have either:
 - a) intolerance to both natalizumab and fingolimod; or
 - b) treatment with both natalizumab and fingolimod is considered clinically inappropriate; and
- h) patient will not be co-prescribed natalizumab or fingolimod.

Stopping Criteria

Any of the following:

Subsidy (Manufacturer's Price) \$

Fully Subsidised

Per

Brand or Generic Manufacturer

continued...

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

Note: Treatment with interferon beta -1-beta, interferon beta-1-alpha and glatiramer acetate, is permitted only if treatment with both natalizumab and fingolimod is not tolerated or treatment with both would be clinically inappropriate. Beta-interferon or glatiramer acetate will not be funded as second line treatments if EDSS progression has occurred on treatment with natalizumab or fingolimod. Patients who have an increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment) and who do not meet the EDSS Stopping Criteria at annual review may switch from either of the beta-interferon's [interferon beta-1beta 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 156 – [Xpharm]		
Inj 20 mg prefilled syringe	1,089.25	28	Copaxone
INTERFERON BETA-1-ALPHA - Special Authority see SA	1564 on page 156 – [Xp	harm]	
Inj 6 million iu prefilled syringe	1,170.00	4	Avonex
Injection 6 million iu per 0.5 ml pen injector	1,170.00	4	Avonex Pen
Inj 6 million iu per vial		4	✓ Avonex
INTERFERON BETA-1-BETA - Special Authority see SA1	564 on page 156 – [Xph	arm]	
Inj 8 million iu per 1 ml	1,322.89	15	Betaferon

Sedatives and Hypnotics

LORMETAZEPAM – Safety medicine; prescriber may determine dispensin	ng frequency	
Tab 1 mg3	3.11 30	
(23	3.50)	Noctamid
‡ Safety cap for extemporaneously compounded oral liquid prepara	itions.	
MIDAZOLAM - Safety medicine; prescriber may determine dispensing fre	quency	
Inj 1 mg per ml, 5 ml10	0.00 10	✔ Pfizer
10).75	Hypnovel
Inj 5 mg per ml, 3 ml11	.90 5	✓ Hypnovel
,		✓ Pfizer
NITRAZEPAM - Safety medicine; prescriber may determine dispensing from	equency	
Tab 5 mg5	5.22 100	✓ Nitrados
‡ Safety cap for extemporaneously compounded oral liquid prepara	itions.	

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer	
PHENOBARBITONE SODIUM - Special Authority see SA1386	below – Retail pharma	су			
Inj 200 mg per ml, 1 ml ampoule	46.20	10	✓ M	artindale \$29	

⇒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.

11 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
TEMAZEPAM – Safety medicine; prescriber may determine dispensing frequency		4
Tab 10 mg1.27	25	✓ Normison
‡ Safety cap for extemporaneously compounded oral liquid preparations.		
TRIAZOLAM - Safety medicine; prescriber may determine dispensing frequency		
Tab 125 mcg5.10	100	
(9.85)		Hypam
‡ Safety cap for extemporaneously compounded oral liquid preparations.		
Tab 250 mcg4.10	100	
(11.20)		Hypam
‡ Safety cap for extemporaneously compounded oral liquid preparations.		
ZOPICLONE - Safety medicine; prescriber may determine dispensing frequency		
Tab 7.5 mg8.99	500	✓ Zopiclone Actavis

Stimulants/ADHD Treatments

Stimulants/ADHD treatments

ATOMOXETINE - Special Authority see SA1416 b	pelow – Retail pharmacy		
Cap 10 mg	107.03	28	Strattera
Cap 18 mg	107.03	28	✓ Strattera
Cap 25 mg		28	✓ Strattera
Cap 40 mg		28	✓ Strattera
Cap 60 mg		28	✓ Strattera
Cap 80 mg		28	✓ Strattera
Cap 100 mg		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

Subsidy (Manufacturer's Price) \$ Fully Subsidised

Per

Brand or Generic Manufacturer

continued...

- 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 dexamphetamine 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 applications meeting the following criteria:

Both:

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

Initial application — (Narcolepsy) only from a neurologist or respiratory specialist. Approvals valid for 24 months where the patient suffers from narcolepsy.

Renewal — (ADHD in patients 5 or over) only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

Both:

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

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

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

Brand or

✔ Ritalin SR

Fully

	(Manufacturer's Price) \$	Sul Per	bsidised Generic Manufacturer
METHYLPHENIDATE HYDROCHLORIDE – Special Authority see a) Only on a controlled drug form b) Safety medicine; prescriber may determine dispensing frequ		tail phar	macy
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

Subsidy

50.00

100

⇒SA1150 Special Authority for Subsidy

Initial application — (ADHD in patients 5 or over) only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria:

All of the following:

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

Initial application — (ADHD in patients under 5) only from a paediatrician or psychiatrist. Approvals valid for 12 months for applications meeting the following criteria:

Both:

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

Initial application — (Narcolepsy) only from a neurologist or respiratory specialist. Approvals valid for 24 months where the patient suffers from narcolepsy.

Renewal — (ADHD in patients 5 or over) only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria: Both:

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

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

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

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

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

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

b) dalety medicine, prescriber may determine dispensing	irequeries		
Tab extended-release 18 mg	58.96	30	Concerta
Tab extended-release 27 mg	65.44	30	Concerta
Tab extended-release 36 mg	71.93	30	Concerta
Tab extended-release 54 mg	86.24	30	Concerta
Cap modified-release 10 mg		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	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 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; and

4 Fither:

- 4.1 Patient is taking a currently subsidised formulation of methylphenidate hydrochloride (immediate-release or sustainedrelease) which has not been effective due to significant administration and/or compliance difficulties; or
- 4.2 There is significant concern regarding the risk of diversion or abuse of immediate-release methylphenidate hydrochloride.

Renewal only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a paediatrician or psychiatrist (in writing). Approvals valid for 24 months for applications meeting the following criteria: Both:

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

MODAFINIL – Special Authority see SA1126 below – Retail pharmacy			
Tab 100 mg72	.50	30	✓ Modavigil

⇒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

(Ma	Subsidy	Fu	ılly	Brand or
	anufacturer's Price)	Subsidis	ed	Generic
	\$	Per	~	Manufacturer

continued...

- 3 Fither:
 - 3.1 An effective dose of a subsidised formulation of methylphenidate or dexamphetamine has been trialled and discontinued because of intolerable side effects; or
 - 3.2 Methylphenidate and dexamphetamine are contraindicated.

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

Treatments for Dementia

DONEPEZIL HYDROCHLORIDE			
* Tab 5 mg	5.48	90	✓ Donepezil-Rex
* Tab 10 mg	10.51	90	✓ Donepezil-Rex
RIVASTIGMINE - Special Authority see SA1488 below -	Retail pharmacy		
Patch 4.6 mg per 24 hour	90.00	30	✓ Exelon
Patch 9.5 mg per 24 hour	90.00	30	✓ Exelon

⇒SA1488 Special Authority for Subsidy

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

- 1 The patient has been diagnosed with dementia; and
- 2 The patient has experienced intolerable nausea and/or vomiting from donepezil tablets.

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

- 1 The treatment remains appropriate; and
- 2 The patient has demonstrated a significant and sustained benefit from treatment.

Treatments for Substance Dependence

BUPRENORPHINE WITH NALOXONE - Special Authority see SA1203 below - Retail pharmacy

- a) No patient co-payment payable
- h) Safety medicine: prescriber may determine dispensing frequency

		inic disperioring frequency	b) daicty medicine, presenter may determine
Suboxone	28	57.40	Tab sublingual 2 mg with naloxone 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:

- 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.

Subsidy (Manufacturer's Price) \$

Fully Subsidised

Per

Brand or Generic Manufacturer

continued...

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

All of the following:

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

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

All of the following:

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

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

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

BUPROPION HYDROCHLORIDE

Tab modified-release 150 mg	4.97	30	Zyban
DISULFIRAM Tab 200 mg	24.30	100	✓ Antabuse
NALTREXONE HYDROCHLORIDE - Special Authority see Sa	A1408 below – Retai	l pharmacy	
Tab 50 mg	76.00	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 Standard.

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

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

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

NICOTINE

Nicotine will not be funded under the Dispensing Frequency Rule in amounts less than 4 weeks of treatment.

Thought will not be furface under the Dispersing Frequency Fr	aic iii airioanto i	ood than + W	cono oi irodiinoni
Patch 7 mg - Up to 28 patch available on a PSO	10.57	28	✓ <u>Habitrol</u>
Patch 14 mg - Up to 28 patch available on a PSO	11.31	28	✓ <u>Habitrol</u>
Patch 21 mg - Up to 28 patch available on a PSO	11.95	28	✓ <u>Habitrol</u>
Lozenge 1 mg - Up to 216 loz available on a PSO	12.91	216	✓ <u>Habitrol</u>
Lozenge 2 mg - Up to 216 loz available on a PSO	14.14	216	✓ <u>Habitrol</u>
Gum 2 mg (Classic) - Up to 384 piece available on a PSO	22.26	384	✓ <u>Habitrol</u>
Gum 2 mg (Fruit) - Up to 384 piece available on a PSO	22.26	384	✓ <u>Habitrol</u>
Gum 2 mg (Mint) - Up to 384 piece available on a PSO	22.26	384	✓ <u>Habitrol</u>
Gum 4 mg (Classic) - Up to 384 piece available on a PSO	25.67	384	✓ <u>Habitrol</u>
Gum 4 mg (Fruit) - Up to 384 piece available on a PSO	25.67	384	✓ <u>Habitrol</u>
Gum 4 mg (Mint) - Up to 384 piece available on a PSO	25.67	384	✓ Habitrol
hitsel Own Own (Observa) to be delicted AMench 0047)			·

(Habitrol Gum 2 mg (Classic) to be delisted 1 March 2017)

(Habitrol Gum 4 mg (Classic) to be delisted 1 March 2017)

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 mg	Tab '
Champix	56	135.48	
Champix	25 OP	Tab 0.5 mg \times 11 and 1 mg \times 1460.48	Tab (

■ 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 guit 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

continued...

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

continued...

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.

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

Chemotherapeutic Agents

Alkylating Agents

BUSULFAN – PCT – Retail pharmacy-Specialist Tab 2 mg	89.25	100	✓ Myleran
CARBOPLATIN - PCT only - Specialist			•
Inj 10 mg per ml, 5 ml vial	15.07	1	✓ DBL Carboplatin
, ,	20.00		✓ Carboplatin Ebewe
Inj 10 mg per ml, 15 ml vial	14.05	1	DBL Carboplatin
	19.50		✓ Carbaccord
	22.50		Carboplatin Ebewe
Inj 10 mg per ml, 45 ml vial	32.59	1	DBL Carboplatin
	48.50		Carbaccord
	50.00		Carboplatin Ebewe
Inj 1 mg for ECP	0.08	1 mg	✓ Baxter
CARMUSTINE - PCT only - Specialist			
Inj 100 mg vial	532.00	1	✓ BiCNU
Inj 100 mg for ECP	532.00	100 mg OP	✓ Baxter
CHLORAMBUCIL - PCT - Retail pharmacy-Specialist			
Tab 2 mg	29.06	25	✓ Leukeran FC
CISPLATIN - PCT only - Specialist			
Inj 1 mg per ml, 50 ml vial	12.20	1	✓ DBL Cisplatin
iiij i iiig pei iiii, 50 iiii viai	15.00	'	✓ Cisplatin Ebewe
Inj 1 mg per ml, 100 ml vial		1	✓ Cisplatin Ebewe
ing i mg por mi, roo mi viai	22.46	•	✓ DBL Cisplatin
Inj 1 mg for ECP		1 mg	✓ Baxter
CYCLOPHOSPHAMIDE		3	
	70.00	FO	✓ Endoxan S29
Tab 50 mg - PCT - Retail pharmacy-Specialist		50	
Western deimakle and mile 0.000 an man 10	158.00	100	✓ Procytox S29
Wastage claimable – see rule 3.3.2 on page 13	25.02	1	✓ Endoxan
Inj 1 g vial – PCT – Retail pharmacy-Specialist	127.80	6	✓ Cytoxan
Inj 2 g vial - PCT only - Specialist		1	✓ Endoxan
Inj 1 mg for ECP - PCT only - Specialist		1 mg	✓ Baxter
, , ,		11119	♥ Buxter
IFOSFAMIDE – PCT only – Specialist	00.00	4	. 4 11-1
Inj 1 g		1	✓ Holoxan
Inj 2 gInj 1 mg for ECP		1 mg	✓ Holoxan✓ Baxter
, ,	0.10	ring	Daxiei
LOMUSTINE - PCT - Retail pharmacy-Specialist			4.4
Cap 10 mg		20	CeeNU
Cap 40 mg	399.15	20	✓ CeeNU
MELPHALAN			
Tab 2 mg - PCT - Retail pharmacy-Specialist		25	✓ Alkeran
Inj 50 mg - PCT only - Specialist	67.80	1	✓ Alkeran
	3,068.83		Mylan
			Melphalan S29

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
DXALIPLATIN - PCT only - Specialist				
Inj 5 mg per ml, 10 ml vial	13.32	1	V (xaliccord
Inj 50 mg vial		1	~ C)xaliplatin Actavis 50
	55.00		v 0)xaliplatin Ebewe
	200.00			loxatin
Inj 100 mg vial	25.01	1	~ 0)xaliplatin Actavis 100
	110.00		v 0)xaliplatin Ebewe
	400.00		✓ E	loxatin
Inj 5 mg per ml, 20 ml vial	16.00	1	V 0	xaliccord
Inj 1 mg for ECP	0.18	1 mg	✓ E	Baxter
THIOTEPA - PCT only - Specialist				
Inj 15 mg vial	CBS	1	✓ E	Bedford S29
, •			✓ T	HIO-TEPA \$29
			✓ T	epadina (\$29)
Inj 100 mg vial	CBS	1		epadina \$29

Antimetabolites

AZACITIDINE - PCT only - Specialist - Special Authority see SA1467 below		
Inj 100 mg vial605.00	1	Vidaza
Inj 1 mg for ECP6.66	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.

(N	Subsidy lanufacturer's Price \$	e) Per	Full Subsidise	d Generic
ALCIUM FOLINATE				
Tab 15 mg - PCT - Retail pharmacy-Specialist	104.26	10	~	DBL Leucovorin Calcium
Inj 3 mg per ml, 1 ml - PCT - Retail pharmacy-Specialist	17.10	5	~	Hospira
Inj 50 mg - PCT - Retail pharmacy-Specialist	18.25	5	~	Calcium Folinate Ebewe
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 1 g - PCT only - Specialist	67.51	1	~	Calcium Folinate Ebewe
Inj 1 mg for ECP - PCT only - Specialist	0.06	1 mg	~	Baxter
APECITABINE – Retail pharmacy-Specialist	00.00	00		Osmasitahina
Tab 150 mg		60		Capecitabine Winthrop
Tab 500 mg	120.00	120	•	Capecitabine Winthrop
LADRIBINE - PCT only - Specialist				
Inj 1 mg per ml, 10 ml		7		Leustatin
Inj 10 mg for ECP	749.96 1	0 mg O	P 🗸	Baxter
Inj 20 mg per ml, 5 ml vial – PCT – Retail pharmacy-Specialist	55.00 80.00	5		Pfizer Hospira
Inj 500 mg - PCT - Retail pharmacy-Specialist		1		Pfizer
.,,g	95.36	5		Hospira
Inj 100 mg per ml, 10 ml vial - PCT - Retail pharmacy-				•
Specialist	8.83	1	/	Pfizer
	42.65		~	Hospira
Inj 100 mg per ml, 20 ml vial - PCT - Retail pharmacy-				
Specialist	17.65	1		Pfizer
	34.47			Hospira
Inj 1 mg for ECP — PCT only — Specialist		10 mg		Baxter
Inj 100 mg intrathecal syringe for ECP - PCT only - Specialist	11.00 1	00 mg C	אר או	Baxter
UDARABINE PHOSPHATE				
Tab 10 mg - PCT - Retail pharmacy-Specialist		20		Fludara Oral
Inj 50 mg - PCT only - Specialist		5		Fludarabine Ebew
	1,430.00			Fludara
Inj 50 mg for ECP - PCT only - Specialist	105.00 5	i0 mg O	۲ 🗸	Baxter
UOROURACIL				
Inj 50 mg per ml, 20 ml vial - PCT only - Specialist		1		Fluorouracil Ebew
Inj 50 mg per ml, 50 ml vial - PCT only - Specialist		1		Fluorouracil Ebew
Inj 50 mg per ml, 100 ml vial - PCT only - Specialist		1	~	Fluorouracil Ebew
Inj 1 mg for ECP - PCT only - Specialist	0.66	100 mg	~	Baxter

//	Subsidy Manufacturer's Price)	Fully Subsidised	Brand or Generic
(r	\$	Per	€ Cubsidised	Manufacturer
EMCITABINE HYDROCHLORIDE - PCT only - Specialist				
Inj 1 g	15 89	1	v 0	emcitabine Ebewe
", ' y	62.50			BL Gemcitabine
	349.20			Gemzar
Inj 200 mg		1		emcitabine Ebewe
"1 200 mg	78.00	•		iemzar
Inj 1 mg for ECP		1 mg		Baxter
		ı mg		JUNIOI
INOTECAN HYDROCHLORIDE – PCT only – Specialist	44.50		٠.	
Inj 20 mg per ml, 2 ml vial	11.50	1	✓ II	inotecan Actavis 40
	41.00		V 0	amptosar
				inotecan-Rex
Inj 20 mg per ml, 5 ml vial	17.80	1		inotecan Actavis
, - Ur,		•	•	100
	100.00		~ (Camptosar
	100.00			inotecan-Rex
Inj 1 mg for ECP	n 19	1 mg		Baxter
, ,	0.10	i ilig	• -	axter
ERCAPTOPURINE – PCT – Retail pharmacy-Specialist				
Tab 50 mg	49.41	25	✓ P	uri-nethol
ETHOTREXATE				
Tab 2.5 mg - PCT - Retail pharmacy-Specialist	3.18	30	✓ T	rexate
Tab 10 mg - PCT - Retail pharmacy-Specialist		50	√ T	rexate
Inj 2.5 mg per ml, 2 ml - PCT - Retail pharmacy-Specialist		5	_	lospira
Inj 7.5 mg prefilled syringe		1		lethotrexate
.,				Sandoz
Inj 10 mg prefilled syringe	14 66	1	√ N	lethotrexate
ing 10 mg promited syringe	14.00	'	V 11	Sandoz
Inj 15 mg prefilled syringe	14 77	1		Methotrexate
IIIJ 15 IIIg preililed syringe	14.77	1	V 1	Sandoz
Let 00 man and fills of south and	44.00			
Inj 20 mg prefilled syringe	14.88	1	V N	lethotrexate
				Sandoz
Inj 25 mg prefilled syringe	14.99	1	✓ N	lethotrexate
				Sandoz
Inj 30 mg prefilled syringe	15.09	1	✓ N	lethotrexate
				Sandoz
Inj 25 mg per ml, 2 ml vial - PCT - Retail pharmacy-Specialist	30.00	5	/ D	BL Methotrexate
				Onco-Vial
DBL Methotrexate Onco-Vial to be Sole Supply on 1 Novemb	er 2016			
Inj 25 mg per ml, 20 ml vial - PCT - Retail pharmacy-				
Specialist	45.00	1	✓ [BL Methotrexate
				Onco-Vial
DBL Methotrexate Onco-Vial to be Sole Supply on 1 Novemb	er 2016			
Inj 100 mg per ml, 10 ml - PCT - Retail pharmacy-Specialist		1	✓ N	Methotrexate Ebew
Inj 100 mg per ml, 50 ml - PCT - Retail pharmacy-Specialist		1	✓ N	Methotrexate Ebew
Inj 1 mg for ECP - PCT only - Specialist		1 mg	_	Baxter
Inj 5 mg intrathecal syringe for ECP - PCT only - Specialist		mg OF		Baxter
HOGUANINE – PCT – Retail pharmacy-Specialist	100.01	0.5		
Tab 40 mg	126.31	25	VL	anvis.

	Subsidy (Manufacturer's F \$	Price) S Per	Fully Subsidised	Brand or Generic Manufacturer	
Other Cytotoxic Agents					
AMSACRINE - PCT only - Specialist					
Inj 50 mg per ml, 1.5 ml ampoule	1,500.00	6	✓ A	msidine \$29	
Inj 75 mg	1,250.00	5	✓ A	msaLyo S29	
ANAGRELIDE HYDROCHLORIDE - PCT - Retail pharmac	v-Specialist				
Cap 0.5 mg		100	✓ A	grylin \$29	
			✓ To	eva S29	
ARSENIC TRIOXIDE - PCT only - Specialist					
Inj 10 mg	4,817.00	10	✓ A	FT \$29	
BLEOMYCIN SULPHATE - PCT only - Specialist					
Inj 15,000 iu, vial	150.48	1		BL Bleomycin Sulfate	
Inj 1,000 iu for ECP	11.64	1,000 iu	✓ B	axter	
BORTEZOMIB - PCT only - Specialist - Special Authority	see SA1576 below				
Inj 1 mg		1	✓ Vo	elcade	
Inj 3.5 mg vial		1	✓ V	elcade	
Inj 1 mg for ECP		1 mg	✓ B	axter	
(Velcade Inj 1 mg to be delisted 1 December 2016)					

⇒SA1576 Special Authority for Subsidy

Initial application — (Treatment naive multiple myeloma/amyloidosis) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Either:
 - 1.1 The patient has treatment-naive symptomatic multiple myeloma; or
 - 1.2 The patient has treatment-naive symptomatic systemic AL amyloidosis *: and
- 2 Maximum of 9 treatment cycles.

