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Introducing PHARMAC

PHARMAC, the Pharmaceutical Management Agency, is a Crown entity established pursuant to the New Zealand Public Health and Disability Act 2000 (The Act). The primary objective of PHARMAC is to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided.

The PHARMAC Board consists of up to five members appointed by the Minister of Health. All decisions relating to PHARMAC's operation are made by or under the authority of the Board. In particular, Board members decide on the strategic direction of PHARMAC and may decide which community pharmaceuticals should be subsidised and at what levels, and determine national prices for some pharmaceuticals to be purchased by and used in DHB Hospitals, and whether or not special conditions are to be applied to such purchases.

Members of the PHARMAC Board

Stuart McLauchlan
Anne Kolbe

Kura Denness
Jens Mueller

David Kerr

Decisions taken by the PHARMAC Board members, or made under the authority of the Board, incorporate a balanced view of the needs of prescribers and patients. The aim is to achieve long-term gains and efficient ways of making pharmaceuticals available to the community and for DHB Hospitals to purchase them.

The following attend PHARMAC's Board meetings as observers

- Murray Georgel, CE MidCentral DHB
- Kate Russell, Chair Consumer Advisory Committee
- Carl Burgess, Chair Pharmacology and Therapeutics Advisory Committee (PTAC)

The functions of PHARMAC are to perform the following, within the amount of funding provided to it in the Pharmaceutical Budget or to DHBs from their own budgets for the use of pharmaceuticals in their hospitals, as applicable, and in accordance with its annual plan and any directions given by the Minister (Section 103 of the Crown Entities Act):

- a) to maintain and manage a pharmaceutical schedule that applies consistently throughout New Zealand, including determining eligibility and criteria for the provision of subsidies;
- b) to manage incidental matters arising out of (a), including in exceptional circumstances providing for subsidies for the supply of pharmaceuticals not on the pharmaceutical schedule;
- c) to engage as it sees fit, but within its operational budget, in research to meet its objectives as set out in Section 47(a) of the Act;
- d) to promote the responsible use of pharmaceuticals;
- e) to manage the purchasing of any or all pharmaceuticals, whether used either in a hospital or outside it, on behalf of DHBs;
- f) any other functions given to PHARMAC by or under any enactment or authorised by the Minister.

The policies and criteria set out in the Pharmaceutical Schedule and PHARMAC's Operating Policies and Procedures arise out of, and are designed to help PHARMAC achieve and perform, PHARMAC's objective and functions under the Act.

However PHARMAC may, having regard to its public law obligations, depart from the strict application of those policies and criteria in certain exceptional cases where it considers this necessary or appropriate in the proper exercise of its statutory discretion and to give effect to its objective and functions, particularly with respect to:

- Determining eligibility and criteria for the provision of subsidies; and
- In exceptional circumstances providing for subsidies for the supply of pharmaceuticals not on the Pharmaceutical Schedule.

Decision Criteria

PHARMAC updates the Pharmaceutical Schedule at regular intervals to notify prescribers, pharmacists, hospital managers and patients of changes to Community Pharmaceutical subsidies and the prices for Hospital Pharmaceuticals. In making decisions about amendments to the Pharmaceutical Schedule, PHARMAC is guided by its Operating Policies and Procedures, as amended or supplemented from time to time. PHARMAC takes into account the following criteria when making decisions about Community Pharmaceuticals:

- the health needs of all eligible people within New Zealand (eligible defined by the Government's then current rules of eligibility);
- the particular health needs of Māori and Pacific peoples;
- the availability and suitability of existing medicines, therapeutic medical devices and related products and related things;
- the clinical benefits and risks of pharmaceuticals;
- the cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services;
- the budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule;
- the direct cost to health service users;

- the Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere; and
- such other criteria as PHARMAC thinks fit. PHARMAC will carry out appropriate consultation when it intends to take any such "other criteria" into account.

The Operating Policies and Procedures, including any supplements, also describe the way in which PHARMAC determines the level of subsidy or purchase price payable for each Community Pharmaceutical or Hospital Pharmaceutical, respectively.

The decision criteria for Hospital Pharmaceuticals are set out in the hospital supplement to the Operating Policies and Procedures and in the introductory part of Section H of the Pharmaceutical Schedule.

Copies of PHARMAC's Operating Policies and Procedures and of any applicable supplements are available on the PHARMAC website (www.pharmac.govt.nz), or on request.

PHARMAC and the Pharmaceutical Schedule:

PHARMAC manages the national Pharmaceutical Schedule, which lists:

- Pharmaceuticals available in the community and subsidised by the Government with funding from the Pharmaceutical Budget; and
- some Pharmaceuticals purchased by DHBs for use in their hospitals, and includes those Hospital Pharmaceuticals for which national prices have been negotiated by PHARMAC.

In the community approximately 1848 Pharmaceuticals are subsidised by the Government. Most are available to all eligible people within New Zealand on prescription by a medical doctor. Some are listed with guidelines or conditions such as 'only if prescribed for a dialysis patient' or 'Special Authority - Retail Pharmacy', to ensure that Pharmaceuticals are used by those people who are most likely to benefit from them. Pharmaceuticals provided to patients for use while in DHB hospitals are not covered by Sections A to G of the Pharmaceutical Schedule.

Section H of the Pharmaceutical Schedule is not a comprehensive list of Pharmaceuticals that are used within the DHB Hospitals. Section H of the Pharmaceutical Schedule includes Pharmaceuticals that can be purchased at a national price by DHBs for use in their hospitals. These are referred to as National Contract Pharmaceuticals.

A list of Discretionary Community Supply Pharmaceuticals, in Section H of the Pharmaceutical Schedule, identifies those products that currently are not subsidised from the Pharmaceutical Budget as Community Pharmaceuticals in Sections A to G of the Pharmaceutical Schedule but which DHBs can at their discretion fund for use in the community from their own budgets Hospital Pharmaceuticals in the Community approval.

PHARMAC's clinical advisors

Pharmacology and Therapeutics Advisory Committee (PTAC)

PHARMAC works closely with the Pharmacology and Therapeutics Advisory Committee (PTAC), an expert medical committee which provides independent advice to PHARMAC on health needs and the clinical benefits of particular pharmaceuticals for use in the community and/or in DHB Hospitals.

The committee members are all senior, practising clinicians. The chair of PTAC sits with the PHARMAC Board in an advisory capacity.

PTAC helps decide which community pharmaceuticals are to be subsidised from public monies by making recommendations to PHARMAC. Part of the role of PTAC is to review whether Community Pharmaceuticals already listed on the Schedule should continue to receive Government funds. The resources freed up can be used to subsidise other community pharmaceuticals with a greater therapeutic worth.

PHARMAC may obtain clinical advice from PTAC in relation to national purchasing strategies for Hospital Pharmaceuticals. There may be additional specialist hospital representatives on PTAC subcommittees, or additional PTAC subcommittees, where PHARMAC considers this necessary.

PTAC members are:

Carl Burgess	MBChB, MD, MRCP (UK), FRACP, FRCP, physician/clinical pharmacologist, Chair
Howard Wilson	BSc, PhD, MB, BS, Dip Obst, FRNZCGP, FRAGCP Deputy Chair
Chris Cameron	MBChB, FRACP, MClin Pharm
Melissa Copland	PhD, BPharm(Hons), RegPharmNZ, FNZCP
Stuart Dalziel	MBChB, PhD, FRACP
Ian Hosford	MBChB, FRANZCP, psychiatrist
Sisira Jayathissa	MMedSc (Clin Epi), MMBS, MD, MRCP (UK), FRCP (Edin), FRACP, FAFPHM, Dip Clin Epi, Dip OHP, Dip HSM, MBS
George Laking	PhD, MD, FRACP
Dee Mangin	MBChB, DPH, RNZCGP
Graham Mills	MBChB, MTropHlth, MD, FRACP, infectious disease specialist and general physician
Mark Weatherall	BA, MBChB, MAppStats, FRACP

Contact PTAC C/- PTAC Secretary, Pharmaceutical Management Agency, PO Box 10 254, WELLINGTON, Email: PTAC@pharmac.govt.nz

PHARMAC's consumer advisors

Consumer Advisory Committee (CAC)

The Consumer Advisory Committee is an advisory committee to the PHARMAC Board. It provides written reports to the Board, and its Chair attends Board meetings as an observer to report on the activities and findings of the Committee, and to comment on consumer issues. While accountable to the Board, the Committee's general working relationship is with the staff of PHARMAC.

The Committee is made up of people from a range of backgrounds and interests including the health of Māori people, Pacific peoples, older people, women and mental health.

For current membership of the Consumer Advisory Committee, visit our website. The Consumer Advisory Committee can be contacted by email: CAC@pharmac.govt.nz, or you can write to the Consumer Advisory Committee at PHARMAC's postal address.

The PHARMAC Team

The PHARMAC team has a wide range of expertise in health, medicine, economics, commerce, critical analysis, and policy development and implementation.

Steffan Crausaz	Chief Executive	Bridget Macfarlane	Programme & Accountability Manager
Paul Alexander	Health Economist		
Richard Anderson	Network and Systems Administrator	Janet Mackay	Programme & Accountability Manager
Julian Apatu	Web Content Leader	Rachel Mackay	Manager, Schedule and Contracts
Katie Appleby	Panel Co-ordinator		
Jason Arnold	Team Leader, Analysis	Trish Mahoney	Contract Manager
Diana Beswetherick	HR Manager	Scott Metcalfe	Chief Advisor Population Medicine / Deputy Medical Director
Stephen Boxall	Creative Director		
Lisa Buxton	Senior Receptionist		
Davina Carpenter	Records Manager	Peter Moodie	Medical Director
Angela Cathro	Māori Health Programmes' Assistant	Christina Newman	Executive Assistant to Chief Executive & Board Secretary
Christine Chapman	Therapeutic Group Manager	Hew Norris	Analyst
Mary Chesterfield	High Cost Drugs Co-ordinator	Leigh Parish	PA to Medical Director / Medical Team Assistant
Ian Craigie	Manager, Technology and Information		
Andrew Davies	Acting Manager, Funding and Procurement	Kylie Parker	Accounts Co-ordinator
		Marama Parore	Manager, Access & Optimal Use & Māori Health
Natalie Davis	Therapeutic Group Manager	Chris Peck	Analyst
Jessica Dougherty	Corporate Team Executive Assistant	Karen Phillips	HR Assistant/Payroll
		Matthew Poynton	Analyst/Health Economist
Sean Dougherty	Funding Systems Development Manager	Rachel Pratt	Panel Co-ordinator
Anrik Drenth	Database Analyst	Dilky Rasiah	Deputy Medical Director
Kim Ellis	Access & Optimal Use Co-ordinator	Awhimai Reynolds	Māori Health Manager
		Alexander Rodgers	Health Economist
Simon England	Communications Manager	Brian Roulston	Contract Manager
Jackie Evans	Senior Therapeutic Group Manager	Fiona Rutherford	Establishment Manager, Medical Devices
		Rico Schoeler	Manager, Analysis and Assessment
John Geering	Systems Architect		
Anne Glennie	Panel Co-ordinator	Carsten Schousboe	Health Economist
Rachel Grocott	Senior Health Economist	Merryn Simmons	PHARMAC Seminar Series Co-ordinator
Rachel Hargreaves	Senior Policy Analyst		
Gerald Jones	Formulary Researcher	Liz Skelley	Finance Manager
Rochelle Harker	PTAC Secretary & Panel Co-ordinator	Stuart Sorrel	Panel Co-ordinator
		Jude Urlich	Manager, Corporate and External Relations
Hayden Holmes	Panel Co-ordinator (Growth Hormone/PAH)	Jayne Watkins	Team Leader, Medical Team
Karen Jacobs	National Programme Manager, One Heart Many Lives	Rachel Werner	Health Economist
		Bryce Wigodsky	Policy Analyst
Donna Jennings	Schedule Analyst	Greg Williams	Senior Therapeutic Group Manager
Marcus Kim	Tender Analyst		
Catherine Kingsbury	Funding and Procurement Assistant	Lisa Williams	Legal Counsel
		Kaye Wilson	Senior Schedule Analyst
Geoff Lawn	Applications Developer / Team Leader IT	Stephen Woodruffe	Therapeutic Group Manager
		Sue Anne Yee	Therapeutic Group Manager
		Michael Young	Analyst

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 (if it differs from the Subsidy) and any access conditions that may apply; and
- some Hospital Pharmaceuticals that are purchased and used by DHB Hospitals, including those for which national prices have been negotiated by PHARMAC.

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

Finding Information in the Pharmaceutical Schedule

Community Pharmaceuticals

For Community Pharmaceuticals, the Schedule is organised in a way to help the reader find Community Pharmaceuticals, which may be used to treat similar conditions. To do this, Community Pharmaceuticals are first classified anatomically, originally based on the Anatomical Therapeutic Chemical (ATC) system, and then further classified under section headings structured for the New Zealand medical system.

- Section **A** lists the General Rules in relation to Community Pharmaceuticals and related products.
- Section **B** lists Community Pharmaceuticals and related products by anatomical classification, which are further divided into one or more therapeutic headings. Community Pharmaceuticals used to treat similar conditions are grouped together.
- Section **C** lists the rules in relation to Extemporaneously Compounded Products (ECPs) and Community Pharmaceuticals that will be subsidised when extemporaneously compounded.
- Section **D** lists the rules in relation to Special Foods and the Special Foods that are subsidised.
- Section **E** Part I lists the Community Pharmaceuticals that are subsidised on a Practitioner's Supply Order (PSO).
- Section **E** Part II lists rural areas for the purpose of PSOs.
- Section **F** lists the Community Pharmaceuticals dispensing period exemptions.
- Section **G** lists the Community Pharmaceuticals eligible for reimbursement of safety cap and related rules.

The listings are displayed alphabetically (where practical) within each level of the classification system. Each anatomical section contains a series of therapeutic headings, some of which may contain a further classification level. Where a Community Pharmaceutical is used in more than one therapeutic area, they may be cross-referenced.

The therapeutic headings in the Pharmaceutical Schedule do not necessarily correspond to the therapeutic groups and therapeutic subgroups, which PHARMAC establishes for the separate purpose of determining the level of subsidy to be paid for each Community Pharmaceutical.

The index located at the back of the book in which Sections A-G of the Pharmaceutical Schedule are published can be used to find page numbers for generic chemical entities, or product brand names.

Hospital Pharmaceuticals

Section **H** lists Pharmaceuticals that DHBs fund from their own budgets. The Hospital Pharmaceuticals are grouped into the following Parts in Section H:

- Part I lists the rules in relation to Hospital Pharmaceuticals.
- Part II lists Hospital Pharmaceuticals for which national contracts exist (National Contract Pharmaceuticals). These are listed alphabetically by generic chemical entity name and line item, the relevant Price negotiated by PHARMAC and, if applicable, an indication of whether it has Hospital Supply Status (HSS) and any associated Discretionary Variance (DV) Pharmaceuticals and DV Limit.
- Part III lists Discretionary Community Supply Pharmaceuticals, which are not Community Pharmaceuticals, but which a DHB Hospital can, in its discretion, fund for use in the community from its own budget.

The index located at the back of the Section H supplement can be used to find page numbers for generic chemical entities, or product brand names, for Hospital Pharmaceuticals.

Explaining drug entries

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

Example

ANATOMICAL HEADING			
		Subsidy (Manufacturer's Price) \$	Fully Brand or Subsidised Generic Per ✓ Manufacturer
THERAPEUTIC HEADING			
CHEMICAL			
Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber.	▲ Presentation, form and strength	10.00	100 ✓ Brand A ✓ Brand B
	Presentation - Available on a PSO	15.00	50 ✓ Brand C
Practitioner's Supply Order	⊕ Presentation - Retail pharmacy-specialist	18.00	250 mL OP ✓ Brand D
Safety cap reimbursed	a) Prescriptions must be written by a paediatrician or paediatric cardiologist; or b) on the recommendation of a paediatrician or a paediatric cardiologist		
Conditions of and restrictions on prescribing (including Special Authority where it applies)			
Three months or six months, as applicable, dispensed all-at-once	* Presentation, form and strength	26.53	100 Brand E
		(35.27)	
CHEMICAL			
Sole Supply			
✓ Fully Subsidised			
▲ Three months supply may be dispensed at one time if endorsed "certified exemption" by the prescriber.			

Glossary

Units of Measure

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

Abbreviations

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

BSO Bulk Supply Order.

CBS Cost Brand Source. There is no set manufacturer's price, and the Government subsidises the product at the price it is obtained by the pharmacy.

CE Compounded Extemporaneously.

CPD Cost Per Dose. The Funder (as defined in Part I of the General Rules) cost of a standard dose, without mark-ups or fees and excluding GST.

ECP Extemporaneously Compounded Preparation.

HSS 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.

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

PSO Practitioner's Supply Order.

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.

* Three months dispensed all-at-once or, in the case of oral contraceptives, six months dispensed all-at-once, unless medicine is endorsed "close control" or "cc" and the endorsement is initialled by the prescriber.

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

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

§29 This medicine is an unapproved medication supplied under Section 29 of the Medicines Act 1981. Practitioners prescribing this medication should:

- be aware of and comply with their obligations under Section 29 of the Medicines Act 1981 and otherwise under that Act and the Medicines Regulations 1984;
- 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 discretions, and make their own prescribing decisions with respect to the use of an unapproved Pharmaceutical or a Pharmaceutical for an indication for which it is not approved.

Note: Where medicines supplied under Section 29 that are used for emergency situations, patient details required under Section 29 of the Medicines Act may be retrospectively provided to the supplier.

Definitions		
Abbrev.	Pharmacy Services Agreement	All other Pharmacy Agreements
[HP3]	Subsidised when dispensed from pharmacies that have a Special Foods Service appended to their Pharmacy Services Agreement by their DHB.	Available from selected pharmacies that have an exclusive contract to dispense Special Foods.
[HP4]	Subsidised when dispensed from pharmacies that have the Monitored Therapy Variation (for Clozapine Services)	Available from selected pharmacies that have an exclusive contract to dispense 'Hospital Pharmacy' [HP4] pharmaceuticals.

Patient costs

Community Pharmaceutical costs met by the Government

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

SALBUTAMOL		
Aerosol inhaler 100 µg per dose	3.80 (6.00)	✓Fully subsidised brand Higher priced brand

Pharmaceutical Co-Payments

Some Community Pharmaceutical costs are met by the patient. Generally a patient pays a prescription charge. In addition a patient will sometimes pay a manufacturer's surcharge, after hours service fee and any special packaging fee.

PRESCRIPTION CHARGE

From 1 September 2008, everyone who is eligible for publicly funded health and disability services should in most circumstances pay only \$3 for subsidised medicines.

All prescriptions from a public hospital, a midwife and a Family Planning Clinic are covered for \$3 co-payments.

Prescriptions from the following providers are approved for \$3 co-payments on subsidised medicines if they meet the specified criteria:

- After Hours Accident and Medical Services with a DHB or a PHO contract.
- Youth Health Clinics with a DHB or a PHO contract.
- Dentists who write a prescription that relates to a service being provided under a DHB contract.
- Private specialists (for example, ophthalmologists and orthopaedics) who write a prescription for a patient receiving a publicly funded service contracted by the DHB.
- General practitioners who write a prescription during normal business hours to a person who is not enrolled in the general practice provided the person is eligible for publicly funded health and disability services and the general practice is part of a PHO.
- Hospices that have a contract with a DHB.

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

To check if a medicine is fully subsidised, refer to the Pharmaceutical Schedule on PHARMAC's website or ask your pharmacist or general practitioner.

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.

NOTE: Information sourced from Ministry of Health Website, for more information please visit www.moh.govt.nz

MANUFACTURER'S SURCHARGE

Not all Community Pharmaceuticals are fully subsidised. Although PHARMAC endeavours to fully subsidise at least one Community Pharmaceutical in each therapeutic group, and has contracts with some suppliers to maintain the price of a particular product, manufacturers are able to set their own price to pharmacies. When these prices exceed the subsidy, the pharmacist may recoup the difference from the patient.

To estimate the amount a patient will pay on top of the prescription charge, take the difference between the manufacturer's price and the subsidy, and multiply this by 1.86. The 1.86 factor represents the pharmacy mark-up on the surcharge plus other costs such as GST. Pharmacies charge different mark-ups so this may vary.

$$\text{Manufacturer's surcharge to patient} = (\text{price} - \text{subsidy}) \times 1.86$$

For example, a Community Pharmaceutical with a supplier (ex-manufacturer) cost of \$11.00 per pack with a \$10.00 subsidy will cost the patient a surcharge of \$1.86 on top of the prescription charge. The most a patient should pay is therefore \$16.86 - being

\$15.00 maximum prescription charge, plus \$1.86.

Hospital Pharmaceutical and Pharmaceutical Cancer Treatment Costs

The cost of purchasing Hospital Pharmaceuticals (for use in DHB hospitals and/or in association with Outpatient services provided in DHB hospitals) is met by the relevant DHB hospital Funder from its own budget. Pharmaceutical Cancer Treatments (for use in DHB hospitals and/or in association with Outpatient services provided in DHB hospitals) are funded through the Combined Pharmaceutical Budget. As required by section 23(7) of the Act, in performing any of their functions in relation to the supply of Pharmaceuticals including Pharmaceutical Cancer Treatments, DHBs must not act inconsistently with the Pharmaceutical Schedule.

PHARMAC web site

PHARMAC has set up an interactive Schedule on the Internet.

Other information about PHARMAC is also available on our website. This includes copies of the Annual Review, Annual Report and Annual Plan, as well as information such as the Pharmaceutical Schedule, Pharmaceutical Schedule Updates, National Hospital Pharmaceutical Strategy, other publications and recent press releases.

Special Authority Applications

Special Authority is an application process in which a prescriber requests government subsidy on a Community Pharmaceutical for a particular person. Applications must be submitted to the Ministry of Health by the prescriber for the request to be processed.

Subsidy

Once approved, the prescriber will be provided a Special Authority number which must appear on the prescription. Specialists who make an application must communicate the valid authority number to the prescriber who will be writing the prescriptions.

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 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.

Criteria for each Special Authority Community Pharmaceutical are updated regularly, based on the decision criteria of PHARMAC.

The appropriateness of the listing of a Community Pharmaceutical in the Special Authority category will also be regularly reviewed.

Applications for inclusion of further Community Pharmaceuticals in the Special Authority category will generally be made by a pharmaceutical supplier.

Special Authority Applications

Application forms can be found at www.pharmac.govt.nz. Requests for fax copies should be made to PHARMAC, phone 04 460 4990. Applications are processed by the Ministry of Health, and should be sent to:

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

For enquiries, phone the Ministry of Health Sector Services Call Centre, free phone 0800 243 666

Note: The Ministry of Health can only provide information on Special Authority applications to prescribers and pharmacists.

Each application must:

- Include the patients name, date of birth and NHI number (codes for AIDS patients' applications)
- Include the practitioner's name, address and Medical Council registration number
- Clearly indicate that the relevant criteria, have been met.
- Be signed by the practitioner.

Named Patient Pharmaceutical Assessment policy

The Named Patient Pharmaceutical Assessment (NPPA) Policy is PHARMAC's process for considering applications about named patients seeking funding for treatments not listed on the Schedule, either at all or for the named patient's clinical circumstances.

For PHARMAC to perform its legislative function of maintaining and managing a Schedule that applies consistently throughout New Zealand, the NPPA Policy will, and must, operate in a way that does not undermine the Schedule decision making process. Together, the Schedule process and the NPPA Policy, ensure there is a pathway for consideration of an individual's clinical circumstances. If an individual has a set of clinical circumstances not covered by the NPPA Policy, the Schedule decision making process is available. It is not the purpose of the NPPA Policy to provide access to every treatment not listed on the Schedule.

There are three main pathways by which named patients can be considered for funding under the NPPA Policy. PHARMAC will exercise its discretion to determine the most appropriate pathway for an application under the NPPA Policy based on the information that is provided.

PHARMAC will assess applications that meet the prerequisites described below 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 (04) 9167553 or (04) 9167521.

Unusual Clinical Circumstance (UCC)

The purpose of the Unusual Clinical Circumstances (UCC) pathway is to provide a process for consideration for funding 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. The prerequisite requirements for UCC consideration are:

- The patient has reasonably tried and failed all alternative funded treatments (or alternative treatments have been contraindicated, or there are no other treatments available), or the patient has experienced such serious side effects with all other relevant funded treatments that treatment has been ceased or cannot reasonably be continued; and
- The patient is experiencing an indication or set of clinical circumstances that are so unusual that PHARMAC is unlikely to consider listing treatments for these on the Schedule; and
- Generally, PHARMAC has not already considered/is not considering, through the Schedule decision making process, the treatment for the patient's clinical circumstances, or has not considered the treatment at all.

Urgent Assessment (UA)

The purpose of the Urgent Assessment (UA) pathway is to provide a process for PHARMAC to consider funding 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. The prerequisite requirements for UA are:

- The patient has reasonably tried and failed all alternative funded treatments (or alternative treatments have been contraindicated, or there are no other treatments available), or the patient has experienced such serious side effects with all other relevant funded treatments that treatment has been ceased or cannot reasonably be continued; and
- The patient is experiencing an indication or set of clinical circumstances that may be experienced by a population group (either currently or over time); and
- The patient has serious clinical circumstances and not receiving the treatment within six to 12 months would lead to either a significant deterioration in a serious clinical condition or the patient would miss the opportunity for significant improvement in clinical outcome (length or quality of life); and
- The treatment has either not been prioritised by PHARMAC, or if it has, PHARMAC has funded the treatment under the NPPA Policy for the same clinical circumstances prior to prioritisation.
- PHARMAC has not declined to list, on the Schedule, this treatment for these clinical circumstances.

Hospital Pharmaceuticals in the Community (HPC)

The purpose of the Hospital Pharmaceuticals in the Community (HPC) pathway is to allow District Health Board hospitals to fund a medicine for a patient in the community if it would be more affordable for the DHB than paying for the treatment that would otherwise need to be provided. PHARMAC's approval is required for any such funding, given DHBs' legislative obligation to act consistently with the Schedule. The prerequisite requirements for HPC are:

- The patient has reasonably tried and failed all alternative cheaper funded treatments (or these alternative treatments have been contraindicated) or the patient has experienced such serious side effects with all other cheaper relevant funded treatments that treatment has been ceased or cannot reasonably be continued; and
- The application is for a DHB hospital to fund a treatment for use in the community for a patient under the care of a DHB hospital clinician (in-patient or out-patient); and
- The treatment is not being used to treat a cancer; and
- The treatment costs less for the DHB than the most likely alternative intervention or outcome; and
- The treatment is being sought for a short-term episode of care (usually a maximum of three months) and is not generally for the treatment of a chronic condition.

SECTION A: GENERAL RULES

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 November 2012 and is to be referred to as the Pharmaceutical Schedule Volume 19 Number 2, 2012. Distribution will be from 20 November 2012. This Schedule comes into force on 1 November 2012.

PART I INTERPRETATIONS AND DEFINITIONS

1.1 In this Schedule, unless the context otherwise requires:

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

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

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

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

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

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

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

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

"Assessed Pharmaceuticals" means the list of Pharmaceuticals set out in Section H Part III of the Schedule, that have been or are being assessed by PHARMAC.

"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 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 registered nurse practising in diabetes health who has authority to prescribe specified diabetes medicines in accordance with regulations made under the Medicines Act 1981, and who is practicing in an approved DHB demonstration site.

“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.

“Discretionary Community Supply Pharmaceutical” means the list of Pharmaceuticals set out in Section H Part IV of the Schedule, which may be funded by a DHB Hospital from its own budget for use in the community.

“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 National Contract Pharmaceuticals, DV Pharmaceuticals, Discretionary Community Supply Pharmaceuticals and Assessed Pharmaceuticals.

“Hospital Pharmaceuticals in the Community (HPC)” means the pathway under the Named Patient Pharmaceutical Assessment policy to allow District Health Board hospitals to fund a medicine for a patient in the community if this is more affordable for the DHB than paying for the treatment that would otherwise need to be provided.

“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 a 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:

SECTION A: GENERAL RULES

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

- a) follows a substantive consultation with an appropriate Specialist;
- b) the consultation to relate to the Patient for whom the Prescription is written;
- c) consultation to mean communication by referral, telephone, letter, facsimile or email;
- d) except in emergencies consultation to precede annotation of the Prescription; and
- e) both the specialist and the General Practitioner must keep a written record of the consultation.

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/healthpros/EC/ECForms>)

“**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 nurse registered with the Nursing Council and who holds a current annual practicing certificate under the HPCA Act 2003 and who is approved by the Nursing Council, to prescribe specified prescription medicines relating to his/her scope of practice including, for the avoidance of doubt, a Diabetes Nurse Prescriber.

“Optometrist” means a person registered as an optometrist with the Optometrists and Dispensing Opticians Board, who holds a current annual practising certificate under the HPCA Act 2003, and who is authorised by regulations under the Medicines Act 1981 and approved by the Optometrists and Dispensing Opticians Board to prescribe specified medicines.

“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 H 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” 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 or a Pharmacist 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.

“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,

SECTION A: GENERAL RULES

b) in the case of treatment recommended by a Specialist, supplied on a Prescription or Practitioner's Supply Order and either:

- i) endorsed with the words "recommended by [name of Specialist and year of authorisation]" and signed by the Practitioner, or
- ii) 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:

- a) follows a substantive consultation with an appropriate Specialist;
- b) the consultation to relate to the Patient for whom the Prescription is written;
- c) consultation to mean communication by referral, telephone, letter, facsimile or email;
- d) except in emergencies consultation to precede annotation of the Prescription; and
- e) both the Specialist and the General Practitioner must keep a written record of consultation.

"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.

"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, 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)
 - i) 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; and
 - ii) the doctor's vocational scope of practice is one of those listed below: — anaesthetics, cardiothoracic surgery, dermatology, diagnostic radiology, emergency medicine, general surgery, internal medicine, neurosurgery, obstetrics and gynaecology, occupational medicine, ophthalmology, oral and maxillofacial surgery, otolaryngology head and neck surgery, orthopaedic surgery, paediatric surgery, paediatrics, pathology, plastic and reconstructive surgery, psychological medicine or psychiatry, public health medicine, radiation oncology, rehabilitation medicine, urology and venereology;
- 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 medicine;
- c) the doctor is recognised by the Ministry of Health as a specialist in relation to a particular area of medicine for the purpose of writing Prescriptions and who has written the Prescription in the course of practising in that area of medicine;
- 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.

"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 P pharmaceutical Assessment policy for funding consideration for treatments for named patients where PHARMAC is also considering or is likely to consider the treatment for Schedule listing, but the patient’s clinical circumstances justify urgent assessment, prior to a decision on Schedule listing.

1.2 In addition to the above interpretations and definitions, unless the content requires otherwise, a reference in the Schedule to:

- a) the singular includes the plural; and
- b) any legislation includes a modification and re-enactment of, legislation enacted in substitution for, and a regulation, Order in Council, and other instrument from time to time issued or made under that legislation, where that legislation, regulation, Order in Council or other instrument has an effect on the prescribing, dispensing or subsidising of Community Pharmaceuticals.

PART II

COMMUNITY PHARMACEUTICALS SUBSIDY

2.1 Community Pharmaceuticals eligible for Subsidy include every medicine, therapeutic medical device or related product, or related thing listed in Sections B to G and I of the Schedule subject to:

- 2.1.1 clauses 2.2 of the Schedule; and
- 2.1.2 clauses 3.1 to 5.4 of the Schedule; and
- 2.1.3 the conditions (if any) specified in Sections B to G and I of the Schedule;

2.2 No claim by a Contractor for payment in respect of the supply of Community Pharmaceuticals will be allowed unless the Community Pharmaceuticals so supplied:

- 2.2.1 comply with the appropriate standards prescribed by regulations for the time being in force under the Medicines Act 1981; or
- 2.2.2 in the absence of any such standards, comply with the appropriate standards for the time being prescribed by the British Pharmacopoeia; or
- 2.2.3 in the absence of the standards prescribed in clauses 2.3.1 and 2.3.2, 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 2.3.1, 2.3.2 and 2.3.3, 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’ and Optometrists’ 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 or Optometrist 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
 - ii) which has been dispensed pursuant to a Prescription sufficient to provide treatment for a period not exceeding one Month, will be subsidised.
 - b) for a Dentist prescription only such quantity as is necessary to provide treatment for a period not exceeding five days will be subsidised.
- 3.1.4 Subject to clauses 3.1.3 and 3.1.7, for a Doctor, Dentist, Dietitian, Midwife 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

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quantity prescribed, the Community Pharmaceutical will only be subsidised as if that Community Pharmaceutical had been dispensed in a Monthly Lot;

- b) more than one Month, the Community Pharmaceutical will be subsidised only if it is dispensed:
 - i) in a 90 Day Lot, where the Community Pharmaceutical is a Pharmaceutical covered by Section F Part I of the Pharmaceutical Schedule; or
 - ii) if the Community Pharmaceutical is not a Pharmaceutical referred to in Section F Part I of the Pharmaceutical Schedule, in Monthly Lots, unless:
 - A) the eligible person or his/her nominated representative endorses the back of the Prescription form with a statement identifying which Access Exemption Criterion (Criteria) applies and signs that statement to this effect; or
 - B) both:
 - 1) the Practitioner endorses the Community Pharmaceutical on the Prescription with the words "certified exemption" written in the Practitioner's own handwriting, or signed or initialled by the Practitioner; and
 - 2) every Community Pharmaceutical endorsed as "certified exemption" is covered by Section F Part II of the Pharmaceutical Schedule.

3.1.5 A Community Pharmaceutical is only eligible for Subsidy if the Prescription under which it has been dispensed was presented to the Contractor:

- a) for a Class B Controlled Drug, within eight days of the date on which the Prescription was written; or
- b) for any other Community Pharmaceutical, within three Months of the date on which the Prescription was written.

3.1.6 No subsidy will be paid for any Prescription, or part thereof, that is not fulfilled within:

- a) in the case of a Prescription for a total supply of from one to three Months, three Months from the date the Community Pharmaceutical was first dispensed; or
- b) in any other case, one Month from the date the Community Pharmaceutical was first dispensed. Only that part of any Prescription that is dispensed within the time frames specified above is eligible for Subsidy.

3.1.7 If a Community Pharmaceutical:

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

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

3.2 Oral Contraceptives

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

3.2.1 The prescribing Doctor, Midwife or Nurse 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, and Certain Antibiotics

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 the liquid oral form of an antibiotic to which a diluent must be added by the Contractor at the time of dispensing 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 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 Dietitians' Prescriptions

The following provisions apply to every Prescription written by a Dietitian:

3.4.1 Prescriptions written by a Dietitian for a Community Pharmaceutical will only be subsidised where they are for either:

- a) special foods, as listed in Section D; or
- b) any other Pharmaceutical that has been identified in Section D of the Pharmaceutical Schedule as being able to be prescribed by a Dietitian,

providing that the products being prescribed are not classified as Prescription Medicines or Restricted Medicines.

3.4.2 For the purposes of Dietitians prescribing pursuant to this clause 3.5, the prescribing and dispensing of these products is required to be in accordance with regulations 41 and 42 of the Medicines Regulations 1984.

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
- b) any other Community Pharmaceutical listed below, being an item that has been identified as being able to be prescribed by a Diabetes Nurse Prescriber, but which is not classified as a Prescription Medicine or a Restricted Medicine:

aspirin, blood glucose diagnostic test meter, blood glucose diagnostic test strip, glucagon hydrochloride inj 1 mg syringe kit, insulin pen needles, insulin syringes disposable with attached needle, 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).

Note: A list of Diabetes Nurse Prescribers will be published periodically in the Update of the Pharmaceutical Schedule for the duration of an initial pilot scheme. After this period there will be no approved DHB demonstration sites and hence no Diabetes Nurse Prescribers.

3.6 Pharmacists' prescriptions

The following apply to every prescription written by a Pharmacist:

3.6.1 Prescriptions written by a pharmacist for a Community Pharmaceutical will only be subsidised where they are for the CareSens, CareSens N and CareSens N POP blood glucose diagnostic meters and annotated appropriately.

3.6.2 The prescribing and dispensing of blood glucose diagnostic meters by Pharmacists must be in accordance

with regulations 41 and 42 of the Medicines Regulations 1984.

PART IV DISPENSING FREQUENCY RULE

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; and the conditions that must be met to enable any claim for payment of handling fees for the additional dispensings made.

"Frequent Dispensing" means:

- for a Community Pharmaceutical referred to in Section F Part I, dispensing in quantities less than one 90 Day Lot (or for oral contraceptives, less than one 180 Day Lot); or
- for any other Community Pharmaceutical, where any of 4.1, 4.2 or 4.3 of Part IV apply, dispensing in quantities less than a Monthly Lot

NOTE patients who have had more frequent dispensings due to being "intellectually impaired, frail, infirm or unable to manage their medicines" will continue to receive the same frequency of dispensings until they are assessed to see if they are eligible for additional support under the Long-Term Condition (LTC) service. The structure of the remainder fee payment provides funding for pharmacy to continue to provide more frequent dispensings for patients until they are assessed.

4.1 Frequent Dispensings for persons in residential care

4.1.1 Pharmaceuticals can be dispensed in quantities of not less than 28 days 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, provided the following conditions are met:

- a) the quantity or period of supply to be dispensed at any one time is not less than 28 days' supply (except under conditions outlined in 4.2.2 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.

4.1.2 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 4.2.2 below.

4.2 Frequent Dispensings for trial periods or safety medicines

4.2.1 If a Pharmacist considers more frequent dispensing is required, this can occur as follows:

- For Long Term Condition (LTC) patients dispensing frequency can occur as often as the dispensing pharmacist deems appropriate to meet the patients compliance and adherence needs;
- For non-LTC patients the dispensing frequency should be no more often than monthly. If Frequent Dispensing more often than monthly is necessary for non-LTC patients, prescriber approval is required. Verbal approval is acceptable, provided that it is annotated by the pharmacist on the Prescription and dated.

NOTE this rule does not override alternative dispensing frequencies as expressly stated in the Medicines Act, Medicines Regulations, Pharmacy Services Agreement, Pharmaceutical Schedule or under rule 4.2.2 Trial Periods or rule 4.2.3 safety and co-prescribed medicines below.

Pharmacy would claim handling fees only on repeats under the above scenarios.

Prescribers can request, and pharmacists may dispense a higher frequency of dispensing in the following circumstances:

4.2.2 Trial Periods

The 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.

4.2.3 Safety and co-prescribed medicines

a) The Community Pharmaceutical is any of the following:

- i) a tri-cyclic antidepressant; or
- ii) an antipsychotic; or
- iii) a benzodiazepine; or
- iv) a Class B Controlled Drug; or
- v) codeine (includes combination products)
- vi) buprenorphine with naloxone

All of the following conditions must be met:

The Community Pharmaceutical has been prescribed for a patient who is not a resident in a Penal Institution, or one of the residential placements or facilities referenced in 4.1 above.

The prescribing Practitioner has:

- Assessed clinical risk and determined the patient requires Frequent Dispensing; and
- Specified the maximum quantity or period of supply to be dispensed for each Community Pharmaceutical at any one time.

b) The Community Pharmaceutical is co-prescribed with one of the Community Pharmaceuticals listed in 4.2.3(a) above and has been prescribed for a patient who is not a resident in a Penal Institution, or one of the residential placements or facilities referenced in 4.1 above. The dispensing pharmacist has:

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

4.3 Frequent Dispensing for Pharmaceutical Supply Management

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

a) PHARMAC has approved and notified pharmacists to annotate Prescriptions for a specified Community Pharmaceutical(s) “out of stock” without prescriber endorsement for a specified time; and

b) the dispensing pharmacist has:

- i) clearly annotated each of the approved Community Pharmaceuticals that appear on the Prescription with the words “out of stock” or “OOS”; and
- ii) initialled the annotation in their own handwriting; and
- iii) has complied with maximum quantity or period of supply to be dispensed at any one time, as specified by PHARMAC at the time of notification.

Note – no claim shall be made to any DHB for subsidised dispensing 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, 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.

5.3 Retail Pharmacy and Hospital Pharmacy-Specialist Restriction

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

5.3.1 Record Keeping

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

5.3.2 Expiry

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

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

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

- 5.3.5 The Rules for Retail Pharmacy-Specialist and Hospital Pharmacy-Specialist will be audited as part of the

Ministry of Health's routine auditing procedures.

5.4 **Pharmaceutical Cancer Treatments**

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

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

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

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

- a) Part 1;
- b) clauses 2.1 to 2.3;
- 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 direction from the Minister of Health as to pharmaceuticals and indications for which DHBs must provide access. As far as reasonably practicable, these Unapproved Indications are marked in the Schedule. However, PHARMAC makes no representation and gives no guarantee as to the accuracy of this information. Practitioners prescribing Pharmaceutical Cancer Treatments for such Unapproved Indications should:

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

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

5.5 **Practitioners prescribing unapproved Pharmaceuticals**

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

- a) in some case, explicitly permit Government funded access to a Pharmaceutical that is not approved under the Medicines Act 1981 or for an Unapproved Indication; or
- b) not explicitly preclude Government funded access to a Pharmaceutical when it is used for an Unapproved Indication;

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

- a) be aware of and comply with their obligations under sections 25 and 29 of the Medicines Act 1981, as applicable, and otherwise under that Act and the Medicines Regulations 1984;
- b) be aware of and comply with their obligations under the Health and Disability Commissioner's Code of Consumer Rights, including the requirement to obtain informed consent from the patient (PHARMAC recommends

SECTION A: GENERAL RULES

that Practitioners obtain written consent); and

- c) exercise their own skill, judgment, expertise and discretion, and make their own prescribing decisions with respect to the use of an unapproved Pharmaceutical or a Pharmaceutical for an Unapproved Indication.

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

5.6 Substitution

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

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

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

5.7 Alteration to Presentation of Pharmaceutical Dispensed

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

5.8 Conflict in Provisions

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

SECTION B: ALIMENTARY TRACT AND METABOLISM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Antacids and Antiflatulants				
Antacids and Reflux Barrier Agents				
ALGINIC ACID				
Sodium alginate 225 mg and magnesium alginate 87.5 mg per sachet	4.50	30	✓	Gaviscon Infant
CALCIUM CARBONATE WITH AMINOACETIC ACID				
* Tab 420 mg with aminoacetic acid 180 mg – Higher subsidy of \$6.30 per 100 tab with Endorsement.....	3.00 (6.30)	100		Titralac
Additional subsidy by endorsement is available for pregnant women. The prescription must be endorsed accordingly. (Titralac Tab 420 mg with aminoacetic acid 180 mg to be delisted 1 May 2013)				
SIMETHICONE				
* Oral liq aluminium hydroxide 200 mg with magnesium hydrox- ide 200 mg and activated simethicone 20 mg per 5 ml	1.50 (4.26)	500 ml		Mylanta P
SODIUM ALGINATE				
* Tab 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg - peppermint flavour	1.80 (8.60)	60		Gaviscon Double Strength
* Oral liq 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml	1.50 (4.95)	500 ml		Acidex
Phosphate Binding Agents				
ALUMINIUM HYDROXIDE				
* Tab 600 mg	12.56	100	✓	Alu-Tab
Antidiarrhoeals				
Agents Which Reduce Motility				
DIPHENOXYLATE HYDROCHLORIDE WITH ATROPINE SULPHATE				
* Tab 2.5 mg with atropine sulphate 25 µg	3.90	100	✓	Diastop
LOPERAMIDE HYDROCHLORIDE – Up to 30 cap available on a PSO				
* Tab 2 mg	8.95	400	✓	Nodia
* Cap 2 mg	8.95	400	✓	Diamide Relief
Rectal and Colonic Anti-inflammatories				
BUDESONIDE				
Cap 3 mg – Special Authority see SA1155 on the next page – Retail pharmacy	166.50	90	✓	Entocort CIR

‡ 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.

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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SA1155 Special Authority for Subsidy

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

Both:

- 1 Mild to moderate ileal, ileocaecal or proximal Crohn's disease; and
- 2 Any of the following:
 - 2.1 Diabetes; or
 - 2.2 Cushingoid habitus; or
 - 2.3 Osteoporosis where there is significant risk of fracture; or
 - 2.4 Severe acne following treatment with conventional corticosteroid therapy; or
 - 2.5 History of severe psychiatric problems associated with corticosteroid treatment; or
 - 2.6 History of major mental illness (such as bipolar affective disorder) where the risk of conventional corticosteroid treatment causing relapse is considered to be high; or
 - 2.7 Relapse during pregnancy (where conventional corticosteroids are considered to be contraindicated).

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

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

Note: Indication marked with * is an Unapproved Indication.

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

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

HYDROCORTISONE ACETATE

Rectal foam 10%, CFC-Free (14 applications)	25.30	21.1 g OP	✓ Colifoam
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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
Enema 1 g per 100 ml	44.12	7	✓ Pentasa
Suppos 500 mg	22.80	20	✓ Asacol
Suppos 1 g	50.96	28	✓ Pentasa

OLSALAZINE

Tab 500 mg	59.86	100	✓ Dipentum
Cap 250 mg	31.51	100	✓ Dipentum

SODIUM CROMOGLYCATE

Cap 100 mg	89.21	100	✓ Nalcrom
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SULPHASALAZINE

* Tab 500 mg – For sulphasalazine oral liquid formulation refer, page 187	11.68	100	✓ Salazopyrin
* Tab EC 500 mg	12.89	100	✓ Salazopyrin EN

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

Corticosteroids

FLUCORTOLONE CAPROATE WITH FLUCORTOLONE PIVALATE AND CINCHOCAINE

Oint 950 µg, with flucortolone pivalate 920 µg, and cinchocaine hydrochloride 5 mg per g	6.35	30 g OP	✓ Ultraproct
Suppos 630 µg, with flucortolone pivalate 610 µg, and cinchocaine hydrochloride 1 mg	2.66	12	✓ Ultraproct

HYDROCORTISONE WITH CINCHOCAINE

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

Antispasmodics and Other Agents Altering Gut Motility

ATROPINE SULPHATE

* Inj 600 µg, 1 ml – Up to 5 inj available on a PSO	71.00	50	✓ AstraZeneca
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HYOSCINE N-BUTYLBROMIDE

* Tab 10 mg	1.48	20	✓ Gastrosoothe
* Inj 20 mg, 1 ml – Up to 5 inj available on a PSO	9.57	5	✓ Buscopan

MEBEVERINE HYDROCHLORIDE

* Tab 135 mg	18.00	90	✓ Colofac
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Antilulcerants

Antisecretory and Cytoprotective

MISOPROSTOL

* Tab 200 µg	52.70	120	✓ Cytotec
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Helicobacter Pylori Eradication

CLARITHROMYCIN

Tab 500 mg – Subsidy by endorsement	10.95	14	✓ Apo-Clarithromycin
a) Maximum of 14 tab per prescription			
b) Subsidised only if prescribed for helicobacter pylori eradication and prescription is endorsed accordingly.			

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

H2 Antagonists

CIMETIDINE – Only on a prescription

* Tab 200 mg	5.00	100	
	(7.50)		Apo-Cimetidine
* Tab 400 mg	10.00	100	
	(12.00)		Apo-Cimetidine

FAMOTIDINE – Only on a prescription

* Tab 20 mg	8.10	250	✓ Famox
* Tab 40 mg	11.35	250	✓ Famox

(Famox Tab 20 mg to be delisted 1 April 2013)

‡ 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.

ALIMENTARY TRACT AND METABOLISM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
RANITIDINE HYDROCHLORIDE – Only on a prescription				
* Tab 150 mg	6.79	250	✓	<u>Arrow-Ranitidine</u>
* Tab 300 mg	9.34	250	✓	<u>Arrow-Ranitidine</u>
* Oral liq 150 mg per 10 ml	5.92	300 ml	✓	<u>Peptisoothe</u>
* Inj 25 mg per ml, 2 ml	8.75	5	✓	<u>Zantac</u>

Proton Pump Inhibitors

LANSOPRAZOLE				
* Cap 15 mg	2.00	28	✓	<u>Solox</u>
	3.27		✓	<u>Lanzol Relief</u>
* Cap 30 mg	2.32	28	✓	<u>Solox</u>
	4.34		✓	<u>Lanzol Relief</u>
OMEPRAZOLE				
For omeprazole suspension refer, page 190				
* Cap 10 mg	2.91	90	✓	<u>Omezol Relief</u>
* Cap 20 mg	3.78	90	✓	<u>Omezol Relief</u>
* Cap 40 mg	5.57	90	✓	<u>Omezol Relief</u>
* Powder – Only in combination	42.50	5 g	✓	<u>Midwest</u>
Only in extemporaneously compounded omeprazole suspension.				
* Inj 40 mg	28.65	5	✓	<u>Dr Reddy's</u> <u>Omeprazole</u>
PANTOPRAZOLE				
* Tab 20 mg	1.23	28	✓	<u>Dr Reddy's</u> <u>Pantoprazole</u>
* Tab 40 mg	1.54	28	✓	<u>Dr Reddy's</u> <u>Pantoprazole</u>
* Inj 40 mg	6.50	1	✓	<u>Pantacid IV</u>

Site Protective Agents

SUCRALFATE				
Tab 1 g	35.50	120		
	(48.28)			Carafate

Diabetes

Hyperglycaemic Agents

GLUCAGON HYDROCHLORIDE				
Inj 1 mg syringe kit – Up to 5 kit available on a PSO	32.00	1	✓	<u>Glucagon Hypokit</u>

Insulin - Short-acting Preparations

INSULIN NEUTRAL				
▲ Inj human 100 u per ml	25.26	10 ml OP	✓	<u>Actrapid</u>
			✓	<u>Humulin R</u>
▲ Inj human 100 u per ml, 3 ml	42.66	5	✓	<u>Actrapid Penfill</u>
			✓	<u>Humulin R</u>

Insulin - Intermediate-acting Preparations

INSULIN ASPART				
▲ Inj 100 iu per ml, 3 ml prefilled pen	52.15	5	✓	<u>NovoMix 30 FlexPen</u>

ALIMENTARY TRACT AND METABOLISM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
INSULIN ISOPHANE				
▲ Inj human 100 u per ml	17.68	10 ml OP	✓	Humulin NPH
			✓	Protaphane
▲ Inj human 100 u per ml, 3 ml	29.86	5	✓	Humulin NPH
			✓	Protaphane Penfill
INSULIN ISOPHANE WITH INSULIN NEUTRAL				
▲ Inj human with neutral insulin 100 u per ml	25.26	10 ml OP	✓	Humulin 30/70
			✓	Mixtard 30
▲ Inj human with neutral insulin 100 u per ml, 3 ml	42.66	5	✓	Humulin 30/70
			✓	PenMix 30
			✓	PenMix 40
			✓	PenMix 50
INSULIN LISPRO WITH INSULIN LISPRO PROTAMINE				
▲ Inj lispro 25% with insulin lispro protamine 75% 100 u per ml, 3 ml	52.15	5	✓	Humalog Mix 25
▲ Inj lispro 50% with insulin lispro protamine 50% 100 u per ml, 3 ml	52.15	5	✓	Humalog Mix 50
Insulin - Long-acting Preparations				
INSULIN GLARGINE				
▲ Inj 100 u per ml, 10 ml	63.00	1	✓	Lantus
▲ Inj 100 u per ml, 3 ml	94.50	5	✓	Lantus
▲ Inj 100 u per ml, 3 ml disposable pen	94.50	5	✓	Lantus SoloStar
Insulin - Rapid Acting Preparations				
INSULIN ASPART				
▲ Inj 100 u per ml, 3 ml	51.19	5	✓	NovoRapid Penfill
▲ Inj 100 u per ml, 10 ml	30.03	1	✓	NovoRapid
INSULIN GLULISINE				
▲ Inj 100 u per ml, 10 ml	27.03	1	✓	Apidra
▲ Inj 100 u per ml, 3 ml	46.07	5	✓	Apidra
▲ Inj 100 u per ml, 3 ml disposable pen	46.07	5	✓	Apidra SoloStar
INSULIN LISPRO				
▲ Inj 100 u per ml, 10 ml	34.92	10 ml OP	✓	Humalog
▲ Inj 100 u per ml, 3 ml	59.52	5	✓	Humalog
Alpha Glucosidase Inhibitors				
ACARBOSE				
* Tab 50 mg	9.82	90	✓	Accarb
			✓	Glucobay
* Tab 100 mg	15.83	90	✓	Accarb
			✓	Glucobay
Oral Hypoglycaemic Agents				
GLIBENCLAMIDE				
* Tab 5 mg	5.00	100	✓	Daonil
GLICLAZIDE				
* Tab 80 mg	17.60	500	✓	<u>Apo-Gliclazide</u>

‡ safety cap

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

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

ALIMENTARY TRACT AND METABOLISM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
GLIPIZIDE				
* Tab 5 mg	3.00	100	✓	Minidiab
METFORMIN HYDROCHLORIDE				
* Tab immediate-release 500 mg	6.15	500	✓	Apotex
	12.30	1,000	✓	Apo-Metformin
* Tab immediate-release 850 mg	5.05	250	✓	Apotex
	10.10	500	✓	Apo-Metformin
<i>(Apotex Tab immediate-release 500 mg to be delisted 1 January 2013)</i>				
<i>(Apotex Tab immediate-release 850 mg to be delisted 1 January 2013)</i>				
PIOGLITAZONE – Special Authority see SA0959 below – Retail pharmacy				
* Tab 15 mg	1.50	28	✓	Pizaccord
* Tab 30 mg	2.50	28	✓	Pizaccord
* Tab 45 mg	3.50	28	✓	Pizaccord

►SA0959 Special Authority for Subsidy

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

Either:

- 1 Patient has not achieved glycaemic control on maximum doses of metformin or a sulphonylurea or where either or both are contraindicated or not tolerated; or
- 2 Patient is on insulin.

