CONSULTATION

PHARMAC
Pharmaceutical Management Agency

25 September 2012

Proposal Relating to the Funding of Certain Pharmaceuticals in DHB Hospitals and in the Community

PHARMAC is seeking feedback on a proposal relating to the establishment of a nationally-consistent list of pharmaceuticals to be funded within DHB hospitals. This list would be published in Part II of Section H of the Pharmaceutical Schedule from 1 July 2013.

As a related issue, we are also seeking feedback on changes to the funding of some pharmaceuticals in the community: new listings and changes to subsidy criteria, as a flow-on effect of this proposal.

This consultation refers to the creation of four therapeutic groups within Section H:

- Alimentary Tract and Metabolism *(gastroenterology, diabetes, metabolic disorders)*
- Infections *(infectious diseases)*
- Respiratory System and Allergies *(respiratory medicine, clinical immunology)*
- Sensory Organs *(ophthalmology)*

Together these four groups also cover products used within otolaryngology.

While these headings primarily relate to pharmaceuticals that are used by clinicians working in the specialities identified above, this is not always the case. As such, while we have distributed this proposal widely, if you consider that there are organisations or individuals that should be made aware of this document, please refer them to this consultation, or let us know.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Monday, 29 October 2012** to:

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Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like withheld.

Level 9, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

If you have any questions about certain products, or would like to arrange a meeting or teleconference to discuss this proposal further, please contact either Sean Dougherty, or:

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All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

We are interested in all feedback relevant to this proposal. However, we are particularly interested in DHB hospitals identifying significant clinical, financial or workflow issues that may arise from parts of this proposal.

Other consultations

This document contains the second section of products that are proposed as inclusions and exclusions from Section H (the first section that we sought feedback on was the Cardiovascular System and Musculoskeletal System therapeutic groups). All of PHARMAC's consultations relevant to this work are available on PHARMAC's website:

www.pharmac.govt.nz/HospitalPharmaceuticals

In total, we expect to seek feedback on the composition of Section H in four sections, with the final two sections being released for consultation over the next six months. At this stage, we anticipate that the third section will include pharmaceuticals relating to the central nervous system, dermatology, endocrinology, obstetrics and gynaecology. We will be seeking feedback for this either late 2012 or early 2013.

The fourth section is likely to cover haematology, oncology, transplant medicine, medical nutrition, intravenous fluids, antidotes, diagnostic agents and extemporaneous compounds; this will be the subject of a consultation document early next year.

Background

Following the Government's decision that PHARMAC should become responsible for the funding of hospital pharmaceuticals, we have reviewed the use of hospital pharmaceuticals

with a view to creating a nationally-consistent list of pharmaceuticals that would be funded in all DHB hospitals. Our intention is that this list would be contained in Part II of Section H of the Pharmaceutical Schedule. Use of pharmaceuticals outside of the list in Section H, or outside of any specified indication restrictions contained in the list, would require approval under a case-by-case exceptions mechanism.

Please note that we released a consultation titled "Proposed Pharmaceutical Schedule Rules for Hospital Pharmaceuticals" in July this year which may provide some useful context for reviewing these lists. This consultation (which closed on 31 August 2012) is still available on our website: **www.pharmac.govt.nz/HospitalPharmaceuticals**. In summary we have proposed that:

- Products included in Part II of Section H would be available for use in all DHB hospitals.
- Restrictions on use, either prescriber-type or indication-based restrictions would apply to some products. Detail as to how these might be implemented is provided.
- Use of products outside the list, or for use outside any indication-based restrictions, would require case-by-case approval under a scheme that we expect to be based on PHARMAC's Named Patient Pharmaceutical Assessment policy. An outline of how this might be implemented differently in DHB hospitals is provided.

The process leading up to a decision on the products to be included in each therapeutic group involves three distinct stages: information collection, clinical advice and consultation. We began by requesting information on the current use of pharmaceuticals in all DHB hospitals and, augmenting this with information provided by relevant professional societies, sought advice from the Pharmacology and Therapeutics Advisory Committee (PTAC), along with its Anti-Infective, Respiratory, Ophthalmology, Diabetes, Gastrointestinal and Hospital Pharmaceuticals Subcommittees.

Minutes of PTAC and PTAC Subcommittee meetings that are relevant to this proposal are available on our website:

www.pharmac.govt.nz/HospitalPharmaceuticals

Details of the proposal

We are proposing to create a list of pharmaceuticals that would be available in all DHB hospitals. The list would be in Section H of the Pharmaceutical Schedule and would use the "therapeutic group" structure that is used in the Pharmaceutical Schedule for community pharmaceuticals (Section B), which is broadly based on the anatomical-therapeutic-chemical (ATC) classification system used by the World Health Organisation.

This proposal relates to the list of pharmaceuticals for four of these therapeutic groups: the Infections group, the Respiratory System and Allergies group, the Sensory Organs group and the Alimentary Tract and Metabolism group.

We note that we have previously sought feedback on the Cardiovascular System group and the Musculoskeletal System group. No decisions have been made on these groups as yet.

Appended to this letter are the lists of pharmaceuticals that are proposed for inclusion in Section H under the four therapeutic groups, along with any proposed prescribing restrictions. These appendices also contain details of products that were also considered, but that we are not proposing to include in Section H at this time.

Please note that:

- if a pharmaceutical does not appear in these appendices, it will be for one of two reasons: first, that it was not considered through this process; or second, that it has been considered as part of another therapeutic group and will be included in a subsequent round of consultation;

- some chemicals will have formulations listed across several sections – for example, low-dose aspirin would be included as part of the antithrombotic agents section (in the Blood and Blood-Forming Organs therapeutic group), and high dose preparations would be listed as analgesic agents (in the Nervous System therapeutic group);

- for a very small number of products, we will address different indications at different times but we will be clear when this is the case, and we expect that this will only be the case for biologic agents – for example, note that infliximab is addressed in three of the four therapeutic groups; and

- we will be seeking feedback on vaccines at a later time.

If you think that a product has been omitted from this process that should not have been, please let us know.

Prescriber-level restrictions

Please note that it is our intention that a prescriber-level restriction would mean that other hospital-based prescribers (that is, other than those specified) would still be able to prescribe those agents, but would need either:

(a) to be using that agent in accordance with their hospital's protocols or guidelines; or

(b) to obtain a recommendation from a specified prescriber for its use.

We note that this will be of particular relevance to the infections section, which would mean that a product with a restriction of, for example, "infectious disease physicians and clinical microbiologists" would still be able to be prescribed by other clinicians, but in a more limited capacity.

Pharmaceuticals not included

The appendices to this letter also detail the pharmaceuticals that we are proposing would be excluded from Part II of Section H at this time. In general, these fall into three categories:

1. Products for which we are of the view that inclusion in Section H should only occur if they become subsidised in the community.
2. Products that have been used in some DHB hospitals, but are not widely used and/or we consider that there is insufficient need for them to be available.

3. Products that are not currently used in DHB hospitals, and we consider that a substantive funding application for these would need to be considered (and in some cases Medsafe registration is yet to be obtained).

Please note however that if the proposal is accepted, and these products are excluded, any of them could be re-considered for inclusion in Section H at any time in the future, through our normal process for considering applications for funding.

Community listings

Should this proposal be accepted, we would also list some of these pharmaceuticals in Section B of the Pharmaceutical Schedule, which would mean that they would be subsidised when dispensed from community pharmacies. We are also proposing to make some amendments to the prescribing criteria for several of these items in the community, which would create better alignment of use between hospitals and the community.

These proposed changes are highlighted in the attached appendices.

ALIMENTARY TRACT AND METABOLISM

Antacids and Antiflatulents

Antacids and Reflux Barrier Agents

ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE AND SIMETICONE

Oral liq 200 mg with magnesium hydroxide 200 mg and simeticone 20 mg per 5 ml

Tab 200 mg with magnesium hydroxide 200 mg and simeticone 20 mg

CALCIUM CARBONATE

Tab 420 mg

SIMETICONE

Oral drops 100 mg per ml

SODIUM ALGINATE WITH MAGNESIUM ALGINATE

Powder for oral soln 225 mg with magnesium alginate 87.5 mg

SODIUM ALGINATE WITH SODIUM BICARBONATE AND CALCIUM CARBONATE

Oral liq 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml

Tab 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg

SODIUM CITRATE

Oral liq 8.8% (300 mmol/L)

Phosphate Binding Agents

ALUMINIUM HYDROXIDE

Tab 600 mg

Antidiarrhoeals and Intestinal Anti-Inflammatory Agents

Antipropulsives

DIPHENOXYLATE HYDROCHLORIDE WITH ATROPINE SULPHATE

Tab 2.5 mg with atropine sulphate 25 mcg

LOPERAMIDE HYDROCHLORIDE

Cap 2 mg

Tab 2 mg

Rectal and Colonic Anti-Inflammatories

BUDESONIDE

Restricted
Must meet community Special Authority criteria

Cap 3 mg

GLYCERYL TRINITRATE

Ointment 0.2%

HYDROCORTISONE ACETATE

Rectal foam 10%

MESALAZINE

Tab 400 mg

Tab EC 500 mg

Tab long-acting 500 mg

Suppos 500 mg

Suppos 1 g

Enema 1 g per 100 ml

OLSALAZINE

Cap 250 mg

Tab 500 mg

SODIUM CROMOGLICATE

Cap 100 mg

SULPHASALAZINE

Tab 500 mg

Tab EC 500 mg

Tumor Necrosis Factor (TNF) Inhibitors

ADALIMUMAB

Restricted
Must meet community Special Authority criteria

Inj 40 mg per 0.8 ml prefilled pen

Inj 40 mg per 0.8 ml prefilled syringe

INFLIXIMAB

Restricted

<u>Initiation - Crohn's disease - gastroenterologist</u>

All of the following:

1. *Patient has severe active Crohn's disease; and*
2. *Any of the following:*
   - 2.1. *Patient has a Crohn's Disease Activity Index (CDAI) score of greater than or equal to 300; or*
   - 2.2. *Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or*
   - 2.3. *Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or*
   - 2.4. *Patient has an ileostomy or colostomy, and has intestinal inflammation; and*
3. *Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and*
4. *Surgery (or further surgery) is considered to be clinically inappropriate; and*
5. *Patient must be reassessed for continuation after 3 months of therapy; and*