Note: Indications marked with * are Unapproved Indications.

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

- 1 Either:
 - 1.1 The patient has relapsed or refractory multiple myeloma; or
 - 1.2 The patient has relapsed or refractory systemic AL amyloidosis *; and
- 2 The patient has received only one prior front line chemotherapy for multiple myeloma or amyloidosis; and
- 3 The patient has not had prior publicly funded treatment with bortezomib; and
- 4 Maximum of 4 treatment cycles.

Note: Indications marked with * are Unapproved Indications.

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

Both:

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

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

continued...

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

Brand or Generic Manufacturer

continued...

a) a known therapeutic chemotherapy regimen and supportive treatments; or

b) a transplant induction chemotherapy regimen, stem cell transplantation and supportive treatments.

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

DACARBAZINE	COLASPASE [L-ASPARAGINASE] – PCT only – Specialist Inj 10,000 iu		1	✓ Leunase
Inj 200 mg vial		102.32	10,000 iu OP	✓ Baxter
Inj 200 mg for ECP				
DACTINOMYCIN [ACTINOMYCIN D]				
Inj 0.5 mg vial		58.06	200 mg OP	✓ Baxter
Inj 0.5 mg for ECP				
DAUNORUBICIN				
Inj 2 mg per ml, 10 ml	Inj 0.5 mg for ECP	145.00	0.5 mg OP	✓ Baxter
Inj 20 mg for ECP	DAUNORUBICIN - PCT only - Specialist			
DOCETAXEL - PCT only - Specialist Inj 20 mg	Inj 2 mg per ml, 10 ml	118.72	1	✓ Pfizer
Inj 20 mg	Inj 20 mg for ECP	118.72	20 mg OP	✓ Baxter
Inj 20 mg	DOCETAXEL - PCT only - Specialist			
Inj 20 mg per ml, 1 ml		13.70	1	✓ DBL Docetaxel
Inj 20 mg per ml, 4 ml	, ,			Docetaxel Sandoz
Inj 80 mg	Inj 20 mg per ml, 1 ml	48.75	1	✓ Taxotere
195.00	Inj 20 mg per ml, 4 ml	195.00	1	✓ Taxotere
Inj 1 mg for ECP	Inj 80 mg	29.99	1	✓ DBL Docetaxel
DOXORUBICIN HYDROCHLORIDE		195.00		Docetaxel Sandoz
Inj 2 mg per ml, 5 ml vial 10.00 1	Inj 1 mg for ECP	0.61	1 mg	✓ Baxter
Inj 2 mg per ml, 5 ml vial 10.00 1	DOXORUBICIN HYDROCHLORIDE - PCT only - Specialist			
Inj 2 mg per ml, 25 ml vial		10.00	1	✓ Doxorubicin Ebewe
Inj 50 mg vial			1	✓ Doxorubicin Ebewe
Inj 2 mg per ml, 50 ml vial 23.00 1		17.00		Arrow-Doxorubicin
S29 \$29	Inj 50 mg vial	40.00	1	DBL Doxorubicin
Inj 2 mg per ml, 50 ml vial				DBL Doxorubicin
Inj 2 mg per ml, 100 ml vial .46.00 1 ✓ Doxorubicin Ebewe 65.00 .47row-Doxorubicin ✓ Arrow-Doxorubicin ✓ Adriamycin ✓ Adriamycin ✓ Baxter EPIRUBICIN HYDROCHLORIDE – PCT only – Specialist Inj 2 mg per ml, 5 ml vial .25.00 1 ✓ Epirubicin Ebewe Inj 2 mg per ml, 25 ml vial .30.00 1 ✓ Epirubicin Ebewe				S29 S29
65.00	Inj 2 mg per ml, 50 ml vial	23.00	1	Doxorubicin Ebewe
150.00	Inj 2 mg per ml, 100 ml vial	46.00	1	Doxorubicin Ebewe
Inj 1 mg for ECP .0.25 1 mg ✓ Baxter EPIRUBICIN HYDROCHLORIDE – PCT only – Specialist .25.00 1 ✓ Epirubicin Ebewe Inj 2 mg per ml, 5 ml vial .30.00 1 ✓ Epirubicin Ebewe		65.00		Arrow-Doxorubicin
EPIRUBICIN HYDROCHLORIDE - PCT only - Specialist Inj 2 mg per ml, 5 ml vial				Adriamycin
Inj 2 mg per ml, 5 ml vial 25.00 1 ✓ Epirubicin Ebewe Inj 2 mg per ml, 25 ml vial 30.00 1 ✓ Epirubicin Ebewe	Inj 1 mg for ECP	0.25	1 mg	✓ Baxter
Inj 2 mg per ml, 25 ml vial	EPIRUBICIN HYDROCHLORIDE - PCT only - Specialist			
··) = ···g ····, = ····· · ··· = ····· = ···· = ···· = ···· = ···· = ···· = ···· = ···· = ···· = ···· = ····		25.00	1	Epirubicin Ebewe
39.38	Inj 2 mg per ml, 25 ml vial	30.00	1	✓ Epirubicin Ebewe
55.55 BBE Epirabicin		39.38		✔ DBL Epirubicin
Hydrochloride				Hydrochloride
Inj 2 mg per ml, 50 ml vial	Inj 2 mg per ml, 50 ml vial	32.50	1	
58.20 ✓ DBL Epirubicin		58.20		DBL Epirubicin
Hydrochloride				•
Inj 2 mg per ml, 100 ml vial	Inj 2 mg per ml, 100 ml vial	65.00	1	•
94.50 ✓ DBL Epirubicin		94.50		
				Hydrochloride
•	Inj 1 mg for ECP	0.36	1 mg	✓ Baxter
·	Inj 1 mg for ECP	0.36	1 mg	✓ Baxter

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Generic
ETOPOSIDE				
Cap 50 mg - PCT - Retail pharmacy-Specialist	340.73	20	V \	/epesid
Cap 100 mg - PCT - Retail pharmacy-Specialist	340.73	10	/ \	/epesid
Inj 20 mg per ml, 5 ml vial - PCT - Retail pharmacy-Special	ist7.90	1	/ <u>[</u>	Rex Medical
Inj 1 mg for ECP - PCT only - Specialist	0.09	1 mg	✓ E	Baxter
ETOPOSIDE PHOSPHATE - PCT only - Specialist				
Inj 100 mg (of etoposide base)	40.00	1	✓ [Etopophos
Inj 1 mg (of etoposide base) for ECP	0.47	1 mg	✓ E	Baxter
HYDROXYUREA - PCT - Retail pharmacy-Specialist				
Cap 500 mg	31.76	100	V	Hydrea
IDARUBICIN HYDROCHLORIDE				•
Inj 5 mg vial - PCT only - Specialist	125.00	1	V 2	Zavedos
Inj 10 mg vial - PCT only - Specialist		1	V 2	Zavedos
Inj 1 mg for ECP - PCT only - Specialist		1 mg	✓ E	Baxter
LENALIDOMIDE – Retail pharmacy-Specialist – Special Authorit Wastage claimable – see rule 3.3.2 on page 13		ı		
Cap 10 mg	6,207.00	21	✓ F	Revlimid
Cap 25 mg	7,627.00	21	✓ F	Revlimid

■ SA1468 Special Authority for Subsidy

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

All of the following:

- 1 Patient has relapsed or refractory multiple myeloma with progressive disease; and
- 2 Either:
 - 2.1 Lenalidomide to be used as third line* treatment for multiple myeloma; or
 - 2.2 Both:
 - 2.2.1 Lenalidomide to be used as second line treatment for multiple myeloma; and
 - 2.2.2 The patient has experienced severe (grade ≥ 3), dose limiting, peripheral neuropathy with either bortezomib or thalidomide that precludes further treatment with either of these treatments; and
- 3 Lenalidomide to be administered at a maximum dose of 25 mg/day in combination with dexamethasone.

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

Both:

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

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

MESNA

Tab 400 mg - PCT - Retail pharmacy-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

	Subsidy (Manufacturer's P		Fully	Brand or Generic
	\$ 	Per		Manufacturer
MITOMYCIN C - PCT only - Specialist				
Inj 5 mg vial	204.08	1	✓ A	rrow
Arrow to be Sole Supply on 1 November 2016				
Inj 1 mg for ECP	42.04	1 mg	✓ B	axter
MITOZANTRONE - PCT only - Specialist				
Inj 2 mg per ml, 10 ml vial	97.50	1	✓ N	litozantrone Ebewe
Inj 1 mg for ECP		1 mg	✓ B	axter
PACLITAXEL - PCT only - Specialist				
Inj 30 mg	45.00	5	✓ P	aclitaxel Ebewe
Inj 100 mg		1	✓ P	aclitaxel Ebewe
	91.67		✓ P	aclitaxel Actavis
Inj 150 mg	26.69	1	✓ P	aclitaxel Ebewe
•	137.50		✓ A	nzatax
			✓ P	aclitaxel Actavis
Inj 300 mg	36.53	1	✓ P	aclitaxel Ebewe
	275.00		✓ A	nzatax
			✓ P	aclitaxel Actavis
Inj 600 mg	73.06	1	✓ P	aclitaxel Ebewe
Inj 1 mg for ECP	0.17	1 mg	✓ B	axter
PEGASPARGASE - PCT only - Special Authority see SA13	25 below			
Inj 3,750 IU per 5 ml		1	v 0	ncaspar S29
	-,			•

■SA1325 Special Authority for Subsidy

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

All of the following:

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

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

All of the following:

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

PENTOSTATIN [DEOXYCOFORMYCIN] - PCT only - Specialis	st		
Inj 10 mg	CBS	1	✓ Nipent S29
PROCARBAZINE HYDROCHLORIDE - PCT - Retail pharmac	y-Specialist		
Cap 50 mg	498.00	50	✓ Natulan S29
TEMOZOLOMIDE - Special Authority see SA1616 on the next p	page – Retail phari	macy	
Cap 5 mg	8.00	5	Temaccord
Cap 20 mg	36.00	5	Temaccord
Cap 100 mg	175.00	5	Temaccord
Cap 250 mg	410.00	5	✓ Temaccord

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

■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 Fither:
 - 1.1 Patient has newly diagnosed glioblastoma multiforme; or
 - 1.2 Patient has newly diagnosed anaplastic astrocytoma*; and
- 2 Temozolomide is to be (or has been) given concomitantly with radiotherapy; and
- 3 Following concomitant treatment temozolomide is to be used for a maximum of 5 days treatment per cycle, at a maximum dose of 200 mg/m² per day.

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

All of the following:

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

Renewal — (high grade gliomas) only from a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Either:

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

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

Both:

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

Note: Indication marked with a * is an Unapproved Indication. Temozolomide is not subsidised for the treatment of relapsed glioblastoma multiforme.

THALIDOMIDE	 PCT only – Specialist – Special Authority see SA1124 belo 	W	
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*.

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

continued...

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.

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Protein-tyrosine Kinase Inhibitors

DASATINIB - Special Authority see SA0976 below - [Xpha	rm]		
Tab 20 mg	3,774.06	60	✓ Sprycel
Tab 50 mg	6,214.20	60	✓ Sprycel
Tab 70 mg	7,692.58	60	✓ Sprycel
Tah 100 mg	6 214 20	30	✓ Sprvcel

⇒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.

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

continued...

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:
 - a) complete haematologic response (as characterised by an absolute neutrophil count (ANC) > 1.5 × 10⁹/L, platelets > 100 × 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
 - b) 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
 - c) 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).</p>
- 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 Author	rity see SA1577 below		
Tab 100 mg	1,000.00	30	✓ Tarceva
Tab 150 mg	1,500.00	30	✓ Tarceva

■SA1577 Special Authority for Subsidy

Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has locally advanced or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
- 2 There is documentation confirming that the disease expresses activating mutations of EGFR tyrosine kinase; and
- 3 Any of the following:
 - 3.1 Patient is treatment naive; or
 - 3.2 Both:
 - 3.2.1 Patient has documented disease progression following treatment with first line platinum based chemotheraby: and
 - 3.2.2 Patient has not received prior treatment with gefitinib; or
 - 3.3 Both:
 - 3.3.1 The patient has discontinued gefitinib within 12 weeks of starting treatment due to intolerance; and
 - 3.3.2 The cancer did not progress while on gefitinib; and
- 4 Erlotinib is to be given for a maximum of 3 months.

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

GEFITINIB − Retail pharmacy-Specialist − Special Authority see SA1578 on the next page
Tab 250 mg1,700.00 30 ✓ Iressa

Subsidy (Manufacturer's Price) Fully Subsidised

Per

Brand or Generic Manufacturer

⇒SA1578 Special Authority for Subsidy

Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has locally advanced, or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
- 2 Either:
 - 2.1 Patient is treatment naive: or
 - 2.2 Both:
 - 2.2.1 The patient has discontinued erlotinib within 12 weeks of starting treatment due to intolerance; and
 - 2.2.2 The cancer did not progress whilst on erlotinib; and
- 3 There is documentation confirming that disease expresses activating mutations of EGFR tyrosine kinase; and
- 4 Gefitinib is to be given for a maximum of 3 months.

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 6 months where radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

IMATINIB MESILATE

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

Tab 100 mg - Special Authority see SA1460 below -

	[Xpharm]	2,400.00	60	✓ Glivec
*	Cap 100 mg	298.90	60	✓ <u>Imatinib-AFT</u>
*	Cap 400 mg	597.80	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: cmlqistcoordinator@pharmac.govt.nz

Wellington

Special Authority criteria for GIST âĂŞ access by application

Funded for patients:

- a) With a diagnosis (confirmed by an oncologist) of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST).
- b) Maximum dose of 400 mg/day.
- c) Applications to be made and subsequent prescriptions can be written by an oncologist.
- d) Initial and subsequent applications are valid for one year. The re-application criterion is an adequate clinical response to the treatment with imatinib (prescriber determined).

LAPATINIB DITOSYLATE - Special Authority see SA1191 below - Retail pharmacy

⇒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:

Fither:

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

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

continued...

- 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);
- 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
- 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 on the next	page – Retail pharmacy		
Tab 200 mg	1,334.70	30	✓ Votrient
Tab 400 mg	2,669.40	30	✓ Votrient

Subsidy (Manufacturer's Price) \$

Fully Subsidised Per

Brand or Generic Manufacturer

⇒SA1190 Special Authority for Subsidy

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

All of the following:

- 1 The patient has metastatic renal cell carcinoma; and
- 2 Any of the following:
 - 2.1 The patient is treatment naive; or
 - 2.2 The patient has only received prior cytokine treatment; or
 - 2.3 Both:
 - 2.3.1 The patient has discontinued sunitinib within 3 months of starting treatment due to intolerance; and
 - 2.3.2 The cancer did not progress whilst on sunitinib; and
- 3 The patient has good performance status (WHO/ECOG grade 0-2); and
- 4 The disease is of predominant clear cell histology; and
 - The patient has intermediate or poor prognosis defined as:
- 5 Any of the following:
 - 5.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or
 - 5.2 Haemoglobin level < lower limit of normal: or
 - 5.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or
 - 5.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or
 - 5.5 Karnofsky performance score of ≤ 70; or
- 5.6 ≥ 2 sites of organ metastasis; and 6 Pazopanib to be used for a maximum of 3 months.

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

Both:

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

Notes: Pazopanib treatment should be stopped if disease progresses.

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

SUNITINIB - Special Authority see SA1266 below - Retail pharmacy

· · · · · · · · · · · · · · · · · · ·			
Cap 12.5 mg	2,315.38	28	Sutent
Cap 25 mg	·	28	✓ Sutent
Cap 50 mg	·	28	✓ Sutent

⇒SA1266 Special Authority for Subsidy

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

All of the following:

- 1 The patient has metastatic renal cell carcinoma; and
- 2 Any of the following:
 - 2.1 The patient is treatment naive; or
 - 2.2 The patient has only received prior cytokine treatment; or
 - 2.3 The patient has only received prior treatment with an investigational agent within the confines of a bona fide clinical trial which has Ethics Committee approval: or
 - 2.4 Both:
 - 2.4.1 The patient has discontinued pazopanib within 3 months of starting treatment due to intolerance; and
 - 2.4.2 The cancer did not progress whilst on pazopanib; and

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

continued...

- 3 The patient has good performance status (WHO/ECOG grade 0-2); and
- 4 The disease is of predominant clear cell histology; and

The patient has intermediate or poor prognosis defined as:

- 5 Any of the following:
 - 5.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or
 - 5.2 Haemoglobin level < lower limit of normal; or
 - 5.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or
 - 5.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or
 - 5.5 Karnofsky performance score of < 70: or
 - 5.6 ≥ 2 sites of organ metastasis; and
- 6 Sunitinib to be used for a maximum of 2 cycles.

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

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

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

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

Notes: Sunitinib treatment should be stopped if disease progresses.

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

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

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

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

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

Endocrine Therapy

For GnRH ANALOGUES - refer to HORMONE PREPARATIONS, Trophic Hormones, page 89

ABIRATERONE ACETATE - Retail pharmacy-Specialist - Special Authority see SA1515 on the next page

Wastage claimable - see rule 3.3.2 on page 13

' Zytiga

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

⇒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 Fither:
 - 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	4.90	28	✓ <u>Bicalaccord</u>
FLUTAMIDE – Retail pharmacy-Specialist Tab 250 mg	55.00	100	✓ Flutamin
MEGESTROL ACETATE - Retail pharmacy-Specialist Tab 160 mg	54.30	30	✓ Apo-Megestrol
OCTREOTIDE			
Inj 50 mcg per ml, 1 ml vial	13.50	5	✓ <u>DBL</u>
Inj 100 mcg per ml, 1 ml vial	22.40	5	✓ DBL
Inj 500 mcg per ml, 1 ml vial	89.40	5	✓ <u>DBL</u>
OCTREOTIDE LAR (SOMATOSTATIN ANALOGUE) - Spe	cial Authority see SA101	6 below – F	Retail pharmacy
Inj LAR 10 mg prefilled syringe		1	✓ Sandostatin LAR
Inj LAR 20 mg prefilled syringe		1	Sandostatin LAR
Inj LAR 30 mg prefilled syringe		1	Sandostatin LAR

⇒SA1016 Special Authority for Subsidy

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

All of the following:

- 1 The patient has nausea* and vomiting* due to malignant bowel obstruction*; and
- 2 Treatment with antiemetics, rehydration, antimuscarinic agents, corticosteroids and analgesics for at least 48 hours has failed; and

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

continued...

3 Octreotide to be given at a maximum dose 1500 mcg daily for up to 4 weeks.

Note: Indications marked with * are Unapproved Indications.

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

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

- 1 The patient has acromegaly; and
- 2 Any of the following:
 - 2.1 Treatment with surgery, radiotherapy and a dopamine agonist has failed; or
 - 2.2 Treatment with octreotide is for an interim period while awaiting the effects of radiotherapy and a dopamine agonist has failed: or
 - 2.3 The patient is unwilling, or unable, to undergo surgery and/or radiotherapy.

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

- 1 IGF1 levels have decreased since starting octreotide; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment.

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

Initial application — (Other Indications) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria: Any of the following:

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

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

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

TAMOXIFFN CITRATE

*	Tab 10 mg17.50	100	Genox
*	Tab 20 mg2.63	30	Genox
	8.75	100	Genox

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
Aromatase Inhibitors				
ANASTROZOLE * Tab 1 mg	26.55	30	✓ A	remed rimidex P-Anastrozole
EXEMESTANE * Tab 25 mg	14.50	30	*	romasin fizer Exemestane
(Aromasin Tab 25 mg to be delisted 1 January 2017)			-	
LETROZOLE * Tab 2.5 mg	2.95	30	√ <u>L</u>	etrole_
Immunosuppressants				
Cytotoxic Immunosuppressants				
AZATHIOPRINE – Retail pharmacy-Specialist * Tab 25 mg		60	✓ A	zamun
** Tab 50 mg - For azathioprine oral liquid formulation refer, page 221 ** Inj 50 mg	13.22	100 1	*	zamun nuran
MYCOPHENOLATE MOFETIL				
Tab 500 mg Cap 250 mg Powder for oral liq 1 g per 5 ml – Subsidy by endorsement	25.00	50 100 5 ml C	✓ 0	elicept elicept elicept

Fusion Proteins

	opoolar riamonty ood or triro bolon	riotan priarriacy		
Inj 25 mg		799.96	4	Enbrel
Inj 50 mg auto	oinjector	1,599.96	4	Enbrel
Ini 50 ma pref	filled syringe	1.599.96	4	✓ Enbrel

⇒SA1478 Special Authority for Subsidy

prescription is endorsed accordingly.

Initial application — (juvenile idiopathic arthritis) only from a named specialist or rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

Fither:

Mycophenolate powder for oral liquid is subsidised only for patients unable to swallow tablets and capsules, and when the

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- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for adalimumab for juvenile idiopathic arthritis (JIA); and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
 - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for JIA; or
- 2 All of the following:
 - 2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
 - 2.2 Patient diagnosed with Juvenile Idiopathic Arthritis (JIA); and

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continued...

- 2.3 Patient has had severe active polyarticular course JIA for 6 months duration or longer; and
- 2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m² weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and
- 2.5 Both:
 - 2.5.1 Either:
 - 2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; or
 - 2.5.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and
 - 2.5.2 Physician's global assessment indicating severe disease.

