

3 August 2012

Proposal Relating to the Funding of Certain Pharmaceuticals in DHB Hospitals

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.

This consultation refers to two therapeutic groups within Section H, *the Cardiovascular System* and *the Musculoskeletal System*. While these headings primarily relate to pharmaceuticals that are used in cardiology and rheumatology, 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.

This is the second consultation document released relating to this work, but the first containing proposed inclusions and exclusions from Section H. All of PHARMAC's consultations relevant to this work are available on PHARMAC's website:

www.pharmac.govt.nz/HospitalPharmaceuticals

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 7 September 2012** to:

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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 Cardiovascular System therapeutic group:

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For the Musculoskeletal System therapeutic group:

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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.

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: we have also recently released a consultation titled "Proposed Pharmaceutical Schedule Rules for Hospital Pharmaceuticals" which may provide some useful context for reviewing these lists. This consultation document is available on our website: **www.pharmac.govt.nz/HospitalPharmaceuticals**. In summary it proposes:

- 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 Cardiovascular Subcommittee, Rheumatology Subcommittee and Hospital Pharmaceuticals Subcommittee.

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 two of these therapeutic groups: the Cardiovascular System group and the Musculoskeletal System group.

Appended to this letter are the lists of pharmaceuticals that are proposed for inclusion in Section H under these two 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 is not included 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;
- antithrombotic agents (antiplatelets, anticoagulants and fibrinolytic agents) are not included in the Cardiovascular System section but will be included in the Blood and Blood-Forming Organs therapeutic group (to be consulted on at a later date);
- while osteoporosis treatments are, in the community Pharmaceutical Schedule, listed under the Musculoskeletal System heading, we will be consulting on these later, alongside other endocrinology treatments;
- 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 funding application for these would need to be considered (and in several 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 changes to the Pharmaceutical Schedule.

CARDIOVASCULAR SYSTEM

Agents Affecting the Renin-Angiotensin System

ACE Inhibitors

CAPTOPRIL

Oral liqid restricted to children under 12 years of age

- Tab 12.5 mg
- Tab 25 mg
- Tab 50 mg
- Oral liq 5 mg per ml

CILAZAPRIL

- Tab 0.5 mg
- Tab 2.5 mg
- Tab 5 mg

ENALAPRIL MALEATE

- Tab 5 mg
- Tab 10 mg
- Tab 20 mg

LISINAPRIL DIHYDRATE

- Tab 5 mg
- Tab 10 mg
- Tab 20 mg

PERINDOPRIL

For continuation only

- Tab 2 mg
- Tab 4 mg

QUINAPRIL

- Tab 5 mg
- Tab 10 mg
- Tab 20 mg

TRANDOLAPRIL

For continuation only

- Cap 1 mg
- Cap 2 mg

ACE Inhibitors with Diuretics

CILAZAPRIL WITH HYDROCHLOROTHIAZIDE

- Tab 5 mg with hydrochlorothiazide 12.5 mg

ENALAPRIL WITH HYDROCHLOROTHIAZIDE

For continuation only

- Tab 20 mg with hydrochlorothiazide 12.5 mg
- #### QUINAPRIL WITH HYDROCHLOROTHIAZIDE
- Tab 10 mg with hydrochlorothiazide 12.5 mg
 - Tab 20 mg with hydrochlorothiazide 12.5 mg

Angiotensin II Antagonists

CANDESARTAN CILEXETIL

Restricted – must meet Special Authority criteria

- Tab 4 mg
- Tab 8 mg
- Tab 16 mg
- Tab 32 mg

LOSARTAN POTASSIUM

- Tab 12.5 mg
- Tab 25 mg
- Tab 50 mg
- Tab 100 mg

Angiotensin II Antagonists with Diuretics

LOSARTAN POTASSIUM WITH HYDROCHLOROTHIAZIDE

- Tab 50 mg with hydrochlorothiazide 12.5 mg

Alpha-Adrenoceptor Blockers

DOXAZOSIN

- Tab 2 mg
- Tab 4 mg

PHENOXYBENZAMINE

- Cap 10 mg
- Inj 50 mg per ml, 2 ml ampoule

PHENTOLAMINE MESYLATE

- Inj 10 mg per ml, 1 ml ampoule

PRAZOSIN

- Tab 1 mg
- Tab 2 mg
- Tab 5 mg

TERAZOSIN

- Tab 1 mg
- Tab 2 mg
- Tab 5 mg

Antiarrhythmics

ADENOSINE

Restricted (10 ml only)