<u>Continuation - Crohn's disease - gastroenterologist</u>

1. *One of the following:*
   - 1.1. *CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab; or*
   - 1.2. *CDAI score is 150 or less; or*
   - 1.3. *The patient has demonstrated an adequate response to treatment but CDAI score cannot be assessed; and*
2. *Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.*

(continued…)

Initiation - Fistulising Crohn's disease - gastroenterologist

All of the following:

1. *Patient has confirmed Crohn's disease; and either:*
   - 1.1. *Patient has one or more complex externally draining enterocutaneous fistula(e); or*
   - 1.2. *Patient has one or more rectovaginal fistula(e); and*
2. *An adequate trial of conventional treatment has not been successful (defined as at least 4 months therapy with an adequate dose of thiopurine or methotrexate); and*
3. *Patient must be reassessed for continuation after 4 months of therapy.*

Continuation - Fistulising Crohn's disease - gastroenterologist

1. *Either:*
   - 1.1. *The number of open draining fistulae have decreased from baseline by at least 50%; or*
   - 1.2. *There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient reported pain; and*
2. *Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.*

Initiation - acute severe fulminant ulcerative colitis - gastroenterologist

1. *Patient has acute, severe fulminant ulcerative colitis; and*
2. *Treatment with intravenous corticosteroids has not been successful; and*
3. *Patient must be reassessed for continuation after 6 weeks of therapy.*

Continuation - severe fulminant ulcerative colitis - gastroenterologist

1. *Where maintenance treatment is considered appropriate, infliximab should be used in combination with immunomodulators and reassessed every 6 months; and*

(continued…)

2. *Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.*

Initiation - severe ulcerative colitis - gastroenterologist

1. *Patient has severe ulcerative colitis; and*
2. *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 for an adequate duration (unless contraindicated) and corticosteroids; and*
3. *Surgery (or further surgery) is considered to be clinically inappropriate; and*
4. *Patient must be reassessed for continuation after 3 months of therapy.*

Continuation - severe ulcerative colitis - gastroenterologist

1. *Patient is continuing to maintain remission and the benefit of continuing infliximab outweighs the risks.*
2. *Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.*

Inj 100 mg

Antihaemorrhoidals

Corticosteroids

CINCHOCAINE HYDROCHLORIDE WITH HYDROCORTISONE

Oint 5 mg with hydrocortisone 5 mg per g

Suppos 5 mg with hydrocortisone 5 mg per g

FLUOCORTOLONE CAPROATE WITH FLUOCORTOLONE PIVALATE AND CINCHOCAINE

Oint 950 mcg with fluocortolone pivalate 920 mcg and cinchocaine hydrochloride 5 mg per g

Suppos 630 mcg with fluocortolone pivalate 610 mcg and cinchocaine hydrochloride 1 mg

Rectal Sclerosants

OILY PHENOL

Inj 5%, 5 ml

Antispasmodics and Other Agents Altering Gut Motility

HYOSCINE BUTYLBROMIDE (SCOPOLAMINE)

Inj 20 mg, 1 ml

Tab 10 mg

MEBEVERINE HYDROCHLORIDE

Tab 135 mg

Antiulcerants

Antisecretory and Cytoprotective

MISOPROSTOL

Tab 200 mcg

H2 Antatonists

CIMETIDINE

Tab 200 mg

Tab 400 mg

RANITIDINE

Tab 150 mg

Tab 300 mg

Oral liq 150 mg per 10 ml

Inj 25 mg per ml, 2 ml

Proton Pump Inhibitors

LANSOPRAZOLE

Cap 15 mg

Cap 30 mg

OMEPRAZOLE

Restricted

Dispersible tablets – only for use in tube-fed patients

Cap 10 mg

Cap 20 mg

Cap 40 mg

Tab dispersible 20 mg

Powder for oral liquid

Inj 40 mg

Inf 40 mg

PANTOPRAZOLE

Tab 20 mg

Tab 40 mg

Inj 40 mg

Site Protective Agents

BISMUTH

Tab 120 mg

SUCRALFATE

Tab 1 g

Bile and Liver Therapy

L-ORNITHINE L-ASPARTATE

Grans for oral liquid 3 g

Diabetes

Alpha Glucosidase Inhibitors

ACARBOSE

Tab 50 mg

Tab 100 mg

Hyperglycaemic Agents

GLUCAGON HYDROCHLORIDE

Inj 1 mg syringe kit

GLUCOSE

Gel 40%

Tab 1.5 g

Insulin – Intermediate-Acting Preparations

INSULIN ASPART

Inj 100 u per ml, 3 ml prefilled pen

INSULIN ISOPHANE

Insulin human 100 u per ml, 10 ml

Insulin human 100 u per ml, 3 ml

INSULIN LISPRO WITH INSULIN LISPRO PROTAMINE

Inj insulin lispro 25% with insulin lispro protamine 75%, 100 u per ml, 3 ml

Inj insulin lispro 50% with insulin lispro protamine 50%, 100 u per ml, 3 ml

INSULIN NEUTRAL WITH INSULIN ISOPHANE

Inj insulin neutral 30% with insulin isophane 70%, 100 u per ml, 10 ml

Inj insulin neutral 30% with insulin isophane 70%, 100 u per ml, 3 ml

Inj insulin neutral 40% with insulin isophane 60%, 100 u per ml, 3 ml

Inj insulin neutral 50% with insulin isophane 50%, 100 u per ml, 3 ml

Insulin – Long-Acting Preparations

INSULIN GLARGINE

Inj 100 u per ml, 10 ml

Inj 100 u per ml, 3 ml

Inj 100 u per ml, 3 ml disposable pen

Insulin – Rapid-Acting Preparations

INSULIN ASPART

Inj 100 u per ml, 10 ml

Inj 100 u per ml, 3 ml

INSULIN GLULISINE

Inj 100 u per ml, 10 ml

Inj 100 u per ml, 3 ml

Inj 100 u per ml, 3 ml disposable pen

INSULIN LISPRO

Inj 100 u per ml, 10 ml

Inj 100 u per ml, 3 ml

Insulin – Short-Acting Preparations

INSULIN NEUTRAL

Inj human 100 u per ml, 10 ml

Inj human 100 u per ml, 3 ml

Oral Hypoglycaemic Agents

DIAZOXIDE

Restricted

For patients with confirmed hypoglycaemia caused by hyperinsulinism

Cap 25 mg

Cap 100 mg

GLIBENCLAMIDE

Tab 5 mg

GLICLAZIDE

Tab 80 mg

GLIPIZIDE

Tab 5 mg

METFORMIN

Tab immediate-release 500 mg

Tab immediate-release 850 mg

PIOGLITAZONE

Restricted

Must meet community Special Authority criteria

Tab 15 mg

Tab 30 mg

Tab 45 mg

Digestives Including Enzymes

PANCREATIC ENZYME

Cap EC 10,000 BP u lipase, 9,000 BP u amylase and 210 BP u protease

Cap EC 25,000 BP u lipase, 18,000 BP u amylase and 1,000 BP u protease

Cap EC 25,000 BP u lipase, 22,500 BP u amylase and 1,250 BP u protease

Powder 25,000 u lipase, 30,000 u amylase and 1,400 u protease per g

URSODEOXYCHOLIC ACID

Restricted
Must meet community Special Authority criteria

Cap 250 mg

Laxatives

Bowel-Cleansing Preparations

CITRIC ACID WITH MAGNESIUM OXIDE AND SODIUM PICOSULFATE

Powder for oral soln 12 g with magnesium oxide 3.5 g and sodium picosulfate 10 mg per sachet

MACROGOL 3350 WITH ASCORBIC ACID, POTASSIUM CHLORIDE AND SODIUM CHLORIDE

Powder for oral soln 755.68 mg with ascorbic acid 85.16 mg, potassium chloride 10.55 mg, sodium chloride 37.33 mg and sodium sulphate 80.62 mg per g, 70 g sachet

Powder for oral soln 755.68 mg with ascorbic acid 85.16 mg, potassium chloride 10.55 mg, sodium chloride 37.33 mg and sodium sulphate 80.62 mg per g, 210 g sachet

MACROGOL 3350 WITH POTASSIUM CHLORIDE, SODIUM BICARBONATE, SODIUM CHLORIDE AND SODIUM SULPHATE

Powder for oral soln 59 g with potassium chloride 0.7425 g, sodium bicarbonate 1.685 g, sodium chloride 1.465 g and sodium sulphate 5.685 g per sachet

Bulk-Forming Agents

ISPAGHULA (PSYLLIUM) HUSK

Powder for oral soln

STERCULIA WITH FRANGULA

Restricted *– continuation only*

Powder for oral soln

Faecal Softeners

DOCUSATE SODIUM

Cap 50 mg

Cap 120 mg

DOCUSATE SODIUM WITH SENNOSIDES

Tab 50 mg with sennosides 8 mg

PARAFFIN

Enema 133 ml

Oral liquid 1 mg per ml

POLOXAMER

Oral drops 10%

Osmotic Laxatives

GLYCEROL

Suppos 1.27 g

Suppos 2.55 g

Suppos 3.6 g

LACTULOSE

Oral liq 10 g per 15 ml

MACROGOL 3350 WITH POTASSIUM CHLORIDE, SODIUM BICARBONATE AND SODIUM CHLORIDE

Restricted
Either:
1. *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; or*
2. *For short-term use for faecal disimpaction.*

Powder for oral soln 6.563 g with potassium chloride 23.3 mg, sodium bicarbonate 89.3 mg and sodium chloride 175.4 mg

Powder for oral soln 13.125 g with potassium chloride 46.6 mg, sodium bicarbonate 178.5 mg and sodium chloride 350.7 mg

SODIUM CITRATE WITH SODIUM LAURYL SULPHOACETATE

Enema 90 mg with sodium lauryl sulphoacetate 9 mg per ml, 5 ml

SODIUM PHOSPHATE WITH PHOSPHORIC ACID

Enema 10% with phosphoric acid 6.58%

Stimulant Laxatives

BISACODYL

Tab 5 mg

Suppos 5 mg

Suppos 10 mg

DANTHRON WITH POLOXAMER

Restricted
Only for the prevention or treatment of constipation in the terminally ill