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

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for adalimumab for rheumatoid arthritis; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
 - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for rheumatoid arthritis: or

2 All of the following:

- 2.1 Patient has had severe and active erosive rheumatoid arthritis for six months duration or longer; and
- 2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2.3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
- 2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with sulphasalazine and hydroxychloroquine sulphate (at maximum tolerated doses); and
- 2.5 Any of the following:
 - 2.5.1 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of ciclosporin; or
 - 2.5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or
 - 2.5.3 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate; and
- 2.6 Either:
 - 2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or
 - 2.6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 2.7 Either:
 - 2.7.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
 - 2.7.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

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Subsidy (Manufacturer's Price) \$

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Per

Brand or Generic Manufacturer

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

Fither:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for adalimumab for severe chronic plague 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 plaque psoriasis; or
- 2 All of the following:
 - 2.1 Either:
 - 2.1.1 Patient has "whole body" severe chronic plague 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 plague psoriasis of the face, or palm of a hand or sole of a foot, where the plague 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 plague 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 plague 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 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 ankylosing spondylitis; or
- 2 All of the following:
 - 2.1 Patient has a confirmed diagnosis of ankylosing spondylitis present for more than six months; and
 - 2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
 - 2.3 Patient has bilateral sacroiliitis demonstrated by plain radiographs, CT or MRI scan; and
 - 2.4 Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal antiinflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of an exercise regime supervised by a physiotherapist; and
 - 2.5 Either:

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Per ✔ Manufacturer

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- 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:

Fither:

1 Both:

- 1.1 The patient has had an initial Special Authority approval for adalimumab for psoriatic arthritis; and
- 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
 - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for psoriatic arthritis; or

2 All of the following:

- 2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and
- 2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
- 2.3 Patient has tried and not responded to at least three months of sulphasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and
- 2.4 Fither:
 - 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints;
 - 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 pvoderma gangrenosum*; and

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Fully Subsidised Brand or Generic Manufacturer

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

Note: Indications marked with * are Unapproved Indications (refer to Interpretations and Definitions).

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

Either:

- 1 Both:
 - 1.1 Fither:
 - 1.1.1 The patient has had an initial Special Authority approval for adalimumab for adult-onset Still's disease (AOSD): or
 - 1.1.2 The patient has been started on tocilizumab for AOSD in a DHB hospital in accordance with the HML rules; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab and/or tocilizumab; or
 - 1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or tocilizumab such that they do not meet the renewal criteria for AOSD; or
- 2 All of the following:
 - 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992:19:424-430); and
 - 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids, non-steroidal anti-inflammatory drugs (NSAIDs) and methotrexate; and
 - 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

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

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

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

All of the following:

- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 3 Either:

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

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- 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 plaque psoriasis at the start of treatment; and
 - 2.1.2 Following each prior etanercept treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-treatment baseline value; or
 - 2.2 Both:
 - 2.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment: and
 - 2.2.2 Fither:
 - 2.2.2.1 Following each prior etanercept treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
 - 2.2.2.2 Following each prior etanercept treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; and
- 3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

Note: A treatment course is defined as a minimum of 12 weeks of etanercept treatment

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

All of the following:

- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 Following 12 weeks of etanercept treatment. BASDAI has improved by 4 or more points from pre-treatment baseline on a 10 point scale, or by 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 Fither:
 - 1.1 Applicant is a rheumatologist; or

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1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and

2 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

ANTITHYMOCYTE GLOBULIN (FQUINE) - PCT only - Specialist

- 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.

Immune Modulators

Inj 50 mg per ml, 5 ml	2,351.25	5	✓ ATGAM
BACILLUS CALMETTE-GUERIN (BCG) VACCINE - PCT only	- Specialist		
Subsidised only for bladder cancer.			
Inj 2-8 × 100 million CFU	149.37	1	✓ OncoTICE
Inj 40 mg per ml, vial	149.37	3	✓ SII-Onco-BCG S29
(SII-Onco-BCG \$29 Ini 40 ma per ml. vial to be delisted 1 Febr	ruarv 2017)		

Monoclonal Antibodies

ADALIMUMAB - Special Authority see SA14	479 below – Retail pharmacy		
Inj 10 mg per 0.2 ml prefilled syringe	1,599.96	2	Humira
Inj 20 mg per 0.4 ml prefilled syringe	1,599.96	2	Humira
Inj 40 mg per 0.8 ml prefilled pen	1,599.96	2	✓ HumiraPen
Inj 40 mg per 0.8 ml prefilled syringe	1,599.96	2	Humira

⇒SA1479 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:

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- 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 for six months duration or longer; and
- 2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2.3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
- 2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with sulphasalazine and hydroxychloroquine sulphate (at maximum tolerated doses); and
- 2.5 Any of the following:
 - 2.5.1 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of ciclosporin; or
 - 2.5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or
 - 2.5.3 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate; and

2.6 Either:

- 2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or
- 2.6.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and

2.7 Either:

- 2.7.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
- 2.7.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Initial application — (Crohn's disease) only from a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has severe active Crohn's disease: and
- 2 Any of the following:
 - 2.1 Patient has a Crohn's Disease Activity Index (CDAI) score of greater than or equal to 300; or
 - 2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
 - 2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
 - 2.4 Patient has an ileostomy or colostomy, and has intestinal inflammation; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and
- 4 Surgery (or further surgery) is considered to be clinically inappropriate.

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

Either:

1 Both:

1.1 The patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and

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- 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 plague 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 plague 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:

Fither:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from etanercept: or
 - 1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for ankylosing spondylitis; or
- 2 All of the following:
 - 2.1 Patient has a confirmed diagnosis of ankylosing spondylitis for more than six months; and
 - 2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
 - 2.3 Patient has bilateral sacroiliitis demonstrated by plain radiographs. CT or MRI scan; and
 - 2.4 Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal antiinflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of an exercise regime supervised by a physiotherapist; and
 - 2.5 Either:
 - 2.5.1 Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following Bath Ankylosing Spondylitis Metrology Index (BASMI) measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right): or
 - 2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the following average normal values corrected for age and gender (see Notes); and
 - 2.6 A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 6 on a 0-10 scale.

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Notes: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure must be no more than 1 month old at the time of initial application.

Average normal chest expansion corrected for age and gender:

18-24 years - Male: 7.0 cm; Female: 5.5 cm

25-34 years - Male: 7.5 cm; Female: 5.5 cm

35-44 years - Male: 6.5 cm; Female: 4.5 cm

45-54 years - Male: 6.0 cm; Female: 5.0 cm

55-64 years - Male: 5.5 cm; Female: 4.0 cm

65-74 years - Male: 4.0 cm; Female: 4.0 cm 75+ years - Male: 3.0 cm; Female: 2.5 cm

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

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for etanercept for psoriatic arthritis; and
 - 12 Fither:
 - 1.2.1 The patient has experienced intolerable side effects from etanercept; or
 - 1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for psoriatic arthritis; or
- 2 All of the following:
 - 2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and
 - 2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and
 - 2.3 Patient has tried and not responded to at least three months of sulphasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and
 - 2.4 Either:
 - 2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints; or
 - 2.4.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
 - 2.5 Any of the following:
 - 2.5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or
 - 2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or
 - 2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Initial application — (juvenile idiopathic arthritis) only from a named specialist or rheumatologist. Approvals valid for 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 juvenile idiopathic arthritis (JIA); and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from etanercept; or
 - 1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for juvenile idiopathic arthritis; or
- 2 All of the following:

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- 2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance: and
- 2.2 Patient diagnosed with JIA; and
- 2.3 Patient has had severe active polyarticular course JIA for 6 months duration or longer; and
- 2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m² weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and
- 2.5 Both:
 - 2.5.1 Either:
 - 2.5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; or
 - 2.5.1.2 Patient has persistent symptoms of poorly-controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and
 - 2.5.2 Physician's global assessment indicating severe disease.

Initial application — (fistulising Crohn's disease) only from a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has confirmed Crohn's disease; and
- 2 Fither:
 - 2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
 - 2.2 Patient has one or more rectovaginal fistula(e); and
- 3 A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application; and
- 4 The patient will be assessed for response to treatment after 4 months' adalimumab treatment (see Note).

Note: A maximum of 4 months' adalimumab will be subsidised on an initial Special Authority approval for fistulising Crohn's disease. Initial application — (pyoderma gangrenosum) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

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

Note: Note: Indications marked with * are Unapproved Indications (refer to (Interpretations and Definitions).

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

Either:

- 1 Both:
 - 1.1 Fither:
 - 1.1.1 The patient has had an initial Special Authority approval for etanercept for adult-onset Still's disease (AOSD);
 - 1.1.2 The patient has been started on tocilizumab for AOSD in a DHB hospital in accordance with the HML rules:
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
 - 1.2.2 The patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab such that they do not meet the renewal criteria for AOSD: or
- 2 All of the following:

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- 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and
- 2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids, 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 Fither:
 - 3.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 3.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 4 Either:
 - 4.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
 - 4.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

Renewal — (Crohn's disease) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria: All of the following:

- 1 Either:
 - 1.1 Applicant is a gastroenterologist; or
 - 1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Either:
 - 2.1 Fither:
 - 2.1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab:

- 2.1.2 CDAI score is 150 or less: or
- 2.2 Both:
 - 2.2.1 The patient has demonstrated an adequate response to treatment but CDAI score cannot be assessed; and
 - 2.2.2 Applicant to indicate the reason that CDAI score cannot be assessed; and
- 3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

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

All of the following:

- 1 Either:
 - 1.1 Applicant is a dermatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and

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2 Either:

- 2.1 Both:
 - 2.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
 - 2.1.2 Following each prior adalimumab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-adalimumab treatment baseline value; or
- 2.2 Both:
 - 2.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
 - 2.2.2 Fither:
 - 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 Fither:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Following 12 weeks of adalimumab treatment, BASDAI has improved by 4 or more points from pre-adalimumab baseline on a 10 point scale, or by 50%, whichever is less; and
- 3 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and
- 4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

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

All of the following:

- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Fither:
 - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician; and
- 3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

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

1 Either:

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

Renewal — (fistulising Crohn's disease) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Fither:
 - 1.1 Applicant is a gastroenterologist; or
 - 1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Either:
 - 2.1 The number of open draining fistulae have decreased from baseline by at least 50%; or
 - 2.2 There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain.

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

All of the following:

- 1 Patient has shown clinical improvement; and
- 2 Patient continues to require treatment; and
- 3 A maximum of 4 doses.

Renewal — (adult-onset Still's disease) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Fither:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 The patient has a sustained improvement in inflammatory markers and functional status.

OMALIZUMAB - Special Authority see SA1490 below - Retail pharmacy

Inj 150 mg vial500.00 1 **V** 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

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- 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. 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.

RITUXIMAB - PCT only - Specialist - Special Authority see SA1152 below

Inj 100 mg per 10 ml vial		2	Mabthera
Inj 500 mg per 50 ml vial	2,688.30	1	Mabthera
Inj 1 mg for ECP	5.64	1 mg	Baxter

▶SA1152 | 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) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria: Either:

- 1 Both:
 - 1.1 The patient has indolent low grade NHL 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 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 macroglob-

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

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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 Fither:
 - 3.1 The patient is chemotherapy treatment naive; or
 - 3.2 Both:
 - 3.2.1 The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment; and
 - 3.2.2 The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy; and
- 4 The patient has good performance status; and
- 5 The patient has good renal function (creatinine clearance ≥ 30 ml/min); and
- 6 The patient does not have chromosome 17p deletion CLL; and
- 7 Rituximab to be administered in combination with fludarabine and cyclophosphamide for a maximum of 6 treatment cycles;
- 8 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration).

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with rituximab is expected to improve symptoms and improve ECOG score to <2.

Renewal — (Post-transplant) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 9 months for applications meeting the following criteria: All of the following:

- 1 The patient has had a rituximab treatment-free interval of 12 months or more; and
- 2 The patient has B-cell post-transplant lymphoproliferative disorder*; and
- 3 To be used for no more than 6 treatment cycles.

Note: Indications marked with * are Unapproved Indications.

Renewal — (Indolent, Low-grade lymphomas) 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 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.

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

Subsidy		Fully	Brand or
Manufacturer's Price)	S	ubsidised	Generic
\$	Per	~	Manufacturer

SILTUXIMAB - Special Authority see SA1596 below - Retail pharmacy

Note: Siltuximab is to be administered at doses no greater than 11 mg/kg every 3 weeks.

Inj 100 mg vial	770.57	1	✓ Sylvant
Inj 400 mg vial	3,082.33	1	Sylvant

⇒SA1596 Special Authority for Subsidy

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

All of the following:

- 1 Patient has severe HHV-8 negative idiopathic multicentric Castleman's Disease; and
- 2 Treatment with an adequate trial of corticosteroids has proven ineffective; and
- 3 Siltuximab is to be administered at doses no greater than 11 mg/kg every 3 weeks.

Renewal only from a haematologist or rheumatologist. Approvals valid for 12 months where the treatment remains appropriate and the patient has sustained improvement in inflammatory markers and functional status.

TRASTUZUMAB - PCT only - Specialist - Special Au	uthority see SA1521 below		
Inj 150 mg vial	1,350.00	1	✓ Herceptin
Inj 440 mg vial	3,875.00	1	✓ Herceptin
Inj 1 mg for ECP	9.36	1 mg	✓ Baxter

■ SA1521 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:

Fither:

- 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 lapatinib treatment for HER 2 positive metastatic breast cancer; and
 - 1.3 Trastuzumab not to be given in combination with lapatinib; and
 - 1.4 Trastuzumab 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 lapatinib treatment for metastatic breast cancer but discontinued lapatinib within 3 months of starting treatment due to intolerance; and
 - 2.3 The cancer did not progress whilst on lapatinib; and
 - 2.4 Trastuzumab not to be given in combination with lapatinib; and
 - 2.5 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:

Subsidy (Manufacturer's Price)	Ç.	Fully	Brand or	
(Manulacturers Frice)	Per	ibsiuiseu	Manufacturer	

continued...

- 1 The patient has early breast cancer expressing HER 2 IHC 3+ or ISH + (including FISH or other current technology); and
- 2 Maximum cumulative dose of 106 mg/kg (12 months' treatment); and
- 3 Any of the following:
 - 3.1 9 weeks' concurrent treatment with adjuvant chemotherapy is planned; or
 - 3.2 12 months' concurrent treatment with adjuvant chemotherapy is planned; or
 - 3.3 12 months' sequential treatment following adjuvant chemotherapy is planned; or
 - 3.4 12 months' treatment with neoadjuvant and adjuvant chemotherapy is planned; or
 - 3.5 Other treatment regimen, in association with adjuvant chemotherapy, is planned.

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

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 The patient received prior adjuvant trastuzumab treatment for early breast cancer; and
- 3 Any of the following:
 - 3.1 All of the following:
 - 3.1.1 The patient has not previously received lapatinib treatment for metastatic breast cancer; and
 - 3.1.2 Trastuzumab not to be given in combination with lapatinib; and
 - 3.1.3 Trastuzumab to be discontinued at disease progression; or
 - 3.2 All of the following:
 - 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; and
 - 3.2.3 Trastuzumab not to be given in combination with lapatinib; and
 - 3.2.4 Trastuzumab to be discontinued at disease progression; or
 - 3.3 All of the following:
 - 3.3.1 The cancer has not progressed at any time point during the previous 12 months whilst on trastuzumab; and
 - 3.3.2 Trastuzumab not to be given in combination with lapatinib; and
 - 3.3.3 Trastuzumab to be discontinued at disease progression.

Note: * For patients with relapsed HER-2 positive disease who have previously received adjuvant trastuzumab for early breast cancer.

Programmed Cell Death-1 (PD-1) Inhibitors

		NIVOLUMAB - PCT only - Specialist - Special Authority see SA1617 below
Opdivo	1	Inj 10 mg per ml, 4 ml vial
✓ Opdivo	1	Inj 10 mg per ml, 10 ml vial2,629.96
✓ Baxter	1 mg	Inj 1 mg for ECP27.62

■ SA1617 Special Authority for Subsidy

Initial application — (unresectable or metastatic melanoma) only from a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has metastatic or unresectable melanoma stage III or IV: and
- 2 Patient has measurable disease as defined by the presence of at least one CT or MRI measurable lesion; and
- 3 Either:
 - 3.1 Patient has not received funded pembrolizumab; or
 - 3.2 Both:

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

continued...

- 3.2.1 Patient has received an initial Special Authority approval for pembrolizumab and has discontinued pembrolizumab within 12 weeks of starting treatment due to intolerance; and
- 3.2.2 The cancer did not progress while the patient was on pembrolizumab; and
- 4 Nivolumab is to be used at a maximum dose of 3 mg/kg every 2 weeks for a maximum of 12 weeks (6 cycles); and
- 5 Baseline measurement of overall tumour burden is documented (see Note); and
- 6 Documentation confirming that the patient has been informed and acknowledges that the initial funded treatment period of nivolumab will not be continued beyond 12 weeks (6 cycles) if their disease progresses during this time.

Renewal — (unresectable or metastatic melanoma) only from a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
 - 1.1 Patient's disease has had a complete response to treatment according to RECIST criteria (see Note; or
 - 1.2 Patient's disease has had a partial response to treatment according to RECIST criteria (see Note); or
 - 1.3 Patient has stable disease according to RECIST criteria (see Note); and
- 2 Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period: and
- 3 No evidence of progressive disease according to RECIST criteria (see Note); and
- 4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; and
- 5 Nivolumab will be used at a maximum dose of 3 mg/kg every 2 weeks for a maximum of 12 weeks (6 cycles).

Notes: Disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer EA, et al. Eur J Cancer 2009;45:228-47). Assessments of overall tumour burden and measurable disease to be undertaken on a minimum of one lesion and maximum of 5 target lesions (maximum two lesions per organ). Target lesions should be selected on the basis of their size (lesions with the longest diameter), be representative of all involved organs, and suitable for reproducible repeated measurements. Target lesion measurements should be assessed using CT or MRI imaging with the same method of assessment and the same technique used to characterise each identified and reported lesion at baseline and every 12 weeks. Response definitions as follows:

- 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.

⇒SA1615 Special Authority for Subsidy

Initial application — (unresectable or metastatic melanoma) only from a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient has metastatic or unresectable melanoma stage III or IV; and
- 2 Patient has measurable disease as defined by the presence of at least one CT or MRI measurable lesion; and
- 3 Either:
 - 3.1 Patient has not received funded nivolumab; or

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

continued...

3.2 Both:

- 3.2.1 Patient has received an initial Special Authority approval for nivolumab and has discontinued nivolumab within 12 weeks of starting treatment due to intolerance; and
- 3.2.2 The cancer did not progress while the patient was on nivolumab; and
- 4 Pembrolizumab is to be used at a maximum dose of 2 mg/kg every 3 weeks for a maximum of 12 weeks (4 cycles); and
- 5 Baseline measurement of overall tumour burden is documented (see Note); and
- 6 Documentation confirming that the patient has been informed and acknowledges that the initial funded treatment period of pembrolizumab will not be continued beyond 12 weeks (4 cycles) if their disease progresses during this time.

Renewal — (unresectable or metastatic melanoma) only from a medical oncologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
 - 1.1 Patient's disease has had a complete response to treatment according to RECIST criteria (see Note; or
 - 1.2 Patient's disease has had a partial response to treatment according to RECIST criteria (see Note); or
 - 1.3 Patient has stable disease according to RECIST criteria (see Note); and
- 2 Response to treatment in target lesions has been determined by radiologic assessment (CT or MRI scan) following the most recent treatment period; and
- 3 No evidence of progressive disease according to RECIST criteria (see Note); and
- 4 The treatment remains clinically appropriate and the patient is benefitting from the treatment; and
- 5 Pembrolizumab will be used at a maximum dose of 2 mg/kg every 3 weeks for a maximum of 12 weeks (4 cycles).

Notes: Disease responses to be assessed according to the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1 (Eisenhauer EA, et al. Eur J Cancer 2009;45:228-47). Assessments of overall tumour burden and measurable disease to be undertaken on a minimum of one lesion and maximum of 5 target lesions (maximum two lesions per organ). Target lesions should be selected on the basis of their size (lesions with the longest diameter), be representative of all involved organs, and suitable for reproducible repeated measurements. Target lesion measurements should be assessed using CT or MRI imaging with the same method of assessment and the same technique used to characterise each identified and reported lesion at baseline and every 12 weeks. Response definitions as follows:

- Complete Response: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target)
 must have reduction in short axis to <10 mm.
- Partial Response: At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.
- Progressive Disease: At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: the appearance of one or more new lesions is also considered progression).
- Stable Disease: Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease.

Other Immunosuppressants

CICLOSPORIN			
Cap 25 mg	44.63	50	✓ Neoral
Cap 50 mg	88.91	50	Neoral
Cap 100 mg	177.81	50	✓ Neoral
Oral liq 100 mg per ml	198.13	50 ml OP	Neoral
EVEROLIMUS – Special Authority see SA1491 on the next page Wastage claimable – see rule 3.3.2 on page 13	e – Retail pharma	асу	
Tab 5 mg	4,555.76	30	✓ Afinitor
Tab 10 mg	6,512.29	30	✓ Afinitor

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Subsidy (Manufacturer's Price) \$ Per

Fully Subsidised Brand or Generic Manufacturer

⇒SA1491 Special Authority for Subsidy

Initial application only from a neurologist or oncologist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 Patient has tuberous sclerosis: and
- 2 Patient has progressively enlarging sub-ependymal giant cell astrocytomas (SEGAs) that require treatment.

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

- 1 Documented evidence of SEGA reduction or stabilisation by MRI within the last 3 months; and
- 2 The treatment remains appropriate and the patient is benefiting from treatment; and
- 3 Everolimus to be discontinued at progression of SEGAs.

Note: MRI should be performed at minimum once every 12 months, more frequent scanning should be performed with new onset of symptoms such as headaches, visual complaints, nausea or vomiting, or increase in seizure activity.