For use in cardiac catheterisation, electrophysiology and MRI

- Inj 3 mg per ml, 2 ml vial
- Inj 3 mg per ml, 10 ml vial

AJMALINE

Cardiologist recommendation required

- Inj 5 mg per ml, 10 ml

AMIODARONE HYDROCHLORIDE

- Inf 50 mg per ml, 3 ml ampoule
- Tab 100 mg
- Tab 200 mg

ATROPINE SULPHATE

- Inj 600 µg, 1 ml

DIGOXIN

- Tab 62.5 mg
- Tab 250 mg
- Oral liq 50 µg per ml
- Inj 250 µg per ml, 2 ml vial

DISOPYRAMIDE PHOSPHATE

- Cap 100 mg
- Cap 150 mg

FLECAINIDE ACETATE

Tab 50 mg
Tab 100 mg
Cap long-acting 100 mg
Cap long-acting 200 mg
Inj 10 mg per ml, 15 ml ampoule

MEXILETINE HYDROCHLORIDE

Cap 150 mg
Cap 250 mg

PROPAFENONE HYDROCHLORIDE

Tab 150 mg

Antihypotensives**MIDODRINE**

Restricted – must meet Special Authority criteria

Tab 2.5 mg
Tab 5 mg

Beta-Adrenoceptor Blockers**ATENOLOL**

Tab 50 mg
Tab 100 mg
Oral liq 25 mg per 5 ml

BISOPROLOL

Tab 2.5 mg
Tab 5 mg
Tab 10 mg

CARVEDILOL

Tab 6.25 mg
Tab 12.5 mg
Tab 25 mg

CELIPROLOL

Tab 200 mg

ESMOLOL HYDROCHLORIDE

Inj 10 mg per ml, 10 ml vial

LABETALOL

Tab 50 mg
Tab 100 mg
Tab 200 mg
Tab 400 mg
Inj 5 mg per ml, 20 ml ampoule

METOPROLOL SUCCINATE

Tab long-acting 23.75 mg
Tab long-acting 47.5 mg
Tab long-acting 95 mg
Tab long-acting 190 mg

METOPROLOL TARTRATE

Tab 50 mg
Tab 100 mg
Tab long-acting 200 mg
Inj 1 mg per ml, 5 ml vial

NADOLOL

Tab 40 mg
Tab 80 mg

PINDOLOL

Tab 5 mg
Tab 10 mg
Tab 15 mg

PROPRANOLOL

Tab 10 mg
Tab 40 mg
Cap long-acting 160 mg
Oral liq 1 mg per ml
Inj 1 mg per ml, 1 ml

SOTALOL

Tab 80 mg
Tab 160 mg
Inj 10 mg per ml, 4 ml ampoule

TIMOLOL MALEATE

Tab 10 mg

Calcium Channel Blockers**Dihydropyridine Calcium Channel Blockers****AMLODIPINE**

Tab 2.5 mg
Tab 5 mg
Tab 10 mg

FELODIPINE

Tab long-acting 2.5 mg
Tab long-acting 5 mg
Tab long-acting 10 mg

ISRADIPINE

Tab 2.5 mg
Cap long-acting 2.5 mg
Cap long-acting 5 mg

NIFEDIPINE

Cap 5 mg
Tab long-acting 10 mg
Tab long-acting 20 mg
Tab long-acting 30 mg
Tab long-acting 60 mg

NIMODIPINE

Tab 30 mg
Inf 200 mcg per ml, 50 ml vial

Other Calcium Channel Blockers**DILTIAZEM HYDROCHLORIDE**

Tab 30 mg
Tab 60 mg
Cap long-acting 120 mg
Cap long-acting 180 mg
Cap long-acting 240 mg
Inj 5 mg per ml, 5 ml

PERHEXILINE MALEATE

Restricted – must meet Special Authority criteria

Tab 100 mg

VERAPAMIL HYDROCHLORIDE

Tab 40 mg
 Tab 80 mg
 Tab long-acting 120 mg
 Tab long-acting 240 mg
 Inj 2.5 mg per ml, 2 ml ampoule

Centrally-Acting Agents**CLONIDINE**

Patch 2.5 mg, 100 µg per day
 Patch 5 mg, 200 µg per day
 Patch 7.5 mg, 300 µg per day

CLONIDINE HYDROCHLORIDE

Tab 150 mcg
 Inj 150 mcg per ml, 1 ml ampoule
 Inj 1.5 mg per ml, 1 ml
 Inj 1.5 mg per ml, 2 ml
 Inj 1.5 mg per ml, 20 ml