Oral liq 25 mg with poloxamer 200 mg per 5 ml

Oral liq 75 mg with poloxamer 1 g per 5 ml

SENNOSIDES

Tab 7.5 mg

Metabolic Disorder Agents

ARGININE

Powder

Inf 600 mg per ml, 25 ml

BETAINE

Restricted – *Metabolic Disorders Physicians, Metabolic Disorders Dietitians*

Powder

HAEM ARGINATE

Inj 25 mg per ml, 10 ml ampoule

IMIGLUCERASE

Restricted
Only for use in patients with approval by the Gaucher's Treatment Panel

Inj 40 iu per ml, 5 ml vial

Inj 40 iu per ml, 10 ml vial

L-CARNITINE

Restricted – *Metabolic Disorders Physicians, Metabolic Disorders Dietitians, Neurologists*

Cap 500 mg

Inj 200 mg per ml, 5 ml

Oral soln 500 mg per 15 ml

SODIUM BENZOATE

Cap 500 mg

Inj 20%

Powder

Soln 100 mg per ml

SODIUM PHENYLBUTYRATE

Inj 200 mg per ml, 10 ml

Oral liq 250 mg per ml

Tab 500 mg

TRIENTINE DIHYDROCHORIDE

Cap 300 mg

Mouth and Throat

BENZYDAMINE HYDROCHLORIDE

Soln 0.15%

Spray 0.15%

BENZYDAMINE HYDROCHLORIDE WITH CETYLPYRIDINIUM CHLORIDE

Lozenge 3 mg with cetylpyridinium chloride 1.33 mg

CARBOXYMETHYLCELLULOSE

Oral spray

CHLORHEXIDINE GLUCONATE

Mouthwash 0.2%

CHOLINE SALICYLATE WITH CETALKONIUM CHLORIDE

Adhesive gel 8.7% with cetalkonium chloride 0.01%

DICHLOROBENZYL ALCOHOL WITH AMYLMETACARESOL

Lozenge 1.2 mg with amylmetacresol 0.6 mg

HYDROGEN PEROXIDE

Soln 10 vol

SODIUM CARBOXYMETHYLCELLULOSE WITH PECTIN AND GELATINE

Paste

Powder

THYMOL GLYCERIN

Compound, BPC

TRIAMCINOLONE ACETONIDE

0.1% in dental paste USP

Products proposed not to be included

The following products were considered as part of the review of this section, and we are proposing that they not be listed in Part II of Section H at this time. Please note that this would not prevent them from being considered for inclusion at a later date.

Cetylpyridinium chloride (lozenge, mouthwash)

Cetylpyridinium chloride with benzocaine (mouthwash)

Chlorpropamide

Cisapride

Dichlorobenzyl alcohol with amylmetacresol and lignocaine (lozenge)

Enoloxone with povidone and sodium hyaluronate (gel)

Famotidine

Hamamelis extract

Hypromellose sodium (gel)

Insulin detemir

Orlistat

Omeprazole with amoxycillin and clarithromycin

Peppermint oil

Phentermine

Propantheline bromide

Rifaximin

Sevelamer hydrochloride

Sitagliptin

Sterculia

Zinc oxide with peru balsam

Please note that we are proposing to exclude famotidine because supply of this product has recently been discontinued.

We are also proposing that the following products not be included. Please note that for each of these, we are proposing that other presentations or strengths would be included in this section.

Aluminium hydroxide with magnesium hydroxide and simeticone

Oral liq 400 mg 400 mg with magnesium hydroxide 400 mg and simeticone 30 mg per 5 ml

Diazoxide

Cap 50 mg

Docusate sodium

Enema 18%

Macrogol 3350 with potassium chloride, sodium bicarbonate, sodium chloride and sodium sulphate

Powder for oral soln 856.92 mg with potassium chloride 112.5 mg, sodium bicarbonate 25.32 mg, sodium chloride 22 mg and sodium sulphate 84.81 mg per g

Simeticone

Cap 100 mg

Sodium alginate with sodium bicarbonate and calcium carbonate

Tab 250 mg with sodium bicarbonate 133.5 mg and calcium carbonate 80 mg tablets

Sodium phosphate with phosphoric acid

Oral liq 16.4% with phosphoric acid 25.14%

Ursodeoxycholic acid

Cap 300 mg

Oral liq 50 mg per ml

Biologic agents

In relation to the proposed listing of adalimumab and infliximab, this list relates only to their use in gastroenterology. We will be addressing use of these in other specialities in other consultation documents.

In particular, please note that infliximab is also included in the Respiratory System and Allergies and the Sensory Organs therapeutic groups, which are also the subject of consultation at this point in time

Proposed change to community pharmaceutical funding

As part of this proposal, we are also proposing to list the following pharmaceutical in the community (Section B of the Pharmaceutical Schedule) from January 2013 as follows (price and subsidy are ex-manufacturer, and exclusive of GST).

Chemical	Formulation	Brand	Pack size	Price and subsidy
L-ornithine L-aspartate	Grans for oral liquid 3 g	Hepa-Merz	100	$427.61

L-ornithine L-aspartate would be subject to the following Special Authority criteria:

Special Authority for Subsidy

Initial application only from a gastroenterologist. Approvals valid without further renewal unless notified where the patient has chronic hepatic encephalopathy which has not responded to treatment with lactulose.

We note that this is an unregistered medicine, and would be supplied in accordance with section 29 of the Medicines Act 1981.

L-ornithine L-aspartate is currently funded for use in the community through the Discretionary Community Supply provisions in Section H of the Pharmaceutical Schedule. Listing in Section B would enable patients to have this product dispensed from their regular community pharmacy.

We note that there are other products in this therapeutic group that could be considered for subsidisation in the community, such as diazoxide, bismuth and trientene. We are currently considering some of these items further, and may be consulting on subsidising additional items through community pharmacies in the coming months.

INFECTIONS

Antibacterials

Aminoglycosides

AMIKACIN

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Respiratory Physicians*

Inj 250 mg per ml, 2 ml
Inj 25 mg in 5 ml syringe
Inj 50 mg in 10 ml syringe
Inj 75 mg in 5 ml syringe

GENTAMICIN SULPHATE

Inj 10 mg per ml, 1 ml
Inj 40 mg per ml, 2 ml

PAROMOMYCIN

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Cap 250 mg

STREPTOMYCIN

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Respiratory Physicians*

Inj 1 g

TOBRAMYCIN

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Respiratory Physicians*

Inj 40 mg per ml, 2 ml
Inj 100 mg per ml, 5 ml

Carbapenems

ERTAPENEM

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Inj 1 g

IMIPENEM WITH CILASTATIN

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Inf 500 mg with 500 mg cilastatin

MEROPENEM

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Inj 500 mg
Inj 1 g

Cephalosporins and Cephamycins (1st Generation)

CEFALEXIN MONOHYDRATE

Cap 500 mg
Grans for oral liq 125 mg per 5 ml
Grans for oral liq 250 mg per 5 ml

CEFAZOLIN SODIUM

Inj 500 mg
Inj 1 g

Cephalosporins and Cephamycins (2nd Generation)

CEFACLOR MONOHYDRATE

Cap 250 mg
Grans for oral liq 125 mg per 5 ml

CEFOXITIN SODIUM

Inj 1 g

CEFUROXIME AXETIL

Tab 250 mg

CEFUROXIME SODIUM

Inj 750 mg
Inj 1.5 g

Cephalosporins and Cephamycins (3rd Generation)

CEFOTAXIME

Inj 500 mg
Inj 1 g

CEFTAZIDIME

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Inj 500 mg
Inj 1 g
Inj 2 g

CEFTRIAXONE SODIUM

Inj 500 mg
Inj 1 g
Inj 2 g

Cephalosporins and Cephamycins (4th Generation)

CEFEPIME

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Inj 1 g
Inj 2 g

Macrolides

AZITHROMYCIN

Restricted
Must meet community criteria - refer to notes at end

Tab 250 mg
Tab 500 mg
Oral liq 200 mg per 5 ml

CLARITHROMYCIN

Restricted
<u>Tab 250 mg and oral liquid</u>
1. Atypical mycobacterial infection; or
2. Mycobacterium tuberculosis infection where there is drug resistance or intolerance to standard pharmaceutical agents.
<u>Tab 500 mg</u>
1. Helicobacter pylori eradication.
<u>Infusion</u>
1. Atypical mycobacterial infection; or
(continued…)

2. *Mycobacterium tuberculosis infection where there is drug resistance or intolerance to standard pharmaceutical agents; or*
3. *Community-acquired pneumonia (clarithromycin is not to be used as the first-line macrolide).*

Tab 250 mg

Tab 500 mg

Grans for oral liq 125 mg per 5 ml

Inf 500 mg

ERYTHROMYCIN ETHYL SUCCINATE

Tab 400 mg

Grans for oral liq 200 mg per 5 ml

Grans for oral liq 400 mg per 5 ml

ERYTHROMYCIN LACTOBIONATE

Inj 1 g

ERYTHROMYCIN STERATE

Restricted *– continuation only*

Tab 250 mg

Tab 500 mg

ROXITHROMYCIN

Tab 150 mg

Tab 300 mg

Penicillins

AMOXYCILLIN

Cap 250 mg

Cap 500 mg

Grans for oral liq 125 mg per 5 ml

Grans for oral liq 250 mg per 5 ml

Inj 250 mg

Inj 500 mg

Inj 1 g

AMOXYCILLIN CLAVULANATE

Tab amoxycillin 500 mg with potassium clavulanate 125 mg

Grans for oral liq amoxycillin 125 mg with potassium clavulanate 31.25 mg per 5 ml

Grans for oral liq amoxycillin 250 mg with potassium clavulanate 62.5 mg per 5 ml

Inj amoxycillin 500 mg with potassium clavulanate 100 mg

Inj amoxycillin 1000 mg with potassium clavulanate 200 mg

BENZATHINE BENZYLPENICILLIN

Inj 1.2 mega u per 2.3 ml (900 mg)

BENYLPENICILLIN SODIUM (PENICILLIN G)

Inj 1 mega u (600 mg)