Diabetes Management

Ketone Testing

KETONE BLOOD BETA-KETONE ELECTRODES – Maximum of 20 strip per prescription

Test strip – Not on a BSO	7.07	10 strip OP	✓	Freestyle Optium Ketone
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SODIUM NITROPRUSSIDE – Maximum of 50 strip per prescription

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

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

Blood Glucose Testing

BLOOD GLUCOSE DIAGNOSTIC TEST METER – Subsidy by endorsement

- Maximum of 1 meter per prescription
- A diagnostic blood glucose test meter is subsidised for a patient who:
 - is receiving insulin or sulphonylurea therapy; or
 - is pregnant and has diabetes; or
 - is on home TPN at risk of hypoglycaemia or hyperglycaemia; or
 - has a genetic or an acquired disorder of glucose homeostasis excluding type 1 or type 2 diabetes and metabolic syndrome.

Only one CareSens meter per patient. No further prescriptions will be subsidised for patients who already have a CareSens meter. For the avoidance of doubt patients who have previously received a funded meter, other than CareSens, are eligible for a CareSens meter. The prescription must be endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of insulin or sulphonylureas.

Meter	9.00	1	✓ FreeStyle Lite
			✓ Freestyle Optium
			✓ On Call Advanced
	19.00		✓ Accu-Chek Performa

Meter with 50 lancets, a lancing device and 10 diagnostic test strips – Note differing brand requirements below – No patient co-payment payable.....

20.00	1 OP	✓ CareSens II
		✓ CareSens N
		✓ CareSens N POP

- CareSens N brand: Brand switch fee payable (Pharmacode 2423138) - see page 185 for details
- CareSens N POP brand: Brand switch fee payable (Pharmacode 2423154) - see page 185 for details
- CareSens II brand: Brand switch fee payable (Pharmacode 2423146) - see page 185 for details

(FreeStyle Lite Meter to be delisted 1 December 2012)

(On Call Advanced Meter to be delisted 1 December 2012)

(Accu-Chek Performa Meter to be delisted 1 December 2012)

BLOOD GLUCOSE DIAGNOSTIC TEST STRIP

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

- Prescribed with insulin or a sulphonylurea but are on a different prescription and endorsed accordingly; or
- Prescribed on the same prescription as insulin or a sulphonylurea in which case the prescription is deemed to be endorsed; or
- Prescribed for a pregnant woman with diabetes and endorsed accordingly; or
- Prescribed for a patient on home TPN at risk of hypoglycaemia or hyperglycaemia and endorsed accordingly; or
- Prescribed for a patient with a genetic or an acquired disorder of glucose homeostasis excluding type 1 or type 2 diabetes and metabolic syndrome and endorsed accordingly.

Blood glucose test strips	10.56	50 test OP	✓ CareSens
			✓ CareSens N
	21.65		✓ Accu-Chek Performa
			✓ FreeStyle Lite
			✓ Freestyle Optium
Blood glucose test strips × 50 and lancets × 5	10.56	50 test OP	✓ CareSens
	19.10		✓ On Call Advanced

(CareSens Blood glucose test strips × 50 and lancets × 5 to be delisted 1 April 2013)

‡ 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.

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

BLOOD GLUCOSE TEST STRIPS (VISUALLY IMPAIRED)

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

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

SensoCard blood glucose test strips are subsidised only if prescribed for a patient who is severely visually impaired and is using a SensoCard Plus Talking Blood Glucose Monitor.

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

Insulin Syringes and Needles

Subsidy is available for disposable insulin syringes, needles, and pen needles if prescribed on the same form as the one used for the supply of insulin or when prescribed for an insulin patient and the prescription is endorsed accordingly.

INSULIN PEN NEEDLES – Maximum of 100 dev per prescription

* 29 g × 12.7 mm	3.15	30	✓ B-D Micro-Fine
	10.50	100	✓ B-D Micro-Fine
	11.75		✓ ABM
* 31 g × 5 mm	11.75	100	✓ SC Profi-Fine
			✓ B-D Micro-Fine
			✓ SC Profi-Fine
* 31 g × 6 mm	10.50	100	✓ ABM
	11.75		✓ Fine Ject
	10.50		
	(26.00)		NovoFine
* 31 g × 8 mm	3.15	30	✓ B-D Micro-Fine
	10.50	100	✓ B-D Micro-Fine
	11.75		✓ ABM
* 32 g × 4 mm	10.50	100	✓ SC Profi-Fine
			✓ B-D Micro-Fine

(SC Profi-Fine 29 g × 12.7 mm to be delisted 1 December 2012)

(SC Profi-Fine 31 g × 5 mm to be delisted 1 December 2012)

(Fine Ject 31 g × 6 mm to be delisted 1 December 2012)

(SC Profi-Fine 31 g × 8 mm to be delisted 1 December 2012)

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
INSULIN SYRINGES, DISPOSABLE WITH ATTACHED NEEDLE – Maximum of 100 dev per prescription			
* Syringe 0.3 ml with 29 g × 12.7 mm needle	13.00	100	✓ ABM
	1.30	10	
	(1.99)		B-D Ultra Fine
	13.00	100	✓ B-D Ultra Fine
			✓ DM Ject
			✓ ABM
* Syringe 0.3 ml with 31 g × 8 mm needle	13.00	100	
	1.30	10	
	(1.99)		B-D Ultra Fine II
	13.00	100	✓ B-D Ultra Fine II
			✓ DM Ject
			✓ ABM
* Syringe 0.5 ml with 29 g × 12.7 mm needle	13.00	100	
	1.30	10	
	(1.99)		B-D Ultra Fine
	13.00	100	✓ B-D Ultra Fine
			✓ DM Ject
			✓ ABM
* Syringe 0.5 ml with 31 g × 8 mm needle	13.00	100	
	1.30	10	
	(1.99)		B-D Ultra Fine II
	13.00	100	✓ B-D Ultra Fine II
			✓ DM Ject
			✓ ABM
* Syringe 1 ml with 29 g × 12.7 mm needle	13.00	100	
	1.30	10	
	(1.99)		B-D Ultra Fine
	13.00	100	✓ B-D Ultra Fine
			✓ DM Ject
			✓ ABM
* Syringe 1 ml with 31 g × 8 mm needle	13.00	100	
	1.30	10	
	(1.99)		B-D Ultra Fine II
	13.00	100	✓ B-D Ultra Fine II
			✓ DM Ject

(DM Ject Syringe 0.3 ml with 29 g × 12.7 mm needle to be delisted 1 December 2012)

(DM Ject Syringe 0.3 ml with 31 g × 8 mm needle to be delisted 1 December 2012)

(DM Ject Syringe 0.5 ml with 29 g × 12.7 mm needle to be delisted 1 December 2012)

(DM Ject Syringe 0.5 ml with 31 g × 8 mm needle to be delisted 1 December 2012)

(DM Ject Syringe 1 ml with 29 g × 12.7 mm needle to be delisted 1 December 2012)

(DM Ject Syringe 1 ml with 31 g × 8 mm needle to be delisted 1 December 2012)

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

INSULIN PUMP – Special Authority see SA1237 below – Retail pharmacy

a) Maximum of 1 device per prescription				
b) Only on a prescription				
c) Maximum of 1 insulin pump per patient each four year period.				
Flat panel, high contrast screen; compatible with standard luer lock infusion sets; waterproof at 12 feet for 24 hours; 0.025 u/hour basal rate; continuous glucose monitoring (CGM) enabled; pink	4,500.00	1	✓	Animas Vibe
Flat panel, high contrast screen; compatible with standard luer lock infusion sets; waterproof at 12 feet for 24 hours; 0.025 u/hour basal rate; continuous glucose monitoring (CGM) enabled ; blue	4,500.00	1	✓	Animas Vibe
Flat panel, high contrast screen; compatible with standard luer lock infusion sets; waterproof at 12 feet for 24 hours; 0.025 u/hour basal rate; continuous glucose monitoring (CGM) enabled; black	4,500.00	1	✓	Animas Vibe
Flat panel, high contrast screen; compatible with standard luer lock infusion sets; waterproof at 12 feet for 24 hours; 0.025 u/hour basal rate; continuous glucose monitoring (CGM) enabled; green	4,500.00	1	✓	Animas Vibe
Flat panel, high contrast screen; compatible with standard luer lock infusion sets; waterproof at 12 feet for 24 hours; 0.025 u/hour basal rate; continuous glucose monitoring (CGM) enabled; silver	4,500.00	1	✓	Animas Vibe

►SA1237 Special Authority for Subsidy

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

The Co-ordinator Phone: (04) 460 4990
 PHARMAC Facsimile: (04) 974 7806
 PO Box 10 254 Email: ipp@pharmac.govt.nz
 Wellington

Insulin Pump Consumables

►SA1240 Special Authority for Subsidy

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

The Co-ordinator Phone: (04) 460 4990
 PHARMAC Facsimile: (04) 974 7806
 PO Box 10 254 Email: ipp@pharmac.govt.nz
 Wellington

INSULIN PUMP ACCESSORIES – Special Authority see SA1240 above – Retail pharmacy

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

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
INSULIN PUMP INFUSION SET – Special Authority see SA1240 on the preceding page – Retail pharmacy			
a) Maximum of 3 dev per prescription			
b) Only on a prescription			
c) Maximum of 1 prescription per 90 days.			
d) Note: One additional pack of infusion sets will be funded per year (Maximum of 13 pack per annum).			
6 mm metal cannula; straight insertion; 60 cm grey line × 10 with 10 needles	130.00	1 OP	✓ Contact-D
8 mm metal cannula; straight insertion; 110 cm grey line × 10 with 10 needles	130.00	1 OP	✓ Contact-D
8 mm metal cannula; straight insertion; 60 cm grey line × 10 with 10 needles	130.00	1 OP	✓ Contact-D
Teflon cannula angle insertion 13 mm; 60 cm grey line × 5 with 10 needles	120.00	1 OP	✓ Comfort Short
Teflon cannula angle insertion 13 mm; with auto injector; 110 cm grey line × 10 with 10 needles	140.00	1 OP	✓ Inset 30
Teflon cannula angle insertion 13 mm; with auto injector; 60 cm blue line × 10 with 10 needles	140.00	1 OP	✓ Inset 30
Teflon cannula angle insertion 13 mm; with auto injector; 60 cm grey line × 10 with 10 needles	140.00	1 OP	✓ Inset 30
Teflon cannula angle insertion 13 mm; with auto injector; 60 cm pink line × 10 with 10 needles	140.00	1 OP	✓ Inset 30
Teflon cannula angle insertion 17 mm; 110 cm grey line × 5 with 10 needles	120.00	1 OP	✓ Comfort
Teflon cannula straight insertion 6 mm; with auto injector; 110 cm grey line × 10 with 10 needles	140.00	1 OP	✓ Inset II
Teflon cannula straight insertion 6 mm; with auto injector; 60 cm blue line × 10 with 10 needles	140.00	1 OP	✓ Inset II
Teflon cannula straight insertion 6 mm; with auto injector; 60 cm grey line × 10 with 10 needles	140.00	1 OP	✓ Inset II
Teflon cannula straight insertion 6 mm; with auto injector; 60 cm pink line × 10 with 10 needles	140.00	1 OP	✓ Inset II
Teflon cannula straight insertion 9 mm; with auto injector; 110 cm grey line × 10 with 10 needles	140.00	1 OP	✓ Inset II
Teflon cannula straight insertion 9 mm; with auto injector; 60 cm blue line × 10 with 10 needles	140.00	1 OP	✓ Inset II
Teflon cannula straight insertion 9 mm; with auto injector; 60 cm grey line × 10 with 10 needles	140.00	1 OP	✓ Inset II
Teflon cannula straight insertion 9 mm; with auto injector; 60 cm pink line × 10 with 10 needles	140.00	1 OP	✓ Inset II
Teflon cannula angle insertion 17 mm; 60 cm grey line × 5 with 10 needles	120.00	1 OP	✓ Comfort

‡ 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.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
INSULIN PUMP RESERVOIR – Special Authority see SA1240 on page 34 – Retail pharmacy				
a) Maximum of 3 dev per prescription				
b) Only on a prescription				
c) Maximum of 1 prescription per 90 days.				
d) Note: One additional packs of reservoirs will be funded per year (Maximum of 13 packs per annum).				
10 × luer lock conversion cartridges 1.8 ml for Paradigm pumps	50.00	1 OP	✓	ADR Cartridge 1.8
10 × luer lock conversion cartridges 3.0 ml for Paradigm pumps	50.00	1 OP	✓	ADR Cartridge 3.0
Cartridge 200 U, luer lock × 10	50.00	1 OP	✓	Animas Cartridge

Digestives Including Enzymes

PANCREATIC ENZYME

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 Forte
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 SA1188 below – Retail pharmacy

Brand switch fee payable (Pharmacode 2405857) - see page 185 for details

Cap 250 mg – For ursodeoxycholic acid oral liquid formula-tion refer, page 187	71.50	100	✓	Ursosan
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►SA1188 Special Authority for Subsidy

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

Either:

- 1 Patient diagnosed with cholestasis of pregnancy; or
- 2 Both:
 - 2.1 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
 - 2.2 Patient not requiring a liver transplant (bilirubin > 170umol/l; decompensated cirrhosis).

Note: Liver biopsy is not usually required for diagnosis but is helpful to stage the disease.

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

Both:

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

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

Note: Ursodeoxycholic acid is not an appropriate therapy for patients requiring a liver transplant (bilirubin > 170 micromol/l; decompensated cirrhosis). These patients should be referred to an appropriate transplant centre. Treatment failure – doubling of serum bilirubin levels, absence of a significant decrease in ALP or ALT and AST, development of varices, ascites or encephalopathy, marked worsening of pruritus or fatigue, histological progression by two stages, or to cirrhosis, need for transplantation.

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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Laxatives**Bulk-forming Agents**

MUCILAGINOUS LAXATIVES – Only on a prescription

* Dry	6.02	500 g OP	✓ <u>Konsyl-D</u>
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MUCILAGINOUS LAXATIVES WITH STIMULANTS

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

Faecal Softeners

DOCUSATE SODIUM – Only on a prescription

* Cap 50 mg	2.57	100	✓ <u>Laxofast 50</u>
* Cap 120 mg	3.48	100	✓ <u>Laxofast 120</u>
* Enema conc 18%	5.40	100 ml OP	✓ <u>Coloxyl</u>

DOCUSATE SODIUM WITH SENNOSIDES

* Tab 50 mg with total sennosides 8 mg	6.38	200	✓ <u>Laxsol</u>
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POLOXAMER – Only on a prescription

Not funded for use in the ear.

* Oral drops 10%	3.78	30 ml OP	✓ <u>Coloxyl</u>
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Osmotic Laxatives

GLYCEROL

* Suppos 3.6 g – Only on a prescription	6.50	20	✓ <u>PSM</u>
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LACTULOSE – Only on a prescription

* Oral liq 10 g per 15 ml	7.68	1,000 ml	✓ <u>Laevolac</u>
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MACROGOL 3350 – Special Authority see SA0891 below – Retail pharmacy

Powder 13.125 g, sachets – Maximum of 60 sach per pre-

scription	10.00	30	✓ <u>Lax-Sachets</u>
	18.14		✓ <u>Movicol</u>

►SA0891 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid for 6 months where the patient has problematic constipation requiring intervention with a per rectal preparation despite an adequate trial of other oral pharmacotherapies including lactulose where lactulose is not contraindicated.

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	✓ <u>Fleet Phosphate Enema</u>
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SODIUM CITRATE WITH SODIUM LAURYL SULPHOACETATE – Only on a prescription

Enema 90 mg with sodium lauryl sulphoacetate 9 mg per ml, 5 ml	25.00	50	✓ <u>Micolette</u>
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‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Stimulant Laxatives				
BISACODYL – Only on a prescription				
* Tab 5 mg	4.99	200	✓	Lax-Tab
* Suppos 5 mg	3.00	6	✓	Dulcolax
* Suppos 10 mg	3.00	6	✓	Dulcolax
DANTHRON WITH POLOXAMER – Only on a prescription				
Note: Only for the prevention or treatment of constipation in the terminally ill.				
Oral liq 25 mg with poloxamer 200 mg per 5 ml	9.50	300 ml	✓	Pinorax
Oral liq 75 mg with poloxamer 1 g per 5 ml	13.95	300 ml	✓	Pinorax Forte
SENNA – Only on a prescription				
* Tab, standardised	0.43	20		
	(1.72)			Senokot
	2.17	100		
	(6.16)			Senokot

Metabolic Disorder Agents

Gaucher's Disease

IMIGLUCERASE – Special Authority see SA0473 below – Retail pharmacy

Inj 40 iu per ml, 200 iu vial 1,072.00 1

Inj 40 iu per ml, 400 iu vial 2,144.00 1

✓ **Cerezyme**

✓ **Cerezyme**

►SA0473 Special Authority for Subsidy

Special Authority approved by the Gaucher's Treatment Panel

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

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

The Co-ordinator, Gaucher's Treatment Panel

PHARMAC, PO Box 10 254

Wellington

Phone: (04) 460 4990

Facsimile: (04) 916 7571

Email: gaucherpanel@pharmac.govt.nz

Mouth and Throat

Agents Used in Mouth Ulceration

BENZADAMINE HYDROCHLORIDE

Soln 0.15% 3.60 200 ml

(8.50)

Difflam

9.00

500 ml

(17.01)

Difflam

CHLORHEXIDINE GLUCONATE

Mouthwash 0.2% 2.68 200 ml OP

3.87

✓ **healthE**

✓ **Rivacol**

CHOLINE SALICYLATE WITH CETALKONIUM CHLORIDE

* Adhesive gel 8.7% with cetalkonium chloride 0.01% 2.06 15 g OP

(5.62)

Bonjela

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
SODIUM CARBOXYMETHYLCELLULOSE			
With pectin and gelatin paste	17.20	56 g OP	✓ Stomahesive
	1.52	5 g OP	
	(3.60)		Orabase
	4.55	15 g OP	
	(7.90)		Orabase
With pectin and gelatin powder	8.48	28 g OP	
	(10.95)		Stomahesive
TRIAMCINOLONE ACETONIDE			
0.1% in Dental Paste USP	4.34	5 g OP	✓ Oracort

Oropharyngeal Anti-infectives

AMPHOTERICIN B			
Lozenges 10 mg	5.86	20	✓ Fungilin
MICONAZOLE			
Oral gel 20 mg per g	8.70	40 g OP	✓ Daktarin
NYSTATIN			
Oral liq 100,000 u per ml	3.19	24 ml OP	✓ Nilstat

Other Oral Agents

For folinic mouthwash, pilocarpine oral liquid or saliva substitute formula refer, page 190

HYDROGEN PEROXIDE			
* Soln 10 vol – Maximum of 200 ml per prescription.....	1.28	100 ml	✓ PSM
THYMOL GLYCERIN			
* Compound, BPC	9.15	500 ml	✓ PSM

Vitamins

Alpha tocopheryl acetate is available fully subsidised for specific patients at the Medical Director of PHARMAC's discretion. Refer to PHARMAC website www.pharmac.govt.nz for the "Alpha tocopheryl acetate information sheet and application form".

Vitamin A

VITAMIN A WITH VITAMINS D AND C

* Soln 1000 u with Vitamin D 400 u and ascorbic acid 30 mg per 10 drops	4.50	10 ml OP	✓ Vitadol C
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Vitamin B

HYDROXOCOBALAMIN

* Inj 1 mg per ml, 1 ml – Up to 6 inj available on a PSO	5.10	3	✓ ABM Hydroxocobalamin
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PYRIDOXINE HYDROCHLORIDE

a) No more than 100 mg per dose			
b) Only on a prescription			
* Tab 25 mg – No patient co-payment payable	2.20	90	✓ PyridoxADE
* Tab 50 mg	12.16	500	✓ Apo-Pyridoxine

THIAMINE HYDROCHLORIDE – Only on a prescription

* Tab 50 mg	5.62	100	✓ Apo-Thiamine
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‡ safety cap

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

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

ALIMENTARY TRACT AND METABOLISM

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

* Tab, strong, BPC	4.70	500	✓	B-PlexADE
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Vitamin C

ASCORBIC ACID

a) No more than 100 mg per dose

b) Only on a prescription

* Tab 100 mg	13.80	500	✓	Vitala-C
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Vitamin D

ALFACALCIDIOL

* Cap 0.25 µg	26.32	100	✓	One-Alpha
* Cap 1 µg	87.98	100	✓	One-Alpha
* Oral drops 2 µg per ml	60.68	20 ml OP	✓	One-Alpha

CALCITRIOL

* Cap 0.25 µg	3.03	30	✓	Airflow
* Cap 0.5 µg	5.62	30	✓	Airflow
* Oral liq 1 µg per ml	39.40	10 ml OP	✓	Rocaltrol solution

CHOLECALCIFEROL

* Tab 1.25 mg (50,000 iu) – Maximum of 12 tab per prescription	7.76	12	✓	Cal-d-Forte
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Multivitamin Preparations

MULTIVITAMINS – Special Authority see SA1036 below – Retail pharmacy

* Powder	72.00	200 g OP	✓	Paediatric Seravit
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►SA1036 Special Authority for Subsidy

Initial application from any relevant practitioner. Approvals valid without further renewal unless notified where the patient has inborn errors of metabolism.

Renewal from any relevant practitioner. Approvals valid without further renewal unless notified where patient has had a previous approval for multivitamins.

VITAMINS

* Tab (BPC cap strength)	8.00	1,000	✓	MultiADE
* Cap (fat soluble vitamins A, D, E, K) – Special Authority see SA1002 below – Retail pharmacy	23.40	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:

Either:

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

Minerals

Calcium

CALCIUM CARBONATE

* Tab eff 1.75 g (1 g elemental)	6.21	30	✓	Calsource
* Tab 1.25 g (500 mg elemental)	6.38	250	✓	Arrow-Calcium

CALCIUM GLUCONATE

* Inj 10%, 10 ml	21.40	10	✓	Mayne
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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Fluoride**SODIUM FLUORIDE**

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

* Tab 256 µg (150 µg elemental iodine)	7.55	90	✓	NeuroKare
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Iron**FERROUS FUMARATE**

* Tab 200 mg (65 mg elemental)	4.35	100	✓	Ferro-tab
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FERROUS FUMARATE WITH FOLIC ACID

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

* Tab long-acting 325 mg (105 mg elemental)	1.01 (4.26)	30		Ferrograd
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	5.06 (15.58)	150		Ferrograd
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* ‡ Oral liq 30 mg per 1 ml (6 mg elemental per 1 ml)	10.30	500 ml	✓	<u>Ferodan</u>
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FERROUS SULPHATE WITH FOLIC ACID

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

* Inj 50 mg per ml, 2 ml	19.90	5	✓	<u>Ferrum H</u>
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Magnesium

For magnesium hydroxide mixture refer, page 190

MAGNESIUM SULPHATE

* Inj 49.3%, 5 ml	26.60	10	✓	Mayne
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Zinc**ZINC SULPHATE**

* Cap 137.4 mg (50 mg elemental)	11.00	100	✓	<u>Zincaps</u>
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Agents Used in the Treatment of Poisonings**CHARCOAL**

* Oral liq 50 g per 250 ml	43.50	250 ml OP	✓	Carbosorb-X
a) Up to 250 ml available on a PSO				
b) Only on a PSO				

SODIUM CALCIUM EDETATE

* Inj 200 mg per ml, 5 ml	53.31 (156.71)	6		Calcium Disodium Versenate
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‡ safety cap

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

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

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

Antianaemics

Hypoplastic and Haemolytic

►SA0922 Special Authority for Subsidy

Initial application only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Both:
 - 1.1 patient in chronic renal failure; and
 - 1.2 Haemoglobin \leq 100g/L; and
- 2 Any of the following:
 - 2.1 Both:
 - 2.1.1 patient is not diabetic; and
 - 2.1.2 glomerular filtration rate \leq 30ml/min; or
 - 2.2 Both:
 - 2.2.1 patient is diabetic; and
 - 2.2.2 glomerular filtration rate \leq 45ml/min; or
 - 2.3 patient is on haemodialysis or peritoneal dialysis.

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

Notes: Erythropoietin beta 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.

The Cockcroft-Gault Formula may be used to estimate glomerular filtration rate (GFR) in persons 18 years and over:

GFR (ml/min) (male) = $(140 - \text{age}) \times \text{Ideal Body Weight (kg)} / 814 \times \text{serum creatinine (mmol/l)}$

GFR (ml/min) (female) = Estimated GFR (male) \times 0.85

ERYTHROPOIETIN ALPHA – Special Authority see SA0922 above – Retail pharmacy

Inj human recombinant 1,000 iu, prefilled syringe	48.68	6	✓ Eprex
Inj human recombinant 2,000 iu, prefilled syringe	120.18	6	✓ Eprex
Inj human recombinant 3,000 iu, prefilled syringe	166.87	6	✓ Eprex
Inj human recombinant 4,000 iu, prefilled syringe	193.13	6	✓ Eprex
Inj human recombinant 5,000 iu, prefilled syringe	243.26	6	✓ Eprex
Inj human recombinant 6,000 iu, prefilled syringe	291.92	6	✓ Eprex
Inj human recombinant 10,000 iu, prefilled syringe	395.18	6	✓ Eprex

ERYTHROPOIETIN BETA – Special Authority see SA0922 above – Retail pharmacy

Inj 2,000 iu, prefilled syringe	120.18	6	✓ NeoRecormon
Inj 3,000 iu, prefilled syringe	166.87	6	✓ NeoRecormon
Inj 4,000 iu, prefilled syringe	193.13	6	✓ NeoRecormon
Inj 5,000 iu, prefilled syringe	243.26	6	✓ NeoRecormon
Inj 6,000 iu, prefilled syringe	291.29	6	✓ NeoRecormon
Inj 10,000 iu, prefilled syringe	395.18	6	✓ NeoRecormon

Megaloblastic

FOLIC ACID

* Tab 0.8 mg	19.80	1,000	✓ Apo-Folic Acid
* Tab 5 mg	10.21	500	✓ Apo-Folic Acid
Oral liq 50 µg per ml	24.00	25 ml OP	✓ Biomed

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
Antifibrinolytics, Haemostatics and Local Sclerosants			
SODIUM TETRADECYL SULPHATE			
* Inj 0.5% 2 ml	23.20 (45.52)	5	Fibro-vein
* Inj 1% 2 ml	25.00 (48.98)	5	Fibro-vein
* Inj 3% 2 ml	28.50 (55.91)	5	Fibro-vein
TRANEXAMIC ACID			
Tab 500 mg	32.92	100	✓ <u>Cyklokapron</u>
Vitamin K			
PHYTOMENADIONE			
Inj 2 mg per 0.2 ml – Up to 5 inj available on a PSO	8.00	5	✓ <u>Konaktion MM</u>
Inj 10 mg per ml, 1 ml – Up to 5 inj available on a PSO	9.21	5	✓ <u>Konaktion MM</u>
Antithrombotic Agents			
Antiplatelet Agents			
ASPIRIN			
* Tab 100 mg	14.00	990	✓ <u>Ethics Aspirin EC</u>
CLOPIDOGREL			
* Tab 75 mg – For clopidogrel oral liquid formulation refer, page 187	16.25	90	✓ <u>Apo-Clopidogrel</u>
DIPYRIDAMOLE			
* Tab 25 mg – For dipyridamole oral liquid formulation refer, page 187	8.36	84	✓ <u>Persantin</u>
* Tab long-acting 150 mg	11.52	60	✓ <u>Pytazen SR</u>
PRASUGREL – Special Authority see SA1201 below – Retail pharmacy			
Tab 5 mg	108.00	28	✓ <u>Effient</u>
Tab 10 mg	120.00	28	✓ <u>Effient</u>

►SA1201 Special Authority for Subsidy

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

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

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

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

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

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

‡ 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.

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

DALTEPARIN SODIUM – Special Authority see SA1270 below – Retail pharmacy

Inj 10,000 iu per 1 ml graduated syringe	77.55	10	✓	Fragmin
Inj 12,500 iu per 0.5 ml prefilled syringe	99.96	10	✓	Fragmin
Inj 15,000 iu per 0.6 ml prefilled syringe	120.05	10	✓	Fragmin
Inj 18,000 iu per 0.72 ml prefilled syringe	158.47	10	✓	Fragmin
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

►SA1270 Special Authority for Subsidy

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

Either:

- 1 Low molecular weight heparin treatment is required during a patient's pregnancy; or
- 2 or 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:

All of the following:

- 1 For the short-term treatment of venous thromboembolism prior to establishing a therapeutic INR with oral anti-coagulant treatment; and
- 2 For the prophylaxis and treatment of venous thromboembolism in high risk surgery; and
- 3 To enable cessation/re-establishment of existing oral anticoagulant treatment pre/post surgery; and
- 4 For the prophylaxis and treatment of venous thromboembolism in Acute Coronary Syndrome surgical intervention; and
- 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	37.24	10	✓	Clexane
Inj 40 mg	49.69	10	✓	Clexane
Inj 60 mg	74.91	10	✓	Clexane
Inj 80 mg	99.86	10	✓	Clexane
Inj 100 mg	125.06	10	✓	Clexane
Inj 120 mg	155.40	10	✓	Clexane
Inj 150 mg	177.60	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.

continued...

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

continued...

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

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

Either:

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

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

HEPARIN SODIUM

Inj 1,000 iu per ml, 5 ml	13.36	10	✓ Mayne
	66.80	50	✓ Mayne
	11.44	10	✓ Pfizer
	46.30	50	✓ Pfizer
Inj 1,000 iu per ml, 35 ml	16.00	1	✓ Mayne
Inj 5,000 iu per ml, 1 ml	14.20	5	✓ Mayne
Inj 5,000 iu per ml, 5 ml	182.00	50	✓ Pfizer
Inj 25,000 iu per ml, 0.2 ml	9.50	5	✓ Mayne

HEPARINISED SALINE

* Inj 10 iu per ml, 5 ml	32.50	50	✓ Pfizer
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PROTAMINE SULPHATE

* Inj 10 mg per ml, 5 ml	22.40	10	
	(95.87)		Artex

Oral Anticoagulants

DABIGATRAN

Cap 75 mg – No more than 2 cap per day	148.00	60	✓ Pradaxa
Cap 110 mg	148.00	60	✓ Pradaxa
Cap 150 mg	148.00	60	✓ Pradaxa

RIVAROXABAN – Special Authority see SA1066 on the next page – Retail pharmacy

Tab 10 mg	153.00	15	✓ Xarelto
	306.00	30	✓ Xarelto

(Xarelto Tab 10 mg to be delisted 1 May 2013)

BLOOD AND BLOOD FORMING ORGANS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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►SA1066 Special Authority for Subsidy

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

Either:

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

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

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

WARFARIN SODIUM

Note: Marevan and Coumadin are not interchangeable.

* Tab 1 mg	3.46	50	✓ Coumadin
	5.69	100	✓ Marevan
* Tab 2 mg	4.31	50	✓ Coumadin
* Tab 3 mg	8.00	100	✓ Marevan
* Tab 5 mg	5.93	50	✓ Coumadin
	9.64	100	✓ Marevan

Blood Colony-stimulating Factors

FILGRASTIM – Special Authority see SA1259 below – Retail pharmacy

Inj 300 µg per 0.5 ml prefilled syringe	540.00	5	✓ <u>Zarzio</u>
Inj 480 µg per 0.5 ml prefilled syringe	864.00	5	✓ <u>Zarzio</u>

►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 ($ANC < 0.5 \times 10^9/L$); or
- 5 Treatment of drug-induced prolonged neutropenia ($ANC < 0.5 \times 10^9/L$).

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

Fluids and Electrolytes

Intravenous Administration

DEXTRASE

* Inj 50%, 10 ml – Up to 5 inj available on a PSO	19.50	5	✓ <u>Biomed</u>
* Inj 50%, 90 ml – Up to 5 inj available on a PSO	11.25	1	✓ <u>Biomed</u>

POTASSIUM CHLORIDE

* Inj 75 mg per ml, 10 ml	55.00	50	✓ AstraZeneca
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BLOOD AND BLOOD FORMING ORGANS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
SODIUM BICARBONATE				
Inj 8.4%, 50 ml	19.95	1	✓	Biomed
a) Up to 5 inj available on a PSO				
b) Not in combination				
Inj 8.4%, 100 ml	20.50	1	✓	Biomed
a) Up to 5 inj available on a PSO				
b) Not in combination				
SODIUM CHLORIDE				
Not funded for use as a nasal drop. Only funded for nebuliser use when in conjunction with an antibiotic intended for nebuliser use.				
Inj 0.9% – Up to 2000 ml available on a PSO	3.06	500 ml	✓	Baxter
	4.06	1,000 ml	✓	Baxter
Only if prescribed on a prescription for renal dialysis, maternity or post-natal care in the home of the patient, or on a PSO for emergency use. (500 ml and 1,000 ml packs)				
Inj 23.4%, 20 ml	31.25	5	✓	Biomed
For Sodium chloride oral liquid formulation refer Standard Formulae, page 190				
Inj 0.9%, 5 ml – Up to 5 inj available on a PSO	10.85	50	✓	Multichem
	15.50		✓	Pfizer
Inj 0.9%, 10 ml – Up to 5 inj available on a PSO	11.50	50	✓	Multichem
	15.50		✓	Pfizer
Inj 0.9%, 20 ml	4.72	6	✓	Pharmacia
	11.79	30	✓	Pharmacia
	8.41	20	✓	Multichem
TOTAL PARENTERAL NUTRITION (TPN) – Retail pharmacy-Specialist				
Infusion	CBS	1 OP	✓	TPN
WATER				
1) On a prescription or Practitioner's Supply Order only when on the same form as an injection listed in the Pharmaceutical Schedule requiring a solvent or diluent; or				
2) On a bulk supply order; or				
3) When used in the extemporaneous compounding of eye drops.				
Purified for inj, 5 ml – Up to 5 inj available on a PSO	10.25	50	✓	Multichem
Purified for inj, 10 ml – Up to 5 inj available on a PSO	11.25	50	✓	Multichem
Purified for inj, 20 ml – Up to 5 inj available on a PSO	6.50	20	✓	Multichem
Oral Administration				
CALCIUM POLYSTYRENE SULPHONATE				
Powder	169.85	300 g OP	✓	Calcium Resonium
COMPOUND ELECTROLYTES				
Powder for soln for oral use 4.4 g – Up to 10 sach available on a PSO	1.12	5	✓	Electral
DEXTROSE WITH ELECTROLYTES				
Soln with electrolytes	6.60	1,000 ml OP	✓	Pedialyte - Bubblegum
			✓	Pedialyte - Fruit
	6.75		✓	Pedialyte - Plain
POTASSIUM BICARBONATE				
Tab eff 315 mg with sodium acid phosphate 1.937 g and sodium bicarbonate 350 mg	82.50	100	✓	Phosphate-Sandoz
For phosphate supplementation				

‡ 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.

BLOOD AND BLOOD FORMING ORGANS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
POTASSIUM CHLORIDE				
* Tab eff 548 mg (14 m eq) with chloride 285 mg (8 m eq)	5.26 (11.85)	60		Chlorvescent
* Tab long-acting 600 mg	7.42	200	✓	<u>Span-K</u>
SODIUM BICARBONATE				
Cap 840 mg	8.52	100	✓	<u>Sodibic</u>
SODIUM POLYSTYRENE SULPHONATE				
Powder	89.10	450 g OP	✓	<u>Resonium-A</u>

Lipid Modifying Agents

Fibrates

BEZAFIBRATE				
* Tab 200 mg	9.75	90	✓	<u>Fibalip</u>
* Tab long-acting 400 mg	5.70	30	✓	<u>Bezalip Retard</u>
GEMFIBROZIL				
* Tab 600 mg	14.00	60	✓	<u>Lipazil</u>

Other Lipid Modifying Agents

ACIPIMOX				
* Cap 250 mg	18.75	30	✓	<u>Olbetam</u>
NICOTINIC ACID				
* Tab 50 mg	4.17	100	✓	<u>Apo-Nicotinic Acid</u>
* Tab 500 mg	16.54	100	✓	<u>Apo-Nicotinic Acid</u>

Resins

CHOLESTYRAMINE WITH ASPARTAME				
Sachets 4 g with aspartame	19.25 (52.68)	50		Questran-Lite
COLESTIPOL HYDROCHLORIDE				
Sachets 5 g	20.00	30	✓	<u>Colestid</u>

HMG CoA Reductase Inhibitors (Statins)

Prescribing Guidelines

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ATORVASTATIN – See prescribing guideline on the preceding page				
* Tab 10 mg	0.84	30	✓	Dr Reddy's Atorvastatin
	2.52	90	✓	Zarator
	0.84	30		Lipitor
	(18.32)			
* Tab 20 mg	1.39	30	✓	Dr Reddy's Atorvastatin
	4.17	90	✓	Zarator
	1.39	30		Lipitor
	(26.70)			
* Tab 40 mg	2.44	30	✓	Dr Reddy's Atorvastatin
	7.32	90	✓	Zarator
	2.44	30		Lipitor
	(37.02)			
* Tab 80 mg	5.41	30	✓	Dr Reddy's Atorvastatin
	16.23	90	✓	Zarator
	5.41	30		Lipitor
	(110.50)			

(Dr Reddy's Atorvastatin Tab 10 mg to be delisted 1 January 2013)

(Lipitor Tab 10 mg to be delisted 1 January 2013)

(Dr Reddy's Atorvastatin Tab 20 mg to be delisted 1 January 2013)

(Lipitor Tab 20 mg to be delisted 1 January 2013)

(Dr Reddy's Atorvastatin Tab 40 mg to be delisted 1 January 2013)

(Lipitor Tab 40 mg to be delisted 1 January 2013)

(Dr Reddy's Atorvastatin Tab 80 mg to be delisted 1 January 2013)

(Lipitor Tab 80 mg to be delisted 1 January 2013)

PRAVASTATIN – See prescribing guideline on the preceding page

* Tab 20 mg	5.44	30	✓	Cholvastin
* Tab 40 mg	9.28	30	✓	Cholvastin

SIMVASTATIN – See prescribing guideline on the preceding page

* Tab 10 mg	1.40	90	✓	Arrow-Simva 10mg
* Tab 20 mg	1.95	90	✓	Arrow-Simva 20mg
* Tab 40 mg	3.18	90	✓	Arrow-Simva 40mg
* Tab 80 mg	9.31	90	✓	Arrow-Simva 80mg

Selective Cholesterol Absorption Inhibitors

EZETIMIBE – Special Authority see SA1045 below – Retail pharmacy

Tab 10 mg	45.90	30	✓	Ezetrol
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SA1045 Special Authority for Subsidy

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

All of the following:

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

continued...

‡ safety cap

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

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

BLOOD AND BLOOD FORMING ORGANS

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

- 3.1 The patient has rhabdomyolysis (defined as muscle aches and creatine kinase more than $10 \times$ normal) when treated with one statin; or
- 3.2 The patient is intolerant to both simvastatin and atorvastatin; or
- 3.3 The patient has not reduced their LDL cholesterol to less than 2.0 mmol/litre with the use of the maximal tolerated dose of atorvastatin.

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

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

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

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

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

Tab 10 mg with simvastatin 10 mg	48.90	30	✓ Vytorin
Tab 10 mg with simvastatin 20 mg	51.60	30	✓ Vytorin
Tab 10 mg with simvastatin 40 mg	55.20	30	✓ Vytorin
Tab 10 mg with simvastatin 80 mg	60.60	30	✓ Vytorin

►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.

Iron Overload

DEFERIPRONE – Special Authority see SA1042 below – Retail pharmacy

Tab 500 mg	533.17	100	✓ Ferriprox
Oral liq 100 mg per 1 ml	266.59	250 ml OP	✓ Ferriprox

►SA1042 Special Authority for Subsidy

Initial application only from a relevant specialist. Approvals valid without further renewal unless notified where the patient has been diagnosed with chronic transfusional iron overload due to congenital inherited anaemia.

Note: For the purposes of this Special Authority, a relevant specialist is defined as a haematologist.

DESFERIOXAMINE MESYLATE

* Inj 500 mg	99.00	10	✓ Mayne
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	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
		✓	

Alpha Adrenoceptor Blockers

DOXAZOSIN MESYLATE

* Tab 2 mg	8.23	500	✓ <u>Apo-Doxazosin</u>
* Tab 4 mg	12.40	500	✓ <u>Apo-Doxazosin</u>

PHENOXYBENZAMINE HYDROCHLORIDE

* Cap 10 mg	7.82	30	✓ <u>Dibenyline S29</u>
	26.05	100	✓ <u>Dibenyline S29</u>

PHENTOLAMINE MESYLATE

* Inj 10 mg per ml, 1 ml	17.97	5	
	(31.65)		Regitine

(Regitine Inj 10 mg per ml, 1 ml to be delisted 1 January 2013)

PRAZOSIN HYDROCHLORIDE

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

TERAZOSIN HYDROCHLORIDE

* Tab 1 mg	1.50	28	✓ <u>Arrow</u>
* Tab 2 mg	0.80	28	✓ <u>Arrow</u>
* Tab 5 mg	1.00	28	✓ <u>Arrow</u>

Agents Affecting the Renin-Angiotensin System

ACE Inhibitors

CAPTAPRIL

* Tab 12.5 mg	2.00	100	✓ <u>m-Captopril</u>
* Tab 25 mg	2.40	100	✓ <u>m-Captopril</u>
* Tab 50 mg	3.50	100	✓ <u>m-Captopril</u>
*† Oral liq 5 mg per ml	94.99	95 ml OP	✓ <u>Capoten</u>

Oral liquid restricted to children under 12 years of age.

CILAZAPRIL

* Tab 0.5 mg	2.85	90	✓ <u>Zapril</u>
* Tab 2.5 mg	6.18	90	✓ <u>Zapril</u>
* Tab 5 mg	9.84	90	✓ <u>Zapril</u>

ENALAPRIL

* Tab 5 mg	1.07	90	✓ <u>m-Enalapril</u>
	1.98		✓ <u>Arrow-Enalapril</u>
* Tab 10 mg	1.32	90	✓ <u>m-Enalapril</u>
	2.44		✓ <u>Arrow-Enalapril</u>
* Tab 20 mg – For enalapril oral liquid formulation refer, page 187	1.72	90	✓ <u>m-Enalapril</u>
	3.24		✓ <u>Arrow-Enalapril</u>

† safety cap

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

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

CARDIOVASCULAR SYSTEM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
LISINAPRIL				
* Tab 5 mg	1.19	30	✓	Arrow-Lisinopril
	3.58	90	✓	Arrow-Lisinopril
* Tab 10 mg	1.36	30	✓	Arrow-Lisinopril
	4.08	90	✓	Arrow-Lisinopril
* Tab 20 mg	1.63	30	✓	Arrow-Lisinopril
	4.88	90	✓	Arrow-Lisinopril

(Arrow-Lisinopril Tab 5 mg to be delisted 1 February 2013)

(Arrow-Lisinopril Tab 10 mg to be delisted 1 February 2013)

(Arrow-Lisinopril Tab 20 mg to be delisted 1 February 2013)

PERINDOPRIL

Perindopril will be funded to the level of the ex-manufacturer price listed in the Schedule for patients who were taking these ACE inhibitors for the treatment of congestive heart failure prior to 1 June 1998. The prescription must be endorsed accordingly. We recommend that the words used to indicate eligibility are "certified condition" or an appropriate description of the patient such as "congestive heart failure", "CHF", "congestive cardiac failure" or "CCF". Definition of Congestive Heart Failure At the request of some prescribers the PTAC Cardiovascular subcommittee has provided a definition of congestive heart failure for the purposes of the funding of the manufacturer's surcharge: "Clinicians should use their clinical judgement. Existing patients would be eligible for the funding of the surcharge if the patient shows signs and symptoms of congestive heart failure, and requires or has in the past required concomitant treatment with a diuretic. The definition could also be considered to include patients post myocardial infarction with an ejection fraction of less than 40%."

* Tab 2 mg – Higher subsidy of \$18.50 per 30 tab with Endorsement.....	3.00	30		
	(18.50)			Coversyl
* Tab 4 mg – Higher subsidy of \$25.00 per 30 tab with Endorsement.....	4.05	30		
	(25.00)			Coversyl

QUINAPRIL

* Tab 5 mg	1.60	30	✓	Accupril
* Tab 10 mg	1.75	30	✓	Accupril
* Tab 20 mg	2.35	30	✓	Accupril

TRANDOLAPRIL

Trandolapril will be funded to the level of the ex-manufacturer price listed in the Schedule for patients who were taking these ACE inhibitors for the treatment of congestive heart failure prior to 1 June 1998. The prescription must be endorsed accordingly. We recommend that the words used to indicate eligibility are "certified condition" or an appropriate description of the patient such as "congestive heart failure", "CHF", "congestive cardiac failure" or "CCF". Definition of Congestive Heart Failure At the request of some prescribers the PTAC Cardiovascular subcommittee has provided a definition of congestive heart failure for the purposes of the funding of the manufacturer's surcharge: "Clinicians should use their clinical judgement. Existing patients would be eligible for the funding of the surcharge if the patient shows signs and symptoms of congestive heart failure, and requires or has in the past required concomitant treatment with a diuretic. The definition could also be considered to include patients post myocardial infarction with an ejection fraction of less than 40%."

* Cap 1 mg – Higher subsidy of \$18.67 per 28 cap with Endorsement.....	3.06	28		
	(18.67)			Gopten
* Cap 2 mg – Higher subsidy of \$27.00 per 28 cap with Endorsement.....	4.43	28		
	(27.00)			Gopten

ACE Inhibitors with Diuretics

CILAZAPRIL WITH HYDROCHLOROTHIAZIDE

* Tab 5 mg with hydrochlorothiazide 12.5 mg	5.36	28	✓	Inhibace Plus
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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ENALAPRIL WITH HYDROCHLOROTHIAZIDE				
* Tab 20 mg with hydrochlorothiazide 12.5 mg	3.32 (8.70)	30		Co-Renitec
QUINAPRIL WITH HYDROCHLOROTHIAZIDE				
* Tab 10 mg with hydrochlorothiazide 12.5 mg	3.37	30	✓	<u>Accuretic 10</u>
* Tab 20 mg with hydrochlorothiazide 12.5 mg	4.57	30	✓	<u>Accuretic 20</u>

Angiotension II Antagonists

CANDESARTAN – Special Authority see SA1223 below – Retail pharmacy

Brand switch fee payable (Pharmacode 2426781) - see page 185 for details

* Tab 4 mg	4.13	90	✓	<u>Candestar</u>
* Tab 8 mg	6.10	90	✓	<u>Candestar</u>
* Tab 16 mg	10.18	90	✓	<u>Candestar</u>
* Tab 32 mg	17.66	90	✓	<u>Candestar</u>

►SA1223 Special Authority for Subsidy

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

Either:

- 1 Patient has persistent ACE inhibitor induced cough that is not resolved by ACE inhibitor retrial (same or new ACE inhibitor); or
- 2 Patient has a history of angioedema.

Initial application — (Unsatisfactory response to ACE inhibitor) from any relevant practitioner. Approvals valid without further renewal unless notified where patient is not adequately controlled on maximum tolerated dose of an ACE inhibitor.

LOSARTAN

* Tab 12.5 mg	2.88	90	✓	<u>Losaar</u>
* Tab 25 mg	3.20	90	✓	<u>Losaar</u>
* Tab 50 mg	5.22	90	✓	<u>Losaar</u>
Tab 50 mg with hydrochlorothiazide 12.5 mg	4.89	30	✓	<u>Arrow-Losartan & Hydrochlorothiazide</u>
* Tab 100 mg	8.68	90	✓	<u>Losaar</u>

Antiarrhythmics

For lignocaine hydrochloride refer to NERVOUS SYSTEM, Anaesthetics, Local, page 123

AMIODARONE HYDROCHLORIDE

▲ Tab 100 mg – Retail pharmacy-Specialist	18.65	30	✓	Aratac
✓			✓	Cordarone-X
▲ Tab 200 mg – Retail pharmacy-Specialist	30.52	30	✓	Aratac
✓			✓	Cordarone-X
Inj 50 mg per ml, 3 ml – Up to 5 inj available on a PSO	60.84	10	✓	Cordarone-X

DIGOXIN

* Tab 62.5 µg – Up to 30 tab available on a PSO	6.67	240	✓	Lanoxin PG
* Tab 250 µg – Up to 30 tab available on a PSO	14.52	240	✓	Lanoxin
*† Oral liq 50 µg per ml	16.60	60 ml	✓	Lanoxin

DISOPYRAMIDE PHOSPHATE

▲ Cap 100 mg	15.00 (23.87)	100		Rythmodan
▲ Cap 150 mg	26.21	100	✓	Rythmodan

† 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.

CARDIOVASCULAR SYSTEM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
FLECAINIDE ACETATE – Retail pharmacy-Specialist				
▲ Tab 50 mg	45.82	60	✓	Tambocor
▲ Tab 100 mg – For flecainide acetate oral liquid formulation refer, page 187	80.92	60	✓	Tambocor
▲ Cap long-acting 100 mg	45.82	30	✓	Tambocor CR
▲ Cap long-acting 200 mg	80.92	30	✓	Tambocor CR
▲ Inj 10 mg per ml, 15 ml	52.45	5	✓	Tambocor
MEXILETINE HYDROCHLORIDE				
▲ Cap 150 mg	65.00	100	✓	Mexiletine Hydrochloride USP S29
▲ Cap 250 mg	102.00	100	✓	Mexiletine Hydrochloride USP S29
PROPafenone Hydrochloride – Retail pharmacy-Specialist				
▲ Tab 150 mg	40.90	50	✓	Rytmonorm

Antihypotensives

MIDODRINE – Special Authority see SA0934 below – Retail pharmacy

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

►SA0934 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 Disabling orthostatic hypotension not due to drugs; and
- 2 Patient has tried fludrocortisone (unless contra-indicated) with unsatisfactory results; and
- 3 Patient has tried non pharmacological treatments such as support hose, increased salt intake, exercise, and elevation of head and trunk at night.

Notes: 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	5.56	500	✓	<u>Mylan Atenolol</u>
	11.12	1,000	✓	<u>Atenolol Tablet USP</u>
* Tab 100 mg	9.12	500	✓	<u>Mylan Atenolol</u>
	18.24	1,000	✓	<u>Atenolol Tablet USP</u>

(Atenolol Tablet USP Tab 50 mg to be delisted 25 November 2012)

(Atenolol Tablet USP Tab 100 mg to be delisted 25 November 2012)

BISOPROLOL FUMARATE

Tab 2.5 mg	3.88	30	✓	<u>Bosvate</u>
Tab 5 mg	4.74	30	✓	<u>Bosvate</u>
Tab 10 mg	9.18	30	✓	<u>Bosvate</u>

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
CARVEDILOL				
* Tab 6.25 mg	21.00	30	✓	Dilatrend
* Tab 12.5 mg	27.00	30	✓	Dilatrend
* Tab 25 mg – For carvedilol oral liquid formulation refer, page 187	33.75	30	✓	Dilatrend
CELIPROLOL				
* Tab 200 mg	19.00	180	✓	Celol
LABETALOL				
* Tab 50 mg	8.23	100	✓	Hybloc
* Tab 100 mg – For labetalol oral liquid formulation refer, page 187	10.06	100	✓	Hybloc
* Tab 200 mg	17.55	100	✓	Hybloc
* Inj 5 mg per ml, 20 ml	59.06 (88.60)	5		Trandate
METOPROLOL SUCCINATE – Brand switch fee payable (Pharmacode 2405873) - see page 185 for details				
* Tab long-acting 23.75 mg	0.96	30	✓	Metoprolol - AFT CR
* Tab long-acting 47.5 mg	1.41	30	✓	Metoprolol - AFT CR
* Tab long-acting 95 mg	2.42	30	✓	Metoprolol - AFT CR
* Tab long-acting 190 mg	4.66	30	✓	Metoprolol - AFT CR
METOPROLOL TARTRATE				
* Tab 50 mg – For metoprolol tartrate oral liquid formulation refer, page 187	16.00	100	✓	Lopresor
* Tab 100 mg	21.00	60	✓	Lopresor
* Tab long-acting 200 mg	18.00	28	✓	Slow-Lopresor
* Inj 1 mg per ml, 5 ml	24.00	5	✓	Lopresor
NADOLOL				
* Tab 40 mg	14.97	100	✓	Apo-Nadolol
* Tab 80 mg	22.19	100	✓	Apo-Nadolol
PINDOLOL				
* Tab 5 mg	5.40	100	✓	Apo-Pindolol
* Tab 10 mg	9.19	100	✓	Apo-Pindolol
* Tab 15 mg	13.80	100	✓	Apo-Pindolol
PROPRANOLOL				
* Tab 10 mg	3.55 3.65	100	✓	Cardinol
			✓	Apo- Propranolol S29
* Tab 40 mg	4.65	100	✓	Apo- Propranolol S29
			✓	Cardinol
* Cap long-acting 160 mg	16.06	100	✓	Cardinol LA
<i>(Cardinol Tab 40 mg to be delisted 1 December 2012)</i>				
SOTALOL				
* Tab 80 mg – For sotalol oral liquid formulation refer, page 187	27.50	500	✓	Mylan
* Tab 160 mg	10.50	100	✓	Mylan
* Inj 10 mg per ml, 4 ml	65.39	5	✓	Sotacor
TIMOLOL MALEATE				
* Tab 10 mg	10.55	100	✓	Apo-Timol

‡ 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.