SIBOLIMI IS	- Special Authority	see SA0866 below	- Retail pharmacy
SILIOLINIOS	- Opeciai Autilionii	A SEE OVOCOO DEION	- Hetali pilaililacy

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	✓ <u>Tacrolimus Sandoz</u>
Cap 1 mg	171.20	100	✓ Tacrolimus Sandoz
Cap 5 mg - For tacrolimus oral liquid formulation refer, page	Э		
221	428.00	50	✓ <u>Tacrolimus Sandoz</u>

■SA1540 Special Authority for Subsidy

Initial application — (organ transplant) only from a relevant specialist. Approvals valid without further renewal unless notified where the patient is an organ transplant recipient.

Initial application — (steroid-resistant nephrotic syndrome*) only from a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

- 1 The patient is a child with steroid-resistant nephrotic syndrome* (SRNS) where ciclosporin has been trialled in combination with prednisone and discontinued because of unacceptable side effects or inadequate clinical response; or
- 2 All of the following:
 - 2.1 The patient is an adult with SRNS; and
 - 2.2 Ciclosporin has been trialled in combination with prednisone and discontinued because of unacceptable side effects or inadequate clinical response; and
 - 2.3 Cyclophosphamide or mycophenolate have been trialled and discontinued because of unacceptable side effects or inadequate clinical response, or these treatments are contraindicated.

Note: Indications marked with * are Unapproved Indications Note: Subsidy applies for either primary or rescue therapy.

Subsidy (Manufacturer's Price) Per \$

Fully Subsidised

Brand or Generic Manufacturer

Antiallergy Preparations

Allergic Emergencies

ICATIBANT - Special Authority see SA1558 below - Retail pharmacy Inj 10 mg per ml, 3 ml prefilled syringe2,668.00 ✓ 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

285.00	1 OP	✓ Venomil S29
305.00	1 OP	✓ Albey
A1367 above -	- Retail pharm	nacy
305.00	1 OP	✓ Albey
305.00	1 OP	✓ Venomil \$29
305.00	1 OP	✓ Albey
	305.00 A1367 above - 305.00	305.00 1 OP A1367 above – Retail pharm305.00 1 OP305.00 1 OP

Antihistamines

CETIRIZINE HYDROCHLORIDE			
* Tab 10 mg	1.59	100	✓ Zetop
*‡ Oral liq 1 mg per ml	2.99	200 ml	✓ <u>Histaclear</u>
CHLORPHENIRAMINE MALEATE			
*‡ Oral liq 2 mg per 5 ml	8.06	500 ml	Histafen

1 OP

✓ Venomil \$29

	Subsidy (Manufacturer's F \$	Price) Sub	Fully Brand sidised Generi	c
DEXTROCHLORPHENIRAMINE MALEATE				
* Tab 2 mg	2.02	40		
	(8.40)		Polaramii	ne
	1.01	20		
	(5.99)		Polaramii	ne
*‡ Oral liq 2 mg per 5 ml	1.77	100 ml		
	(10.29)		Polaramii	ne
FEXOFENADINE HYDROCHLORIDE				
* Tab 60 mg	4 34	20		
* Idb 00 mg	(11.53)	20	Telfast	
* Tab 120 mg	` ,	30	Tellast	
* 1ab 120 mg		30	Telfast	
	(29.81) 4.74	10	Tellast	
	****	10	Talfact	
	(11.53)		Telfast	
LORATADINE				
* Tab 10 mg	1.28	100	Lorafix	
Lorafix to be Sole Supply on 1 October 2016				
* Oral liq 1 mg per ml	4.25	200 ml	✓ LoraPae	d
PROMETHAZINE HYDROCHLORIDE				
* Tab 10 mg	1 79	50	✓ Allersoo	tha
* Tab 25 mg		50	✓ Allersoo	
*‡ Oral lig 1 mg per 1 ml		100 ml	✓ Allersoo	
		100 1111	Allersoo	uie
* Inj 25 mg per ml, 2 ml ampoule – Up to 5 inj available on a		-		
PSO	15.54	5	Hospira	
Hospira to be Sole Supply on 1 November 2016				
TRIMEPRAZINE TARTRATE				
‡ Oral liq 30 mg per 5 ml	2.79	100 ml OP		
	(8.06)		Vallergan	Forte
Inhaled Corticosteroids				
BECLOMETHASONE DIPROPIONATE				
Aerosol inhaler, 50 mcg per dose	0.20	200 dose OP	✓ Qvar	
Aerosol inhaler, 50 mcg per dose CFC-free		200 dose OP	✓ Gval ✓ Beclazor	no E0
		200 dose OP	✓ Qvar	le 50
Aerosol inhaler, 100 mcg per dose				. 100
Aerosol inhaler, 100 mcg per dose CFC-free		200 dose OP	✓ Beclazor	
Aerosol inhaler, 250 mcg per dose CFC-free	22.6/	200 dose OP	✓ Beclazor	ie 250
BUDESONIDE				
Powder for inhalation, 100 mcg per dose	17.00	200 dose OP	✔ Pulmicor	rt
			Turbuh	aler
Powder for inhalation, 200 mcg per dose	19.00	200 dose OP	✔ Pulmicor	rt
			Turbuh	-
Powder for inhalation, 400 mcg per dose	32.00	200 dose OP	✓ Pulmico	
i oraci ioi ililialation, 400 meg pei 405e	02.00	200 dose OF	Turbuh	

		10111 3131		ND ALLEMONES
	Subsidy (Manufacturer's \$		Fully bsidised	Brand or Generic Manufacturer
FLUTICASONE				
Aerosol inhaler, 50 mcg per dose		120 dose OP	√ F	loair
Aerosol inhaler, 50 mcg per dose CFC-free		120 dose OP		lixotide
Powder for inhalation, 50 mcg per dose		60 dose OP		lixotide Accuhaler
Powder for inhalation, 100 mcg per dose		60 dose OP		lixotide Accuhaler
Aerosol inhaler, 125 mcg per dose Aerosol inhaler, 125 mcg per dose CFC-free		120 dose OP 120 dose OP		loair Iixotide
Aerosol inhaler, 125 mcg per dose CFC-free		120 dose OP		loair
Aerosol inhaler, 250 mcg per dose CFC-free		120 dose OP		lixotide
Powder for inhalation, 250 mcg per dose		60 dose OP		lixotide Accuhaler
Inhaled Long-acting Beta-adrenoceptor Agonis				
initialed Long-acting Beta-adrenoceptor Agonis	เร			
EFORMOTEROL FUMARATE				
Powder for inhalation, 6 mcg per dose, breath activated	10.32	60 dose OP		
	(16.90)		C	xis Turbuhaler
Powder for inhalation, 12 mcg per dose, and monodose de				
vice		60 dose	_	
	(35.80)		F	oradil
INDACATEROL				
Powder for inhalation 150 mcg	61.00	30 dose OP		nbrez Breezhaler
Powder for inhalation 300 mcg	61.00	30 dose OP	V 0	nbrez Breezhaler
SALMETEROL				
Aerosol inhaler CFC-free, 25 mcg per dose		120 dose OP		erevent
Aerosol inhaler 25 mcg per dose		120 dose OP		leterol
Powder for inhalation, 50 mcg per dose, breath activated	25.00	60 dose OP	√ S	erevent Accuhaler
Inhaled Corticosteroids with Long-Acting Beta-	Adrenocept	or Agonists	;	
BUDESONIDE WITH EFORMOTEROL				
Aerosol inhaler 100 mcg with eformoterol fumarate 6 mcg	18 23	120 dose OP	· • v	annair
Powder for inhalation 100 mcg with eformoterol fumarat		120 0030 01	•	annan
6 mcg		120 dose OP	√ s	ymbicort
		0 0000 0.		Turbuhaler 100/6
Aerosol inhaler 200 mcg with eformoterol fumarate 6 mcg	21.40	120 dose OP	V	annair
Powder for inhalation 200 mcg with eformoterol fumarat				
6 mcg		120 dose OP	√ S	ymbicort
				Turbuhaler 200/6
Powder for inhalation 400 mcg with eformoterol fumarat	е			
12 mcg - No more than 2 dose per day	44.08	60 dose OP	√ S	ymbicort
				Turbuhaler 400/12
FLUTICASONE FUROATE WITH VILANTEROL				
Powder for inhalation 100 mcg with vilanterol 25 mcg	44.08	30 dose OP	✓ B	reo Ellipta

	Subsidy	Duis-s) O :	Fully	Brand or
	(Manufacturer's \$	Price) Subs	sidised •	Generic Manufacturer
FLUTICASONE WITH SALMETEROL				
Aerosol inhaler 50 mcg with salmeterol 25 mcg	33.74	120 dose OP	✓ S	eretide
	37.48		✓ R	
Aerosol inhaler 125 mcg with salmeterol 25 mcg		120 dose OP		eretide
Powder for inhalation 100 mcg with salmeterol 50 mcg - No	49.69		✓ R	exair
more than 2 dose per day		60 dose OP	✓ S	eretide Accuhaler
Powder for inhalation 250 mcg with salmeterol 50 mcg - No				
more than 2 dose per day	44.08	60 dose OP	✓ See	eretide Accuhaler
Beta-Adrenoceptor Agonists				
SALBUTAMOL				
‡ Oral liq 400 mcg per ml		150 ml	✓ Ve	entolin
Infusion 1 mg per ml, 5 ml		10		
Inj 500 mcg per ml, 1 ml - Up to 5 inj available on a PSO	(130.21)	5		entolin entolin
, , ,	12.30	3	V V(antonn
Inhaled Beta-Adrenoceptor Agonists				
SALBUTAMOL				
Aerosol inhaler, 100 mcg per dose CFC free - Up to 1000			4-	
dose available on a PSO	3.80	200 dose OP	✓ R	espigen
				alamol
	(6.00)		Ve	entolin
Nebuliser soln, 1 mg per ml, 2.5 ml ampoule - Up to 30 neb				
available on a PSO		20	✓ <u>A</u>	<u>sthalin</u>
Nebuliser soln, 2 mg per ml, 2.5 ml ampoule – Up to 30 neb available on a PSO		20	✓ A	sthalin
TERBUTALINE SULPHATE		20	<u> </u>	<u>Julianni</u>
Powder for inhalation, 250 mcg per dose, breath activated	22.00	200 dose OP	✓ B	ricanyl Turbuhaler
Anticholinergic Agents				,
Antionomicigio Agento				
PRATROPIUM BROMIDE				
Aerosol inhaler, 20 mcg per dose CFC-free – Up to 400 dose available on a PSO		200 dose OP	. / A	trovent
Nebuliser soln, 250 mcg per ml, 1 ml – Up to 40 neb available		200 dose OF	VA	lioveiii
on a PSO		20	✓ U	nivent
Nebuliser soln, 250 mcg per ml, 2 ml - Up to 40 neb available				
on a PSO	3.37	20	✓ U	nivent
Inhaled Beta-Adrenoceptor Agonists with Anticl	holinergic A	gents		
SALBUTAMOL WITH IPRATROPIUM BROMIDE				
Aerosol inhaler, 100 mcg with ipratropium bromide, 20 mcg				
per dose CFC-free		12.19 200 dose OP 🗸 Duolin		uolin HFA
Nebuliser soln, 2.5 mg with ipratropium bromide 0.5 mg per		00		all:-
vial, 2.5 ml ampoule - Up to 20 neb available on a PSO	3.59	20	✓ <u>D</u>	<u>uoiin</u>

Subsidy (Manufacturer's Price) \$

Fully Subsidised Per

Brand or Generic Manufacturer

Long-Acting Muscarinic Antagonists

GLYCOPYRRONIUM - Subsidy by endorsement

a) Inhaled glycopyrronium treatment will not be subsidised if patient is also receiving treatment with subsidised tiotropium or umeclidinium.

b) Glycopyrronium powder for inhalation 50 mcg per dose is subsidised only for patients who have been diagnosed as having COPD using spirometry, and the prescription is endorsed accordingly.

✓ Seebri Breezhaler 30 dose OP

TIOTROPIUM BROMIDE - Special Authority see SA1568 below - Retail pharmacy

Tiotropium treatment will not be subsidised if patient is also receiving treatment with subsidised inhaled glycopyrronium or umeclidinium.

Powder for inhalation, 18 mcg per dose50.37 30 dose Spiriva 60 dose OP Spiriva Respimat

⇒SA1568 Special Authority for Subsidy

Initial application only from a general practitioner or relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

All of the following:

- 1 To be used for the long-term maintenance treatment of bronchospasm and dyspnoea associated with COPD; and
- 2 In addition to standard treatment, the patient has trialled a short acting bronchodilator dose of at least 40 μg ipratropium g.i.d for one month; and
- 3 Fither:

The patient's breathlessness according to the Medical Research Council (UK) dyspnoea scale is:

- 3.1 Grade 3 (stops for breath after walking about 100 meters or after a few minutes on the level); or
- 3.2 Grade 4 (too breathless to leave the house, or breathless when dressing or undressing); and
- 4 All of the following:

Applicant must state recent measurement of:

- 4.1 Actual FEV₁ (litres); and
- 4.2 Predicted FEV1 (litres); and
- 4.3 Actual FEV₁ as a % of predicted (must be below 60%); and
- 5 Either:
 - 5.1 Patient is not a smoker (for reporting purposes only); or
 - 5.2 Patient is a smoker and has been offered smoking cessation counselling; and
- 6 The patient has been offered annual influenza immunisation.

Renewal only from a general practitioner or relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Patient is compliant with the medication; and
- 2 Patient has experienced improved COPD symptom control (prescriber determined).

UMECLIDINIUM - Subsidy by endorsement

- a) Umeclidinium will not be subsidised if patient is also receiving treatment with subsidised inhaled glycopyrronium or tiotropium bromide.
- b) Umeclidinium powder for inhalation 62.5 mcg per dose is subsidised only for patients who have been diagnosed as having COPD using spirometry, and the prescription is endorsed accordingly.

30 dose OP ✓ Incruse Ellipta

Subsidy (Manufacturer's Price)

Fully Subsidised Per

Brand or Generic Manufacturer

Long-Acting Muscarinic Antagonists with Long-Acting Beta-Adrenoceptor Agonists

Combination long acting muscarinic antagonist and long acting beta-2 agonist will not be subsidised if patient is also receiving treatment with a combination inhaled corticosteroid and long acting beta-2 agonist.

⇒SA1584 Special Authority for Subsidy

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

- 1 Patient has been stabilised on a long acting muscarinic antagonist; and
- 2 The prescriber considers that the patient would receive additional benefit from switching to a combination product.

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

- 1 Patient is compliant with the medication; and
- 2 Patient has experienced improved COPD symptom control (prescriber determined).

GLYCOPYRRONIUM WITH INDACATEROL - Special Authority see SA1584 above - Retail pharmacy			
Powder for Inhalation 50 mcg with indacaterol 110 mcg81.00 30	dose OP VIIIbro Breezhaler		
TIOTROPIUM BROMIDE WITH OLODATEROL - Special Authority see SA1584 abov	e – Retail pharmacy		
Soln for inhalation 2.5 mcg with olodaterol 2.5 mcg81.00 60	dose OP Spiolto Respimat		
UMECLIDINIUM WITH VILANTEROL - Special Authority see SA1584 above - Retail	pharmacy		

Powder for inhalation 62.5 mcg with vilanterol 25 mcg77.00

30 dose OP ✓ Anoro Ellipta

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 mg18	8.48	28 🗸	Singulair
Tab 5 mg18	8.48	28	✓ Singulair
Tab 10 mg18	8.48	28	/ Singulair

⇒SA1421 | Special Authority for Subsidy

Initial application — (Pre-school wheeze) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 To be used for the treatment of intermittent severe wheezing (possibly viral) in children under 5 years; and
- 2 The patient has had at least three episodes in the previous 12 months of acute wheeze severe enough to seek medical attention.

Renewal — (Pre-school wheeze) from any relevant practitioner. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

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

All of the following:

- 1 Patient has been trialled with maximal asthma therapy, including inhaled corticosteroids and long-acting beta-adrenoceptor agonists: and
- 2 Patient continues to receive optimal inhaled corticosteroid therapy; and
- 3 Patient continues to experience frequent episodes of exercise-induced bronchoconstriction.

Initial application — (aspirin desensitisation) only from a clinical immunologist or allergist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

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

continued...

- 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

NSAID where challenge would be considered dangerous.		
Mast Cell Stabilisers		
NEDOCROMIL Aerosol inhaler, 2 mg per dose CFC-free28.07	112 dose OP	✓ Tilade
SODIUM CROMOGLYCATE Powder for inhalation, 20 mg per dose	50 dose 112 dose OP	✓ Intal Spincaps ✓ Intal Forte CFC Free
Methylxanthines		
AMINOPHYLLINE * Inj 25 mg per ml, 10 ml ampoule – Up to 5 inj available on a PSO118.25 THEOPHYLLINE	5	✓ <u>DBL Aminophylline</u>

* Tab long-acting 250 mg21.51 *‡ Oral lig 80 mg per 15 ml15.50 Mucolytics

DORNASE ALFA - Special Authority see SA0611 below - Retail pharmacy Nebuliser soln, 2.5 mg per 2.5 ml ampoule250.00

✔ Pulmozyme

✓ Nuelin-SR ✓ Nuelin

100

500 ml

►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 Facsimile: (04) 916 7571

PHARMAC, PO Box 10 254 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 CHI ORIDE

Not funded for use as a nasal drop.

90 ml OP

✓ Biomed

Nasal Preparations

Allergy Prophylactics

BECLOMETHAS	ONE DIF	PROPIC	ONATE
-------------	---------	--------	-------

Metered aqueous nasal spray, 50 mcg per dose2.35	200 dose OP	
(5.26)		Alanase
Metered aqueous nasal spray, 100 mcg per dose2.46	200 dose OP	
(6.00)		Alanase

	Subsidy (Manufacturer's	Price) Subs	Fully Brand or sidised Generic
	\$	Per	✓ Manufacturer
BUDESONIDE			
Metered aqueous nasal spray, 50 mcg per dose	2.35	200 dose OP	
	(5.26)		Butacort Aqueous
Metered aqueous nasal spray, 100 mcg per dose		200 dose OP	D. dans at Assessment
	(6.00)		Butacort Aqueous
FLUTICASONE PROPIONATE	0.40	100 1 00	4
Metered aqueous nasal spray, 50 mcg per dose	2.18	120 dose OP	✓ <u>Flixonase Hayfever</u> & Allergy
IPRATROPIUM BROMIDE			<u>a Allergy</u>
Aqueous nasal spray, 0.03%	3 05	15 ml OP	✓ Univent
	0.00	13 1111 01	<u>Onivent</u>
Respiratory Devices			
MASK FOR SPACER DEVICE			
a) Up to 20 dev available on a PSO			
b) Only on a PSO			
c) Only for children aged six years and under	0.00		4
Small	2.20	1	✓ e-chamber Mask
PEAK FLOW METER			
a) Up to 10 dev available on a PSO			
b) Only on a PSO Low range	0.54	1	✓ Mini-Wright AFS
Low range	9.54	ı	Low Range
Normal range	9.54	1	✓ Mini-Wright
•			Standard
SPACER DEVICE			
a) Up to 20 dev available on a PSO			
b) Only on a PSO			
220 ml (single patient)		1	e-chamber Turbo
510 ml (single patient)	5.12	1	✓ e-chamber La Grande
800 ml	6 50	1	✓ Volumatic
	0.50	· ·	+ volumatic
Respiratory Stimulants			
CAFFINE CITRATE			

CAFFEINE CITRALE		
Oral liq 20 mg per ml (10 mg base per ml)	14.85	25 ml OP

nl OP V Biomed

	Subsidy (Manufacturer's \$	Price) Sub Per	Fully sidised	Brand or Generic Manufacturer
Ear Preparations				
ACETIC ACID WITH 1, 2- PROPANEDIOL DIACETATE AND BET For Vosol ear drops with hydrocortisone powder refer Standa Ear drops 2% with 1, 2-Propanediol diacetate 3% and benzethonium chloride 0.02%	ırd Formulae, pa İ	ge 224 35 ml OP	√ Vo	loze
FLUMETASONE PIVALATE		00 1111 01	•	
Ear drops 0.02% with clioquinol 1%	4.46	7.5 ml OP		ocacorten-Viaform ED's ocorten-Vioform
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCI	N AND NYSTAT	ïN	V LO	corten-violorm
Ear drops 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 mcg per g)	7.5 ml OP	✓ Ke	enacomb
Ear/Eye Preparations				
DEXAMETHASONE WITH FRAMYCETIN AND GRAMICIDIN Ear/Eye drops 500 mcg with framycetin sulphate 5 mg and gramicidin 50 mcg per ml		8 ml OP		
	(9.27)		Sc	ofradex
FRAMYCETIN SULPHATE Ear/Eye drops 0.5%	4.13 (8.65)	8 ml OP	So	oframycin
Eye Preparations				
Eye preparations are only funded for use in the eye, unless explicit	citly stated other	wise.		
Anti-Infective Preparations				
ACICLOVIR * Eye oint 3%	14.92 37.53	4.5 g OP		ruPOS ovirax
CHLORAMPHENICOL			4 4.	
Eye oint 1% Eye drops 0.5% Funded for use in the ear*. Indications marked with * are learth.	0.98	4 g OP 10 ml OP cations.		nlorsig nlorafast
CIPROFLOXACIN	••			
Eye Drops 0.3%For treatment of bacterial keratitis or severe bacterial conj		5 ml OP nt to chloramph		loxan
FUSIDIC ACID Eye drops 1%		5 g OP		ıcithalmic
GANCICLOVIR				
Eye gel 0.15%	37.53	5 g OP	✓ Vi	rgan S29
GENTAMICIN SULPHATE Eye drops 0.3%	11.40	5 ml OP	✓ Ge	enoptic
PROPAMIDINE ISETHIONATE	0.07	10 ml OD		

(7.99)

10 ml OP

Brolene

	Subsidy (Manufacturer's I \$	Price) Sub Per	Fully Brand or osidised Generic Manufacturer
TOBRAMYCIN Eye oint 0.3% Eye drops 0.3%		3.5 g OP 5 ml OP	✓ <u>Tobrex</u> ✓ <u>Tobrex</u>
Corticosteroids and Other Anti-Inflammatory Pro	eparations		
DEXAMETHASONE * Eye oint 0.1% * Eye drops 0.1%	4.50	3.5 g OP 5 ml OP	✓ <u>Maxidex</u> ✓ <u>Maxidex</u>
* Eye oint 0.1% with neomycin sulphate 0.35% and polymyxin b sulphate 6,000 u per g* * Eye drops 0.1% with neomycin sulphate 0.35% and polymyxin xin b sulphate 6,000 u per ml	5.39	3.5 g OP 5 ml OP	✓ <u>Maxitrol</u> ✓ Maxitrol
DICLOFENAC SODIUM * Eye drops 0.1%	13.80	5 ml OP	✓ <u>Voltaren Ophtha</u>
EVOCABASTINE Eye drops 0.5 mg per ml Eye drops 0.5 mg per ml		5 ml OP 4 ml OP	FML Livostin
LODOXAMIDE Eye drops 0.1%PREDNISOLONE ACETATE	8.71	10 ml OP	✓ <u>Lomide</u>
Eye drops 0.12% Eye drops 1% (Pred Mild Eye drops 0.12% to be delisted 1 October 2016)		5 ml OP 5 ml OP	✓ Pred Mild ✓ Pred Forte
PREDNISOLONE SODIUM PHOSPHATE – Special Authority ser Eye drops 0.5%, single dose (preservative free)		r – Retail pharr 20 dose	nacy Minims Prednisolone
■ SA1547 Special Authority for Subsidy Initial application only from an ophthalmologist. Approvals valid Both: 1. Patient has severe inflammation; and	for 6 months for	applications m	eeting the following criteria:

1 Patient has severe inflammation; and

SODIUM CROMOGLYCATE

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.

