CONSULTATION

PHARMAC
Pharmaceutical Management Agency

19 November 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 a further four therapeutic groups within Section H:

- Dermatologicals *(dermatology, wound management)*
- Genito-Urinary System *(obstetrics, gynaecology, urology)*
- Hormone Preparations *(endocrinology)*
- Nervous System *(addiction medicine, anaesthesia, analgesia, neurology, psychiatry)*

While these headings primarily relate to pharmaceuticals that are used by clinicians working in the specialities identified above, this is not always the case. For example, the Hormone Preparations section includes corticosteroids, which are used widely. 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 **Friday, 21 December 2012** to:

Sean Dougherty
Funding Systems Development Manager
PHARMAC
PO Box 10 254
Wellington 6143

Email: sean.dougherty@pharmac.govt.nz

Fax: 04 460 4995

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:

For the Dermatologicals therapeutic group:

Greg Williams
Senior Therapeutic Group Manager
greg.williams@pharmac.govt.nz

For the Genito-Urinary System and Hormone Preparations therapeutic groups:

Christine Chapman
Therapeutic Group Manager
christine.chapman@pharmac.govt.nz

For the Nervous System therapeutic group (addiction medicine, anaesthesia, analgesia, psychiatry):

Geraldine MacGibbon
Senior Therapeutic Group Manager
geraldine.macgibbon@pharmac.govt.nz

For the Nervous System therapeutic group (neurology):

Natalie Davis
Therapeutic Group Manager
natalie.davis@pharmac.govt.nz

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 third section of products that are proposed as inclusions and exclusions from Section H. Previous consultation documents have covered the Alimentary Tract & Metabolism, Cardiovascular System, Infections, Musculoskeletal System, Respiratory System & Allergies and Sensory Organs therapeutic groups. All of PHARMAC's consultations relevant to this work are available on PHARMAC's website:

www.pharmac.govt.nz/HospitalPharmaceuticals

We expect to seek feedback on the fourth and final section in late February, which will include pharmaceuticals relating to haematology, oncology, transplant medicine, medical nutrition and radiology. It will also include several products that are used by multiple specialities, such as intravenous fluids, antidotes, vaccines and extemporaneous compounds.

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 Dermatologicals group, the Genito-Urinary System group, the Hormone Preparations group and the Nervous System group.

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 (or may have been the subject of an earlier 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); and

- 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.

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

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 an amendment to the prescribing criteria of one 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.

DERMATOLOGICALS

Antiacne Preparations

ADAPALENE

Cream 0.1%

Gel 0.1%

BENZOYL PEROXIDE

Soln 5%

ISOTRETINOIN

Restricted
Must meet community Special Authority criteria

Cap 10 mg

Cap 20 mg

TRETINOIN

Cream 0.05%

Antipruritic Preparations

CALAMINE

Lotion

CROTAMITON

Cream 10%

Barrier Creams and Emollients

Barrier Creams

DIMETHICONE

Cream 5%

ZINC

Cream

Oint

Paste

ZINC AND CASTOR OIL

Cream

Oint

ZINC WITH WOOL FAT

Cream zinc 15.25% with wool fat 4% *{e.g.Sudocrem}*

Emollients

AQUEOUS CREAM

Cream

CETOMACROGOL

Cream

CETOMACROGOL WITH GLYCEROL

Cream 90% with glycerol 10%

EMULSIFYING OINTMENT

Oint

GLYCEROL WITH PARAFFIN

Cream glycerol 10% with white soft paraffin 5% and liquid paraffin 10% *{e.g. QV Cream}*

OIL IN WATER EMULSION

Cream

PARAFFIN

White soft

Yellow soft

Oint liquid paraffin 50% with white soft paraffin 50% *{e.g. Duoleum}*

PARAFFIN WITH WOOL FAT

Lotn liquid paraffin 15.9% with wool fat 0.6% *{e.g. DP Lotion, Alpha Keri Lotion}*

Lotn liquid paraffin 91.7% with wool fat 3% *{e.g. Alpha Keri Bath Oil}*

UREA

Cream 10%

WOOL FAT

Cream

Corticosteroids

BETAMETHASONE DIPROPIONATE

Cream 0.05%

Oint 0.05%

BETAMETHASONE VALERATE

Cream 0.1%

Lotion 0.1%

Oint 0.1%

CLOBETASOL PROPIONATE

Cream 0.05%

Oint 0.05%

CLOBETASONE BUTYRATE

Cream 0.05%

DIFLUCORTOLONE VALERATE

Restricted *– continuation only*

Cream 0.1%

Fatty oint 0.1%

HYDROCORTISONE

Cream 1%

HYDROCORTISONE BUTYRATE

Lipocream 0.1%

Milky emul 0.1%

Oint 0.1%

HYDROCORTISONE WITH WOOL FAT AND PARAFFIN LIQUID

Lotion 1% with paraffin liquid 15.9% and wool fat 0.6%

METHYLPREDNISOLONE ACEPONATE

Cream 0.1%

Oint 0.1%

MOMETASONE FUROATE

Cream 0.1%

Lotion 0.1%

Oint 0.1%

TRIAMCINOLONE ACETONIDE

Cream 0.02%

Oint 0.02%

Corticosteroids with Anti-Infective Agents

BETAMETHASONE VALERATE WITH CLIOQUINOL

Restricted

Either:

1. *For the treatment of intertrigo; or*
2. *For continuation use.*

Cream 0.1% with clioquiniol 3%

Oint 0.1% with clioquiniol 3%

BETAMETHASONE VALERATE WITH FUSIDIC ACID

Cream 0.1% with fusidic acid 2%

HYDROCORTISONE WITH MICONAZOLE

Cream 1% with miconazole nitrate 2%

HYDROCORTISONE WITH NATAMYCIN AND NEOMYCIN

Cream 1% with natamycin 1% and neomycin sulphate 0.5%

Oint 1% with natamycin 1% and neomycin sulphate 0.5%

TRIAMCINOLONE ACETONIDE WITH GRAMICIDIN, NEOMYCIN AND NYSTATIN

Cream 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 mcg per g

Psoriasis and Eczema Preparations

ACITRETIN

Restricted

Must meet community Special Authority criteria

Cap 10 mg

Cap 25 mg

ADALIMUMAB

Restricted

Must meet community Special Authority criteria

Inj 40 mg per 0.8 ml pen

Inj 40 mg per 0.8 ml syringe

CALCIPOTRIOL

Cream 50 mcg per g

Oint 50 mcg per g

Soln 50 mcg per ml

COAL TAR WITH SALICYLIC ACID AND SULPHUR

Oint 12% with salicylic acid 2% and sulphur 4%

COAL TAR WITH TRIETHANOLAMINE LARYL SULPHATE AND FLUORESCEIN

Soln 2.3% with triethanolamine lauryl sulphate and fluorescein sodium

ETANERCEPT

Restricted

Must meet community Special Authority criteria

Inj 25 mg vial

Inj 50 mg autoinjector

Inj 50 mg syringe

INFLIXIMAB

Restricted

<u>Initiation (plaque psoriasis, prior TNF use) - dermatologist</u>

Both:

1. *The patient has had an initial Special Authority approval for adalimumab or etanercept for severe chronic plaque psoriasis; and*
2. *Either:*
   - 2.1. *The patient has experienced intolerable side effects from adalimumab or etanercept; or*
   - 2.2. *The patient has received insufficient benefit from etanercept to meet the renewal criteria for adalimumab or etanercept for severe chronic plaque psoriasis; and*
3. *Infliximab to be administered at doses no greater than 5 mg/kg; and*
4. *Patient must be reassessed for continuation after 3 doses.*

<u>Initiation (plaque psoriasis, treatment-naïve) - dermatologist</u>

All of the following:

1. *Either:*
   - 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*
   - 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. *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*
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*
4. *The most recent PASI assessment is no more than 1 month old at the time of application; and*
5. *infliximab to be administered at doses no greater than 5 mg/kg; and*
6. *Patient must be reassessed for continuation after 3 doses.*

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.