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

Dihydropyridine Calcium Channel Blockers (DHP CCBs)

AMLODIPINE

* Tab 2.5 mg	2.45	100	✓	<u>Apo-Amlodipine</u>
* Tab 5 mg – For amlodipine oral liquid formulation refer, page 187	2.65	100	✓	<u>Apo-Amlodipine</u>
* Tab 10 mg	4.15	100	✓	<u>Apo-Amlodipine</u>

FELODIPINE

* Tab long-acting 2.5 mg	2.90	30	✓	Plendil ER
* Tab long-acting 5 mg	3.10	30	✓	Plendil ER
	9.30	90	✓	Felo 5 ER
* Tab long-acting 10 mg	4.60	30	✓	Plendil ER
	13.80	90	✓	Felo 10 ER

(Felo 5 ER Tab long-acting 5 mg to be delisted 1 January 2013)

(Felo 10 ER Tab long-acting 10 mg to be delisted 1 January 2013)

ISRADIPINE

* Cap long-acting 2.5 mg	7.50	30	✓	Dynacirc-SRO
* Cap long-acting 5 mg	7.85	30	✓	Dynacirc-SRO

NIFEDIPINE

* Tab long-acting 10 mg	17.72	60	✓	Adalat 10
* Tab long-acting 20 mg	7.30	100	✓	Nyefax Retard
* Tab long-acting 30 mg	8.56	30	✓	Adefin XL
	5.50		✓	Arrow-Nifedipine XR
	(19.90)			Adalat Oros
* Tab long-acting 60 mg	12.28	30	✓	Adefin XL
	8.00		✓	Arrow-Nifedipine XR
	(29.50)			Adalat Oros

Other Calcium Channel Blockers

DILTIAZEM HYDROCHLORIDE

* Tab 30 mg	4.60	100	✓	<u>Dilzem</u>
* Tab 60 mg – For diltiazem hydrochloride oral liquid formulation refer, page 187	8.50	100	✓	<u>Dilzem</u>
* Cap long-acting 120 mg	4.34	30	✓	Cardizem CD
* Cap long-acting 180 mg	6.50	30	✓	Cardizem CD
* Cap long-acting 240 mg	8.67	30	✓	Cardizem CD

PERHEXILINE MALEATE – Special Authority see SA1260 on the next page – Retail pharmacy

* Tab 100 mg	62.90	100	✓	Pexsig
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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised	Brand or Generic Manufacturer
			✓	

►SA1260 Special Authority for Subsidy

Initial application only from a cardiologist or general physician. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Patient has refractory angina; and
- 2 Patient is on the maximal tolerated dose of a beta-blocker, a calcium channel blocker and a long acting nitrate.

Renewal only from a cardiologist or any relevant practitioner on the recommendation of a cardiologist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

VERAPAMIL HYDROCHLORIDE

* Tab 40 mg	7.01	100	✓ <u>Isoptin</u>
* Tab 80 mg – For verapamil hydrochloride oral liquid formula- tion refer, page 187.....	11.74	100	✓ <u>Isoptin</u>
* Tab long-acting 120 mg	15.20	250	✓ <u>Verpamil SR</u>
* Tab long-acting 240 mg	25.00	250	✓ <u>Verpamil SR</u>
* Inj 2.5 mg per ml, 2 ml – Up to 5 inj available on a PSO	7.54	5	✓ <u>Isoptin</u>

Centrally Acting Agents

CLONIDINE

* TDDS 2.5 mg, 100 µg per day – Only on a prescription	23.30	4	✓ <u>Catapres-TTS-1</u>
* TDDS 5 mg, 200 µg per day – Only on a prescription	32.80	4	✓ <u>Catapres-TTS-2</u>
* TDDS 7.5 mg, 300 µg per day – Only on a prescription	41.20	4	✓ <u>Catapres-TTS-3</u>

CLONIDINE HYDROCHLORIDE

* Tab 150 µg	33.00	100	✓ <u>Catapres</u>
* Inj 150 µg per ml, 1 ml	16.07	5	✓ <u>Catapres</u>

METHYLDOPA

* Tab 125 mg	14.25	100	✓ <u>Prodopa</u>
* Tab 250 mg	15.10	100	✓ <u>Prodopa</u>
* Tab 500 mg	23.15	100	✓ <u>Prodopa</u>

Diuretics

Loop Diuretics

BUMETANIDE

* Tab 1 mg	16.36	100	✓ <u>Burinex</u>
* Inj 500 µg per ml, 4 ml	7.95	5	✓ <u>Burinex</u>

FUROSEMIDE

* Tab 40 mg – Up to 30 tab available on a PSO.....	10.25	1,000	✓ <u>Diurin 40</u>
* Tab 500 mg	25.00	50	✓ <u>Urex Forte</u>
*† Oral liq 10 mg per ml	10.66	30 ml OP	✓ <u>Lasix</u>
* Infusion 10 mg per ml, 25 ml	48.14	5	✓ <u>Lasix</u>
* Inj 10 mg per ml, 2 ml – Up to 5 inj available on a PSO	1.30	5	✓ <u>Fruzemide-Clarix</u>

Potassium Sparing Diuretics

AMILORIDE

† Oral liq 1 mg per ml	30.00	25 ml OP	✓ <u>Biomed</u>
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SPIRONOLACTONE

* Tab 25 mg	4.60	100	✓ <u>Spirotone</u>
* Tab 100 mg	15.15	100	✓ <u>Spirotone</u>
† Oral liq 5 mg per ml	30.00	25 ml OP	✓ <u>Biomed</u>

† safety cap

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

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

CARDIOVASCULAR SYSTEM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Potassium Sparing Combination Diuretics				
AMILORIDE WITH FRUSEMIDE				
* Tab 5 mg with frusemide 40 mg	8.63	28	✓	Frumil
AMILORIDE WITH HYDROCHLOROTHIAZIDE				
* Tab 5 mg with hydrochlorothiazide 50 mg	5.00	50	✓	Moduretic
Thiazide and Related Diuretics				
BENDROFLUAZIDE				
* Tab 2.5 mg – Up to 150 tab available on a PSO.....	6.48	500	✓	<u>Arrow-Bendrofluzide</u>
May be supplied on a PSO for reasons other than emergency.				
* Tab 5 mg	9.95	500	✓	<u>Arrow-Bendrofluzide</u>
CHLOROTHIAZIDE				
‡ Oral liq 50 mg per ml	26.00	25 ml OP	✓	Biomed
CHLORTHALIDONE				
* Tab 25 mg	4.80	30	✓	Igrotan ^{\$29}
	8.00	50	✓	Hygroton
INDAPAMIDE				
* Tab 2.5 mg	2.95	90	✓	<u>Dapa-Tabs</u>
Nitrates				
GLYCERYL TRINITRATE				
* Tab 600 µg – Up to 100 tab available on a PSO	8.00	100 OP	✓	<u>Lycinate</u>
* Aerosol spray, 400 µg per dose – Up to 250 dose available on a PSO	4.45	250 dose OP	✓	<u>Glytrin</u>
* TDDS 5 mg	16.56	30	✓	<u>Nitroderm TTS</u>
* TDDS 10 mg	19.50	30	✓	<u>Nitroderm TTS</u>
ISOSORBIDE MONONITRATE				
* Tab 20 mg	17.10	100	✓	<u>Ismo 20</u>
* Tab long-acting 40 mg	7.50	30	✓	<u>Corangin</u>
* Tab long-acting 60 mg	3.94	90	✓	<u>Duride</u>
Sympathomimetics				
ADRENALINE				
Inj 1 in 1,000, 1 ml – Up to 5 inj available on a PSO	4.98	5	✓	Aspen Adrenaline
	5.25		✓	Mayne
Inj 1 in 10,000, 10 ml – Up to 5 inj available on a PSO	27.00	5	✓	Mayne
	49.00	10	✓	Aspen Adrenaline
ISOPRENALINE HYDROCHLORIDE				
* Inj 200 µg per ml, 1 ml	36.80	25		Isuprel
	(135.00)			
Vasodilators				
AMYL NITRITE				
* Ampoule, 0.3 ml crushable	62.92	12		Baxter
	(73.40)			

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

* Inj 20 mg per ml, 1 ml25.90 5 ✓ **Apresoline**

MINOXIDIL – Special Authority see SA1271 below – Retail pharmacy

▲ Tab 10 mg70.00 100 ✓ **Loniten**

►SA1271 Special Authority for Subsidy

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

NICORANDIL – Special Authority see SA1263 below – Retail pharmacy

▲ Tab 10 mg27.95 60 ✓ **Ikorel**

▲ Tab 20 mg33.28 60 ✓ **Ikorel**

►SA1263 Special Authority for Subsidy

Initial application only from a cardiologist or general physician. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 Patient has refractory angina; and
- 2 Patient is on the maximal tolerated dose of a beta-blocker, a calcium channel blocker and a long acting nitrate.

Renewal only from a cardiologist or any relevant practitioner on the recommendation of a cardiologist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

OXYPENTIFYLLINE

Tab 400 mg36.94 50
(42.26) Trental 400

PAPAVERINE HYDROCHLORIDE

* Inj 12 mg per ml, 10 ml73.12 5 ✓ **Mayne**

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 7512, Fax: (04) 974 4858, Email: PAH@pharmac.govt.nz

AMBRISANTAN – Special Authority see SA0967 above – Retail pharmacy

Tab 5 mg4,585.00 30 ✓ **Volibris**

Tab 10 mg4,585.00 30 ✓ **Volibris**

BOSENTAN – Special Authority see SA0967 above – Retail pharmacy

Tab 62.5 mg4,585.00 60 ✓ **Tracleer**

Tab 125 mg4,585.00 60 ✓ **Tracleer**

Phosphodiesterase Type 5 Inhibitors

►SA1086 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 7512, Fax: (04) 974 4858, Email: PAH@pharmac.govt.nz

‡ 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.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
SILDENAFIL – Special Authority see SA1086 on the preceding page – Retail pharmacy				
Tab 25 mg	39.00	4	✓	Viagra
Tab 50 mg	43.50	4	✓	Viagra
Tab 100 mg – For sildenafil oral liquid formulation refer, page 187	47.00	4	✓	Viagra

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 7512, Fax: (04) 974 4858, Email: PAH@pharmac.govt.nz

ILOPROST – Special Authority see SA0969 above – Retail pharmacy

Nebuliser soln 10 µg per ml, 2 ml	1,185.00	30	✓	Ventavis
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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
	✓	

Antiacne Preparations

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 87

ADAPALENE

- Maximum of 30 g per prescription
- Only on a prescription

Crm 0.1%	22.89	30 g OP	✓ Differin
Gel 0.1%	22.89	30 g OP	✓ Differin

ISOTRETINOIN – Special Authority see SA0955 below – Retail pharmacy

Cap 10 mg	18.71	120	✓ Oratane
	28.07	180	✓ Oratane
Cap 20 mg	28.91	120	✓ Oratane
	43.37	180	✓ Oratane

(Oratane Cap 10 mg to be delisted 1 April 2013)

(Oratane Cap 20 mg to be delisted 1 April 2013)

SA0955 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:

- Patient has had an adequate trial on other available treatments and has received an inadequate response from these treatments or these are contraindicated; and
- Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice; and
- Applicant has an up to date knowledge of the treatment options for acne and is aware of the safety issues around isotretinoin and is competent to prescribe isotretinoin; and
- Either:
 - 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
 - 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:

All of the following:

- Patient has had an adequate trial on other available treatments and has received an inadequate response from these treatments or these are contraindicated; and
- Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice; and
- Applicant has an up to date knowledge of the treatment options for acne and is aware of the safety issues around isotretinoin and is competent to prescribe isotretinoin; and
- Either:
 - 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
 - Patient is male.

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

TRETINOIN

Crm 0.5 mg per g – Maximum of 50 g per prescription	13.90	50 g OP	✓ ReTrieve
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‡ 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.

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

Antibacterials Topical

For systemic antibacterials, refer to INFECTIONS, Antibacterials, page 87

FUSIDIC ACID

Crm 2%	3.25	15 g OP	✓ Foban
a) Maximum of 15 g per prescription			
b) Only on a prescription			
c) Not in combination			
Oint 2%	3.25	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	10 g OP	✓ Crystacide
		15 g OP	✓ Crystaderm

(Crystacide Crm 1% to be delisted 1 April 2013)

MUPIROICIN

Oint 2%	6.60 (9.26)	15 g OP	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			
b) Not in combination			

Antifungals Topical

For systemic antifungals, refer to INFECTIONS, Antifungals, page 92

AMOROLFINE

a) Only on a prescription			
b) Not in combination			
Nail soln 5%	37.86 (61.87)	5 ml OP	Loceryl

CICLOPIROX OLAMINE

a) Only on a prescription			
b) Not in combination			
Nail soln 8%	19.85	3 g OP	✓ Batrafen
Nail-soln 8%	8.23	7 ml OP	✓ Apo-Ciclopirox
Soln 1%	4.36 (11.54)	20 ml OP	Batrafen

CLOTRIMAZOLE

* Crm 1%	0.54	20 g OP	✓ Clomazol
a) Only on a prescription			
b) Not in combination			
* Soln 1%	4.36 (7.55)	20 ml OP	Canesten
a) Only on a prescription			
b) Not in combination			

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ECONAZOLE NITRATE				
Crm 1%	1.00 (7.48)	20 g OP		Pevaryl
a) Only on a prescription				
b) Not in combination				
Foaming soln 1%, 10 ml sachets	9.89 (17.23)	3		Pevaryl
a) Only on a prescription				
b) Not in combination				
MICONAZOLE NITRATE				
* Crm 2%	0.46	15 g OP	✓	Multichem
a) Only on a prescription				
b) Not in combination				
* Lotn 2%	4.36 (10.03)	30 ml OP		Daktarin
a) Only on a prescription				
b) Not in combination				
* Tinct 2%	4.36 (12.10)	30 ml OP		Daktarin
a) Only on a prescription				
b) Not in combination				
NYSTATIN				
Crm 100,000 u per g	1.00 (7.90)	15 g OP		Mycostatin
a) Only on a prescription				
b) Not in combination				
Antipruritic Preparations				
CALAMINE				
a) Only on a prescription				
b) Not in combination				
Crm, aqueous, BP	1.77 (2.78)	100 g	✓	Home Essential healthE
Lotn, BP	13.45	2,000 ml	✓	PSM
<i>(healthE Crm, aqueous, BP to be delisted 1 February 2013)</i>				
CROTAMITON				
a) Only on a prescription				
b) Not in combination				
Crm 10%	3.48	20 g OP	✓	Itch-Soothe
MENTHOL – Only in combination				
Only in combination with aqueous cream, 10% urea cream, wool fat with mineral oil lotion, 1% hydrocortisone with wool fat and mineral oil lotion, and glycerol, paraffin and cetyl alcohol lotion				
Crystals	6.50	25 g	✓	PSM
	6.92		✓	MidWest
	29.60	100 g	✓	MidWest

‡ 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.

Corticosteroids Topical

For systemic corticosteroids, refer to CORTICOSTEROIDS AND RELATED AGENTS, page 79

Corticosteroids - Plain

BETAMETHASONE DIPROPIONATE

Crm 0.05%	2.96	15 g OP	
	(6.91)		Diprosone
	8.97	50 g OP	
	(18.36)		Diprosone
Crm 0.05% in propylene glycol base	4.33	30 g OP	
	(13.83)		Diprosone OV
Oint 0.05%	2.96	15 g OP	
	(6.51)		Diprosone
	8.97	50 g OP	
	(17.11)		Diprosone
Oint 0.05% in propylene glycol base	4.33	30 g OP	
	(13.83)		Diprosone OV

BETAMETHASONE VALERATE

* Crm 0.1%	3.20	50 g OP	✓ Beta Cream
* Oint 0.1%	3.20	50 g OP	✓ Beta Ointment
* Lotn 0.1%	10.05	50 ml OP	✓ Betnovate

CLOBETASOL PROPIONATE

* Crm 0.05%	3.48	30 g OP	✓ Dermol
* Oint 0.05%	3.48	30 g OP	✓ Dermol

CLOBETASONE BUTYRATE

Crm 0.05%	5.38	30 g OP	
	(7.09)		Eumovate
	16.13	100 g OP	
	(22.00)		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
	14.00	500 g	✓ Pharmacy Health
* Powder – Only in combination	44.00	25 g	✓ ABM
Up to 5% in a dermatological base (not proprietary Topical Corticosteroid – Plain) with or without other dermatological galenicals. Refer, page 186			

HYDROCORTISONE BUTYRATE

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
HYDROCORTISONE WITH WOOL FAT AND MINERAL OIL				
Lotn 1% with wool fat hydrous 3% and mineral oil – Only on a prescription.....	9.95	250 ml	✓	<u>DP Lotn HC</u>
METHYLPREDNISOLONE ACEPONATE				
Crm 0.1%	4.95	15 g OP	✓	<u>Advantan</u>
Oint 0.1%	4.95	15 g OP	✓	<u>Advantan</u>
MOMETASONE FUROATE				
Crm 0.1%	1.78	15 g OP	✓	<u>m-Mometasone</u>
	3.42	45 g OP	✓	<u>m-Mometasone</u>
Oint 0.1%	1.78	15 g OP	✓	<u>m-Mometasone</u>
	3.42	45 g OP	✓	<u>m-Mometasone</u>
Lotn 0.1%	7.35	30 ml OP	✓	<u>Elocon</u>
TRIAMCINOLONE ACETONIDE				
Crm 0.02%	6.63	100 g OP	✓	<u>Aristocort</u>
Oint 0.02%	6.69	100 g OP	✓	<u>Aristocort</u>

Corticosteroids - Combination

BETAMETHASONE VALERATE WITH CLIOQUINOL – Only on a prescription				
Crm 0.1% with clioquinol 3%	3.49	15 g OP		
	(4.90)			Betnovate-C
Oint 0.1% with clioquinol 3%	3.49	15 g OP		
	(4.90)			Betnovate-C
BETAMETHASONE VALERATE WITH FUSIDIC ACID				
Crm 0.1% with fusidic acid 2%	3.49	15 g OP		
	(10.45)			Fucicort
a) Maximum of 15 g per prescription				
b) Only on a prescription				
HYDROCORTISONE WITH MICONAZOLE – Only on a prescription				
* Crm 1% with miconazole nitrate 2%	2.10	15 g OP	✓	<u>Micreme H</u>
HYDROCORTISONE WITH NATAMYCIN AND NEOMYCIN – Only on a prescription				
Crm 1% with natamycin 1% and neomycin sulphate 0.5%	2.79	15 g OP	✓	<u>Pimafucort</u>
Oint 1% with natamycin 1% and neomycin sulphate 0.5%	2.79	15 g OP	✓	<u>Pimafucort</u>
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCIN AND NYSTATIN				
Crm 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 µg per g – Only on a prescription.....	3.49	15 g OP		
	(6.60)			Viaderm KC

Disinfecting and Cleansing Agents

CHLORHEXIDINE GLUCONATE – Subsidy by endorsement				
a) No more than 500 ml per month				
b) Only if prescribed for a dialysis patient and the prescription is endorsed accordingly.				
* Handrub 1% with ethanol 70%	4.39	500 ml	✓	<u>healthE</u>
* Soln 4%	5.90	500 ml	✓	<u>Orion</u>

‡ safety cap

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

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

DERMATOLOGICALS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
TRICLOSAN – Subsidy by endorsement				
a) Maximum of 500 ml per prescription				
b)				
a) Only if prescribed for a patient identified with Methicillin-resistant Staphylococcus aureus (MRSA) prior to elective surgery in hospital and the prescription is endorsed accordingly; or				
b) Only if prescribed for a patient with recurrent Staphylococcus aureus infection and the prescription is endorsed accordingly				
Soln 1%	4.50	500 ml OP	✓	Pharmacy Health
	5.90		✓	healthE

Barrier Creams and Emollients

Barrier Creams

ZINC AND CASTOR OIL

* Oint BP	3.83	500 g	✓	Multichem
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Emollients

AQUEOUS CREAM

* Crm	1.96	500 g	✓	AFT
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CETOMACROGOL

* Crm BP	3.15	500 g	✓	PSM
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EMULSIFYING OINTMENT

* Oint BP	3.04	500 g	✓	AFT
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OIL IN WATER EMULSION

* Crm	2.63	500 g	✓	healthE Fatty Cream
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UREA

* Crm 10%	3.07	100 g OP	✓	Nutraplus
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WOOL FAT WITH MINERAL OIL – Only on a prescription

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

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

PARAFFIN

White soft – Only in combination	3.58 (7.78)	500 g		IPW
	20.20	2,500 g	✓	IPW
	3.58 (8.69)	500 g		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%	3.27	25 g OP	✓	Betadine
a) Maximum of 100 g per prescription				
b) Only on a prescription				
Antiseptic soln 10%	0.19 (4.45)	15 ml		Betadine
	1.28 (8.25)	100 ml		Betadine
	6.20	500 ml	✓	Betadine
	1.28 (4.20)	100 ml		Riodine
	6.20	500 ml	✓	Riodine
Skin preparation, povidone iodine 10% with 30% alcohol	1.63 (3.65)	100 ml		Betadine Skin Prep
	10.00	500 ml	✓	Betadine Skin Prep
Skin preparation, povidone iodine 10% with 70% alcohol	1.63 (6.04)	100 ml		Orion
	8.13 (18.63)	500 ml		Orion

Parasiticial Preparations

GAMMA BENZENE HEXACHLORIDE

Crm 1%	3.50	50 g OP	✓	Benhex
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IVERMECTIN – Special Authority see SA1225 below – Retail pharmacy

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

►SA1225 Special Authority for Subsidy

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

Both:

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

continued...

‡ safety cap

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

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

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

continued...

- 2.1.1 The patient is in the community; and
- 2.1.2 Any of the following:
 - 2.1.2.1 Patient has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
 - 2.1.2.2 The community patient is physically or mentally unable to comply with the application instructions of topical therapy; or
 - 2.1.2.3 The patient has previously tried and failed to clear infestation using topical therapy; or
- 2.2 All of the following:
 - 2.2.1 The Patient is a resident in an institution; and
 - 2.2.2 All residents of the institution with scabies or at risk of carriage are to be treated for scabies concurrently; and
 - 2.2.3 Any of the following:
 - 2.2.3.1 Patient has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
 - 2.2.3.2 The patient is physically or mentally unable to comply with the application instructions of topical therapy; or
 - 2.2.3.3 Previous topical therapy has been tried and failed to clear the infestation.

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

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

Any of the following:

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

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

Both:

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

2.1 Both:

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

2.2 All of the following:

- 2.2.1 The Patient is a resident in an institution; and
- 2.2.2 All residents of the institution with scabies or at risk of carriage are to be treated for scabies concurrently; and
- 2.2.3 Any of the following:
 - 2.2.3.1 Patient has a severe scabies hyperinfestation (Crusted/ Norwegian scabies); or
 - 2.2.3.2 The patient is physically or mentally unable to comply with the application instructions of topical therapy; or
 - 2.2.3.3 Previous topical therapy has been tried and failed to clear the infestation.

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

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

Any of the following:

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

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
MALATHION			
Liq 0.5%	3.79	200 ml OP	✓ A-Lices
Shampoo 1%	2.83	30 ml OP	✓ A-Lices
PERMETHRIN			
Crm 5%	4.20	30 g OP	✓ Lyderm
Lothn 5%	3.24	30 ml OP	✓ A-Scabies

Psoriasis and Eczema Preparations

ACITRETIN – Special Authority see SA0954 below – Retail pharmacy

Cap 10 mg	35.95	100	✓ Neotigason
	38.66	60	✓ Novatrein
Cap 25 mg	83.11	60	✓ Novatrein
	85.40	100	✓ Neotigason

SA0954 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 treatment options for psoriasis and of disorders of keratinisation and is aware 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:

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 treatment options for psoriasis and of disorders of keratinisation and is aware 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.

BETAMETHASONE DIPROPIONATE WITH CALCIPOTRIOL

Oint 500 µg with calcipotriol 50 µg	26.12	30 g OP	✓ Daivobet
Topical gel 500 µg with calcipotriol 50 µg	26.12	30 g OP	✓ Daivobet

CALCIPOTRIOL

Crm 50 µg per g	16.00	30 g OP	✓ Daivonex
	45.00	100 g OP	✓ Daivonex
Oint 50 µg per g	20.20	30 g OP	✓ Daivonex
	45.00	100 g OP	✓ Daivonex
Soln 50 µg per ml	16.00	30 ml OP	✓ Daivonex
	33.79	60 ml OP	✓ Daivonex

(Daivonex Oint 50 µg per g to be delisted 1 May 2013)

(Daivonex Soln 50 µg per ml to be delisted 1 May 2013)

‡ 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.

DERMATOLOGICALS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
COAL TAR				
Soln BP – Only in combination	12.95	200 ml	✓	Midwest
Up to 10 % Only in combination with a dermatological base or proprietary Topical Corticosteroid – Plain, refer, page 186				
With or without other dermatological galenicals.				
COAL TAR WITH ALLANTOIN, MENTHOL, PHENOL AND SULPHUR				
Soln 5% with sulphur 0.5%, menthol 0.75%, phenol 0.5% and allantoin crm 2.5%	3.43 (4.35)	30 g OP		Egopsoryl TA
	6.59 (8.00)	75 g OP		Egopsoryl TA
COAL TAR WITH SALICYLIC ACID AND SULPHUR				
Soln 12% with salicylic acid 2% and sulphur 4% oint	7.95	40 g OP	✓	Coco-Scalp
SALICYLIC ACID				
Powder – Only in combination	18.88	250 g	✓	PSM
1) Only in combination with a dermatological base or proprietary Topical Corticosteroid – Plain or collodion flexible, refer, page 186				
2) With or without other dermatological galenicals.				
3) Maximum 20 g or 20 ml per prescription when prescribed with white soft paraffin or collodion flexible.				
SULPHUR				
Precipitated – Only in combination	6.35	100 g	✓	Midwest
1) Only in combination with a dermatological base or proprietary Topical Corticosteroid – Plain, refer, page 186				
2) With or without other dermatological galenicals.				
TAR WITH TRIETHANOLAMINE LAURYL SULPHATE AND FLUORESCEIN – Only on a prescription				
* Soln 2.3% with triethanolamine lauryl sulphate and fluores- cein sodium	3.05 5.82	500 ml 1,000 ml	✓ ✓	Pinetarsol Pinetarsol

Scalp Preparations

BETAMETHASONE VALERATE				
* Scalp app 0.1%	7.22	100 ml OP	✓	Beta Scalp
CLOBETASOL PROPIONATE				
* Scalp app 0.05%	6.36	30 ml OP	✓	Dermol
HYDROCORTISONE BUTYRATE				
Scalp lotn 0.1%	3.65	100 ml OP	✓	Locoid
KETOCONAZOLE				
Shampoo 2%	3.08	100 ml OP	✓	Sebizole
a) Maximum of 100 ml per prescription				
b) Only on a prescription				

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
Sunscreens			
SUNSCREENS, PROPRIETARY – Subsidy by endorsement			
Only if prescribed for a patient with severe photosensitivity secondary to a defined clinical condition and the prescription is endorsed accordingly.			
Crm	2.55 (5.89)	100 g OP	Hamilton Sunscreen
Lotion	2.55	100 ml OP	✓ Marine Blue Lotion SPF 30+
	5.10	200 ml OP	✓ Marine Blue Lotion SPF 30+
	3.19 (6.94)	125 ml OP	Aquasun 30+

Wart Preparations

For salicylic acid preparations refer to PSORIASIS AND ECZEMA PREPARATIONS, page 69

IMIQUIMOD – Special Authority see SA0923 below – Retail pharmacy

Crm 5%	62.00	12	✓ Aldara
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►SA0923 Special Authority for Subsidy

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

Any of the following:

- 1 The patient has external anogenital warts and podophyllotoxin has been tried and failed (or is contraindicated); or
- 2 The patient has external anogenital warts and podophyllotoxin is unable to be applied accurately to the site; or
- 3 The patient has confirmed superficial basal cell carcinoma where other standard treatments, including surgical excision, are contraindicated or inappropriate.

Notes: Superficial basal cell carcinoma

- Surgical excision remains first-line treatment for superficial basal cell carcinoma as it has a higher cure rate than imiquimod and allows histological assessment of tumour clearance.
- Imiquimod has not been evaluated for the treatment of superficial basal cell carcinoma within 1 cm of the hairline, eyes, nose, mouth or ears.
- Imiquimod is not indicated for recurrent, invasive, infiltrating, or nodular basal cell carcinoma.

External anogenital warts

- Imiquimod is only indicated for external genital and perianal warts (condyloma acuminata).

Renewal from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Any of the following:

- 1 Inadequate response to initial treatment for anogenital warts; or
- 2 New confirmed superficial basal cell carcinoma where other standard treatments, including surgical excision, are contraindicated or inappropriate; or
- 3 Inadequate response to initial treatment for superficial basal cell carcinoma.

Note: Every effort should be made to biopsy the lesion to confirm that it is a superficial basal cell carcinoma.

PODOPHYLLOTOXIN

Soln 0.5%	33.60	3.5 ml OP	✓ Condyline
a) Maximum of 3.5 ml per prescription			
b) Only on a prescription			

Other Skin Preparations

Antineoplastics

FLUOROURACIL SODIUM

Crm 5%	26.49	20 g OP	✓ Efudix
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‡ safety cap

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

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

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

For aspirin & chloroform application refer, page 190

CAPSAICIN – Subsidy by endorsement

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

Crm 0.075%	12.50	45 g OP	✓ Zostrix HP
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Wound Management Products

MAGNESIUM SULPHATE

* Paste	2.98	80 g	
	(4.90)		PSM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Contraceptives - Non-hormonal				
Condoms				
CONDOMS				
* 49 mm – Up to 144 dev available on a PSO.....	13.36	144	✓	MarquisTantiliza
			✓	Shield 49
* 52 mm – Up to 144 dev available on a PSO.....	13.36	144	✓	Marquis Selecta
			✓	Marquis Sensolite
			✓	Marquis Supalite
* 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	✓	Shield Blue
	13.36	144	✓	Shield Blue
	1.11	12	✓	Gold Knight
	13.36	144	✓	Gold Knight
			✓	Marquis Black
			✓	Marquis Titillata
* 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
* 53 mm extra strength – 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 Conformata
* 56 mm – Up to 144 dev available on a PSO.....	1.11	12	✓	Gold Knight
	13.36	144	✓	Gold Knight
			✓	Durex Extra Safe
			✓	Durex Select
				Flavours
* 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
Contraceptive Devices				
DIAPHRAGM – Up to 1 dev available on a PSO				
One of each size is permitted on a PSO.				
* 65 mm	42.90	1	✓	Ortho All-flex
* 70 mm	42.90	1	✓	Ortho All-flex
* 75 mm	42.90	1	✓	Ortho All-flex
* 80 mm	42.90	1	✓	Ortho All-flex
INTRA-UTERINE DEVICE				
a) Up to 40 dev available on a PSO				
b) Only on a PSO				
* IUD	39.50	1	✓	Multiload Cu 375
			✓	Multiload Cu 375 SL

‡ 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.

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

Contraceptives - Hormonal

Combined Oral Contraceptives

►SA0500 Special Authority for Alternate Subsidy

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

Both:

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

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

Either:

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

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

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

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

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

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

ETHINYLOESTRADIOL WITH DESOGESTREL

* Tab 20 µg with desogestrel 150 µg	6.62	63	
	(16.50)		Mercilon 21
a) Higher subsidy of \$13.80 per 63 tab with Special Authority see SA0500 above			
b) Up to 63 tab available on a PSO			
* Tab 20 µg with desogestrel 150 µg and 7 inert tab	6.62	84	
	(16.50)		Mercilon 28
a) Higher subsidy of \$13.80 per 84 tab with Special Authority see SA0500 above			
b) Up to 84 tab available on a PSO			
* Tab 30 µg with desogestrel 150 µg	6.62	63	
	(16.50)		Marvelon 21
a) Higher subsidy of \$13.80 per 63 tab with Special Authority see SA0500 above			
b) Up to 63 tab available on a PSO			
* Tab 30 µg with desogestrel 150 µg and 7 inert tab	6.62	84	
	(16.50)		Marvelon 28
a) Higher subsidy of \$13.80 per 84 tab with Special Authority see SA0500 above			
b) Up to 84 tab available on a PSO			

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ETHINYLLOESTRADIOL WITH LEVONORGESTREL				
* Tab 50 µg with levonorgestrel 125 µg and 7 inert tab – Up to 84 tab available on a PSO	9.45	84	✓	Microgynon 50 ED
* Tab 30 µg with levonorgestrel 150 µg	6.62	63		
	(16.50)			Microgynon 30
a) Higher subsidy of \$15.00 per 63 tab with Special Authority see SA0500 on the preceding page				
b) Up to 63 tab available on a PSO				
* Tab 30 µg with levonorgestrel 150 µg and 7 inert tab	2.45	84	✓	Ava 30 ED
a) Brand switch fee payable (Pharmacode 2405865) - see page 185 for details				
b) Up to 84 tab available on a PSO				
ETHINYLLOESTRADIOL WITH NORETHISTERONE				
* Tab 35 µg with norethisterone 1 mg – Up to 63 tab available on a PSO	6.62	63	✓	Brevinor 1/21
* Tab 35 µg with norethisterone 1 mg and 7 inert tab – Up to 84 tab available on a PSO	6.62	84	✓	Brevinor 1/28
* Tab 35 µg with norethisterone 500 µg – Up to 63 tab available on a PSO	6.62	63	✓	Brevinor 21
* Tab 35 µg with norethisterone 500 µg and 7 inert tab – Up to 84 tab available on a PSO	6.62	84	✓	Norimin
NORETHISTERONE WITH MESTRANOL				
* Tab 1 mg with mestranol 50 µg and 7 inert tab	6.62	84		
	(13.80)			Norinyl-1/28
a) Higher subsidy of \$13.80 per 84 tab with Special Authority see SA0500 on the preceding page				
b) Up to 84 tab available on a PSO				

Combined Oral Contraceptives - Other

ETHINYLLOESTRADIOL WITH LEVONORGESTREL				
* Tab 20 µg with levonorgestrel 100 µg and 7 inert tab – Up to 84 tab available on a PSO	2.95	84	✓	Ava 20 ED
	(16.50)			Loette
	(16.50)			Microgynon 20 ED
<i>(Loette Tab 20 µg with levonorgestrel 100 µg and 7 inert tab to be delisted 1 December 2012)</i>				
<i>(Microgynon 20 ED Tab 20 µg with levonorgestrel 100 µg and 7 inert tab to be delisted 1 December 2012)</i>				

Progestogen-only Contraceptives

►SA0500 Special Authority for Alternate Subsidy

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

Both:

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

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

Either:

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

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

continued. . .

‡ safety cap

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

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

GENITO-URINARY SYSTEM

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

continued...

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

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

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

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

LEVONORGESTREL

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

* Subdermal implant (2 × 75 mg rods)	133.65	1	✓ <u>Jadelle</u>
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MEDROXYPROGESTERONE ACETATE

* Inj 150 mg per ml, 1 ml syringe – Up to 5 inj available on a PSO	7.15	1	✓ <u>Depo-Provera</u>
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NORETHISTERONE

* Tab 350 µg – Up to 84 tab available on a PSO	6.00	84	✓ <u>Noriday 28</u>
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Emergency Contraceptives

LEVONORGESTREL

* Tab 1.5 mg	12.50	1	✓ <u>Postinor-1</u>
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:

- \$3.00 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 µg and 7 inert tabs	3.89	84	✓ <u>Ginet 84</u>
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Gynaecological Anti-infectives

ACETIC ACID WITH HYDROXYQUINOLINE AND RICINOLEIC ACID

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

8.43 (24.00)	100 g OP	Aci-Jel
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CLOTRIMAZOLE

* Vaginal crm 1% with applicators	1.30	35 g OP	✓ <u>Clomazol</u>
* Vaginal crm 2% with applicators	2.50	20 g OP	✓ <u>Clomazol</u>

MICONAZOLE NITRATE

* Vaginal crm 2% with applicator	2.75 (4.10)	40 g OP	Micreme
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	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
NYSTATIN			
Vaginal crm 100,000 u per 5 g with applicator(s)	4.71	75 g OP	✓ Nilstat

Myometrial and Vaginal Hormone Preparations

ERGOMETRINE MALEATE			
Inj 500 µg per ml, 1 ml – Up to 5 inj available on a PSO	31.00	5	✓ <u>DBL Ergometrine</u>
OESTRIOL			
* Crm 1 mg per g with applicator	6.30	15 g OP	✓ Ovestin
* Pessaries 500 µg	6.53	15	✓ Ovestin
OXYTOCIN – Up to 5 inj available on a PSO			
Inj 5 iu per ml, 1 ml	5.94	5	✓ Syntocinon
Inj 10 iu per ml, 1 ml	7.48	5	✓ Syntocinon
Inj 5 iu with ergometrine maleate 500 µg per ml, 1 ml	11.13	5	✓ <u>Syntometrine</u>

Pregnancy Tests - hCG Urine

PREGNANCY TESTS - HCG URINE			
a) Up to 200 test available on a PSO			
b) Only on a PSO			
Cassette	22.80	40 test OP	✓ Innovacon hCG One Step Pregnancy Test

Urinary Agents

For urinary tract Infections refer to INFECTIONS, Antibacterials, page 102

5-Alpha Reductase Inhibitors

FINASTERIDE – Special Authority see SA0928 below – Retail pharmacy			
* Tab 5 mg	5.10	30	✓ <u>Rex Medical</u>

►SA0928 Special Authority for Subsidy

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

Both:

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

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

Alpha-1A Adrenoreceptor Blockers

TAMSULOSIN HYDROCHLORIDE – Special Authority see SA1032 below – Retail pharmacy			
* Cap 400 µg	5.98	30	✓ <u>Tamsulosin-Rex</u>

►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.

‡ 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.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Other Urinary Agents				
OXYBUTYNIN				
* Tab 5 mg	44.79	500	✓	Apo-Oxybutynin
* Oral liq 5 mg per 5 ml	50.40	473 ml	✓	Apo-Oxybutynin
POTASSIUM CITRATE				
Oral liq 3 mmol per ml – Special Authority see SA1083 below				
– Retail pharmacy	30.00	200 ml OP	✓	Biomed

SA1083 Special Authority for Subsidy

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

Both:

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

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

SODIUM CITRO-TARTRATE

* Grans eff 4 g sachets2.71 28 ✓ Ural

SOLIFENACIN SUCCINATE – Special Authority see SA0998 below – Retail pharmacy

Tab 5 mg56.50 30 ✓ Vesicare

Tab 10 mg56.50 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 oxybutynin.

TOLTERODINE – Special Authority see SA1272 below – Retail pharmacy

Tab 1 mg14.56 56 ✓ Arrow-Tolterodine

Tab 2 mg14.56 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 oxybutynin.

Detection of Substances in Urine

ORTHO-TOLIDINE

* Compound diagnostic sticks7.50 50 test OP
(8.25) Hemastix

TETRABROMOPHENOL

* Blue diagnostic strips7.02 100 test OP
(13.92) Albustix

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Anabolic Agents				
NANDROLONE DECANOATE – Retail pharmacy-Specialist				
Inj 50 mg per ml, 1 ml	21.16	1	✓	Deca-Durabolin Orgaject ^{S29}
<i>(Deca-Durabolin Orgaject ^{S29} Inj 50 mg per ml, 1 ml to be delisted 1 January 2013)</i>				
Corticosteroids and Related Agents for Systemic Use				
BETAMETHASONE SODIUM PHOSPHATE WITH BETAMETHASONE ACETATE				
* Inj 3.9 mg with betamethasone acetate 3 mg per ml, 1 ml	19.20 (33.60)	5		Celestone Chronodose
DEXAMETHASONE				
* Tab 1 mg – Retail pharmacy-Specialist	5.87	100	✓	<u>Douglas</u>
Up to 30 tab available on a PSO				
* Tab 4 mg – Retail pharmacy-Specialist	8.16	100	✓	<u>Douglas</u>
Up to 30 tab available on a PSO				
Oral liq 1 mg per ml – Retail pharmacy-Specialist	45.00	25 ml OP	✓	<u>Biomed</u>
Oral liq prescriptions:				
1) Must be written by a Paediatrician or Paediatric Cardiologist; or				
2) On the recommendation of a Paediatrician or Paediatric Cardiologist.				
DEXAMETHASONE SODIUM PHOSPHATE				
Dexamethasone sodium phosphate injection will not be funded for oral use.				
* Inj 4 mg per ml, 1 ml – Up to 5 inj available on a PSO	21.50	5	✓	<u>Hospira</u>
* Inj 4 mg per ml, 2 ml – Up to 5 inj available on a PSO	31.00	5	✓	<u>Hospira</u>
FLUDROCORTISONE ACETATE				
* Tab 100 µg	14.32	100	✓	<u>Florinef</u>
HYDROCORTISONE				
* Tab 5 mg	8.10	100	✓	<u>Douglas</u>
* Tab 20 mg – For hydrocortisone oral liquid formulation refer, page 187	20.32	100	✓	<u>Douglas</u>
* Inj 50 mg per ml, 2 ml	3.99	1	✓	<u>Solu-Cortef</u>
a) Up to 5 inj available on a PSO				
b) Only on a PSO				
METHYLPREDNISOLONE – Retail pharmacy-Specialist				
* Tab 4 mg	60.00	100	✓	<u>Medrol</u>
* Tab 100 mg	166.52	20	✓	<u>Medrol</u>
METHYLPREDNISOLONE ACETATE				
Inj 40 mg per ml, 1 ml	6.70	1	✓	<u>Depo-Medrol</u>
METHYLPREDNISOLONE ACETATE WITH LIGNOCAINE				
Inj 40 mg per ml with lignocaine 1 ml	7.50	1	✓	<u>Depo-Medrol with Lidocaine</u>

‡ safety cap

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

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

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
METHYLPREDNISOLONE SODIUM SUCCINATE – Retail pharmacy-Specialist				
Inj 40 mg per ml, 1 ml	7.50	1	✓	<u>Solu-Medrol</u>
.....	151.40	25	✓	<u>Solu-Medrol</u>
Inj 62.5 mg per ml, 2 ml	18.50	1	✓	<u>Solu-Medrol</u>
.....	412.59	25	✓	<u>Solu-Medrol</u>
Inj 500 mg	18.00	1	✓	<u>Solu-Medrol</u>
Inj 1 g	37.50	1	✓	<u>Solu-Medrol</u>
<i>(Solu-Medrol Inj 40 mg per ml, 1 ml to be delisted 1 January 2013)</i>				
<i>(Solu-Medrol Inj 62.5 mg per ml, 2 ml to be delisted 1 January 2013)</i>				
PREDNISOLONE SODIUM PHOSPHATE				
* Oral liq 5 mg per ml – Up to 30 ml available on a PSO	9.95	30 ml OP	✓	<u>Redipred</u>
Restricted to children under 12 years of age.				
PREDNISONE				
* Tab 1 mg	10.68	500	✓	<u>Apo-Prednisone</u>
* Tab 2.5 mg	12.09	500	✓	<u>Apo-Prednisone</u>
* Tab 5 mg – Up to 30 tab available on a PSO	11.09	500	✓	<u>Apo-Prednisone</u>
* Tab 20 mg	29.03	500	✓	<u>Apo-Prednisone</u>
TETRACOSACTRIN				
* Inj 250 µg	177.18	10	✓	<u>Synacthen</u>
* Inj 1 mg per ml, 1 ml	29.56	1	✓	<u>Synacthen Depot</u>
TRIAMCINOLONE ACETONIDE				
Inj 10 mg per ml, 1 ml	21.90	5	✓	<u>Kenacort-A</u>
Inj 40 mg per ml, 1 ml	53.79	5	✓	<u>Kenacort-A40</u>

Sex Hormones Non Contraceptive

Androgen Agonists and Antagonists

CYPROTERONE ACETATE – Retail pharmacy-Specialist				
Tab 50 mg	18.80	50	✓	<u>Siterone</u>
Tab 100 mg	34.25	50	✓	<u>Siterone</u>
TESTOSTERONE				
Transdermal patch, 2.5 mg per day	80.00	60	✓	<u>Androderm</u>
TESTOSTERONE CYPIONATE – Retail pharmacy-Specialist				
Inj long-acting 100 mg per ml, 10 ml	76.50	1	✓	<u>Depo-Testosterone</u>
TESTOSTERONE ESTERS – Retail pharmacy-Specialist				
Inj 250 mg per ml, 1 ml	12.98	1	✓	<u>Sustanon Ampoules</u>
TESTOSTERONE UNDECANOATE – Retail pharmacy-Specialist				
Cap 40 mg	31.17	60	✓	<u>Andriol Testocaps</u>
.....	51.95	100	✓	<u>Arrow-Testosterone</u>
<i>(Arrow-Testosterone Cap 40 mg to be delisted 1 January 2013)</i>				

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

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 $2 \times$ 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.

Prescribing Guideline

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

‡ safety cap

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

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

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Oestrogens				
OESTRADIOL – See prescribing guideline on the preceding page				
* Tab 1 mg	4.12 (10.55)	28 OP		Estrofem
* Tab 2 mg	4.12 (10.55)	28 OP		Estrofem
* TDDS 25 µg per day	3.01 (10.86)	8		Estradot
a) Higher subsidy of \$10.86 per 8 patch with Special Authority see SA1018 on the preceding page				
b) No more than 2 patch per week				
c) Only on a prescription				
* TDDS 3.9 mg (releases 50 µg of oestradiol per day)	4.12 (13.18) (32.50)	4		Climara 50 Femtran 50
a) Higher subsidy of \$13.18 per 4 patch with Special Authority see SA1018 on the preceding page				
b) No more than 1 patch per week				
c) Only on a prescription				
* TDDS 50 µg per day	4.12 (13.18)	8		Estradot 50 µg
a) Higher subsidy of \$13.18 per 8 patch with Special Authority see SA1018 on the preceding page				
b) No more than 2 patch per week				
c) Only on a prescription				
* TDDS 7.8 mg (releases 100 µg of oestradiol per day)	7.05 (16.14) (35.00)	4		Climara 100 Femtran 100
a) Higher subsidy of \$16.14 per 4 patch with Special Authority see SA1018 on the preceding page				
b) No more than 1 patch per week				
c) Only on a prescription				
* TDDS 100 µg per day	7.05 (16.14)	8		Estradot
a) Higher subsidy of \$16.14 per 8 patch with Special Authority see SA1018 on the preceding page				
b) No more than 2 patch per week				
c) Only on a prescription				
OESTRADIOL VALERATE – See prescribing guideline on the preceding page				
* Tab 1 mg	8.24	56	✓	Progyanova
* Tab 2 mg	8.24	56	✓	Progyanova
OESTROGENS – See prescribing guideline on the preceding page				
* Conjugated, equine tab 300 µg	3.01 (11.48)	28		Premarin
* Conjugated, equine tab 625 µg	4.12 (11.48)	28		Premarin

Progestogens

MEDROXYPROGESTERONE ACETATE – See prescribing guideline on the preceding page

* Tab 2.5 mg	3.09	30	✓	Provera
* Tab 5 mg	13.06	100	✓	Provera
* Tab 10 mg	6.85	30	✓	Provera

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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Progestogen and Oestrogen Combined Preparations

OESTRADIOL WITH NORETHISTERONE – See prescribing guideline on page 81

* Tab 1 mg with 0.5 mg norethisterone acetate	5.40 (14.52)	28 OP	Kliovance
* Tab 2 mg with 1 mg norethisterone acetate	5.40 (14.52)	28 OP	Kliogest
* Tab 2 mg with 1 mg norethisterone acetate (10), and 2 mg oestradiol tab (12) and 1 mg oestradiol tab (6)	5.40 (14.52)	28 OP	Trisequens

OESTROGENS WITH MEDROXYPROGESTERONE – See prescribing guideline on page 81

* Tab 625 µg conjugated equine with 2.5 mg medroxyproges- terone acetate tab (28)	5.40 (22.96)	28 OP	Premia 2.5 Continuous
* Tab 625 µg conjugated equine with 5 mg medroxyproges- terone acetate tab (28)	5.40 (22.96)	28 OP	Premia 5 Continuous

Other Oestrogen Preparations

ETHINYLLOESTRADIOL

* Tab 10 µg	17.60	100	✓ <u>NZ Medical and Scientific</u>
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OESTRIOL

* Tab 2 mg	7.00	30	✓ <u>Ovestin</u>
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Other Progestogen Preparations

LEVONORGESTREL

* Levonorgestrel - releasing intrauterine system 20 µg/24 hr – Special Authority see SA0782 below – Retail pharmacy	269.50	1	✓ <u>Mirena</u>
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▶SA0782 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 µg/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.

Initial application — (Previous use before 1 October 2002) 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 had a clinical diagnosis of heavy menstrual bleeding; and
- 2 Patient demonstrated clinical improvement of heavy menstrual bleeding; and
- 3 Applicant to state date of the previous insertion.

Note: Applications are not to be made for use in patients as contraception except where they meet the above criteria.

continued...

‡ safety cap

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

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

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

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

Renewal only from a relevant specialist or general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Either:
 - 1.1 Patient demonstrated clinical improvement of heavy menstrual bleeding; or
 - 1.2 Previous insertion was removed or expelled within 3 months of insertion; and
- 2 Applicant to state date of the previous insertion.

MEDROXYPROGESTERONE ACETATE

* Tab 100 mg – Retail pharmacy-Specialist	96.50	100	✓ Provera
* Tab 200 mg – Retail pharmacy-Specialist	70.50	30	✓ Provera

NORETHISTERONE

* Tab 5 mg – Up to 30 tab available on a PSO	26.50	100	✓ Primolut N
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Thyroid and Antithyroid Agents

CARBIMAZOLE

* Tab 5 mg	10.80	100	✓ Neo-Mercazole
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LEVOTHYROXINE

* Tab 25 µg	3.89	90	✓ Synthroid
	43.24	1,000	✓ Synthroid
‡ Safety cap for extemporaneously compounded oral liquid preparations.			
* Tab 50 µg	1.71	28	✓ Goldshield
	4.05	90	✓ Synthroid
	45.00	1,000	✓ Synthroid
	64.28		✓ Eltroxin
‡ Safety cap for extemporaneously compounded oral liquid preparations.			
* Tab 100 µg	1.78	28	✓ Goldshield
	4.21	90	✓ Synthroid
	66.78	1,000	✓ Eltroxin

‡ Safety cap for extemporaneously compounded oral liquid preparations.

PROPYLTHIOURACIL – Special Authority see SA1199 below – Retail pharmacy

Tab 50 mg	35.00	100	✓ PTU ^{\$29}
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►SA1199 Special Authority for Subsidy

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

Both:

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

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

Trophic Hormones

Growth Hormones

►SA0755 Special Authority for Subsidy

Special Authority approved by the Growth Hormone Committee

Notes: Subject to 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:

continued...

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

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

NZGHC Coordinator

PHARMAC, PO Box 10-254, WELLINGTON

Tel: 0800 808 476, Fax: (09) 929 3221, Email: growthhormone@pharmac.govt.nz

SOMATROPIN – Special Authority see SA0755 on the preceding page

* Inj cartridge 16 iu (5.3 mg)	160.00	1	✓ <u>Genotropin</u>
* Inj cartridge 36 iu (12 mg)	360.00	1	✓ <u>Genotropin</u>

GnRH Analogues

GOSERELIN ACETATE

Inj 3.6 mg	166.20	1	✓ <u>Zoladex</u>
Inj 10.8 mg	443.76	1	✓ <u>Zoladex</u>

LEUPRORELIN

Inj 3.75 mg	221.60	1	✓ <u>Lucrin Depot</u>
Inj 3.75 mg prefilled syringe	221.60	1	✓ <u>Lucrin Depot PDS</u>
Inj 7.5 mg	166.20	1	✓ <u>Eligard</u>
Inj 11.25 mg	591.68	1	✓ <u>Lucrin Depot</u>
Inj 11.25 mg prefilled syringe	591.68	1	✓ <u>Lucrin Depot PDS</u>
Inj 22.5 mg	443.76	1	✓ <u>Eligard</u>
Inj 30 mg	591.68	1	✓ <u>Eligard</u>
Inj 30 mg prefilled syringe	1,109.40	1	✓ <u>Lucrin Depot PDS</u>
Inj 45 mg	832.05	1	✓ <u>Eligard</u>

Vasopressin Agonists

DESMOPRESSIN

▲ Nasal drops 100 µg per ml – Retail pharmacy-Specialist	39.03	2.5 ml OP	✓ <u>Minirin</u>
▲ Nasal spray 10 µg per dose – Retail pharmacy-Specialist	27.48	6 ml OP	✓ <u>Desmopressin- PH&T</u>
Inj 4 µg per ml, 1 ml – Special Authority see SA0090 below			
– Retail pharmacy	67.18	10	✓ <u>Minirin</u>

►SA0090 Special Authority for Subsidy

Initial application only from a relevant specialist. Approvals valid for 2 years where the patient cannot use desmopressin nasal spray or nasal drops.

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

Other Endocrine Agents

CABERGOLINE

Tab 0.5 mg – Maximum of 2 tab per prescription; can be waived by Special Authority see SA1031 on the next page	6.25	2	✓ <u>Dostinex</u>
	25.00	8	✓ <u>Dostinex</u>
	6.25	2	
	(16.50)		Arrow-Cabergoline
	25.00	8	
	(66.00)		Arrow-Cabergoline

(Arrow-Cabergoline Tab 0.5 mg to be delisted 1 December 2012)

‡ 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.