FLUCLOXACILLIN SODIUM

Cap 250 mg

Cap 500 mg

Grans for oral liq 125 mg per 5 ml

Grans for oral liq 250 mg per 5 ml

Inj 250 mg

Inj 500 mg

Inj 1 g

PHENOXYMETHYLPENICILLIN (PENICILLIN V)

Cap 250 mg

Cap 500 mg

Grans for oral liq 125 mg per 5 ml

Grans for oral liq 250 mg per 5 ml

PIPERACILLIN WITH TAZOBACTAM

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Respiratory Physicians*

Inj 4 g with tazobactam 0.5 g

PROCAINE PENICILLIN

Inj 1.5 mega u

TICARCILLIN WITH CLAVULANIC ACID

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Respiratory Physicians*

Inj 3 g with clavulanic acid 0.1 mg

Quinolones

CIPROFLOXACIN

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Tab 250 mg

Tab 500 mg

Tab 750 mg

Oral liq 250 mg per 5 ml

Oral liq 500 mg per 5 ml

Inf 2 mg per ml, 100 ml

MOXIFLOXACIN

Restricted *- Infectious Disease Physicians, Clinical Microbiologists*

Any of the following:

1. *Active tuberculosis, with any of the following:*
   - 1.1. *Documented resistance to one or more first-line medications; or*
   - 1.2. *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*
   - 1.3. *Impaired visual acuity (considered to preclude ethambutol use); or*
   - 1.4. *Significant pre-existing liver disease or hepatotoxicity from tuberculosis medications; or*
   - 1.5. *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; or*

(continued…)

3. Immunocompromised patient with pneumonia that is unresponsive to first-line treatment; or
4. Pneumococcal pneumonia with proven resistance to other antibiotics.

Tab 400 mg

Inf 400 mg per 250 ml

NORFLOXACIN

Restricted
For uncomplicated urinary tract infections that are unresponsive to a first line agent, or with proven resistance to first line agents.

Tab 400 mg

Tetracyclines

DEMECLOCYCLINE HYDROCHLORIDE

Cap 150 mg

DOXYCYCLINE

Restricted
Tab 50 mg – continuation only

Tab 50 mg

Tab 100 mg

Inj 5 mg per ml, 20 ml

MINOCYCLINE HYDROCHLORIDE

Restricted
Cap 100 mg – continuation only

Tab 50 mg

Cap 100 mg

TETRACYCLINE

Tab 250 mg

TIGECYCLINE

***Restricted** – Infectious Disease Physicians, Clinical Microbiologists*

Inj 50 mg

Other Antibiotics

AZTREONAM

***Restricted** – Infectious Disease Physicians, Clinical Microbiologists*

CHLORAMPHENICOL

***Restricted** – Infectious Disease Physicians, Clinical Microbiologists*

Inj 1 g

CLINDAMYCIN HYDROCHLORIDE

***Restricted** – Infectious Disease Physicians, Clinical Microbiologists*

Cap 150 mg

Oral liq 75 mg per 5 ml

CLINDAMYCIN PHOSPHATE

***Restricted** – Infectious Disease Physicians, Clinical Microbiologists*

Inj 150 mg per ml, 4 ml

COLISTIN SULPHOMETHATE (COLESTIMETHATE)

***Restricted** – Infectious Disease Physicians, Clinical Microbiologists, Respiratory Physicians*

Inj 150 mg per ml, 1 ml

CO-TRIMOXAZOLE

Tab trimethoprim 80 mg and sulphamethoxazole 400 mg

Oral liq trimethoprim 40 mg and sulphamethoxazole 200 mg per 5 ml

Inj trimethoprim 80 mg and sulphamethoxazole 400 mg per 5 ml

DAPTOMYCIN

***Restricted** – Infectious Disease Physicians, Clinical Microbiologists*

Inj 350 mg

FUSIDIC ACID

Restricted
Tablets - Infectious Disease Physicians, Clinical Microbiologists

Tab 250 mg

Crm 2%

Oint 2%

HEXAMINE HIPPURATE

Tab 1 g

HYDROGEN PEROXIDE

Crm 1%

LINCOMYCIN

***Restricted** – Infectious Disease Physicians, Clinical Microbiologists*

Inj 300 mg per ml, 2 ml

LINEZOLID

***Restricted** – Infectious Disease Physicians, Clinical Microbiologists*

Tab 600 mg

Oral liq 20 mg per ml

Inf 2 mg per ml, 300 ml

MUPIROCIN

Oint 2%

Nasal oint 2%

NITROFURANTOIN

Tab 50 mg

Tab 100 mg

SILVER SULPHADIAZINE

Crm 1%

SULFADIAZINE SODIUM

***Restricted** – Infectious Disease Physicians, Clinical Microbiologists, Maternal-Foetal Medicine Specialists*

Tab 500 mg

TEICOPLANIN

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Inj 400 mg

TRIMETHOPRIM

Tab 100 mg

Tab 300 mg

VANCOMYCIN

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Inj 50 mg per ml, 10 ml

Antifungals

Imidazoles

CLOTRIMAZOLE

Restricted
Solution 1% - continuation only

Crm 1%

Soln 1%

Vaginal crm 1%, with applicator

Vaginal crm 2%, with applicator

ECONAZOLE NITRATE

Restricted
Cream - continuation only

Crm 1%

Foaming solution 1%

KETOCONAZOLE

Restricted
Tablets – Infectious Disease Physicians, Clinical Microbiologists, Dermatologists

Tab 200 mg

Shampoo 2%

MICONAZOLE

Oral gel 20 mg per g

MICONAZOLE NITRATE

Restricted
Lotion - continuation only

Crm 2%

Lotion 2%

Tincture 2%

Vaginal crm 2% with applicator

Polyene Antimycotics

AMPHOTERICIN B

Restricted (infusions) *- Infectious Disease Physicians, Clinical Microbiologists, Haematologists, Oncologists, Transplant Specialists and Respiratory Physicians*

Either:

1. *Proven or probable invasive fungal infection, to be prescribed under an established protocol; or*
2. *Both:*
   - 2.1. *Possible invasive fungal infection; and*
   - 2.2 *A multidisciplinary team (including an Infectious Disease physician or a Clinical Microbiologist) considers the treatment to be appropriate.*

Inf 50 mg

Inf (liposomal) 50 mg

Lozenge 10 mg

NYSTATIN

Cap 500,000 u

Tab 500,000 u

Oral liquid 100,000 u per ml

Crm 100,000 u per g

Vaginal crm 100,000 u per 5 g with applicator(s)

Triazoles

FLUCONAZOLE

Restricted *- Consultants*

Cap 50 mg

Cap 150 mg

Cap 200 mg

Oral liquid 50 mg per 5 ml

Inf 2 mg per ml, 50 ml

ITRACONAZOLE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Clinical Immunologists*

Cap 100 mg

Oral liquid 10 mg per ml

POSACONAZOLE

Restricted *- Haematologist or Infectious Disease Physician*

Initiation (6 weeks' treatment):

Both:

1. *Either:*
   - 1.1. *Patient has acute myeloid leukaemia; or*
   - 1.2. *Patient is planned to receive a stem cell transplant and is at high risk for aspergillus infection; and*
2. *Patient is to be treated with high dose remission induction therapy or re-induction therapy*

Continuation (6 weeks' treatment):

Both:

1. *Patient has previously received posaconazole prophylaxis during remission induction therapy; and*
2. *Any of the following:*
   - 2.1 *Patient is to be treated with high dose remission re-induction therapy; or*
   - 2.2 *Patient is to be treated with high dose consolidation therapy; or*
   - 2.3 *Patient is receiving a high risk stem cell transplant.*

Oral liquid 40 mg per ml

VORICONAZOLE

Restricted *- Haematologist, Infectious Disease Physician or Clinical Microbiologist*

<u>Proven or probable aspergillus infection</u>

Both:

1. *Patient is immunocompromised; and*
2. *Patient has proven or probable invasive aspergillus infection.*

<u>Possible aspergillus infection</u>

All of the following:

1. *Patient is immunocompromised; and*
2. *Patient has possible invasive aspergillus infection; and*
3. *A multidisciplinary team (including an Infectious Disease Physician) considers the treatment to be appropriate.*

<u>Resistant candidasis infections and other moulds</u>

All of the following:

1. *Patient is immunocompromised, and*
2. *Either:*
   - 2.1. *Patient has fluconazole resistant candidasis; or*
   - 2.2. *Patient has mould strain such as Fusarium spp. and Scedosporium spp; and*
3. *A multidisciplinary team (including an Infectious Disease Physician or Clinical Microbiologist) considers the treatment to be appropriate.*

Tab 50 mg

Tab 200 mg

Oral liq 40 mg per ml

Inf 200 mg

Other Antifungals

AMOROLFINE

Restricted *– continuation only*

Nail solution 5%

CASPOFUNGIN

Restricted *- Infectious Disease Physicians, Clinical Microbiologists, Haematologists, Oncologists, Transplant Specialists and Respiratory Physicians*

Either:

1. *Proven or probable invasive fungal infection, to be prescribed under an established protocol; or*
2. *Both:*
   - 2.1. *Possible invasive fungal infection; and*
   - 2.2 *A multidisciplinary team (including an Infectious Disease physician or a Clinical Microbiologist) considers the treatment to be appropriate.*

Inf 50 mg

Inf 70 mg

CICLOPIROX OLAMINE

Restricted

<u>Solution 1%</u> - continuation only

Nail solution 8%

Solution 1%

FLUCYTOSINE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Cap 500 mg

TERBINAFINE

Tab 250 mg

Antimycobacterials

Antileprotics

CLOFAZAMINE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Dermatologists*

Cap 50 mg

DAPSONE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Dermatologists*

Tab 25 mg

Tab 100 mg

Antituberculotics

CYCLOSERINE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Respiratory Physicians*

Cap 250 mg

ETHAMBUTOL HYDROCHLORIDE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Respiratory Physicians*

Tab 100 mg

Tab 400 mg

ISONIAZID

Restricted *– Internal Medicine Physicians, Clinical Microbiologists, Dermatologists, Public Health Physicians*

Tab 100 mg

ISONIAZID WITH RIFAMPICIN

Restricted *– Internal Medicine Physicians, Clinical Microbiologists, Dermatologists, Public Health Physicians*