METHYLDOPA

Tab 125 mg
 Tab 250 mg
 Tab 500 mg

Diuretics**Loop Diuretics****BUMETANIDE**

Tab 1 mg
 Inj 500 mcg per ml, 4 ml

FUROSEMIDE (FRUSEMIDE)

Tab 40 mg
 Tab 500 mg
 Oral liq 10 mg per ml
 Inj 10 mg per ml, 2 ml ampoule
 Inf 10 mg per ml, 25 ml ampoule

Osmotic Diuretics**MANNITOL**

Inf 10%, 1000 ml
 Inf 15%, 500 ml
 Inf 20%, 500 ml

Potassium Sparing Combination Diuretics**AMILORIDE WITH FUROSEMIDE**

Tab 5 mg with furosemide 40 mg

AMILORIDE WITH HYDROCHLOROTHIAZIDE

Tab 5 mg with hydrochlorothiazide 50 mg

Potassium Sparing Diuretics**AMILORIDE HYDROCHLORIDE**

Tab 5 mg
 Oral liq 1 mg per ml

SPIRONOLACTONE

Tab 25 mg
 Tab 100 mg
 Oral liq 5 mg per ml

Thiazide and Related Diuretics**BENDROFLUMETHAZIDE (BENDROFLUAZIDE)**

Tab 2.5 mg
 Tab 5 mg

CHLORATALIDONE (CHLORTHALIDONE)

Tab 25 mg

CHLOROTHIAZIDE

Oral liq 50 mg per ml

INDAPAMIDE

Tab 2.5 mg

METOLAZONE

Restricted – for the treatment of patients with refractory heart failure who are unresponsive to Angiotensin Converting Enzyme (ACE) inhibitors, Angiotensin Receptor Blockers (ARBs) and diuretics

Tab 5 mg

Lipid-Modifying Agents**Fibrates****BEZAFIBRATE**

Tab 200 mg
 Tab long-acting 400 mg

GEMFIBROZIL

Tab 600 mg

Resins**CHOLESTYRAMINE**

Sachets 4 g

COLESTIPOL HYDROCHLORIDE

Sachets 5 g

HMG CoA Reductase Inhibitors (Statins)**ATORVASTATIN**

Tab 10 mg
 Tab 20 mg
 Tab 40 mg
 Tab 80 mg

PRAVASTATIN

Tab 10 mg
 Tab 20 mg
 Tab 40 mg

SIMVASTATIN

Tab 10 mg
 Tab 20 mg
 Tab 40 mg
 Tab 80 mg

Selective Cholesterol Absorption Inhibitors**EZETIMIBE**

Restricted – must meet Special Authority criteria

Tab 10 mg

EZETIMIBE WITH SIMVASTATIN

Restricted – must meet Special Authority criteria

Tab 10 mg with simvastatin 10 mg

Tab 10 mg with simvastatin 20 mg

Tab 10 mg with simvastatin 40 mg

Tab 10 mg with simvastatin 80 mg

Other Lipid Modifying Agents**ACIPIMOX**

Cap 250 mg

NICOTINIC ACID

Tab 50 mg

Tab 500 mg

Nitrates**GLYCERYL TRINITRATE**

Tab 600 mcg

Oral spray, 400 mcg per dose

Patch 25 mg, 5 mg per day

Patch 50 mg, 10 mg per day

Inf 1 mg per ml, 5 ml

Inf 5 mg per ml, 10 ml

Inf 1 mg per ml, 50 ml

ISOSORBIDE MONONITRATE

Tab 20 mg

Tab long-acting 40 mg

Tab long-acting 60 mg

Other Cardiac Agents**LEVOSIMENDAN****Restricted**Heart transplant

1. For use as a bridge to heart transplant, in patients who have been accepted for transplant; or
2. for the treatment of heart failure following heart transplant.