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
►SA1031 Special Authority for Waiver of Rule			
Initial application only from an obstetrician, endocrinologist or gynaecologist. Approvals valid without further renewal unless notified where the patient has pathological hyperprolactinemia.			
Renewal only from an obstetrician, endocrinologist or gynaecologist. 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.			
CLOMIPHENE CITRATE			
Tab 50 mg	29.84	10	✓ Serophene
DANAZOL – Retail pharmacy-Specialist			
Cap 100 mg	68.33	100	✓ Azol
Cap 200 mg	97.83	100	✓ Azol
GESTRINONE – Retail pharmacy-Specialist			
Cap 2.5 mg	101.87	8 OP	✓ Dimetriose
<i>(Dimetriose Cap 2.5 mg to be delisted 1 December 2012)</i>			
METYRAPONE			
Cap 250 mg – Retail pharmacy-Specialist	238.00	50	✓ Metopirone

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

Anthelmintics

MEBENDAZOLE – Only on a prescription

Tab 100 mg	24.19	24	✓ <u>De-Worm</u>
Oral liq 100 mg per 5 ml	2.18	15 ml	
	(7.17)		Vermox

Antibacterials

a) For topical antibacterials, refer to DERMATOLOGICALS, page 62

b) For anti-infective eye preparations, refer to SENSORY ORGANS, page 181

Cephalosporins and Cephamycins

CEFACLOR MONOHYDRATE

Cap 250 mg	24.57	100	✓ <u>Ranbaxy-Cefaclor</u>
Grans for oral liq 125 mg per 5 ml	3.53	100 ml	✓ <u>Ranbaxy-Cefaclor</u>

CEFAZOLIN SODIUM – Subsidy by endorsement

Only if prescribed for dialysis or cystic fibrosis patient and the prescription is endorsed accordingly.

Inj 500 mg	3.99	5	✓ <u>AFT</u>
Inj 1 g	3.99	5	✓ <u>AFT</u>

CEFOXITIN SODIUM – Retail pharmacy-Specialist – Subsidy by endorsement

Only if prescribed for dialysis or cystic fibrosis patient and the prescription is endorsed accordingly.

Inj 1 g	55.00	5	✓ <u>Mayne</u>
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CEFTRIAXONE SODIUM – Subsidy by endorsement

a) Up to 5 inj available on a PSO

b) Subsidised only if prescribed for a dialysis or cystic fibrosis patient, or the treatment of confirmed ciprofloxacin-resistant gonorrhoea, or the treatment of suspected meningitis in patients who have a known allergy to penicillin, and the prescription or PSO is endorsed accordingly.

Inj 500 mg	2.70	1	✓ <u>Veracol</u>
Inj 1 g	10.49	5	✓ <u>Aspen Ceftriaxone</u>

CEFUROXIME AXETIL – Subsidy by endorsement

Only if prescribed for prophylaxis of endocarditis and the prescription is endorsed accordingly.

Tab 250 mg	29.40	50	✓ <u>Zinnat</u>
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CEFUROXIME SODIUM

Inj 250 mg – Maximum of 3 inj per prescription; can be waived

by endorsement.....20.97 10 ✓ Mayne

Waiver by endorsement must state that the prescription is for dialysis or cystic fibrosis patient.

Inj 750 mg – Maximum of 1 inj per prescription; can be waived

by endorsement.....6.96 5 ✓ m-Cefuroxime

Waiver by endorsement must state that the prescription is for dialysis or cystic fibrosis patient.

Inj 1.5 g – Retail pharmacy-Specialist – Subsidy by endorse-

ment.....2.65 1 ✓ Mylan
4.04 ✓ Zinacef

Only if prescribed for dialysis or cystic fibrosis patient and the prescription is endorsed accordingly.

CEPHALEXIN MONOHYDRATE

Cap 500 mg	8.90	20	✓ <u>Cephalexin ABM</u>
Grans for oral liq 125 mg per 5 ml	8.50	100 ml	✓ <u>Cephalexin Sandoz</u>
Grans for oral liq 250 mg per 5 ml	11.50	100 ml	✓ <u>Cephalexin Sandoz</u>

‡ safety cap

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

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

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

AZITHROMYCIN

Tab 500 mg – Subsidy by endorsement; can be waived by

Special Authority see SA1130 below..... 5.95 2 OP ✓ **Arrow-Azithromycin**

a) Up to 8 tab available on a PSO

b) Maximum of 2 tab per prescription; can be waived by Special Authority see SA1130 below

c) Subsidised only if prescribed for patients with uncomplicated urethritis or cervicitis proven or presumed to be due to chlamydia trachomatis and their sexual contacts and prescription or PSO is endorsed accordingly; can be waived by Special Authority see SA1130.

Grans for oral liq 200 mg per 5 ml 6.60 15 ml ✓ **Zithromax**

Maximum of 5 days per prescription; can be waived by endorsement for the following patients: For Endorsement, patient has either:

i) Received a lung transplant and requires treatment or prophylaxis for bronchiolitis obliterans syndrome *; or

ii) Cystic fibrosis and has chronic infection with *Pseudomonas aeruginosa* or *Pseudomonas* related gram negative organisms *

* Unapproved indications

►SA1130 Special Authority for Waiver of Rule

Initial application — (Cystic Fibrosis) only from a respiratory specialist or paediatrician. Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

- 1 The applicant is part of multidisciplinary team experienced in the management of cystic fibrosis; and
- 2 The patient has been definitively diagnosed with cystic fibrosis; and
- 3 The patient has chronic infection with *Pseudomonas aeruginosa* or *Pseudomonas* related gram negative organisms as defined by two positive respiratory tract cultures at least three months apart; and
- 4 The patient has negative cultures for non-tuberculous mycobacteria.

Notes: Caution is advised if using azithromycin as an antibiotic in the treatment of cystic fibrosis patients with pneumonia.

Testing for non-tuberculosis mycobacteria should occur annually.

Initial application — (bronchiolitis obliterans syndrome) only from a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 Patient has received a lung transplant; and
- 2 Azithromycin is to be used for prophylaxis of bronchiolitis obliterans syndrome*; and
- 3 The applicant is experienced in managing patients who have received a lung transplant.

Renewal — (bronchiolitis obliterans syndrome) only from a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 The patient remains well and free from bronchiolitis obliterans syndrome*; and
- 2 The applicant is experienced in managing patients who have received a lung transplant.

Note: Indications marked with * are Unapproved Indications

CLARITHROMYCIN – Maximum of 500 mg per prescription; can be waived by Special Authority see SA1131 on the next page

Tab 250 mg 4.19 14 ✓ **Apo-Clarithromycin**

Grans for oral liq 125 mg per 5 ml 23.12 70 ml ✓ **Klacid**

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
SA1131 Special Authority for Waiver of Rule			
Initial application — (Mycobacterial infections) only from a respiratory specialist, infectious disease specialist or paediatrician. Approvals valid for 2 years for applications meeting the following criteria:			
Either:			
1 Atypical mycobacterial infection; or			
2 Mycobacterium tuberculosis infection where there is drug-resistance or intolerance to standard pharmaceutical agents.			
Renewal — (Mycobacterial infections) only from a respiratory specialist, infectious disease specialist or paediatrician. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.			
ERYTHROMYCIN ETHYL SUCCINATE			
Tab 400 mg – Up to 30 tab available on a PSO.....	16.95	100	✓ E-Mycin
Grans for oral liq 200 mg per 5 ml – Up to 200 ml available on a PSO.....	4.35	100 ml	✓ E-Mycin
Grans for oral liq 400 mg per 5 ml – Up to 200 ml available on a PSO.....	5.85	100 ml	✓ E-Mycin
ERYTHROMYCIN LACTOBIONATE			
Inj 1 g	10.93	1	✓ Erythrocin IV
ERYTHROMYCIN STEARATE			
Tab 250 mg – Up to 30 tab available on a PSO.....	14.95 (22.29)	100	ERA
Tab 500 mg	29.90 (44.58)	100	ERA
ROXITHROMYCIN			
Tab 150 mg	7.48	50	✓ <u>Arrow- Roxithromycin</u>
Tab 300 mg	14.40	50	✓ <u>Arrow- Roxithromycin</u>

Penicillins

AMOXYCILLIN			
Cap 250 mg – Up to 30 cap available on a PSO.....	16.18	500	✓ <u>Alphamox</u>
Cap 500 mg	26.50	500	✓ <u>Alphamox</u>
Grans for oral liq 125 mg per 5 ml – Up to 200 ml available on a PSO.....	1.55	100 ml	✓ Ospamox
Grans for oral liq 250 mg per 5 ml – Up to 200 ml available on a PSO.....	1.10	100 ml	✓ Ospamox
Drops 125 mg per 1.25 ml	4.00	30 ml OP	✓ Ospamox Paediatric Drops
Inj 250 mg	12.96	10	✓ <u>Ibiamox</u>
Inj 500 mg	15.08	10	✓ <u>Ibiamox</u>
Inj 1 g – Up to 5 inj available on a PSO.....	21.94	10	✓ <u>Ibiamox</u>

‡ safety cap

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

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

INFECTIONS - AGENTS FOR SYSTEMIC USE

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
AMOXYCILLIN CLAVULANATE				
Tab amoxycillin 500 mg with potassium clavulanate 125 mg – Up to 30 tab available on a PSO	12.55 26.00	100	✓ ✓	Curam Duo Synermox
Grans for oral liq amoxycillin 125 mg with potassium clavulanate 31.25 mg per 5 ml – Up to 200 ml available on a PSO	1.61 (2.20)	100 ml	✓	Augmentin Curam
Grans for oral liq amoxycillin 250 mg with potassium clavulanate 62.5 mg per 5 ml – Up to 200 ml available on a PSO	2.19 (3.85)	100 ml	✓	Augmentin Curam
<i>(Synermox Tab amoxycillin 500 mg with potassium clavulanate 125 mg to be delisted 1 December 2012)</i>				
<i>(Curam Grans for oral liq amoxycillin 125 mg with potassium clavulanate 31.25 mg per 5 ml to be delisted 1 February 2013)</i>				
<i>(Curam Grans for oral liq amoxycillin 250 mg with potassium clavulanate 62.5 mg per 5 ml to be delisted 1 February 2013)</i>				
BENZATHINE BENZYL PENICILLIN				
Inj 1.2 mega u per 2.3 ml – Up to 5 inj available on a PSO	315.00	10	✓	Bicillin LA
BENZYL PENICILLIN SODIUM (PENICILLIN G)				
Inj 600 mg – Up to 5 inj available on a PSO	11.50	10	✓	Sandoz
FLUCLOXACILLIN SODIUM				
Cap 250 mg – Up to 30 cap available on a PSO	22.00 (32.00)	250	✓	Staphlex AFT
Cap 500 mg	74.00 (110.00)	500	✓	Staphlex AFT
Grans for oral liq 125 mg per 5 ml – Up to 200 ml available on a PSO	2.49	100 ml	✓	AFT
Grans for oral liq 250 mg per 5 ml – Up to 200 ml available on a PSO	3.25	100 ml	✓	AFT
Inj 250 mg	10.86	10	✓	Flucloxin
Inj 500 mg	11.32	10	✓	Flucloxin
Inj 1 g – Up to 5 inj available on a PSO	14.28	10	✓	Flucloxin
<i>(AFT Cap 250 mg to be delisted 1 January 2013)</i>				
<i>(AFT Cap 500 mg to be delisted 1 January 2013)</i>				
PHENOXYMETHYL PENICILLIN (PENICILLIN V)				
Cap potassium salt 250 mg – Up to 30 cap available on a PSO	9.71	50	✓	Cilicaine VK
Cap potassium salt 500 mg	11.70	50	✓	Cilicaine VK
Grans for oral liq 125 mg per 5 ml – Up to 200 ml available on a PSO	1.68	100 ml	✓	AFT
Grans for oral liq 250 mg per 5 ml – Up to 200 ml available on a PSO	1.78	100 ml	✓	AFT
PROCAINE PENICILLIN				
Inj 1.5 mega u – Up to 5 inj available on a PSO	123.50	5	✓	Cilicaine

Tetracyclines

DOXYCYCLINE HYDROCHLORIDE				
* Tab 50 mg – Up to 30 tab available on a PSO	2.90 (6.00)	30		Doxy-50
* Tab 100 mg – Up to 30 tab available on a PSO	7.95	250	✓	Doxine

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
MINOCYCLINE HYDROCHLORIDE				
* Tab 50 mg	5.79 (12.05)	60		Mino-tabs
* Cap 100 mg	19.32 (52.04)	100		Minomycin
Other Antibiotics				
For topical antibiotics, refer to DERMATOLOGICALS, page 62				
CIPROFLOXACIN				
Tab 250 mg – Up to 5 tab available on a PSO	2.20	28	✓	<u>Cipflox</u>
Tab 500 mg – Up to 5 tab available on a PSO	3.00	28	✓	<u>Cipflox</u>
Tab 750 mg – Retail pharmacy-Specialist	5.15	28	✓	<u>Cipflox</u>
CLINDAMYCIN				
Cap hydrochloride 150 mg – Maximum of 4 cap per prescrip- tion; can be waived by endorsement - Retail pharmacy - Specialist	9.90	16	✓	<u>Clindamycin ABM</u>
Inj phosphate 150 mg per ml, 4 ml – Retail pharmacy- Specialist	160.00	10	✓	<u>Dalacin C</u>
CO-TRIMOXAZOLE				
* Tab trimethoprim 80 mg and sulphamethoxazole 400 mg – Up to 30 tab available on a PSO	20.97	500	✓	<u>Trisul</u>
* Oral liq trimethoprim 40 mg and sulphamethoxazole 200 mg per 5 ml – Up to 200 ml available on a PSO	2.15	100 ml	✓	<u>Deprim</u>
COLISTIN SULPHOMETHATE – Retail pharmacy-Specialist – Subsidy by endorsement Only if prescribed for dialysis or cystic fibrosis patient and the prescription is endorsed accordingly.				
Inj 150 mg	65.00	1	✓	<u>Colistin-Link</u>
FUSIDIC ACID				
Tab 250 mg – Retail pharmacy-Specialist	34.50	12	✓	<u>Fucidin</u>
Inj 500 mg sodium fusidate per 10 ml – Retail pharmacy- Specialist – Subsidy by endorsement	12.87 (17.80)	1		Fucidin
Only if prescribed for a dialysis or cystic fibrosis patient and the prescription is endorsed accordingly.				
GENTAMICIN SULPHATE				
Inj 10 mg per ml, 1 ml – Subsidy by endorsement	8.56	5	✓	<u>Mayne</u>
Only if prescribed for a dialysis or cystic fibrosis patient or for prophylaxis of endocarditis and the prescription is endorsed accordingly.				
Inj 40 mg per ml, 2 ml – Subsidy by endorsement	6.50	10	✓	<u>Pfizer</u>
Only if prescribed for a dialysis or cystic fibrosis patient or for prophylaxis of endocarditis and the prescription is endorsed accordingly.				
LINCOMYCIN – Retail pharmacy-Specialist				
Inj 300 mg per ml, 2 ml	80.00	5	✓	<u>Lincocin</u>
MOXIFLOXACIN – Special Authority see SA1065 on the next page – Retail pharmacy No patient co-payment payable				
Tab 400 mg	52.00	5	✓	<u>Avelox</u>

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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►SA1065 Special Authority for Subsidy

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

Either:

1 Both:

1.1 Active tuberculosis*; and

1.2 Any of the following:

1.2.1 Documented resistance to one or more first-line medications; or

1.2.2 Suspected resistance to one or more first-line medications (tuberculosis assumed to be contracted in an area with known resistance), as part of regimen containing other second-line agents; or

1.2.3 Impaired visual acuity (considered to preclude ethambutol use); or

1.2.4 Significant pre-existing liver disease or hepatotoxicity from tuberculosis medications; or

1.2.5 Significant documented intolerance and/or side effects following a reasonable trial of first-line medications; or

2 Mycobacterium avium-intracellulare complex not responding to other therapy or where such therapy is contraindicated*.

Note: Indications marked with * are Unapproved Indications (refer to Section A: General Rules, Part I (Interpretations and Definitions) and Part IV (Miscellaneous Provisions) rule 4.6).

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.

TOBRAMYCIN

Inj 40 mg per ml, 2 ml – Subsidy by endorsement29.32 5 ✓ **DBL Tobramycin**
Only if prescribed for dialysis or cystic fibrosis patient and the prescription is endorsed accordingly.

TRIMETHOPRIM

* Tab 300 mg – Up to 30 tab available on a PSO.....8.94 50 ✓ **TMP**

VANCOMYCIN HYDROCHLORIDE – Subsidy by endorsement

Only if prescribed for a dialysis or cystic fibrosis patient or in the treatment of pseudomembranous colitis or for prophylaxis of endocarditis and the prescription is endorsed accordingly.

Inj 500 mg3.58 1 ✓ **Mylan**

Antifungals

a) For topical antifungals refer to DERMATOLOGICALS, page 62

b) For topical antifungals refer to GENITO URINARY, page 76

FLUCONAZOLE

Cap 50 mg – Retail pharmacy-Specialist4.77 28 ✓ **Ozole**

Cap 150 mg – Subsidy by endorsement0.91 1 ✓ **Ozole**

a) Maximum of 1 cap per prescription; can be waived by endorsement - Retail pharmacy - Specialist

b) Patient has vaginal candida albicans and the practitioner considers that a topical imidazole (used intra-vaginally) is not recommended and the prescription is endorsed accordingly; can be waived by endorsement - Retail pharmacy - Specialist.

Cap 200 mg – Retail pharmacy-Specialist13.34 28 ✓ **Ozole**

Powder for oral suspension 10 mg per ml – Special Authority
see SA1148 below – Retail pharmacy34.56 35 ml ✓ **Diflucan**

►SA1148 Special Authority for Subsidy

Initial application 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 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.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ITRACONAZOLE – Retail pharmacy-Specialist				
Cap 100 mg	4.25	15	✓	<u>Itrazole</u>
KETOCONAZOLE				
Tab 200 mg – Retail pharmacy-Specialist	38.12	30	✓	<u>Nizoral</u>
NYSTATIN				
Tab 500,000 u	14.16	50	✓	<u>Nilstat</u>
Cap 500,000 u	12.81	50	✓	<u>Nilstat</u>
TERBINAFINE				
* Tab 250 mg – For terbinafine oral liquid formulation refer, page 187	1.78	14	✓	<u>Dr Reddy's Terbinafine</u>
VORICONAZOLE – Special Authority see SA1273 below – Retail pharmacy				
Tab 50 mg	730.00	56	✓	<u>Vfend</u>
Tab 200 mg	2,930.00	56	✓	<u>Vfend</u>
Powder for oral suspension 40 mg per ml	730.00	70 ml	✓	<u>Vfend</u>

►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:

Both:

- 1 Patient is immunocompromised; and
- 2 Any of the following:
 - 2.1 Patient has proven or probable invasive aspergillus infection; or
 - 2.2 Patient has possible invasive aspergillus infection; or
 - 2.3 Patient has fluconazole resistant candidiasis; or
 - 2.4 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:

Both:

- 1 Patient is immunocompromised; and
- 2 Any of the following:
 - 2.1 Patient continues to require treatment for proven or probable invasive aspergillus infection; or
 - 2.2 Patient continues to require treatment for possible invasive aspergillus infection; or
 - 2.3 Patient has fluconazole resistant candidiasis; or
 - 2.4 Patient has mould strain such as *Fusarium* spp. and *Scedosporium* spp.

Antimalarials

HYDROXYCHLOROQUINE SULPHATE

* Tab 200 mg 18.00 100 ✓ **Plaquenil**

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 16.50 10 ✓ **Arrow-Ornidazole**

‡ 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.

INFECTIONS - AGENTS FOR SYSTEMIC USE

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

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

DAPSONE – No patient co-payment payable

Tab 25 mg	95.00	100	✓	Dapsone
Tab 100 mg	110.00	100	✓	Dapsone

ETHAMBUTOL HYDROCHLORIDE – No patient co-payment payable

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

ISONIAZID – Retail pharmacy-Specialist

No patient co-payment payable

* Tab 100 mg	20.00	100	✓	PSM
* Tab 100 mg with rifampicin 150 mg	90.04	100	✓	Rifinah
* Tab 150 mg with rifampicin 300 mg	179.57	100	✓	Rifinah

PYRAZINAMIDE – Retail pharmacy-Specialist

No patient co-payment payable

* Tab 500 mg – For pyrazinamide oral liquid formulation refer, page 187	59.00	100	✓	AFT-Pyrazinamide
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RIFABUTIN – Retail pharmacy-Specialist

No patient co-payment payable

* Cap 150 mg – For rifabutin oral liquid formulation refer, page 187	213.19	30	✓	<u>Mycobutin</u>
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RIFAMPICIN – Retail pharmacy-Specialist

No patient co-payment payable

* Tab 600 mg	114.40	30	✓	Rifadin
* Cap 150 mg	58.66	100	✓	Rifadin
* Cap 300 mg	122.36	100	✓	Rifadin
* Oral liq 100 mg per 5 ml	12.66	60 ml	✓	Rifadin

Antivirals

For eye preparations refer to Eye Preparations, Anti-Infective Preparations, page 181

Hepatitis B Treatment

ADEFOVIR DIPIVOXIL – Special Authority see SA0829 below – Retail pharmacy

Tab 10 mg	670.00	30	✓	Hepsera
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►SA0829 Special Authority for Subsidy

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

All of the following:

- 1 Patient has confirmed Hepatitis B infection (HBsAg+); and Documented resistance to lamivudine, defined as:
- 2 Patient has raised serum ALT ($> 1 \times \text{ULN}$); and
- 3 Patient has HBV DNA greater than 100,000 copies per mL, or viral load ≥ 10 fold over nadir; and
- 4 Detection of M204I or M204V mutation; and
- 5 Either:
 - 5.1 Both:

continued...

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

- 5.1.1 Patient is cirrhotic; and
- 5.1.2 adefovir dipivoxil to be used in combination with lamivudine; or
- 5.2 Both:
 - 5.2.1 Patient is not cirrhotic; and
 - 5.2.2 adefovir dipivoxil to be used as monotherapy.

Renewal only from a gastroenterologist or infectious disease specialist. Approvals valid for 2 years where in the opinion of the treating physician, treatment remains appropriate and patient is benefiting from treatment.

Notes: Lamivudine should be added to adefovir dipivoxil if a patient develops documented resistance to adefovir dipivoxil, defined as:

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

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

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

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

Adefovir dipivoxil should be avoided in pregnant women and children.

ENTECAVIR – Special Authority see SA0977 below – Retail pharmacy

Tab 0.5 mg	400.00	30	✓ Baraclude
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SA0977 Special Authority for Subsidy

Initial application only from a gastroenterologist or infectious disease specialist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

- 1 Patient has confirmed Hepatitis B infection (HBsAg positive for more than 6 months); and
- 2 Patient is Hepatitis B nucleoside analogue treatment-naïve; and
- 3 Entecavir dose 0.5 mg/day; and
- 4 Either:
 - 4.1 ALT greater than upper limit of normal; or
 - 4.2 Bridging fibrosis or cirrhosis (Metavir stage 3 or greater) on liver histology; and
- 5 Either:
 - 5.1 HBeAg positive; or
 - 5.2 patient has $\geq 2,000$ IU HBV DNA units per ml and fibrosis (Metavir stage 2 or greater) on liver histology; and
- 6 No continuing alcohol abuse or intravenous drug use; and
- 7 Not co-infected with HCV, HIV or HDV; and
- 8 Neither ALT nor AST greater than 10 times upper limit of normal; and
- 9 No history of hypersensitivity to entecavir; and
- 10 No previous documented lamivudine resistance (either clinical or genotypic).

Notes:

- Entecavir should be continued for 6 months following documentation of complete HBeAg seroconversion (defined as loss of HBeAg plus appearance of anti-HBe plus loss of serum HBV DNA) for patients who were HBeAg positive prior to commencing this agent. This period of consolidation therapy should be extended to 12 months in patients with advanced fibrosis (Metavir Stage F3 or F4).
- Entecavir should be taken on an empty stomach to improve absorption.

LAMIVUDINE – Special Authority see SA0832 on the next page – Retail pharmacy

Tab 100 mg	32.50	28	✓ Zetlam
	143.00		✓ Zeffix
Oral liq 5 mg per ml	90.00	240 ml	✓ Zeffix

‡ 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.

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

SA0832 Special Authority for Subsidy

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

Both:

- 1 Any of the following:
 - 1.1 All of the following:
 - 1.1.1 HBsAg positive for more than 6 months; and
 - 1.1.2 HBeAg positive or HBV DNA positive defined as > 100,000 copies per ml by quantitative PCR at a reference laboratory; and
 - 1.1.3 ALT greater than twice upper limit of normal or bridging fibrosis or cirrhosis (Metavir stage 3 or 4 or equivalent) on liver histology clinical/radiological evidence of cirrhosis; or
 - 1.2 HBV DNA positive cirrhosis prior to liver transplantation; or
 - 1.3 HBsAg positive and have had a liver, kidney, heart, lung or bone marrow transplant; or
 - 1.4 Hepatitis B surface antigen positive (HbsAg) patient who is receiving chemotherapy for a malignancy, or who has received such treatment within the previous two months; and
- 2 All of the following:
 - 2.1 No continuing alcohol abuse or intravenous drug use; and
 - 2.2 Not coinfected with HCV or HDV; and
 - 2.3 Neither ALT nor AST greater than 10 times upper limit of normal; and
 - 2.4 No history of hypersensitivity to lamivudine; and
 - 2.5 No previous lamivudine therapy with genotypically proven lamivudine resistance.

Renewal only from a gastroenterologist, infectious disease specialist, paediatrician or general physician. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

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

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

Renewal when given in combination with adefovir dipivoxil for patients with cirrhosis and resistance to lamivudine
- 2 All of the following:
 - 2.1 Lamivudine to be used in combination with adefovir dipivoxil; and
 - 2.2 Patient is cirrhotic; and
 - Documented resistance to lamivudine, defined as:
 - 2.3 Patient has raised serum ALT ($> 1 \times \text{ULN}$); 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 ($> 1 \times \text{ULN}$); 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	1.98	25	✓ Lovir
* Tab dispersible 400 mg	6.64	56	✓ Lovir
* Tab dispersible 800 mg	7.38	35	✓ Lovir

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
VALACICLOVIR – Special Authority see SA0957 below – Retail pharmacy			
Tab 500 mg	102.72	30	✓ Valtrex

►SA0957 Special Authority for Subsidy

Initial application — (recurrent genital herpes) from any medical practitioner. Approvals valid for 12 months where the patient has genital herpes with 2 or more breakthrough episodes in any 6 month period while treated with aciclovir 400 mg twice daily.

Renewal — (recurrent genital herpes) from any medical practitioner. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.

Initial application — (ophthalmic zoster) from any medical practitioner. Approvals valid without further renewal unless notified where the patient has previous history of ophthalmic zoster and the patient is at risk of vision impairment.

Initial application — (CMV prophylaxis) from any medical practitioner. Approvals valid for 3 months where the patient has undergone organ transplantation.

VALGANCICLOVIR – Special Authority see SA1274 below – Retail pharmacy

Tab 450 mg	3,000.00	60	✓ Valcyte
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►SA1274 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.

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 retinitis 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 retinitis 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 SA1047 below

Endorsement for treatment of HIV/AIDS: Prescription is deemed to be endorsed if tenofovir disoproxil fumarate is co-prescribed with another anti-retroviral subsidised under Special Authority SA1025 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/AIDS is included in the count of up to 4 subsidised antiretrovirals for the purposes of Special Authority SA1025, page 99

Tab 300 mg	531.00	30	✓ Viread
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‡ safety cap

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

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

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

SA1047 Special Authority for Waiver of Rule

Initial application — (Confirmed Hepatitis B) only from a gastroenterologist, infectious disease specialist or general physician.

Approvals valid without further renewal unless notified for applications meeting the following criteria:

Either:

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

Initial application — (Pregnant) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 Patient is HBsAg positive and pregnant; and
- 2 Either:
 - 2.1 HBV DNA > 20,000 IU/mL and ALT > ULN; or
 - 2.2 HBV DNA > 100 million IU/mL and ALT normal.

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) only from a gastroenterologist, infectious disease specialist or general physician. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 Patient is HBsAg positive and pregnant; and
- 2 Either:
 - 2.1 HBV DNA > 20,000 IU/mL and ALT > ULN; or
 - 2.2 HBV DNA > 100 million IU/mL and ALT normal.

Notes:

- Tenofovir disoproxil fumarate should be stopped 6 months following HBsAg seroconversion for patients who were HBsAg positive prior to commencing this agent and 6 months following HBsAg seroconversion for patients who were HBsAg negative prior to commencing this agent.
- The recommended dose of Tenofovir disoproxil fumarate for the treatment of all three indications is 300 mg once daily.
- In patients with renal insufficiency (calculated creatinine clearance less than 50ml/min), Tenofovir disoproxil fumarate dose should be reduced in accordance with the approved Medsafe datasheet guidelines.
- Tenofovir disoproxil fumarate is not approved for use in children.

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

Antiretrovirals

►SA1025 Special Authority for Subsidy

Initial application — (Confirmed HIV/AIDS) 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 < 350 cells/mm³.

Notes: Tenofovir disoproxil fumarate prescribed under endorsement for HIV/AIDS 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/AIDS) 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/AIDS 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 Either:
 - 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.

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

continued...

‡ safety cap

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

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

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

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 Either:
 - 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.

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

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

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

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

Non-nucleosides Reverse Transcriptase Inhibitors

EFAVIRENZ – Special Authority see SA1025 on the preceding page – Retail pharmacy

Tab 50 mg	158.33	30	✓ Stocrin ^{\$29}
Tab 200 mg	474.99	90	✓ Stocrin
Tab 600 mg	474.99	30	✓ Stocrin

ETRAVIRINE – Special Authority see SA1025 on the preceding page – Retail pharmacy

Tab 100 mg	770.00	120	✓ Intelence
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NEVIRAPINE – Special Authority see SA1025 on the preceding page – Retail pharmacy

Tab 200 mg	95.94	60	✓ Nevirapine Alphapharm
	319.80		✓ Viramune
Oral suspension 10 mg per ml	134.55	240 ml	✓ Viramune Suspension

Nucleosides Reverse Transcriptase Inhibitors

ABACAVIR SULPHATE – Special Authority see SA1025 on page 99 – Retail pharmacy

Tab 300 mg	229.00	60	✓ Ziagen
Oral liq 20 mg per ml	50.00	240 ml OP	✓ Ziagen

ABACAVIR SULPHATE WITH LAMIVUDINE – Special Authority see SA1025 on page 99 – Retail pharmacy

Note: abacavir with lamivudine (combination tablets) counts as two anti-retroviral medications for the purposes of the anti-retroviral Special Authority.

Tab 600 mg with lamivudine 300 mg	630.00	30	✓ Kivexa
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DIDANOSINE [DDI] – Special Authority see SA1025 on page 99 – Retail pharmacy

Cap 125 mg	115.05	30	✓ Videx EC
Cap 200 mg	184.08	30	✓ Videx EC
Cap 250 mg	230.10	30	✓ Videx EC
Cap 400 mg	368.16	30	✓ Videx EC

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
EMTRICITABINE – Special Authority see SA1025 on page 99 – Retail pharmacy				
Cap 200 mg	307.20	30	✓	Emtriva
LAMIVUDINE – Special Authority see SA1025 on page 99 – Retail pharmacy				
Tab 150 mg	153.60	60	✓	3TC
Oral liq 10 mg per ml	50.00	240 ml OP	✓	3TC
STAVUDINE [D4T] – Special Authority see SA1025 on page 99 – Retail pharmacy				
Cap 30 mg	377.80	60	✓	Zerit
Cap 40 mg	503.80	60	✓	Zerit
ZIDOVUDINE [AZT] – Special Authority see SA1025 on page 99 – Retail pharmacy				
Cap 100 mg	145.00	100	✓	Retrovir
Oral liq 10 mg per ml	29.00	200 ml OP	✓	Retrovir
ZIDOVUDINE [AZT] WITH LAMIVUDINE – Special Authority see SA1025 on page 99 – Retail pharmacy				
Note: zidovudine [AZT] with lamivudine (combination tablets) counts as two anti-retroviral medications for the purposes of the anti-retroviral Special Authority.				
Tab 300 mg with lamivudine 150 mg	63.50	60	✓	Alphapharm
	667.20		✓	Combivir

Protease Inhibitors

ATAZANAVIR SULPHATE – Special Authority see SA1025 on page 99 – Retail pharmacy				
Cap 150 mg	568.34	60	✓	Reyataz
Cap 200 mg	757.79	60	✓	Reyataz
DARUNAVIR – Special Authority see SA1025 on page 99 – Retail pharmacy				
Tab 400 mg	837.50	60	✓	Prezista
Tab 600 mg	1,190.00	60	✓	Prezista
INDINAVIR – Special Authority see SA1025 on page 99 – Retail pharmacy				
Cap 200 mg	519.75	360	✓	Crixivan
Cap 400 mg	519.75	180	✓	Crixivan
LOPINAVIR WITH RITONAVIR – Special Authority see SA1025 on page 99 – Retail pharmacy				
Tab 100 mg with ritonavir 25 mg	183.75	60	✓	Kaletra
Tab 200 mg with ritonavir 50 mg	735.00	120	✓	Kaletra
Oral liq 80 mg with ritonavir 20 mg per ml	735.00	300 ml OP	✓	Kaletra
RITONAVIR – Special Authority see SA1025 on page 99 – Retail pharmacy				
Tab 100 mg	43.31	30	✓	Norvir
Oral liq 80 mg per ml	103.98	90 ml OP	✓	Norvir

Strand Transfer Inhibitors

RALTEGRAVIR POTASSIUM – Special Authority see SA1025 on page 99 – Retail pharmacy				
Tab 400 mg	1,090.00	60	✓	Isentress

Antiretrovirals - Additional Therapies

HIV Fusion Inhibitors

ENFUVIRTIDE – Special Authority see SA0845 below – Retail pharmacy				
Powder for inj 90 mg per ml × 60	2,380.00	1	✓	Fuzeon

‡ 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.

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

►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

- 1) Diagnosis
 - Anti-HCV positive on at least two occasions with a positive PCR for HCV-RNA and preferably confirmed by a supplementary RIBA test; or
 - PCR-RNA positive for HCV on at least 2 occasions if antibody negative; or
 - Anti-HCV positive on at least two occasions with a positive supplementary RIBA test with a negative PCR for HCV RNA but with a liver biopsy consistent with 2(b) following.
- 2) Establishing Active Chronic Liver Disease
 - Confirmed HCV infection and serum ALT/AST levels measured on at least three occasions over six months averaging $> 1.5 \times$ upper limit of normal. (ALT is the preferable enzyme); or
 - Liver biopsy showing significant inflammatory activity (active hepatitis) with or without cirrhosis. This is not a necessary requirement for those patients with coagulopathy. (Some patients have active disease on histology with normal transaminase enzymes).

Exclusion Criteria

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

Dosage

The current recommended dosage is 3 million units of interferon alpha-2a or interferon alpha-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.

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
INTERFERON ALPHA-2A – PCT – Retail pharmacy-Specialist			
See prescribing guideline on the preceding page			
Inj 3 m iu prefilled syringe	31.32	1	✓ Roferon-A
Inj 6 m iu prefilled syringe	62.64	1	✓ Roferon-A
Inj 9 m iu prefilled syringe	93.96	1	✓ Roferon-A
INTERFERON ALPHA-2B – PCT – Retail pharmacy-Specialist			
See prescribing guideline on the preceding page			
Inj 18 m iu, 1.2 ml multidose pen	187.92	1	✓ Intron-A
Inj 30 m iu, 1.2 ml multidose pen	313.20	1	✓ Intron-A
Inj 60 m iu, 1.2 ml multidose pen	626.40	1	✓ Intron-A
PEGYLATED INTERFERON ALPHA-2A – Special Authority see SA1134 on the next page – Retail pharmacy			
See prescribing guideline on the preceding page			
Inj 135 µg prefilled syringe	362.00	1	✓ Pegasys
	1,448.00	4	✓ Pegasys
Inj 180 µg prefilled syringe	450.00	1	✓ Pegasys
	1,800.00	4	✓ Pegasys
Inj 135 µg prefilled syringe × 4 with ribavirin tab 200 mg × 112	1,799.68	1 OP	✓ Pegasys RBV Combination Pack
Inj 135 µg prefilled syringe × 4 with ribavirin tab 200 mg × 168	1,975.00	1 OP	✓ Pegasys RBV Combination Pack
Inj 180 µg prefilled syringe × 4 with ribavirin tab 200 mg × 112	2,059.84	1 OP	✓ Pegasys RBV Combination Pack
Inj 180 µg prefilled syringe × 4 with ribavirin tab 200 mg × 168	2,190.00	1 OP	✓ Pegasys RBV Combination Pack

►SA1134 **Special Authority for Subsidy**

Initial application — (chronic hepatitis C - genotype 1, 4, 5 or 6 infection or co-infection with HIV) from any specialist.

Approvals valid for 18 months for applications meeting the following criteria:

Both:

- 1 Either:
 - 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; and
- 2 Maximum of 48 weeks therapy.

Notes:

- Consider stopping treatment if there is absence of a virological response (defined as at least a 2-log reduction in viral load) following 12 weeks of treatment since this is predictive of treatment failure.
- Consider reducing treatment to 24 weeks if serum HCV RNA level at Week 4 is undetectable by sensitive PCR assay (less than 50IU/ml) AND Baseline serum HCV RNA is less than 400,000IU/ml

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:

continued...

‡ safety cap

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

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

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

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

Notes:

- Approved dose is 180 µg once weekly.
- The recommended dose of Pegylated Interferon-alpha 2a is 180 µg once weekly.
- In patients with renal insufficiency (calculated creatinine clearance less than 50ml/min), Pegylated Interferon-alpha 2a dose should be reduced to 135 µg once weekly.
- In patients with neutropaenia and thrombocytopaenia, dose should be reduced in accordance with the datasheet guidelines.
- Pegylated Interferon-alpha 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 187	22.20	100	✓ Nifuran
* Tab 100 mg	37.50	100	✓ Nifuran

NORFLOXACIN

Tab 400 mg – Maximum of 6 tab per prescription; can be waived by endorsement - Retail pharmacy - Specialist.....	15.45	100	✓ <u>Arrow-Norfloxacina</u>
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	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Anticholinesterases

NEOSTIGMINE

Inj 2.5 mg per ml, 1 ml	140.00	50	✓	AstraZeneca
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PYRIDOSTIGMINE BROMIDE

▲ Tab 60 mg	38.90	100	✓	Mestinon
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Non-steroidal Anti-inflammatory Drugs (NSAIDs)

►SA1038 Special Authority for Manufacturers Price

Note: Subsidy for patients with existing approvals prior to 1 September 2010. Approvals valid without further renewal unless notified. No new approvals will be granted from 1 September 2010.

DICLOFENAC SODIUM

* Tab EC 25 mg	1.63	50	✓	Diclofenac Sandoz
* Tab 50 mg dispersible – Additional subsidy by Special Authority see SA1038 above – Retail pharmacy	1.50 (8.00)	20		Voltaren D
* Tab EC 50 mg	2.13	50	✓	Diclofenac Sandoz
* Tab long-acting 75 mg	24.52	500	✓	Dicla SR
* Tab long-acting 100 mg	42.25	500	✓	Dicla SR
* Inj 25 mg per ml, 3 ml	12.00	5	✓	Voltaren
Up to 5 inj available on a PSO				
* Suppos 12.5 mg	1.85	10	✓	Voltaren
* Suppos 25 mg	2.22	10	✓	Voltaren
* Suppos 50 mg	3.84	10	✓	Voltaren
Up to 10 supp available on a PSO				
* Suppos 100 mg	6.36	10	✓	Voltaren

IBUPROFEN – Additional subsidy by Special Authority see SA1038 above – Retail pharmacy

* Tab 200 mg	12.75	1,000	✓	Arrowcare
* Tab 400 mg	0.77 (4.56)	30		Brufen
* Tab 600 mg	1.15 (6.84)	30		Brufen
* Tab long-acting 800 mg	8.12	30	✓	Brufen SR
*† Oral liq 100 mg per 5 ml	2.69	200 ml	✓	Fenpaed

KETOPROFEN

* Cap long-acting 100 mg	21.56	100	✓	Oruvail SR
* Cap long-acting 200 mg	43.12	100	✓	Oruvail SR

MEFENAMIC ACID – Additional subsidy by Special Authority see SA1038 above – Retail pharmacy

* Cap 250 mg	0.50 (5.60)	20		Ponstan
	1.25 (9.16)	50		Ponstan

NAPROXEN

* Tab 250 mg	21.25	500	✓	Noflam 250
* Tab 500 mg	22.25	250	✓	Noflam 500
* Tab long-acting 750 mg	18.00	90	✓	Naprosyn SR 750
* Tab long-acting 1,000 mg	21.00	90	✓	Naprosyn SR 1000

† 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.

MUSCULOSKELETAL SYSTEM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
SULINDAC – Additional subsidy by Special Authority see SA1038 on the preceding page – Retail pharmacy				
* Tab 100 mg	2.66 (8.55)	50		Aclin
* Tab 200 mg	3.36 (15.10)	50		Aclin
TENOXICAM				
* Tab 20 mg	23.75	100	✓	Tilcotil
* Inj 20 mg	9.95	1	✓	AFT
TIAPROFENIC ACID				
* Tab 300 mg	19.26	60	✓	Surgam

NSAIDs Other

INDOMETHACIN				
* Suppos 100 mg	14.50	30	✓	Arthrexin
<i>(Arthrexin Suppos 100 mg to be delisted 1 December 2012)</i>				
MELOXICAM – Special Authority see SA1034 below – Retail pharmacy				
* Tab 7.5 mg	11.50	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.

Antirheumatoid Agents

AURANOFIN				
Tab 3 mg	68.99	60	✓	Ridaura
			✓	Ridaura s29 s29
LEFLUNOMIDE				
Tab 10 mg	55.00	30	✓	AFT-Leflunomide
			✓	Arava
Tab 20 mg	76.00	30	✓	AFT-Leflunomide
			✓	Arava
Tab 100 mg	54.44	3	✓	Arava
<i>(AFT-Leflunomide Tab 10 mg to be delisted 1 March 2013)</i>				
<i>(AFT-Leflunomide Tab 20 mg to be delisted 1 March 2013)</i>				
PENICILLAMINE				
Tab 125 mg	61.93	100	✓	D-Penamine
Tab 250 mg	98.98	100	✓	D-Penamine
SODIUM AUROTHIOMALATE				
Inj 10 mg per 0.5 ml	76.87	10	✓	Myocrisin
Inj 20 mg per 0.5 ml	113.17	10	✓	Myocrisin
Inj 50 mg per 0.5 ml	217.23	10	✓	Myocrisin

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
Tumour Necrosis Factor (TNF) Inhibitors			
ADALIMUMAB – Special Authority see SA1156 below – Retail pharmacy			
Inj 40 mg per 0.8 ml prefilled pen	1,799.92	2	✓ HumiraPen
Inj 40 mg per 0.8 ml prefilled syringe	1,799.92	2	✓ Humira

►SA1156 Special Authority for Subsidy

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

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from etanercept; or
 - 1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for rheumatoid arthritis; or
- 2 All of the following:
 - 2.1 Patient has had severe and active erosive rheumatoid arthritis 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 cyclosporin; 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

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‡ safety cap

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

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

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and
- 4 Surgery (or further surgery) is considered to be clinically inappropriate.

Initial application — (severe chronic plaque psoriasis) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from etanercept; or
 - 1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for severe chronic plaque psoriasis; or
- 2 All of the following:
 - 2.1 Either:
 - 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 15, where lesions have been present for at least 6 months from the time of initial diagnosis; or
 - 2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
 - 2.2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, cyclosporin, or acitretin; and
 - 2.3 A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
 - 2.4 The most recent PASI assessment is no more than 1 month old at the time of application.

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 15, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

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

Either:

- 1 Both:
 - 1.1 The patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; and
 - 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from etanercept; or
 - 1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for ankylosing spondylitis; or
- 2 All of the following:
 - 2.1 Patient has a confirmed diagnosis of ankylosing spondylitis for more than six months; and
 - 2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
 - 2.3 Patient has bilateral sacroiliitis demonstrated by plain radiographs, CT or MRI scan; and
 - 2.4 Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of an exercise regime supervised by a physiotherapist; and
 - 2.5 Either:

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Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic 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 following average normal values corrected for age and gender (see Notes); and

2.6 A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 6 on a 0-10 scale.

Notes: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure must be no more than 1 month old at the time of initial application.

Average normal chest expansion corrected for age and gender:

18-24 years - Male: 7.0 cm; Female: 5.5 cm

25-34 years - Male: 7.5 cm; Female: 5.5 cm

35-44 years - Male: 6.5 cm; Female: 4.5 cm

45-54 years - Male: 6.0 cm; Female: 5.0 cm

55-64 years - Male: 5.5 cm; Female: 4.0 cm

65-74 years - Male: 4.0 cm; Female: 4.0 cm

75+ years - Male: 3.0 cm; Female: 2.5 cm

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

Either:

1 Both:

1.1 The patient has had an initial Special Authority approval for etanercept for psoriatic arthritis; and

1.2 Either:

1.2.1 The patient has experienced intolerable side effects from etanercept; or

1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for psoriatic arthritis; or

2 All of the following:

2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and

2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and

2.3 Patient has tried and not responded to at least three months of sulphasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and

2.4 Either:

2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints; or

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

2.5 Any of the following:

2.5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or

2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or

2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Renewal — (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

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

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- 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 3 Either:
 - 3.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 3.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 4 Either:
 - 4.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
 - 4.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

Renewal — (Crohn's disease) only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist.

Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Applicant is a gastroenterologist; or
 - 1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Either:
 - 2.1 Either:
 - 2.1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab; or
 - 2.1.2 CDAI score is 150 or less; or
 - 2.2 Both:
 - 2.2.1 The patient has demonstrated an adequate response to treatment but CDAI score cannot be assessed; and
 - 2.2.2 Applicant to indicate the reason that CDAI score cannot be assessed; and
- 3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Renewal — (severe chronic plaque psoriasis) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Applicant is a dermatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
 - 2.1.2 Following each prior adalimumab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-adalimumab treatment baseline value; or
 - 2.2 Both:
 - 2.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
 - 2.2.2 Either:
 - 2.2.2.1 Following each prior adalimumab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or

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

2.2.2.2 Following each prior adalimumab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-adalimumab treatment baseline value; and

3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Note: A treatment course is defined as a minimum of 12 weeks adalimumab treatment

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

All of the following:

- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and
- 2 Following 12 weeks 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 Either:
 - 2.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 2.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician; and
- 3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ETANERCEPT — Special Authority see SA1157 below — Retail pharmacy

Inj 25 mg	949.96	4	✓ Enbrel
Inj 50 mg autoinjector	1,899.92	4	✓ Enbrel
Inj 50 mg prefilled syringe	1,899.92	4	✓ Enbrel

►SA1157 Special Authority for Subsidy

Initial application — (juvenile idiopathic arthritis) only from a named specialist or rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 2 Patient diagnosed with Juvenile Idiopathic Arthritis (JIA); and
- 3 Patient has had severe active polyarticular course JIA for 6 months duration or longer; and
- 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
- 5 Both:
 - 5.1 Either:
 - 5.1.1 Patient has persistent symptoms of poorly-controlled and active disease in at least 20 swollen, tender joints; or

continued...

‡ safety cap

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

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

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

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

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 cyclosporin; or

2.5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or

2.5.3 Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate; and

2.6 Either:

2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or

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

2.7 Either:

2.7.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or

2.7.2 C-reactive protein levels not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

Initial application — (severe chronic plaque psoriasis) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

1 Both:

1.1 The patient has had an initial Special Authority approval for adalimumab for severe chronic plaque psoriasis; and

1.2 Either:

1.2.1 The patient has experienced intolerable side effects from adalimumab; or

1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe chronic plaque psoriasis; or

2 All of the following:

2.1 Either:

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

- 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, cyclosporin, or acitretin; and
- 2.3 A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 2.4 The most recent PASI assessment is no more than 1 month old at the time of application.

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 15, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

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

Either:

1 Both:

- 1.1 The patient has had an initial Special Authority approval for adalimumab for ankylosing spondylitis; and
- 1.2 Either:
 - 1.2.1 The patient has experienced intolerable side effects from adalimumab; or
 - 1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for ankylosing spondylitis; or

2 All of the following:

- 2.1 Patient has a confirmed diagnosis of ankylosing spondylitis present for more than six months; and
- 2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
- 2.3 Patient has bilateral sacroiliitis demonstrated by plain radiographs, CT or MRI scan; and
- 2.4 Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of 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 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

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‡ safety cap

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

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

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

65-74 years - Male: 4.0 cm; Female: 4.0 cm

75+ years - Male: 3.0 cm; Female: 2.5 cm

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

Either:

1 Both:

1.1 The patient has had an initial Special Authority approval for adalimumab for psoriatic arthritis; and

1.2 Either:

1.2.1 The patient has experienced intolerable side effects from adalimumab; or

1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for psoriatic arthritis; or

2 All of the following:

2.1 Patient has had severe active psoriatic arthritis for six months duration or longer; and

2.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose; and

2.3 Patient has tried and not responded to at least three months of sulphasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses); and

2.4 Either:

2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints; or

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

2.5 Any of the following:

2.5.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or

2.5.2 Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; or

2.5.3 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months.

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

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

- 2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
- 3 Either:
 - 3.1 Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
 - 3.2 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; and
- 4 Etanercept to be administered at doses no greater than 50 mg every 7 days.

Renewal — (severe chronic plaque psoriasis) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Applicant is a dermatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
 - 2.1.2 Following each prior etanercept treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-treatment baseline value; or
 - 2.2 Both:
 - 2.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and
 - 2.2.2 Either:
 - 2.2.2.1 Following each prior etanercept treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or
 - 2.2.2.2 Following each prior etanercept treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; and
- 3 Etanercept to be administered at doses no greater than 50 mg every 7 days.

Note: A treatment course is defined as a minimum of 12 weeks of etanercept treatment

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

All of the following:

- 1 Either:
 - 1.1 Applicant is a rheumatologist; or
 - 1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept treatment; and
- 2 Following 12 weeks 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 Either:
 - 1.1 Applicant is a rheumatologist; or

continued...

‡ safety cap

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

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

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

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

Drugs Affecting Bone Metabolism

Alendronate for Osteoporosis

►SA1039 Special Authority for Subsidy

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

Any of the following:

- 1 History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) \geq 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score \leq -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 \leq -3.0 (see Note); or
- 5 A 10-year risk of hip fracture \geq 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see 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 glucocorticosteroid therapy (\geq 5 mg per day prednisone equivalents) and has already received or is expected to receive therapy for at least three months; and
- 2 Any of the following:
 - 2.1 The patient has documented BMD \geq 1.5 standard deviations below the mean normal value in young adults (i.e. T-Score \leq -1.5) (see Note); or
 - 2.2 The patient has a history of one significant osteoporotic fracture demonstrated radiologically; or
 - 2.3 The patient has had a Special Authority approval for zoledronic acid (Underlying cause - glucocorticosteroid therapy) or raloxifene.

Renewal — (Underlying cause was, and remains, glucocorticosteroid therapy) from any relevant practitioner. Approvals valid for 1 year where the patient is continuing systemic glucocorticosteroid therapy (\geq 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) \geq 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score \leq -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

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	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
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- 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 $\geq 3\%$, 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 used by National Institute for Health and Clinical Excellence (NICE) guidance indicates 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.
- 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 the preceding page – Retail pharmacy

* Tab 70 mg22.90 4 ✓ **Fosamax**

ALENDRONATE SODIUM WITH CHOLECALCIFEROL – Special Authority see SA1039 on the preceding page – Retail pharmacy

* Tab 70 mg with cholecalciferol 5,600 iu22.90 4 ✓ **Fosamax Plus**

Alendronate for Paget's Disease

►SA0949 Special Authority for Subsidy

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

Both:

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

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

ALENDRONATE SODIUM – Special Authority see SA0949 above – Retail pharmacy

* Tab 40 mg133.00 30 ✓ **Fosamax**

Other Treatments

CALCITONIN

* Inj 100 iu per ml, 1 ml110.00 5 ✓ **Miacalcic**

ETIDRONATE DISODIUM – See prescribing guideline on the next page

* Tab 200 mg15.80 100 ✓ **Arrow-Etidronate**

‡ 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.

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

Etidronate for osteoporosis should be prescribed for 14 days (400 mg in the morning) and repeated every three months. It should not be taken at the same time of the day as any calcium supplementation (minimum dose – 500 mg per day of elemental calcium). Etidronate should be taken at least 2 hours before or after any food or fluid, except water.