Tab 100 mg with rifampicin 150 mg

Tab 150 mg with rifampicin 300 mg

PARA-AMINOSALICYLIC ACID

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Respiratory Physicians*

Grans for oral liq 4 g

PROTIONAMIDE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Respiratory Physicians*

Tab 250 mg

PYRAZINAMIDE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Respiratory Physicians*

Tab 500 mg

RIFABUTIN

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Respiratory Physicians, Gastroenterologists*

Cap 150 mg

RIFAMPICIN

Restricted *– Internal Medicine Physicians, Clinical Microbiologists, Dermatologists, Paediatricians, Dermatologists and Public Health Physicians*

Cap 150 mg

Cap 300 mg

Tab 600 mg

Oral liq 100 mg per 5 ml

Inf 600 mg

Antiparasitics

Anthelmintics

ALBENDAZOLE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Tab 200 mg

IVERMECTIN

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Dermatologists*

Tab 3 mg

MEBENDAZOLE

Tab 100 mg

Oral liq 100 mg per 5 ml

PRAZIQUANTEL

Tab 600 mg

Antiprotozoals

ARTEMETHER WITH LUMEFANTRINE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Tab 20 mg with lumefantrine 120 mg

ARTESUNATE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Inj 60 mg vial

ATOVAQUONE WITH PROGUANIL HYDROCHLORIDE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Tab 250 mg with proguanil hydrochloride 100 mg

CHLOROQUINE PHOSPHATE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Dermatologists, Rheumatologists*

Tab 250 mg

MEFLOQUINE HYDROCHLORIDE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Dermatologists, Rheumatologists*

Tab 250 mg

METRONIDAZOLE

Tab 200 mg

Tab 400 mg

Oral liq benzoate 200 mg per 5 ml

Suppos 500 mg

Topical gel 0.75%

Inf 5 mg per ml, 100 ml

NITAZOXANIDE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Tab 500 mg

Oral liq 100 mg per 5 ml

ORNIDAZOLE

Tab 500 mg

PENTAMIDINE ISETHIONATE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Inj 300 mg

PRIMAQUINE PHOSPHATE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Tab 7.5 mg

PYRIMETHAMINE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Maternal-Foetal Medicine Specialists*

Tab 25 mg

QUININE HYDROCHLORIDE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Inj 300 mg per ml, 2 ml

QUININE SULPHATE

Tab 300 mg

SODIUM STIBOGLUCONATE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Inj 100 mg per ml, 1 ml

SPIRAMYCIN

Restricted *– Maternal-Foetal Medicine Specialists*

Inj 500 mg

Ectoparasiticides

GAMMA BENZENE HEXACHLORIDE

Crm 1%

MALATHION (MALDISON)

Lotn 0.5%

Shampoo 1%

PERMETHRIN

Crm 5%

Lotn 5%

Antiretrovirals

Restricted
Must meet community Special Authority criteria

Non-Nucleosides Reverse Transcriptase Inhibitors

EFAVIRENZ

Tab 50 mg

Tab 200 mg

Tab 600 mg

Oral liq 30 mg per ml

ETRAVIRINE

Tab 100 mg

NEVIRAPINE

Oral suspension 10 mg per ml

Tab 200 mg

Nucleosides Reverse Transcriptase Inhibitors

ABACAVIR SULPHATE

Oral liq 20 mg per ml

Tab 300 mg

ABACAVIR SULPHATE WITH LAMIVUDINE

Tab 600 mg with lamivudine 300 mg

DIDANOSINE [DDI]

Cap 125 mg

Cap 200 mg

Cap 250 mg

Cap 400 mg

EMTRICITABINE

Cap 200 mg

LAMIVUDINE

Oral liq 10 mg per ml

Tab 150 mg

STAVUDINE

Cap 30 mg

Cap 40 mg

Powder for oral soln 1 mg per ml

ZIDOVUDINE [AZT]

Cap 100 mg

Oral liq 10 mg per ml

Inf 10 mg per ml, 20 ml

ZIDOVUDINE [AZT] WITH LAMIVUDINE

Tab 300 mg with lamivudine 150 mg

Protease Inhibitors

ATAZANAVIR SULPHATE

Cap 150 mg

Cap 200 mg

DARUNAVIR

Tab 400 mg

Tab 600 mg

INDINAVIR

Cap 200 mg

Cap 400 mg

LOPINAVIR WITH RITONAVIR

Oral liq 80 mg with ritonavir 20 mg per ml

Tab 100 mg with ritonavir 25 mg

Tab 200 mg with ritonavir 50 mg

RITONAVIR

Tab 100 mg

Oral liq 80 mg per ml

Strand Transfer Inhibitors

RALTEGRAVIR POTASSIUM

Tab 400 mg

HIV Fusion Inhibitors

ENFUVIRTIDE

Inj 90 mg per ml, 1.1 ml

Antivirals

Hepatitis B

ADEFOVIR DIPIVOXIL

Restricted
Must meet community Special Authority criteria

Tab 10 mg

ENTECAVIR

Restricted
Must meet community Special Authority criteria

Tab 0.5 mg

LAMIVUDINE

Restricted
Must meet community Special Authority criteria

Oral liq 5 mg per ml

Tab 100 mg

TENOFOVIR DISOPROXIL FUMARATE

Restricted
Must meet community Special Authority criteria

Tab 300 mg

Herpesviridae

ACICLOVIR

Tab dispersible 200 mg

Tab dispersible 400 mg

Tab dispersible 800 mg

Inf 25 mg per ml, 10 ml

CIDOFOVIR

Restricted *– Infectious Disease Physicians, Clinical Microbiologists, Otolaryngologists, Oral Surgeons*

Inj 75 mg pe ml, 5 ml

FOSCARNET SODIUM HEXAHYDRATE

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Inf 24 mg per ml, 250 ml

GANCICLOVIR

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Inf 500 mg

VALACICLOVIR

Restricted
Must meet community Special Authority criteria

Tab 500 mg

VALGANCICLOVIR

Restricted
Must meet community Special Authority criteria

Tab 450 mg

Immune Modulators

INTERFERON ALPHA-2A

Inj 3 m iu prefilled syringe

Inj 6 m iu prefilled syringe

Inj 9 m iu prefilled syringe

INTERFERON ALPHA-2B

Inj 18 m iu, 1.2 ml multidose pen

Inj 30 m iu, 1.2 ml multidose pen

Inj 60 m iu, 1.2 ml multidose pen

INTERFERON GAMMA

Restricted *– Infectious Disease Physicians, Clinical Microbiologists*

Inj 100 µg in 0.5 ml vial

PEGYLATED INTERFERON ALPHA-2A

Restricted
Must meet community Special Authority criteria

Inj 135 µg prefilled syringe

Inj 180 µg prefilled syringe

PEGYLATED INTERFERON ALPHA-2A WITH RIBAVIRIN

Restricted
Must meet community Special Authority criteria

Inj 135 µg prefilled syringe with ribavirin tab 200 mg

Inj 180 µg prefilled syringe with ribavirin tab 200 mg

Products proposed not to be included

The following products were considered as part of the review of this section, and we are proposing that they not be listed in Part II of Section H at this time. Please note that this would not prevent them from being considered for inclusion at a later date.

Bifonazole

Capreomycin

Cefamandole nafate

Cefpirome

Cefpodoxime proxetil

Cefradine

Doripenem

Ethionamide

Fosfomycin

Gatofloxacin

Levamisole

Levofloxacin

Lymecycline

Malathion with permethrin

Melaleuca oil

Miconazole nitrate with zinc

Neomycin

Netilmicin

Oseltamivir

Palivizumab

Piperacillin

Pivmecillinam

Pyrantel embonate

Quinupristin with dalfopristin

Quinine dihydrochloride

Temocillin

Tinidazole

Zanamavir

We are also proposing that the following products not be included. Please note that for each of these, we are proposing that other presentations or strengths would be included in this section.

Aciclovir

Cream 5%

Amoxycillin

Drops 125 mg per ml, 1.25 ml

Cefotaxime

Inj 2 g

Cefuroxime sodium

Inj 250 mg

Ciclopirox olamine

Cream 1%

Clotrimazole

Vaginal cream 10%

Pessaries 100 mg

Pessaries 500 mg

Entecavir

Tab 1 mg

Erythromycin lactobionate

Inj 300 mg

Flucytosine

Cap 100 mg

Inj 2 mg per ml, 50 ml

Inf 10 mg per ml, 250 ml

Fusidic acid

Inj 50 mg per ml, 10 ml

Ganciclovir

Cap 250 mg

Ivermectin

Tab 6 mg

Ketoconazole

Cream 2%

Shampoo 1%

Linezolid

Tab 250 mg

Mebendazole

Chocolate squares, 100 mg

Metronidazole

Vaginal gel 0.75%

Topical gel 0.5%

Suppos 1 g

Miconazole nitrate

Dusting powder 2%

Spray powder 2%

Mupirocin

Inj 400 mg

Praziquantel

Tab 500 mg

Stavudine

Cap 20 mg

Terbinafine

Cream 1%

Gel 1%

Tobramycin

Nebuliser soln, 60 mg per ml, 5 ml ampoule

Some of these products are currently included in Part II of Section H, because PHARMAC has established national pricing contracts for them. As part of this proposal PHARMAC would delist the following products from Section H with effect from 1 July 2013:

Amoxycillin, drops 100 mg per ml (Ospamox)

Cefotaxime, inj 2 g (Cefotaxime Sandoz)

Doripenem, vial for infusion 500 mg (Doribax)

Erythromycin lactobionate, inj 300 mg (Mayne)

Miconazole nitrate, powder 2% (Daktarin)

The applicable national contracts would be terminated in relation to these products (but would continue in force in relation to any other products) if this proposal is implemented.

Azithromycin

We are proposing that prescribing of azithromycin be subject to the same restrictions that apply to its subsidisation in the community. Please note that we have recently consulted on changes to the criteria for azithromycin oral liquid. If you would like a copy of that consultation document, please let us know.

Prescriber restrictions

Please note that it is our intention that a prescriber-level restriction would mean that other hospital-based prescribers (that is, other than those specified) would still be able to prescribe those agents, but would need either:

(a) to be using that agent in accordance with their hospital's protocols or guidelines; or
(b) to obtain a recommendation from a specified prescriber for its use.