Heart failure – cardiologist or intensivist recommendation required

1. For the treatment of severe acute decompensated heart failure that is non-responsive to dobutamine.

Inf 2.5 mg per ml, 5 ml vial

Inf 2.5 mg per ml, 10 ml vial

Sympathomimetics**ADRENALINE**

Inj 1 in 1,000, 1 ml ampoule

Inj 1 in 10,000, 10 ml ampoule

Inj 1 in 10,000, 10 ml syringe

Inj 1 mg per ml, 30 ml

DOBUTAMINE HYDROCHLORIDE

Inf 12.5 mg per ml, 20 ml vial

DOPAMINE HYDROCHLORIDE

Inf 40 mg per ml, 5 ml ampoule

EPHEDRINE

Inf 30 mg per ml, 1 ml syringe

Inf 30 mg per ml, 1 ml ampoule

ISOPRENALINE

Inj 200 mcg per ml, 1 ml ampoule

Inj 200 mcg per ml, 5 ml ampoule

METARAMINOL

Inj 0.5 mg per ml, 20 ml syringe

Inj 1 mg per ml, 1 ml ampoule

Inj 1 mg per ml, 10 ml syringe

Inj 10 mg per ml, 1 ml

NORADRENALINE

Inf 0.06 mg per ml, 50 ml syringe

Inf 0.06 mg per ml, 100 ml bag

Inf 0.1 mg per ml, 100 ml bag

Inf 0.12 mg per ml, 50 ml syringe

Inf 0.12 mg per ml, 100 ml bag

Inf 0.16 mg per ml, 50 ml syringes

Inf 1 mg per ml, 2 ml ampoule

Inf 1 mg per ml, 100 ml bag

PHENYLEPHRINE HYDROCHLORIDE

Inj 10 mg per ml, 1 ml vial

Vasodilators**ALPROSTADIL**

Inj 500 mcg per ml, 1 ml ampoule

AMYL NITRITE

Cap, 0.3 ml crushable

DIAZOXIDE

Inj 15 mg per ml, 20 ml ampoule

HYDRALAZINE HYDROCHLORIDE**Restricted**Either:

1. For the treatment of refractory hypertension; or
2. For the treatment of heart failure, in combination with a nitrate, in patients who are intolerant or have not responded to ACE inhibitors and/or angiotensin receptor blockers

Tab 25 mg

Inj 20 mg per ml, 1 ml

MILRINONE

Inj 1 mg per ml, 10 ml

MINOXIDIL

Restricted – for patients with severe refractory hypertension which has failed to respond to extensive multiple therapies

Tab 10 mg

PAPAVERINE HYDROCHLORIDE

Inj 12 mg per ml, 10 ml ampoule

Inj 30 mg per ml, 1 ml vial

PENTOXIFYLLINE (OXPENTIFYLLINE)

Tab 400 mg

SODIUM NITROPRUSSIDE

Inj 50 mg, vial

Endothelin Receptor Antagonists

AMBRISENTAN

Restricted - only for use in patients with approval by the Pulmonary Arterial Hypertension Panel

Tab 5 mg

Tab 10 mg

BOSENTAN

Restricted - only for use in patients with approval by the Pulmonary Arterial Hypertension Panel

Tab 62.5 mg

Tab 125 mg

Phosphodiesterase (PDE) Type 5 Inhibitors

SILDENAFIL

Restricted

Any of the following:

1. patients with approval by the Pulmonary Arterial Hypertension Panel; or
2. for use in neonatal units for persistent pulmonary hypertension of the newborn (PPHN); or
3. for use in weaning patients from inhaled nitric oxide.

Tab 25 mg

Tab 50 mg

Tab 100 mg

Prostacyclin Analogues

ILOPROST

Restricted (nebuliser solution only)

Any of the following:

1. patients with approval by the Pulmonary Arterial Hypertension Panel; or
2. for diagnostic use in catheter laboratories; or
3. following mitral or tricuspid valve surgery.

Inj 100 mcg per ml, 0.5 ml

Nebuliser soln 10 mcg per ml, 2 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.

Acebutolol

Cyclopenthiazine

Dronaderone

Guantethidine monosulphate

Hydrochlorothiazide (tablets)

Irbesartan

Ivabradine

Lignocaine with glucose (bags)

Nicardipine

Rosuvastatin

Tadalafil

Triamterene with hydrochlorothiazide

Vardenafil

Vernakalant

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.

Adenosine

Inj 10 mg per ml, 2 ml

Atropine

Inj 500 µg, 5 ml syringe

Inj 1000 µg, 10 ml syringe

Diltiazem

Cap long-acting 90 mg (twice daily)

Cap long-acting 120 mg (twice daily)

Esmolol

Inj 250 mg per ml, 10 ml

Labetalol

Oral liquid

Sildenafil

Tab 20 mg

There are a few items that have been highlighted in this process for which PTAC has indicated that a funding application should be considered. This applies to dronaderone, ivabradine, nicardipine and vernakalant, as well as the use of sildenafil in cardiac surgery. We will be considering these products further over the coming months, and will discuss this issue further with relevant parties.