PAMIDRONATE DISODIUM

Inj 3 mg per ml, 5 ml	18.75	1	✓	Pamisol
Inj 3 mg per ml, 10 ml	37.50	1	✓	Pamisol
Inj 6 mg per ml, 10 ml	75.00	1	✓	Pamisol
Inj 9 mg per ml, 10 ml	112.50	1	✓	Pamisol

RALOXIFENE HYDROCHLORIDE – Special Authority see SA1138 below – Retail pharmacy

* Tab 60 mg	53.76	28	✓	Evista
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►SA1138 Special Authority for Subsidy

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

Any of the following:

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

Notes:

- BMD (including BMD used to derive T-Score) must be measured using dual-energy x-ray absorptiometry (DXA). Quantitative ultrasound and quantitative computed tomography (QCT) are not acceptable.
- Evidence used by the UK National Institute for Health and Clinical Excellence (NICE) in developing its guidance indicates 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 \leq -2.5 and, therefore, do not require BMD measurement for raloxifene funding.
- Osteoporotic fractures are the incident events for severe (established) osteoporosis, and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces that would not ordinarily cause fracture (minimal trauma). The WHO has quantified this as forces equivalent to a fall from a standing height or less.
- A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body.

TERIPARATIDE – Special Authority see SA1139 below – Retail pharmacy

Inj 250 µg per ml, 2.4 ml	490.00	1	✓	Forteo
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►SA1139 Special Authority for Subsidy

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

All of the following:

- The patient has severe, established osteoporosis; and
- The patient has a documented T-score less than or equal to -3.0 (see Notes); and
- The patient has had two or more fractures due to minimal trauma; and

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

continued...

- 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:

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

ZOLEDRONIC ACID – Special Authority see SA1187 below – Retail pharmacy

Soln for infusion 5 mg in 100 ml600.00 100 ml ✓ 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:

- Paget's disease; and
- Any of the following:
 - Bone or articular pain; or
 - Bone deformity; or
 - Bone, articular or neurological complications; or
 - Asymptomatic disease, but risk of complications; or
 - Preparation for orthopaedic surgery; and
- The patient will not be prescribed more than one infusion 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:

- Any of the following:
 - History of one significant osteoporotic fracture demonstrated radiologically and documented bone mineral density (BMD) \geq 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score \leq -2.5) (see Note); or
 - History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
 - History of two significant osteoporotic fractures demonstrated radiologically; or
 - Documented T-Score \leq -3.0 (see Note); or
 - A 10-year risk of hip fracture \geq 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or
 - Patient has had a Special Authority approval for alendronate (Underlying cause - Osteoporosis) or raloxifene; and
- The patient will not be prescribed more than one infusion 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:

- The patient is receiving systemic glucocorticosteroid therapy (\geq 5 mg per day prednisone equivalents) and has already received or is expected to receive therapy for at least three months; and

continued...

‡ safety cap

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

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

Subsidy (Manufacturer's Price) \$	Fully Subsidised Per ✓	Brand or Generic Manufacturer
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2 Any of the following:

- 2.1 The patient has documented BMD \geq 1.5 standard deviations below the mean normal value in young adults (i.e. T-Score \leq -1.5) (see Note); or
- 2.2 The patient has a history of one significant osteoporotic fracture demonstrated radiologically; or
- 2.3 The patient has had a Special Authority approval for alendronate (Underlying cause - glucocorticosteroid therapy) or raloxifene; and

3 The patient will not be prescribed more than one infusion 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 one infusion 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 glucocorticosteroid therapy (\geq 5 mg per day prednisone equivalents); and
- 2 The patient will not be prescribed more than one infusion 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) \geq 2.5 standard deviations below the mean normal value in young adults (i.e. T-Score \leq -2.5) (see Note); or
- 1.2 History of one significant osteoporotic fracture demonstrated radiologically, and either the patient is elderly, or densitometry scanning cannot be performed because of major logistical, technical or pathophysiological reasons. It is unlikely that this provision would apply to many patients under 75 years of age; or
- 1.3 History of two significant osteoporotic fractures demonstrated radiologically; or
- 1.4 Documented T-Score \leq -3.0 (see Note); or
- 1.5 A 10-year risk of hip fracture \geq 3%, calculated using a published risk assessment algorithm (e.g. FRAX or Garvan) which incorporates BMD measurements (see Note); or
- 1.6 Patient has had a Special Authority approval for alendronate (Underlying cause was glucocorticosteroid therapy but patient now meets the 'Underlying cause - Osteoporosis' criteria) or raloxifene; and

2 The patient will not be prescribed more than one infusion 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 used by National Institute for Health and Clinical Excellence (NICE) guidance indicates 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 \leq -2.5 and, therefore, do not require BMD measurement for treatment with bisphosphonates.
- c) Osteoporotic fractures are the incident events for severe (established) osteoporosis and can be defined using the WHO definitions of osteoporosis and fragility fracture. The WHO defines severe (established) osteoporosis as a T-score below -2.5 with one or more associated fragility fractures. Fragility fractures are fractures that occur as a result of mechanical forces

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

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

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

Hyperuricaemia and Antigout

ALLOPURINOL			
* Tab 100 mg	15.90	1,000	✓ <u>Apo-Allopurinol</u>
* Tab 300 mg – For allopurinol oral liquid formulation refer, page 187	16.75	500	✓ <u>Apo-Allopurinol</u>
COLCHICINE			
* Tab 500 µg	9.60	100	✓ <u>Colgout</u>
PROBENECID			
* Tab 500 mg	55.00	100	✓ <u>Probenecid-AFT</u>

Muscle Relaxants

BACLOFEN			
* Tab 10 mg – For baclofen oral liquid formulation refer, page 187	4.75	100	✓ <u>Pacifen</u>
DANTROLENE SODIUM			
* Cap 25 mg	32.96 (65.00)	100	Dantrium
* Cap 50 mg	51.70 (77.00)	100	Dantrium
ORPHENADRINE CITRATE			
Tab 100 mg	18.54	100	✓ <u>Norflex</u>
QUININE SULPHATE			
* Tab 300 mg	54.06	500	✓ <u>Q 300</u>

‡ Safety cap for extemporaneously compounded oral liquid preparations.

‡ 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.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Agents for Parkinsonism and Related Disorders				
Dopamine Agonists and Related Agents				
AMANTADINE HYDROCHLORIDE				
▲ Cap 100 mg	38.24	60	✓	<u>Symmetrel</u>
APOMORPHINE HYDROCHLORIDE				
▲ Inj 10 mg per ml, 2 ml	110.00	5	✓	Apomine
BROMOCRIPTINE MESYLATE				
* Tab 2.5 mg	32.08	100	✓	Apo-Bromocriptine
* Cap 5 mg	60.43	100	✓	Apo-Bromocriptine
ENTACAPONE				
▲ Tab 200 mg	47.92	100	✓	Entapone
	116.00		✓	Comtan
LEVODOPA WITH BENSERAZIDE				
* Tab dispersible 50 mg with benserazide 12.5 mg	10.00	100	✓	Madopar Dispersible
* Cap 50 mg with benserazide 12.5 mg	8.00	100	✓	Madopar 62.5
* Cap 100 mg with benserazide 25 mg	12.50	100	✓	Madopar 125
* Cap long-acting 100 mg with benserazide 25 mg	17.00	100	✓	Madopar HBS
* Cap 200 mg with benserazide 50 mg	25.00	100	✓	Madopar 250
LEVODOPA WITH CARBIDOPA				
* Tab 100 mg with carbidopa 25 mg – For levodopa with car- bidopa oral liquid formulation refer, page 187	10.00	50	✓	Sindopa
	20.00	100	✓	Sinemet
* Tab long-acting 200 mg with carbidopa 50 mg	47.50	100	✓	Sinemet CR
* Tab 250 mg with carbidopa 25 mg	40.00	100	✓	Sinemet
LISURIDE HYDROGEN MALEATE				
▲ Tab 200 µg	27.50	30	✓	Dopergin
PERGOLIDE				
▲ Tab 0.25 mg	48.00	100	✓	<u>Permax</u>
▲ Tab 1 mg	170.00	100	✓	<u>Permax</u>
PRAMIPEXOLE HYDROCHLORIDE				
▲ Tab 0.125 mg	1.95	30	✓	<u>Dr Reddy's Pramipexole</u>
▲ Tab 0.25 mg	2.40	30	✓	<u>Dr Reddy's Pramipexole</u>
▲ Tab 0.5 mg	4.20	30	✓	<u>Dr Reddy's Pramipexole</u>
ROPINIROLE HYDROCHLORIDE				
▲ Tab 0.25 mg	6.20	84	✓	<u>Ropin</u>
▲ Tab 1 mg	15.95	84	✓	<u>Ropin</u>
▲ Tab 2 mg	24.95	84	✓	<u>Ropin</u>
▲ Tab 5 mg	38.00	84	✓	<u>Ropin</u>
SELEGILINE HYDROCHLORIDE				
* Tab 5 mg	16.06	100	✓	Apo-Selegiline

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

▲ Tab 100 mg	126.20	100	✓	Tasmar
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Anticholinergics

BENZTROPINE MESYLATE

Tab 2 mg	7.99	60	✓	Benztrop
Inj 1 mg per ml, 2 ml	95.00	5	✓	Cogentin
a) Up to 5 inj available on a PSO				
b) Only on a PSO				

ORPHENADRINE HYDROCHLORIDE

Tab 50 mg	35.15	250	✓	Disipal
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PROCYCLIDINE HYDROCHLORIDE

Tab 5 mg	7.40	100	✓	Kemadrin
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Agents for Essential Tremor, Chorea and Related Disorders

TETRABENAZINE

Tab 25 mg	178.00	112	✓	Motetis
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Anaesthetics

Local

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.				

LIGNOCAINE HYDROCHLORIDE

Viscous soln 2%	55.00	200 ml	✓	Xylocaine Viscous
Inj 1%, 5 ml – Up to 5 inj available on a PSO	35.00	50	✓	Xylocaine
Inj 2%, 5 ml – Up to 5 inj available on a PSO	23.00	50	✓	Xylocaine
Inj 1%, 20 ml – Up to 5 inj available on a PSO	20.00	5	✓	Xylocaine
Inj 2%, 20 ml – Up to 5 inj available on a PSO	15.00	5	✓	Xylocaine

LIGNOCAINE WITH CHLORHEXIDINE

Gel 2% with chlorhexidine 0.05%, 10 ml urethral syringes –				
Subsidy by endorsement.....	43.26	10	✓	Pfizer
a) Up to 5 each available on a PSO				
b) Subsidised only if prescribed for urethral or cervical administration and the prescription is endorsed accordingly.				

LIGNOCAINE WITH PRILOCAINE – Special Authority see SA0906 below – Retail pharmacy

Crm 2.5% with prilocaïne 2.5%	45.00	30 g OP	✓	EMLA
Crm 2.5% with prilocaïne 2.5% (5 g tubes)	45.00	5	✓	EMLA

►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.

‡ 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.

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

For Anti-inflammatory NSAIDs refer to MUSCULOSKELETAL, page 106

Non-opioid Analgesics

ASPIRIN

* Tab EC 300 mg	2.00	100	
	(8.10)		Aspec 300
* Tab dispersible 300 mg – Up to 30 tab available on a PSO	2.00	100	✓ <u>Ethics Aspirin</u>

NEFOPAM HYDROCHLORIDE

Tab 30 mg	23.40	90	✓ <u>Acupan</u>
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PARACETAMOL

* Tab 500 mg – Up to 30 tab available on a PSO	9.38	1,000	✓ <u>Parafast</u>
*† Oral liq 120 mg per 5 ml	2.21	500 ml	✓ <u>Ethics Paracetamol</u>
a) Up to 200 ml available on a PSO			
b) Not in combination			
*† Oral liq 250 mg per 5 ml	6.70	1,000 ml	✓ <u>Paracare Double Strength</u>
a) Up to 100 ml available on a PSO			
b) Not in combination			
* Suppos 125 mg	7.49	20	✓ <u>Panadol</u>
* Suppos 250 mg	14.40	20	✓ <u>Panadol</u>
* Suppos 500 mg	20.70	50	✓ <u>Paracare</u>

TRAMADOL HYDROCHLORIDE

Cap 50 mg	4.95	100	✓ <u>Arrow-Tramadol</u>
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Opioid Analgesics

CODEINE PHOSPHATE – Safety medicine; prescriber may determine dispensing frequency

Tab 15 mg	5.39	100	✓ <u>PSM</u>
Tab 30 mg	8.25	100	✓ <u>PSM</u>
Tab 60 mg	17.76	100	✓ <u>PSM</u>

DIHYDROCODEINE TARTRATE

Tab long-acting 60 mg	27.27	60	✓ <u>DHC Continus</u>
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FENTANYL

a) Only on a controlled drug form			
b) No patient co-payment payable			
c) Safety medicine; prescriber may determine dispensing frequency			
Transdermal patch 12.5 µg per hour	8.90	5	✓ <u>Mylan Fentanyl Patch</u>
Transdermal patch 25 µg per hour	9.15	5	✓ <u>Mylan Fentanyl Patch</u>
Transdermal patch 50 µg per hour	11.50	5	✓ <u>Mylan Fentanyl Patch</u>
Transdermal patch 75 µg per hour	13.60	5	✓ <u>Mylan Fentanyl Patch</u>
Transdermal patch 100 µg per hour	14.50	5	✓ <u>Mylan Fentanyl Patch</u>

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
FENTANYL CITRATE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
Inj 50 µg per ml, 2 ml	4.50	10	✓	<u>Boucher and Muir</u>
Inj 50 µg per ml, 10 ml	11.77	10	✓	<u>Boucher and Muir</u>
METHADONE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
d) For methadone hydrochloride oral liquid refer, page 190				
e) Extemporaneously compounded methadone will only be reimbursed at the rate of the cheapest form available (methadone powder, not methadone tablets).				
Tab 5 mg	1.85	10	✓	<u>Methatabs</u>
‡ Oral liq 2 mg per ml	5.55	200 ml	✓	<u>Biodone</u>
‡ Oral liq 5 mg per ml	5.55	200 ml	✓	<u>Biodone Forte</u>
‡ Oral liq 10 mg per ml	6.55	200 ml	✓	<u>Biodone Extra Forte</u>
Inj 10 mg per ml, 1 ml	61.00	10	✓	<u>AFT</u>
MORPHINE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
‡ Oral liq 1 mg per ml	8.84	200 ml	✓	<u>RA-Morph</u>
‡ Oral liq 2 mg per ml	11.62	200 ml	✓	<u>RA-Morph</u>
‡ Oral liq 5 mg per ml	14.65	200 ml	✓	<u>RA-Morph</u>
‡ Oral liq 10 mg per ml	21.55	200 ml	✓	<u>RA-Morph</u>
MORPHINE SULPHATE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
Tab immediate-release 10 mg	2.80	10	✓	<u>Sevredol</u>
Tab long-acting 10 mg	1.98	10	✓	<u>Arrow-Morphine LA</u>
Tab immediate-release 20 mg	5.52	10	✓	<u>Sevredol</u>
Tab long-acting 30 mg	3.15	10	✓	<u>Arrow-Morphine LA</u>
Tab long-acting 60 mg	7.20	10	✓	<u>Arrow-Morphine LA</u>
Tab long-acting 100 mg	7.85	10	✓	<u>Arrow-Morphine LA</u>
Cap long-acting 10 mg	2.22	10	✓	<u>m-Eslon</u>
Cap long-acting 30 mg	3.20	10	✓	<u>m-Eslon</u>
Cap long-acting 60 mg	6.90	10	✓	<u>m-Eslon</u>
Cap long-acting 100 mg	8.05	10	✓	<u>m-Eslon</u>
Inj 5 mg per ml, 1 ml – Up to 5 inj available on a PSO	5.51	5	✓	<u>DBL Morphine Sulphate</u>
Inj 10 mg per ml, 1 ml – Up to 5 inj available on a PSO	4.79	5	✓	<u>DBL Morphine Sulphate</u>
Inj 15 mg per ml, 1 ml – Up to 5 inj available on a PSO	5.01	5	✓	<u>DBL Morphine Sulphate</u>
Inj 30 mg per ml, 1 ml – Up to 5 inj available on a PSO	5.30	5	✓	<u>DBL Morphine Sulphate</u>

‡ safety cap

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

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

NERVOUS SYSTEM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
MORPHINE TARTRATE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
Inj 80 mg per ml, 1.5 ml	30.00	5	✓	<u>Hospira</u>
Inj 80 mg per ml, 5 ml	75.00	5	✓	<u>Hospira</u>
OXYCODONE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) See prescribing guideline below				
c) No patient co-payment payable				
d) Safety medicine; prescriber may determine dispensing frequency				
Tab controlled-release 5 mg	7.51	20	✓	<u>OxyContin</u>
Tab controlled-release 10 mg	11.14	20	✓	<u>OxyContin</u>
Tab controlled-release 20 mg	18.93	20	✓	<u>OxyContin</u>
Tab controlled-release 40 mg	33.29	20	✓	<u>OxyContin</u>
Tab controlled-release 80 mg	58.03	20	✓	<u>OxyContin</u>
Cap 5 mg	2.83	20	✓	<u>OxyNorm</u>
Cap 10 mg	5.58	20	✓	<u>OxyNorm</u>
Cap 20 mg	9.77	20	✓	<u>OxyNorm</u>
‡ Oral liq 5 mg per 5 ml	11.20	250 ml	✓	<u>OxyNorm</u>
Inj 10 mg per ml, 1 ml	10.08	5	✓	<u>Oxycodone Orion</u>
	14.40		✓	<u>OxyNorm</u>
Inj 10 mg per ml, 2 ml	19.87	5	✓	<u>Oxycodone Orion</u>
	28.80		✓	<u>OxyNorm</u>

Prescribing Guideline

Prescribers should note that oxycodone is significantly more expensive than long-acting morphine sulphate and clinical advice suggests that it is reasonable to consider this as a second-line agent to be used after morphine.

PARACETAMOL WITH CODEINE – Safety medicine; prescriber may determine dispensing frequency

* Tab paracetamol 500 mg with codeine phosphate 8 mg	2.70	100	✓	<u>Paracetamol + Codeine (Relieve)</u>
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PETHIDINE HYDROCHLORIDE

a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
Tab 50 mg	3.20	10	✓	<u>PSM</u>
Tab 100 mg	4.20	10	✓	<u>PSM</u>
Inj 50 mg per ml, 1 ml – Up to 5 inj available on a PSO	5.51	5	✓	<u>DBL Pethidine Hydrochloride</u>
Inj 50 mg per ml, 2 ml – Up to 5 inj available on a PSO	5.83	5	✓	<u>DBL Pethidine Hydrochloride</u>

Antidepressants

Cyclic and Related Agents

AMITRIPTYLINE – Safety medicine; prescriber may determine dispensing frequency

Tab 10 mg	2.77	50	✓	<u>Amirol</u>
	3.32	100	✓	<u>Arrow - Amitriptyline</u>
Tab 25 mg	1.85	100	✓	<u>Amitrip</u>
Tab 50 mg	3.60	100	✓	<u>Amitrip</u>

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
CLOMIPRAMINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency			
Tab 10 mg	12.60	100	✓ Apo-Clomipramine
Tab 25 mg	8.68	100	✓ Apo-Clomipramine
DOTHIEPIN HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency			
Tab 75 mg	10.50	100	✓ Dopress
Cap 25 mg	6.17	100	✓ Dopress
DOXEPIN HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency			
Cap 10 mg	6.30	100	✓ Anten
Cap 25 mg	6.86	100	✓ Anten
Cap 50 mg	8.55	100	✓ Anten
IMIPRAMINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency			
Tab 10 mg	5.48	50	✓ Tofranil
Tab 25 mg	8.80	50	✓ Tofranil
MAPROTILINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency			
Tab 25 mg	25.06	100	✓ Ludiomil
Tab 75 mg	21.01	30	✓ Ludiomil
MIANSERIN HYDROCHLORIDE – Special Authority see SA1048 below – Retail pharmacy			
Tab 30 mg	24.86	30	✓ Tolvon

►SA1048 Special Authority for Subsidy

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

Either:

1 Both:

1.1 Depression; and

1.2 Either:

1.2.1 Co-existent bladder neck obstruction; or

1.2.2 Cardiovascular disease; or

2 Both:

2.1 The patient has a severe major depressive episode; and

2.2 Either:

2.2.1 The patient must have had a trial of two different antidepressants and was unable to tolerate the treatments or failed to respond to an adequate dose over an adequate period of time (usually at least four weeks); or

2.2.2 Both:

2.2.2.1 The patient is currently a hospital in-patient as a result of an acute depressive episode; and

2.2.2.2 The patient must have had a trial of one other antidepressant and either could not tolerate it or failed to respond to an adequate dose over an adequate period of time.

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

NORTRIPTYLINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency

Tab 10 mg	6.69	100	✓ Norpress
Tab 25 mg	14.77	180	✓ Norpress

Monoamine-Oxidase Inhibitors (MAOIs) - Non Selective

PHENELZINE SULPHATE

* Tab 15 mg95.00 100 ✓ Nardil

TRANLYCYPROMINE SULPHATE

* Tab 10 mg22.94 50 ✓ Parnate

‡ 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.

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Monoamine-Oxidase Type A Inhibitors

MOCLOBEMIDE

Note: There is a significant cost differential between moclobemide and fluoxetine (moclobemide being about three times more expensive). For depressive syndromes it is therefore more cost-effective to start treatment with fluoxetine first before considering prescribing moclobemide.

* Tab 150 mg	69.23	500	✓ Apo-Moclobemide
* Tab 300 mg	31.33	100	✓ Apo-Moclobemide

Selective Serotonin Reuptake Inhibitors

CITALOPRAM HYDROBROMIDE

* Tab 20 mg	2.34	84	✓ Arrow-Citalopram
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ESCITALOPRAM

* Tab 10 mg	2.65	28	✓ Loxalate
* Tab 20 mg	4.20	28	✓ Loxalate

FLUOXETINE HYDROCHLORIDE

* Tab dispersible 20 mg, scored – Subsidy by endorsement	2.50	30	✓ Fluox
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Subsidised by endorsement

1) When prescribed for a patient who cannot swallow whole tablets or capsules and the prescription is endorsed accordingly; or

2) When prescribed in a daily dose that is not a multiple of 20 mg in which case the prescription is deemed to be endorsed. Note: Tablets should be combined with capsules to facilitate incremental 10 mg doses.

* Cap 20 mg	2.70	84	✓ Fluox
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PAROXETINE HYDROCHLORIDE

* Tab 20 mg	2.38	30	✓ Loxamine
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SERTRALINE

* Tab 50 mg	5.40	90	✓ Arrow-Sertraline
* Tab 100 mg	9.60	90	✓ Arrow-Sertraline

Other Antidepressants

MIRTAZAPINE – Special Authority see SA0994 below – Retail pharmacy

Tab 30 mg	8.78	30	✓ Avanza
Tab 45 mg	13.95	30	✓ Avanza

►SA0994 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 a severe major depressive episode; and

2 Either:

2.1 The patient must have had a trial of two different antidepressants and was unable to tolerate the treatments or failed to respond to 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 either could not tolerate it or failed to respond to an adequate dose over an adequate period of time.

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

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
VENLAFAXINE – Special Authority see SA1061 below – Retail pharmacy				
Tab 37.5 mg	12.67	28	✓	Arrow-Venlafaxine XR
Tab 75 mg	19.00	28	✓	Arrow-Venlafaxine XR
Tab 150 mg	23.41	28	✓	Arrow-Venlafaxine XR
Cap 37.5 mg	15.84	28	✓	Efexor XR
Cap 75 mg	31.67	28	✓	Efexor XR
Cap 150 mg	38.82	28	✓	Efexor XR

►SA1061 Special Authority for Subsidy

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

Both:

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

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

Antiepilepsy Drugs

Agents for Control of Status Epilepticus

CLONAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Inj 1 mg per ml, 1 ml	19.00	5	✓	Rivotril
DIAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Inj 5 mg per ml, 2 ml – Subsidy by endorsement	9.24	5	✓	Mayne
a) Up to 5 inj available on a PSO				
b) Only on a PSO				
c) PSO must be endorsed "not for anaesthetic procedures".				
Rectal tubes 5 mg – Up to 5 tube available on a PSO	25.05	5	✓	Stesolid
Rectal tubes 10 mg – Up to 5 tube available on a PSO	30.50	5	✓	Stesolid
PARALDEHYDE				
* Inj 5 ml	1,500.00	5	✓	AFT
PHENYTOIN SODIUM				
* Inj 50 mg per ml, 2 ml – Up to 5 inj available on a PSO	69.24	5	✓	Mayne
* Inj 50 mg per ml, 5 ml – Up to 5 inj available on a PSO	77.27	5	✓	Mayne

‡ 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.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Control of Epilepsy				
CARBAMAZEPINE				
* Tab 200 mg	14.53	100	✓	Tegretol
* Tab long-acting 200 mg	16.98	100	✓	Tegretol CR
* Tab 400 mg	34.58	100	✓	Tegretol
* Tab long-acting 400 mg	39.17	100	✓	Tegretol CR
*‡ Oral liq 100 mg per 5 ml	26.37	250 ml	✓	Tegretol
CLOBAZAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	9.12	50	✓	Frisium
‡ Safety cap for extemporaneously compounded oral liquid preparations.				
CLONAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 500 µg	6.68	100	✓	Paxam
Tab 2 mg	12.75	100	✓	Paxam
‡ Oral drops 2.5 mg per ml	7.38	10 ml OP	✓	Rivotril
ETHOSUXIMIDE				
* Cap 250 mg	32.90	200	✓	Zarontin
*‡ Oral liq 250 mg per 5 ml	13.60	200 ml	✓	Zarontin
GABAPENTIN – Special Authority see SA1071 below – Retail pharmacy				
▲ Cap 100 mg	7.16	100	✓	Nupentin
▲ Cap 300 mg – For gabapentin oral liquid formulation refer, page 187	11.50	100	✓	Nupentin
▲ Cap 400 mg	14.75	100	✓	Nupentin

►SA1071 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) from any relevant practitioner. Approvals valid for 3 months where the patient has tried and failed, or has been unable to tolerate, treatment with a tricyclic antidepressant.

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) 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 (prescriber determined); or
- 2 The patient has previously demonstrated clinical responsiveness to gabapentin and has now developed neuropathic pain in a new site.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
GABAPENTIN (NEURONTIN) – Special Authority see SA0973 below – Retail pharmacy				
▲ Tab 600 mg	67.50	100	✓	Neurontin
▲ Cap 100 mg	13.26	100	✓	Neurontin
▲ Cap 300 mg – For gabapentin (neurontin) oral liquid formu- lation refer, page 187	39.76	100	✓	Neurontin
▲ Cap 400 mg	53.01	100	✓	Neurontin

►SA0973 Special Authority for Subsidy

Notes: Subsidy for patients pre-approved by PHARMAC on 1 August 2009. Approvals valid without further renewal unless notified. No new approvals will be granted from 1 August 2009.

LACOSAMIDE – Special Authority see SA1125 below – Retail pharmacy

▲ Tab 50 mg	25.04	14	✓	Vimpat
▲ Tab 100 mg	50.06	14	✓	Vimpat
	200.24	56	✓	Vimpat
▲ Tab 150 mg	75.10	14	✓	Vimpat
	300.40	56	✓	Vimpat
▲ Tab 200 mg	400.55	56	✓	Vimpat

►SA1125 Special Authority for Subsidy

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

Both:

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

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

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

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

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	19.38	56	✓	Logem
	20.40		✓	Arrow-Lamotrigine
	29.09		✓	Mogine
▲ Tab dispersible 50 mg	32.97	56	✓	Lamictal
	34.70		✓	Logem
			✓	Arrow-Lamotrigine
			✓	Mogine
▲ Tab dispersible 100 mg	47.89		✓	Lamictal
	56.91	56	✓	Logem
	59.90		✓	Arrow-Lamotrigine
			✓	Mogine
	79.16		✓	Lamictal

‡ 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.

NERVOUS SYSTEM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
LEVETIRACETAM				
Tab 250 mg	24.03	60	✓	Levetiracetam-Rex
Tab 500 mg – For levetiracetam oral liquid formulation refer, page 187	28.71	60	✓	Levetiracetam-Rex
Tab 750 mg	45.23	60	✓	Levetiracetam-Rex
PHENOBARBITONE				
For phenobarbitone oral liquid refer, page 190				
* Tab 15 mg	25.00	500	✓	PSM
* Tab 30 mg	26.00	500	✓	PSM
PHENYTOIN SODIUM				
* Tab 50 mg	42.09	200	✓	Dilantin Infatab
* Cap 30 mg	19.13	200	✓	Dilantin
* Cap 100 mg	17.21	200	✓	Dilantin
*‡ Oral liq 30 mg per 5 ml	19.16	500 ml	✓	Dilantin
PRIMIDONE				
* Tab 250 mg	17.25	100	✓	Apo-Primidone
SODIUM VALPROATE				
* Tab 100 mg	13.65	100	✓	Epilim Crushable
* Tab 200 mg EC	27.44	100	✓	Epilim
* Tab 500 mg EC	52.24	100	✓	Epilim
*‡ Oral liq 200 mg per 5 ml	20.48	300 ml	✓	Epilim S/F Liquid
			✓	Epilim Syrup
* Inj 100 mg per ml, 4 ml	41.50	1	✓	Epilim IV
TOPIRAMATE				
▲ Tab 25 mg	11.07	60	✓	Arrow-Topiramate
	26.04		✓	Topamax
▲ Tab 50 mg	18.81	60	✓	Arrow-Topiramate
	44.26		✓	Topamax
▲ Tab 100 mg	31.99	60	✓	Arrow-Topiramate
	75.25		✓	Topamax
▲ Tab 200 mg	55.19	60	✓	Arrow-Topiramate
	129.85		✓	Topamax
▲ Sprinkle cap 15 mg	20.84	60	✓	Topamax
▲ Sprinkle cap 25 mg	26.04	60	✓	Topamax
VIGABATRIN – Special Authority see SA1072 below – Retail pharmacy				
▲ Tab 500 mg	119.30	100	✓	Sabril

►SA1072 Special Authority for Subsidy

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

Both:

1 Either:

1.1 Patient has infantile spasms; or

1.2 Both:

1.2.1 Patient has epilepsy; and

1.2.2 Either:

1.2.2.1 Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents; or

1.2.2.2 Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal treatment with other antiepilepsy agents; and

continued...

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

2 Either:

2.1 Patient is, or will be, receiving regular automated visual field testing (ideally before starting therapy and on a 6-monthly basis thereafter); or

2.2 It is impractical or impossible (due to comorbid conditions) to monitor the patient's visual fields.

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

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

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

Both:

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

2 Either:

2.1 Patient is receiving regular automated visual field testing (ideally every 6 months) on an ongoing basis for duration of treatment with vigabatrin; or

2.2 It is impractical or impossible (due to comorbid conditions) to monitor the patient's visual fields.

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

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

Antimigraine Preparations

For Anti-inflammatory NSAIDS refer to MUSCULOSKELETAL, page 106

Acute Migraine Treatment

ERGOTAMINE TARTRATE WITH CAFFEINE

Tab 1 mg with caffeine 100 mg31.00 100 ✓ **Cafergot**

METOCLOPRAMIDE HYDROCHLORIDE WITH PARACETAMOL

Tab 5 mg with paracetamol 500 mg6.77 60 ✓ **Paramax**

RIZATRIPTAN – Brand switch fee payable (Pharmacode 2405849) - see page 185 for details

Tab orodispersible 10 mg18.00 30 ✓ **Rizamelt**

SUMATRIPTAN

Tab 50 mg1.55 4 ✓ **Arrow-Sumatriptan**

38.83 100 ✓ **Arrow-Sumatriptan**

Tab 100 mg1.55 2 ✓ **Arrow-Sumatriptan**

77.66 100 ✓ **Arrow-Sumatriptan**

Inj 12 mg per ml, 0.5 ml – Maximum of 10 inj per prescription36.00 2 OP ✓ **Arrow-Sumatriptan**

Prophylaxis of Migraine

For Beta Adrenoceptor Blockers refer to CARDIOVASCULAR SYSTEM, page 54

CLONIDINE HYDROCHLORIDE

* Tab 25 µg19.25 100 ✓ **Dixarit**

PIZOTIFEN

* Tab 500 µg21.10 100 ✓ **Sandomigran**

‡ 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.

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

For Antispasmodics refer to ALIMENTARY TRACT, page 27

APREPITANT – Special Authority see SA0987 below – Retail pharmacy

Cap 2 × 80 mg and 1 × 125 mg116.00 3 OP ✓ **Emend Tri-Pack**

►SA0987 Special Authority for Subsidy

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

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

BETAHISTINE DIHYDROCHLORIDE

* Tab 16 mg10.00 84 ✓ **Vergo 16**

CYCLIZINE HYDROCHLORIDE

Tab 50 mg0.59 10 ✓ **Nausicalm**

CYCLIZINE LACTATE

Inj 50 mg per ml, 1 ml14.95 5 ✓ **Nausicalm**

DOMPERIDONE

* Tab 10 mg – For domperidone oral liquid formulation refer,
page 18711.99 100 ✓ **Motilium**

HYOSCINE (SCOPOLAMINE) – Special Authority see SA0939 below – Retail pharmacy

Patch 1.5 mg11.95 2 ✓ **Scopoderm TTS**

►SA0939 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 Control of intractable nausea, vomiting, or inability to swallow saliva in the treatment of malignancy or chronic disease; and
- 2 Patient cannot tolerate or does not adequately respond to oral anti-nausea agents; and
- 3 The applicant must specify the underlying malignancy or chronic disease.

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

HYOSCINE HYDROBROMIDE

* Inj 400 µg per ml, 1 ml6.66 5 ✓ **Mayne**

METOCLOPRAMIDE HYDROCHLORIDE

* Tab 10 mg3.95 100 ✓ **Metamide**

* Inj 5 mg per ml, 2 ml – Up to 5 inj available on a PSO4.50 10 ✓ **Pfizer**

ONDANSETRON

* Tab 4 mg5.10 30 ✓ **Dr Reddy's**

* Tab disp 4 mg0.68 4 ✓ **Dr Reddy's**

1.70 10 ✓ **Dr Reddy's**

17.18 ✓ **Zofran Zydys**

* Tab 8 mg1.70 10 ✓ **Dr Reddy's**

* Tab disp 8 mg2.00 10 ✓ **Dr Reddy's**

✓ **Dr Reddy's**

✓ **Dr Reddy's**

✓ **Dr Reddy's**

✓ **Dr Reddy's**

✓ **Dr Reddy's**

✓ **Dr Reddy's**

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PROCHLORPERAZINE				
* Tab 3 mg buccal	5.97 (15.00)	50		Buccastem
* Tab 5 mg – Up to 30 tab available on a PSO.....	16.85	500	✓	Antinaus
* Inj 12.5 mg per ml, 1 ml – Up to 5 inj available on a PSO	25.81	10	✓	Stemetil
* Suppos 25 mg	23.87	5	✓	Stemetil
PROMETHAZINE THEOCLATE				
* Tab 25 mg	1.20 (6.24)	10		Avomine
TROPISETRON				
a) Maximum of 6 cap per prescription				
b) Maximum of 3 cap per dispensing				
c) Not more than one prescription per month.				
Cap 5 mg	77.41	5	✓	Navoban

Antipsychotics

Guidelines for the use of atypical antipsychotic agents

Diagnosis: Schizophrenia and related psychoses when positive symptoms (delusions, hallucinations and thought disorder) are prominent and/or disabling or when both positive symptoms and negative symptoms (flattened affect, emotional and social withdrawal and poverty of speech) are present. Treatment: Before initiating atypical antipsychotic therapy, physicians should consider whether the patient is likely to respond to and/or tolerate conventional antipsychotic therapy and, where appropriate, trial one or more conventional agent prior to use of an atypical agent.

General

AMISULPRIDE – Safety medicine; prescriber may determine dispensing frequency

Tab 100 mg	22.52	30	✓	Solian
Tab 200 mg	97.03	60	✓	Solian
Tab 400 mg	185.44	60	✓	Solian
Oral liq 100 mg per ml	55.44	60 ml	✓	Solian

ARIPIPRAZOLE – Special Authority see SA0920 below – Retail pharmacy

Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	123.54	30	✓	Abilify
Tab 15 mg	175.28	30	✓	Abilify
Tab 20 mg	213.42	30	✓	Abilify
Tab 30 mg	260.07	30	✓	Abilify

►SA0920 Special Authority for Subsidy

Initial application 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 trialed 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 trialed and has been discontinued, or is in the process of being discontinued, because of inadequate clinical response.

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

‡ safety cap

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

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

NERVOUS SYSTEM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
CHLORPROMAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg – Up to 30 tab available on a PSO.....	12.36	100	✓	Largactil
Tab 25 mg – Up to 30 tab available on a PSO.....	13.02	100	✓	Largactil
Tab 100 mg – Up to 30 tab available on a PSO.....	30.61	100	✓	Largactil
Inj 25 mg per ml, 2 ml – Up to 5 inj available on a PSO	25.66	10	✓	Largactil
CLOZAPINE – Hospital pharmacy [HP4]				
Safety medicine; prescriber may determine dispensing frequency				
Tab 25 mg	13.37	50	✓	Clozaril
	26.74	100	✓	Clozaril
	6.69	50	✓	Clopine
	13.37	100	✓	Clopine
Tab 50 mg	8.67	50	✓	Clopine
	17.33	100	✓	Clopine
Tab 100 mg	34.65	50	✓	Clozaril
	69.30	100	✓	Clozaril
	17.33	50	✓	Clopine
	34.65	100	✓	Clopine
Tab 200 mg	34.65	50	✓	Clopine
	69.30	100	✓	Clopine
Suspension 50 mg per ml	17.33	100 ml	✓	Clopine
HALOPERIDOL – Safety medicine; prescriber may determine dispensing frequency				
Tab 500 µg – Up to 30 tab available on a PSO	5.42	100	✓	Serenace
Tab 1.5 mg – Up to 30 tab available on a PSO.....	8.20	100	✓	Serenace
Tab 5 mg – Up to 30 tab available on a PSO.....	25.84	100	✓	Serenace
Oral liq 2 mg per ml – Up to 200 ml available on a PSO	19.87	100 ml	✓	Serenace
Inj 5 mg per ml, 1 ml – Up to 5 inj available on a PSO	18.74	10	✓	Serenace
LEVOMEPROMAZINE – Safety medicine; prescriber may determine dispensing frequency				
Tab 25 mg	16.93	100	✓	Nozinan
Tab 100 mg	43.96	100	✓	Nozinan
Inj 25 mg per ml, 1 ml	73.68	10	✓	Nozinan
LITHIUM CARBONATE – Safety medicine; prescriber may determine dispensing frequency				
Tab 250 mg	34.30	500	✓	Lithicarb FC
Tab 400 mg	12.83	100	✓	Lithicarb FC
Tab long-acting 400 mg	19.20	100	✓	Priadel
Cap 250 mg	9.42	100	✓	Douglas
OLANZAPINE – Safety medicine; prescriber may determine dispensing frequency				
Tab 2.5 mg	2.00	28	✓	Dr Reddy's Olanzapine
	(51.07)		✓	Olanzine Zyprexa
Tab 5 mg	3.85	28	✓	Dr Reddy's Olanzapine
	(101.21)		✓	Olanzine Zyprexa
Tab 10 mg	6.35	28	✓	Dr Reddy's Olanzapine
	(204.49)		✓	Olanzine Zyprexa

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
PERICYAZINE – Safety medicine; prescriber may determine dispensing frequency				
Tab 2.5 mg	12.49	100	✓	Neulactil
Tab 10 mg	44.45	100	✓	Neulactil
QUETIAPINE – Safety medicine; prescriber may determine dispensing frequency				
Tab 25 mg	7.00	60	✓	Dr Reddy's Quetiapine
	10.50	90	✓	Seroquel
Tab 100 mg	14.00	60	✓	Quetapel
			✓	Dr Reddy's Quetiapine
			✓	Seroquel
Tab 200 mg	21.00	90	✓	Quetapel
	24.00	60	✓	Dr Reddy's Quetiapine
			✓	Seroquel
Tab 300 mg	36.00	90	✓	Quetapel
	40.00	60	✓	Dr Reddy's Quetiapine
			✓	Seroquel
	60.00	90	✓	Quetapel
RISPERIDONE – Safety medicine; prescriber may determine dispensing frequency				
Tab 0.5 mg	3.51	60	✓	Apo-Risperidone
			✓	Dr Reddy's Risperidone
			✓	Ridal
	1.17 (2.86)	20		Risperdal
Tab 1 mg	6.00	60	✓	Apo-Risperidone
			✓	Dr Reddy's Risperidone
			✓	Ridal
Tab 2 mg	11.00	60		Risperdal
			✓	Apo-Risperidone
			✓	Dr Reddy's Risperidone
			✓	Ridal
Tab 3 mg	15.00	60		Risperdal
			✓	Apo-Risperidone
			✓	Dr Reddy's Risperidone
			✓	Ridal
Tab 4 mg	20.00	60		Risperdal
			✓	Apo-Risperidone
			✓	Dr Reddy's Risperidone
			✓	Ridal
Oral liq 1 mg per ml	18.35	30 ml		Risperdal
			✓	Apo-Risperidone
			✓	Risperon
				Risperdal

‡ 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.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
TRIFLUOPERAZINE HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 1 mg	9.83	100	✓	Stelazine
Tab 2 mg	14.64	100	✓	Stelazine
Tab 5 mg	16.66	100	✓	Stelazine
ZIPRASIDONE – Subsidy by endorsement				
a) Safety medicine; prescriber may determine dispensing frequency				
b) Ziprasidone is subsidised for patients suffering from schizophrenia or related psychoses after a trial of an effective dose of risperidone or quetiapine that has been discontinued, or is in the process of being discontinued, because of unacceptable side effects or inadequate response, and the prescription is endorsed accordingly.				
Cap 20 mg	87.88	60	✓	Zeldox
Cap 40 mg	164.78	60	✓	Zeldox
Cap 60 mg	247.17	60	✓	Zeldox
Cap 80 mg	329.56	60	✓	Zeldox
ZUCLOPENTHIXOL HYDROCHLORIDE – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	31.45	100	✓	Clopixol

Depot Injections

FLUPENTHIXOL DECANOATE – Safety medicine; prescriber may determine dispensing frequency				
Inj 20 mg per ml, 1 ml – Up to 5 inj available on a PSO	13.14	5	✓	Fluanxol
Inj 20 mg per ml, 2 ml – Up to 5 inj available on a PSO	20.90	5	✓	Fluanxol
Inj 100 mg per ml, 1 ml – Up to 5 inj available on a PSO	40.87	5	✓	Fluanxol
FLUPHENAZINE DECANOATE – Safety medicine; prescriber may determine dispensing frequency				
Inj 12.5 mg per 0.5 ml, 0.5 ml – Up to 5 inj available on a PSO	17.60	5	✓	Modecate
Inj 25 mg per ml, 1 ml – Up to 5 inj available on a PSO	27.90	5	✓	Modecate
Inj 100 mg per ml, 1 ml – Up to 5 inj available on a PSO	154.50	5	✓	Modecate
HALOPERIDOL DECANOATE – Safety medicine; prescriber may determine dispensing frequency				
Inj 50 mg per ml, 1 ml – Up to 5 inj available on a PSO	28.39	5	✓	Haldol
Inj 100 mg per ml, 1 ml – Up to 5 inj available on a PSO	55.90	5	✓	Haldol Concentrate
OLANZAPINE PAMOATE MONOHYDRATE – Special Authority see SA1146 below – Retail pharmacy				
Safety medicine; prescriber may determine dispensing frequency				
Inj 210 mg	280.00	1	✓	Zyprexa Relprevv
Inj 300 mg	460.00	1	✓	Zyprexa Relprevv
Inj 405 mg	560.00	1	✓	Zyprexa Relprevv

►SA1146 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 The patient has schizophrenia; and
- 2 The patient has tried but failed to comply with treatment using oral atypical antipsychotic agents; and
- 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 for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 The patient has had less than 12 months' treatment with olanzapine depot injection; and
 - 1.2 There is no clinical reason to discontinue treatment; or
- 2 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 olanzapine depot injection.

Note: The patient should be monitored for post-injection syndrome for at least two hours after each injection.

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
PIPTHIAZINE PALMITATE – Safety medicine; prescriber may determine dispensing frequency			
Inj 50 mg per ml, 1 ml – Up to 5 inj available on a PSO	178.48	10	✓ Piportil
Inj 50 mg per ml, 2 ml – Up to 5 inj available on a PSO	353.32	10	✓ Piportil
RISPERIDONE – Special Authority see SA0926 below – Retail pharmacy			
Safety medicine; prescriber may determine dispensing frequency			
Inj 25 mg per 2 ml	175.00	1	✓ Risperdal Consta
Inj 37.5 mg per 2 ml	230.00	1	✓ Risperdal Consta
Inj 50 mg per 2 ml	280.00	1	✓ Risperdal Consta

►SA0926 | 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 The patient has schizophrenia or other psychotic disorder; and
- 2 Has tried but failed to comply with treatment using oral atypical antipsychotic agents; and
- 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 for applications meeting the following criteria:

Either:

- 1 Both:
 - 1.1 The patient has had less than 12 months treatment with risperidone depot injection; and
 - 1.2 There is no clinical reason to discontinue treatment; or
- 2 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 risperidone depot injection.

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

ZUCLOPENTHIXOL DECANOATE – Safety medicine; prescriber may determine dispensing frequency			
Inj 200 mg per ml, 1 ml – Up to 5 inj available on a PSO	19.80	5	✓ Clopixol

Orodispersible Antipsychotics

OLANZAPINE – Safety medicine; prescriber may determine dispensing frequency			
Orodispersible tab 5 mg	6.36	28	✓ Dr Reddy's Olanzapine
Orodispersible tab 10 mg	8.76	28	✓ Olanzapine-D ✓ Dr Reddy's Olanzapine
Wafer 5 mg	6.36 (102.19)	28	✓ Olanzapine-D Zyprexa Zydis
Wafer 10 mg	8.76 (204.37)	28	Zyprexa Zydis
RISPERIDONE – Special Authority see SA0927 on the next page – Retail pharmacy			
Safety medicine; prescriber may determine dispensing frequency			
Orally-disintegrating tablets 0.5 mg	21.42	28	✓ Risperdal Quicklet
Orally-disintegrating tablets 1 mg	42.84	28	✓ Risperdal Quicklet
Orally-disintegrating tablets 2 mg	85.71	28	✓ Risperdal Quicklet

‡ 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.

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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►SA0927 Special Authority for Subsidy

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

Both:

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

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

Both:

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

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

Both:

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

Note: Risperdal Quicklets cost significantly more than risperidone tablets and should only be used where necessary.

Anxiolytics

ALPRAZOLAM – Safety medicine; prescriber may determine dispensing frequency

Tab 250 µg	3.15	50	✓ Arrow-Alprazolam
‡ Safety cap for extemporaneously compounded oral liquid preparations.			
Tab 500 µg	4.10	50	✓ Arrow-Alprazolam
‡ Safety cap for extemporaneously compounded oral liquid preparations.			
Tab 1 mg	7.25	50	✓ Arrow-Alprazolam
‡ Safety cap for extemporaneously compounded oral liquid preparations.			

BUSPIRONE HYDROCHLORIDE – Special Authority see SA0863 below – Retail pharmacy

Tab 5 mg	28.00	100	✓ Pacific Buspirone
Tab 10 mg	17.00	100	✓ Pacific Buspirone

►SA0863 Special Authority for Subsidy

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

Both:

- 1 For use only as an anxiolytic; and
- 2 Other agents are contraindicated or have failed.

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

DIAZEPAM – Safety medicine; prescriber may determine dispensing frequency

Tab 2 mg	11.44	500	✓ Arrow-Diazepam
‡ Safety cap for extemporaneously compounded oral liquid preparations.			
Tab 5 mg	13.71	500	✓ Arrow-Diazepam
‡ Safety cap for extemporaneously compounded oral liquid preparations.			

LORAZEPAM – Safety medicine; prescriber may determine dispensing frequency

Tab 1 mg	16.42	250	✓ Ativan
‡ Safety cap for extemporaneously compounded oral liquid preparations.			
Tab 2.5 mg	11.17	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 dispensing frequency				
Tab 10 mg	5.89	100	✓	Ox-Pam
‡ Safety cap for extemporaneously compounded oral liquid preparations.				
Tab 15 mg	8.13	100	✓	Ox-Pam
‡ Safety cap for extemporaneously compounded oral liquid preparations.				

Multiple Sclerosis Treatments

►SA1062 Special Authority for Subsidy

Special Authority approved by the Multiple Sclerosis Treatment Committee

Notes: Budget managed by appointed clinicians on the Multiple Sclerosis Treatment Assessments Committee (MSTAC).

Applications will be considered by MSTAC at its regular meetings and approved subject to eligibility according to the Entry and Stopping criteria (below).

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

The coordinator	Phone: 04 460 4990
Multiple Sclerosis Treatment Assessment Committee	Facsimile: 04 916 7571
PHARMAC PO Box 10 254	Email: mstaccordinator@pharmac.govt.nz
Wellington	

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

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

These agents will NOT be subsidised if dispensed from a community or hospital pharmacy. Regular supplies will be distributed to all approved patients or their clinicians by courier.

Prescribers must send quarterly prescriptions for approved patients to the MSTAC coordinator.

Only prescriptions for 6 million iu of interferon beta-1-alpha per week, or 8 million iu of interferon beta-1-beta every other day, or 20 mg glatiramer acetate daily will be subsidised.

Appeals against MSTAC's decision and/or the processing of any application may be lodged with the MSTAC coordinator. Concerns that cannot be or have not been adequately addressed by MSTAC will be forwarded to a separate Appeal Committee if necessary.

Switching between treatments is permitted within the 12 month approval period without reapproval by MSTAC. The MSTAC coordinator should be notified of the change and a new prescription provided.

Entry Criteria

- 1) Diagnosis of multiple sclerosis (MS) must be confirmed by a neurologist. Diagnosis should as a rule include MRI confirmation. For patients diagnosed before MRI was widely utilised in New Zealand, confirmation of diagnosis via clinical assessment and laboratory/ancillary data must be provided; and
- 2) patients must have active relapsing MS (confirmed by MR scan where necessary) with or without underlying progression; and
- 3) patients must have either:
 - a) EDSS score 2.5 - 5.5 with 2+ relapses:
 - experienced at least 2 significant relapses of MS in the previous 12 months, and
 - an EDSS score of between 2.5 and 5.5 inclusive; or
 - b) EDSS score 2.0 with 3+ relapses:
 - experienced at least 3 significant relapses of MS in the previous 12 months, and
 - an EDSS score of 2.0; and
- 4) Each relapse must:
 - a) be confirmed by a neurologist or general physician (the patient may not necessarily have been seen 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);

continued...

‡ safety cap

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

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

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

continued...

- last at least one week;
 - follow a period of stability of at least one month;
 - be severe enough to change either the EDSS or at least one of the Kurtzke functional systems scores by at least 1 point;
 - be distinguishable from the effects of general fatigue; and
 - not be associated with a fever ($T > 37.5^{\circ}\text{C}$); and
- applications must be made at least four weeks after the date of the onset of the last known relapse; and
 - patients must have no previous history of lack of response to beta-interferon or glatiramer acetate (see criteria for stopping).
 - applications must be submitted to the Multiple Sclerosis Treatment Assessment Committee (MSTAC) by the patient's neurologist or a general physician; and
 - patients must agree (via informed consent) to co-operate if as a result of their meeting the stopping criteria, funding is withdrawn. Patients must agree to the collection of clinical data relating to their MS and use of those data by PHARMAC; and
 - patients must agree to allow clinical data to be collected and reviewed by MSTAC annually for each year in which they receive funding for beta-interferon or glatiramer acetate.

Stopping Criteria

- Confirmed progression of disability that is sustained for six months during a minimum of one year of treatment. Progression of disability is defined as any of:
 - an increase of 2 EDSS points where starting EDSS was 2.0; or
 - an increase of 1.5 EDSS points where starting EDSS was 2.5 or 3.0; or
 - an increase of 1 EDSS point where starting EDSS 3.5 or greater; or
 - an increase in EDSS score to 6.0 or more; or
- stable or increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment)(see note); or
- pregnancy and/or lactation; or
- within the 12 month approval year, intolerance to interferon beta-1-alpha, and/or interferon beta-1-beta and/or glatiramer acetate; or
- non-compliance with treatment, including refusal to undergo annual assessment or refusal to allow the results of the assessment to be submitted to MSTAC; or
- patients may, subject to conclusions drawn from published evidence available at the time, be excluded if they develop a high titre of neutralising anti-bodies to beta-interferon or glatiramer acetate.

Note: Patients who have a stable or increasing relapse rate over 12 months of treatment (compared with the relapse rate on starting treatment) and who do not meet any of the other Stopping Criteria at annual review may switch to a different class of funded treatment (i.e. patients may switch from either of the beta-interferons [interferon beta-1-beta or interferon beta-1-alpha] to glatiramer acetate or vice versa). Patients may switch classes of treatment for this reason 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 stable or increasing relapse rate over 12 months of treatment).