Eye drops 2%	5 ml OP	✓ <u>Rexacrom</u>	
Glaucoma Preparations - Beta Blockers			
BETAXOLOL * Eye drops 0.25%	5 ml OP 5 ml OP	✓ Betoptic S ✓ Betoptic	
LEVOBUNOLOL	5 ml OP	✓ Betagan	

	Subsidy		Fully Brand or
	(Manufacturer's		osidised Generic
	<u> </u>	Per	✓ Manufacturer
TIMOLOL			
* Eye drops 0.25%	1.45	5 ml OP	✓ Arrow-Timolol
* Eye drops 0.25%, gel forming	3.30	2.5 ml OP	✓ Timoptol XE
Timoptol XE to be Sole Supply on 1 October 2016			-
* Eye drops 0.5%	1.45	5 ml OP	✓ Arrow-Timolol
* Eye drops 0.5%, gel forming	3.78	2.5 ml OP	✓ Timoptol XE
Timoptol XE to be Sole Supply on 1 October 2016			
Glaucoma Preparations - Carbonic Anhydrase II	nhibitors		
ACETAZOLAMIDE			
* Tab 250 mg - For acetazolamide oral liquid formulation refer,			
page 221		100	✓ Diamox
1 0	17.00	100	₽ <u>Biamox</u>
BRINZOLAMIDE * Eye Drops 1%	0.77	E ml OD	. / A===t
	9.77	5 ml OP	✓ Azopt
DORZOLAMIDE HYDROCHLORIDE			
* Eye drops 2%		5 ml OP	
	(17.44)		Trusopt
DORZOLAMIDE WITH TIMOLOL			
* Eye drops 2% with timolol 0.5%	3.45	5 ml OP	✓ <u>Arrow-Dortim</u>
Glaucoma Preparations - Prostaglandin Analogu	ues		
BIMATOPROST			
* Eye drops 0.03%	3.65	3 ml OP	✓ Bimatoprost Actavis
Tyc Grops 0.00%	(18.50)	01111 01	Lumigan
Bimatoprost Actavis to be Sole Supply on 1 October 2016	, ,		= 3ga.:
(Lumigan Eye drops 0.03% to be delisted 1 October 2016)			
LATANOPROST			
* Eye drops 0.005%	1 50	2.5 ml OP	✓ Hysite
		2.0 1111 01	· <u>myono</u>
TRAVOPROST	10.50	2.5 ml OP	✓ Travatan
	19.50	2.5 IIII OF	₩ II avalali
Glaucoma Preparations - Other			
BRIMONIDINE TARTRATE			
* Eye drops 0.2%	4.32	5 ml OP	✓ Arrow-Brimonidine
BRIMONIDINE TARTRATE WITH TIMOLOL MALEATE			
* Eye drops 0.2% with timolol maleate 0.5%	18.50	5 ml OP	✓ Combigan
, ,		5 iii 5i	
PILOCARPINE HYDROCHLORIDE * Eye drops 1%	4 26	15 ml OP	✓ Isopto Carpine
* Eye drops 1% * Eye drops 2% * Eye drops 2%		15 ml OP	✓ Isopto Carpine ✓ Isopto Carpine
* Eye drops 4%		15 ml OP	✓ Isopto Carpine ✓ Isopto Carpine
Subsidised for oral use pursuant to the Standard Formulae		10 1111 01	- ioopto outpillo
* Eye drops 2% single dose - Special Authority see SA0895			
on the next page – Retail pharmacy		20 dose	✓ Minims Pilocarpine



Subsidy (Manufacturer's Price) \$

2 00

15 ml OP

Fully Subsidised

Per

Brand or Generic Manufacturer

⇒SA0895 | Special Authority for Subsidy

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

- 1 Patient has to use an unpreserved solution due to an allergy to the preservative; or
- 2 Patient wears soft contact lenses.

Note: Minims for a general practice are considered to be "tools of trade" and are not approved as special authority items.

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

Mydriatics and Cycloplegics

ATDODINE CHI DUATE

AII	HOF INE SOLFTIALE		
*	Eye drops 1%17.36	15 ml OP	✓ <u>Atropt</u>
CY	CLOPENTOLATE HYDROCHLORIDE		
*	Eye drops 1%8.76	15 ml OP	Cyclogyl
TR	OPICAMIDE		
*	Eye drops 0.5%7.15	15 ml OP	Mydriacyl
*	Eye drops 1%	15 ml OP	✓ Mydriacyl

Preparations for Tear Deficiency

For acetylcysteine eye	drops refer Standard	Formulae, page 224
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HYPROMELLOSE * Eve drops 0.5%

4 Lyo dropo 0.0 /		10 1111 01	
	(3.92)		Methopt
HYPROMELLOSE WITH DEXTRAN			
* Eve drone 0.3% with devtron 0.1%	2.20	15 ml OP	A Poly-Toors

Eve grops 0.3% with dextran 0.1%2.30 POLYVINYI ALCOHOL

10	LI VIIVIE ALCOHOL		
*	Eye drops 1.4%	15 ml OP	✓ <u>Vistil</u>
*	Eye drops 3%	15 ml OP	✓ Vistil Forte

Preservative Free Ocular Lubricants

⇒SA1388 Special Authority for Subsidy

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

- 1 Confirmed diagnosis by slit lamp of severe secretory dry eye; and
- 2 Either:
 - 2.1 Patient is using eye drops more than four times daily on a regular basis; or
 - 2.2 Patient has had a confirmed allergic reaction to preservative in eye drop.

Renewal from any relevant practitioner. Approvals valid for 24 months where the patient continues to require lubricating eye drops and has benefited from treatment.

CARBOMER - Special Authority see SA1388 above - Retail pharmacy

30 ✔ Poly-Gel

MACROGOL 400 AND PROPYLENE GLYCOL - Special Authority see SA1388 above - Retail pharmacy Eye drops 0.4% and propylene glycol 0.3%, 0.4 ml4.30 ✓ Systane Unit Dose

SODIUM HYALURONATE [HYALURONIC ACID] - Special Authority see SA1388 above - Retail pharmacy

10 ml OP ✓ Hvlo-Fresh

Hylo-Fresh has a 6 month expiry after opening. The Pharmacy Procedures Manual restriction allowing one bottle per month is not relevant and therefore only the prescribed dosage to the nearest OP may be claimed.

SENSORY ORGANS

	Subsidy (Manufacturer's Pr \$	rice) Sub Per	Fully sidised	Brand or Generic Manufacturer
Other Eye Preparations				
NAPHAZOLINE HYDROCHLORIDE * Eye drops 0.1%	4.15	15 ml OP	✓ <u>N</u>	aphcon Forte
OLOPATADINE Eye drops 0.1%	17.00	5 ml OP	✓ P	atanol
PARAFFIN LIQUID WITH SOFT WHITE PARAFFIN * Eye oint with soft white paraffin	3.63	3.5 g OP	✓ R	efresh Night Time
PARAFFIN LIQUID WITH WOOL FAT * Eye oint 3% with wool fat 3%	3.63	3.5 g OP	✓ <u>P</u>	oly-Visc
RETINOL PALMITATE Eye oint 138 mcg per g	3.80	5 g OP	✓ V	itA-POS

Subsidy (Manufacturer's Price)

Fully Subsidised

Per

Brand or Generic Manufacturer

Agents Used in the Treatment of Poisonings

Antidotes

ACETYLCYSTEINE - Hetaii pharmacy-Specialist		
Inj 200 mg per ml, 10 ml ampoule78.34	10	✓ DBL Acetylcysteine

NALOXONE HYDROCHLORIDE

- a) Up to 5 inj available on a PSO
- b) Only on a PSO
- * Inj 400 mcg per ml, 1 ml ampoule48.84 5 ✔ Hospira

Removal and Elimination

CHARCOAL

*	Oral liq 50 g per 250 ml43.50	250 ml OP	✓ Carbosorb-X
	a) Up to 250 ml available on a PSO		
	b) Only on a BOO		

b) Only on a PSO

DEFERASIROX - Special Authority see SA1492 below - Retail pharmacy Wastana claimable - see rule 3 3 2 on page 13

Wastage claimable See rule 0.0.2 on page 10			
Tab 125 mg dispersible	276.00	28	Exjade
Tab 250 mg dispersible	552.00	28	Exjade
Tab 500 mg dispersible	1,105.00	28	Exjade

⇒SA1492 Special Authority for Subsidy

Initial application only from a haematologist. Approvals valid for 2 years for applications meeting the following criteria: All of the following:

- 1 The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia; and
- 2 Deferasirox is to be given at a daily dose not exceeding 40 mg/kg/day; and
- 3 Any of the following:
 - 3.1 Treatment with maximum tolerated doses of deferiprone monotherapy or deferiprone and desferrioxamine combination therapy have proven ineffective as measured by serum ferritin levels, liver or cardiac MRI T2*; or
 - 3.2 Treatment with deferiprone has resulted in severe persistent vomiting or diarrhoea; or
 - 3.3 Treatment with deferiprone has resulted in arthritis; or
 - 3.4 Treatment with deferiprone is contraindicated due to a history of agranulocytosis (defined as an absolute neutrophil count (ANC) of < 0.5 cells per μ L) or recurrent episodes (greater than 2 episodes) of moderate neutropenia (ANC 0.5 - 1.0 cells per μ L).

Renewal only from a haematologist. Approvals valid for 2 years for applications meeting the following criteria: Fither:

- 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 on the n	next page - Retail pharm	acy	
Tab 500 mg	533.17	100	✓ Ferriprox
Oral liq 100 mg per 1 ml	266.59	250 ml OP	✔ Ferriprox



(Man	Subsidy ufacturer's Price)	F Subsidi	ully	Brand or Generic
1	\$	Per	~	Manufacturer

■SA1480 Special Authority for Subsidy

Initial application only from a haematologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Fither:

- 1 The patient has been diagnosed with chronic iron overload due to congenital inherited anaemia; or
- 2 The patient has been diagnosed with chronic iron overload due to acquired red cell aplasia.

DESFERRIOXAMINE MESILATE			
* Inj 500 mg vial	51.52	10	✓ Desferal
SODIUM CALCIUM EDETATE			
* Inj 200 mg per ml, 5 ml	53.31	6	
, •	(156.71)		Calcium Disodium Versenate

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 pharmacyspecialist).
 - c) Menthol crystals only in the following bases:

Aqueous cream

Urea cream 10%

Wool fat with mineral oil lotion

Hydrocortisone 1% with wool fat and mineral oil lotion

Glycerol, paraffin and cetyl alcohol lotion.

Glossary

Dermatological base: The products listed in the Barrier creams and Emollients section and the Topical Corticosteroids-Plain section of the Pharmaceutical Schedule are classified as dermatological bases for the purposes of extemporaneous compounding and are the bases to which the dermatological galenicals can be added. Also the dermatological bases in the Barrier Creams and Emollients section of the Pharmaceutical Schedule can be used for diluting proprietary Topical Corticosteroid-Plain preparations. The following products are dermatological bases:

- Aqueous cream
- Cetomacrogol cream BP
- Collodion flexible
- Emulsifying ointment BP
- · Hydrocortisone with wool fat and mineral oil lotion
- Oil in water emulsion
- Urea cream 10%
- · White soft paraffin
- Wool fat with mineral oil lotion
- Zinc and castor oil ointment BP
- Proprietary Topical Corticosteroid-Plain preparations

Dermatological galenical: Dermatological galenicals will only be subsidised when added to a dermatological base. More than one dermatological galenical can be added to a dermatological base.

The following are dermatological galenicals:

- Coal tar solution up to 10%
- Hydrocortisone powder up to 5%
- Menthol crystals
- · Salicylic acid powder
- Sulphur precipitated powder

Standard formulae: Standard formulae are a list of 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 Flecainide 20 mg/ml Rifabutin 20 mg/ml
Allopurinol 20 mg/ml Gabapentin 100 mg/ml Sildenafil 2 mg/ml
Amlodipine 1 mg/ml Hydrocortisone 1 mg/ml Sotalol 5 mg/ml

Azathioprine 50 mg/ml
Baclofen 10 mg/ml
Carvedilol 1 mg/ml
Clopidogrel 5 mg/ml
Diltiazem hydrochloride 12 mg/ml
Labetolol 10 mg/ml
Levetiracetam 100 mg/ml
Levetiracetam 100 mg/ml
Levedopa with carbidopa (5 mg levodopa 1.25 mg carbidopa)/ml
Tramadol 10 mg/ml
Ursodeoxycholic acid 50 mg/ml

Dipyridamole 10 mg/ml

Metoprolol tartrate 10 mg/ml

Valganciclovir 60 mg/ml*

Verapamil hydrochloride 50 mg/ml

Enalapril 1 mg/ml Pyrazinamide 100 mg/ml

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.

^{*}Note this is a DCS formulation

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 pholcodine linctus).
- Extemporaneously compounding an oral liquid with more than one solid dose chemical.
- Mixing more than one extemporaneously compounded oral liquid mixture.
- Mixing one or more extemporaneously compounded oral liquid mixtures with one or more proprietary oral liquids.
- The addition of a chemical/powder/agent/solution to a proprietary oral liquid or extemporaneously compounded oral mixture.

Standard formulae

A list of standard formulae is contained in this section. All ingredients associated with a standard formula will be subsidised and an appropriate compounding fee paid.

Prescribers may prescribe or pharmacists may add extra non-subsidised ingredients, but these extra ingredients will not be reimbursed. The subsidised ingredients in the formula will be reimbursed and a compounding fee paid.

Dermatological Preparations

Proprietary topical corticosteroid preparations may be diluted with a dermatological base (see page 220) 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).

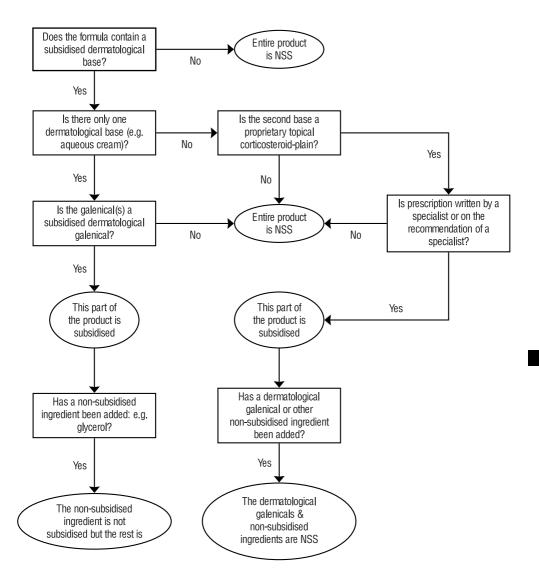
One or more dermatological galenicals may be added to a dermatological base (including proprietary topical corticosteroid preparations). Prescribers may prescribe or pharmacists may add extra non-subsidised ingredients, but these extra ingredients will not be reimbursed. The subsidised ingredients in 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		PHENOBARBITONE ORAL LIQUID	
Acetylcysteine inj 200 mg per ml, 10 ml	qs	Phenobarbitone Sodium	1 g
Suitable eye drop base	qs	Glycerol BP	70 ml
, ,	•	Water	to 100 ml
ASPIRIN AND CHLOROFORM APPLICATI	-		
Aspirin Soluble tabs 300 mg	12 tabs	PHENOBARBITONE SODIUM PAEDIATRI	C ORAL
Chloroform	to 100 ml	LIQUID (10 mg per ml)	
CODEINE LINCTUS PAEDIATRIC (3 mg pe	er 5 ml)	Phenobarbitone Sodium	400 mg
Codeine phosphate	60 mg	Glycerol BP	4 ml
Glycerol	40 ml	Water	to 40 ml
Preservative	qs		
Water	to 100 ml	PILOCARPINE ORAL LIQUID	
CODEINE LINCTUS DIABETIC (15 mg per	r 5 ml)	Pilocarpine 4% eye drops	qs
Codeine phosphate	300 mg	Preservative	qs
Glycerol	40 ml	Water	to 500 ml
Preservative	qs	(Preservative should be used if quantity su	pplied is for
Water	to 100 ml	more than 5 days.)	
FOLINIC MOUTHWASH			
Calcium folinate 15 mg tab	1 tab	SALIVA SUBSTITUTE FORMULA	
Preservative	qs	Methylcellulose	5 g
Water	to 500 ml	Preservative	qs
(Preservative should be used if quantity sup	oplied is for	Water	to 500 ml
more than 5 days. Maximum 500 ml per pre		(Preservative should be used if quantity su	
, , ,	,	more than 5 days. Maximum 500 ml per pro	escription.)
MAGNESIUM HYDROXIDE 8% MIXTURE	075 ~		
Magnesium hydroxide paste 29%	275 g	SODIUM CHLORIDE ORAL LIQUID	
Methyl hydroxybenzoate Water	1.5 g	Sodium chloride inj 23.4%, 20 ml	qs
	to 1,000 ml	Water	qs
METHADONE MIXTURE		(Only funded if prescribed for treatment of I	hyponatraemia)
Methadone powder	qs		
Glycerol	qs	VANCOMYCIN ORAL SOLUTION (50 mg)	per ml)
Water	to 100 ml	Vancomycin 500 mg injection	10 vials
METHYL HYDROXYBENZOATE 10% SOL	UTION	Glycerol BP	40 ml
Methyl hydroxybenzoate	10 g	Water	to 100 ml
Propylene glycol	to 100 ml	(Only funded if prescribed for treatment of	Clostridium
(Use 1 ml of the 10% solution per 100 ml of	f oral liquid	difficile following metronidazole failure)	
mixture)			
OMEDDA ZOLE OLIODENOLONI		VOSOL FAR DROPS	

OMEPRAZOLE SUSPENSION

Omeprazole capules or powder Sodium bicarbonate powder BP qs 8.4 g Water to 100 ml

VOSOL EAR DROPS

WITH HYDROCORTISONE POWDER 1% Hydrocortisone powder Vosol Ear Drops 1% to 35 ml

	Subsidy (Manufacturer's Price) \$	Sub Per	Fully osidised	Brand or Generic Manufacturer	
temporaneously Compounded Preparations and Galenicals					
IZOIN					

BENZOIN	04.40	500 ···!	
Tincture compound BP		500 ml	Dharman, Haalth
	(39.90) 2.44	50 ml	Pharmacy Health
	(5.10)	JU IIII	Pharmacy Health
CHLOROFORM - Only in combination			•
Only in aspirin and chloroform application.			
Chloroform BP		500 ml	✓ PSM
CODEINE PHOSPHATE - Safety medicine; prescriber may determ	ine dispensino	g frequency	
Powder - Only in combination		25 g	
	(90.09)	_	Douglas
	12.62	5 g	Douglas
a) Only in extemporaneously compounded codeine linctus di	(25.46)	aina linctus no	Douglas adiatric
b) ‡ Safety cap for extemporaneously compounded oral liqui			iculati Ic.
COLLODION FLEXIBLE Collodion flexible	10.20	100 ml	✓ PSM
	13.30	100 1111	₩ FOIVI
COMPOUND HYDROXYBENZOATE – Only in combination			
Only in extemporaneously compounded oral mixtures. Soln	30.00	100 ml	✓ Midwest
	34.18	100 1111	✓ David Craig
SLYCERIN WITH SODIUM SACCHARIN - Only in combination			
Only in combination with Ora-Plus.			
Suspension	32.50	473 ml	✓ Ora-Sweet SF
SLYCERIN WITH SUCROSE – Only in combination			
Only in combination with Ora-Plus.			
Suspension	32.50	473 ml	✔ Ora-Sweet
GLYCEROL			
* Liquid - Only in combination		500 ml	✓ healthE Glycerol BP
Only in extemporaneously compounded oral liquid preparation	ons.		
MAGNESIUM HYDROXIDE			
Paste 29%	22.61	500 g	✓ PSM
METHADONE HYDROCHLORIDE			
a) Only on a controlled drug form			
b) No patient co-payment payable	anau.		
 c) Safety medicine; prescriber may determine dispensing frequency d) Extemporaneously compounded methadone will only be rein 		rate of the of	heanest form available (method
powder, not methadone tablets).	ווטטוסכט מו וווכ	iale oi lile oi	neapest ioini avallable (illetilat
Powder		1 g	✓ AFT
‡ Safety cap for extemporaneously compounded oral liquid p		3	
METHYL HYDROXYBENZOATE			
Powder	8.00	25 g	✓ PSM
	8.98		✓ Midwest
METHYLCELLULOSE			
Powder	36.95	100 g	✓ MidWest
Suspension - Only in combination	32.50	473 ml	✔ Ora-Plus

EXTEMPORANEOUSLY COMPOUNDED PREPARATIONS AND GALENICALS

	Subsidy (Manufacturer's P \$	rice) Sul Per	Fully bsidised	Brand or Generic Manufacturer
METHYLCELLULOSE WITH GLYCERIN AND SODIUM SACCHA Suspension		ombination 473 ml	v 0	ra-Blend SF
METHYLCELLULOSE WITH GLYCERIN AND SUCROSE - Only Suspension		473 ml	v 0	Pra-Blend
PHENOBARBITONE SODIUM				
Powder – Only in combination	52.50 325.00	10 g 100 g		lidWest lidWest
a) Only in children up to 12 yearsb) ‡ Safety cap for extemporaneously compounded oral lic	quid preparations.			
PROPYLENE GLYCOL				
Only in extemporaneously compounded methyl hydroxybenzo			√ P	CM
Liq	10.50	500 ml		SW lidwest
(PSM Liq to be delisted 1 November 2016)	11.20		•	num oot
SODIUM BICARBONATE				
Powder BP - Only in combination	8.95 9.80	500 g	✓ N	lidwest
	(29.50)		D	avid Craig
Only in extemporaneously compounded omeprazole and le	ansoprazole susp	ension.		
SYRUP (PHARMACEUTICAL GRADE) – Only in combination Only in extemporaneously compounded oral liquid preparation	ins.			
Liq		2,000 ml	✓ N	lidwest
WATER				
Tap - Only in combination	0.00	1 ml	V T	ap water

EXPLANATORY NOTES

The list of special foods to which Subsidies apply is contained in this section. The list of available products, guidelines for use, subsidies and charges is reviewed as required. Applications for new listings and changes to subsidies and access criteria will be considered by the special foods sub-committee of PTAC which meets as and when required. In all cases, subsidies are available by Special Authority only. This means that, unless a patient has a valid Special Authority number for their special food requirements, they must pay the full cost of the products themselves.

