CONSULTATION

PHARMAC
Pharmaceutical Management Agency

**25 July 2014**

# Proposal to amend or remove funding restrictions from various pharmaceuticals

PHARMAC is seeking feedback on a proposal to remove or amend the funding restrictions for a number of pharmaceuticals from 1 October 2014. The proposed changes are summarised below. Details of the proposed changes and background information can be found on the following pages.

The Special Authority and/or hospital medicines list (HML) restrictions for the following products would be removed from 1 October 2014 (unless another date is specified below):

- Bee and wasp venom allergy treatments
- Bicalutamide
- Imiquimod (from 1 February 2015)
- Mycophenolate mofetil
- Nicorandil
- Perhexiline maleate

The funding rules for the following products would be amended to widen funded access from 1 October 2014:

- Acitretin: some of the prescriber-related criteria would be amended or removed from the Special Authority.
- Adalimumab, etanercept and tocilizumab: access would be widened to include adult-onset Still's disease.
- Benzydamine hydrochloride: full subsidy would be available via prescription endorsement in the community for patients with oral mucositis resulting from cancer treatment.
- Deferiprone: access would be widened to include acquired red cell aplasia.
- Gabapentin (Arrow-Gabapentin and Nupentin brands only): access would be widened to include uraemic pruritus and the requirement to trial a tricyclic antidepressant prior to gabapentin would be removed.
- Insulin pump and insulin pump consumables: access would be widened to include cystic fibrosis-related diabetes;
- Isotretinoin: some of the prescriber-related criteria would be amended or removed from the Special Authority, and the requirement for a trial of other available treatments prior to accessing isotretinoin would be removed.
- Midodrine: the requirement for a trial of fludrocortisone and other non-pharmacological treatments prior to accessing midodrine would be removed.

## Feedback sought

PHARMAC welcomes feedback on this proposal. **Please specify in your response which product(s) your feedback relates to.** To provide feedback, please submit it in writing by **5 pm** on **Friday, 8 August 2014** to:


Geraldine MacGibbon
Senior Therapeutic Group Manager
PHARMAC

Email: july25consult@pharmac.govt.nz
Fax: 04 460 4995
Post: PO Box 10 254, Wellington 6143


All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.




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

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. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. 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 it withheld. PHARMAC will give due consideration to any such request.

**Details of the proposal**

The proposal is to remove or amend the funding access restrictions applying to various pharmaceuticals in Section B of the Pharmaceutical Schedule and in the Hospital Medicines List (HML; Part II of Section H of the Pharmaceutical Schedule). Existing restrictions for these pharmaceuticals can be found on PHARMAC's website at the links below – for practical reasons these have not been reproduced in this consultation document.

www.pharmac.govt.nz/PharmaceuticalSchedule/Schedule?osq
www.pharmac.health.nz/tools-resources/pharmaceutical-schedule/section-h/

Unless another date is specified below, all proposed changes would occur on 1 October 2014.

***In relation to the removal of Special Authorities and hospital restrictions***

- The Special Authority and hospital restrictions would be removed from the listings of the following products in Section B and Part II of Section H of the Pharmaceutical Schedule. There would be no change to the price, subsidy, presentation, or listed brand of these pharmaceuticals as a result of this proposal.

| **Chemical (Therapeutic Group Subheading)** | **Presentation** | **Brand** |
|---|---|---|
| Bee and wasp venom allergy treatment (Antiallergy Preparations) | Treatment Kits (bee venom, paper wasp venom and yellow jacket venom) and Maintenance Kit (bee venom) | Albay |
| Bicalutamide (Endocrine Therapy) | Tab 50 mg | Bicalaccord |
| Imiquimod (Wart Preparations) (change from 1 February 2015) | Crm 5%, 250 mg sachet | Aldara<br>Apo-Imiquimod Cream 5% (to be listed 1 December 2014) |
| Mycophenolate mofetil (Immunosuppressants) | Cap 250 mg, tab 500 mg, powder for oral liq 1 g per 5 ml<br>Inj 500 mg vial (HML only) | Cellcept |
| Nicorandil (Vasodilators) | Tab 10 mg and 20 mg | Ikorel |
| Perhexiline maleate (Calcium Channel Blockers) | Tab 100 mg | Pexsig |

### *In relation to acitretin*

- The Special Authority for acitretin cap 10 mg and 25 mg (Neotigason and Novatretin) in Section B of the Pharmaceutical Schedule would be amended as follows (additions in bold, deletions in strikethrough) and re-numbered accordingly:

> Initial application from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:
> All of the following:
> 1 Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice; and
> 2 Applicant has an up to date knowledge of ~~the treatment options for psoriasis and of disorders of keratinisation and is aware of~~ the safety issues around acitretin and is competent to prescribe acitretin; and
> 3 Either:
> 3.1 Patient is female and has been counselled and understands the risk of teratogenicity if acitretin is used during pregnancy and the applicant has ensured that the possibility of pregnancy has been excluded prior to the commencement of the treatment and that the patient is informed that she must not become pregnant during treatment and for a period of two years after the completion of the treatment; or
> 3.2 Patient is male.
> Renewal from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:
> ~~All of the following:~~
> ~~1 Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice; and~~
> ~~2 Applicant has an up to date knowledge of the treatment options for psoriasis and of disorders of keratinisation and is aware of the safety issues around acitretin and is competent to prescribe acitretin; and~~
> 3 Either:
> 3.1 Patient is female and has been counselled and understands the risk of teratogenicity if acitretin is used during pregnancy and the applicant has ensured that the possibility of pregnancy has been excluded prior to the commencement of the treatment and that the patient is informed that she must not become pregnant during treatment and for a period of two years after the completion of the treatment; or
> 3.2 Patient is male.

### *In relation to adalimumab, etanercept, and tocilizumab*

- The following new indication would be added to the Special Authorities for adalimumab inj 20 mg per 0.4 ml prefilled syringe and inj 40 mg per 0.8 ml prefilled pen and syringe (Humira and HumiraPen) and etanercept inj 25 mg and inj 50 mg autoinjector and prefilled syringe (Enbrel) in Section B of the Pharmaceutical Schedule:

> **Initial application - (adult-onset Still's disease)** only from a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:
> Either:
> 1 Both:
> 1.1 Either:
> 1.1.1 The patient has had an initial Special Authority approval for etanercept or adalimumab (as applicable) for adult-onset Still's disease (AOSD); or
> 1.2.1 The patient has been started on tocilizumab for AOSD in a DHB hospital in accordance with the HML rules; and
> 1.2 Either:

1.2.1 The patient has experienced intolerable side effects from etanercept, adalimumab or tocilizumab (as applicable); or

1.2.2 The patient has received insufficient benefit from at least a three-month trial of etanercept, adalimumab or tocilizumab (as applicable) such that they do not meet the renewal criteria for AOSD; or

2 All of the following:

2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and

2.2 Patient has tried and not responded to at least 6 months of glucocorticosteroids, non-steroidal anti-inflammatory drugs (NSAIDs) and methotrexate; and

2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

**Renewal - (adult-onset Still's disease)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:

1 Either:

1.1 Applicant is a rheumatologist; or

1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with etanercept or adalimumab (as applicable) treatment; and

2 The patient has a sustained improvement in inflammatory markers and functional status.

- The restrictions for adalimumab, etanercept, and tocilizumab inj 20 mg per ml, 4 ml, 10 ml and 20 ml vial (Actemra) in Part II of Section H of the Pharmaceutical Schedule would be amended in the same way.

### *In relation to benzydamine hydrochloride*

- Benzydamine hydrochloride solution 0.15% (Difflam), which is not currently fully subsidised, would be fully subsidised in Section B of the Pharmaceutical Schedule by prescription endorsement as follows:

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

### *In relation to deferiprone*

- The Special Authority for deferiprone tab 500 mg and oral liq 100 mg per 1 ml (Ferriprox) in Section B of the Pharmaceutical Schedule would be amended as follows (deletions in strikethrough, additions in bold):

Initial application only from a ~~relevant specialist~~ **haematologist**. Approvals valid without further renewal unless notified for applications meeting the following criteria:
**Either:**

1 The patient has been diagnosed with chronic transfusional iron overload due to congenital inherited anaemia; **or**

**2 The patient has been diagnosed with chronic transfusional iron overload due to acquired red cell aplasia.**

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

- The restrictions for deferiprone in Part II of Section H of the Pharmaceutical Schedule would be amended in the same way.

### *In relation to gabapentin*

- The neuropathic pain criteria in the Special Authority for gabapentin cap 100 mg, 300 mg and 400 mg (Arrow-Gabapentin and Nupentin brands only) in Section B of the Pharmaceutical Schedule would be amended as follows (deletions in strikethrough, additions in bold):

  Initial application - (Neuropathic pain **and Chronic Kidney Disease-associated pruritus**) from any relevant practitioner. Approvals valid for 3 months for applications meeting the following criteria:
  Either:
  ~~1 The patient has tried and failed, or has been unable to tolerate, treatment with a tricyclic antidepressant.~~
  **1 The patient has been diagnosed with neuropathic pain; or**
  **2 Both:**
  **2.1 The patient has Chronic Kidney Disease Stage 5-associated pruritus* where no other cause for pruritus can be identified (e.g. scabies, allergy); and**
  **2.2 The patient has persistent pruritus not relieved with a trial of emollient/moisturising creams alone.**

  Renewal - (Neuropathic pain **and Chronic Kidney Disease-associated pruritus**) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
  Either:
  1 The patient has demonstrated a marked improvement in their control of pain or itch (prescriber determined); or
  2 The patient has previously demonstrated clinical responsiveness to gabapentin and has now developed neuropathic pain in a new site.