GLATIRAMER ACETATE – Special Authority see SA1062 on the preceding page		
Inj 20 mg prefilled syringe	1,089.25	28 ✓ Copaxone
INTERFERON BETA-1-ALPHA – Special Authority see SA1062 on the preceding page		
Inj 6 million iu prefilled syringe	1,425.10	4 ✓ Avonex
Inj 6 million iu per vial	1,425.10	4 ✓ Avonex
INTERFERON BETA-1-BETA – Special Authority see SA1062 on the preceding page		
Inj 8 million iu per 1 ml	1,322.89	15 ✓ Betaferon

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Sedatives and Hypnotics				
LORMETAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 1 mg	3.11 (23.50)	30		Noctamid
‡ Safety cap for extemporaneously compounded oral liquid preparations.				
MIDAZOLAM – Safety medicine; prescriber may determine dispensing frequency				
Inj 1 mg per ml, 5 ml	10.00 10.75	10	✓ Pfizer ✓ Hypnovel	
Inj 5 mg per ml, 3 ml	11.90	5	✓ Hypnovel ✓ Pfizer	
NITRAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 5 mg	2.00 (4.98)	100		Nitrados
‡ Safety cap for extemporaneously compounded oral liquid preparations.				
TEMAZEPAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 10 mg	1.27	25	✓ <u>Normison</u>	
‡ Safety cap for extemporaneously compounded oral liquid preparations.				
TRIAZOLAM – Safety medicine; prescriber may determine dispensing frequency				
Tab 125 µg	5.10 (7.25)	100		Hypam
‡ Safety cap for extemporaneously compounded oral liquid preparations.				
Tab 250 µg	4.10 (8.70)	100		Hypam
‡ Safety cap for extemporaneously compounded oral liquid preparations.				
ZOPICLONE				
Tab 7.5 mg	1.90 11.90	30 500	✓ Apo-Zopiclone ✓ Apo-Zopiclone	

Stimulants/ADHD Treatments

Stimulants/ADHD treatments

ATOMOXETINE – Special Authority see SA0951 below – Retail pharmacy				
Cap 10 mg	107.03	28	✓ Strattera	
Cap 18 mg	107.03	28	✓ Strattera	
Cap 25 mg	107.03	28	✓ Strattera	
Cap 40 mg	107.03	28	✓ Strattera	
Cap 60 mg	107.03	28	✓ Strattera	
Cap 80 mg	139.11	28	✓ Strattera	
Cap 100 mg	139.11	28	✓ Strattera	

SA0951 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:

continued...

‡ safety cap

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

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

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

continued...

- 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; 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.

DEXAMPHEMAMINE SULPHATE – Special Authority see SA1149 below – Retail pharmacy

a) Only on a controlled drug form

b) Safety medicine; prescriber may determine dispensing frequency

Tab 5 mg 16.50 100 ✓ PSM

▶▶SA1149 Special Authority for Subsidy

Initial application — (ADHD in patients 5 or over) only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a relevant specialist. 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 relevant specialist has been consulted within the last 2 years and has recommended treatment for the patient.

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 relevant specialist. 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 relevant specialist has been consulted within the last 2 years and has recommended treatment for the patient.

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 (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
METHYLPHENIDATE HYDROCHLORIDE – Special Authority see SA1150 below – Retail pharmacy				
a) Only on a controlled drug form				
b) Safety medicine; prescriber may determine dispensing frequency				
Tab immediate-release 5 mg	3.20	30	✓	Rubifen
Tab immediate-release 10 mg	3.00	30	✓	Ritalin
			✓	Rubifen
Tab immediate-release 20 mg	7.85	30	✓	Rubifen
Tab sustained-release 20 mg	10.95	30	✓	Rubifen SR
	50.00	100	✓	Ritalin SR

►SA1150 Special Authority for Subsidy

Initial application — (ADHD in patients 5 or over) only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a relevant specialist. 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 relevant specialist has been consulted within the last 2 years and has recommended treatment for the patient.

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 relevant specialist. 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 relevant specialist has been consulted within the last 2 years and has recommended treatment for the patient.

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

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

METHYLPHENIDATE HYDROCHLORIDE EXTENDED-RELEASE – Special Authority see SA1151 on the next page – Retail pharmacy

a) Only on a controlled drug form			
b) Safety medicine; prescriber may determine dispensing frequency			
Tab extended-release 18 mg	58.96	30	✓ Concerta
Tab extended-release 27 mg	65.44	30	✓ Concerta
Tab extended-release 36 mg	71.93	30	✓ Concerta
Tab extended-release 54 mg	86.24	30	✓ Concerta
Cap modified-release 10 mg	19.50	30	✓ Ritalin LA
Cap modified-release 20 mg	25.50	30	✓ Ritalin LA
Cap modified-release 30 mg	31.90	30	✓ Ritalin LA
Cap modified-release 40 mg	38.25	30	✓ Ritalin LA

‡ 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.

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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►SA1151 Special Authority for Subsidy

Initial application only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 24 months for applications meeting the following criteria:

All of the following:

- 1 ADHD (Attention Deficit and Hyperactivity Disorder); and
- 2 Diagnosed according to DSM-IV or ICD 10 criteria; and
- 3 Either:
 - 3.1 Applicant is a paediatrician or psychiatrist; or
 - 3.2 Applicant is a medical practitioner and confirms that a relevant specialist has been consulted within the last 2 years and has recommended treatment for the patient; and
- 4 Either:
 - 4.1 Patient is taking a currently subsidised formulation of methylphenidate hydrochloride (immediate-release or sustained-release) which has not been effective due to significant administration and/or compliance difficulties; or
 - 4.2 There is significant concern regarding the risk of diversion or abuse of immediate-release methylphenidate hydrochloride.

Renewal only from a paediatrician, psychiatrist or medical practitioner on the recommendation of a relevant specialist. 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 relevant specialist has been consulted within the last 2 years and has recommended treatment for the patient.

MODAFINIL – Special Authority see SA1126 below – Retail pharmacy

Tab 100 mg	72.50	30	✓ Modavigil
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►SA1126 Special Authority for Subsidy

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

All of the following:

- 1 The patient has a diagnosis of narcolepsy and has excessive daytime sleepiness associated with narcolepsy occurring almost daily for three months or more; and
- 2 Either:
 - 2.1 The patient has a multiple sleep latency test with a mean sleep latency of less than or equal to 10 minutes and 2 or more sleep onset rapid eye movement periods; or
 - 2.2 The patient has at least one of: cataplexy, sleep paralysis or hypnagogic hallucinations; and
- 3 Either:
 - 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	7.71	90	✓ Donepezil-Rex
* Tab 10 mg	14.06	90	✓ Donepezil-Rex

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

Treatments for Opioid Overdose

NALOXONE HYDROCHLORIDE

- a) Up to 5 inj available on a PSO
- b) Only on a PSO

* Inj 400 µg per ml, 1 ml 33.00 5 ✓ Mayne

Treatments for Substance Dependence

BUPRENORPHINE WITH NALOXONE – Special Authority see SA1203 below – Retail pharmacy

- a) No patient co-payment payable
- b) Safety medicine; prescriber may determine dispensing frequency

Tab sublingual 2 mg with naloxone 0.5 mg 57.40 28 ✓ Suboxone
Tab sublingual 8 mg with naloxone 2 mg 166.00 28 ✓ Suboxone

►SA1203 Special Authority for Subsidy

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

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

All of the following:

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

‡ 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.

NERVOUS SYSTEM

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
BUPROPION HYDROCHLORIDE				
Tab modified-release 150 mg	65.00	30	✓	Zyban
DISULFIRAM				
Tab 200 mg	24.30	100	✓	Antabuse
NALTREXONE HYDROCHLORIDE – Special Authority see SA0909 below – Retail pharmacy				
Tab 50 mg	123.00	30	✓	Nalttraccord

►SA0909 Special Authority for Subsidy

Initial application from any medical practitioner. Approvals valid for 3 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 medical practitioner. Approvals valid for 3 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.

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

NICOTINE

Nicotine will not be funded under the Dispensing Frequency Rule in amounts less than 4 weeks of treatment.

Patch 7 mg – Up to 28 patch available on a PSO	18.13	28	✓	Habitrol
Patch 14 mg – Up to 28 patch available on a PSO	18.81	28	✓	Habitrol
Patch 21 mg – Up to 28 patch available on a PSO	19.14	28	✓	Habitrol
Lozenge 1 mg – Up to 216 loz available on a PSO	19.94	216	✓	Habitrol
Lozenge 2 mg – Up to 216 loz available on a PSO	24.27	216	✓	Habitrol
Gum 2 mg (Classic) – Up to 384 piece available on a PSO	36.47	384	✓	Habitrol
Gum 2 mg (Fruit) – Up to 384 piece available on a PSO	36.47	384	✓	Habitrol
Gum 2 mg (Mint) – Up to 384 piece available on a PSO	36.47	384	✓	Habitrol
Gum 4 mg (Classic) – Up to 384 piece available on a PSO	42.04	384	✓	Habitrol
Gum 4 mg (Fruit) – Up to 384 piece available on a PSO	42.04	384	✓	Habitrol
Gum 4 mg (Mint) – Up to 384 piece available on a PSO	42.04	384	✓	Habitrol

VARENICLINE TARTRATE – Special Authority see SA1161 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 3 months' varenicline will be subsidised on each Special Authority approval.

Tab 1 mg	67.74	28	✓	Champix
	135.48	56	✓	Champix
Tab 0.5 mg × 11 and 1 mg × 14	60.48	25 OP	✓	Champix

►SA1161 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:

continued...

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

continued...

- 3.1 The patient has tried but failed to quit smoking after at least two separate trials of nicotine replacement therapy, at least one of which included the patient receiving comprehensive advice on the optimal use of nicotine replacement therapy; or
- 3.2 The patient has tried but failed to quit smoking using bupropion or nortriptyline; and
- 4 The patient has not used funded varenicline in the last 12 months; and
- 5 Varenicline is not to be used in combination with other pharmacological smoking cessation treatments and the patient has agreed to this; and
- 6 The patient is not pregnant; and
- 7 The patient will not be prescribed more than 3 months' funded varenicline (see note).

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

All of the following:

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

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

Note: a maximum of 3 months' varenicline will be subsidised on each Special Authority approval.

‡ 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.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Chemotherapeutic Agents				
Alkylating Agents				
BUSULPHAN – PCT – Retail pharmacy-Specialist				
Tab 2 mg	59.50	100	✓	Myleran
CARBOPLATIN – PCT only – Specialist				
Inj 10 mg per ml, 5 ml	20.00	1	✓	Carboplatin Ebewe
Inj 10 mg per ml, 15 ml	19.50	1	✓	Carbaccord
.....	22.50		✓	Carboplatin Ebewe
Inj 10 mg per ml, 45 ml	48.50	1	✓	Carbaccord
.....	50.00		✓	Carboplatin Ebewe
.....			✓	DBL Carboplatin
Inj 10 mg per ml, 100 ml	105.00	1	✓	Carboplatin Ebewe
Inj 1 mg for ECP	0.15	1 mg	✓	Baxter
CARMUSTINE – PCT only – Specialist				
Inj 100 mg	204.13	1	✓	BicNU
Inj 100 mg for ECP	204.13	100 mg OP	✓	Baxter
CHLORAMBUCIL – PCT – Retail pharmacy-Specialist				
Tab 2 mg	22.35	25	✓	Leukeran FC
CISPLATIN – PCT only – Specialist				
Inj 1 mg per ml, 50 ml	15.00	1	✓	Cisplatin Ebewe
.....	19.00		✓	Mayne
Inj 1 mg per ml, 100 ml	21.00	1	✓	Cisplatin Ebewe
.....	38.00		✓	Mayne
Inj 1 mg for ECP	0.27	1 mg	✓	Baxter
CYCLOPHOSPHAMIDE				
Tab 50 mg – PCT – Retail pharmacy-Specialist	25.71	50	✓	<u>Cycloblastin</u>
Inj 1 g – PCT – Retail pharmacy-Specialist	26.70	1	✓	Endoxan
.....	127.80	6	✓	Cytoxan
Inj 2 g – PCT only – Specialist	56.90	1	✓	Endoxan
Inj 1 mg for ECP – PCT only – Specialist	0.03	1 mg	✓	Baxter
IFOSFAMIDE – PCT only – Specialist				
Inj 1 g	96.00	1	✓	Holoxan
Inj 2 g	180.00	1	✓	Holoxan
Inj 1 mg for ECP	0.10	1 mg	✓	Baxter
LOMUSTINE – PCT only – Specialist				
Cap 10 mg	132.59	20	✓	CeeNU
Cap 40 mg	399.15	20	✓	CeeNU
MELPHALAN				
Tab 2 mg – PCT – Retail pharmacy-Specialist	31.31	25	✓	Alkeran
Inj 50 mg – PCT only – Specialist	52.15	1	✓	Alkeran

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
OXALIPLATIN – PCT only – Specialist – Special Authority see SA0900 below				
Inj 50 mg	15.32	1	✓	Oxaliplatin Actavis 50
	55.00		✓	Oxaliplatin Ebewe
	200.00		✓	Eloxatin
Inj 100 mg	25.01	1	✓	Oxaliplatin Actavis 100
	110.00		✓	Oxaliplatin Ebewe
	400.00		✓	Eloxatin
Inj 1 mg for ECP	0.28	1 mg	✓	Baxter

▶SA0900 | Special Authority for Subsidy

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

Either:

- 1 Both:
 - 1.1 The patient has metastatic colorectal cancer; and
 - 1.2 To be used for first or second line use as part of a combination chemotherapy regimen; or
- 2 Both:
 - 2.1 The patient has stage III (Duke's C) colorectal* cancer; and
 - 2.2 Adjuvant oxaliplatin to be given in combination with a fluoropyrimidine (fluorouracil or capecitabine).

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:

Either:

- 1 The patient requires continued therapy; or
- 2 The tumour has relapsed and requires re-treatment.

Note: Indications marked with * are Unapproved Indications, oxaliplatin is indicated for adjuvant treatment of stage III (Duke's C) colon cancer after complete resection of the primary tumour.

THIOTEPA – PCT only – Specialist

Inj 15 mg	CBS	1	✓	Bedford S29
			✓	THIO-TEPA S29

Antimetabolites

CALCIUM FOLINATE

Tab 15 mg – PCT – Retail pharmacy-Specialist	82.45	10	✓	DBL Leucovorin Calcium
Inj 3 mg per ml, 1 ml – PCT – Retail pharmacy-Specialist	17.10	5	✓	Mayne
Inj 50 mg – PCT – Retail pharmacy-Specialist	24.50	5	✓	Calcium Folate Ebewe
Inj 100 mg – PCT only – Specialist	9.75	1	✓	Calcium Folate Ebewe
Inj 300 mg – PCT only – Specialist	30.00	1	✓	Calcium Folate Ebewe
Inj 1 g – PCT only – Specialist	90.00	1	✓	Calcium Folate Ebewe
Inj 1 mg for ECP – PCT only – Specialist	0.10	1 mg	✓	Baxter

CAPECITABINE – Retail pharmacy-Specialist – Special Authority see SA1049 on the next page

Tab 150 mg	115.00	60	✓	Xeloda
Tab 500 mg	705.00	120	✓	Xeloda

‡ 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.

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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►SA1049 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:

Any of the following:

- 1 The patient has advanced gastrointestinal malignancy; or
- 2 The patient has metastatic breast cancer; or
- 3 The patient has stage III (Duke's stage C) colorectal*# cancer and undergone surgery; or
- 4 Both:
 - 4.1 The patient has stage II (Dukes' stage B) colorectal* cancer and has undergone surgery; and
 - 4.2 Any of the following:
 - 4.2.1 The patient has stage T4 disease; or
 - 4.2.2 The patient has vascular invasion; or
 - 4.2.3 Fewer than 10 lymph nodes were examined at resection; or
- 5 All of the following:
 - 5.1 The patient has locally advanced (clinically or radiologically staged T3/T4: N0,1,2) rectal cancer; and
 - 5.2 Surgery is planned; and
 - 5.3 Capecitabine to be given prior to surgery (neoadjuvant); and
 - 5.4 Capecitabine to be given at a maximum dose of 825 mg/m² twice daily in combination with radiation therapy for a maximum of 6 weeks; or
- 6 Both:
 - 6.1 The patient has poor venous access or needle phobia*; and
 - 6.2 The patient requires a substitute for single agent fluoropyrimidine*.

Note: Indications marked with * are Unapproved Indications, # capecitabine is approved for stage III (Duke's stage C) colon cancer.

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:

Either:

- 1 The patient requires continued therapy; or
- 2 The tumour has relapsed and requires re-treatment.

CLADRIBINE – PCT only – Specialist

Inj 2 mg per ml, 5 ml	873.00	1	✓ Litak S29
Inj 1 mg per ml, 10 ml	5,249.72	7	✓ Leustatin
Inj 10 mg for ECP	749.96	10 mg OP	✓ Baxter

(Litak ~~S29~~ Inj 2 mg per ml, 5 ml to be delisted 1 December 2012)

CYTARABINE

Inj 100 mg – PCT – Retail pharmacy-Specialist	76.00	5	✓ Pfizer
	80.00		✓ Mayne
Inj 500 mg – PCT – Retail pharmacy-Specialist	18.15	1	✓ Pfizer
	95.36	5	✓ Mayne
Inj 1 g – PCT – Retail pharmacy-Specialist	37.00	1	✓ Pfizer
	42.65		✓ Mayne
Inj 2 g – PCT – Retail pharmacy-Specialist	31.00	1	✓ Pfizer
	34.47		✓ Mayne
Inj 1 mg for ECP – PCT only – Specialist	0.27	10 mg	✓ Baxter
Inj 100 mg intrathecal syringe for ECP – PCT only – Specialist	15.20	100 mg OP	✓ Baxter

FLUDARABINE PHOSPHATE – PCT only – Specialist

Tab 10 mg	433.50	20	✓ Fludara Oral
Inj 50 mg	525.00	5	✓ Fludarabine Ebewe
	1,430.00		✓ Fludara
Inj 50 mg for ECP	105.00	50 mg OP	✓ Baxter

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
FLUOROURACIL SODIUM				
Inj 50 mg per ml, 10 ml – PCT only – Specialist.....	26.25	5	✓	Fluorouracil Ebewe
Inj 50 mg per ml, 20 ml – PCT only – Specialist.....	7.50	1	✓	Fluorouracil Ebewe
Inj 25 mg per ml, 100 ml – PCT only – Specialist.....	13.55	1	✓	Mayne
Inj 50 mg per ml, 50 ml – PCT only – Specialist.....	18.00	1	✓	Fluorouracil Ebewe
Inj 50 mg per ml, 100 ml – PCT only – Specialist.....	34.50	1	✓	Fluorouracil Ebewe
Inj 1 mg for ECP – PCT only – Specialist.....	0.77	100 mg	✓	Baxter
GEMCITABINE HYDROCHLORIDE – PCT only – Specialist – Special Authority see SA1087 below				
Inj 1 g	62.50	1	✓	DBL Gemcitabine
			✓	Gemcitabine Actavis 1000
	349.20		✓	Gemcitabine Ebewe
Inj 200 mg	12.50	1	✓	Gemzar
			✓	Gemcitabine Actavis 200
	78.00		✓	Gemcitabine Ebewe
Inj 1 mg for ECP	0.07	1 mg	✓	Gemzar
			✓	Baxter

SA1087 Special Authority for Subsidy

Initial application — (Hodgkin's Disease) 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 Hodgkin's Disease*; and
- 2 Any of the following:
 - 2.1 Disease has failed to respond to second line salvage chemotherapy treatment; or
 - 2.2 Disease has relapsed following transplant; or
 - 2.3 The patient is unsuitable for, or intolerant to, second-line salvage chemotherapy or high dose chemotherapy and transplant; and
- 3 Gemcitabine to be given for a maximum of 6 treatment cycles.

Note: Indications marked with a * are Unapproved Indications.

Initial application — (T-Cell Lymphoma) 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 T-cell Lymphoma*; and
- 2 Gemcitabine to be given for a maximum of 6 treatment cycles.

Note: Indications marked with a * are Unapproved Indications.

Initial application — (Cholangiocarcinoma) 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 locally advanced or metastatic, cholangiocarcinoma*; and
- 2 Gemcitabine to be given for a maximum of 8 treatment cycles.

Notes: Cholangiocarcinoma encompasses epithelial tumours of the hepatobiliary tree, including tumours of bile ducts, ampulla of Vater and gallbladder.

Indications marked with a * are Unapproved Indications.

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

Either:

- 1 Both:
 - 1.1 The patient has macroscopically resected (R0) pancreatic carcinoma*; and

continued...

‡ safety cap

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

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

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
continued...			
1.2 Adjuvant gemcitabine to be administered for a maximum of 6 cycles; or			
2 Both:			
2.1 The patient has advanced pancreatic carcinoma; and			
2.2 The patient is gemcitabine treatment naïve.			
Note: Indications marked with a * are Unapproved Indications.			
Renewal — (Pancreatic 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 received gemcitabine for advanced pancreatic carcinoma; and			
2 The patient has not received gemcitabine for adjuvant treatment pancreatic carcinoma; and			
3 The patient requires continued therapy.			
Initial application — (Other indications) 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:			
Any of the following:			
1 The patient has non small cell lung carcinoma (stage IIIa, or above); or			
2 The patient has advanced malignant mesothelioma; or			
3 The patient has ovarian, fallopian tube* or primary peritoneal carcinoma*; or			
4 The patient has advanced transitional cell carcinoma of the urothelial tract (locally advanced or metastatic).			
Note: Indications marked with a * are Unapproved Indications.			
Renewal — (Other indications) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:			
Either:			
1 The patient requires continued therapy; or			
2 The tumour has relapsed and requires re-treatment.			
IRINOTECAN – PCT only – Specialist – Special Authority see SA0878 below			
Inj 20 mg per ml, 2 ml9.34	1	✓	Irinotecan Actavis 40
41.00		✓	Camptosar
Inj 20 mg per ml, 5 ml23.34	1	✓	Irinotecan-Rex
100.00		✓	Irinotecan Actavis 100
Inj 1 mg for ECP0.24	1 mg	✓	Camptosar
		✓	Irinotecan-Rex
		✓	Baxter
SA0878 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:			
Both:			
1 The patient has metastatic colorectal cancer; and			
2 Either:			
2.1 To be used for first or second line use as part of a combination chemotherapy regimen; or			
2.2 As single agent chemotherapy in fluoropyrimidine-relapsed disease.			
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:			
Either:			
1 The patient requires continued therapy; or			
2 The tumour has relapsed and requires re-treatment.			
MERCAPTOPURINE – PCT – Retail pharmacy-Specialist			
Tab 50 mg47.06	25	✓	Purinethol

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
METHOTREXATE				
* Tab 2.5 mg – PCT – Retail pharmacy-Specialist	5.22	30	✓	Methoblastin
* Tab 10 mg – PCT – Retail pharmacy-Specialist	40.93	50	✓	Methoblastin
* Inj 2.5 mg per ml, 2 ml – PCT – Retail pharmacy-Specialist	23.65	5	✓	Mayne
* Inj 25 mg per ml, 2 ml – PCT – Retail pharmacy-Specialist	48.00	5	✓	Hospira
* Inj 25 mg per ml, 20 ml – PCT – Retail pharmacy-Specialist	90.00	1	✓	Hospira
* Inj 100 mg per ml, 10 ml – PCT – Retail pharmacy-Specialist	25.00	1	✓	Methotrexate Ebewe
* Inj 25 mg per ml, 40 ml – PCT – Retail pharmacy-Specialist	25.00	1	✓	DBL Methotrexate S29
* Inj 100 mg per ml, 50 ml – PCT – Retail pharmacy-Specialist	125.00	1	✓	Methotrexate Ebewe
* Inj 1 mg for ECP – PCT only – Specialist	0.10	1 mg	✓	Baxter
* Inj 5 mg intrathecal syringe for ECP – PCT only – Specialist	4.73	5 mg OP	✓	Baxter
THIOGUANINE – PCT – Retail pharmacy-Specialist				
Tab 40 mg	97.16	25	✓	Lanvis

Other Cytotoxic Agents

AMISACRINE – PCT only – Specialist				
Inj 75 mg	CBS	6	✓	Amsidine S29
ANAGRELIDE HYDROCHLORIDE – PCT only – Specialist – Special Authority see SA0879 below				
Cap 0.5 mg	CBS	100	✓	Agrylin S29
			✓	Teva S29

SA0879 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:

Both:

- 1 The patient has primary thrombocythaemia; and
- 2 Either:
 - 2.1 is at high risk (previous thromboembolic disease, bleeding or platelet count >1500/ml); or
 - 2.2 is intolerant or refractory to hydroxyurea or interferon.

Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.

Note: It is recommended that treatment with anagrelide be initiated only on the recommendation of a haematologist.

ARSENIC TRIOXIDE – PCT only – Specialist				
Inj 10 mg	4,817.00	10	✓	AFT S29
BLEOMYCIN SULPHATE – PCT only – Specialist				
Inj 15,000 iu	120.00	1	✓	DBL Bleomycin Sulfate
Inj 1,000 iu for ECP	9.28	1,000 iu	✓	Baxter
BORTEZOMIB – PCT only – Specialist – Special Authority see SA1127 on the next page				
Inj 1 mg	540.70	1	✓	Velcade
Inj 3.5 mg	1,892.50	1	✓	Velcade
Inj 1 mg for ECP	594.77	1 mg	✓	Baxter

‡ safety cap

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

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

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
SA1127 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 15 months for applications meeting the following criteria:			
Both:			
1 Either:			
1.1 The patient has treatment-naïve symptomatic multiple myeloma; or			
1.2 The patient has treatment-naïve 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:			
a) a known therapeutic chemotherapy regimen and supportive treatments; or			
b) a transplant induction chemotherapy regimen, stem cell transplantation and supportive treatments.			
Refer to datasheet for recommended dosage and number of doses of bortezomib per treatment cycle.			
COLASPASE [L-ASPARAGINASE] – PCT only – Specialist			
Inj 10,000 iu	102.32	1	✓ Leunase
Inj 10,000 iu for ECP	102.32	10,000 iu OP	✓ Baxter
DACARBAZINE – PCT only – Specialist			
Inj 200 mg	48.00	1	✓ Hospira
Inj 200 mg for ECP	48.00	200 mg OP	✓ Baxter
DACTINOMYCIN [ACTINOMYCIN D] – PCT only – Specialist			
Inj 0.5 mg	13.52	1	✓ Cosmegen
Inj 0.5 mg for ECP	13.52	0.5 mg OP	✓ Baxter
DAUNORUBICIN – PCT only – Specialist			
Inj 2 mg per ml, 10 ml	118.72	1	✓ Pfizer
Inj 20 mg for ECP	118.72	20 mg OP	✓ Baxter
DOCETAXEL – PCT only – Specialist			
Inj 20 mg	48.75	1	✓ Docetaxel Ebewe
	460.00		✓ Taxotere
Inj 80 mg	195.00	1	✓ Docetaxel Ebewe
	1,650.00		✓ Taxotere
Inj 1 mg for ECP	2.63	1 mg	✓ Baxter

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
DOXORUBICIN – PCT only – Specialist				
Inj 10 mg	10.00	1	✓	Doxorubicin Ebewe
Inj 50 mg	40.00	1	✓	DBL Doxorubicin
			✓	DBL Doxorubicin S29 S29
			✓	Doxorubicin Ebewe
Inj 100 mg	80.00	1	✓	Doxorubicin Ebewe
Inj 200 mg	150.00	1	✓	Adriamycin
			✓	Doxorubicin Ebewe
Inj 1 mg for ECP	0.88	1 mg	✓	Baxter
EPIRUBICIN – PCT only – Specialist				
Inj 2 mg per ml, 5 ml	25.00	1	✓	Epirubicin Ebewe
Inj 2 mg per ml, 25 ml	39.38	1	✓	DBL Epirubicin Hydrochloride
	87.50		✓	Epirubicin Ebewe
Inj 2 mg per ml, 50 ml	58.20	1	✓	DBL Epirubicin Hydrochloride
	125.00		✓	Epirubicin Ebewe
Inj 2 mg per ml, 100 ml	94.50	1	✓	DBL Epirubicin Hydrochloride
	210.00		✓	Epirubicin Ebewe
Inj 1 mg for ECP	0.82	1 mg	✓	Baxter
ETOPOSIDE				
Cap 50 mg – PCT – Retail pharmacy-Specialist	340.73	20	✓	Vepesid
Cap 100 mg – PCT – Retail pharmacy-Specialist	340.73	10	✓	Vepesid
Inj 20 mg per ml, 5 ml – PCT – Retail pharmacy-Specialist	25.00	1	✓	Mayne
	612.20	10	✓	Vepesid
Inj 1 mg for ECP – PCT only – Specialist	0.30	1 mg	✓	Baxter
ETOPOSIDE PHOSPHATE – PCT only – Specialist				
Inj 100 mg (of etoposide base)	40.00	1	✓	Etopophos
Inj 1 mg (of etoposide base) for ECP	0.47	1 mg	✓	Baxter
HYDROXYUREA – PCT – Retail pharmacy-Specialist				
Cap 500 mg	31.76	100	✓	Hydrea
IDARUBICIN HYDROCHLORIDE – PCT only – Specialist				
Cap 5 mg	115.00	1	✓	Zavedos
Cap 10 mg	144.50	1	✓	Zavedos
Inj 5 mg	100.00	1	✓	Zavedos
Inj 10 mg	200.00	1	✓	Zavedos
Inj 1 mg for ECP	22.20	1 mg	✓	Baxter
MESNA – PCT only – Specialist				
Tab 400 mg	210.65	50	✓	Uromitexan
Tab 600 mg	314.40	50	✓	Uromitexan
Inj 100 mg per ml, 4 ml	137.04	15	✓	Uromitexan
Inj 100 mg per ml, 10 ml	314.66	15	✓	Uromitexan
Inj 1 mg for ECP	2.29	100 mg	✓	Baxter
MITOMYCIN C – PCT only – Specialist				
Inj 5 mg	72.75	1	✓	Arrow
Inj 1 mg for ECP	16.13	1 mg	✓	Baxter

‡ safety cap

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

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

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
MITOZANTRONE – PCT only – Specialist				
Inj 2 mg per ml, 5 ml	110.00	1	✓	Mitozantrone Ebewe
Inj 2 mg per ml, 10 ml	100.00	1	✓	Mitozantrone Ebewe
Inj 2 mg per ml, 12.5 ml	407.50	1	✓	Onkotrone
Inj 1 mg for ECP	5.65	1 mg	✓	Baxter
PACLITAXEL – PCT only – Specialist				
Inj 30 mg	137.50	5	✓	Paclitaxel Ebewe
Inj 100 mg	91.67	1	✓	Paclitaxel Actavis
			✓	Paclitaxel Ebewe
Inj 150 mg	137.50	1	✓	Anzatax
			✓	Paclitaxel Actavis
			✓	Paclitaxel Ebewe
Inj 300 mg	275.00	1	✓	Anzatax
			✓	Paclitaxel Actavis
			✓	Paclitaxel Ebewe
Inj 600 mg	550.00	1	✓	Paclitaxel Ebewe
Inj 1 mg for ECP	1.02	1 mg	✓	Baxter
PENTOSTATIN [DEOXYCOFORMYCIN] – PCT only – Specialist				
Inj 10 mg	CBS	1	✓	Nipent S29
PROCARBAZINE HYDROCHLORIDE – PCT only – Specialist				
Cap 50 mg	225.00	50	✓	Natulan S29
TEMOZOLOMIDE – Special Authority see SA1063 below – Retail pharmacy				
Cap 5 mg	16.00	5	✓	<u>Temaccord</u>
Cap 20 mg	72.00	5	✓	<u>Temaccord</u>
Cap 100 mg	350.00	5	✓	<u>Temaccord</u>
Cap 250 mg	820.00	5	✓	<u>Temaccord</u>

►SA1063 Special Authority for Subsidy

Initial application only from a relevant specialist. Approvals valid for 10 months for applications meeting the following criteria:

All of the following:

- 1 Either:
 - 1.1 Patient has newly diagnosed glioblastoma multiforme; or
 - 1.2 Patient has newly diagnosed anaplastic astrocytoma; and
- 2 Temozolomide is to be (or has been) given concomitantly with radiotherapy; and
- 3 Following concomitant treatment temozolomide is to be used for a maximum of six cycles of 5 days treatment, at a maximum dose of 200 mg/m².

Notes: Indication marked with a * is an Unapproved Indication. Temozolomide is not subsidised for the treatment of relapsed glioblastoma multiforme. Reapplications will not be approved.

Studies of temozolomide show that its benefit is predominantly in those patients with a good performance status (WHO grade 0 or 1 or Karnofsky score >80), and in patients who have had at least a partial resection of the tumour.

THALIDOMIDE – PCT only – Specialist – Special Authority see SA1124 on the next page

Cap 50 mg	504.00	28	✓	Thalomid
Cap 100 mg	1,008.00	28	✓	Thalomid

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
➡SA1124 Special Authority for Subsidy			
Initial application only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:			
Either:			
1 The patient has multiple myeloma; or			
2 The patient has systemic AL amyloidosis*.			
Renewal only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid without further renewal unless notified where the patient has obtained a response from treatment during the initial approval period.			
Notes: Prescription must be written by a registered prescriber in the thalidomide risk management programme operated by the supplier.			
Maximum dose of 400 mg daily as monotherapy or in a combination therapy regimen.			
Indication marked with * is an Unapproved Indication.			
TRETINOIN			
Cap 10 mg – PCT – Retail pharmacy-Specialist	435.90	100	✓ Vesanoid
VINBLASTINE SULPHATE			
Inj 10 mg – PCT – Retail pharmacy-Specialist	27.50	1	✓ Mayne
	137.50	5	✓ Mayne
Inj 1 mg for ECP – PCT only – Specialist	3.05	1 mg	✓ Baxter
VINCRISTINE SULPHATE			
Inj 1 mg per ml, 1 ml – PCT – Retail pharmacy-Specialist	108.00	5	✓ Hospira
Inj 1 mg per ml, 2 ml – PCT – Retail pharmacy-Specialist	116.00	5	✓ Hospira
Inj 1 mg for ECP – PCT only – Specialist	15.77	1 mg	✓ Baxter
VINORELBINE – PCT only – Specialist – Special Authority see SA1013 below			
Inj 10 mg per ml, 1 ml	12.85	1	✓ Navelbine
	42.00		✓ Vinorelbine Ebewe
Inj 10 mg per ml, 5 ml	64.25	1	✓ Navelbine
	210.00		✓ Vinorelbine Ebewe
Inj 1 mg for ECP	1.45	1 mg	✓ Baxter

➡SA1013 Special Authority for Subsidy

Initial application — (Hodgkin's Disease) 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 Hodgkin's Disease*; and
- 2 Any of the following:
 - 2.1 Disease has failed to respond to second-line salvage chemotherapy treatment; or
 - 2.2 Disease has relapsed following transplant; or
 - 2.3 The patient is unsuitable for, or intolerant to, second-line salvage chemotherapy or high dose chemotherapy and transplant; and
- 3 Vinorelbine to be given for a maximum of 6 treatment cycles.

Initial application — (T-Cell Lymphoma) 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 T-cell Lymphoma*; and
- 2 Vinorelbine to be given for a maximum of 6 treatment cycles.

Initial application — (Other indications) 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:

Any of the following:

- 1 The patient has metastatic breast cancer; or

continued...

‡ safety cap

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

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

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

continued...

- 2 The patient has non-small cell lung cancer (stage IIIa, or above); or
- 3 All of the following:
 - 3.1 The patient has stage IB-IIIa non-small cell lung cancer; and
 - 3.2 Vinorelbine is to be given as adjuvant treatment in combination with cisplatin; and
 - 3.3 The patient has good performance status (WHO/ECOG grade 0-1).

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

Either:

- 1 The patient requires continued therapy; or
- 2 The tumour has relapsed and requires re-treatment.

Note: Indications marked with a * are Unapproved Indications.

Protein-tyrosine Kinase Inhibitors

DASATINIB – Special Authority see SA0976 below

Tab 20 mg	3,774.06	60	✓ Sprycel
Tab 50 mg	6,214.20	60	✓ Sprycel
Tab 70 mg	7,692.58	60	✓ Sprycel
Tab 100 mg	6,214.20	30	✓ Sprycel

►SA0976 Special Authority for Subsidy

Special Authority approved by the CML/GIST Co-ordinator

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

The CML/GIST Co-ordinator	Phone: (04) 460 4990
PHARMAC	Facsimile: (04) 916 7571
PO Box 10 254	Email: mary.chesterfield@pharmac.govt.nz
Wellington	

Special Authority criteria for CML - access by application

- a) Funded for patients with diagnosis (confirmed by a haematologist) of a chronic myeloid leukaemia (CML) in blast crisis, accelerated phase, or in chronic phase.
- b) Maximum dose of 140 mg/day for accelerated or blast phase, and 100 mg/day for chronic phase CML.
- c) Subsidised for use as monotherapy only.
- d) Initial approvals valid seven months.
- e) Subsequent approval(s) are granted on application and are valid for six months. The first reapplication (after seven months) should provide details of the haematological response. The third reapplication should provide details of the cytogenetic response after 14-18 months from initiating therapy. All other reapplications should provide details of haematological response, and cytogenetic response if such data is available. Applications to be made and subsequent prescriptions can be written by a haematologist or an oncologist.

Note: Dasatinib is indicated for the treatment of adults with chronic, accelerated or blast phase CML with resistance or intolerance to prior therapy including imatinib.

Guideline on discontinuation of treatment for patients with CML

- a) Prescribers should consider discontinuation of treatment if, after 6 months from initiating therapy, a patient did not obtain a haematological response as defined as any one of the following three levels of response:
 - 1) complete haematologic response (as characterised by an absolute neutrophil count (ANC) $> 1.5 \times 10^9/L$, platelets $> 100 \times 10^9/L$, absence of peripheral blood (PB) blasts, bone marrow (BM) blasts $< 5\%$ (or FISH Ph+ 0-35% metaphases), and absence of extramedullary disease); or
 - 2) no evidence of leukaemia (as characterised by an absolute neutrophil count (ANC) $> 1.0 \times 10^9/L$, platelets $> 20 \times 10^9/L$, absence of peripheral blood (PB) blasts, bone marrow (BM) blasts $< 5\%$ (or FISH Ph+ 0-35% metaphases), and absence of extramedullary disease); or

continued...

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

3) return to chronic phase (as characterised by BM and PB blasts < 15%, BM and PB blasts and promyelocytes < 30%, PB basophils < 20% and absence of extramedullary disease other than spleen and liver).

b) Prescribers should consider discontinuation of treatment if, after 18 months from initiating therapy, a patient did not obtain a major cytogenetic response defined as 0-35% Ph+ metaphases.

ERLOTINIB HYDROCHLORIDE – Retail pharmacy-Specialist – Special Authority see SA1044 below

Tab 100 mg	3,100.00	30	✓ Tarceva
Tab 150 mg	3,950.00	30	✓ Tarceva

▶SA1044 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 advanced, unresectable, Non Small Cell Lung Cancer (NSCLC); and
- 2 Patient has documented disease progression following treatment with first line platinum based chemotherapy; and
- 3 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

Tab 250 mg – Special Authority see SA1226 below	1,700.00	30	✓ Iressa
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▶SA1226 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:

Either:

- 1 All of the following:
 - 1.1 Patient has treatment naive locally advanced, or metastatic, unresectable, non-squamous Non Small Cell Lung Cancer (NSCLC); and
 - 1.2 There is documentation confirming that disease expresses activating mutations of EGFR tyrosine kinase; and
 - 1.3 Gefitinib is to be given for a maximum of 3 months; or
- 2 The patient received gefitinib treatment prior to 1 August 2012 and radiological assessment (preferably including CT scan) indicates NSCLC has not progressed.

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 MESYLATE – Special Authority see SA0643 below

Tab 100 mg	2,400.00	60	✓ Glivec
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▶SA0643 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: mary.chesterfield@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 600 mg/day for accelerated or blast phase, and 400 mg/day for chronic phase CML.
- c) Subsidised for use as monotherapy only.
- d) Initial approvals valid seven months.

continued...

‡ safety cap

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

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

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

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:
- 1) complete haematologic response (as characterised by an absolute neutrophil count (ANC) $> 1.5 \times 10^9/L$, platelets $> 100 \times 10^9/L$, absence of peripheral blood (PB) blasts, bone marrow (BM) blasts $< 5\%$ (or FISH Ph+ 0-35% metaphases), and absence of extramedullary disease); or
 - 2) no evidence of leukaemia (as characterised by an absolute neutrophil count (ANC) $> 1.0 \times 10^9/L$, platelets $> 20 \times 10^9/L$, absence of peripheral blood (PB) blasts, bone marrow (BM) blasts $< 5\%$ (or FISH Ph+ 0-35% metaphases), and absence of extramedullary disease); or
 - 3) return to chronic phase (as characterised by BM and PB blasts $< 15\%$, BM and PB blasts and promyelocytes $< 30\%$, PB basophils $< 20\%$ and absence of extramedullary disease other than spleen and liver).
- b) Prescribers should consider discontinuation of treatment if after 18 months from initiating therapy a patient did not obtain a major cytogenetic response defined as 0-35% Ph+ metaphases.

Special Authority criteria for GIST – access by application

- a) Funded for patients:
- 1) with a diagnosis (confirmed by an oncologist) of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST); and
 - 2) who have immunohistochemical documentation of c-kit (CD117) expression by the tumour.
- b) Maximum dose of 400 mg/day.
- c) Applications to be made and subsequent prescriptions can be written by an oncologist.
- d) Initial and subsequent applications are valid for one year. The re-application criterion is an adequate clinical response to the treatment with imatinib (prescriber determined).

LAPATINIB DITOSYLATE – Special Authority see SA1191 below – Retail pharmacy

Tab 250 mg	1,899.00	70	✓ Tykerb
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►SA1191 Special Authority for Subsidy

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

Either:

- 1 All of the following:
 - 1.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
 - 1.2 The patient has not previously received trastuzumab treatment for HER 2 positive metastatic breast cancer; and
 - 1.3 Lapatinib not to be given in combination with trastuzumab; and
 - 1.4 Lapatinib to be discontinued at disease progression; or
- 2 All of the following:
 - 2.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
 - 2.2 The patient started trastuzumab for metastatic breast cancer but discontinued trastuzumab within 3 months of starting treatment due to intolerance; and
 - 2.3 The cancer did not progress whilst on trastuzumab; and
 - 2.4 Lapatinib not to be given in combination with trastuzumab; and
 - 2.5 Lapatinib to be discontinued at disease progression.

continued...

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

continued...

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

All of the following:

- 1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
- 2 The cancer has not progressed at any time point during the previous 12 months whilst on lapatinib; and
- 3 Lapatinib not to be given in combination with trastuzumab; and
- 4 Lapatinib to be discontinued at disease progression.

PAZOPANIB – Special Authority see SA1190 below – Retail pharmacy

Tab 200 mg	1,334.70	30	✓ Votrient
Tab 400 mg	2,669.40	30	✓ Votrient

▶SA1190 Special Authority for Subsidy

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

All of the following:

- 1 The patient has metastatic renal cell carcinoma; and
- 2 Any of the following:
 - 2.1 The patient is treatment naive; or
 - 2.2 The patient has only received prior cytokine treatment; or
 - 2.3 Both:
 - 2.3.1 The patient has discontinued sunitinib within 3 months of starting treatment due to intolerance; and
 - 2.3.2 The cancer did not progress whilst on sunitinib; and
- 3 The patient has good performance status (WHO/ECOG grade 0-2); and
- 4 The disease is of predominant clear cell histology; and
The patient has intermediate or poor prognosis defined as:
- 5 Any of the following:
 - 5.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or
 - 5.2 Haemoglobin level < lower limit of normal; or
 - 5.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or
 - 5.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or
 - 5.5 Karnofsky performance score of ≤ 70; or
 - 5.6 ≥ 2 sites of organ metastasis; and
- 6 Pazopanib to be used for a maximum of 3 months.

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

Both:

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

Notes: Pazopanib treatment should be stopped if disease progresses.

Poor prognosis patients are defined as having at least 3 of criteria 5.1-5.6. Intermediate prognosis patients are defined as having 1 or 2 of criteria 5.1-5.6.

SUNITINIB – Special Authority see SA1266 on the next page – Retail pharmacy

Cap 12.5 mg	2,315.38	28	✓ Sutent
Cap 25 mg	4,630.77	28	✓ Sutent
Cap 50 mg	9,261.54	28	✓ Sutent

‡ 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.

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

►SA1266 Special Authority for Subsidy

Initial application — (RCC) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist.

Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 The patient has metastatic renal cell carcinoma; and
- 2 Any of the following:
 - 2.1 The patient is treatment naive; or
 - 2.2 The patient has only received prior cytokine treatment; or
 - 2.3 The patient has only received prior treatment with an investigational agent within the confines of a bona fide clinical trial which has Ethics Committee approval; or
 - 2.4 Both:
 - 2.4.1 The patient has discontinued pazopanib within 3 months of starting treatment due to intolerance; and
 - 2.4.2 The cancer did not progress whilst on pazopanib; and
- 3 The patient has good performance status (WHO/ECOG grade 0-2); and
- 4 The disease is of predominant clear cell histology; and
The patient has intermediate or poor prognosis defined as:
- 5 Any of the following:
 - 5.1 Lactate dehydrogenase level > 1.5 times upper limit of normal; or
 - 5.2 Haemoglobin level < lower limit of normal; or
 - 5.3 Corrected serum calcium level > 10 mg/dL (2.5 mmol/L); or
 - 5.4 Interval of < 1 year from original diagnosis to the start of systemic therapy; or
 - 5.5 Karnofsky performance score of ≤ 70; or
 - 5.6 ≥ 2 sites of organ metastasis; and
- 6 Sunitinib to be used for a maximum of 2 cycles.

Initial application — (GIST) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist.

Approvals valid for 3 months for applications meeting the following criteria:

Both:

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

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

Both:

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

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.

Notes: RCC - 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

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

For GnRH ANALOGUES – refer to HORMONE PREPARATIONS, Tropic Hormones, page 84

BICALUTAMIDE – Special Authority see SA0941 below – Retail pharmacy

Tab 50 mg	10.00	28	✓ Bicalaccord
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►SA0941 Special Authority for Subsidy

Initial application from any medical practitioner. Approvals valid without further renewal unless notified where the patient has advanced prostate cancer.

FLUTAMIDE – Retail pharmacy-Specialist

Tab 250 mg	55.00	100	✓ Flutamin
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MEGESTROL ACETATE – Retail pharmacy-Specialist

Tab 160 mg	51.55	30	✓ Apo-Megestrol
	57.92		✓ Megace

(Megace Tab 160 mg to be delisted 1 February 2013)

OCTREOTIDE (SOMATOSTATIN ANALOGUE) – Special Authority see SA1016 below – Retail pharmacy

Inj 50 µg per ml, 1 ml	19.24	5	✓ Octreotide MaxRx
Inj 100 µg per ml, 1 ml	36.38	5	✓ Octreotide MaxRx
Inj 500 µg per ml, 1 ml	131.25	5	✓ Octreotide MaxRx
Inj LAR 10 mg prefilled syringe	1,772.50	1	✓ Sandostatin LAR
Inj LAR 20 mg prefilled syringe	2,358.75	1	✓ Sandostatin LAR
Inj LAR 30 mg prefilled syringe	2,951.25	1	✓ Sandostatin LAR

►SA1016 Special Authority for Subsidy

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

All of the following:

- 1 The patient has nausea* and vomiting* due to malignant bowel obstruction*; and
- 2 Treatment with antiemetics, rehydration, antimuscarinic agents, corticosteroids and analgesics for at least 48 hours has failed; and
- 3 Octreotide to be given at a maximum dose 1500 µg 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.

continued...

‡ safety cap

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

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

Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Note: In patients with Acromegaly octreotide treatment should be discontinued if IGF1 levels have not decreased after 3 months treatment. In patients treated with radiotherapy octreotide treatment should be withdrawn every 2 years, for 1 month, for assessment of remission. Octreotide treatment should be stopped where there is biochemical evidence of remission (normal IGF1 levels) following octreotide treatment withdrawal for at least 4 weeks

Initial application — (Other Indications) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Any of the following:

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

Note: The use of octreotide in patients with fistulae, oesophageal varices, miscellaneous diarrhoea and hypotension will not be funded as a Special Authority item

Renewal — (Other Indications) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 2 years where the treatment remains appropriate and the patient is benefiting from treatment.

TAMOXIFEN CITRATE

* Tab 10 mg	10.80	100	✓ Genox
* Tab 20 mg	8.75	100	✓ Genox

Aromatase Inhibitors

ANASTROZOLE

* Tab 1 mg	26.55	30	✓ Aremed ✓ Arimidex ✓ DP-Anastrozole
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EXEMESTANE

* Tab 25 mg	22.57	30	✓ <u>Aromasin</u>
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LETROZOLE

* Tab 2.5 mg	4.85 (9.00)	30	✓ Letraccord Letara
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(Letara Tab 2.5 mg to be delisted 1 January 2013)

Immunosuppressants

Cytotoxic Immunosuppressants

AZATHIOPRINE – Retail pharmacy-Specialist

* Tab 50 mg – For azathioprine oral liquid formulation refer, page 187	18.45	100	✓ <u>Imuprine</u>
* Inj 50 mg	60.00	1	✓ <u>Imuran</u>

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
MYCOPHENOLATE MOFETIL – Special Authority see SA1041 below – Retail pharmacy			
Dispensing pharmacy should check which brand to dispense with the prescriber if prescribed generically.			
Tab 500 mg	60.00	50	✓ Ceptolate
			✓ Myaccord
	70.00		✓ Cellcept
Cap 250 mg	30.00	50	✓ Ceptolate
	60.00	100	✓ Myaccord
	70.00		✓ Cellcept
Powder for oral liq 1 g per 5 ml – Subsidy by endorsement	285.00	165 ml OP	✓ Cellcept
Mycophenolate powder for oral liquid is subsidised only for patients unable to swallow tablets and capsules, and when the prescription is endorsed accordingly.			

►SA1041 Special Authority for Subsidy

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

Either:

- 1 Transplant recipient; or
- 2 Both:
 - Patients with diseases where
 - 2.1 Steroids and azathioprine have been trialled and discontinued because of unacceptable side effects or inadequate clinical response; and
 - 2.2 Either:
 - Patients with diseases where
 - 2.2.1 Cyclophosphamide has been trialled and discontinued because of unacceptable side effects or inadequate clinical response; or
 - 2.2.2 Cyclophosphamide treatment is contraindicated.

Immune Modulators

ANTITHYMOCYTE GLOBULIN (EQUINE) – PCT only – Specialist			
Inj 50 mg per ml, 5 ml	2,137.50	5	✓ ATGAM
BACILLUS CALMETTE-GUERIN (BCG) VACCINE – PCT only – Specialist			
Subsidised only for bladder cancer.			
Inj 2-8 × 100 million CFU	187.37	1	✓ OncoTICE
RITUXIMAB – PCT only – Specialist – Special Authority see SA1152 below			
Inj 100 mg per 10 ml vial	1,075.50	2	✓ Mabthera
Inj 500 mg per 50 ml vial	2,688.30	1	✓ Mabthera
Inj 1 mg for ECP	5.64	1 mg	✓ Baxter

►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:

continued...

‡ safety cap

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

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

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

continued...

- 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 macroglobulinaemia.

Initial application — (Aggressive CD20 positive NHL) only from a relevant specialist or medical practitioner on the recommendation of a relevant specialist. Approvals valid for 12 months for applications meeting the following criteria:

Either:

- 1 All of the following:
 - 1.1 The patient has treatment naive aggressive CD20 positive NHL; and
 - 1.2 To be used with a multi-agent chemotherapy regimen given with curative intent; and
 - 1.3 To be used for a maximum of 8 treatment cycles; or
- 2 Both:
 - 2.1 The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy; and
 - 2.2 To be used for a maximum of 6 treatment cycles.

Note: 'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia

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

All of the following:

- 1 The patient has progressive Binet stage A, B or C chronic lymphocytic leukaemia (CLL) requiring treatment; and
- 2 The patient is rituximab treatment naive; and
- 3 Either:
 - 3.1 The patient is chemotherapy treatment naive; or
 - 3.2 Both:
 - 3.2.1 The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment; and
 - 3.2.2 The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy; and
- 4 The patient has good performance status; and
- 5 The patient has good renal function (creatinine clearance \geq 30 ml/min); and
- 6 The patient does not have chromosome 17p deletion CLL; and
- 7 Rituximab to be administered in combination with fludarabine and cyclophosphamide for a maximum of 6 treatment cycles; and
- 8 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration).

Note: 'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with rituximab is expected to improve symptoms and improve ECOG score to <2.

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

All of the following:

- 1 The patient has had a rituximab treatment-free interval of 12 months or more; and
- 2 The patient has B-cell post-transplant lymphoproliferative disorder*; and
- 3 To be used for no more than 6 treatment cycles.

Note: Indications marked with * are Unapproved Indications.

continued...

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

continued...

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

TRASTUZUMAB – PCT only – Specialist – Special Authority see SA1192 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

►SA1192 Special Authority for Subsidy

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

Either:

- 1 All of the following:
 - 1.1 The patient has metastatic breast cancer expressing HER-2 IHC 3+ or ISH+ (including FISH or other current technology); and
 - 1.2 The patient has not previously received 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:

continued...

‡ safety cap

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

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

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

All of the following:

- 1 The patient has early breast cancer expressing HER 2 IHC 3+ or ISH + (including FISH or other current technology); and
- 2 Maximum cumulative dose of 106 mg/kg (12 months' treatment); and
- 3 Any of the following:
 - 3.1 9 weeks' concurrent treatment with adjuvant chemotherapy is planned; or
 - 3.2 12 months' concurrent treatment with adjuvant chemotherapy is planned; or
 - 3.3 12 months' sequential treatment following adjuvant chemotherapy is planned; or
 - 3.4 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.