Eligibility for Special Authority

Special Authorities will be approved for patients meeting conditions specified under the *Conditions and Guidelines* for each product. In some cases there are also limits to how products can be prescribed (for example quantity, use or duration). Only those brands, presentations and flavours of special foods listed in this section are subsidised.

Who can apply for Special Authority?

Initial Applications: Only from a dietitian, relevant specialist or a vocationally registered general

practitioner.

Reapplications: Only from a dietitian, relevant specialist or a vocationally registered general

practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or a vocationally registered general practitioner. Other general practitioners must include the name of the dietitian, relevant specialist or voca-

tionally 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 Growth deficiency An inability to gain or maintain weight resulting in physiological impairment. Where the weight of the child is less than the fifth or possibly third percentile for

their age, with evidence of malnutrition

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

Brand or Generic Manufacturer

Nutrient Modules

Carbohydrate

⇒SA1522 Special Authority for Subsidy

Initial application — (Cystic fibrosis or kidney disease) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

- Either:
 - 1 cystic fibrosis; or
 - 2 chronic kidney disease.

Initial application — (Indications other than cystic fibrosis or renal failure) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:
Any of the following:

- 1 cancer in children: or
- 2 cancers affecting alimentary tract where there are malabsorption problems in patients over the age of 20 years; or
- 3 faltering growth in an infant/child; or
- 4 bronchopulmonary dysplasia; or
- 5 premature and post premature infant; or
- 6 inborn errors of metabolism; or
- 7 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula. **Renewal — (Cystic fibrosis or renal failure)** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

- Both:
 - 1 The treatment remains appropriate and the patient is benefiting from treatment; and
 - 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis or renal failure) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

CARBOHYDRATE SUPPLEMENT - Special Authority see SA1522 above - Hospital pharmacy [HP3]

Carbohydrate And Fat

▶SA1376 Special Authority for Subsidy

Initial application — **(Cystic fibrosis)** only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 Infant or child aged four years or under; and
 - 2 cystic fibrosis.

Subsidy (Manufacturer's Price) \$

Fully Subsidised Per

Brand or Generic Manufacturer

Soluble Powder

continued...

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria: Both:

- 1 infant or child aged four years or under: and
- 2 Any of the following:
 - 2.1 cancer in children: or
 - 2.2 faltering growth; or
 - 2.3 bronchopulmonary dysplasia; or
 - 2.4 premature and post premature infants.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria: Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria: Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

CARBOHYDRATE AND FAT SUPPLEMENT - S	Special Authority see SA1376 on th	e previous page –	Hospital pharmacy [HP3
Powder (neutral)	60.31	400 g OP ✓	Duocal Super

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 biliarv atresia: or
- 8 for use in a ketogenic diet; or
- 9 chyle leak; or
- 10 ascites: or
- 11 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

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

continued...

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula.

Renewal — (Inborn errors of metabolism) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

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.

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]

	openial right of controls on the provided page	noopital prialinaoy	[0]
Emulsion (neutral))12.30	200 ml OP	✓ Calogen
	30.75	500 ml OP	✓ Calogen
Emulsion (strawbe	erry)12.30	200 ml OP	✓ Calogen
Oil	30.00	500 ml OP	✓ MCT oil (Nutricia)
Oil, 250 ml	114.92	4 OP	✓ Liquigen

Protein

⇒SA1524 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 protein losing enteropathy; or
- 2 high protein needs; or
- 3 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula. **Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

PROTEIN SUPPLEMENT – Special Authority see SA1524 above – Hospital pharmacy [HP3]
Powder7.90 225 g OP ✓ Pro
8.95 227 g OP ✓ Re

✓ Protifar✓ ResourceBeneprotein

Powder (vanilla)12.90

275 a OP

✔ Promod

Subsidy (Manufacturer's Price)

Fully Subsidised Brand or Generic Manufacturer

Oral Supplements/Complete Diet (Nasogastric/Gastrostomy Tube Feed)

Respiratory Products

⇒SA1094 | Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient has CORD and hypercapnia, defined as a CO2 value exceeding 55 mmHg.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

CORD ORAL FEED 1.5KCAL/ML - Special Authority see SA1094 above - Hospital pharmacy [HP3]

237 ml OP Pulmocare

Diabetic Products

⇒SA1095 | Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient is a type I or and II diabetic who is suffering weight loss and malnutrition that requires nutritional support.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

DIABETIC ENTERAL FEED 1KCAL/ML - Special Authority see SA1095 above - Hospital pharmacy [HP3]

1.000 ml OP ✓ Diason RTH Glucerna Select RTH

DIABETIC ORAL FEED 1KCAL/ML - Special Authority see SA1095 above - Hospital pharmacy [HP3]

Liquid (strawberry	1.50	200 ml OP	Diasip
Liquid (vanilla)	1.50	200 ml OP	✓ Diasip
	1.88	250 ml OP	✓ Glucerna Select
	1.78	237 ml OP	
	(2.10)		Resource Diabetic

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:

(2.10)

Any of the following:

- 1 Patient has metabolic disorders of fat metabolism; or
- 2 Patient has a chyle leak: or

continued...

Sustagen Diabetic



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

Brand or Generic Manufacturer

continued...

3 Modified as a modular feed, made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule, for adults.

Note: Patients are required to meet any Special Authority criteria associated with all of the products used in the modular formula. **Renewal** only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

FAT MODIFIED FEED - Special Authority see SA1525 on the previous page - Hospital pharmacy [HP3]

Paediatric Products For Children Awaiting Liver Transplant

⇒SA1098 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient is a child (up to 18 years) who requires a liver transplant.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL FEED 1KCAL/ML - Special Authority see SA1098 above - Hospital pharmacy [HP3]

Paediatric Products For Children With Chronic Renal Failure

⇒SA1099 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient is a child (up to 18 years) with acute or chronic kidney disease.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL FEED 1KCAL/ML - Special Authority see SA1099 above - Hospital pharmacy [HP3]

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

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.

and all all all all all all all all all al			
PAEDIATRIC ENTERAL FEED 1.5KCAL/ML - Special Authority Liquid		ve – Hospital p 500 ml OP	harmacy [HP3] Nutrini Energy RTH
PAEDIATRIC ENTERAL FEED 1KCAL/ML - Special Authority s Liquid		e – Hospital pha 500 ml OP	armacy [HP3] ✓ Nutrini RTH ✓ Pediasure RTH
PAEDIATRIC ENTERAL FEED WITH FIBRE 1.5KCAL/ML - Special Liquid	,	SA1379 above 500 ml OP	e – Hospital pharmacy [HP3] ✓ Nutrini Energy Multi Fibre
PAEDIATRIC ORAL FEED – Special Authority see SA1379 above Powder (vanilla)		rmacy [HP3] 850 g OP	✓ Pediasure
PAEDIATRIC ORAL FEED 1.5KCAL/ML - Special Authority see Liquid (strawberry) Liquid (vanilla)	1.60	Hospital pharn 200 ml OP 200 ml OP	nacy [HP3] Fortini Fortini
PAEDIATRIC ORAL FEED 1KCAL/ML – Special Authority see S Liquid (chocolate)	1.07 1.07	lospital pharma 200 ml OP 200 ml OP 200 ml OP 250 ml OP	cy [HP3] Pediasure Pediasure Pediasure Pediasure Pediasure
PAEDIATRIC ORAL FEED WITH FIBRE 1.5KCAL/ML - Special Liquid (chocolate) Liquid (strawberry) Liquid (vanilla)	1.60 1.60	1379 above – F 200 ml OP 200 ml OP 200 ml OP	Hospital pharmacy [HP3] Fortini Multi Fibre Fortini Multi Fibre Fortini Multi Fibre



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 S Liquid			acy [HP3] Nepro HP RTH
RENAL ORAL FEED 1.8 KCAL/ML - Special Authority see SA11 Liquid			[HP3] ✓ Nepro HP (strawberry) ✓ Nepro HP (vanilla)
RENAL ORAL FEED 2 KCAL/ML - Special Authority see SA110	1 above – Hospit	tal pharmacy [H	IP3]
Liquid	2.88	237 ml OP	
	(3.31)		NovaSource Renal
Liquid (apricot) 125 ml	11.52	4 OP	Renilon 7.5
Liquid (caramel) 125 ml	11.52	4 OP	Renilon 7.5

Specialised And Elemental Products

⇒SA1377 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 malabsorption: or
- 2 short bowel syndrome; or
- 3 enterocutaneous fistulas; or
- 4 eosinophilic oesophagitis; or
- 5 inflammatory bowel disease; or
- 6 patients with multiple food allergies requiring enteral feeding.

Notes: Each of these products is highly specialised and would be prescribed only by an expert for a specific disorder. The alternative is hospitalisation.

Elemental 028 Extra is more expensive than other products listed in this section and should only be used where the alternatives have been tried first and/or are unsuitable.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL ELEMENTAL FEED 1KCAL/ML	 Special Authority see SA1377 	above – Ho	spital pharmacy [HP3]
Powder	7.50	76 g OP	Alitraq

	Subsidy (Manufacturer's Price \$	Fully) Subsidised Per 🗸	
ENTERAL/ORAL SEMI-ELEMENTAL FEED 1.5KCAL/ML - Spermacy [HP3] Liquid	ŕ	A1377 on the prev	
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	18 OP / I	ital pharmacy [HP3] Elemental 028 Extra Elemental 028 Extra Elemental 028 Extra
ORAL ELEMENTAL FEED 1KCAL/ML – Special Authority see SA Powder (unflavoured)			al pharmacy [HP3] Vivonex TEN
SEMI-ELEMENTAL ENTERAL FEED 1KCAL/ML - Special Autho	•		– Hospital pharmacy [HP3] Peptisorb

Paediatric Products For Children With Low Energy Requirements

■SA1196 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 Child aged one to eight years; and
- 2 The child has a low energy requirement but normal protein and micronutrient requirements.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Standard Supplements

►SA1554 Special Authority for Subsidy

Initial application — (Children - indications other than exclusive enteral nutrition for Crohn's disease) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 The patient is under 18 years of age; and
- 2 Any of the following:
 - 2.1 The patient has a condition causing malabsorption; or
 - 2.2 The patient has failure to thrive: or
 - 2.3 The patient has increased nutritional requirements; and
- 3 Nutrition goal has been set (eg reach a specific weight or BMI).

Renewal — (Children - indications other than exclusive enteral nutrition for Crohn's disease) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria: All of the following:

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

Subsidised Generic Manufacturer

continued...

- 1 The patient is under 18 years of age; and
 - 2 The treatment remains appropriate and the patient is benefiting from treatment; and
 - 3 A nutrition goal has been set (eg reach a specific weight or BMI).

Initial application — (Children - exclusive enteral nutrition for Crohn's disease) only from a gastroenterologist or dietitian on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 The patient is under 18 years of age; and
- 2 It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease; and
- 3 Dietitians must include the name of the gastroenterologist recommending treatment and the date the gastroenterologist was contacted

Renewal — (Children - exclusive enteral nutrition for Crohn's disease) only from a gastroenterologist, dietitian on the recommendation of a gastroenterologist or vocationally registered general practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 The patient is under 18 years of age; and
- 2 It is to be used as exclusive enteral nutrition for the treatment of Crohn's disease; and
- 3 General Practitioners and dietitians must include the name of the gastroenterologist recommending treatment and the date the gastroenterologist was contacted.

Initial application — (Adults) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

1 Any of the following:

Patient is Malnourished

- 1.1 Patient has a body mass index (BMI) of less than 18.5 kg/m2; or
- 1.2 Patient has unintentional weight loss greater than 10% within the last 3-6 months; or
- 1.3 Patient has a BMI of less than 20 kg/m2 and unintentional weight loss greater than 5% within the last 3-6 months; and
- 2 Any of the following:

Patient has not responded to first-line dietary measures over a 4 week period by:

- 2.1 Increasing their food intake frequency (eg snacks between meals); or
- 2.2 Using high-energy foods (e.g. milkshakes, full fat milk, butter, cream, cheese, sugar etc); or
- 2.3 Using over the counter supplements (e.g. Complan); and
- 3 A nutrition goal has been set (e.g. to reach a specific weight or BMI).

Renewal — (Adults) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 A nutrition goal has been set (eg reach a specific weight or BMI); and
- 2 Any of the following:

Patient is Malnourished

- 2.1 Patient has a body mass index (BMI) of less than 18.5 kg/m2; or
- 2.2 Patient has unintentional weight loss greater than 10% within the last 3-6 months; or
- 2.3 Patient has a BMI of less than 20 kg/m2 and unintentional weight loss greater than 5% within the last 3-6 months.

Initial application — (Short-term medical condition) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

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

continued...

- 1 Is being fed via a nasogastric tube or a nasogastric tube is to be inserted for feeding; or
- 2 Malignancy and is considered likely to develop malnutrition as a result; or
- 3 Is undergoing a bone marrow transplant; or
- 4 Tempomandibular surgery or glossectomy; or
- 5 Both:
 - 5.1 Pregnant; and
 - 5.2 Any of the following:
 - 5.2.1 Patient is in early pregnancy (<13 weeks) and has severe clinical hyperemesis gravidarum requiring admission to hospital and is unlikely to meet her nutritional requirements due to continuing hyperemesis gravidarum; or</p>
 - 5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or
 - 5.2.3 Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met.

Renewal — (Short-term medical condition) 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</p>
 - 5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or
 - 5.2.3 Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met.

Initial application — (Long-term medical condition) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube refer to specific medical condition criteria); or
- 2 Cystic Fibrosis; or
- 3 Liver disease; or
- 4 Chronic Renal failure: or
- 5 Inflammatory bowel disease; or
- 6 Chronic obstructive pulmonary disease with hypercapnia; or
- 7 Short bowel syndrome: or
- 8 Bowel fistula: or
- 9 Severe chronic neurological conditions: or

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

continued...

- 10 Epidermolysis bullosa: or
- 11 AIDS (CD4 count < 200 cells/mm³); or
- 12 Chronic pancreatitis.

Renewal — (Chronic disease OR tube feeding for patients who have previously been funded under Special Authority forms SA0702 or SA0583) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube refer to specific medical condition criteria); or
- 2 Cystic Fibrosis; or
- 3 Liver disease; or
- 4 Chronic Renal failure: or
- 5 Inflammatory bowel disease; or
- 6 Chronic obstructive pulmonary disease with hypercapnia; or
- 7 Short bowel syndrome; or
- 8 Bowel fistula; or
- 9 Severe chronic neurological conditions.

o develo difformo ficultoriogidal confattorio.		
ENTERAL FEED 1.5KCAL/ML - Special Authority see SA1554 on page 235 - Liquid7.00		cy [HP3] ✓ Nutrison Energy
ENTERAL FEED 1KCAL/ML - Special Authority see SA1554 on page 235 - Ho	spital pharmacy	[HP3]
Liquid	250 ml OP	✓ Isosource Standard✓ Osmolite
5.29	1,000 ml OP	✓ Isosource Standard RTH
		Nutrison Standard RTH
		✓ Osmolite RTH
(Osmolite Liquid to be delisted 1 October 2016)		
ENTERAL FEED WITH FIBRE 1 KCAL/ML - Special Authority see SA1554 on	page 235 – Hosr	nital pharmacy [HP3]
Liquid	237 ml OP	
2.65	500 ml OP	✓ Jevity RTH
5.29	1,000 ml OP	✓ Jevity RTH
		✓ Nutrison Multi Fibre
ENTERAL FEED WITH FIBRE 1.5KCAL/ML - Special Authority see SA1554 or	n page 235 – Hos	spital pharmacy [HP3]
Liquid1.75	250 ml OP	,
7.00	1,000 ml OP	Ensure Plus RTH
		Jevity HiCal RTH

Nutrison Energy

Multi Fibre

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

ORAL FEED (POWDER) - Special Authority see SA1554 on page 235 - 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 \$14.90 per 840

g with Endorsement		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.

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 235 - 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 up to \$1.33 per 237 ml			
with Endorsement	0.85	237 ml OP	
	(1.33)		Ensure Plus
	0.72	200 ml OP	
	(1.26)		Ensure Plus
	(1.26)		Fortisip
Liquid (fruit of the forest) - Higher subsidy of \$1.26 per 200	, ,		·
ml with Endorsement	0.72	200 ml OP	
	(1.26)		Ensure Plus
Liquid (strawberry) - Higher subsidy of \$1.26 per 200 ml with	, ,		
Endorsement	0.72	200 ml OP	
	(1.26)		Ensure Plus
	(1.26)		Fortisip
Liquid (vanilla) - Higher subsidy of up to \$1.33 per 237 ml	, ,		
with Endorsement	0.85	237 ml OP	
	(1.33)		Ensure Plus
	0.72	200 ml OP	
	(1.26)		Ensure Plus
	(1.26)		Fortisip

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

ORAL FEED WITH FIBRE 1.5 KCAL/ML - Special Authority see SA1554 on page 235 - Hospital pharmacy [HP3]

Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, or who have severe epidermolysis bullosa. The prescription must be endorsed accordingly.

Liquid (chocolate) - Higher subsidy of \$1.26 per 200 ml with			
Endorsement	0.72	200 ml OP	
	(1.26)		Fortisip Multi Fibre
Liquid (strawberry) - Higher subsidy of \$1.26 per 200 ml with			
Endorsement	0.72	200 ml OP	
	(1.26)		Fortisip Multi Fibre
Liquid (vanilla) - Higher subsidy of \$1.26 per 200 ml with			
Endorsement	0.72	200 ml OP	
	(1.26)		Fortisip Multi Fibre

High Calorie Products

■SA1195 | Special Authority for Subsidy

Initial application — (Cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

All of the following:

- 1 Cystic fibrosis: and
- 2 other lower calorie products have been tried; and
- 3 patient has substantially increased metabolic requirements.