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

- The restrictions for gabapentin (including tab 600 mg) in Part II of Section H of the Pharmaceutical Schedule would be amended in the same way.

### *In relation to insulin pump and insulin pump consumables*

- The first criterion in the "Initial criteria for Subsidy" for insulin pump and insulin pump consumables for hypoglycaemia and for HbA1c in Section B of the Pharmaceutical Schedule would be amended to include cystic fibrosis-related insulin dependence as follows (additions in bold):

  1. Patient has type 1 diabetes or has undergone a pancreatectomy **or has cystic fibrosis-related insulin dependence**;

### *In relation to isotretinoin*

- The Special Authority for isotretinoin cap 10 mg and 25 mg (Oratane) in Section B of the Pharmaceutical Schedule would be amended as follows (additions in bold, deletions in strikethrough) and re-numbered accordingly:

  Initial application from any relevant practitioner. Approvals valid for 1 year for applications meeting the following criteria:
  All of the following:
  ~~1 Patient has had an adequate trial on other available treatments and has received an inadequate response from these treatments or these are contraindicated; and~~

2 Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice; and

3 Applicant has an up to date knowledge of ~~the treatment options for acne and is aware of~~ the safety issues around isotretinoin and is competent to prescribe isotretinoin; and

4 Either:

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

4.2 Patient is male.

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

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

~~All of the following:~~

~~1 Patient has had an adequate trial on other available treatments and has received an inadequate response from these treatments or these are contraindicated; and~~

~~2 Applicant is a vocationally registered dermatologist, vocationally registered general practitioner, or nurse practitioner working in a relevant scope of practice; and~~

~~3 Applicant has an up to date knowledge of the treatment options for acne and is aware of the safety issues around isotretinoin and is competent to prescribe isotretinoin; and~~

4 Either:

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

4.2 Patient is male.

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

***In relation to midodrine***

- The initial Special Authority criteria for midodrine tab 2.5 mg and 5 mg (Gutron) in Section B of the Pharmaceutical Schedule would be amended as follows (deletions in strikethrough):

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

~~All of the following:~~

1 **Patient has** disabling orthostatic hypotension not due to drugs~~; and~~

~~2 Patient has tried fludrocortisone (unless contra-indicated) with unsatisfactory results; and~~

~~3 Patient has tried non pharmacological treatments such as support hose, increased salt intake, exercise, and elevation of head and trunk at night.~~

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

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

**Further Information**

The proposed changes for each pharmaceutical are generally in line with recommendations from PHARMAC's Pharmacology and Therapeutics Advisory Committee (PTAC) or one of the PTAC Subcommittees (subsequently ratified by PTAC). The table below contains links to the most recent relevant PTAC or Subcommittee meeting minutes. Further information for some of the proposed changes can be found in PHARMAC's Application Tracker at www.pharmac.govt.nz/ApplicationTracker; specific links are provided below where relevant. Please contact Geraldine MacGibbon if further information is required (contact details on page 1 of this document).

| **Pharmaceutical** | **Link to PTAC minutes and Application Tracker (where relevant)** |
|---|---|
| Acitretin, bicalutamide, bee and wasp venom allergy treatments, imiquimod, isotretinoin, midodrine, nicorandil and perhexiline | www.pharmac.health.nz/assets/ptac-minutes-2014-05.pdf |
| Gabapentin | www.pharmac.health.nz/assets/ptac-minutes-2014-05.pdf<br><br>www.pharmac.govt.nz/ApplicationTracker?ProposalId=1202 |
| Mycophenolate mofetil | www.pharmac.health.nz/assets/ptac-minutes-2014-05.pdf<br><br>www.pharmac.govt.nz/ApplicationTracker?SearchTerm=mycophenolate+mofetil |
| Adalimumab, etanercept, tocilizumab | www.pharmac.health.nz/assets/ptac-minutes-2013-05.pdf<br><br>www.pharmac.govt.nz/ApplicationTracker?ProposalId=800 |
| Benzydamine | www.pharmac.health.nz/assets/ptac-catsop-subcommittee-minutes-2013-03-22.pdf<br><br>www.pharmac.govt.nz/ApplicationTracker?ProposalId=788 |
| Deferiprone | www.pharmac.health.nz/assets/ptac-catsop-subcommittee-minutes-2010-11.pdf<br><br>www.pharmac.govt.nz/ApplicationTracker?ProposalId=435 |
| Insulin pumps and consumables | www.pharmac.health.nz/assets/ptac-diabetes-subcommittee-minutes-2013-12.pdf<br><br>www.pharmac.govt.nz/ApplicationTracker?ProposalId=807 |