Other Immunosuppressants

CYCLOSPORIN

Cap 25 mg	59.50	50	✓ Neoral
Cap 50 mg	118.54	50	✓ Neoral
Cap 100 mg	237.08	50	✓ Neoral
Oral liq 100 mg per ml	198.13	50 ml OP	✓ Neoral

SIROLIMUS – Special Authority see SA0866 on the next page – Retail pharmacy

Tab 1 mg	813.00	100	✓ Rapamune
Tab 2 mg	1,626.00	100	✓ Rapamune
Oral liq 1 mg per ml	487.80	60 ml OP	✓ Rapamune

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
➡SA0866 Special Authority for Subsidy			
Initial application from any medical practitioner. Approvals valid without further renewal unless notified where the drug is to be used for rescue therapy for an organ transplant recipient.			
Notes: Rescue therapy defined as unresponsive to calcineurin inhibitor treatment as defined by refractory rejection; or intolerant to calcineurin inhibitor treatment due to any of the following:			
<ul style="list-style-type: none"> ● GFR<30 ml/min; or ● Rapidly progressive transplant vasculopathy; or ● Rapidly progressive obstructive bronchiolitis; or ● HUS or TTP; or ● Leukoencephalopathy; or ● Significant malignant disease 			
TACROLIMUS – Special Authority see SA0669 below – Retail pharmacy			
Cap 0.5 mg	214.00	100	✓ Prograf
Cap 1 mg	428.00	100	✓ Prograf
Cap 5 mg – For tacrolimus oral liquid formulation refer, page 187	1,070.00	50	✓ Prograf

➡SA0669 Special Authority for Subsidy			
Initial application only from a relevant specialist. Approvals valid without further renewal unless notified where the patient is an organ transplant recipient.			
Note: Subsidy applies for either primary or rescue therapy.			

‡ 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.

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

BEE VENOM ALLERGY TREATMENT – Special Authority see SA0053 below – Retail pharmacy

Maintenance kit - 6 vials 120 µg freeze dried venom, 6 diluent			
1.8 ml	285.00	1 OP	✓ Albay
Treatment kit - 1 vial 550 µg freeze dried venom, 1 diluent			
9 ml, 3 diluent 1.8 ml	285.00	1 OP	✓ Albay

SA0053 Special Authority for Subsidy

Initial application only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 RAST or skin test positive; and
- 2 Patient has had severe generalised reaction to the sensitising agent.

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

WASP VENOM ALLERGY TREATMENT – Special Authority see SA0053 below – Retail pharmacy

Treatment kit (Paper wasp venom) - 1 vial 550 µg freeze dried			
polister venom, 1 diluent 9 ml, 1 diluent 1.8 ml	285.00	1 OP	✓ Albay
Treatment kit (Yellow jacket venom) - 1 vial 550 µg freeze			
dried vespusula venom, 1 diluent 9 ml, 1 diluent 1.8 ml	285.00	1 OP	✓ Albay

SA0053 Special Authority for Subsidy

Initial application only from a relevant specialist. Approvals valid for 2 years for applications meeting the following criteria:

Both:

- 1 RAST or skin test positive; and
- 2 Patient has had severe generalised reaction to the sensitising agent.

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

Antihistamines

CETIRIZINE HYDROCHLORIDE

* Tab 10 mg	1.59	100	✓ Zetop
*‡ Oral liq 1 mg per ml	3.52	200 ml	✓ Cetirizine - AFT

CHLORPHENIRAMINE MALEATE

*‡ Oral liq 2 mg per 5 ml	8.06	500 ml	✓ Histafen
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DEXTROCHLORPHENIRAMINE MALEATE

* Tab 2 mg	1.01	20	
	(4.93)		Polaramine
	2.02	40	
	(7.99)		Polaramine
*‡ Oral liq 2 mg per 5 ml	1.77	100 ml	
	(10.29)		Polaramine

FEXOFENADINE HYDROCHLORIDE

* Tab 60 mg	4.34	20	
	(11.53)		Telfast
* Tab 120 mg	4.74	10	
	(11.53)		Telfast
	14.22	30	
	(29.81)		Telfast

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
LORATADINE				
* Tab 10 mg	2.09	100	✓	Loraclear Hayfever Relief
* Oral liq 1 mg per ml	3.10	100 ml	✓	Lorapaed
PROMETHAZINE HYDROCHLORIDE				
* Tab 10 mg	1.99	50	✓	Allersoothe
* Tab 25 mg	2.99	50	✓	Allersoothe
*† Oral liq 5 mg per 5 ml	3.10	100 ml	✓	Promethazine Winthrop Elixir
* Inj 25 mg per ml, 2 ml – Up to 5 inj available on a PSO	11.00	5	✓	Mayne
TRIMEPAZINE TARTRATE				
† Oral liq 30 mg per 5 ml	2.79 (8.06)	100 ml OP		Vallergan Forte

Inhaled Corticosteroids

BECLOMETHASONE DIPROPIONATE				
Aerosol inhaler, 100 µg per dose CFC-free	12.50	200 dose OP	✓	Beclazone 100
Aerosol inhaler, 250 µg per dose CFC-free	22.67	200 dose OP	✓	Beclazone 250
Aerosol inhaler, 50 µg per dose CFC-free	8.54	200 dose OP	✓	Beclazone 50
BUDESONIDE				
Powder for inhalation, 100 µg per dose	17.00	200 dose OP	✓	Pulmicort Turbuhaler
Powder for inhalation, 200 µg per dose	15.20 19.00	200 dose OP	✓	Budenocort
			✓	Pulmicort Turbuhaler
Powder for inhalation, 400 µg per dose	25.60 32.00	200 dose OP	✓	Budenocort
			✓	Pulmicort Turbuhaler
FLUTICASONE				
Aerosol inhaler, 50 µg per dose CFC-free	7.50	120 dose OP	✓	Flixotide
Powder for inhalation, 50 µg per dose	7.50	60 dose OP	✓	Flixotide Accuhaler
Powder for inhalation, 100 µg per dose	7.50	60 dose OP	✓	Flixotide Accuhaler
Aerosol inhaler, 125 µg per dose CFC-free	13.60	120 dose OP	✓	Flixotide
Aerosol inhaler, 250 µg per dose CFC-free	27.20	120 dose OP	✓	Flixotide
Powder for inhalation, 250 µg per dose	13.60	60 dose OP	✓	Flixotide Accuhaler

Inhaled Long-acting Beta-adrenoceptor Agonists

Prescribing Guideline for Inhaled Long-Acting Beta-Adrenoceptor Agonists

The addition of inhaled long-acting beta-adrenoceptor agonists (LABAs) to inhaled corticosteroids is recommended:

- For younger children (aged under 12 years) where asthma is poorly controlled despite using inhaled corticosteroids for at least three months at total daily doses of 200 µg beclomethasone or budesonide (or 100 µg fluticasone).
- For adults and older children (aged 12 years and over) where asthma is poorly controlled despite using inhaled corticosteroids for at least three months at total daily doses of 400 µg beclomethasone or budesonide (or 200 µg fluticasone).

Note:

Further information on the place of inhaled corticosteroids and inhaled LABAs in the management of asthma can be found in the New Zealand guidelines for asthma in adults (www.nzgg.org.nz) and in the New Zealand guidelines for asthma in children aged 1-15 (www.paediatrics.org.nz).

† 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.

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
EFORMOTEROL FUMARATE – See prescribing guideline on the preceding page				
Powder for inhalation, 6 µg per dose, breath activated	10.32 (16.90)	60 dose OP		Oxis Turbuhaler
Powder for inhalation, 12 µg per dose, and monodose device	20.64 (35.80)	60 dose		Foradil
SALMETEROL – See prescribing guideline on the preceding page				
Aerosol inhaler CFC-free, 25 µg per dose	26.46	120 dose OP	✓	Serevent
Powder for inhalation, 50 µg per dose, breath activated	26.46	60 dose OP	✓	Serevent Accuhaler

Inhaled Corticosteroids with Long-Acting Beta-Adrenoceptor Agonists

►SA1179 Special Authority for Subsidy

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

Either:

- All of the following:
 - Patient is a child under the age of 12; and
 - Has been treated with inhaled corticosteroids of at least 400 µg per day beclomethasone or budesonide, or 200 µg per day fluticasone; and
 - The prescriber considers that the patient would receive additional clinical benefit from switching to a combination product; or
- All of the following:
 - Patient is over the age of 12; and
 - Has been treated with inhaled corticosteroids of at least 800 µg per day beclomethasone or budesonide, or 500 µg per day fluticasone; and
 - The prescriber considers that the patient would receive additional clinical benefit from switching to a combination product.

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

BUDESONIDE WITH EFORMOTEROL – Special Authority see SA1179 above – Retail pharmacy

Aerosol inhaler 100 µg with eformoterol fumarate 6 µg	26.49	120 dose OP	✓	Vannair
Powder for inhalation 100 µg with eformoterol fumarate 6 µg	55.00	120 dose OP	✓	Symbicort Turbuhaler 100/6
Aerosol inhaler 200 µg with eformoterol fumarate 6 µg	31.25	120 dose OP	✓	Vannair
Powder for inhalation 200 µg with eformoterol fumarate 6 µg	60.00	120 dose OP	✓	Symbicort Turbuhaler 200/6
Powder for inhalation 400 µg with eformoterol fumarate 12 µg – No more than 2 dose per day	60.00	60 dose OP	✓	Symbicort Turbuhaler 400/12

FLUTICASONE WITH SALMETEROL – Special Authority see SA1179 above – Retail pharmacy

Aerosol inhaler 50 µg with salmeterol 25 µg	37.48	120 dose OP	✓	Seretide
Aerosol inhaler 125 µg with salmeterol 25 µg	49.69	120 dose OP	✓	Seretide
Powder for inhalation 100 µg with salmeterol 50 µg – No more than 2 dose per day	37.48	60 dose OP	✓	Seretide Accuhaler
Powder for inhalation 250 µg with salmeterol 50 µg – No more than 2 dose per day	49.69	60 dose OP	✓	Seretide Accuhaler

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

SALBUTAMOL

‡ Oral liq 2 mg per 5 ml	1.20	90 ml	✓	Broncolin S29
	1.99	150 ml	✓	Salapin
			✓	Ventolin
Infusion 1 mg per ml, 5 ml	118.38	10		Ventolin
	(130.21)			
Inj 500 µg per ml, 1 ml – Up to 5 inj available on a PSO	12.90	5	✓	Ventolin

Inhaled Beta-Adrenoceptor Agonists

SALBUTAMOL

Aerosol inhaler, 100 µg per dose CFC free – Up to 1000 dose available on a PSO	3.80	200 dose OP	✓	Respigen
	(6.00)		✓	Salamol
				Ventolin
Nebuliser soln, 1 mg per ml, 2.5 ml – Up to 30 neb available on a PSO	3.25	20	✓	Asthalin
Nebuliser soln, 2 mg per ml, 2.5 ml – Up to 30 neb available on a PSO	3.44	20	✓	Asthalin

TERBUTALINE SULPHATE

Powder for inhalation, 250 µg per dose, breath activated	22.00	200 dose OP	✓	Bricanyl Turbuhaler
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Inhaled Anticholinergic Agents

IPRATROPIUM BROMIDE

Aerosol inhaler, 20 µg per dose CFC-free	16.20	200 dose OP	✓	Atrovent
Nebuliser soln, 250 µg per ml, 1 ml – Up to 40 neb available on a PSO	3.79	20	✓	Univent
Nebuliser soln, 250 µg per ml, 2 ml – Up to 40 neb available on a PSO	4.06	20	✓	Univent

TIOTROPIUM BROMIDE – Special Authority see SA1193 below – Retail pharmacy

Powder for inhalation, 18 µg per dose	70.00	30 dose	✓	Spiriva
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►SA1193 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:

- To be used for the long-term maintenance treatment of bronchospasm and dyspnoea associated with COPD; and
- In addition to standard treatment, the patient has trialed a short acting bronchodilator of at least 40 µg ipratropium q.i.d for one month; and
- Either:

The patient's breathlessness according to the Medical Research Council (UK) dyspnoea scale is:

 - Grade 4 (stops for breath after walking about 100 meters or after a few minutes on the level); or
 - Grade 5 (too breathless to leave the house, or breathless when dressing or undressing); and

Applicant must state recent measurement of:
- All of the following:
 - Actual FEV₁ (litres); and
 - Predicted FEV₁ (litres); and

continued...

‡ safety cap

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

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

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

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:

All of the following:

1 Patient is compliant with the medication; and

2 Patient has experienced improved COPD symptom control (prescriber determined); and

Applicant must state recent measurement of:

3 All of the following:

3.1 Actual FEV₁ (litres); and

3.2 Predicted FEV₁ (litres); and

3.3 Actual FEV₁ as a % of predicted.

Inhaled Beta-Adrenoceptor Agonists with Anticholinergic Agents

SALBUTAMOL WITH IPRATROPIUM BROMIDE

Aerosol inhaler, 100 µg with ipratropium bromide, 20 µg per

dose CFC-free 12.19 200 dose OP ✓ Duolin HFA

Nebuliser soln, 2.5 mg with ipratropium bromide 0.5 mg per

vial, 2.5 ml – Up to 20 neb available on a PSO 3.75 20 ✓ Duolin

Leukotriene Receptor Antagonists

MONTELUKAST – Special Authority see SA1227 below – Retail pharmacy

Prescribing Guideline: Clinical evidence indicates that the effectiveness of montelukast is strongest when montelukast is used in short treatment courses.

Tab 4 mg 18.48 28 ✓ Singulair

Tab 5 mg 18.48 28 ✓ Singulair

Tab 10 mg 18.48 28 ✓ Singulair

SA1227 Special Authority for Subsidy

Initial application — (Pre-school wheeze) from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:

1 To be used for the treatment of intermittent severe wheezing (possibly viral) in children under 5 years; and

2 The patient has trialled inhaled corticosteroids at a dose of up to 400 µg per day beclomethasone or budesonide, or 200 µg per day fluticasone for at least one month; and

3 The patient continues to have at least three severe exacerbations at least one of which required hospitalisation (defined as in-patient stay or prolonged Emergency Department treatment) in the past 12 months.

Renewal — (Pre-school wheeze) from any relevant practitioner. Approvals valid for 1 year 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:

Both:

1 Patient is being treated with maximal asthma therapy, including inhaled corticosteroids and long-acting beta-adrenoceptor agonists; and

2 Patient continues to experience frequent episodes of exercise-induced bronchoconstriction.

continued...

continued...

All of the following:

- ## Mast Cell Stabilisers

NEDOCROMIL

Aerosol inhaler, 2 mg per dose CFC-free	28.07	112 dose OP	✓ Tilade
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SODIUM CROMOGLYCAT

Powder for inhalation, 20 mg per dose	17.94	50 dose	✓ Intal Spincaps
Aerosol inhaler, 5 mg per dose CFC-free	28.07	112 dose OP	✓ Intal Forte CFC Free
			✓ Vicrom

(Vicrom Aerosol inhaler, 5 mg per dose CFC-free to be delisted 1 March 2013)

Methylxanthines

AMINOPHYLLINE

* Inj 25 mg per ml, 10 ml – Up to 5 inj available on a PSO	53.75	5	✓ DBL Aminophylline
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THEOPHYLLINE

* Tab long-acting 250 mg	21.51	100	✓ Nuelin-SR
*† Oral liq 80 mg per 15 ml	15.50	500 ml	✓ Nuelin

Mucolytics

DORNASE ALFA – Special Authority see SA0611 below – Retail pharmacy

Nebuliser soln, 2.5 mg per 2.5 ml ampoule	250.00	6	✓ Pulmozyme
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SA0611 Special Authority for Subsidy

Special Authority approved by the Cystic Fibrosis Advisory Panel

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

The Co-ordinator, Cystic Fibrosis Advisory Panel Phone: (04) 460 4990

PHARMAC, PO Box 10 254

Wellington

Phone: (04) 460 4990

Facsimile: (04) 916 7571

Email: CFPanel@pharmac.govt.nz

Prescriptions for patients approved for treatment must be written by respiratory physicians or paediatricians who have experience and expertise in treating cystic fibrosis.

SODIUM CHLORIDE

Not funded for use as a nasal drop.

Soln 7%	23.50	90 ml OP	✓ Biomed
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RESPIRATORY SYSTEM AND ALLERGIES

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Nasal Preparations				
Allergy Prophylactics				
BECLOMETHASONE DIPROPIONATE				
Metered aqueous nasal spray, 50 µg per dose	2.35 (4.85)	200 dose OP		Alanase
Metered aqueous nasal spray, 100 µg per dose	2.46 (5.75)	200 dose OP		Alanase
BUDESONIDE				
Metered aqueous nasal spray, 50 µg per dose	2.35 (4.85)	200 dose OP		Butacort Aqueous
Metered aqueous nasal spray, 100 µg per dose	2.61 (5.75)	200 dose OP		Butacort Aqueous
FLUTICASONE PROPIONATE				
Metered aqueous nasal spray, 50 µg per dose	13.34	120 dose OP	✓	<u>Flixonase Hayfever & Allergy</u>
IPRATROPIUM BROMIDE				
Aqueous nasal spray, 0.03%	4.03	15 ml OP	✓	<u>Univent</u>
SODIUM CROMOGLYCATE				
Nasal spray, 4%	15.85	22 ml OP	✓	<u>Rex</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				
Size 2	2.99	1	✓	<u>EZ-fit Paediatric Mask</u>
PEAK FLOW METER				
a) Up to 10 dev available on a PSO				
b) Only on a PSO				
Low range	11.44	1	✓	<u>Breath-Alert</u>
Normal range	11.44	1	✓	<u>Breath-Alert</u>
SPACER DEVICE				
a) Up to 20 dev available on a PSO				
b) Only on a PSO				
230 ml (single patient)	4.72	1	✓	<u>Space Chamber Plus</u>
800 ml	8.50	1	✓	<u>Volumatic</u>
SPACER DEVICE AUTOCLAVABLE				
a) Up to 5 dev available on a PSO				
b) Only on a PSO				
230 ml (autoclavable) – Subsidy by endorsement	11.60	1	✓	<u>Space Chamber</u>
Available where the prescriber requires a spacer device that is capable of sterilisation in an autoclave and the PSO is endorsed accordingly.				

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

Respiratory Stimulants

CAFFEINE CITRATE

Oral liq 20 mg per ml (10 mg base per ml)	14.85	25 ml OP	✓ Biomed
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‡ safety cap

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

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

SENSORY ORGANS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Ear Preparations				
ACETIC ACID WITH 1, 2- PROpanEDIOL DIACETATE AND BENZETHONIUM				
For Vosol ear drops with hydrocortisone powder refer, page 190				
Ear drops 2% with 1, 2-Propanediol diacetate 3% and benzethonium chloride 0.02%	6.97	35 ml OP	✓	Vosol
CHLORAMPHENICOL				
Ear drops 0.5%	2.20	5 ml OP	✓	Chloromycetin
FLUMETASONE PIVALATE				
Ear drops 0.02% with clioquinol 1%	4.46	7.5 ml OP	✓	Locacorten-Viaform ED's
			✓	Locorten-Vioform
TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCIN AND NYSTATIN				
Ear drops 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 µg per g	5.16	7.5 ml OP	✓	Kenacomb

Ear/Eye Preparations

DEXAMETHASONE WITH FRAMYCETIN AND GRAMICIDIN				
Ear/Eye drops 500 µg with framycetin sulphate 5 mg and gramicidin 50 µg per ml	4.50 (9.27)	8 ml OP		Sofradex
FRAMYCETIN SULPHATE				
Ear/Eye drops 0.5%	4.13 (8.65)	8 ml OP		Soframycin

Eye Preparations

Eye preparations are only funded for use in the eye. The exception is pilocarpine eye drops 1%, 2% and 4% which are subsidised for oral use pursuant to the Standard Formulae.

Anti-Infective Preparations

ACICLOVIR				
* Eye oint 3%	37.53	4.5 g OP	✓	Zovirax
CHLORAMPHENICOL				
Eye oint 1%	2.76	4 g OP	✓	Chlorsig
Eye drops 0.5%	1.20	10 ml OP	✓	Chlorafast
CIPROFLOXACIN				
Eye Drops 0.3%	12.43	5 ml OP	✓	Ciloxan
For treatment of bacterial keratitis or severe bacterial conjunctivitis resistant to chloramphenicol.				
FUSIDIC ACID				
Eye drops 1%	4.50	5 g OP	✓	Fucithalmic
GENTAMICIN SULPHATE				
Eye drops 0.3%	11.40	5 ml OP	✓	Genoptic
PROPAMIDINE ISETHIONATE				
* Eye drops 0.1%	2.97 (7.99)	10 ml OP		Brolene

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
TOBRAMYCIN				
Eye oint 0.3%	10.45	3.5 g OP	✓	<u>Tobrex</u>
Eye drops 0.3%	11.48	5 ml OP	✓	<u>Tobrex</u>

Corticosteroids and Other Anti-Inflammatory Preparations

DEXAMETHASONE				
* Eye oint 0.1%	5.86	3.5 g OP	✓	<u>Maxidex</u>
* Eye drops 0.1%	4.50	5 ml OP	✓	<u>Maxidex</u>
DEXAMETHASONE WITH NEOMYCIN AND POLYMYXIN B SULPHATE				
* Eye oint 0.1% with neomycin sulphate 0.35% and polymyxin B sulphate 6,000 u per g	5.39	3.5 g OP	✓	<u>Maxitrol</u>
* Eye drops 0.1% with neomycin sulphate 0.35% and polymy- xin B sulphate 6,000 u per ml	4.50	5 ml OP	✓	<u>Maxitrol</u>
DICLOFENAC SODIUM				
* Eye drops 1 mg per ml	13.80	5 ml OP	✓	<u>Voltaren Ophtha</u>
FLUOROMETHOLONE				
* Eye drops 0.1%	3.80	5 ml OP	✓	<u>Flucon</u>
	4.05		✓	<u>FML</u>
LEVOCABASTINE				
Eye drops 0.5 mg per ml	8.71 (10.34)	4 ml OP		Livostin
LODOXAMIDE TROMETAMOL				
Eye drops 0.1%	8.71	10 ml OP	✓	<u>Lomide</u>
PREDNISOLONE ACETATE				
* Eye drops 0.12%	4.50	5 ml OP	✓	<u>Pred Mild</u>
* Eye drops 1%	4.50	5 ml OP	✓	<u>Pred Forte</u>
SODIUM CROMOGLYCATE				
Eye drops 2%	1.18	5 ml OP	✓	<u>Rexacrom</u>

Glaucoma Preparations - Beta Blockers

BETAXOLOL HYDROCHLORIDE				
* Eye drops 0.25%	11.80	5 ml OP	✓	<u>Betoptic S</u>
* Eye drops 0.5%	7.50	5 ml OP	✓	<u>Betoptic</u>
LEVOBUNOLOL				
* Eye drops 0.25%	7.00	5 ml OP	✓	<u>Betagan</u>
* Eye drops 0.5%	7.00	5 ml OP	✓	<u>Betagan</u>
TIMOLOL MALEATE				
* Eye drops 0.25%	2.08	5 ml OP	✓	<u>Arrow-Timolol</u>
* Eye drops 0.25%, gel forming	3.30	2.5 ml OP	✓	<u>Timoptol XE</u>
* Eye drops 0.5%	2.08	5 ml OP	✓	<u>Arrow-Timolol</u>
* Eye drops 0.5%, gel forming	3.78	2.5 ml OP	✓	<u>Timoptol XE</u>

Glaucoma Preparations - Carbonic Anhydrase Inhibitors

ACETAZOLAMIDE				
* Tab 250 mg – For acetazolamide oral liquid formulation refer, page 187	17.03	100	✓	<u>Diamox</u>

‡ safety cap

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

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

SENSORY ORGANS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
BRINZOLAMIDE				
* Eye Drops 1%	9.77	5 ml OP	✓	Azopt
DORZOLAMIDE HYDROCHLORIDE				
* Eye drops 2%	9.77 (13.95)	5 ml OP		Trusopt
DORZOLAMIDE HYDROCHLORIDE WITH TIMOLOL MALEATE				
* Eye drops 2% with timolol maleate 0.5%	15.50	5 ml OP	✓	Cosopt

Glaucoma Preparations - Prostaglandin Analogues

BIMATOPROST – Retail pharmacy-Specialist				
* Eye drops 0.03%	18.50	3 ml OP	✓	Lumigan
LATANOPROST – Retail pharmacy-Specialist				
* Eye drops 50 µg per ml, 2.5 ml	1.99	2.5 ml OP	✓	Hysite
TRAVOPROST – Retail pharmacy-Specialist				
* Eye drops 0.004%	19.50	2.5 ml OP	✓	Travatan

Glaucoma Preparations - Other

BRIMONIDINE TARTRATE				
* Eye Drops 0.2% – Brand switch fee payable (Pharmacode 2425823) - see page 185 for details	6.45	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
PILOCARPINE				
* Eye drops 1%	4.26	15 ml OP	✓	Isopto Carpine
* Eye drops 2%	5.35	15 ml OP	✓	Isopto Carpine
* Eye drops 4%	7.99	15 ml OP	✓	Isopto Carpine
* Eye drops 2% single dose – Special Authority see SA0895 below – Retail pharmacy	31.95 (32.72)	20 dose		Minims

►SA0895 Special Authority for Subsidy

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

- 1 Patient has to use an unpreserved solution due to an allergy to the preservative; or
- 2 Patient wears soft contact lenses.

Note: Minims for a general practice are considered to be “tools of trade” and are not approved as special authority items.

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

Mydriatics and Cycloplegics

ATROPINE SULPHATE				
* Eye drops 1%	17.36	15 ml OP	✓	Atropt
CYCLOPENTOLATE HYDROCHLORIDE				
* Eye drops 1%	8.76	15 ml OP	✓	Cyclogyl
HOMATROPINE HYDROBROMIDE				
* Eye drops 2%	7.18	15 ml OP	✓	Isopto Homatropine

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
TROPICAMIDE				
* Eye drops 0.5%	7.15	15 ml OP	✓	<u>Mydracyl</u>
* Eye drops 1%	8.66	15 ml OP	✓	<u>Mydracyl</u>

Preparations for Tear Deficiency

For acetylcysteine eye drops refer, page 190

HYPROMELLOSE				
* Eye drops 0.3%	2.62	15 ml OP	✓	<u>Poly-Tears</u>
* Eye drops 0.5%	2.00	15 ml OP		
	(3.92)			Methopt

POLYVINYL ALCOHOL				
* Eye drops 1.4%	2.68	15 ml OP	✓	<u>Vistil</u>
* Eye drops 3%	3.75	15 ml OP	✓	<u>Vistil Forte</u>

TYLOXAPOL				
* Eye drops 0.25%	8.63	15 ml OP	✓	<u>Enuclene</u>
<i>(Enuclene Eye drops 0.25% to be delisted 1 May 2013)</i>				

Other Eye Preparations

NAPHAZOLINE HYDROCHLORIDE				
* Eye drops 0.1%	4.15	15 ml OP	✓	<u>Naphcon Forte</u>
PARAFFIN LIQUID WITH SOFT WHITE PARAFFIN				
* Eye oint with soft white paraffin	3.63	3.5 g OP	✓	<u>Lacri-Lube</u>
PARAFFIN LIQUID WITH WOOL FAT LIQUID				
* Eye oint 3% with wool fat liq 3%	3.63	3.5 g OP	✓	<u>Poly-Visc</u>
PHENYLEPHRINE HYDROCHLORIDE				
* Eye drops 0.12%	4.47	15 ml OP	✓	<u>Prefrin</u>
<i>(Prefrin Eye drops 0.12% to be delisted 1 March 2013)</i>				

‡ 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.

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

Various

May only be claimed once per patient.

PHARMACY SERVICES

* Brand switch fee	4.33	1 fee	<ul style="list-style-type: none"> ✓ BSF Arrow-Brimonidine ✓ BSF Ava 30 ED ✓ BSF Candestar ✓ BSF CareSens II ✓ BSF CareSens N ✓ BSF CareSens N POP ✓ BSF Metoprolol - AFT CR
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- a) The Pharmacode for BSF CareSens N is 2423138 - see also page 31
- b) The Pharmacode for BSF CareSens II is 2423146 - see also page 31
- c) The Pharmacode for BSF CareSens N POP is 2423154 - see also page 31
- d) The Pharmacode for BSF Ava 30 ED is 2405865 - see also page 75
- e) The Pharmacode for BSF Metoprolol - AFT CR is 2405873 - see also page 55
- f) The Pharmacode for BSF Arrow-Brimonidine is 2425823 - see also page 183
- g) The Pharmacode for BSF Candestar is 2426781 - see also page 53

(BSF Arrow-Brimonidine Brand switch fee to be delisted 1 January 2013)

(BSF Ava 30 ED Brand switch fee to be delisted 1 March 2013)

(BSF Candestar Brand switch fee to be delisted 1 February 2013)

(BSF CareSens II Brand switch fee to be delisted 1 March 2013)

(BSF CareSens N Brand switch fee to be delisted 1 March 2013)

(BSF CareSens N POP Brand switch fee to be delisted 1 March 2013)

(BSF Metoprolol - AFT CR Brand switch fee to be delisted 1 December 2012)

INTRODUCTION

The following extemporaneously compounded products are eligible for subsidy:

- The “Standard Formulae”.
- Oral liquid mixtures for patients unable to swallow subsidised solid dose oral formulations.
- The preparation of syringe drivers when prescribed by a general practitioner.
- Dermatological preparations
 - a) One or more subsidised dermatological galenical(s) in a subsidised dermatological base.
 - b) Dilution of proprietary Topical Corticosteroid-Plain preparations with a dermatological base (Retail pharmacy-specialist).
 - 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 BP - up to 10%
- Hydrocortisone powder - up to 5%
- Menthol crystals
- Salicylic acid powder
- Sulphur precipitated powder

Standard formulae: Standard formulae are a list of formulae for ECPs that are subsidised. Their ingredients are listed under the appropriate therapeutic heading in Section B of the Pharmaceutical Schedule and also in Section C.

Explanatory notes

Oral liquid mixtures

Oral liquid mixtures are subsidised for patients unable to swallow subsidised solid oral dose forms where no suitable alternative proprietary formulation is subsidised. Suitable alternatives include dispersible and sublingual formulations, oral liquid formulations or rectal formulations. Before extemporaneously compounding an oral liquid mixture, other alternatives such as dispersing the solid dose form (if appropriate) or crushing the solid dose form in jam, honey or soft foods such as yoghurt should be explored.

The Emixt website www.pharminfotech.co.nz has evidence-based formulations which are intended to standardise compounded oral liquids within New Zealand.

Pharmaceuticals with standardised formula for compounding in Ora products

Acetazolamide 25 mg/ml	Flecainide 20 mg/ml	Rifabutin 20 mg/ml
Allopurinol 20 mg/ml	Gabapentin 100 mg/ml	Sildenafil 2 mg/ml
Amlodipine 1 mg/ml	Gabapentin (Neurontin) 100 mg/ml	Sotalol 15 mg/ml
Azathioprine 50 mg/ml	Hydrocortisone 1 mg/ml	Sulphasalazine 100 mg/ml
Baclofen 10 mg/ml	Labetolol 10 mg/ml	Tacrolimus 1 mg/ml
Carvedilol 1 mg/ml	Levetiracetam 100 mg/ml	Terbinafine 25 mg/ml
Clopidogrel 5 mg/ml	Levodopa with carbidopa (5 mg levodopa + 1.25 mg carbidopa)/ml	Ursodeoxycholic acid 50 mg/ml
Diltiazem hydrochloride 12 mg/ml	Metoprolol tartrate 10 mg/ml	Valganciclovir 60 mg/ml*
Dipyridamole 10 mg/ml	Nitrofurantoin 10 mg/ml	Verapamil hydrochloride 50 mg/ml
Domperidone 1 mg/ml	Pyrazinamide 100 mg/ml	
Enalapril 1 mg/ml		

*Note this is a DCS formulation

PHARMAC endorses the recommendations of the Emixt website and encourages New Zealand pharmacists to use these formulations when compounding is appropriate. The Emixt website also provides stability and expiry data for compounded products. For the majority of products compounded with Ora-Blend, Ora-Blend SF, Ora-Plus, Ora-Sweet or Ora-Sweet SF a four week expiry is appropriate.

Please note that no oral liquid mixture will be eligible for Subsidy unless all the requirements of Section B and C of the Schedule applicable to that pharmaceutical are met.

Some community pharmacies may not have appropriate equipment to compound all of the listed products, please use appropriate clinical judgement.

Subsidy for extemporaneously compounded oral liquid mixtures is based on:

Solid dose form	qs
Preservative	qs
Suspending agent	qs
Water	to 100%

or

Solid dose form	qs
Ora-Blend, Ora-Blend SF, Ora-Plus, Ora-Sweet and/or Ora-Sweet SF	to 100%

Prescribers may prescribe or pharmacists may add extra non-subsidised ingredients such as flavouring and colouring agents, but these extra ingredients will not be reimbursed. The subsidised ingredients in the formula will be reimbursed and a compounding fee paid.

The majority of extemporaneously compounded oral liquid mixtures should contain a preservative and suspending agent.

- Ora-Blend, Ora-Blend SF, Ora-Plus, Ora-Sweet and Ora-Sweet SF when used correctly are an appropriate preservative and suspending agent.
- Methylcellulose 3% is considered a suitable suspending agent and compound hydroxybenzoate solution or methyl hydroxybenzoate 10% solution are considered to be suitable preservatives. Usually 1 ml of these preservative solutions is added to 100 ml of oral liquid mixture.

Some solid oral dose forms are not appropriate for compounding into oral liquid mixtures and should therefore not be used/considered for extemporaneously compounded oral liquid mixtures. This includes long-acting solid dose formulations, enteric coated tablets or capsules, sugar coated tablets, hard gelatin capsules and chemotherapeutic agents.

The following practices will not be subsidised:

- Where a Standard Formula exists in the Pharmaceutical Schedule for a solid dose form, compounding the solid dose form in Ora-Blend, Ora-Blend SF, Ora-Plus, Ora-Sweet and/or Ora-Sweet SF.
- Mixing one or more proprietary oral liquids (eg an antihistamine with pholcodine linctus).
- Extemporaneously compounding an oral liquid with more than one solid dose chemical.
- Mixing more than one extemporaneously compounded oral liquid mixture.
- Mixing one or more extemporaneously compounded oral liquid mixtures with one or more proprietary oral liquids.
- The addition of a chemical/powder/agent/solution to a proprietary oral liquid or extemporaneously compounded oral mixture.

Standard formulae

A list of standard formulae is contained in this section. All ingredients associated with a standard formula will be subsidised and an appropriate compounding fee paid.

Prescribers may prescribe or pharmacists may add extra non-subsidised ingredients, but these extra ingredients will not be reimbursed. The subsidised ingredients in the formula will be reimbursed and a compounding fee paid.

Dermatological Preparations

Proprietary topical corticosteroid preparations may be diluted with a dermatological base (see page 186) from the Barrier Creams and Emollients section of the Pharmaceutical Schedule (Retail pharmacy-Specialist). Dilution of proprietary topical corticosteroid preparations should only be prescribed for withdrawing patients off higher strength proprietary topical corticosteroid products where there is no suitable proprietary product of a lower strength available or an extemporaneously compounded product with up to 5% hydrocortisone is not appropriate. (In general proprietary topical corticosteroid preparations should not be diluted because dilution effects can be unpredictable and may not be linear, and usually there is no stability data available for diluted products).

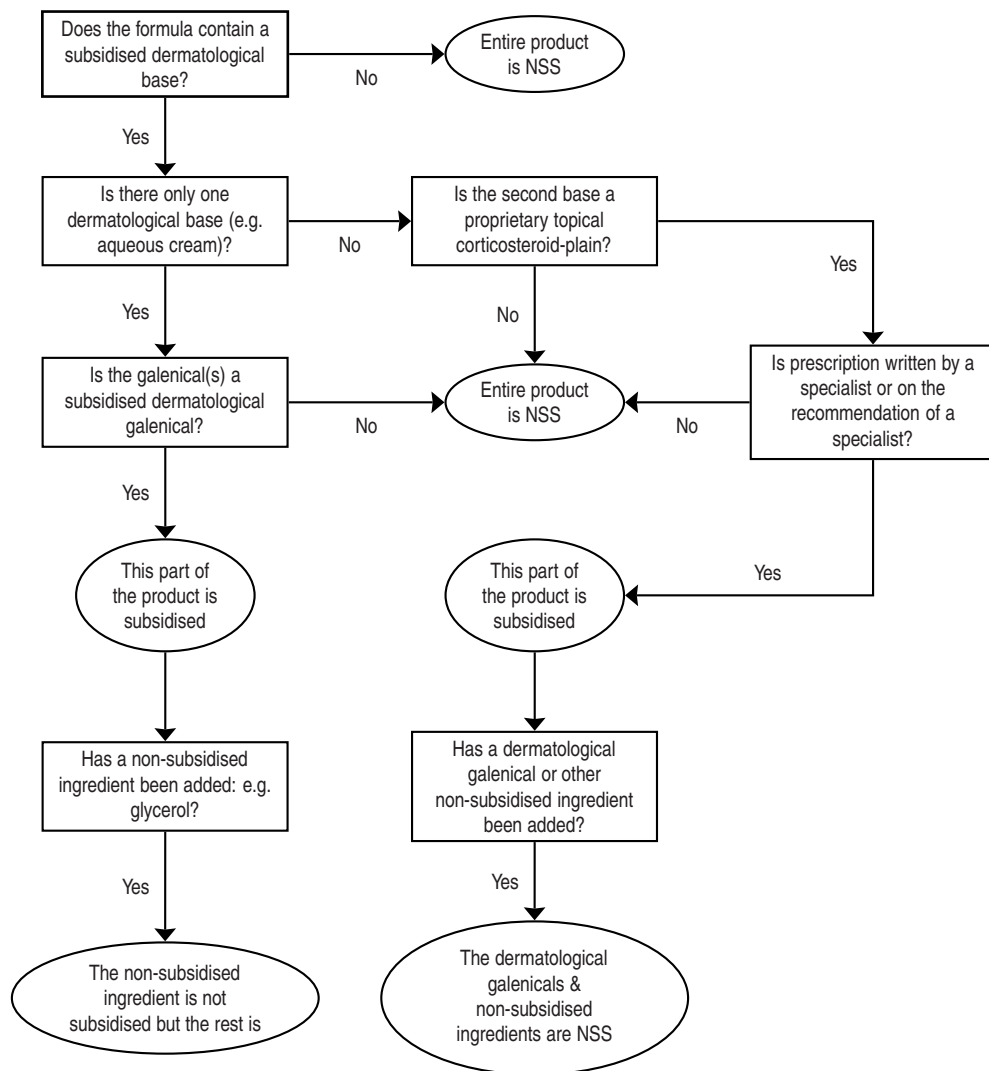
One or more dermatological galenicals may be added to a dermatological base (including proprietary topical corticosteroid preparations). Prescribers may prescribe or pharmacists may add extra non-subsidised ingredients, but these extra ingredients will not be reimbursed. The subsidised ingredients in the formula will be reimbursed and a compounding fee paid.

The addition of dermatological galenicals to diluted proprietary Topical Corticosteroids-Plain will not be subsidised.

The flow diagram on the next page may assist you in deciding whether or not a dermatological ECP is subsidised.

Dermatological ECPs

Is it subsidised?



Standard Formulae

ACETYLCYSTEINE EYE DROPS

Acetylcysteine inj 200 mg per ml, 10 ml	qs
Suitable eye drop base	qs

ASPIRIN AND CHLOROFORM APPLICATION

Aspirin Soluble tabs 300 mg	12 tabs
Chloroform	to 100 ml

CODEINE LINCTUS PAEDIATRIC (3 mg per 5 ml)

Codeine phosphate	60 mg
Glycerol	40 ml
Preservative	qs
Water	to 100 ml

CODEINE LINCTUS DIABETIC (15 mg per 5 ml)

Codeine phosphate	300 mg
Glycerol	40 ml
Preservative	qs
Water	to 100 ml

FOLINIC MOUTHWASH

Calcium folinate 15 mg tab	1 tab
Preservative	qs
Water	to 500 ml

(Preservative should be used if quantity supplied is for more than 5 days. Maximum 500 ml per prescription.)

MAGNESIUM HYDROXIDE MIXTURE

Magnesium hydroxide paste	275 g
Methyl hydroxybenzoate	1.5 g
Water	770 ml

METHADONE MIXTURE

Methadone powder	qs
Glycerol	qs
Water	to 100 ml

METHYL HYDROXYBENZOATE 10% SOLUTION

Methyl hydroxybenzoate	10 g
Propylene glycol	to 100 ml

(Use 1 ml of the 10% solution per 100 ml of oral liquid mixture)

OMEPRAZOLE SUSPENSION

Omeprazole capsules or powder	qs
Sodium bicarbonate powder BP	8.4 g
Water	to 100 ml

PHENOBARBITONE ORAL LIQUID

Phenobarbitone Sodium	1 g
Glycerol BP	70 ml
Water	to 100 ml

PHENOBARBITONE SODIUM PAEDIATRIC ORAL LIQUID (10 mg per ml)

Phenobarbitone Sodium	400 mg
Glycerol BP	4 ml
Water	to 40 ml

PILOCARPINE ORAL LIQUID

Pilocarpine 4% eye drops	qs
Preservative	qs
Water	to 500 ml

(Preservative should be used if quantity supplied is for more than 5 days.)

SALIVA SUBSTITUTE FORMULA

Methylcellulose	5 g
Preservative	qs
Water	to 500 ml

(Preservative should be used if quantity supplied is for more than 5 days. Maximum 500 ml per prescription.)

SODIUM CHLORIDE ORAL LIQUID

Sodium chloride inj 23.4%, 20 ml	qs
Water	qs

(Only funded if prescribed for treatment of hyponatraemia)

VOSOL EAR DROPS

WITH HYDROCORTISONE POWDER 1%

Hydrocortisone powder	1%
Vosol Ear Drops	to 35 ml

EXTEMPORANEOUSLY COMPOUNDED PREPARATIONS AND GALENICALS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Extemporaneously Compounded Preparations and Galenicals				
ACETYLCYSTEINE – Retail pharmacy-Specialist				
Inj 200 mg per ml, 10 ml	178.00	10	✓	<u>Martindale</u>
				<u>Acetylcysteine</u>
Inj 200 mg per ml, 30 ml	219.00	4	✓	<u>Acetadote</u>
BENZOIN				
Tincture compound BP	2.44	50 ml		
	(5.10)			PSM
	24.42	500 ml		
	(38.00)			PSM
CHLOROFORM – Only in combination				
Only in aspirin and chloroform application.				
Chloroform BP	25.50	500 ml	✓	PSM
CODEINE PHOSPHATE – Safety medicine; prescriber may determine dispensing frequency				
Powder – Only in combination	12.62	5 g		
	(25.46)			Douglas
	63.09	25 g		
	(90.09)			Douglas
a) Only in extemporaneously compounded codeine linctus diabetic or codeine linctus paediatric.				
b) ‡ Safety cap for extemporaneously compounded oral liquid preparations.				
COLLODION FLEXIBLE				
Collodion flexible	19.30	100 ml	✓	PSM
COMPOUND HYDROXYBENZOATE – Only in combination				
Only in extemporaneously compounded oral mixtures.				
Soln	34.18	100 ml	✓	David Craig
GLYCERIN WITH SODIUM SACCHARIN – Only in combination				
Only in combination with Ora-Plus.				
Suspension	36.80	473 ml	✓	Ora-Sweet SF
GLYCERIN WITH SUCROSE – Only in combination				
Only in combination with Ora-Plus.				
Suspension	36.80	473 ml	✓	Ora-Sweet
GLYCEROL				
* Liquid – Only in combination	17.86	2,000 ml	✓	<u>healthE</u>
Only in extemporaneously compounded oral liquid preparations.				
MAGNESIUM HYDROXIDE				
Paste	22.61	500 g	✓	PSM
METHADONE HYDROCHLORIDE				
a) Only on a controlled drug form				
b) No patient co-payment payable				
c) Safety medicine; prescriber may determine dispensing frequency				
d) Extemporaneously compounded methadone will only be reimbursed at the rate of the cheapest form available (methadone powder, not methadone tablets).				
Powder	7.84	1 g	✓	AFT
‡ Safety cap for extemporaneously compounded oral liquid preparations.				
METHYL HYDROXYBENZOATE				
Powder	8.00	25 g	✓	PSM
	8.98		✓	Midwest

EXTEMPORANEOUSLY COMPOUNDED PREPARATIONS AND GALENICALS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
METHYLCELLULOSE				
Powder	14.00 (17.72)	100 g	✓	ABM MidWest
Suspension – Only in combination	36.80	473 ml	✓	Ora-Plus
METHYLCELLULOSE WITH GLYCERIN AND SODIUM SACCHARIN – Only in combination				
Suspension	36.80	473 ml	✓	Ora-Blend SF
METHYLCELLULOSE WITH GLYCERIN AND SUCROSE – Only in combination				
Suspension	36.80	473 ml	✓	Ora-Blend
PHENOBARBITONE SODIUM				
Powder – Only in combination	52.50 325.00	10 g 100 g	✓ ✓	MidWest MidWest
a) Only in children up to 12 years				
b) ‡ Safety cap for extemporaneously compounded oral liquid preparations.				
PROPYLENE GLYCOL				
Only in extemporaneously compounded methyl hydroxybenzoate 10% solution.				
Liq	10.50 11.25	500 ml	✓ ✓	PSM Midwest
SODIUM BICARBONATE				
Powder BP – Only in combination	8.95 9.80 (29.50)	500 g	✓	Midwest David Craig
Only in extemporaneously compounded omeprazole and lansoprazole suspension.				
SYRUP (PHARMACEUTICAL GRADE) – Only in combination				
Only in extemporaneously compounded oral liquid preparations.				
Liq	21.75	2,000 ml	✓	Midwest
WATER				
Tap – Only in combination	0.00	1 ml	✓	Tap water

EXPLANATORY NOTES

The list of special foods to which Subsidies apply is contained in this section. The list of available products, guidelines for use, subsidies and charges is reviewed as required. Applications for new listings and changes to subsidies and access criteria will be considered by the special foods sub-committee of PTAC which meets as and when required. In all cases, subsidies are available by Special Authority only. This means that, unless a patient has a valid Special Authority number for their special food requirements, they must pay the full cost of the products themselves.

Eligibility for Special Authority

Special Authorities will be approved for patients meeting conditions specified under the *Conditions and Guidelines* for each product. In some cases there are also limits to how products can be prescribed (for example quantity, use or duration). Only those brands, presentations and flavours of special foods listed in this section are subsidised.

Who can apply for Special Authority?

Initial Applications: Only from a dietitian, relevant specialist or a vocationally registered general practitioner.

Reapplications: Only from a dietitian, relevant specialist or a vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or a vocationally registered general practitioner. Other general practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.

All applications must be made on an official form available from the PHARMAC website www.pharmac.govt.nz. All applications must include specific details as requested on the form relating to the application. Applications must be forwarded to:

Ministry of Health Sector Services
Private Bag 3015
WHANGANUI 4540
Freefax 0800 100 131

Subsidies and manufacturer's surcharges

The Subsidies for some special foods are based on the lowest priced product within each group. Where this is so, or where special foods are otherwise not fully subsidised, a manufacturer's surcharge may be payable by the patient. The manufacturer's surcharge is the difference between the price of the product and the subsidy attached to it and may be subject to mark-ups applied at a pharmacy level. As a result the manufacturer's surcharge may vary. Fully subsidised alternatives are available in most cases (as indicated by a tick in the left hand column). Patients should only have to pay a co-payment on these products.

Where are special foods available from?

Distribution arrangements for special foods vary from region to region. Special foods are available from hospital pharmacies providing an outpatient dispensing service as well as retail pharmacies in the Northern, Midland and Central (including Nelson and Blenheim) regions.

Definitions

Failure to thrive An inability to gain or maintain weight resulting in physiological impairment.
Growth deficiency Where the weight of the child is less than the fifth or possibly third percentile for their age, with evidence of malnutrition

Dietitian Prescribing

Prescriptions from Dietitians will be only valid for subsidy where they are for special foods, as listed in this section, or where they are for the following products:

ASCORBIC ACID

- ✓ Tab 100 mg

CALCIUM CARBONATE

- ✓ Tab eff 1.75 g (1 g elemental)
- ✓ Tab 1.25 g (500 mg elemental)

COMPOUND ELECTROLYTES

- ✓ Powder for soln for oral use 4.4 g

DEXTROSE WITH ELECTROLYTES

- ✓ Soln with electrolytes

FERROUS FUMARATE

- ✓ Tab 200 mg (65 mg elemental)

FERROUS FUMARATE WITH FOLIC ACID

- ✓ Tab 310 mg (100 mg elemental) with folic acid 350 µg

FERROUS SULPHATE

- Tab long-acting 325 mg (105 mg elemental)
- ✓ Oral liq 30 mg per 1 ml (6 mg elemental per 1 ml)

FERROUS SULPHATE WITH FOLIC ACID

- Tab long-acting 325 mg (105 mg elemental) with folic acid 350 µg

FOLIC ACID

- ✓ Tab 0.8 mg

MULTIVITAMINS

- ✓ Powder

PANCREATIC ENZYME

- ✓ Cap EC 10,000 BP u lipase, 9,000 BP u amylase and 210 BP u protease

POTASSIUM BICARBONATE

- ✓ Tab eff 315 mg with sodium acid phosphate 1.937 g and sodium bicarbonate 350 mg

POTASSIUM CHLORIDE

- Tab eff 548 mg (14 m eq) with chloride 285 mg (8 m eq)
- ✓ Tab long-acting 600 mg

POTASSIUM IODATE

- ✓ Tab 256 µg (150 µg elemental iodine)

PYRIDOXINE HYDROCHLORIDE

- ✓ Tab 25 mg
- ✓ Tab 50 mg

SODIUM CHLORIDE

- ✓ Inj 23.4%, 20 ml

SODIUM FLUORIDE

- ✓ Tab 1.1 mg (0.5 mg elemental)

THIAMINE HYDROCHLORIDE

- ✓ Tab 50 mg

VITAMIN A WITH VITAMINS D AND C

- ✓ Soln 1000 u with Vitamin D 400 u and ascorbic acid 30 mg per 10 drops

VITAMIN B COMPLEX

- ✓ Tab, strong, BPC

VITAMINS

- ✓ Tab (BPC cap strength)
- ✓ Cap (fat soluble vitamins A, D, E, K)

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

Nutrient Modules

Carbohydrate

►SA1090 Special Authority for Subsidy

Initial application — (Cystic fibrosis or renal failure) 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 renal failure or continuous ambulatory peritoneal dialysis (CAPD) patient.

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 failure to thrive; or
- 4 growth deficiency; or
- 5 bronchopulmonary dysplasia; or
- 6 premature and post premature infant; or
- 7 inborn errors of metabolism.

Renewal — (Cystic fibrosis or renal failure) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis or renal failure) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

CARBOHYDRATE SUPPLEMENT – Special Authority see SA1090 above – Hospital pharmacy [HP3]

Powder	5.29	400 g OP	✓ Polycal
	1.30	368 g OP	
	(12.00)		Moducal

Carbohydrate And Fat

►SA1091 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 aged four years or under; and
- 2 cystic fibrosis.

Initial application — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

continued...

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

continued...

- 1 infant aged four years or under; and
- 2 Any of the following:
 - 2.1 cancer in children; or
 - 2.2 failure to thrive; or
 - 2.3 growth deficiency; or
 - 2.4 bronchopulmonary dysplasia; or
 - 2.5 premature and post premature infants.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner.

Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

CARBOHYDRATE AND FAT SUPPLEMENT – Special Authority see SA1091 on the preceding page – Hospital pharmacy [HP3]

Powder (neutral)60.31 400 g OP ✓ **Duocal Super**
Soluble Powder

Fat

►SA1092 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 failure to thrive where other high calorie products are inappropriate or inadequate; or
- 2 growth deficiency; or
- 3 bronchopulmonary dysplasia; or
- 4 fat malabsorption; or
- 5 lymphangiectasia; or
- 6 short bowel syndrome; or
- 7 infants with necrotising enterocolitis; or
- 8 biliary atresia.

Renewal — (Inborn errors of metabolism) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

continued...

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

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 SA1092 on the preceding page – Hospital pharmacy [HP3]

Emulsion (neutral)	12.30	200 ml OP	✓ Calogen
	30.75	500 ml OP	✓ Calogen
Emulsion (strawberry)	12.30	200 ml OP	✓ Calogen
Oil	28.73	250 ml OP	✓ Liquigen
	30.00	500 ml OP	✓ MCT oil (Nutricia)

Protein

►SA1093 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:

Either:

- 1 protein losing enteropathy; or
- 2 high protein needs (eg burns).

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 SA1093 above – Hospital pharmacy [HP3]

Powder	7.90	225 g OP	✓ Protifar
	8.95	227 g OP	✓ Resource
			Beneprotein
Powder (vanilla)	12.90	275 g OP	✓ Promod

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.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

CORD ORAL FEED 1.5KCAL/ML – Special Authority see SA1094 above – Hospital pharmacy [HP3]

Liquid	1.66	237 ml OP	✓ Pulmocare
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Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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Diabetic Products

▶▶SA1095 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient is a type I or and II diabetic who is suffering weight loss and malnutrition that requires nutritional support.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

DIABETIC ENTERAL FEED 1KCAL/ML – Special Authority see SA1095 above – Hospital pharmacy [HP3]

Liquid	7.50	1,000 ml OP	✓ Diasion RTH ✓ Glucerna Select RTH
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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

▶▶SA1096 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:

Either:

- 1 Patient has metabolic disorders of fat metabolism; or
- 2 Patient has chylothorax.