Continuation (plaque psoriasis) – dermatologist

All of the following:

1. *Either:*
   - 1.1. *Both:*
     - 1.1.1. *Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and*
     - 1.1.2. *Following each prior infliximab 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-infliximab treatment baseline value; or*
   - 1.2. *Both:*
     - 1.2.1. *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*
     - 1.2.2. *Either:*
       - 1.2.2.1. *Following each prior infliximab 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*
       - 1.2.2.2. *Following each prior infliximab 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-infliximab treatment baseline value; and*
2. *Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks; and*
3. *Patient must be reassessed for continuation after every 3 doses.*

Inj 100 mg

METHOXSALEN (8-METHOXYPSORALEN)

Cap 10 mg

Lotn 1.2%

POTASSIUM PERMANGANATE

Tab 400 mg

Scalp Preparations

BETAMETHASONE VALERATE

Scalp app 0.1%

CLOBETASOL PROPIONATE

Scalp app 0.05%

HYDROCORTISONE BUTYRATE

Scalp lotion 0.1%

Wart Preparations

IMIQUIMOD

Restricted
Must meet community Special Authority criteria

Cream 5%

PODOPHYLLOTOXIN

Soln 0.5%

SILVER NITRATE

Sticks with applicator

Other Skin Preparations

SUNSCREEN

Cream

Lotn

Antineoplastics

FLUOROURACIL SODIUM

Cream 5%

METHYL AMINOLEVULINATE HYDROCHLORIDE

Restricted
Dermatologists, Plastic Surgeons

Cream 16%

Wound Management Products

CALCIUM GLUCONATE

Gel 2.5%

HYDROGEN PEROXIDE

Soln 10 vol (3%)

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.

Adapalene with benzoyl peroxide

Benzalkonium chloride with triclosan and paraffin

Benzalkonium with panthenol

Cetomacrogol with paraffin and cetyl alcohol

Cetrimide (shampoo)

Clindamycin (solution)

Coal tar (shampoo)

Coal tar with allantoin, menthol, phenol and sulphur

Dimethicone with calamine and retinol palmitate

Dimethicone with cetyl alcohol and glycerol

Dithranol

Heparinoid

Hydrocortisone acetate

Hydrocortisone butyrate with chlorquinaldol

Magnesium sulphate (paste)

Oily cream

Paraffin with retinol palmitate

Pimecrolimus

Podophyllum resin with salicylic acid

Retinol palmitate (ointment)

Salicylic acid (gel)

Salicylic acid with lactic acid

Tar with coal tar and cade oil

Urea with lactic acid

Ustekinumab

Zinc oxide with glycerol

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.

Benzoyl peroxide

Gel 2.5%

Gel 5%

Gel 10 %

Clobetasone butyrate

Oint 0.05%

Dimethicone

Cream 10%

Hydrocortisone

Cream 0.5%

Hydrocortisone with miconazole

Cream 0.5% with miconazole nitrate 2%

Hydrogen peroxide

Soln 20 vol (6%)

Isotretinoin

Gel 0.05%

Paraffin

Cream liquid paraffin 12.6% with white soft paraffin 14.5% and wool fat 1%

Triamcinolone acetonide with gramicidin, neomycin and nystatin

Oint 1 mg with nystatin 100,000 u, neomycin sulphate 2.5 mg and gramicidin 250 mcg per g

Urea

Oint 25%

Vitamin E

Cream

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:

Retinol palmitate, oint 25 g (PSM)

Retinol palmitate, oint 50 g (healthE)

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.

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 as part of this proposal.

Cetomacrogol with glycerol

To create more alignment with the community Pharmaceutical Schedule (section B), we propose that cetomacrogol with glycerol would be subsidised in Section B of the Pharmaceutical Schedule from 1 April 2013 as follows (price and subsidy are ex-manufacturer and exclusive of GST):

Chemical	Formulation	Brand	Pack size	Price and subsidy
Cetomacrogol with glycerol	Crm 90% with glycerol 10%	Pharmacy Health	500 g OP	$4.50

Magnesium sulphate paste

We are also proposing to delist magnesium sulphate paste from Section B of the Pharmaceutical Schedule from 1 October 2013. The Dermatology Subcommittee has recommended that this not be included in Section H, as there is insufficient evidence to support its use. As the proposal is not to include this in Section H, we also intend to remove the listing from Section B.

GENITO-URINARY SYSTEM

Contraceptives

Antiandrogen Oral Contraceptives

CYPROTERONE ACETATE WITH ETHINYLOESTRADIOL

Tab 2 mg with ethinyloestradiol 35 mcg

Combined Oral Contraceptives

ETHINYLOESTRADIOL WITH DESOGESTREL

Tab 20 µg with desogestrel 150 mcg

Tab 30 mcg with desogestrel 150 mcg

ETHINYLOESTRADIOL WITH LEVONORGESTREL

Tab 20 mcg with levonorgestrel 100 mcg

Tab 30 mcg with levonorgestrel 150 mcg

Tab 50 mcg with levonorgestrel 125 mcg

ETHINYLOESTRADIOL WITH NORETHISTERONE

Tab 35 mcg with norethisterone 500 mcg

Tab 35 mcg with norethisterone 1 mg

NORETHISTERONE WITH MESTRANOL

Tab 1 mg with mestranol 50 mcg

Emergency Contraception

LEVONORGESTREL

Tab 750 mcg

Tab 1.5 mg

Progestogen-Only Contraceptives

LEVONORGESTREL

Restricted (intra-uterine device)
Must meet community Special Authority criteria

Tab 30 mcg

Subdermal implant 75 mg

Intra-uterine device, 20 mcg per day

MEDROXYPROGESTERONE ACETATE

Inj 150 mg per ml, 1 ml syringe

NORETHISTERONE

Tab 350 mcg

Other Gynaecological and Obstetric Preparations

ACETIC ACID

Soln 3%

Soln 5%

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

CARBOPROST TROMETAMOL

Inj 250 mcg per ml, 1 ml ampoule

DINOPROSTONE

Pessaries 10 mg

Vaginal gel 1 mg in 2.5 ml

Vaginal gel 2 mg in 2.5 ml

ERGOMETRINE MALEATE

Inj 500 mcg per ml, 1 ml ampoule

MIFEPRISTONE

Tab 200 mg

OESTRIOL

Crm 1 mg per g with applicator

Pessaries 500 mcg

OXYTOCIN

Inj 5 iu per ml, 1 ml ampoule

Inj 10 iu per ml, 1 ml ampoule

OXYTOCIN WITH ERGOMETRINE MALEATE

Inj 5 iu oxytocin with ergometrine maleate 500 mcg per ml, 1 ml ampoule

PROGESTERONE

Restricted
Only for use in women with previous preterm delivery (less than 28 weeks) and/or a short cervix (< 25 mm).

Cap 100 mg

TERBUTALINE

Restricted *- obstetricians*

Inj 500 mcg ampoule

Urologicals

5-Alpha Reductase Inhibitors

FINASTERIDE

Restricted
Must meet community Special Authority criteria

Tab 5 mg

Alpha-1A Adrenoceptor Blockers

TAMSULOSIN

Restricted
Must meet community Special Authority criteria

Cap 400 mcg

Urinary Alkalisers

POTASSIUM CITRATE

Restricted
Must meet community Special Authority criteria

Oral liq 3 mmol per ml

SODIUM CITRO-TARTRATE

Grans eff 4 g sachets

Urinary Antispasmodics

OXYBUTYNIN

Tab 5 mg

Oral liq 5 mg per 5 ml

SOLIFENACIN SUCCINATE

Restricted
Must meet community Special Authority criteria

Tab 5 mg

Tab 10 mg

TOLTERODINE TARTRATE

Restricted
Must meet community Special Authority criteria

Tab 1 mg

Tab 2 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.