Proposed changes to community pharmaceutical funding

To create more alignment with the community Pharmaceutical Schedule (section B), we are proposing to list some new items in Section B, and to amend the subsidy restrictions for others. We expect that these changes will be made as soon as practicable – likely from January 2013.

New listings

As part of this proposal, we are also proposing that the following pharmaceuticals would be subsidised in the Infections therapeutic group in the community (Section B of the Pharmaceutical Schedule) as follows (prices and subsidised are ex-manufacturer, and exclusive of GST):

Chemical	Formulation	Brand or Manufacturer	Pack size	Price and subsidy
Antiparasitics				
Albendazole	Tab 200 mg	GSK	28	$1,381.42
Primaquine phosphate	Tab 7.5 mg	Primacin	56	$117.00
Pyrimethamine	Tab 25 mg	Daraprim	30	$26.14
Praziquantel	Tab 600 mg	Biltricide	8	$50.40
Antiretrovirals				
Efavirenz	Oral liq 30 mg per ml	Stocrin	180 ml OP	$145.79
Stavudine	Powder for oral soln 1 mg per ml	Zerit	200 ml OP	$100.76
Antimycobacterials				
Clofazamine	Cap 50 mg	Lamprene	100	$197.50
Cycloserine	Cap 250 mg	King	100	$1,140.63
Protionamide	Tab 250 mg	Peteha	100	$346.59
Antifungals				
Itraconazole	Oral liq 10 mg per ml	Sporanox	150 ml OP	$141.80
Antibacterials				
Sulfadiazine sodium	Tab 500 mg	Wockhardt	56	$221.00

Albendazole, primaquine phosphate, pyrimethamine, efavirenz liquid, stavudine liquid, clofazamine, cycloserine, protionamide and sulfadiazine sodium are not registered medicines in New Zealand, and therefore would be supplied in accordance with section 29 of the Medicines Act.

We note that there are other products in this therapeutic group that could be considered for subsidisation in the community. We are currently considering some of these items further, and may be consulting on subsidising additional items through community pharmacies in the coming months.

Albendazole would be subject to the following Special Authority restriction:

> **Special Authority for Subsidy**
>
> Initial application from Infectious Disease Physician or Clinical Microbiologist. Approvals valid for six months where the patient has hydatids.
>
> Renewal from Infectious Disease Physician or Clinical Microbiologist. Approvals valid for six months where the treatment remains appropriate and the patient is benefitting from the treatment.

Primaquine would be subject to the following Special Authority restriction:

> **Special Authority for Subsidy**
>
> Initial application from an Infectious Disease Physician or Clinical Microbiologist. Approvals valid for one month for applications meeting the following criteria:
>
> 1 The patient has vivax or ovale malaria; and
> 2 Primaquine is to be given for a maximum of 21 days.

Pyrimethamine and sulphadiazine sodium would be subject to the following Special Authority criteria:

> **Special Authority for Subsidy**
>
> Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:
>
> Any of the following:
>
> 1 For the treatment of toxoplasmosis in patients with HIV for a period of 3 months; or
> 2 For pregnant patients for the term of the pregnancy; or
> 3 For infants with congenital toxoplasmosis until 12 months of age.

The oral liquid forms of efavirenz and stavudine would be subject to the Special Authority criteria that apply other antiretrovirals.

Clofazamine would be subject to the following prescribing restriction:

> Retail pharmacy-Specialist
>
> Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or dermatologist

Cycloserine and protionamide would be subject to the following prescriber restriction:

> Retail pharmacy-Specialist
>
> Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or respiratory physician

Itraconazole oral liquid would be subject to the following Special Authority restriction:

> **Special Authority for Subsidy**
>
> Initial application from any relevant practitioner. Approvals valid for six months where the patient has a congenital immune deficiency.
>
> Renewal from any relevant practitioner. Approvals valid for six months where the treatment remains appropriate and the patient is benefitting from the treatment.

Restriction changes

To better align the funding restrictions in the community with prescribing restrictions in DHB hospitals, we are proposing to make the following changes to restrictions on several currently subsidised pharmaceuticals (additions in bold, deletions in strikethrough):

The restriction applying to clindamycin (cap hydrochloride 150 mg) would be amended as follows:

> Maximum of 4 cap per prescription; can be waived by endorsement – Retail pharmacy-Specialist. **Specialist must be an infectious disease physician or a clinical microbiologist**

The restriction applying to colistin sulphomethate would be amended as follows:

~~Retail pharmacy-Specialist –~~ Subsidy by endorsement

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

The restrictions apply to clindamycin (inj phosphate 150 mg per ml, 4 ml), fusidic acid (tab 250 mg) and lincomycin would be amended as follows (additions in bold):

Retail pharmacy-Specialist

Prescriptions must be written by, or on the recommendation of, an infectious disease physician or a clinical microbiologist

The restriction applying to itraconazole (cap 100 mg) would be amended as follows (additions in bold):

~~Retail pharmacy-Specialist~~

Subsidy by endorsement

Funded for tinea vesicolor where topical treatment has not been successful and diagnosis has been confirmed by mycology, or for tinea unguium where terbenafine has not been successful in eradication or the patient is intolerant to terbenafine and diagnosis has been confirmed by mycology and the prescription is endorsed accordingly. Can be waived by endorsement – Retail pharmacy - Specialist. Specialist must be an infectious disease physician, clinical microbiologist or dermatologist.

The restriction applying to ketoconazole (tab 200 mg) would be amended as follows (additions in bold):

Retail pharmacy-Specialist

Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or dermatologist

The restrictions applying to interferon alpha-2a and interferon alpha-2b would be amended as follows (additions in bold):

PCT – Retail pharmacy-Specialist

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

Dapsone would have the following prescribing restriction added:

Retail pharmacy-Specialist

Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or dermatologist

Ethambutol would have the following prescribing restriction added:

Retail pharmacy-Specialist

Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or respiratory physician

The restriction applying to isoniazid and isoniazid with rifampicin would be amended as follows (additions in bold):

Retail pharmacy-Specialist

Prescriptions must be written by, or on the recommendation of, an internal medicine physician, clinical microbiologist, dermatologist or public health physician

The restriction applying to pyrazinamide would be amended as follows:

Retail pharmacy-Specialist

Prescriptions must be written by, or on the recommendation of, an infectious disease physician, clinical microbiologist or respiratory physician

The restriction applying to rifabutin would be amended as follows:

Retail pharmacy-Specialist

Prescriptions must be written by, or on the recommendation of, an infectious disease physician, respiratory physician or gastroenterologist

The restriction applying to rifampicin would be amended as follows:

For confirmed recurrent Staphylococcus aureus infection in combination with other effective anti-staphylococcal antimicrobial based on susceptibilities and the prescription is endorsed accordingly; can be waived by endorsement – Retail pharmacy – Specialist. Specialist must be an internal medicine physician, clinical microbiologist, dermatologist, paediatrician, or public health physician.

All three strengths of ciprofloxacin tablets would be subject to the following endorsement restriction, and would replace the 'Retail pharmacy-Specialist' restriction that applies to the 750 mg tablet:

Subsidy by endorsement

a) Subsidised only if:
  i. Patient has either
    (a) microbiologically confirmed and clinically significant pseudomonas infection; or
    (b) prostatitis; or
    (c) pyelonephritis; or
    (d) gonorrhoea; or
  ii. Prescription or PSO is written by, or on the recommendation of, an infectious disease physician or a clinical microbiologist; and
b) The prescription or PSO is endorsed accordingly.

The restriction applying to norfloxacin would be replaced as follows:

~~Maximum of 6 tab per prescription; can be waived by endorsement - Retail pharmacy - Specialist.~~

Subsidy by endorsement

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

Products to be delisted

We are also proposing to delist the following items from Section B of the Pharmaceutical Schedule from 1 July 2013:

Chemical	Formulation	Brand(s)
Cefoxitin sodium	Inj 1 g	Mayne
Cefuroxime sodium	Inj 250 mg	Mayne
Cefuroxime sodium	Inj 1.5 g	Mylan / Zinacef
Fusidic acid	Inj 500 mg sodium fusidate per 10 ml	Fucidin

We are also proposing to delist an additional strength of cefuroxime sodium from Section B of the Pharmaceutical Schedule from 1 January 2015:

Chemical	Formulation	Brand(s)
Cefuroxime sodium	Inj 750 mg	m-Cefuroxime

The proposal to delist these items from Section B is based on recommendations from the Anti-Infective Subcommittee that it is not necessary for these items to be subsidised in the community. We note that cefoxitin and cefuroxime sodium (750 mg and 1.5 g) would still remain available for use by DHB hospitals.

RESPIRATORY SYSTEM AND ALLERGIES

Antiallergy Preparations

Allergy Desensitisation

BEE VENOM ALLERGY TREATMENTS

Restricted
Must meet community Special Authority criteria

Maintenance kit - 6 vials 120 mcg freeze dried venom, 6 diluent 1.8 ml

Treatment kit - 1 vial 550 mcg freeze dried venom, 1 diluent 9 ml, 3 diluent 1.8 ml

WASP VENOM ALLERGY TREATMENT

Restricted
Must meet community Special Authority criteria

Treatment kit (paper wasp venom) - 1 vial 500 mcg freeze dried polister venom, 1 diluent 9 ml, 1 diluent 1.8 ml

Treatment kit (yellow jacket venom) - 1 vial 550 mcg freeze dried vespula venom, 1 diluent 9 ml, 1 diluent 1.8 ml