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
 - 1.1 any condition causing malabsorption; or
 - 1.2 faltering growth in an infant/child; or
 - 1.3 increased nutritional requirements: or
 - 1.4 fluid restricted; and
- 2 other lower calorie products have been tried; and
- 3 patient has substantially increased metabolic requirements or is fluid restricted.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per Manufacturer ENTERAL FEED 2 KCAL/ML - Special Authority see SA1195 on the previous page - Hospital pharmacy [HP3] 500 ml OP ✓ Nutrison Concentrated 11.00 1.000 ml OP ✓ Two Cal HN RTH ORAL FEED 2 KCAL/ML - Special Authority see SA1195 on the previous page - Hospital pharmacy [HP3] Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube, or who have severe epidermolysis bullosa. The prescription must be endorsed accordingly. Liquid (vanilla) - Higher subsidy of \$1.90 per 200 ml with 200 ml OP Two Cal HN (1.90)

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]

Powder2.81 1,000 g OP

(5.15) Healtheries Simple
Baking Mix

	Subsidy (Manufacturer's F		Fully Brand or lised Generic Manufacturer
GLUTEN FREE BREAD MIX – Special Authority see SA1107 or Powder		ge – Hospital pha 1,000 g OP	rmacy [HP3] NZB Low Gluten
	(1.102)		Bread Mix
	4.77		
	(8.71)		Bakels Gluten Free Health Bread Mix
	3.51		
	(10.87)		Horleys Bread Mix
GLUTEN FREE FLOUR - Special Authority see SA1107 on the	previous page -	Hospital pharmac	y [HP3]
Powder		2,000 g OP	
	(18.10)		Horleys Flour
GLUTEN FREE PASTA - Special Authority see SA1107 on the p	orevious page – F	Hospital pharmacy	/ [HP3]
Buckwheat Spirals	2.00	250 g OP	
	(3.11)		Orgran
Corn and Vegetable Shells	2.00	250 g OP	
	(2.92)		Orgran
Corn and Vegetable Spirals	2.00	250 g OP	
	(2.92)		Orgran
Rice and Corn Lasagne Sheets		200 g OP	
	(3.82)		Orgran
Rice and Corn Macaroni		250 g OP	•
B: 10 B	(2.92)	050 00	Orgran
Rice and Corn Penne		250 g OP	
Dies and Maine Dasta Crivela	(2.92)	050 = OD	Orgran
Rice and Maize Pasta Spirals		250 g OP	Oraron
Rice and Millet Spirals	(2.92)	250 g OP	Orgran
nice and while ophais	(3.11)	250 g OF	Oraron
Rice and corn spaghetti noodles	` '	375 g OP	Orgran
nice and com spagnetti noodies	(2.92)	3/3 y OF	Orgran
Vegetable and Rice Spirals	` '	250 g OP	Orgini
rogolabio and riloo opiialo	(2.92)	200 g Oi	Orgran
Italian long style spaghetti	` '	220 g OP	J.g.uii
	(3.11)	o g o.	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

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

Supplements For MSUD

AMINOACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE - Special Authority see SA1108 on the previous page

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		30	✔ PKU Anamix Junior
Infant formula		400 g OP	✓ PKU Anamix Infant
Powder (orange)	221.00	500 g OP	XP Maxamaid
, ,	320.00	ŭ	XP Maxamum
Powder (unflavoured)	221.00	500 g OP	XP Maxamaid
,	320.00	ŭ	✓ XP Maxamum
Liquid (berry)	13.10	125 ml OP	PKU Anamix Junior
			LQ
Liquid (orange)	13.10	125 ml OP	✔ PKU Anamix Junior
1 (3 /			LQ
Liquid (unflavoured)	13.10	125 ml OP	✔ PKU Anamix Junior
4 (LQ
Liquid (forest berries), 250 ml carton	540.00	18 OP	✓ Easiphen Liquid
Liquid (juicy berries) 62.5 ml		60 OP	✓ PKU Lophlex LQ 10
Liquid (juicy citrus) 62.5 ml	939.00	60 OP	✓ PKU Lophlex LQ 10
Liquid (juicy orange) 62.5 ml	939.00	60 OP	✓ PKU Lophlex LQ 10
Liquid (juicy berries) 125 ml		30 OP	✓ PKU Lophlex LQ 20
Liquid (juicy citrus) 125 ml		30 OP	✓ PKU Lophlex LQ 20
Liquid (juicy orange) 125 ml		30 OP	✓ PKU Lophlex LQ 20

Foods

LOW PROTEIN BAKING MIX - Special Authority see SA1108 on the previous page - Hospital pharmacy [HP3]
Powder8.22 500 g OP ✓ Loprofin Mix

LOW PROTEIN PASTA - Special Authority see SA1108 on the previous page - Hospital pharmacy [HP3]

LOW PROTEIN PASTA — Special Authority see SATTUG	on the previous page – r	тозрнаг рпанна	acy [np3]	
Animal shapes	11.91	500 g OP	✓ Loprofin	
Lasagne	5.95	250 g OP	✓ Loprofin	
Low protein rice pasta	11.91	500 g OP	✓ Loprofin	
Macaroni		250 g OP	✓ Loprofin	
Penne	11.91	500 g OP	✓ Loprofin	
Spaghetti	11.91	500 g OP	✓ Loprofin	
Spirals	11 91	500 a OP	✓ Lonrofin	

Infant Formulae

For Premature Infants



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

Brand or Generic Manufacturer

⇒SA1198 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 The infant was born before 33 weeks gestation or weighed less than 1.5 kg at birth; and
- 2 Fither:
 - 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 - H	ospital pharr	macy [HP3]	
Powder	6.00	48.5 g OP	Vivonex Pediatric
	53.00	400 g OP	✓ Neocate LCP
Powder (unflavoured)	53.00	400 g OP	✓ Elecare
			✓ Elecare LCP
			✓ Neocate Advance
			✓ Neocate Gold
Powder (vanilla)	53.00	400 g OP	✓ Elecare
,		•	✓ Neocate Advance

(Vivonex Pediatric Powder to be delisted 1 April 2017)

■SA1219 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Any of the following:

- 1 Extensively hydrolysed formula has been reasonably trialled and is inappropriate due to documented severe intolerance or allergy or malabsorption; or
- 2 History of anaphylaxis to cows milk protein formula or dairy products; or
- 3 Eosinophilic oesophagitis.

Note: A reasonable trial is defined as a 2-4 week trial.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

Subsidy (Manufacturer's		ully Brand or sed Generic	
\$	Per	✓ Manufacturer	

continued...

- 1 An assessment as to whether the infant can be transitioned to a cows milk protein, soy, or extensively hydrolysed infant formula has been undertaken; and
- 2 The outcome of the assessment is that the infant continues to require an amino acid infant formula; and
- 3 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

EXTENSIVELY HYDROLYSED FORMULA - Special Authority see SA1557 below - Hospital pharmacy [HP3]

■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 lgE 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

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 SA	1197 above – Retail pharmacy
Powder (unflavoured)35	5.50 300 g OP KetoCal 4:
	✓ Ketocal 3:1
Powder (vanilla)	5.50 300 g OP ✓ KetoCal 4:

Pharmaceuticals and quantities that may be obtained on a Practitioner's Supply Order

ADRENALINE	CEFTRIAXONE
✓ Inj 1 in 1,000, 1 ml ampoule5	✓ Inj 500 mg vial – Subsidy by endorsement –
✓ Inj 1 in 10,000, 10 ml ampoule5	See note on page 965
AMINOPHYLLINE	✓ Inj 1 g vial – Subsidy by endorsement – See
✓ Inj 25 mg per ml, 10 ml ampoule5	note on page 965
AMIODARONE HYDROCHLORIDE	CHARCOAL
✓ Inj 50 mg per ml, 3 ml ampoule	✓ Oral liq 50 g per 250 ml250 ml
AMOXICILLIN	CHLORPROMAZINE HYDROCHLORIDE
✓ Cap 250 mg30	✓ Tab 10 mg30
✓ Cap 500 mg30	✓ Tab 25 mg30
✓ Grans for oral liq 125 mg per 5 ml 200 ml	✓ Tab 100 mg30
✓ Grans for oral liq 250 mg per 5 ml	✓ Inj 25 mg per ml, 2 ml5
✓ Inj 1 g vial5	CIPROFLOXACIN
AMOXICILLIN WITH CLAVULANIC ACID	✓ Tab 250 mg – See note on page 99 5
✓ Tab 500 mg with clavulanic acid 125 mg30	✓ Tab 500 mg – See note on page 99 5
✓ Grans for oral liq amoxicillin 125 mg with	CO-TRIMOXAZOLE
clavulanic acid 31.25 mg per	✓ Tab trimethoprim 80 mg and
5 ml200 ml	sulphamethoxazole 400 mg30
✓ Grans for oral liq amoxicillin 250 mg with	✓ Oral liq trimethoprim 40 mg and
clavulanic acid 62.5 mg per 5 ml200 ml	sulphamethoxazole 200 mg per
ASPIRIN	5 ml200 ml
✓ Tab dispersible 300 mg30	COMPOUND ELECTROLYTES
	✓ Powder for oral soln10
ATROPINE SULPHATE ✓ Inj 600 mcg per ml, 1 ml ampoule5	CONDOMS
	✓ 49 mm144
AZITHROMYCIN	✓ 52 mm144
✓ Tab 500 mg – See note on page 968	✓ 52 mm extra strength144
BENDROFLUMETHIAZIDE [BENDROFLUAZIDE]	✓ 53 mm144
✓ Tab 2.5 mg – See note on page 60150	✓ 53 mm (chocolate)144
BENZATHINE BENZYLPENICILLIN	✓ 53 mm (strawberry)
✓ Inj 900 mg (1.2 million units) in 2.3 ml syringe	54 mm, shaped
	✓ 56 mm
BENZTROPINE MESYLATE	✓ 56 mm, shaped144
✓ Inj 1 mg per ml, 2 ml10	✓ 60 mm144
BENZYLPENICILLIN SODIUM (PENICILLIN G)	CYPROTERONE ACETATE WITH
✓ Inj 600 mg (1 million units) vial5	ETHINYLOESTRADIOL WITH
BLOOD GLUCOSE DIAGNOSTIC TEST METER	✓ Tab 2 mg with ethinyloestradiol 35 mcg and
✓ Meter with 50 lancets, a lancing device and	7 inert tabs168
10 diagnostic test strips – Subsidy by	
endorsement – See note on page 261	DEXAMETHASONE
BLOOD GLUCOSE DIAGNOSTIC TEST STRIP	✓ Tab 0.5 mg – Retail pharmacy-Specialist
✓ Blood glucose test strips – See note on page	
26	DEXAMETHASONE PHOSPHATE
	✓ Inj 4 mg per ml, 1 ml ampoule – See note on
BLOOD KETONE DIAGNOSTIC TEST METER ✓ Meter – See note on page 251	page 845
• Weter - See Hote on page 25	continued

PRACTITIONER'S SUPPLY ORDERS

(continued)		✓ Tab 35 mcg with norethisterone 1 mg and	
✓ Inj 4 mg per ml, 2 ml ampoule – See note on		7 inert tab	
page 84	5	✓ Tab 35 mcg with norethisterone 500 mcg	63
DIAPHRAGM		✓ Tab 35 mcg with norethisterone 500 mcg	
- · · · · · · · · · · · · · · · · · · ·	4	and 7 inert tab	84
✓ 65 mm – See note on page 77✓ 70 mm – See note on page 77		ELLIQUOVA QUILLINI	
		FLUCLOXACILLIN	00
 ✓ 75 mm – See note on page 77 ✓ 80 mm – See note on page 77 		✓ Cap 250 mg	
▶ 80 min – See note on page 77	'	✓ Grans for oral liq 25 mg per ml	
DIAZEPAM		Grans for oral liq 50 mg per ml	
✓ Inj 5 mg per ml, 2 ml ampoule – Subsidy by		✓ Inj 1 g vial	10
endorsement – See note on page 138	5	FLUPENTHIXOL DECANOATE	
✓ Rectal tubes 5 mg		✓ Inj 20 mg per ml, 1 ml	5
✓ Rectal tubes 10 mg		✓ Inj 20 mg per ml, 2 ml	
•		✓ Inj 100 mg per ml, 1 ml	
DICLOFENAC SODIUM			
✓ Inj 25 mg per ml, 3 ml ampoule		FLUPHENAZINE DECANOATE	
✓ Suppos 50 mg	. 10	✓ Inj 12.5 mg per 0.5 ml, 0.5 ml	5
DIGOXIN		✓ Inj 25 mg per ml, 1 ml	
✓ Tab 62.5 mcg	20	✓ Inj 25 mg per ml, 2 ml	5
✓ Tab 250 mcg		✓ Inj 100 mg per ml, 1 ml	5
✓ Tab 250 Hicg	. 30		
DOXYCYCLINE		FUROSEMIDE [FRUSEMIDE]	00
Tab 50 mg	. 30	✓ Tab 40 mg	
✓ Tab 100 mg		✓ Inj 10 mg per ml, 2 ml ampoule	5
•		GLUCAGON HYDROCHLORIDE	
ERGOMETRINE MALEATE	_	✓ Inj 1 mg syringe kit	5
✓ Inj 500 mcg per ml, 1 ml ampoule	5	• iiij i iiig syiiiigs kkiiiiiiiiiiiiiiiiiiiiiiiiiiiiiii	
ERYTHROMYCIN ETHYL SUCCINATE		GLUCOSE [DEXTROSE]	
✓ Tab 400 mg	20	✓ Inj 50%, 10 ml ampoule	5
✓ Grans for oral liq 200 mg per 5 ml		✓ Inj 50%, 90 ml bottle	5
✓ Grans for oral liq 400 mg per 5 ml		OLYGERY TRINITRATE	
Charle for oral liq 100 mg por 0 mi		GLYCERYL TRINITRATE	400
ERYTHROMYCIN STEARATE		✓ Tab 600 mcg	
Tab 250 mg	. 30	✓ Oral pump spray, 400 mcg per dose	
ETHINNI OFOTRADIOL MITH DECOCEOTRE		✓ Oral spray, 400 mcg per dose	250 dose
ETHINYLOESTRADIOL WITH DESOGESTREL		GLYCOPYRRONIUM BROMIDE	
Tab 20 mcg with desogestrel 150 mcg and		✓ Inj 200 mcg per ml, 1 ml ampoule	10
7 inert tab	84	Fing 200 mag per mi, 1 mi ampoule	
Tab 30 mcg with desogestrel 150 mcg and		HALOPERIDOL	
7 inert tab	84	✓ Tab 500 mcg	30
ETHINYLOESTRADIOL WITH LEVONORGESTREL		✓ Tab 1.5 mg	30
		✓ Tab 5 mg	30
✓ Tab 20 mcg with levonorgestrel 100 mcg and	0.4	✓ Oral liq 2 mg per ml	200 ml
7 inert tab	04	✓ Inj 5 mg per ml, 1 ml ampoule	5
✓ Tab 50 mcg with levonorgestrel 125 mcg and	0.4		
7 inert tab		HALOPERIDOL DECANOATE	_
Tab 30 mcg with levonorgestrel 150 mcg	. 63	✓ Inj 50 mg per ml, 1 ml	5
✓ Tab 30 mcg with levonorgestrel 150 mcg and		✓ Inj 100 mg per ml, 1 ml	5
7 inert tab	84	HYDROCORTISONE	
ETHINYLOESTRADIOL WITH NORETHISTERONE		✓ Inj 100 mg vial	5
✓ Tab 35 mcg with norethisterone 1 mg	63	, ,	
- 145 00 may with norothistorone i my	. 00	С	ontinued

continued)	MORPHINE SULPHATE
HYDROXOCOBALAMIN	✓ Inj 5 mg per ml, 1 ml ampoule – Only on a
✓ Inj 1 mg per ml, 1 ml ampoule6	controlled drug form5
HYOSCINE N-BUTYLBROMIDE	✓ Inj 10 mg per ml, 1 ml ampoule – Only on a controlled drug form
✓ Inj 20 mg, 1 ml5	✓ Inj 15 mg per ml, 1 ml ampoule – Only on a
INTRA-UTERINE DEVICE	controlled drug form5
✓ IUD 29.1 mm length × 23.2 mm width40	✓ Inj 30 mg per ml, 1 ml ampoule – Only on a
✓ IUD 33.6 mm length × 29.9 mm width	controlled drug form5
✓ IUD 35.5 mm length × 19.6 mm width40	NALOVONE HVDDOOHLODIDE
IPRATROPIUM BROMIDE	NALOXONE HYDROCHLORIDE ✓ Inj 400 mcg per ml, 1 ml ampoule
✓ Aerosol inhaler, 20 mcg per dose	
CFC-free	NICOTINE
✓ Nebuliser soln, 250 mcg per ml, 1 ml40	✓ Patch 7 mg – See note on page 165
✓ Nebuliser soln, 250 mcg per ml, 2 ml40	✓ Patch 14 mg – See note on page 16528 ✓ Patch 21 mg – See note on page 16528
IVERMECTIN	✓ Lozenge 1 mg – See note on page 165216
✓ Tab 3 mg – See note on page 72100	✓ Lozenge 2 mg – See note on page 165216
	✓ Gum 2 mg (Classic) – See note on page 165384
KETONE BLOOD BETA-KETONE ELECTRODES	✓ Gum 2 mg (Fruit) – See note on page 165
✓ Test strip10	✓ Gum 2 mg (Mint) – See note on page 165
LEVONORGESTREL	✓ Gum 4 mg (Classic) – See note on page 165 384
Tab 30 mcg	✓ Gum 4 mg (Fruit) – See note on page 165384
✓ Tab 1.5 mg5	✓ Gum 4 mg (Mint) – See note on page 165384
LIDOCAINE (LICALOCAINE)	NORETHISTERONE
LIDOCAINE [LIGNOCAINE]	✓ Tab 350 mcg84
✓ Gel 2%, 10 ml urethral syringe – Subsidy by	✓ Tab 5 mg30
endorsement – See note on page 1315	•
LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE	OXYTOCIN ✓ Inj 5 iu per ml, 1 ml ampoule5
✓ Inj 1%, 5 ml ampoule25	✓ Inj 10 iu per ml, 1 ml ampoule5
✓ Inj 2%, 5 ml ampoule5	Fing to ta per fin, 1 fin ampoule
✓ Inj 1%, 20 ml ampoule	OXYTOCIN WITH ERGOMETRINE MALEATE
✓ Inj 2%, 20 ml ampoule5	✓ Inj 5 iu with ergometrine maleate 500 mcg
LIDOCAINE [LIGNOCAINE] WITH CHLORHEXIDINE	per ml, 1 ml5
✓ Gel 2% with chlorhexidine 0.05%, 10 ml	PARACETAMOL
urethral syringes – Subsidy by	✓ Tab 500 mg30
endorsement – See note on page 1325	✓ Oral liq 120 mg per 5 ml
LOPERAMIDE HYDROCHLORIDE	✓ Oral liq 250 mg per 5 ml100 ml
✓ Tab 2 mg30	PEAK FLOW METER
✓ Cap 2 mg	✓ Low range10
	✓ Normal range
MASK FOR SPACER DEVICE	•
✓ Small – See note on page 21220	PETHIDINE HYDROCHLORIDE
MEDROXYPROGESTERONE ACETATE	✓ Inj 50 mg per ml, 1 ml – Only on a controlled
✓ Inj 150 mg per ml, 1 ml syringe5	drug form
	✓ Inj 50 mg per ml, 2 ml – Only on a controlled
METOCLOPRAMIDE HYDROCHLORIDE ✓ Inj 5 mg per ml, 2 ml ampoule	drug form5
Fing 5 mg per mi, 2 mi ampoule	PHENOXYMETHYLPENICILLIN (PENICILLIN V)
METRONIDAZOLE	✓ Cap 250 mg30
✓ Tab 200 mg30	continued

PRACTITIONER'S SUPPLY ORDERS

continued)
✓ Cap 500 mg
PHENYTOIN SODIUM ✓ Inj 50 mg per ml, 2 ml ampoule
PHYTOMENADIONE ✓ Inj 2 mg per 0.2 ml
PIPOTHIAZINE PALMITATE ✓ Inj 50 mg per ml, 1 ml – Subsidy by endorsement – See note on page 149
PREDNISOLONE ✓ Oral liq 5 mg per ml – See note on page 8430 ml
PREDNISONE ✓ Tab 5 mg30
PREGNANCY TESTS - HCG URINE ✓ Cassette
PROCAINE PENICILLIN ✓ Inj 1.5 g in 3.4 ml syringe5
PROCHLORPERAZINE ✓ Tab 5 mg
PROMETHAZINE HYDROCHLORIDE ✓ Inj 25 mg per ml, 2 ml ampoule
SALBUTAMOL ✓ Inj 500 mcg per ml, 1 ml5

✓ Aerosol inhaler, 100 mcg per dose CFC
free
SALBUTAMOL WITH IPRATROPIUM BROMIDE Nebuliser soln, 2.5 mg with ipratropium bromide 0.5 mg per vial, 2.5 ml ampoule20
SILVER SULPHADIAZINE ✓ Crm 1%250 g
SODIUM BICARBONATE ✓ Inj 8.4%, 50 ml 5 ✓ Inj 8.4%, 100 ml 5
SODIUM CHLORIDE ✓ Inj 0.9%, bag – See note on page 52
✓ Inj 0.9%, 5 ml – See note on page 52
SPACER DEVICE ✓ 220 ml (single patient) 20 ✓ 510 ml (single patient) 20 ✓ 800 ml 20
TRIMETHOPRIM ✓ Tab 300 mg30
VERAPAMIL HYDROCHLORIDE ✓ Inj 2.5 mg per ml, 2 ml ampoule
WATER ✓ Purified for inj, 5 ml – See note on page 53
ZUCLOPENTHIXOL DECANOATE

✓ Inj 200 mg per ml, 1 ml......5

Leeston

I incoln

Oxford

Rakaia

Rolleston

Rotherham

Templeton

Waikari

Methven

Rural Areas for Practitioner's Supply Orders

Tairua

NORTH ISLAND Northland DHB Dargaville Hikurangi Kaeo Kaikohe

Kaitaia Kawakawa Kerikeri Mangonui Maungaturoto Moerewa

Naunauru Paihia Rawene Ruakaka Russell Tutukaka Waipu Whangaroa Waitemata DHB

Helensville Huapai Kumeu Snells Beach Waimauku Warkworth Wellsford

Auckland DHB Great Barrier Island

Oneroa Ostend

Counties Manukau DHB

Tuakau Waiuku

Waikato DHB Coromandel Huntly Kawhia Matamata Morrinsville

Ngatea Otorohanga Paeroa Pauanui Reach Putaruru Raglan

Taumarunui Te Aroha Te Kauwhata Te Kuiti Tokoroa Waihi Whangamata Whitianga

Bay of Plenty DHB Edaecumbe Katikati Kawerau Murupara Opotiki Taneatua Te Kaha Waihi Reach Whakatane

Lakes DHB Mangakino Turangi

Tairawhiti DHB Ruatoria Te Araroa Te Karaka Te Puia Springs Tikitiki Tokomaru Bay Tolaga Bay

Taranaki DHB Eltham Inglewood Manaia Oakura Okato Opunake Patea Stratford Waverley

Hawkes Bay DHB Chatham Islands Waipawa Waipukurau Wairoa

Whanganui DHB Bulls

Marton Ohakune Raetihi Taihape Waiouru

Dannevirke Foxton I evin Otaki Pahiatua Shannon

Woodville

MidCentral DHB

South Canterbury DHB Fairlie Wairarapa DHB Geraldine Carteron Pleasant Point Featherston Temuka Grevtown Twizel Martinborough Waimate

SOUTH ISLAND

Nelson/Marlborough DHB

Havelock Southern DHB Manua Alexandra Motueka Balclutha Murchison Cromwell Picton Gore Takaka Kurow Wakefield Lawrence

Lumsden West Coast DHB Mataura Dobson Milton Grevmouth Oamaru Hokitika Oban Karamea Otautau Reefton Outram South Westland Owaka Westport Palmerston Whataroa Queenstown Canterbury DHB Ranfurly

Akaroa Riverton Roxburah Amberlev Tananui Amuri Cheviot Te Anau Darfield Tokonui Diamond Harbour Tuatapere Wanaka Hanmer Springs Kaikoura Winton

SECTION F: PART I

A Community Pharmaceutical identified with a * within the other sections of the Pharmaceutical Schedule:

- a) is exempt from any requirement to dispense in Monthly Lots;
- b) will only be subsidised if it is dispensed in a 90 Day Lot unless it is under the Dispensing Frequency Rule.