Alprostatil (intracavernosal)

Atosiban

Desogestrel

Dinoprost trometamol

Drospirenone with ethinyloestradiol

Ethinyloestradiol with gestodene

Etonogestrel

Methylergometrine

Nonoxynol-9

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.

Oxybutynin

Patch 36 mg

Potassium citrate

Tab 540 mg

Tamsulosin

Tab long-acting 400 mcg

Levonorgestrel IUD

The use of levonorgestrel intra-uterine devices (Mirena) for indications other than heavy menstrual bleeding, such as contraception and endometriosis, has been raised through this process.

In line with the advice from PTAC, we are proposing that other indications not be included in the prescribing criteria at this time. However, we intend to consider this issue further over the coming months, and we will be discussing this issue with relevant parties.

It is likely that, if we do implement wider prescribing criteria in DHB hospitals, we would also amend the Special Authority criteria in the community.

HORMONE PREPARATIONS

Androgen Agonists and Antagonists

CYPROTERONE ACETATE

Tab 50 mg

Tab 100 mg

TESTOSTERONE

Transdermal patch 2.5 mg per day

TESTOSTERONE CYPIONATE

Inj long-acting 100 mg per ml, 10 ml

TESTOSTERONE ESTERS

Inj testosterone decanoate 100 mg, testosterone isocarproate 60 mg, testosterone phenylpropionate 60 mg and testosterone propionate 30 mg per ml, 1 ml

TESTOSTERONE UNDECANOATE

Cap 40 mg

Inj 250 mg per ml, 4 ml

Calcium Homeostasis

ALENDRONATE SODIUM

Restricted
Must meet community Special Authority criteria

Tab 40 mg

Tab 70 mg

ALENDRONATE SODIUM WITH CHOLECALCIFEROL

Restricted
Must meet community Special Authority criteria

Tab 70 mg with cholecalciferol 5600 iu

CALCITONIN

Inj 100 iu per ml, 1 ml

ETIDRONATE DISODIUM

Tab 200 mg

PAMIDRONATE

Inj 3 mg per ml, 5 ml

Inj 3 mg per ml, 10 ml

Inj 6 mg per ml, 10 ml

Inj 9 mg per ml, 10 ml

RALOXIFENE

Restricted
Must meet community Special Authority criteria

Tab 60 mg

TERIPARATIDE

Restricted
Must meet community Special Authority criteria

Inj 250 µg per ml, 2.4 ml

ZOLEDRONIC ACID

Restricted
4 mg in 5 ml
Only for hypercalcaemia of malignancy
5 mg in 100 ml
Must meet community Special Authority criteria

Inj 4 mg in 5 ml

Inj 5 mg in 100 ml

Corticosteroids

BETAMETHASONE SODIUM PHOSPHATE WITH BETAMETHASONE ACETATE

Inj 3.9 mg with betamethasone acetate 3 mg per ml, 1 ml

DEXAMETHASONE

Tab 1 mg

Tab 4 mg

Oral liq 1 mg per ml

DEXAMETHASONE SODIUM PHOSPHATE

Inj 4 mg per ml, 1 ml

Inj 4 mg per ml, 2 ml

FLUDROCORTISONE ACETATE

Tab 100 mcg

HYDROCORTISONE

Tab 5 mg

Tab 20 mg

Inj 50 mg per ml, 2 ml

METHYLPREDNISOLONE

Tab 4 mg

Tab 100 mg

METHYLPREDNISOLONE ACETATE

Inj 40 mg per ml, 1 ml

METHYLPREDNISOLONE ACETATE WITH LIGNOCAINE

Inj 40 mg per ml with lignocaine 1 ml

METHYLPREDNISOLONE SODIUM SUCCINATE

Inj 40 mg per ml, 1 ml

Inj 62.5 mg per ml, 2 ml

Inj 500 mg

Inj 1 g

PREDNISOLONE

Oral liq 5 mg per ml

Enema 20 mg in 100 ml

PREDNISONE

Tab 1 mg

Tab 2.5 mg

Tab 5 mg

Tab 20 mg

TRIAMCINOLONE ACETONIDE

Inj 10 mg per ml, 1 ml

Inj 40 mg per ml, 1 ml

TRIAMCINOLONE HEXACETONIDE

Inj 20 mg per ml, 1 ml

Hormone Replacement Therapy

Oestrogens

OESTRADIOL

- Tab 1 mg
- Tab 2 mg
- Transdermal patch 25 mcg per day
- Transdermal patch 50 mcg per day
- Transdermal patch 100 mcg per day

OESTRADIOL VALERATE

- Tab 1 mg
- Tab 2 mg

OESTROGENS

- Conjugated, equine tab 300 mcg
- Conjugated, equine tab 625 mcg

Progestogen and Oestrogen Combined Preparations

OESTRADIOL WITH NORETHISTERONE

- Tab 1 mg with 0.5 mg norethisterone acetate
- Tab 2 mg with 1 mg norethisterone acetate
- Tab 2 mg with 1 mg norethisterone acetate (10), and 2 mg oestradiol tab (12) and 1 mg oestradiol tab (6)

OESTROGENS WITH MEDROXYPROGESTERONE

- Tab 625 mcg conjugated equine with 2.5 mg medroxyprogesterone acetate tab
- Tab 625 mcg conjugated equine with 5 mg medroxyprogesterone acetate tab

Progestogens

MEDROXYPROGESTERONE ACETATE

- Tab 2.5 mg
- Tab 5 mg
- Tab 10 mg

Other Endocrine Agents

CABERGOLINE

- Tab 0.5 mg

CLOMIPHENE CITRATE

- Tab 50 mg

DANAZOL

- Cap 100 mg
- Cap 200 mg

GESTRINONE

- Cap 2.5 mg

METYRAPONE

- Cap 250 mg

PENTAGASTRIN

- Inj 0.5 mg in 2 ml

SECRETIN PENTAHYDROCHLORIDE

- Inj 100 u

Other Oestrogen Preparations

ETHINYLOESTRADIOL

- Tab 10 mcg

OESTRIOL

- Tab 2 mg
- Inj 50 mg
- Implant 50 mg

Other Progestogen Preparations

MEDROXYPROTESTERONE

- Tab 100 mg
- Tab 200 mg

NORETHISTERONE

- Tab 5 mg

Pituitary and Hypothalamic Hormones and Analogues

CORTICOTROPIN RELEASING HORMONE (OVINE)

- Inj 100 mcg

THYROTROPIN ALFA

- Inj 900 mcg

Adrenocorticorticostropic Hormones

TETRACOSACTIDE (TETRACOSACTRIN)

- Inj 250 mcg
- Inj 1 mg per ml, 1 ml

GnRH Agonists and Antagonists

BUSERELIN

- Inj 1 mg per ml, 5.5 ml

GONADORELIN

- Inj 100 mcg

GOSERELIN ACETATE

- Inj 3.6 mg
- Inj 10.8 mg

LEUPRORELIN

- Inj 3.75 mg
- Inj 7.5 mg
- Inj 11.25 mg
- Inj 22.5 mg
- Inj 30 mg
- Inj 45 mg

Gonadatrophins

CHORIOGONADOTROPIN ALFA

- Inj 250 mcg

Growth Hormone

SOMATROPIN

Restricted

Only for use in patients with approval by the Growth Hormone Committee

- Inj 16 iu per vial (5.3 mg)
- Inj 36 iu per vial (12 mg)

Thyroid and Antithyroid Preparations

CARBIMAZOLE

- Tab 5 mg

IODINE

- Soln BP 50 mg per ml

LEVOTHYROXINE

Tab 25 mcg

Tab 50 mcg

Tab 100 mcg

LIOTHYRONINE SODIUM

Inj 20 mcg

POTASSIUM PERCHLORATE

Cap 200 mg

PROPYLTHIOURACIL

Restricted
Must meet community Special Authority criteria

Tab 50 mg

PROTIRELIN

Inj 0.2 mg in 2 ml

Vasopressin Agents

DESMOPRESSIN

Tab 100 mcg

Inj 4 mcg per ml, 1 ml

Inj 15 mcg per ml, 1 ml

Nasal drops 100 mcg per ml

Nasal spray 10 mcg per dose

TERLIPRESSIN

Inj 1 mg

VASOPRESSIN

Inj 20 u per 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.