Allergy Prophylactics

BECLOMETHASONE DIPROPIONATE

Aqueous nasal spray 50 mcg per dose

Aqueous nasal spray 100 mcg per dose

BUDESONIDE

Aqueous nasal spray 50 mcg per dose

Aqueous nasal spray 100 mcg per dose

FLUTICASONE PROPIONATE

Aqueous nasal spray 50 mcg per dose

IPRATROPIUM BROMIDE

Aqueous nasal spray 0.03%

SODIUM CROMOGLYCATE

Aqueous nasal spray 4%

Antihistamines

CETIRIZINE HYDROCHLORIDE

Oral liq 1 mg per ml

Tab 10 mg

CHLORPHENIRAMINE MALEATE

Inj 10 mg per ml, 1 ml ampoule

Oral liq 2 mg per 5 ml

CYPROHEPTADINE HYDROCHLORIDE

Tab 4 mg

FEXOFENADINE HYDROCHLORIDE

Tab 60 mg

Tab 120 mg

Tab 180 mg

LORATADINE

Oral liq 1 mg per ml

Tab 10 mg

PROMETHAZINE HYDROCHLORIDE

Inj 25 mg per ml, 2 ml ampoule

Oral liq 5 mg per 5 ml

Tab 10 mg

Tab 25 mg

TRIMEPRAZINE TARTRATE

Oral liq 30 mg per 5 ml

Anticholinergic Agents

IPRATROPIUM BROMIDE

Aerosol inhaler 20 mcg per dose

Nebuliser soln 250 mcg per ml, 1 ml

Nebuliser soln 250 mcg per ml, 2 ml

TIOTROPIUM BROMIDE

Restricted
Must meet community Special Authority criteria

Powder for inhalation 18 mcg per dose

Anticholinergic Agents with Beta-Adrenoceptor Agonists

SALBUTAMOL WITH IPRATROPIUM BROMIDE

Aerosol inhaler 100 mcg with ipratropium bromide 20 mcg per dose

Nebuliser soln 2.5 mg with ipratropium bromide 0.5 mg per 2.5 ml vial

Beta-Adrenoceptor Agonists

SALBUTAMOL

Aerosol inhaler, 100 mcg per dose

Infusion 1 mg per ml, 5 ml ampoule

Inj 500 mcg per ml, 1 ml ampoule

Nebuliser soln 1 mg per ml, 2.5 ml

Nebuliser soln 2 mg per ml, 2.5 ml

Oral liq 2 mg per 5 ml

TERBUTALINE SULPHATE

Powder for inhalation 250 mcg per dose

Inj 0.5 mg per ml, 1 ml amp

Cough Suppressants

PHOLCODINE

Oral liq 1 mg per ml

Decongestants

OXYMETAZOLINE HYDROCHLORIDE

Aqueous nasal spray 0.25 mg per ml

Aqueous nasal spray 0.5 mg per ml

PSEUDOEPHEDRINE HYDROCHLORIDE

Tab 60 mg

SODIUM CHLORIDE

Aqueous nasal spray 6.5 mg per ml

SODIUM CHLORIDE WITH SODIUM BICARBONATE

Soln for nasal irrigation

XYLOMETAZOLINE HYDROCHLORIDE

Aqueous nasal spray 0.05%

Aqueous nasal spray 0.1%

Nasal drops 0.05%

Nasal drops 0.1%

Inhaled Corticosteroids

BECLOMETHASONE DIPROPIONATE

Aerosol inhaler 50 mcg per dose

Aerosol inhaler 100 mcg per dose

Aerosol inhaler 250 mcg per dose

BUDESONIDE

Powder for inhalation 100 mcg per dose

Powder for inhalation 200 mcg per dose

Powder for inhalation 400 mcg per dose

Nebuliser soln 250 mcg per ml, 2 ml

Nebuliser soln 500 mcg per ml, 2 ml

FLUTICASONE

Aerosol inhaler 50 mcg per dose

Aerosol inhaler 125 mcg per dose

Aerosol inhaler 250 mcg per dose

Powder for inhalation 50 mcg per dose

Powder for inhalation 100 mcg per dose

Powder for inhalation 250 mcg per dose

Leukotriene Receptor Antagonists

MONTELUKAST

Restricted

Must meet community Special Authority criteria

Tab 4 mg

Tab 5 mg

Tab 10 mg

Long-Acting Beta-Adrenoceptor Agonists

EFORMOTEROL FUMARATE

Powder for inhalation 6 mcg per dose

Powder for inhalation 12 mcg per dose

SALMETEROL

Aerosol inhaler 25 mcg per dose

Powder for inhalation 50 mcg per dose

Inhaled Corticosteroids with Long-Acting Beta-Adrenoceptor Agonists

BUDESONIDE WITH EFORMOTEROL

Restricted

Must meet community Special Authority criteria

Aerosol inhaler 100 mcg with eformoterol fumarate 6 mcg

Aerosol inhaler 200 mcg with eformoterol fumarate 6 mcg

Powder for inhalation 100 mcg with eformoterol fumarate 6 mcg

Powder for inhalation 200 mcg with eformoterol fumarate 6 mcg

Powder for inhalation 400 mcg with eformoterol fumarate 12 mcg

FLUTICASONE WITH SALMETEROL

Restricted

Must meet community Special Authority criteria

Aerosol inhaler 50 mcg with salmeterol 25 mcg

Aerosol inhaler 125 mcg with salmeterol 25 mcg

Powder for inhalation 100 mcg with salmeterol 50 mcg

Powder for inhalation 250 mcg with salmeterol 50 mcg

Mast Cell Stabilisers

NEDOCROMIL

Aerosol inhaler 2 mg per dose

SODIUM CROMOGLICATE

Aerosol inhaler 5 mg per dose

Powder for inhalation 20 mcg per dose

Methylxanthines

AMINOPHYLLINE

Inj 25 mg per ml, 10 ml ampoule

CAFFEINE CITRATE

Inj 20 mg per ml, 2.5 ml ampoule (caffeine 10 mg per ml)

Oral liq 20 mg per ml (caffeine 10 mg per ml)

THEOPHYLLINE

Oral liq 80 mg per 15 ml

Tab long-acting 250 mg

Mucolytics and Expectorants

DORNASE ALFA

Restricted

Either:

1. *for use in patients with approval by the Cystic Fibrosis Advisory Panel; or*
2. *for use in the treatment of pleural effusion.*

Nebuliser soln 2.5 mg per 2.5 ml ampoule

SODIUM CHLORIDE

Nebuliser soln 7%

Pulmonary Surfactants

BERACTANT

Soln 200 mg per 8 ml vial

PORACTANT ALFA

Soln 120 mg per 1.5 ml vial

Soln 240 mg per 3 ml vial

Respiratory Stimulants

DOXAPRAM

Inj 20 mg per ml, 5 ml vial

Sclerosing Agents

TALC

Powder

Soln (slurry) 100 mg per ml, 50 ml

Tumor Necrosis Factor (TNF) Inhibitors

INFLIXIMAB

Restricted

Both:

1. *Patient has life-threatening pulmonary sarcoidosis that is refractory to other treatments; and*
2. *Treatment is to be prescribed by, or has been recommended by, a physician with expertise in the treatment of pulmonary sarcoidosis.*

Inj 100 mg

Products proposed not to be included

The following products were considered as part of the review of this section, and we are proposing that they not be listed in Part II of Section H at this time. Please note that this would not prevent them from being considered for inclusion at a later date.

Adrenaline (auto-injectors)

Bromhexine hydrochloride

Dextrochlorpheniramine maleate

Dextromethorphan

Diphenhydramine hydrochloride

Guaifenesin

Guaifenesin with bromhexine hydrochloride

Menthol

Omalizumab

Opiate squill

We are also proposing that the following products not be included. Please note that for each of these, we are proposing that other presentations or strengths would be included in this section.

Aminophylline

Tab modified-release 350 mg

Fluticasone with salmeterol

Aerosol inhaler 250 mcg with salmeterol 25 mcg

Powder for inhalation 500 mcg with salmeterol 50 mcg

Pholcodine

Oral liq 2 mg per ml

Oral liq 3 mg per ml

Sodium chloride

Aqueous nasal spray 7.4 mg per ml

Dornase alfa

The issue of dornase alfa in acute settings has been raised through this process. While we are not proposing that this be included in the prescribing criteria at this time, we intend to consider this further over the coming months, and we will be discussing this issue with relevant parties.

Infliximab

Please note that we will be addressing the use of infliximab in other specialities in other consultation documents; it is also included in the Sensory Organs and the Alimentary Tract and Metabolism therapeutic groups, which are the subject of consultation at this point in time.

Desensitisation products

Bee and wasp venom desensitisation kits, which are subsidised in the community, have been proposed for inclusion in Section H. We are intending to review the use of other desensitisation products in DHB hospitals, and will be discussing this issue with relevant parties as this review progresses.

SENSORY ORGANS

Ear Preparations

ACETIC ACID WITH PROPYLENE GLYCOL

Ear drops 2.3% with propylene glycol 2.8%

CHLORAMPHENICOL

Ear drops 0.5%

CIPROFLOXACIN WITH HYDROCORTISONE

Ear drops 0.2% with hydrocortisone 1%

DOCUSATE SODIUM

Ear drops 0.5%

FLUMETASONE PIVALATE WITH CLIOQUINOL

Ear drops 0.02% with clioquinol 1%

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

Ear / Eye Preparations

DEXAMETHASONE WITH FRAMYCETIN AND GRAMICIDIN

Ear/eye drops 500 µg with framycetin sulphate 5 mg and gramicidin 50 µg per ml

FRAMYCETIN SULPHATE

Ear/eye drops 0.5%

Eye Preparations

Anti-Infective Preparations

ACICLOVIR

Eye oint 3%

CHLORAMPHENICOL

Eye drops 0.5%

Eye drops 0.5%, single dose

Eye oint 1%

CIPROFLOXACIN

Eye drops 0.3%

DIBROMPROPAMIDINE (PROPAMIDINE) ISETHIONATE

Eye drops 0.1%

FUSIDIC ACID

Eye drops 1%

GENTAMICIN SULPHATE

Eye drops 0.3%

NATAMYCIN

Eye drops 5%

SULPHACETAMIDE SODIUM

Eye drops 10%

TOBRAMYCIN

Eye drops 0.3%

Eye oint 0.3%

Antineovascularisation Agents

BEVACIZUMAB

Restricted

Either:

1. *Ocular neovascularisation; or*
2. *Exudative ocular angiopathy.*

Inj 25 mg per ml, 4 ml vial

Inj 25 mg per ml, 16 ml vial

RANIBIZUMAB

Restricted

Initiation:

1. *Either:*
   - 1.1. *Age-related macular degeneration; or*
   - 1.2. *Chorodial neovascular membrane; and*
2. *Any of the following:*
   - 2.1. *The patient has had a severe ophthalmic inflammatory response following bevacizumab; or*
   - 2.2. *The patient has had a myocardial infarction or stroke within the last three months; or*
   - 2.3. *The patient has failed to respond to bevacizumab following three intraocular injections; or*
   - 2.4. *The patient is of child-bearing potential and has not completed a family.*