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 SA1096 above – Hospital pharmacy [HP3]

Powder	60.48	400 g OP	✓ Monogen
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High Protein Products

▶▶SA1097 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 Anorexia and weight loss; and
- 2 Either:
 - 2.1 decompensating liver disease without encephalopathy; or
 - 2.2 protein losing gastro-enteropathy.

continued...

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

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.

HIGH PROTEIN ORAL FEED 1KCAL/ML – Special Authority see SA1097 on the preceding page – Hospital pharmacy [HP3]

Liquid 1.90 200 ml OP ✓ **Fortimel Regular**

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 is awaiting liver transplant.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL FEED 1KCAL/ML – Special Authority see SA1098 above – Hospital pharmacy [HP3]

Powder 78.97 400 g OP ✓ **Generaid Plus**

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 chronic renal failure.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL/ORAL FEED 1KCAL/ML – Special Authority see SA1099 above – Hospital pharmacy [HP3]

Liquid 54.00 400 g OP ✓ **Kindergen**

Paediatric Products

►SA1224 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 failure to thrive; or

continued...

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
continued...			
2.4 increased nutritional requirements.			
Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:			
Both:			
1 The treatment remains appropriate and the patient is benefiting from treatment; and			
2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.			
PAEDIATRIC ENTERAL FEED 1KCAL/ML – Special Authority see SA1224 on the preceding page – Hospital pharmacy [HP3]			
Liquid	2.68	500 ml OP	✓ Nutrini RTH ✓ PediaSure RTH
PAEDIATRIC ENTERAL FEED WITH FIBRE 1.5KCAL/ML – Special Authority see SA1224 on the preceding page – Hospital pharmacy [HP3]			
Liquid	6.00	500 ml OP	✓ Nutrini Energy Multi Fibre ✓ Nutrini Energy RTH
PAEDIATRIC ORAL FEED – Special Authority see SA1224 on the preceding page – Hospital pharmacy [HP3]			
Powder (vanilla)	20.00	900 g OP	✓ PediaSure
PAEDIATRIC ORAL FEED 1.5KCAL/ML – Special Authority see SA1224 on the preceding page – Hospital pharmacy [HP3]			
Liquid (strawberry)	1.60	200 ml OP	✓ Fortini
Liquid (vanilla)	1.60	200 ml OP	✓ Fortini
PAEDIATRIC ORAL FEED 1KCAL/ML – Special Authority see SA1224 on the preceding page – Hospital pharmacy [HP3]			
Liquid (chocolate)	1.07	200 ml OP	✓ PediaSure
Liquid (strawberry)	1.07	200 ml OP	✓ PediaSure
Liquid (vanilla)	1.07	200 ml OP	✓ PediaSure
	1.27	237 ml OP	✓ PediaSure
PAEDIATRIC ORAL FEED WITH FIBRE 1.5KCAL/ML – Special Authority see SA1224 on the preceding page – Hospital pharmacy [HP3]			
Liquid (chocolate)	1.60	200 ml OP	✓ Fortini Multi Fibre
Liquid (strawberry)	1.60	200 ml OP	✓ Fortini Multi Fibre
Liquid (vanilla)	1.60	200 ml OP	✓ Fortini Multi Fibre

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 renal failure.

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 2 KCAL/ML – Special Authority see SA1101 above – Hospital pharmacy [HP3]

Liquid 6.08 500 ml OP ✓ Nepro RTH

SPECIAL FOODS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
RENAL ORAL FEED 2KCAL/ML – Special Authority see SA1101 on the preceding page – Hospital pharmacy [HP3]				
Liquid	2.43	200 ml OP	✓	Nepro (strawberry)
	2.88 (3.31)	237 ml OP	✓	Nepro (vanilla)
Liquid (apricot)	2.88	125 ml OP	✓	NovaSource Renal
Liquid (caramel)	2.88	125 ml OP	✓	Renilon 7.5

Specialised And Elemental Products

►SA1102 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 pancreatitis.

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 SA1102 above – Hospital pharmacy [HP3]

Powder	4.40	79 g OP	✓	Vital HN
	7.50	76 g OP	✓	Alitraq

ORAL ELEMENTAL FEED 0.8KCAL/ML – Special Authority see SA1102 above – Hospital pharmacy [HP3]

Liquid (grapefruit)	9.50	250 ml OP	✓	Elemental 028 Extra
Liquid (pineapple & orange)	9.50	250 ml OP	✓	Elemental 028 Extra
Liquid (summer fruit)	9.50	250 ml OP	✓	Elemental 028 Extra

ORAL ELEMENTAL FEED 1KCAL/ML – Special Authority see SA1102 above – Hospital pharmacy [HP3]

Powder (unflavoured)	4.50	80.4 g OP	✓	Vivonex TEN
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SEMI-ELEMENTAL ENTERAL FEED 1KCAL/ML – Special Authority see SA1102 above – Hospital pharmacy [HP3]

Liquid	12.04	1,000 ml OP	✓	Peptisorb
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Undialysed End Stage Renal Failure

►SA1103 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 undialysed end stage renal failure.

Note: Where possible, the requirements for oral supplementation should be established in conjunction with assessment by a dietitian.

continued...

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

continued...

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

RENAL ORAL FEED 1KCAL/ML – Special Authority see SA1103 on the preceding page – Hospital pharmacy [HP3]

Liquid 3.80 237 ml OP ✓ **Suplena**

Paediatric Products For Children With Low Energy Requirements

►SA1196 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 Child aged one to eight years; and
- 2 The child has a low energy requirement but normal protein and micronutrient requirements.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

PAEDIATRIC ENTERAL FEED WITH FIBRE 0.75 KCAL/ML – Special Authority see SA1196 above – Hospital pharmacy [HP3]

Liquid 4.00 500 ml OP ✓ **Nutrini Low Energy
Multi Fibre**

Standard Supplements

►SA1228 Special Authority for Subsidy

Initial application — (Children) 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) 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:

- 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 — (Adults) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 months for applications meeting the following criteria:

continued...

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

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 — (Adults transitioning from hospital Discretionary Community Supply) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had up to a 30 day supply of a 1.0 or a 1.5 kcal/ml Standard Oral Supplement; and
- 2 A nutrition goal has been set (eg reach a specific weight or BMI); and
- 3 Any of the following:
 - Patient is Malnourished
 - 3.1 Patient has a body mass index (BMI) of less than 18.5 kg/m²; or
 - 3.2 Patient has unintentional weight loss greater than 10% within the last 3-6 months; or
 - 3.3 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:

- 1 Is being feed 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
- 5 Both:
 - 5.1 Pregnant; and
 - 5.2 Any of the following:
 - 5.2.1 Patient is in early pregnancy (<13 weeks) and has severe clinical hyperemesis gravidarum requiring admission to hospital and is unlikely to meet her nutritional requirements due to continuing hyperemesis gravidarum; or
 - 5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or

continued...

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

continued...

- 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
- 5 Both:
 - 5.1 Pregnant; and
 - 5.2 Any of the following:
 - 5.2.1 Patient is in early pregnancy (<13 weeks) and has severe clinical hyperemesis gravidarum requiring admission to hospital and is unlikely to meet her nutritional requirements due to continuing hyperemesis gravidarum; or
 - 5.2.2 Patient has clinical hyperemesis gravidarum continuing past 13 weeks and either there is concern that the patient is unlikely to meet the Institute of Medicine's (1990) recommended weight gain guidelines for pregnancy or the patient's weight has not increased past her booking/pre-pregnancy weight; or
 - 5.2.3 Patient is having multiple births and is under the care of an obstetric team who consider the nutritional needs of the patient are not being met.

Initial application — (Long-term medical condition) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Any of the following:

- 1 Is being fed via a tube or a tube is to be inserted for the purpose of feeding (not nasogastric tube - refer to specific medical condition criteria); or
- 2 Cystic Fibrosis; or
- 3 Liver disease; or
- 4 Chronic Renal failure; or
- 5 Inflammatory bowel disease; or
- 6 Chronic obstructive pulmonary disease with hypercapnia; or
- 7 Short bowel syndrome; or
- 8 Bowel fistula; or
- 9 Severe chronic neurological conditions; or
- 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.

SPECIAL FOODS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ENTERAL FEED 1.5KCAL/ML – Special Authority see SA1228 on page 202 – Hospital pharmacy [HP3]				
Liquid	7.00	1,000 ml	✓	Nutrison Energy
ENTERAL FEED 1KCAL/ML – Special Authority see SA1228 on page 202 – Hospital pharmacy [HP3]				
Liquid	1.24	250 ml OP	✓	Isosource Standard
			✓	Osmolite
	2.65	500 ml OP	✓	Nutrison Standard RTH
	5.29	1,000 ml OP	✓	Nutrison Standard RTH
			✓	Isosource Standard RTH
	2.65	500 ml OP	✓	Osmolite RTH
	5.29	1,000 ml OP	✓	Osmolite RTH
ENTERAL FEED WITH FIBRE 1 KCAL/ML – Special Authority see SA1228 on page 202 – Hospital pharmacy [HP3]				
Liquid	1.32	237 ml OP	✓	Jevity
	2.65	500 ml OP	✓	Nutrison Multi Fibre
	5.29	1,000 ml OP	✓	Nutrison Multi Fibre
	2.65	500 ml OP	✓	Jevity RTH
	5.29	1,000 ml OP	✓	Jevity RTH
ENTERAL FEED WITH FIBRE 1.5KCAL/ML – Special Authority see SA1228 on page 202 – Hospital pharmacy [HP3]				
Liquid	1.75	250 ml OP	✓	Ensure Plus HN
	7.00	1,000 ml OP	✓	Ensure Plus RTH
			✓	Jevity HiCal RTH
			✓	Nutrison Energy Multi Fibre
ORAL FEED (POWDER) – Special Authority see SA1228 on page 202 – Hospital pharmacy [HP3]				
Powder (chocolate)	10.22	900 g OP	✓	Sustagen Hospital Formula
	13.00		✓	Ensure
Powder (vanilla)	9.50	900 g OP	✓	Fortisip
	10.22		✓	Sustagen Hospital Formula
	13.00		✓	Ensure

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
ORAL FEED 1.5KCAL/ML – Special Authority see SA1228 on page 202 – Hospital pharmacy [HP3]				
Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube. The prescription must be endorsed accordingly.				
Liquid (banana) – Higher subsidy of \$1.26 per 200 ml with				
Endorsement.....	0.72 (1.26) (1.26)	200 ml OP		Ensure Plus Fortisip
Liquid (chocolate) – Higher subsidy of up to \$1.33 per 237 ml				
with Endorsement.....	0.72 (1.26) 0.85 (1.33) 0.72 (1.26)	200 ml OP 237 ml OP 200 ml OP		Ensure Plus Ensure Plus Fortisip
Liquid (fruit of the forest) – Higher subsidy of \$1.26 per 200 ml				
with Endorsement.....	0.72 (1.26)	200 ml OP		Ensure Plus
Liquid (strawberry) – Higher subsidy of up to \$1.33 per				
237 ml with Endorsement.....	0.72 (1.26) 0.85 (1.33) 0.72 (1.26)	200 ml OP 237 ml OP 200 ml OP		Ensure Plus Ensure Plus Fortisip
Liquid (toffee) – Higher subsidy of \$1.26 per 200 ml with En-				
dorsement.....	0.72 (1.26)	200 ml OP		Fortisip
Liquid (tropical fruit) – Higher subsidy of \$1.26 per 200 ml				
with Endorsement.....	0.72 (1.26)	200 ml OP		Fortisip
Liquid (vanilla) – Higher subsidy of up to \$1.33 per 237 ml				
with Endorsement.....	0.72 (1.26) 0.85 (1.33) 0.72 (1.26)	200 ml OP 237 ml OP 200 ml OP		Ensure Plus Ensure Plus Fortisip
ORAL FEED WITH FIBRE 1.5 KCAL/ML – Special Authority see SA1228 on page 202 – Hospital pharmacy [HP3]				
Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube. The prescription must be endorsed accordingly.				
Liquid (chocolate) – Higher subsidy of \$1.26 per 200 ml with				
Endorsement.....	0.72 (1.26)	200 ml OP		Fortisip Multi Fibre
Liquid (strawberry) – Higher subsidy of \$1.26 per 200 ml with				
Endorsement.....	0.72 (1.26)	200 ml OP		Fortisip Multi Fibre
Liquid (vanilla) – Higher subsidy of \$1.26 per 200 ml with				
Endorsement.....	0.72 (1.26)	200 ml OP		Fortisip Multi Fibre

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

Adult Products High Calorie

►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 failure to thrive; or
 - 1.3 increased nutritional requirements; or
 - 1.4 fluid restricted; and
- 2 other lower calorie products have been tried; and
- 3 patient has substantially increased metabolic requirements or is fluid restricted.

Renewal — (Cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

Renewal — (Indications other than cystic fibrosis) only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

ENTERAL FEED 2KCAL/ML – Special Authority see SA1195 above – Hospital pharmacy [HP3]

Liquid	5.50	500 ml OP	✓ Nutrison Concentrated
	11.00	1,000 ml OP	✓ Two Cal HN RTH

ORAL FEED 2KCAL/ML – Special Authority see SA1195 above – Hospital pharmacy [HP3]

Additional subsidy by endorsement is available for patients being bolus fed through a feeding tube. The prescription must be endorsed accordingly.

Liquid (vanilla) – Higher subsidy of \$2.25 per 237 ml with			
Endorsement	1.14 (2.25)	237 ml OP	Two Cal HN

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

Food Thickeners

►SA1106 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient has motor neurone disease with swallowing disorder.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

FOOD THICKENER – Special Authority see SA1106 above – Hospital pharmacy [HP3]

Powder	7.25	380 g OP	✓ Karicare Food Thickener
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Gluten Free Foods

The funding of gluten free foods is no longer being actively managed by PHARMAC from 1 April 2011. This means that we are no longer considering the listing of new products, or making subsidy, or other changes to the existing listings. As a result we anticipate that the range of funded items will reduce over time. Management of Coeliac disease with a gluten free diet is necessary for good outcomes. A range of gluten free options are available through retail outlets.

►SA1107 Special Authority for Subsidy

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

Either:

- 1 Gluten enteropathy has been diagnosed by biopsy; or
- 2 Patient suffers from dermatitis herpetiformis.

GLUTEN FREE BAKING MIX – Special Authority see SA1107 above – Hospital pharmacy [HP3]

Powder	2.81	1,000 g OP	Healthies Simple Baking Mix
	(5.15)		

GLUTEN FREE BREAD MIX – Special Authority see SA1107 above – Hospital pharmacy [HP3]

Powder	3.93	1,000 g OP	NZB Low Gluten Bread Mix
	(7.32)		
	4.77		
	(8.71)		Bakels Gluten Free Health Bread Mix
	3.51		
	(10.87)		Horleys Bread Mix

GLUTEN FREE FLOUR – Special Authority see SA1107 above – Hospital pharmacy [HP3]

Powder	5.62	2,000 g OP	Horleys Flour
	(18.10)		

SPECIAL FOODS

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
GLUTEN FREE PASTA – Special Authority see SA1107 on the preceding page – Hospital pharmacy [HP3]				
Buckwheat Spirals	2.00 (3.11)	250 g OP		Orgran
Corn and Vegetable Shells	2.00 (2.92)	250 g OP		Orgran
Corn and Vegetable Spirals	2.00 (2.92)	250 g OP		Orgran
Rice and Corn Lasagne Sheets	1.60 (3.82)	200 g OP		Orgran
Rice and Corn Macaroni	2.00 (2.92)	250 g OP		Orgran
Rice and Corn Penne	2.00 (2.92)	250 g OP		Orgran
Rice and Maize Pasta Spirals	2.00 (2.92)	250 g OP		Orgran
Rice and Millet Spirals	2.00 (3.11)	250 g OP		Orgran
Rice and corn spaghetti noodles	2.00 (2.92)	375 g OP		Orgran
Vegetable and Rice Spirals	2.00 (2.92)	250 g OP		Orgran
Italian long style spaghetti	2.00 (3.11)	220 g OP		Orgran

Foods And Supplements For Inborn Errors Of Metabolism

►SA1108 Special Authority for Subsidy

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

Any of the following:

- 1 Dietary management of homocystinuria; or
- 2 Dietary management of maple syrup urine disease; or
- 3 Dietary management of phenylketonuria (PKU); or
- 4 For use as a supplement to the Ketogenic diet in patients diagnosed with epilepsy.

Supplements For Homocystinuria

AMINOACID FORMULA WITHOUT METHIONINE – Special Authority see SA1108 above – Hospital pharmacy [HP3]
Powder461.94 500 g OP ✓ **XMET Maxamum**

Supplements For MSUD

AMINOACID FORMULA WITHOUT VALINE, LEUCINE AND ISOLEUCINE – Special Authority see SA1108 above – Hospital pharmacy [HP3]

Powder300.54 500 g OP ✓ **MSUD Maxamaid**
437.22 ✓ **MSUD Maxamum**

	Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
Supplements For PKU				
AMINOACID FORMULA WITHOUT PHENYLALANINE – Special Authority see SA1108 on the preceding page – Hospital pharmacy [HP3]				
Tabs	99.00	75 OP	✓	Phlexy 10
Sachets (tropical)	324.00	30	✓	Phlexy 10
Infant formula	174.72	400 g OP	✓	PKU Anamix Infant
Powder (orange)	221.00	500 g OP	✓	XP Maxamaid
	320.00		✓	XP Maxamum
Powder (unflavoured)	221.00	500 g OP	✓	XP Maxamaid
	320.00		✓	XP Maxamum
Liquid (berry)	13.10	125 ml OP	✓	PKU Anamix Junior LQ
	15.65	62.5 ml OP	✓	PKU Lophlex LQ 10
	31.20	125 ml OP	✓	PKU Lophlex LQ 20
Liquid (citrus)	15.65	62.5 ml OP	✓	PKU Lophlex LQ 10
	31.20	125 ml OP	✓	PKU Lophlex LQ 20
Liquid (forest berries)	30.00	250 ml OP	✓	Easiphen Liquid
Liquid (orange)	13.10	125 ml OP	✓	PKU Anamix Junior LQ
	15.65	62.5 ml OP	✓	PKU Lophlex LQ 10
	31.20	125 ml OP	✓	PKU Lophlex LQ 20
Liquid (unflavoured)	13.10	125 ml OP	✓	PKU Anamix Junior LQ

Foods

LOW PROTEIN BAKING MIX – Special Authority see SA1108 on the preceding page – Hospital pharmacy [HP3]

Powder	8.22	500 g OP	✓	Loprofin Mix
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LOW PROTEIN PASTA – Special Authority see SA1108 on the preceding page – Hospital pharmacy [HP3]

Animal shapes	11.91	500 g OP	✓	Loprofin
Lasagne	5.95	250 g OP	✓	Loprofin
Low protein rice pasta	11.91	500 g OP	✓	Loprofin
Macaroni	5.95	250 g OP	✓	Loprofin
Penne	11.91	500 g OP	✓	Loprofin
Spaghetti	11.91	500 g OP	✓	Loprofin
Spirals	11.91	500 g OP	✓	Loprofin

Infant Formulae

For Premature Infants

PREMATURE BIRTH FORMULA – Special Authority see SA1221 below – Hospital pharmacy [HP3]

Liquid	0.75	100 ml OP	✓	S26LBW Gold RTF
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(S26LBW Gold RTF Liquid to be delisted 1 April 2013)

►SA1221 Special Authority for Subsidy

Note: Subsidy for patients approved prior to 1 July 2012. Approvals valid for 6 months. No new approvals will be granted from 1 July 2012.

PRETERM POST-DISCHARGE INFANT FORMULA – Special Authority see SA1198 on the next page – Hospital pharmacy [HP3]

Powder	15.25	400 g OP	✓	S-26 Gold Premgro
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Subsidy (Manufacturer's Price) \$	Per	Fully Subsidised ✓	Brand or Generic Manufacturer
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►SA1198 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 The infant was born before 33 weeks gestation or weighed less than 1.5 kg at birth; and
- 2 Either:
 - 2.1 The infant has faltering growth (downward crossing of percentiles); or
 - 2.2 The infant is not maintaining, or is considered unlikely to maintain, adequate growth on standard infant formula.

For Williams Syndrome

►SA1110 Special Authority for Subsidy

Initial application only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year where the patient is an infant suffering from Williams Syndrome and associated hypercalcaemia.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Both:

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and date contacted.

LOW CALCIUM INFANT FORMULA – Special Authority see SA1110 above – Hospital pharmacy [HP3]

Powder	44.40	400 g OP	✓ Locasol
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Gastrointestinal and Other Malabsorptive Problems

AMINO ACID FORMULA – Special Authority see SA1219 below – Hospital pharmacy [HP3]

Powder	6.00	48.5 g OP	✓ Vivonex Pediatric
	53.00	400 g OP	✓ Neocate
			✓ Neocate LCP
Powder (tropical)	53.00	400 g OP	✓ Neocate Advance
Powder (unflavoured)	53.00	400 g OP	✓ Elecare
			✓ Elecare LCP
			✓ Neocate Advance
			✓ Neocate Gold
Powder (vanilla)	53.00	400 g OP	✓ Elecare
			✓ Neocate Advance

►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.

Renewal only from a dietitian, relevant specialist, vocationally registered general practitioner or general practitioner on the recommendation of a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 An assessment as to whether the infant can be transitioned to a cows milk protein, soy, or extensively hydrolysed infant formula has been undertaken; and

continued...

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
continued...			
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 SA1220 below – Hospital pharmacy [HP3]			
Powder	15.21	450 g OP	✓ Pepti Junior Gold

►SA1220 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 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 diarrhea; or
- 5 Biliary atresia; or
- 6 Cholestatic liver diseases causing malabsorption; or
- 7 Chylous ascite; or
- 8 Chylothorax; or
- 9 Cystic fibrosis; or
- 10 Proven fat malabsorption; or
- 11 Severe intestinal motility disorders causing significant malabsorption; or
- 12 Intestinal failure.

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 date contacted.

Renewal — (Step Down from Amino Acid Formula) 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 The infant is currently receiving funded amino acid formula; and
- 2 The infant is to be trialled on, or transitioned to, an extensively hydrolysed formula; and
- 3 General Practitioners must include the name of the dietitian, relevant specialist or vocationally registered general practitioner and the date contacted.

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.

SPECIAL FOODS

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
HIGH FAT FORMULA WITH VITAMINS, MINERALS AND TRACE ELEMENTS AND LOW IN PROTEIN AND CARBOHYDRATE – Special Authority see SA1197 on the preceding page – Retail pharmacy			
Powder (vanilla)	35.50	300 g OP	✓ KetoCal

Pharmaceuticals and quantities that may be obtained on a Practitioner's Supply Order

ADRENALINE	
✓ Inj 1 in 1,000, 1 ml	5
✓ Inj 1 in 10,000, 10 ml	5

AMINOPHYLLINE	
✓ Inj 25 mg per ml, 10 ml	5

AMIODARONE HYDROCHLORIDE	
✓ Inj 50 mg per ml, 3 ml	5

AMOXICILLIN	
✓ Cap 250 mg	30
✓ Grans for oral liq 125 mg per 5 ml	200 ml
✓ Grans for oral liq 250 mg per 5 ml	200 ml
✓ Inj 1 g	5

AMOXICILLIN CLAVULANATE	
✓ Tab amoxicillin 500 mg with potassium clavulanate 125 mg	30
✓ Grans for oral liq amoxicillin 125 mg with potassium clavulanate 31.25 mg per 5 ml	200 ml
✓ Grans for oral liq amoxicillin 250 mg with potassium clavulanate 62.5 mg per 5 ml	200 ml

ASPIRIN	
✓ Tab dispersible 300 mg	30

ATROPINE SULPHATE	
✓ Inj 600 µg, 1 ml	5

AZITHROMYCIN	
✓ Tab 500 mg – Subsidy by endorsement – See note on page 88	8

BENDROFLUAZIDE	
✓ Tab 2.5 mg – See note on page 58	150

BENZATHINE BENZYL PENICILLIN	
✓ Inj 1.2 mega u per 2.3 ml	5

BENZTROPINE MESYLATE	
✓ Inj 1 mg per ml, 2 ml	5

BENZYL PENICILLIN SODIUM (PENICILLIN G)	
✓ Inj 600 mg	5

CEFTRIAZONE SODIUM	
✓ Inj 500 mg – Subsidy by endorsement – See note on page 87	5
✓ Inj 1 g – Subsidy by endorsement – See note on page 87	5

CHARCOAL	
✓ Oral liq 50 g per 250 ml	250 ml

CHLORPROMAZINE HYDROCHLORIDE	
✓ Tab 10 mg	30
✓ Tab 25 mg	30
✓ Tab 100 mg	30
✓ Inj 25 mg per ml, 2 ml	5

CIPROFLOXACIN	
✓ Tab 250 mg	5
✓ Tab 500 mg	5

CO-TRIMOXAZOLE	
✓ Tab trimethoprim 80 mg and sulphamethoxazole 400 mg	30
✓ Oral liq trimethoprim 40 mg and sulphamethoxazole 200 mg per 5 ml	200 ml

COMPOUND ELECTROLYTES	
✓ Powder for soln for oral use 4.4 g	10

CONDOMS	
✓ 49 mm	144
✓ 52 mm	144
✓ 52 mm extra strength	144
✓ 53 mm	144
✓ 53 mm (chocolate)	144
✓ 53 mm (strawberry)	144
✓ 53 mm extra strength	144
✓ 54 mm, shaped	144
✓ 55 mm	144
✓ 56 mm	144
✓ 56 mm, shaped	144
✓ 60 mm	144

DEXAMETHASONE	
✓ Tab 1 mg – Retail pharmacy-Specialist	30
✓ Tab 4 mg – Retail pharmacy-Specialist	30

DEXAMETHASONE SODIUM PHOSPHATE	
✓ Inj 4 mg per ml, 1 ml – See note on page 79	5
✓ Inj 4 mg per ml, 2 ml – See note on page 79	5

DEXTROSE	
✓ Inj 50%, 10 ml	5
✓ Inj 50%, 90 ml	5

DIAPHRAGM	
✓ 65 mm – See note on page 73	1
✓ 70 mm – See note on page 73	1
✓ 75 mm – See note on page 73	1
✓ 80 mm – See note on page 73	1

continued...

(continued)

DIAZEPAM

- ✓ Inj 5 mg per ml, 2 ml – Subsidy by endorsement – See note on page 130 5
- ✓ Rectal tubes 5 mg 5
- ✓ Rectal tubes 10 mg 5

DICLOFENAC SODIUM

- ✓ Inj 25 mg per ml, 3 ml 5
- ✓ Suppos 50 mg 10

DIGOXIN

- ✓ Tab 62.5 µg 30
- ✓ Tab 250 µg 30

DOXYCYCLINE HYDROCHLORIDE

- Tab 50 mg 30
- ✓ Tab 100 mg 30

ERGOMETRINE MALEATE

- ✓ Inj 500 µg per ml, 1 ml 5

ERYTHROMYCIN ETHYL SUCCINATE

- ✓ Tab 400 mg 30
- ✓ Grans for oral liq 200 mg per 5 ml 200 ml
- ✓ Grans for oral liq 400 mg per 5 ml 200 ml

ERYTHROMYCIN STEARATE

- Tab 250 mg 30

ETHINYLLOESTRADIOL WITH DESOGESTREL

- Tab 20 µg with desogestrel 150 µg 63
- Tab 20 µg with desogestrel 150 µg and 7 inert tab 84
- Tab 30 µg with desogestrel 150 µg 63
- Tab 30 µg with desogestrel 150 µg and 7 inert tab 84

ETHINYLLOESTRADIOL WITH LEVONORGESTREL

- ✓ Tab 50 µg with levonorgestrel 125 µg and 7 inert tab 84
- Tab 30 µg with levonorgestrel 150 µg 63
- ✓ Tab 30 µg with levonorgestrel 150 µg and 7 inert tab 84
- ✓ Tab 20 µg with levonorgestrel 100 µg and 7 inert tab 84

ETHINYLLOESTRADIOL WITH NORETHISTERONE

- ✓ Tab 35 µg with norethisterone 1 mg 63
- ✓ Tab 35 µg with norethisterone 1 mg and 7 inert tab 84
- ✓ Tab 35 µg with norethisterone 500 µg 63
- ✓ Tab 35 µg with norethisterone 500 µg and 7 inert tab 84

FLUCLOXACILLIN SODIUM

- ✓ Cap 250 mg 30
- ✓ Grans for oral liq 125 mg per 5 ml 200 ml
- ✓ Grans for oral liq 250 mg per 5 ml 200 ml
- ✓ Inj 1 g 5

FLUPENTHIXOL DECANOATE

- ✓ Inj 20 mg per ml, 1 ml 5
- ✓ Inj 20 mg per ml, 2 ml 5
- ✓ Inj 100 mg per ml, 1 ml 5

FLUPHENAZINE DECANOATE

- ✓ Inj 12.5 mg per 0.5 ml, 0.5 ml 5
- ✓ Inj 25 mg per ml, 1 ml 5
- ✓ Inj 100 mg per ml, 1 ml 5

FUROSEMIDE

- ✓ Tab 40 mg 30
- ✓ Inj 10 mg per ml, 2 ml 5

GLUCAGON HYDROCHLORIDE

- ✓ Inj 1 mg syringe kit 5

GLYCERYL TRINITRATE

- ✓ Tab 600 µg 100
- ✓ Aerosol spray, 400 µg per dose 250 dose

HALOPERIDOL

- ✓ Tab 500 µg 30
- ✓ Tab 1.5 mg 30
- ✓ Tab 5 mg 30
- ✓ Oral liq 2 mg per ml 200 ml
- ✓ Inj 5 mg per ml, 1 ml 5

HALOPERIDOL DECANOATE

- ✓ Inj 50 mg per ml, 1 ml 5
- ✓ Inj 100 mg per ml, 1 ml 5

HYDROCORTISONE

- ✓ Inj 50 mg per ml, 2 ml 5

HYDROXOCOBALAMIN

- ✓ Inj 1 mg per ml, 1 ml 6

HYOSCINE N-BUTYLBROMIDE

- ✓ Inj 20 mg, 1 ml 5

INTRA-UTERINE DEVICE

- ✓ IUD 40

IPRATROPIUM BROMIDE

- ✓ Nebuliser soln, 250 µg per ml, 1 ml 40
- ✓ Nebuliser soln, 250 µg per ml, 2 ml 40

IVERMECTIN

- ✓ Tab 3 mg – See note on page 67 100

continued...

✓ fully subsidised brand available

(continued)

LEVONORGESTREL

✓ Tab 30 µg.....	84
✓ Tab 1.5 mg.....	5

LIGNOCAINE

✓ Gel 2%, 10 ml urethral syringe – Subsidy by endorsement – See note on page 124	5
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LIGNOCAINE HYDROCHLORIDE

✓ Inj 1%, 5 ml	5
✓ Inj 2%, 5 ml	5
✓ Inj 1%, 20 ml	5
✓ Inj 2%, 20 ml	5

LIGNOCAINE WITH CHLORHEXIDINE

✓ Gel 2% with chlorhexidine 0.05%, 10 ml urethral syringes – Subsidy by endorsement – See note on page 124	5
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LOPERAMIDE HYDROCHLORIDE

✓ Tab 2 mg.....	30
✓ Cap 2 mg.....	30

MASK FOR SPACER DEVICE

✓ Size 2 – See note on page 179	20
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MEDROXYPROGESTERONE ACETATE

✓ Inj 150 mg per ml, 1 ml syringe.....	5
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METOCLOPRAMIDE HYDROCHLORIDE

✓ Inj 5 mg per ml, 2 ml	5
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METRONIDAZOLE

✓ Tab 200 mg.....	30
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MORPHINE SULPHATE

✓ Inj 5 mg per ml, 1 ml – Only on a controlled drug form	5
✓ Inj 10 mg per ml, 1 ml – Only on a controlled drug form	5
✓ Inj 15 mg per ml, 1 ml – Only on a controlled drug form	5
✓ Inj 30 mg per ml, 1 ml – Only on a controlled drug form	5

NALOXONE HYDROCHLORIDE

✓ Inj 400 µg per ml, 1 ml.....	5
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NICOTINE

✓ Patch 7 mg – See note on page 149	28
✓ Patch 14 mg – See note on page 149	28
✓ Patch 21 mg – See note on page 149	28
✓ Lozenge 1 mg – See note on page 149.....	216
✓ Lozenge 2 mg – See note on page 149.....	216
✓ Gum 2 mg (Classic) – See note on page 149.....	384
✓ Gum 2 mg (Fruit) – See note on page 149.....	384

✓ Gum 2 mg (Mint) – See note on page 149	384
✓ Gum 4 mg (Classic) – See note on page 149.....	384
✓ Gum 4 mg (Fruit) – See note on page 149	384
✓ Gum 4 mg (Mint) – See note on page 149	384

NORETHISTERONE

✓ Tab 350 µg.....	84
✓ Tab 5 mg.....	30

NORETHISTERONE WITH MESTRANOL

Tab 1 mg with mestranol 50 µg and 7 inert tab	84
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OXYTOCIN

✓ Inj 5 iu per ml, 1 ml	5
✓ Inj 10 iu per ml, 1 ml	5
✓ Inj 5 iu with ergometrine maleate 500 µg per ml, 1 ml	5

PARACETAMOL

✓ Tab 500 mg.....	30
✓ Oral liq 120 mg per 5 ml	200 ml
✓ Oral liq 250 mg per 5 ml	100 ml

PEAK FLOW METER

✓ Low range	10
✓ Normal range.....	10

PETHIDINE HYDROCHLORIDE

✓ Inj 50 mg per ml, 1 ml – Only on a controlled drug form	5
✓ Inj 50 mg per ml, 2 ml – Only on a controlled drug form	5

PHENOXYMETHYLPENICILLIN (PENICILLIN V)

✓ Cap potassium salt 250 mg	30
✓ Grans for oral liq 125 mg per 5 ml	200 ml
✓ Grans for oral liq 250 mg per 5 ml	200 ml

PHENYTOIN SODIUM

✓ Inj 50 mg per ml, 2 ml	5
✓ Inj 50 mg per ml, 5 ml	5

PHYTOMENADIONE

✓ Inj 2 mg per 0.2 ml	5
✓ Inj 10 mg per ml, 1 ml	5

PIPOTHAZINE PALMITATE

✓ Inj 50 mg per ml, 1 ml	5
✓ Inj 50 mg per ml, 2 ml	5

PREDNISOLONE SODIUM PHOSPHATE

✓ Oral liq 5 mg per ml – See note on page 80	30 ml
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PREDNISONE

✓ Tab 5 mg.....	30
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continued...

✓ fully subsidised brand available

Please refer to Section A for a definition, and conditions of supply, of Practitioner's Supply Orders.

(continued)

PREGNANCY TESTS - HCG URINE

✓ Cassette..... 200 test

PROCAINE PENICILLIN

✓ Inj 1.5 mega u..... 5

PROCHLORPERAZINE

✓ Tab 5 mg..... 30

✓ Inj 12.5 mg per ml, 1 ml..... 5

PROMETHAZINE HYDROCHLORIDE

✓ Inj 25 mg per ml, 2 ml..... 5

SALBUTAMOL

✓ Inj 500 µg per ml, 1 ml..... 5

✓ Aerosol inhaler, 100 µg per dose CFC
free 1000 dose

✓ Nebuliser soln, 1 mg per ml, 2.5 ml 30

✓ Nebuliser soln, 2 mg per ml, 2.5 ml 30

SALBUTAMOL WITH IPRATROPIUM BROMIDE

✓ Nebuliser soln, 2.5 mg with ipratropium
bromide 0.5 mg per vial, 2.5 ml 20

SILVER SULPHADIAZINE

✓ Crm 1%..... 250 g

SODIUM BICARBONATE

✓ Inj 8.4%, 50 ml..... 5

✓ Inj 8.4%, 100 ml..... 5

SODIUM CHLORIDE

✓ Inf 0.9% – See note on page 47 2000 ml

✓ Inj 0.9%, 5 ml – See note on page 47 5

✓ Inj 0.9%, 10 ml – See note on page 47 5

SPACER DEVICE

✓ 230 ml (single patient) 20

✓ 800 ml 20

SPACER DEVICE AUTOCLAVABLE

✓ 230 ml (autoclavable) – Subsidy by
endorsement – See note on page 179 5

TRIMETHOPRIM

✓ Tab 300 mg 30

VERAPAMIL HYDROCHLORIDE

✓ Inj 2.5 mg per ml, 2 ml 5

WATER

✓ Purified for inj, 5 ml – See note on page 47 5

✓ Purified for inj, 10 ml – See note on page 47 5

✓ Purified for inj, 20 ml – See note on page 47 5

ZUCLOPENTHIXOL DECANOATE

✓ Inj 200 mg per ml, 1 ml 5

✓ fully subsidised brand available

Rural Areas for Practitioner's Supply Orders

NORTH ISLAND**Northland DHB**

Dargaville
Hikurangi
Kaeo
Kaikohe
Kaitiaki
Kawakawa
Kerikeri
Mangonui
Maungaturoto
Moerewa
Ngunguru
Paihia
Rawene
Ruakaka
Russell
Tutukaka
Waipu
Whangaroa

Waitemata DHB

Helensville
Huapai
Kumeu
Snells Beach
Waimauku
Warkworth
Wellsford

Auckland DHB

Great Barrier Island
Oneroa
Ostend

Counties Manukau DHB

Tuakau
Waiuku

Waikato DHB

Coromandel
Huntly
Kawhia
Matamata
Morrinsville
Ngatea
Otorohanga
Paeroa
Pauanui Beach
Putaruru
Raglan

Tairua
Taumarunui
Te Aroha
Te Kauwhata
Te Kuiti
Tokoroa
Waihi
Whangamata
Whitianga

Bay of Plenty DHB

Edgecumbe
Katikati
Kawerau
Murupara
Opotiki
Taneatua
Te Kaha
Waihi Beach
Whakatane

Lakes DHB

Mangakino
Turangi

Tairāwhiti DHB

Ruatoria
Te Araroa
Te Karaka
Te Puia Springs
Tikitiki
Tokomaru Bay
Tolaga Bay

Taranaki DHB

Eltham
Inglewood
Manaia
Oakura
Okato
Opunake
Patea
Stratford
Waverley

Hawkes Bay DHB

Chatham Islands
Waipawa
Waipukurau
Wairoa

Whanganui DHB

Bulls

Marton
Ohakune
Raetihi
Taihape
Waiouru

MidCentral DHB

Dannevirke
Foxton
Levin
Otaki
Pahiatua
Shannon
Woodville

Wairarapa DHB

Carterton
Featherston
Greytown
Martinborough

SOUTH ISLAND**Nelson/Marlborough DHB**

Havelock
Mapua
Motueka
Murchison
Picton
Takaka
Wakefield

West Coast DHB

Dobson
Greymouth
Hokitika
Karamea
Reefton
South Westland
Westport
Whataroa

Canterbury DHB

Akaroa
Amberley
Amuri
Cheviot
Darfield
Diamond Harbour
Hanmer Springs
Kaikoura

Leeston
Lincoln
Methven
Oxford
Rakaia
Rolleston
Rotherham
Templeton
Waikari

South Canterbury DHB

Fairlie
Geraldine
Pleasant Point
Temuka
Twizel
Waimate

Southern DHB

Alexandra
Balclutha
Cromwell
Gore
Kurow
Lawrence
Lumsden
Mataura
Milton
Oamaru
Oban
Otautau
Outram
Owaka
Palmerston
Queenstown
Ranfurly
Riverton
Roxburgh
Tapanui
Te Anau
Tokonui
Tuatapere
Wanaka
Winton

SECTION F: COMMUNITY PHARMACEUTICALS DISPENSING PERIOD EXEMPTIONS

SECTION F: PART I

A Community Pharmaceutical identified with a * within the other sections of the Pharmaceutical Schedule:

- a) is exempt from any requirement to dispense in Monthly Lots;
- b) will only be subsidised if it is dispensed in a 90 Day Lot unless it is under the Dispensing Frequency Rule.

A Community Pharmaceutical that is an oral contraceptive and that is identified with a * within the other sections of the Pharmaceutical Schedule:

- a) is exempt from any requirement to dispense in Monthly Lots;
- b) will only be subsidised if it is dispensed in a 180 Day Lot unless it is under the Dispensing Frequency Rule.

SECTION F: PART II: CERTIFIED EXEMPTIONS AND ACCESS EXEMPTIONS TO MONTHLY DISPENSING

A Community Pharmaceutical, other than a Community Pharmaceutical identified with a * within the other sections of the Pharmaceutical Schedule, may be dispensed in a 90 Day Lot if:

- a) the Community Pharmaceutical is identified with a ▲ within the other sections of the Pharmaceutical Schedule and the prescriber/pharmacist has endorsed/annotated the Prescription item(s) on the Prescription to which the exemption applies "certified exemption".

In endorsing/annotating the Prescription items for a certified exemption, the prescriber/pharmacist is certifying that:

- i) the patient wished to have the medicine dispensed in a quantity greater than a Monthly Lot; and
 - ii) the patient has been stabilised on the same medicine for a reasonable period of time; and
 - iii) the prescriber/pharmacist has reason to believe the patient will continue on the medicine and is compliant.
- b) a patient, who has difficulty getting to and from a pharmacy, signs the back of the Prescription to qualify for an Access Exemption. In signing the Prescription, the patient or his or her nominated representative must also certify which of the following criteria they meet:
 - i) have limited physical mobility;
 - ii) live and work more than 30 minutes from the nearest pharmacy by their normal form of transport;
 - iii) are relocating to another area;
 - iv) are travelling extensively and will be out of town when the repeat prescriptions are due.

SECTION F: PART III: FLEXIBLE AND VARIABLE DISPENSING PERIODS FOR PHARMACY

A Community Pharmaceutical, other than a Community Pharmaceutical identified with a * within the other sections of the Pharmaceutical Schedule, may be dispensed in variable dispensing periods under the following conditions:

- a) for stock management where the original pack(s) result in dispensing greater than 30 days supply,
- b) to synchronise a patients medication where multiple medicines result in uneven supply periods, note if dispensing a medicine other than a Pharmaceutical identified with a * please refer to Section F; Part II

Note – the total quantity and dispensing period can not exceed the total quantity and period prescribed on the prescription.

The following Community Pharmaceuticals are identified with a ▲ within the other sections of the Pharmaceutical Schedule and may be dispensed in a 90 Day Lot if endorsed as a certified exemption in accordance with paragraph (a) in Section F Part II above.

ALIMENTARY TRACT AND METABOLISM

INSULIN ASPART

INSULIN ASPART

INSULIN GLARGINE

INSULIN GLULISINE

INSULIN ISOPHANE

INSULIN ISOPHANE WITH INSULIN NEUTRAL

INSULIN LISPRO

INSULIN LISPRO WITH INSULIN LISPRO PROTAMINE

INSULIN NEUTRAL

CARDIOVASCULAR SYSTEM

AMIODARONE HYDROCHLORIDE

Tab 100 mg Cordarone-X

Tab 200 mg Cordarone-X

DISOPYRAMIDE PHOSPHATE

FLECAINIDE ACETATE

Tab 50 mg Tambocor

Tab 100 mg Tambocor

Cap long-acting 100 mg Tambocor CR

Cap long-acting 200 mg Tambocor CR

MEXILETINE HYDROCHLORIDE

MINOXIDIL

NICORANDIL

PROPAFENONE HYDROCHLORIDE

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES

DESMOPRESSIN

Nasal drops 100 µg per
ml MinirinNasal spray 10 µg per
dose Desmopressin-PH&T**MUSCULOSKELETAL SYSTEM**

PYRIDOSTIGMINE BROMIDE

NERVOUS SYSTEM

AMANTADINE HYDROCHLORIDE

APOMORPHINE HYDROCHLORIDE

ENTACAPONE

GABAPENTIN

GABAPENTIN (NEURONTIN)

LACOSAMIDE

LAMOTRIGINE

LISURIDE HYDROGEN MALEATE

PERGOLIDE

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.

Reimbursement

Pharmacists will be reimbursed according to their agreement. Where an additional fee is paid on safety caps it will be paid on all dispensings of oral liquid preparations for those pharmaceuticals listed in Section G of the Pharmaceutical Schedule unless the practitioner has endorsed or the contractor has annotated the Prescription or Practitioner's Supply Order that a safety cap has not been supplied.

Safety Caps (NZS 5825:1991)

20 mm.....	.Clic-Loc, United Closures & Plastics PLC, England Kerr, Cormack Packaging, Sydney, under licence to Kerr USA
24 mm.....	.Clic-Loc, United Closures & Plastics PLC, England Clic-Loc, ACI Closures under license to Owens-Illinois Kerr, Cormack Packaging, Sydney, under licence to Kerr USA
28 mm.....	.Clic-Loc, United Closures & Plastics PLC, England Clic-Loc, ACI Closures under license to Owens-Illinois Kerr, Cormack Packaging, Sydney, under licence to Kerr USA PDL Squeezlok PDL FG

ALIMENTARY TRACT AND METABOLISM**FERROUS SULPHATE**

Oral liq 30 mg per 1 ml Ferodan
(6 mg elemental per
1 ml)

CARDIOVASCULAR SYSTEM**AMILORIDE**

Oral liq 1 mg per ml Biomed

CAPTOPRIL

Oral liq 5 mg per ml Capoten

CHLOROTHIAZIDE

Oral liq 50 mg per ml Biomed

DIGOXIN

Oral liq 50 µg per ml Lanoxin

FUROSEMIDE

Oral liq 10 mg per ml Lasix

SPIRONOLACTONE

Oral liq 5 mg per ml Biomed

HORMONE PREPARATIONS - SYSTEMIC EXCLUDING CONTRACEPTIVE HORMONES**LEVOTHYROXINE**

Tab 25 µg Synthroid
Tab 50 µg Eltroxin
Goldshield
Synthroid
Tab 100 µg Eltroxin
Goldshield
Synthroid

(Extemporaneously compounded oral liquid preparations)

MUSCULOSKELETAL SYSTEM**IBUPROFEN**

Oral liq 100 mg per 5 ml Fenpaed

QUININE SULPHATE

Tab 300 mg Q 300

(Extemporaneously compounded oral liquid preparations)

NERVOUS SYSTEM**ALPRAZOLAM**

Tab 250 µg Arrow-Alprazolam
Tab 500 µg Arrow-Alprazolam
Tab 1 mg Arrow-Alprazolam

(Extemporaneously compounded oral liquid preparations)

CARBAMAZEPINE

Oral liq 100 mg per 5 ml Tegretol

CLOBAZAM

Tab 10 mg Frisium
(Extemporaneously compounded oral liquid preparations)

CLONAZEPAM

Oral drops 2.5 mg per ml Rivotril

DIAZEPAM

Tab 2 mg Arrow-Diazepam
Tab 5 mg Arrow-Diazepam
(Extemporaneously compounded oral liquid preparations)

ETHOSUXIMIDE

Oral liq 250 mg per 5 ml Zarontin

LORAZEPAM

Tab 1 mg Ativan
Tab 2.5 mg Ativan
(Extemporaneously compounded oral liquid preparations)

LORMETAZEPAM

Tab 1 mg Noctamid
(Extemporaneously compounded oral liquid preparations)

METHADONE HYDROCHLORIDE

Oral liq 2 mg per ml Biodone
Oral liq 5 mg per ml Biodone Forte
Oral liq 10 mg per ml Biodone Extra Forte

MORPHINE HYDROCHLORIDE

Oral liq 1 mg per ml RA-Morph
Oral liq 2 mg per ml RA-Morph
Oral liq 5 mg per ml RA-Morph
Oral liq 10 mg per ml RA-Morph

NITRAZEPAM

Tab 5 mg Nitrados
(Extemporaneously compounded oral liquid preparations)

OXAZEPAM

Tab 10 mg Ox-Pam
Tab 15 mg Ox-Pam
(Extemporaneously compounded oral liquid preparations)

OXYCODONE HYDROCHLORIDE

Oral liq 5 mg per 5 ml OxyNorm

PARACETAMOL

Oral liq 120 mg per 5 ml Ethics Paracetamol
Oral liq 250 mg per 5 ml Paracare Double Strength

PHENYTOIN SODIUM

Oral liq 30 mg per 5 ml Dilantin

222

(Extemporaneously compounded oral liquid preparations)

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
Vaccinations			
BACILLUS CALMETTE-GUERIN VACCINE – Hospital pharmacy [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) have 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.moh.govt.nz/immunisation or www.bcgatlas.org/index.php .			
Inj multi-dose vial (10 dose) 0.5 ml	0.00	1	✓ BCG Vaccine
DIPHTHERIA AND TETANUS VACCINE – Hospital pharmacy [Xpharm]			
For adults aged 45 and 65 years old, and for susceptible individuals.			
Inj 0.5 ml	0.00	1	✓ ADT Booster
DIPHTHERIA, TETANUS AND PERTUSSIS VACCINE – Hospital pharmacy [Xpharm]			
For children aged 11 years old.			
Inj 0.5 ml	0.00	1	✓ Boostrix
DIPHTHERIA, TETANUS, PERTUSSIS AND POLIO VACCINE – Hospital pharmacy [Xpharm]			
For children aged 4 years old.			
Inj 0.5 ml	0.00	1	✓ Infanrix-IPV
DIPHTHERIA, TETANUS, PERTUSSIS, POLIO, HEPATITIS B AND HAEMOPHILUS INFLUENZAE TYPE B VACCINE – Hospital pharmacy [Xpharm]			
For children aged 6 weeks, 3 months, and 5 months old.			
Inj 0.5 ml	0.00	1	✓ Infanrix-hexa
HAEMOPHILUS INFLUENZAE TYPE B VACCINE – Hospital pharmacy [Xpharm]			
For children aged 15 months old, children aged 0-16 years with functional asplenia, or for patients pre- and post-splenectomy.			
Inj 0.5 ml	0.00	1	✓ Act-HIB
HEPATITIS B VACCINE – Hospital pharmacy [Xpharm]			
For household or sexual contacts of known hepatitis B carriers, or for children born to mothers who are hepatitis B surface antigen (HBsAg) positive.			
Inj 0.5 ml	0.00	1	✓ HBvaxPro
HUMAN PAPILOMAVIRUS VACCINE – Hospital pharmacy [Xpharm]			
Three doses over a period of six months for young women aged between 12 and 19 years old.			
Inj 0.5 ml	0.00	1	✓ Gardasil
INFLUENZA VACCINE – Hospital pharmacy [Xpharm]			
Inj	90.00	10	✓ Fluorix ✓ Fluvax

A) is available 1 March until vaccine supplies are exhausted each year for patients who meet the following criteria, as set by the Ministry of Health:

- a) all people 65 years of age and over;
- b) people under 65 years of age with:
 - i) the following cardiovascular disease:
 - 1) ischaemic heart disease,
 - 2) congestive heart disease,
 - 3) rheumatic heart disease,
 - 4) congenital heart disease, or
 - 5) cerebro-vascular disease;
 - ii) the following chronic respiratory disease:
 - 1) asthma, if on a regular preventative therapy, or
 - 2) other chronic respiratory disease with impaired lung function;

continued...

NATIONAL IMMUNISATION SCHEDULE

	Subsidy (Manufacturer's Price) \$	Fully Subsidised Per	Brand or Generic Manufacturer
continued...			
iii) diabetes;			
iv) chronic renal disease;			
v) any cancer, excluding basal and squamous skin cancers if not invasive;			
vi) the following other conditions:			
a) autoimmune disease,			
b) immune suppression,			
c) HIV,			
d) transplant recipients,			
e) neuromuscular and CNS diseases,			
f) haemoglobinopathies,			
g) children on long term aspirin, or			
h) pregnancy.			
c) people under 18 years of age living within the boundaries of the Canterbury District Health Board.			
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.			
D) Influenza Vaccine does not fall within the definition Community Pharmaceutical as it is not funded directly from the Pharmaceutical Budget. Pharmacists are unable to claim for the dispensing of influenza vaccine from the Funder.			
MEASLES, MUMPS AND RUBELLA VACCINE – Hospital pharmacy [Xpharm]			
For children aged 15 months and 4 years old or for any individual susceptible to measles, mumps or rubella.			
Inj 0.5 ml0.00	1	✓	M-M-R II
MENINGOCOCCAL A, C, Y AND W-135 VACCINE – Hospital pharmacy [Xpharm]			
For patients pre- and post-splenectomy or children aged 0-16 years with functional asplenia. For organisation and community based outbreaks.			
Inj 0.5 ml0.00	1	✓	Menomune
PNEUMOCOCCAL (PCV13) VACCINE – Hospital pharmacy [Xpharm]			
For high risk children under the age of 5 and those aged less than 16 years pre- or post-splenectomy or with functional asplenia.			
Inj 0.5 ml0.00	1	✓	Prevenar 13
PNEUMOCOCCAL POLYSACCHARIDE VACCINE – Hospital pharmacy [Xpharm]			
For patients pre- and post-splenectomy or children aged 0-16 years with functional asplenia.			
Inj 0.5 ml0.00	1	✓	Pneumovax 23
PNEUMOCOCCAL VACCINE – Hospital pharmacy [Xpharm]			
For children aged 6 weeks, 3 months, and 5 months, and 15 months old.			
Inj 0.5 ml0.00	1	✓	Synflorix
POLIOMYELITIS VACCINE – Hospital pharmacy [Xpharm]			
A primary course of three doses for previously unvaccinated individuals.			
Inj 0.5 ml0.00	1	✓	IPOL

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