Betamethasone sodium phosphate

Cinacalcet hydrochloride

Cortisone acetate

Dydrogesterone

Follitropin alfa

Follitropin beta

Ganirelix

Nandrolone decanoate

Oxandrolone

Pegvisomant

Strontium ranelate

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.

Cyproterone acetate

Inj 100 mg per ml, 3 ml

Desmopressin

Tab 200 mg

Nasal spray 150 mcg per dose

Leuprorelin

Inj 5 mg per ml, 2.8 ml

Levothyroxine

Injection

Liothyronine

Tab 20 mg

Oestradiol

Pessaries 25 mcg

Testosterone

Gel 50 mg per 5 g sachet

Implant 200 mg

Prednisolone

Tab 5 mg

Progesterone

Inj 100 mg in 2 ml

Triamcinolone hexacetonide

Inj 20 mg per ml, 5 ml

Zoledronic acid

As part of this review, the Endocrinology Subcommittee has recommended that the access criteria for zoledronic acid be widened to include the treatment of children with osteogenesis imperfecta. We intend to consider this further over the coming months, and we will be discussing this issue with relevant parties.

NERVOUS SYSTEM

Agents for Parkinsonism and Related Disorders

Agents for Essential Tremor, Chorea and Related Disorders

CLOSTRIDIUM BOTULINUM TYPE A TOXIN
- Inj 100 u vial
- Inj 500 u vial

TETRABENAZINE
- Tab 25 mg

Anticholinergics

BENZTROPINE MESYLATE
- Inj 1 mg per ml, 2 ml ampoule
- Tab 2 mg

ORPHENADRINE HYDROCHLORIDE
- Tab 50 mg

PROCYCLIDINE HYDROCHLORIDE
- Tab 5 mg

Dopamine Agonists and Related Agents

AMANTADINE HYDROCHLORIDE
- Cap 100 mg

APOMORPHINE HYDROCHLORIDE
- Inj 10 mg per ml, 1 ml ampoule
- Inj 10 mg per ml, 2 ml ampoule

BROMOCRIPTINE
- Tab 2.5 mg
- Cap 5 mg

ENTACAPONE
- Tab 200 mg

LEVODOPA WITH BENSERAZIDE
- Cap 50 mg with benserazide 12.5 mg
- Tab dispersible 50 mg with benserazide 12.5 mg
- Cap 100 mg with benserazide 25 mg
- Cap long-acting 100 mg with benserazide 25 mg
- Cap 200 mg with benserazide 50 mg

LEVODOPA WITH CARBIDOPA
- Tab 100 mg with carbidopa 25 mg
- Tab 250 mg with carbidopa 25 mg
- Tab long-acting 200 mg with carbidopa 50 mg

LISURIDE HYDROGEN MALEATE
- Tab 200 mcg

PERGOLIDE
- Tab 0.25 mg
- Tab 1 mg

PRAMIPEXOLE HYDROCHLORIDE
- Tab 0.125 mg
- Tab 0.25 mg
- Tab 0.5 mg

ROPINIROLE HYDROCHLORIDE
- Tab 0.25 mg
- Tab 1 mg
- Tab 2 mg
- Tab 5 mg

SELEGILINE HYDROCHLORIDE
- Tab 5 mg

TOLCAPONE
- Tab 100 mg

Anaesthetics

General Anaesthetics

DESFLURANE
- Liq 240 ml

DEXMEDETOMIDINE HYDROCHLORIDE
- Inj 100 mcg per ml, 2 ml vial

ETOMIDATE
- Inj 2 mg per ml, 10 ml ampoule

ISOFLURANE
- Liq 250 ml

KETAMINE HYDROCHLORIDE
- Inj 1 mg per ml, 100 ml bag
- Inj 10 mg per ml, 10 ml syringe
- Inj 100 mg per ml, 2 ml vial

PROPOFOL
- Inj 10 mg per ml, 20 ml vial
- Inj 10 mg per ml, 20 ml ampoule
- Inj 10 mg per ml, 50 ml vial
- Inj 10 mg per ml, 50 ml syringe
- Inj 10 mg per ml, 100 ml vial

SEVOFLURANE
- Liq 250 ml

THIOPENTAL (THIOPENTONE) SODIUM
- Inj 500 mg ampoule

Local Anaesthetics

ARTICAINE HYDROCHLORIDE WITH ADRENALINE
- Inj 4% with adrenaline 1:100,000, 2.2 ml dental cartridge

BUPIVACAINE HYDROCHLORIDE
- Inj 1.25 mg per ml, 100 ml bag
- Inj 1.25 mg per ml, 200 ml bag
- Inj 2.5 mg per ml, 20 ml ampoule
- Inj 2.5 mg per ml, 100 ml bag
- Inj 2.5 mg per ml, 200 ml bag
- Inj 5 mg per ml, 4 ml amp
- Inj 5 mg per ml, 10 ml ampoule
- Inj 5 mg per ml, 20 ml ampoule

BUPIVACAINE HYDROCHLORIDE WITH ADRENALINE
- Inj 2.5 mg per ml with adrenaline 1:400,000, 20 ml vial
- Inj 5 mg per ml with adrenaline 1:200,000, 20 ml vial