Continuation:

1. *Documented benefit after three doses must be demonstrated to continue.*
2. *In the case of but previous non-response to bevacizumab, a retrial of bevacizumab is required to confirm non-response before continuing with ranibizumab.*

Inj 10 mg per ml, 0.23 ml vial

Inj 10 mg per ml, 0.3 ml vial

Beta Blockers

BETAXOLOL HYDROCHLORIDE

Eye drops 0.25%

Eye drops 0.5%

LEVOBUNOLOL

Eye drops 0.25%

Eye drops 0.5%

TIMOLOL MALEATE

Eye drops 0.25%

Eye drops 0.25%, gel forming

Eye drops 0.5%

Eye drops 0.5%, gel forming

Carbonic Anhydrase Inhibitors

ACETAZOLAMIDE

Tab 250 mg

Inj 500 mg in 10 ml vial

BRINZOLAMIDE

Eye drops 1%

DORZOLAMIDE HYDROCHLORIDE

Eye drops 2%

(continued…)

DORZOLAMIDE HYDROCHLORIDE WITH TIMOLOL MALEATE

Eye drops 2% with timolol maleate 0.5%

Corticosteroids and Other Anti-Inflammatory Preparations

DEXAMETHASONE

Eye drops 0.1%

Eye oint 0.1%

DEXAMETHASONE WITH NEOMYCIN AND POLYMYXIN B SULPHATE

Eye drops 0.1% with neomycin sulphate 0.35% and polymyxin B sulphate 6,000 u per g

Eye oint 0.1% with neomycin sulphate 0.35% and polymyxin B sulphate 6,000 u per g

DEXAMETHASONE WITH TOBRAMYCIN

Eye drops 0.1% with tobramycin 0.3%

DICLOFENAC SODIUM

Eye drops 1 mg per ml

Eye drops 1 mg per ml, single dose

FLUOROMETHOLONE

Eye drops 0.1%

INFLIXIMAB

Restricted

Initiation - severe, vision-threatening ocular inflammation requiring rapid control:

Both:

1. *Patient has severe, vision-threatening ocular inflammation requiring rapid control, and*
2. *Either:*
   - 2.1. *Patient has failed to achieve control of severe vision-threatening ocular inflammation following high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids; or*
   - 2.2. *Patient developed new inflammatory symptoms while receiving high dose steroids.*

(continued…)

Initiation - chronic ocular inflammation resistant to other agents:

Both:

1. *Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and*
2. *Patient has tried at least two other immunomodulatory agents.*

Continuation:

For indications other than Behçet's disease, patients should undergo a trial withdrawal of infliximab once inflammation is controlled.

Inj 100 mg

KETOROLAC

Eye drops 0.5%

LEVOCABASTINE

Eye drops 0.5 mg per ml

LODOXAMIDE TROMETAMOL

Eye drops 0.1%

PREDNISOLONE ACETATE

Eye drops 0.12%

Eye drops 1%

PREDNISOLONE SODIUM PHOSPHATE

Eye drops 0.5%, single dose

SODIUM CROMOGLYCATE

Eye drops 2%

Decongestants and Antiallergics

NAPHAZOLINE HYDROCHLORIDE

Eye drops 0.1%

OLOPATADINE

Restricted *– patients under 12 years of age*

Eye drops 0.1%

PHENYLEPHRINE HYDROCHLORIDE

Eye drops 0.12%

Diagnostic Agents

FLUORESCEIN SODIUM

Eye drops 2%, single dose

Ophthalmic strips 1 mg

FLUORESCEIN SODIUM WITH LIGNOCAINE HYDROCHLORIDE

Eye drops 0.25% with lignocaine hydrochloride 4%, single dose

ROSE BENGAL

Ophthalmic strips 1%

LISSAMINE GREEN

Ophthalmic strips 1.5 mg

Miotics

ACETYLCHOLINE CHLORIDE

Irrigation soln 20 mg in 2 ml vial

PILOCARPINE

Eye drops 1%

Eye drops 2%

Eye drops 2%, single dose

Eye drops 4%

Mydriatics and Cycloplegics

ATROPINE SULPHATE

Eye drops 0.5%

Eye drops 1%

Eye drops 1%, single dose

CYCLOPENTOLATE HYDROCHLORIDE

Eye drops 0.5%, single dose

Eye drops 1%

Eye drops 1%, single dose

PHENYLEPHRINE HYDROCHLORIDE

Eye drops 2.5%, single dose

Eye drops 10%, single dose

TROPICAMIDE

Eye drops 0.5%

Eye drops 0.5%, single dose

Eye drops 1%

Eye drops 1%, single dose

Ocular Anaesthetics

OXYBUPROCAINE HYDROCHLORIDE

Eye drops 0.4%, single dose

TETRACAINE (AMETHOCAINE) HYDROCHLORIDE

Eye drops 0.5%, single dose

Eye drops 1%, single dose

Other Eye Preparations

BALANCED SALT SOLUTION

Eye drops

Irrigation soln 250 ml

Irrigation soln 500 ml

Preparations for Tear Deficiency and Ocular Lubricants

CARBOMER

Ophthalmic gel 0.2%

Ophthalmic gel 0.3%, single dose

CARMELLOSE SODIUM

Eye drops 0.5%

Eye drops 0.5%, single dose

Eye drops 1%

Eye drops 1%, single dose

HYPROMELLOSE

Eye drops 0.5%

HYPROMELLOSE WITH DEXTRAN

Eye drops 0.3% with dextran 0.1%

Eye drops 0.3% with dextran 0.1%, single dose

PARAFFIN LIQUID WITH SOFT WHITE PARAFFIN

Eye oint with soft white paraffin

PARAFFIN LIQUID WITH WOOL FAT LIQUID

Eye oint 3% with wool fat liquid 3%

POLYVINYL ALCOHOL

Eye drops 1.4%

Eye drops 3%

POLYVINYL ALCOHOL WITH POVIDONE

Eye drops 1.4% with povidone 0.6%, single dose

TYLOXAPOL

Eye drops 0.25%

Prostaglandin Analogues

BIMATOPROST

Eye drops 0.03%

LATANOPROST

Eye drops 50 µg per ml

TRAVOPROST

Eye drops 0.004%

Sympathomimetics

APRACLONIDINE

Eye drops 0.5%

BRIMONIDINE TARTRATE

Eye drops 0.2%

BRIMONIDINE TARTRATE WITH TIMOLOL MALEATE

Eye drops 0.2% with timolol maleate 0.5%

Viscoelastic Substances

HYPROMELLOSE

Inj 2%, 1 ml syringe

SODIUM HYALURONATE

Inj 10 mg per ml, 0.4 ml

Inj 10 mg per ml, 0.55 ml

Inj 10 mg per ml, 0.85 ml

Inj 14 mg per ml, 0.55 ml

Inj 14 mg per ml, 0.85 ml

Inj 23 mg per ml, 0.6 ml

SODIUM HYALURONATE WITH CHONDROITIN SULPHATE

Inj 10 mg per ml, 0.4 ml (1) and inj 30 mg per ml with chondroitin sulphate 40 mg per ml, 0.35 ml (1)

Inj 10 mg per ml, 0.55 ml (1) and inj 30 mg per ml with chondroitin sulphate 40 mg per ml, 0.5 ml (1)

Inj 30 mg with chondroitin sulphate 40 mg per ml, 0.75 ml

Products proposed not to be included

The following products were considered as part of the review of this section, and we are proposing that they not be listed in Part II of Section H at this time. Please note that this would not prevent them from being considered for inclusion at a later date.

Acetylcysteine (proprietary eye drops)

Carbachol

Ciclosporin (ophthalmic preparations)

Flurbiprofen

Homatropine

Macrogol 400 with propylene glycol

Naphazoline hydrochloride with antazoline phosphate

Phenylephrine hydrochloride with zinc sulphate

Proxymetacaine

Travoprost with timolol

Verteporfin

Please note that while we are proposing not to include commercially-manufactured acetylcysteine eye drops, compounded eye drops (from acetylcysteine injection) would be able to be used.

We are also proposing that the following products not be included. Please note that for each of these, we are proposing that other presentations or strengths would be included in this section.

Brimonidine tartrate

Eye drops 0.15%

Fluorescein sodium

Eye drops 1%, single dose

Hypromellose

Eye drops 0.3%

Eye drops 2%

Rose bengal

Eye drops 1%, single dose

Sodium hyaluronate

Inj 16 mg per ml, 0.25 ml

Inj 16 mg per ml, 0.5 ml

Inj 16 mg per ml, 0.8 ml

Please note that we have received clinical advice on the benefits of ciclosporin eye drops and prednisolone sodium phosphate eye drops. We will be considering these products further over the coming months, and will discuss this issue further with relevant parties as this work progresses.

Biologic agents

Please note, that in relation to the proposed listing of bevacizumab and infliximab, this list relates only to their use in ophthalmology. We will be addressing use of these in other specialities in other consultation documents.

In particular, please note that infliximab is also included in the Respiratory System and Allergies and the Alimentary Tract and Metabolism therapeutic groups, which are also the subject of consultation at this point in time

Proposed changes to community pharmaceutical funding

To create more alignment with the community Pharmaceutical Schedule (section B), we are proposing to make two amendments in Section B.

Olopatadine

We propose that olopatadine would be subsidised in the Sensory Organs therapeutic group in the community (Section B of the Pharmaceutical Schedule) from 1 January 2013 as follows (prices and subsidised are ex-manufacturer, and exclusive of GST):

Chemical	Formulation	Brand	Pack size	Price and subsidy
Olopatadine	Eye drops 0.1%	Patanol	5 ml OP	$17.00

Olopatadine would be subject to the following prescribing restrictions in Section B:

a) Only for patients under 12 years of age.
b) Prescriptions must be recommended by an ophthalmologist.

Homatropine

We are also proposing to delist homatropine (eye drops 2%) from Section B of the Pharmaceutical Schedule from 1 July 2013. We note that usage of homatropine is now at very low levels, and the Ophthalmology Subcommittee has advised us that there is not a need for this to remain subsidised in the community or to be available in DHB hospitals.