A Community Pharmaceutical that is an oral contraceptive and that is identified with a * within the other sections of the Pharmaceutical Schedule:

- a) is exempt from any requirement to dispense in Monthly Lots;
- b) will only be subsidised if it is dispensed in a 180 Day Lot unless it is 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.

The following Community Pharmaceuticals are identified with a \triangle 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

Cordarone-X

Cordarone-X

Tambocor

INSULIN NEUTRAL

CARDIOVASCULAR SYSTEM

AMIODARONE HYDROCHLORIDE Tab 100 mg Corda

Tab 200 mg

DISOPYRAMIDE PHOSPHATE

FLECAINIDE ACETATE

Tab 50 mg

Cap long-acting 100 mg
Cap long-acting 200 mg
Tambocor CR
Tambocor CR

MEXILETINE HYDROCHLORIDE

MINOXIDIL

NICORANDIL

PROPAFENONE HYDROCHLORIDE

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

DESMOPRESSIN ACETATE

Nasal drops 100 mcg Minirin

per ml

Nasal spray 10 mcg per Desmopressin-PH&T

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 are required, under the Code of Ethics of the Pharmacy Council of New Zealand, to endeavour to use safety caps when dispensing any of the medicines listed in Section G in an oral liquid formulation pursuant to a prescription or Practitioner's Supply Order. This includes all proprietary and extemporaneously compounded oral liquid preparations of those pharmaceuticals listed in Section G of the Pharmaceutical Schedule. These medicines will be identified throughout Section B of the Pharmaceutical Schedule with the symbol '‡'.

Exemptions

Oral liquid preparations of the pharmaceuticals listed in Section G of the Pharmaceutical Schedule will be dispensed in a container with a safety cap unless:

- the practitioner has endorsed the Prescription or Practitioner's Supply Order, stating that, the Pharmaceutical is not to be dispensed in a container with a safety cap; or
- the Contractor has annotated the Prescription or Practitioner's Supply Order stating that, because of infirmity of the particular person, the Pharmaceutical to be used by that person should not be dispensed in a container with a safety cap; or
- the Pharmaceutical is packaged in an Original Pack so designed that on the professional judgement of the Contractor, transfer to a container with a safety cap would be inadvisable or a retrograde procedure.

Reimbursment

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 lig 30 mg (6 mg el- Ferodan

emental) per 1 ml

CARDIOVASCULAR SYSTEM

AMILORIDE HYDROCHLORIDE

Oral liq 1 mg per ml Biomed

CAPTOPRIL

Oral lig 5 mg per ml Capoten

CHI OROTHIAZIDE

Oral lig 50 mg per ml Biomed

DIGOXIN

Oral liq 50 mcg per ml Lanoxin

FUROSEMIDE [FRUSEMIDE]

Oral lig 10 mg per ml Lasix

SPIRONOLACTONE

Oral liq 5 mg per ml Biomed

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

LEVOTHYROXINE

Tab 25 mcg Synthroid Eltroxin

Tab 50 mcg

Synthroid Tab 100 mcg Eltroxin

Synthroid

(Extemporaneously compounded oral liquid preparations)

LEVOTHYROXINE (MERCURY PHARMA)

Tab 50 mcg Mercury Pharma

Tab 100 mcg Mercury Pharma

(Extemporaneously compounded oral liquid preparations)

INFECTIONS - AGENTS FOR SYSTEMIC USE

QUININE SULPHATE

Tab 300 mg 0.300

(Extemporaneously compounded oral liquid preparations)

NERVOUS SYSTEM

ALPRAZOLAM

Tab 250 mcg Xanax Xanax Tab 500 mcg

Tab 1 mg Xanax

(Extemporaneously compounded oral liquid preparations)

CARBAMAZEPINE

Oral lig 20 mg per ml Tegretol CLOBAZAM

Frisium Tab 10 mg

(Extemporaneously compounded oral liquid preparations)

CLONAZEPAM

Oral drops 2.5 mg per Rivotril

DIAZEPAM

Tab 2 mg Arrow-Diazepam Arrow-Diazepam Tab 5 mg

(Extemporaneously compounded oral liquid preparations)

ETHOSUXIMIDE

Oral lig 250 mg per 5 ml Zarontin

LORAZEPAM

Tab 1 mg Ativan Ativan Tab 2.5 mg

(Extemporaneously compounded oral liquid preparations)

I ORMFTAZFPAM

Tab 1 mg Noctamid

(Extemporaneously compounded oral liquid preparations)

METHADONE HYDROCHLORIDE

Oral liq 2 mg per ml Biodone Biodone Forte Oral lig 5 mg per ml

Biodone Extra Forte Oral lig 10 mg per ml

MORPHINE HYDROCHLORIDE

Oral lig 1 mg per ml RA-Morph Oral lig 2 mg per ml RA-Morph Oral lig 5 mg per ml RA-Morph

Oral lig 10 mg per ml RA-Morph

NITRAZFPAM

Nitrados Tab 5 mg

(Extemporaneously compounded oral liquid preparations)

OXAZEPAM

Tab 10 mg Ox-Pam Tab 15 mg Ox-Pam

(Extemporaneously compounded oral liquid preparations)

OXYCODONE HYDROCHLORIDE

Oral lig 5 mg per 5 ml OxvNorm

PARACETAMOL

Oral lig 120 mg per 5 ml Paracare

Oral lig 250 mg per 5 ml Paracare Double Strength

PHENYTOIN SODIUM

Oral lig 30 mg per 5 ml Dilantin

SAFETY CAP MEDICINES

SODIUM VALPROATE

Oral liq 200 mg per 5 ml Epilim S/F Liquid

Epilim Syrup

TEMAZEPAM

Tab 10 mg Normison

(Extemporaneously compounded oral liquid preparations)

TRIAZOLAM

Tab 125 mcg Hypam Tab 250 mcg Hypam

(Extemporaneously compounded oral liquid preparations)

RESPIRATORY SYSTEM AND ALLERGIES

CETIRIZINE HYDROCHLORIDE

Oral liq 1 mg per ml Histaclear

CHLORPHENIRAMINE MALEATE

Oral liq 2 mg per 5 ml Histafen

DEXTROCHLORPHENIRAMINE MALEATE

Oral liq 2 mg per 5 ml Polaramine

PROMETHAZINE HYDROCHLORIDE

Oral liq 1 mg per 1 ml Allersoothe

SALBUTAMOL

Oral lig 400 mcg per ml Ventolin

THEOPHYLLINE

Oral liq 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

owder AFT

(Extemporaneously compounded oral liquid preparations)

PHENOBARBITONE SODIUM

Powder MidWest

(Extemporaneously compounded oral liquid preparations)

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

Vaccinations

ADULT DIPHTHERIA AND TETANUS VACCINE - [Xpharm]

Ini 2 IU diphtheria toxoid with 20 IU tetanus toxoid in 0.5 ml0.00 5 ADT Booster ✔ ADT Booster

Any of the following:

- 1) For vaccination of patients aged 45 and 65 years old; or
- 2) For vaccination of previously unimmunised or partially immunised patients: or
- 3) For revaccination following immunosuppression; or
- 4) For boosting of patients with tetanus-prone wounds: or
- 5) For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician.

Note: Please refer to the Immunisation Handbook for appropriate schedule for catch up programmes.

BACILLUS CALMETTE-GUERIN VACCINE - [Xpharm]

For infants at increased risk of tuberculosis. Increased risk is defined as:

- 1) living in a house or family with a person with current or past history of TB; or
- 2) having one or more household members or carers who within the last 5 years lived in a country with a rate of TB > or equal to 40 per 100,000 for 6 months or longer; or
- 3) during their first 5 years will be living 3 months or longer in a country with a rate of TB > or equal to 40 per 100,000 Note a list of countries with high rates of TB are available at www.health.govt.nz/tuberculosis (search for downloads) or www.bcgatlas.org/index.php.
- Ini Mycobacterium bovis BCG (Bacillus Calmette-Guerin).

Danish strain 1331, live attenuated, vial with diluent0.00 BCG Vaccine

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 per-

tussis toxoid, 8 mcg pertussis filamentous haemagluttinin 10 Boostrix ' Boostrix '

	Subsidy (Manufacturer's Price)	Si Per	Fully ubsidised	Brand or Generic Manufacturer
DIPHTHERIA, TETANUS, PERTUSSIS AND POLIO VACCINE — Funded for any of the following: 1) A single dose for children up to the age of 7 who have co 2) A course of four vaccines is funded for catch up program immunisation; or 3) An additional four doses (as appropriate) are funded for or post splenectomy; pre- or post solid organ transplant, or 4) Five doses will be funded for children requiring solid organ Note: Please refer to the Immunisation Handbook for appropring 30 IU diphtheria toxoid with 40 IU tetanus toxoid, 25 mcg pertussis stoxoid, 25 mcg pertussis filamentous haemagluttinin, 8 mcg pertactin and 80 D-antigen units poliomyelitis virus in 0.5ml syringe	mpleted primary immumes for children (to the (re-)immunisation for prenal dialysis and other transplantation.	e age o	of 10 years s post HSC erely immu ogrammes	CT, or chemotherapy; pre inosuppressive regimens
DIPHTHERIA, TETANUS, PERTUSSIS, POLIO, HEPATITIS B AN Funded for patients meeting any of the following criteria: 1) Up to four doses for children up to and under the age of 1 2) An additional four doses (as appropriate) are funded for are patients post haematopoietic stem cell transplantatic organ transplant, renal dialysis and other severely immur 3) Up to five doses for children up to and under the age of 1 Note: A course of up-to four vaccines is funded for catch up to complete full primary immunisation. Please refer to the In programmes. Inj 30IU diphtheriatoxoid with 40IU tetanustoxoid, 25mcg pertussistoxoid, 25mcg pertussisfilamentoushaemagluttinin, 8 mcgpertactin, 80 D-AgUpoliovirus, 10mcghepatitisB-surfaceantigen in 0.5ml syringe	10 for primary immunis (re-)immunisation for con, or chemotherapy; posuppressive regimer 0 receiving solid orgal programmes for child promunisation Handbool	FLUEN sation; ochildren ore or p ns; or n transp Iren (up	ZAE TYPE or up to and oost splend olantation. to and up e appropri	I under the age of 10 who ectomy; pre- or post solic
HAEMOPHILUS INFLUENZAE TYPE B VACCINE – [Xpharm] One dose for patients meeting any of the following: 1) For primary vaccination in children; or 2) An additional dose (as appropriate) is funded for (re-)im tation, or chemotherapy; functional asplenic; pre or pos cochlear implants, renal dialysis and other severely immu. 3) For use in testing for primary immunodeficiency disease paediatrician. Inj 10 mcg vial with diluent syringe	at splenectomy; pre- of unosuppressive regimes, on the recommend	s post I or post ens; or dation o	naematopi solid orga of an interi	oietic stem cell transplan n transplant, pre- or pos nal medicine physician o
Inj 1440 ELISA units in 1 ml syringeInj 720 ELISA units in 0.5 ml syringe		1	✓ <u>Ha</u>✓ <u>Ha</u>	<u>avrix</u> avrix Junior

	INATIONAL		MISAII	ON SCHEDULE
()	Subsidy Manufacturer's Price) \$	Sı Per	Fully obsidised	Brand or Generic Manufacturer
HEPATITIS B RECOMBINANT VACCINE - [Xpharm]				
Inj 5 mcg per 0.5 ml vial	0.00	1	✓ <u>H</u>	BvaxPRO
Funded for patients meeting any of the following criteria:				
1) for household or sexual contacts of known acute hepatitis B	patients or hepatit	is B carr	iers; or	
for children born to mothers who are hepatitis B surface ant				
for children up to and under the age of 18 years inclusive wh	no are considered n	ot to ha	ve achiev	ed a positive serology and
require additional vaccination; or				
for HIV positive patients; or				
5) for hepatitis C positive patients; or				
6) for patients following non-consensual sexual intercourse; or				
7) for patients following immunosuppression; or				
8) for transplant patients; or				
following needle stick injury.				
Inj 10 mcg per 1 ml vial	0.00	1	✓ <u>H</u>	BvaxPRO
Funded for patients meeting any of the following criteria:				
for household or sexual contacts of known acute hepatitis B			iers; or	
2) for children born to mothers who are hepatitis B surface ant	0 1 0/1			
3) for children up to and under the age of 18 years inclusive wh	no are considered n	ot to ha	ve achiev	ed a positive serology and
require additional vaccination; or				
4) for HIV positive patients; or				
5) for hepatitis C positive patients; or				
6) for patients following non-consensual sexual intercourse; or7) for patients following immunosuppression; or				
8) for transplant patients; or				
9) following needle stick injury.				
, , ,	0.00	1		BvaxPRO
Inj 40 mcg per 1 ml vial Funded for any of the following criteria:	0.00	1	V <u>n</u>	DVAXPHU
1) for dialysis patients; or				
2) for liver or kidney transplant patient.				
, , , ,	[V1			
HUMAN PAPILLOMAVIRUS (6, 11, 16 AND 18) VACCINE [HPV] —				
Maximum of three doses for patient meeting any of the following 1) Females aged under 20 years old; or	criteria:			
2) Patients aged under 26 years old with confirmed HIV infection	on: or			
Fatients aged under 20 years old with commined rife infections. For use in transplant (including stem cell) patients; or	011, 01			
4) An additional dose for patients under 26 years of age post of a second control of the /li>	hemotherany			
		10		audaail
Inj 120 mcg in 0.5 ml syringe	0.00	10 1	_	<u>ardasil</u> ardasil
		1	<u> </u>	aiuaəii

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

INFLUENZA VACCINE - [Xpharm]

- A) is available each year for patients who meet the following criteria, as set by PHARMAC:
 - a) all people 65 years of age and over; or
 - b) people under 65 years of age who:
 - i) have any of the following cardiovascular diseases:
 - a) ischaemic heart disease, or
 - b) congestive heart failure, or
 - c) rheumatic heart disease, or
 - d) congenital heart disease, or
 - e) 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 and under who have been hospitalised for respiratory illness or have a history of significant respiratory illness;

Unless meeting the criteria set out above, the following conditions are excluded from funding:

- a) asthma not requiring regular preventative therapy,
- b) hypertension and/or dyslipidaemia without evidence of end-organ disease.
- B) Doctors are the only Contractors entitled to claim payment from the Funder for the supply of influenza vaccine to patients eligible under the above criteria for subsidised immunisation and they may only do so in respect of the influenza vaccine listed in the Pharmaceutical Schedule.
- C) Individual DHBs may fund patients over and above the above criteria. The claiming process for these additional patients should be determined between the DHB and Contractor, or
- D) Stock of the seasonal influenza vaccine is typically available from February until late July with suppliers being required to ensure supply until at least 30 June. Exact start and end dates for each season will be notified each year.

nj 45 mcg in 0.5 ml syringe	90.00	10	Fluarix
, , ,			✓ Influya

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

Inj 1000 TCID50 measles, 12500 TCID50 mumps and

MENINGOCOCCAL (GROUPS A, C, Y AND W-135) CONGUGATE VACCINE - [Xpharm]

Any of the following:

- 1) Up to three doses and a booster every five years for patients pre- and post splenectomy and for patients with functional or anatomic asplenia, HIV, complement deficiency (acquired or inherited), or pre or post solid organ transplant; or
- 2) One dose for close contacts of meningococcal cases; or
- 3) A maximum of two doses for bone marrow transplant patients; or
- 4) A maximum of two doses for patients following immunosuppression*.

Note: children under seven years of age require two doses 8 weeks apart, a booster dose three years after the primary series and then five yearly.

*Immunosuppression due to steroid or other immunosuppressive therapy must be for a period of greater than 28 days.

Inj 4 mcg of each meningococcal polysaccharide conjugated

to a total of approximately 48 mcg of diphtheria toxoid

carrier per 0.5 ml vial0.00

Menactra

MENINGOCOCCAL C CONGUGATED 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.

Subsidy Fully Brand or (Manufacturer's Price) Subsidised Generic Per Manufacturer \$ PNEUMOCOCCAL (PCV13) VACCINE - [Xpharm] Any of the following: 1) A primary course of four doses for previously unvaccinated individuals up to the age of 59 months inclusive; or 2) Up to three doses as appropriate to complete the primary course of immunisation for individuals under the age of 59 months who have received one to three doses of PCV10: or 3) One dose is funded for high risk children (over the age of 17 months and up to the age of 18) who have previously received four doses of PCV10: or 4) Up to an additional four doses (as appropriate) are funded for (re-)immunisation of patients with HIV, for patients post haematopoietic stem cell transplantation, or chemotherapy; pre- or post splenectomy; functional asplenia, pre- or postsolid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, or primary immunodeficiency; or 5) For use in testing for primary immunodeficiency diseases, on the recommendation of an internal medicine physician or paediatrician. Note: please refer to the Immunisation Handbook for the appropriate schedule for catch up programmes Prevenar 13 1 ✔ Prevenar 13 PNEUMOCOCCAL (PPV23) POLYSACCHARIDE VACCINE - [Xpharm] Either: 1) Up to three doses (as appropriate) for patients with HIV, for patients post haematopoietic stem cell transplant, or chemotherapy; pre- or post-splenectomy or with functional asplenia, pre- or post-solid organ transplant, renal dialysis, complement deficiency (acquired or inherited), cochlear implants, or primary immunodeficiency; or 2) Up to two doses are funded for high risk children to the age of 18. Inj 575 mcg in 0.5 ml prefilled syringe (25 mcg of each 23 pneumococcal serotype)0.00 1 Pneumovax 23 POLIOMYELITIS VACCINE - [Xpharm] Up to three doses for patients meeting either of the following: 1) For partially vaccinated or previously unvaccinated individuals; or 2) For revaccination following immunosuppression. Note: Please refer to the Immunisation Handbook for appropriate schedule for catch-up programmes. ✓ IPOL ROTAVIRUS LIVE REASSORTANT ORAL VACCINE - [Xpharm] Maximum of three doses for patients meeting the following: 1) first dose to be administered in infants aged under 15 weeks of age; and 2) no vaccination being administered to children aged 8 months or over. Oral susp G1, G2, G3, G4, P1(8)11.5 million CCID50 units 10 ✓ RotaTea

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

VARICELLA VACCINE [CHICKEN POX VACCINE] - [Xpharm]

Maximum of two doses for any of the following:

- 1) For non-immune patients:
- 2) a) with chronic liver disease who may in future be candidates for transplantation; or
 - b) with deteriorating renal function before transplantation; or
 - c) prior to solid organ transplant; or
 - d) prior to any elective immunosuppression*.
- 3) For patients at least 2 years after bone marrow transplantation, on advice of their specialist.
- 4) For patients at least 6 months after completion of chemotherapy, on advice of their specialist.
- 5) For HIV positive non immune to varicella with mild or moderate immunosuppression on advice of HIV specialist.
- 6) For patients with inborn errors of metabolism at risk of major metabolic decompensation, with no clinical history of varicella.
- 7) For household contacts of paediatric patients who are immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella.
 8) For household contacts of adult patients who have no clinical history of varicella and who are severely immunocompro-
- 8) For household contacts of adult patients who have no clinical history of varicella and who are severely immunocompromised, or undergoing a procedure leading to immune compromise where the household contact has no clinical history of varicella.

* immunosuppression due to steroid or other immunosuppression	ve therapy must be	e for a treat	tment perio	od of greater tha	n 28 days
Inj 2000 PFU vial with diluent	0.00	1	✓ Vai	rilrix	-

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