BUPIVACAINE HYDROCHLORIDE WITH FENTANYL

Inj 1.25 mg with fentanyl 2 mcg per ml, 15 ml syringe

Inj 1.25 mg with fentanyl 2 mcg per ml, 20 ml syringe

Inj 1.25 mg with fentanyl 2 mcg per ml, 50 ml syringe

Inf 1.25 mg with fentanyl 2 mcg per ml, 100 ml bag

Inf 1.25 mg with fentanyl 2 mcg per ml, 200 ml bag

BUPIVACAINE HYDROCHLORIDE WITH GLUCOSE

Inj 0.5% with glucose 8%, 4 ml ampoule

COCAINE HYDROCHLORIDE

Paste 5%

Soln 4%, 2 ml oral syringe

ETHYL CHLORIDE

Spray 100 ml

LIGNOCAINE HYDROCHLORIDE

Inj 1%, 5 ml ampoule

Inj 1%, 20 ml ampoule

Inj 2%, 5 ml ampoule

Inj 2%, 20 ml ampoule

Gel 2%, 10 ml urethral syringes

Gel 2%

Oral (viscous) soln 2%

Spray 10%

Soln 4%

LIGNOCAINE HYDROCHLORIDE WITH ADRENALINE

Inj 1% with adrenaline 1:100,000, 5 ml ampoule

Inj 1% with adrenaline 1:200,000, 20 ml vial

Inj 2% with adrenaline 1:200,000, 20 ml vial

Inj 2% with adrenaline 1:80,000, 1.7 ml dental cartridge

Inj 2% with adrenaline 1:80,000, 2.2 ml dental cartridge

LIGNOCAINE HYDROCHLORIDE WITH ADRENALINE AND TETRACAINE HYDROCHLORIDE

Inj 4% with adrenaline 0.1% and tetracaine hydrochloride 0.5%, 5 ml syringe

LIGNOCAINE HYDROCHLORIDE WITH CHLORHEXIDINE

Gel 2% with chlorhexidine 0.05%, 10 ml urethral syringes

LIGNOCAINE HYDROCHLORIDE WITH PHENYLEPHRINE HYDROCHLORIDE

Nasal spray 5% with phenylephrine hydrochloride 0.5%

LIGNOCAINE WITH PRILOCAINE

Crm 2.5% with prilocaine 2.5%

Patch 25 mcg with prilocaine 25 mcg

PRILOCAINE HYDROCHLORIDE

Inj 0.5%, 50 ml vial

Inj 2%, 5 ml ampoule

ROPIVACAINE HYDROCHLORIDE

Inj 2 mg per ml, 10 ml ampoule

Inj 2 mg per ml, 20 ml ampoule

Inj 2 mg per ml, 100 ml bag

Inj 2 mg per ml, 200 ml bag

Inj 7.5 mg per ml, 10 ml ampoule

Inj 7.5 mg per ml, 20 ml ampoule

Inj 10 mg per ml, 10 ml ampoule

Inj 10 mg per ml, 20 ml ampoule

ROPIVACAINE HYDROCHLORIDE WITH FENTANYL

Inj 2 mg with fentanyl 2 mcg per ml, 100 ml bag

Inj 2 mg with fentanyl 2 mcg per ml, 200 ml bag

TETRACAINE (AMETHOCAINE) HYDROCHLORIDE

Gel 4%

Other Drugs used in Anaesthesia

ATRACURIUM BESYLATE

Inj 10 mg per ml, 2.5 ml ampoule

Inj 10 mg per ml, 5 ml ampoule

GLYCOPYRROLATE BROMIDE

Inj 0.2 mg per ml, 1 ml ampoule

GLYCOPYRROLATE BROMIDE WITH NEOSTIGMINE

Inj 0.5 mg with neostigmine 2.5 mg, 1 ml ampoule

MIVACURIUM CHLORIDE

Inj 2 mg per ml, 5 ml ampoule

Inj 2 mg per ml, 10 ml ampoule

NEOSTIGMINE

Inj 2.5 mg per ml, 1 ml

ROCURONIUM BROMIDE

Inj 10 mg per ml, 5 ml vial

PANCURONIUM BROMIDE

Inj 2 mg per ml, 2 ml ampoule

SUXAMETHONIUM CHLORIDE

Inj 50 mg per ml, 2 ml ampoule

VECURONIUM BROMIDE

Inj 4 mg ampoule

Inj 10 mg vial

Analgesics

Non-Opioid Analgesics

ASPIRIN

Tab dispersible 300 mg

Tab EC 300 mg

CAPSAICIN

Restricted
Must meet community Special Authority criteria

Crm 0.075%

NEFOPAM HYDROCHLORIDE

Tab 30 mg

PARACETAMOL

Restricted (injection)

Intravenous paracetamol is only to be used where other routes are unavailable or impractical, or where there is reduced absorption. The need for IV paracetamol must be re-assessed every 24 hours.

- Tab 500 mg
- Tab soluble 500 mg
- Oral liq 120 mg per 5 ml
- Oral liq 250 mg per 5 ml
- Suppos 25 mg
- Suppos 50 mg
- Suppos 125 mg
- Suppos 250 mg
- Suppos 500 mg
- Inj 10 mg per ml, 50 ml vial
- Inj 10 mg per ml, 100 ml vial

SUCROSE

- Oral liq 667 mg per g

Opioid Analgesics

ALFENTANIL HYDROCHLORIDE

- Inj 0.5 mg per ml, 2 ml ampoule

CODEINE PHOSPHATE

- Tab 15 mg
- Tab 30 mg
- Tab 60 mg

DIHYDROCODEINE TARTRATE

- Tab long-acting 60 mg

FENTANYL

- Patch 12.5 mcg per hour
- Patch 25 mcg per hour
- Patch 50 mcg per hour
- Patch 75 mcg per hour
- Patch 100 mcg per hour
- Inj 10 mcg per ml, 50 ml bag
- Inj 10 mcg per ml, 50 ml syringe
- Inj 10 mcg per ml, 100 ml bag
- Inj 20 mcg per ml, 50 ml syringe
- Inj 50 mcg per ml, 2 ml ampoule
- Inj 50 mcg per ml, 10 ml ampoule

METHADONE HYDROCHLORIDE

- Tab 5 mg
- Oral liq 2 mg per ml
- Oral liq 5 mg per ml
- Oral liq 10 mg per ml
- Inj 10 mg per ml, 1 ml vial

MORPHINE HYDROCHLORIDE

- Oral liq 1 mg per ml
- Oral liq 2 mg per ml
- Oral liq 5 mg per ml
- Oral liq 10 mg per ml

MORPHINE SULPHATE

- Tab immediate-release 10 mg
- Tab immediate-release 20 mg
- Tab long-acting 10 mg
- Tab long-acting 30 mg
- Tab long-acting 60 mg
- Tab long-acting 100 mg
- Cap long-acting 10 mg
- Cap long-acting 30 mg
- Cap long-acting 60 mg
- Cap long-acting 100 mg
- Inj 200 mcg in 0.4 ml
- Inj 1 mg per ml, 0.3 ml syringe
- Inj 1 mg per ml, 10 ml syringe
- Inj 1 mg per ml, 50 ml syringe
- Inj 1 mg per ml, 100 ml bag
- Inj 2 mg per ml, 30 ml syringe
- Inj 5 mg per ml, 1 ml ampoule
- Inj 10 mg per ml, 1 ml ampoule
- Inj 10 mg per ml, 100 ml bag
- Inj 10 mg per ml, 100 mg cassette
- Inj 15 mg per ml, 1 ml ampoule
- Inj 30 mg per ml, 1 ml ampoule

MORPHINE TARTRATE

- Inj 80 mg per ml, 1.5 ml ampoule
- Inj 80 mg per ml, 5 ml ampoule

OXYCODONE HYDROCHLORIDE

- Cap 5 mg
- Cap 10 mg
- Cap 20 mg
- Oral liq 5 mg per 5 ml
- Tab controlled-release 5 mg
- Tab controlled-release 10 mg
- Tab controlled-release 20 mg
- Tab controlled-release 40 mg
- Tab controlled-release 80 mg
- Inj 1 mg per ml, 100 ml bag
- Inj 10 mg per ml, 1 ml ampoule
- Inj 10 mg per ml, 2 ml ampoule
- Inj 50 mg per ml, 1 ml ampoule

PARACETAMOL WITH CODEINE

- Tab paracetamol 500 mg with codeine phosphate 8 mg

PETHIDINE HYDROCHLORIDE

- Tab 50 mg
- Tab 100 mg
- Inj 5 mg per ml, 100 ml bag
- Inj 10 mg per ml, 50 ml syringe
- Inj 50 mg per ml, 1 ml ampoule
- Inj 50 mg per ml, 2 ml ampoule