MUSCULOSKELETAL SYSTEM

Anticholinesterases

EDROPHONIUM CHLORIDE

Restricted – for the diagnosis of myasthenia gravis

Inj 10 mg per ml, 1 ml

NEOSTIGMINE

Inj 2.5 mg per ml, 1 ml

PYRIDOSTIGMINE BROMIDE

Tab 60 mg

Antirheumatoid Agents

AURANOFIN

Tab 3 mg

HYDROXYCHLOROQUINE

Tab 200 mg

LEFLUNOMIDE

Tab 10 mg

Tab 20 mg

PENICILLIMINE

Tab 125 mg

Tab 250 mg

SODIUM AUROTHIOMALATE

Inj 10 mg per 0.5 ml

Inj 20 mg per 0.5 ml

Inj 50 mg per 0.5 ml

Tumor Necrosis Factor (TNF) Inhibitors

ADALIMUMAB

Restricted – must meet Special Authority criteria

Inj 40 mg per 0.8 ml pen

Inj 40 mg per 0.8 ml syringe

ETANERCEPT

Restricted – must meet Special Authority criteria

Inj 25 mg

Inj 50 mg autoinjector

Inj 50 mg syringe

Other Biologic Agents

RITUXIMAB

Restricted – refer to next page

Inj 100 mg per 10 ml vial

Inj 500 mg per 10 ml vial

Enzymes

HYALURONIDASE

Inj 1500 iu

Hyperuricaemia and Antigout

ALLOPURINOL

Tab 100 mg

Tab 300 mg

COLCHICINE

Tab 500 µg

PROBENECID

Tab 500 mg

RASBURICASE

Restricted – haematologist recommendation required

Inf 1.5 mg

Muscle Relaxants

BACLOFEN

Tab 10 mg

Oral liq 5 mg per 5 ml

Inj 0.05 mg per ml, 1 ml

Inj 2 mg per ml, 5 ml

DANTROLENE

Cap 25 mg

Cap 50 mg

Inj 1 mg per ml, 20 ml

ORPHENADRINE CITRATE

Tab 100 mg

Non-Steroidal Anti-Inflammatory Drugs

DICLOFENAC SODIUM

Tab EC 25 mg

Tab EC 50 mg

Tab 50 mg dispersible

Tab long-acting 75 mg

Tab long-acting 100 mg

Suppos 12.5 mg

Suppos 25 mg

Suppos 50 mg

Suppos 100 mg

Inj 25 mg per ml, 3 ml

IBUPROFEN

Restricted

400 mg and 600 mg tablets – continuation only

Tab 200 mg

Tab 400 mg

Tab 600 mg

Tab long-acting 800 mg

Oral liq 100 mg per 5 ml

Inj 5 mg per ml, 2 ml

INDOMETHACIN

Cap 25 mg

Cap 50 mg

Cap long-acting 75 mg

Suppos 100 mg

Inj 1 mg

KETOPROFEN

Cap long-acting 100 mg

Cap long-acting 200 mg

MEFENAMIC ACID*Restricted – continuation only*

Cap 250 mg

MELOXICAM*Restricted – must meet Special Authority criteria*

Tab 7.5 mg

NAPROXEN

Tab 250 mg

Tab 500 mg

Tab long-acting 750 mg

Tab long-acting 1 g

PARECOXIB

Inj 40 mg

SULINDAC*Restricted – continuation only*

Tab 100 mg

Tab 200 mg

TENOXICAM

Tab 20 mg

Inj 10 mg per ml, 2 ml

TIAPROFENIC ACID

Tab 300 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.

Abatacept

Anakinra

Arnica

Benzbromarone

Celecoxib

Diclofenac potassium

Etoricoxib

Golimumab

Ibuprofen lysine

Infliximab (for rheumatology use)

Methyl salicylate with menthol

Methyl salicylate with menthol and eucalyptus oil

Naproxen sodium

Piroxicam

Tocilizumab

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.

Capsaicin*

Cream 0.025%

Diclofenac

Gel 1%

Leflunomide

Tab 100 mg

Orphenadrine citrate

Inj 30 mg per ml, 2 ml

* The other strength of capsaicin cream (0.075%) is subsidised in the community and so would be included in Section H. This will be included in a later consultation document alongside analgesic agents.

Biologic agents

In relation to the proposed listing of adalimumab, etanercept, infliximab and rituximab, this consultation document relates only to their use in rheumatology. We will be addressing use in other specialities, such as dermatology, gastroenterology and ophthalmology, in other consultation documents.

We are proposing that the access criteria for infliximab do not include use for rheumatoid arthritis and other rheumatological indications, and any such use would require approval under an exceptions mechanism.

We have recently received a funding application for the use of infliximab (and other TNF inhibitors) for Behçet's disease and are currently considering this for inclusion in Section H.

The access criteria for rituximab for use in rheumatoid arthritis are the subject of a separate consultation letter issued on 30 July 2012. If you would like a copy of that consultation document, please let us know; consultation on that proposal closes on 14 August 2012.