REMIFENTANIL HYDROCHLORIDE

- Inj 1 mg vial
- Inj 2 mg vial

TRAMADOL HYDROCHLORIDE

Cap 50 mg
Tab sustained-release 100 mg
Tab sustained-release 150 mg
Tab sustained-release 200 mg
Oral drops 100 mg per ml
Inj 10 mg per ml, 100 ml bag
Inj 50 mg per ml, 1 ml ampoule
Inj 50 mg per ml, 2 ml ampoule

Antidepressants

Cyclic and Related Agents

AMITRIPTYLINE

Tab 10 mg
Tab 25 mg
Tab 50 mg

CLOMIPRAMINE HYDROCHLORIDE

Tab 10 mg
Tab 25 mg

DOTHIEPIN HYDROCHLORIDE

Cap 25 mg
Tab 75 mg

DOXEPIN HYDROCHLORIDE

Cap 10 mg
Cap 25 mg
Cap 50 mg

IMIPRAMINE HYDROCHLORIDE

Tab 10 mg
Tab 25 mg

MAPROTILINE HYDROCHLORIDE

Tab 25 mg
Tab 75 mg

MIANSERIN HYDROCHLORIDE

Restricted
Must meet community Special Authority criteria

Tab 30 mg

NORTRIPTYLINE HYDROCHLORIDE

Tab 10 mg
Tab 25 mg

Monoamine-Oxidase Inhibitors – Non-Selective

PHENELZINE SULPHATE

Tab 15 mg

TRANYLCYPROMINE SULPHATE

Tab 10 mg

Monoamine-Oxidase Type A Inhibitors

MOCLOBEMIDE

Tab 150 mg
Tab 300 mg

Other Antidepressants

MIRTAZAPINE

Restricted
Must meet community Special Authority criteria

Tab 30 mg
Tab 45 mg

VENLAFAXINE

Restricted
Must meet community Special Authority criteria

Cap modified release 37.5 mg
Cap modified release 75 mg
Cap modified release 150 mg
Tab modified release 37.5 mg
Tab modified release 75 mg
Tab modified release 150 mg
Tab modified release 225 mg

Selective Serotonin Reuptake Inhibitors

CITALOPRAM HYDROBROMIDE

Tab 20 mg

ESCITALOPRAM

Tab 10 mg
Tab 20 mg

FLUOXETINE HYDROCHLORIDE

Cap 20 mg
Tab dispersible 20 mg, scored

PAROXETINE HYDROCHLORIDE

Tab 20 mg

SERTRALINE

Tab 50 mg
Tab 100 mg

Antiepilepsy Drugs

Agents for Control of Status Epilepticus

CLONAZEPAM

Inj 1 mg per ml, 1 ml ampoule

DIAZEPAM

Rectal tubes 5 mg
Rectal tubes 10 mg
Inj 5 mg per ml, 2 ml ampoule

LORAZEPAM

Inj 2 mg vial
Inj 4 mg per ml, 1 ml vial

PARALDEHYDE

Inj 5 mg ampoule

PHENYTOIN SODIUM

Inj 50 mg per ml, 2 ml ampoule
Inj 50 mg per ml, 5 ml ampoule

Control of Epilepsy

CARBAMAZEPINE

Oral liq 100 mg per 5 ml
Tab 200 mg
Tab 400 mg
Tab long-acting 200 mg
Tab long-acting 400 mg

CLOBAZAM

Tab 10 mg

CLONAZEPAM

Tab 500 mcg
Tab 2 mg
Oral drops 2.5 mg per ml

ETHOSUXIMIDE

Cap 250 mg
Oral liq 250 mg per 5 ml

GABAPENTIN

Restricted
Must meet community Special Authority criteria

Cap 100 mg
Cap 300 mg
Cap 400 mg
Tab 600 mg

LACOSAMIDE

Restricted
Must meet community Special Authority criteria

Tab 50 mg
Tab 100 mg
Tab 150 mg
Tab 200 mg
Inj 10 mg per ml, 20 ml

LAMOTRIGINE

Tab dispersible 2 mg
Tab dispersible 5 mg
Tab dispersible 25 mg
Tab dispersible 50 mg
Tab dispersible 100 mg

LEVETIRACETAM

Tab 250 mg
Tab 500 mg
Tab 750 mg
Inj 100 mg per ml, 5 ml

PHENOBARBITONE

Tab 15 mg
Tab 30 mg
Inj 200 mg per ml, 1 ml ampoule

PHENYTOIN

Tab 50 mg

PHENYTOIN SODIUM

Cap 30 mg
Cap 100 mg
Oral liq 30 mg per 5 ml

PRIMIDONE

Tab 250 mg

SODIUM VALPROATE

Tab 100 mg
Tab EC 200 mg
Tab EC 500 mg
Oral liq 200 mg per 5 ml
Inj 100 mg per ml, 4 ml vial

TOPIRAMATE

Tab 25 mg
Tab 50 mg
Tab 100 mg
Tab 200 mg
Sprinkle cap 15 mg
Sprinkle cap 25 mg

VIGABATRIN

Restricted
Must meet community Special Authority criteria

Tab 500 mg

Antimigraine Preparations

Acute Migraine Treatment

DIHYDROERGOTAMINE MESYLATE

Inj 1 mg per ml, 1 ml ampoule

ERGOTAMINE TARTRATE WITH CAFFEINE

Tab 1 mg with caffeine 100 mg

METOCLOPRAMIDE HYDROCHLORIDE WITH PARACETAMOL

Tab 5 mg with paracetamol 500 mg

RIZATRIPTAN BENZOATE

Orodispersible tablet 10 mg

SUMATRIPTAN

Tab 50 mg
Tab 100 mg
Inj 12 mg per ml, 0.5 ml cartridge

Prophylaxis of Migraine

CLONIDINE HYDROCHLORIDE

Tab 25 mcg

PIZOTIFEN

Tab 500 mcg

Antinausea and Vertigo Agents

APREPITANT

Restricted
Must meet community Special Authority criteria

Cap 2 x 80 mg and 1 x 125 mg

BETAHISTINE

Tab 16 mg

CYCLIZINE HYDROCHLORIDE

Tab 50 mg

CYCLIZINE LACTATE

Inj 50 mg per ml, 1 ml ampoule

DOMPERIDONE

Tab 10 mg

DROPERIDOL

Inj 2.5 mg per ml, 1 ml ampoule

HYOSCINE HYDROBROMIDE

Restricted (patches)

Any of the following:

1 *Control of intractable nausea, vomiting, or inability to swallow saliva in the treatment of malignancy or chronic disease where the patient cannot tolerate or does not adequately respond to oral anti-nausea agents; or*

2 *Control of clozapine-induced hypersalivation where trials of at least two other alternative treatments have proven ineffective; or*

3. *For treatment of post-operative nausea and vomiting where cyclizine, droperidol and a 5HT3 antagonist have proven ineffective, are not tolerated or are contraindicated.*

Patch 1.5 mg

Inj 400 mcg per ml, 1 ml ampoule

METOCLOPRAMIDE HYDROCHLORIDE

Tab 10 mg

Oral liq 5 mg per 5 ml

Inj 5 mg per ml, 2 ml ampoule

ONDANSETRON

Tab 4 mg

Tab 8 mg

Tab dispersible 4 mg

Tab dispersible 8 mg

Inj 2 mg per ml, 2 ml ampoule

Inj 2 mg per ml, 4 ml ampoule

PROCHLORPERAZINE

Tab 3 mg buccal

Tab 5 mg

Inj 12.5 mg per ml, 1 ml ampoule

Suppos 25 mg

PROMETHAZINE THEOCLATE

Restricted *– continuation only*

Tab 25 mg

TROPISETRON

Cap 5 mg

Inj 1 mg per ml, 2 ml ampoule

Inj 1 mg per ml, 5 ml ampoule

Antipsychotic Agents

General

AMISULPRIDE

Tab 100 mg

Tab 200 mg

Tab 400 mg

Oral liq 100 mg per ml

ARIPIPRAZOLE

Restricted

Must meet community Special Authority criteria

Tab 10 mg

Tab 15 mg

Tab 20 mg

Tab 30 mg

CHLORPROMAZINE HYDROCHLORIDE

Tab 10 mg

Tab 25 mg

Tab 100 mg

Oral liq 10 mg per ml

Inj 25 mg per ml, 2 ml ampoule

CLOZAPINE

Tab 25 mg

Tab 50 mg

Tab 100 mg

Tab 200 mg

Oral liq 50 mg per ml

HALOPERIDOL

Tab 500 mcg

Tab 1.5 mg

Tab 5 mg

Oral liq 2 mg per ml

Inj 5 mg per ml, 1ml ampoule

LEVOMEPROMAZINE MALEATE

Tab 25 mg

Tab 100 mg

Inj 25 mg per ml, 1 ml ampoule

LITHIUM CARBONATE

Cap 250 mg

Tab 250 mg

Tab 400 mg

Tab long-acting 400 mg

OLANZAPINE

Tab 2.5 mg

Tab 5 mg

Tab 10 mg

Inj 10 mg vial

PERICYAZINE

Tab 2.5 mg

Tab 10 mg

QUETIAPINE

Tab 25 mg

Tab 100 mg

Tab 200 mg

Tab 300 mg

RISPERIDONE

Tab 0.5 mg
Tab 1 mg
Tab 2 mg
Tab 3 mg
Tab 4 mg
Oral liq 1 mg per ml

TRIFLUOPERAZINE HYDROCHLORIDE

Tab 1 mg
Tab 2 mg
Tab 5 mg

ZIPRASIDONE

Restricted (capsules)
Must meet community Endorsement criteria

Cap 20 mg
Cap 40 mg
Cap 60 mg
Cap 80 mg
Inj 20 mg
Inj 100 mg

ZUCLOPENTHIXOL ACETATE

Inj 50 mg per ml, 1 ml ampoule
Inj 50 mg per ml, 2 ml ampoule

ZUCLOPENTHIXOL HYDROCHLORIDE

Tab 10 mg

Depot Injections

FLUPENTHIXOL DECANOATE

Inj 20 mg per ml, 1 ml ampoule
Inj 20 mg per ml, 2 ml ampoule
Inj 100 mg per ml, 1 ml ampoule

FLUPHENAZINE DECANOATE

Inj 12.5 mg per 0.5 ml ampoule
Inj 25 mg per ml, 1 ml ampoule
Inj 100 mg per ml, 1 ml ampoule

HALOPERIDOL DECANOATE

Inj 50 mg per ml, 1 ml ampoule
Inj 100 mg per ml, 1 ml ampoule

OLANZAPINE

Restricted
Must meet community Special Authority criteria

Inj 210 mg vial
Inj 300 mg vial
Inj 405 mg vial

PIPOTHIAZINE PALMITATE

Inj 50 mg per ml, 1 ml ampoule
Inj 50 mg per ml, 2 ml ampoule

RISPERIDONE

Restricted
Must meet community Special Authority criteria

Inj 25 mg per 2 ml vial
Inj 37.5 mg per 2 ml vial
Inj 50 mg per 2 ml vial

ZUCLOPENTHIXOL DECANOATE

Inj 200 mg per ml, 1 ml ampoule

Orodispersible Antipsychotics

RISPERIDONE

Restricted
Must meet community Special Authority criteria

Orodispersible tablet 0.5 mg
Orodispersible tablet 1 mg
Orodispersible tablet 2 mg

OLANZAPINE

Orodispersible tablet 5 mg
Orodispersible tablet 10 mg

Anxiolytics

ALPRAZOLAM

Tab 250 mcg
Tab 500 mcg
Tab 1 mg

BUSPIRONE HYDROCHLORIDE

Restricted
Must meet community Special Authority criteria

Tab 5 mg
Tab 10 mg

DIAZEPAM

Tab 2 mg
Tab 5 mg

LORAZEPAM

Tab 1 mg
Tab 2.5 mg

OXAZEPAM

Tab 10 mg
Tab 15 mg

Multiple Sclerosis Treatments

Restricted
Multiple sclerosis treatments are only for use in patients with approval by the Multiple Sclerosis Treatment Assessments Committee

GLATIRAMER ACETATE

Inj 20 mg syringe

INTERFERON BETA-1-ALPHA

Inj 6 million iu vial
Inj 6 million iu syringe

INTERFERON BETA-1-BETA

Inj 8 million iu per 1 ml vial

Sedatives and Hypnotics

CHLORAL HYDRATE

Oral liq 100 mg per ml

Oral liq 200 mg per ml

LORMETAZEPAM

Restricted *– continuation only*

Tab 1 mg

MIDAZOLAM

Tab 7.5 mg

Oral liq 2 mg per ml

Inj 1 mg per ml, 5 ml ampoule

Inj 5 mg per ml, 3 ml ampoule

NITRAZEPAM

Tab 5 mg

TEMAZEPAM

Tab 10 mg

TRIAZOLAM

Restricted *– continuation only*

Tab 125 mcg

Tab 250 mcg

ZOPICLONE

Tab 7.5 mg

Stimulants / ADHD Treatments

ATOMOXETINE

Restricted *Must meet community Special Authority criteria*

Cap 10 mg

Cap 18 mg

Cap 25 mg

Cap 40 mg

Cap 60 mg

Cap 80 mg

Cap 100 mg

CAFFEINE

Tab 100 mg

DEXAMPHETAMINE SULPHATE

Restricted
Must meet community Special Authority criteria

Tab 5 mg

METHYLPHENIDATE HYDROCHLORIDE

Restricted
Must meet community Special Authority criteria

Tab immediate-release 5 mg

Tab immediate-release 10 mg

Tab immediate-release 20 mg

Tab sustained-release 20 mg

Tab extended-release 18 mg

Tab extended-release 27 mg

Tab extended-release 36 mg

Tab extended-release 54 mg

Cap modified-release 10 mg

Cap modified-release 20 mg

Cap modified-release 30 mg

Cap modified-release 40 mg

MODAFINIL

Restricted
Must meet community Special Authority criteria

Tab 100 mg

Treatments for Dementia

DONEPEZIL

Tab 5 mg

Tab 10 mg

Treatments for Substance Dependence

BUPRENORPHINE WITH NALOXONE

Restricted
Must meet community Special Authority criteria

Tab 2 mg with naloxone 0.5 mg

Tab 8 mg with naloxone 2 mg

BUPROPION HYDROCHLORIDE

Tab modified-release 150 mg

DISULFIRAM

Tab 200 mg

NALTREXONE HYDROCHLORIDE

Restricted
Either:

1. *For use in accordance with the community Special Authority criteria; or*
2. *For the treatment of opioid-induced constipation.*

Tab 50 mg

NICOTINE

Gum 2 mg

Gum 4 mg

Lozenge 1 mg

Lozenge 2 mg

Patch 7 mg per 24 hours

Patch 14 mg per 24 hours

Patch 21 mg per 24 hours

VARENICLINE

Restricted
Must meet community Special Authority criteria

Tab 0.5 mg (11) and tab 1 mg (14)

Tab 1 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.

- Acamprosate
- Amylobarbitone sodium
- Chlordiazepoxide hydrochloride
- Droxidopa
- Duloxetine
- Felbamate
- Flunitrazepam
- Galantamine
- Ibuprofen with codeine phosphate
- Lignocaine with cetrimide
- Mecolazine hydrochloride
- Melatonin
- Memantine hydrochloride
- Mepivacaine hydrochloride
- Methysergide maleate
- Natalizumab
- Oxcarbazepine
- Paliperidone
- Paracetamol with caffeine
- Paracetamol with ibuprofen
- Pimozide
- Piracetam
- Pregabalin
- Procaine hydrochloride
- Procaine hydrochloride with adrenaline and atropine sulphate
- Reboxetine mesylate
- Retigabine
- Rivastigmine
- Trimipramine maleate

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.

- Bromocriptine
  - Tab 10 mg
- Bupivacaine hydrochloride
  - Inj 2.5 mg per ml, 200 ml bag
  - Inj 3.75 mg per ml, 20 ml
- Bupivacaine hydrochloride with adrenaline
  - Inj 5 mg per ml with adrenaline 1:200:000, 2.2 ml dental cartridge
  - Inj 2.5 mg per ml with adrenaline 1:400,000, 10 ml vial
  - Inj 5 mg per ml with adrenaline 1:200,000, 10 ml vial
- Bupivacaine hydrochloride with fentanyl
  - Inj 0.625 mg with fentanyl 2 mcg per ml, 100 ml bag
  - Inj 0.625 mg with fentanyl 2 mcg per ml, 200 ml bag
- Buprenorphine
  - Patch 5 mcg per hour
  - Patch 10 mcg per hour
  - Patch 20 mcg per hour
  - Inj 0.3 mg per ml, 1 ml ampoule
- Codeine phosphate
  - Inj 50 mg per ml, 1 ml
- Diazepam
  - Oral liq 10 mg per 10 ml
- Domperidone
  - Oral liq 1 mg per ml
  - Suppos 10 mg
- Droperidol
  - Inj 5 mg per ml, 2 ml ampoule
- Fentanyl
  - Inj 20 mcg per ml, 100 ml bag
  - Inj 10 mcg per ml, 10 ml syringe
  - Inj 50 mcg per ml, 50 ml syringe
- Ketamine
  - Inj 1 mg per ml, 10 ml syringe
- Lamotrigine
  - Tab dispersible 200 mg
- Levetiracetam
  - Tab 1000 mg
  - Oral liq 100 mg per ml
- Lignocaine hydrochloride
  - Inj 0.5%, 5 ml
  - Inj 1%, 10 ml syringe
  - Inj 2%, 5 ml syringe
  - Inj 2%, 2 ml ampoule

Inj 2%, 2.2 ml dental cartridge

Inj 2%, 50 ml ampoule

Patch 5%

Oint 5%

Metoclopramide

Suppos 10 mg

Morphine sulphate

Cap long-acting 200 mg

Inj 1 mg per ml, 2 ml syringe

Inj 1 mg per ml, 30 ml syringe

Nicotine

Inhaler 10 mg per dose

Nasal spray 10 mg per ml, 10 ml

Patch 5 mg per 16 hours

Patch 10 mg per 16 hours

Patch 15 mg per 16 hours

Sublingual tablet 2 mg

Paracetamol

Cap 500 mg

Tab soluble 250 mg

Paracetamol with codeine

Tab 500 mg with codeine 15 mg

Pergolide

Tab 0.05 mg

Pethidine hydrochloride

Inj 50 mg per ml, 1.5 ml ampoule

Phenobarbitone

Inj 20 mg in 0.5 ml

Prochlorperazine

Suppos 5 mg

Propofol

Inj 20 mg per ml, 50 ml syringe

Inj 20 mg per ml, 50 ml vial/ampoule

Remifentanil hydrochloride

Inj 5 mg vial

Rocuronium bromide

Inj 10 mg per ml, 10 ml vial

Ropinirole

Tab 0.25 mg (42), 0.5 mg (42), 1 mg (21)

Tab 0.5 mg (42), 1 mg (21), 2 mg (63)

Topiramate

Sprinkle cap 50 mg

Tramadol

Tab sustained-release 50 mg

Trifluoperazine hydrochloride

Oral liq 1 mg per ml

Venlafaxine

Tab 75 mg

Zuclopenthixol decanoate

Inj 500 mg per ml, 1 ml ampoule

Zuclopenthixol hydrochloride

Tab 25 mg

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:

Lignocaine hydrochloride inj 1%, 2 ml (Xylocaine)

Lignocaine hydrochloride inj 2%, 2 ml (Xylocaine)

Morphine sulphate inj 1 mg per ml, 30 ml prefilled syringe (Biomed)

Propofol inj 2%, 50 ml prefilled syringe (Diprivan)

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.

Sugammadex

This proposal does not include the listing of sugammadex in Section H. We are currently working through a number issues relating to sugammadex, and hope to be able to consult either on its inclusion or exclusion in the coming months.

Methoxyflurane

The proposal also does not include the listing of methoxyflurane in Section H. We intend to consider this product further over the coming months, and we will be discussing this issue with relevant parties.

Stiripentol

The use of stiripentol for Dravet syndrome has been highlighted to us through this review process. We are still considering stiripentol, and expect to be consulting on this separately in the near future.

Gabapentin

Through this process we have been made aware of peri-operative use of gabapentin in DHB hospitals, although such use is not currently part of this proposal. We will be considering this further in the next few months and will consult on it separately next year.

Proposed changes to community pharmaceutical funding

As part of this proposal, we are also proposing to make the following changes to list the following pharmaceutical in the community (Section B of the Pharmaceutical Schedule) from 1 April 2013.

Phenobarbitone

Phenobarbitone injection (200 mg per ml, 1 ml ampoule) would be listed in Section B of the Pharmaceutical Schedule at the following price and subsidy (ex-manufacturer, exclusive of GST):

Chemical	Formulation	Brand	Pack size	Price and subsidy
Phenobarbitone	Inj 200 mg per ml, 1 ml ampoule	Martindale	10	$46.20

Phenobarbitone injection would be subject to the following Special Authority restriction:

> Initial application from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:
> Both:
> 1 For the treatment of terminal agitation that is unresponsive to other agents; and
> 2 The applicant is part of a multidisciplinary team working in palliative care

Background

Following a request from palliative care clinicians, the Analgesic Subcommittee recommended that phenobarbitone injection be subsidised in the community for terminal agitation with a high priority. We note that phenobarbitone injection is not a registered medicine in New Zealand, and so would be supplied under section 29 of the Medicines Act 1981.

Hyoscine (scopolamine)

The Special Authority applying to hyoscine (scopolamine) patch 1.5 mg (Scopoderm TTS) would be replaced as follows (deletions in strikethrough, additions in bold):

> Initial application from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:
> ~~All of the following~~ **Either**:
> 1 Control of intractable nausea, vomiting, or inability to swallow saliva in the treatment of malignancy or chronic disease~~; and~~ **where the patient cannot tolerate or does not adequately respond to oral anti-nausea agents; or**
> ~~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.~~
> **2 Control of clozapine-induced hypersalivation where trials of at least two other alternative treatments have proven ineffective.**
>
> Renewal from any relevant practitioner. Approvals valid for 1 year where the treatment remains appropriate and the patient is benefiting from treatment.

Background

Following a series of queries from clinicians, the Mental Health Subcommittee of PTAC considered the funding of hyoscine patches for clozapine-induced hypersalivation (CIH) at its June 2012 meeting.

The Subcommittee noted that current treatment options for CIH include benztropine, atropine drops or terazosin. However, not all patients respond to these treatments and CIH is a significant issue that can lead to clozapine treatment discontinuation.

The Subcommittee considered that there is very little evidence for the efficacy of hyoscine patches (or any other agent) in CIH; however, it would be easy to ascertain clinical efficacy for this indication. The Subcommittee recommended widening access to hyoscine patches for CIH with a high priority.