NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

29 August 2014

Decisions to amend or remove restrictions on various funded pharmaceuticals

PHARMAC is pleased to announce decisions to remove or amend the funding restrictions for a number of pharmaceuticals. All of these, except for the decision regarding macrogol 3350, were the subject of a consultation letter dated 25 July 2014, available on PHARMAC's website at /www.pharmac.health.nz/news/consultation-2014-07-25-various-pharmaceuticals/

The proposals were approved essentially as consulted on, with the exception of the proposed changes to bee and wasp venom allergy treatments for which no decision has been made at this time.

A summary of the decisions is provided below; for further details please refer to the consultation letter.

The Special Authority and/or Hospital Medicines List (HML) Restrictions for the following products will be removed from 1 October 2014 (unless another date is specified below):

- Bicalutamide.
- Imiquimod (from 1 February 2015).
- Mycophenolate mofetil.
- Nicorandil.
- Perhexiline maleate.

The funding rules for the following products will be amended from 1 October 2014:

- Acitretin: some of the prescriber-related criteria will be amended or removed from the Special Authority.
- Adalimumab, etanercept and tocilizumab: access will be widened to include adult-onset Still's disease.
- Benzydamine hydrochloride: full subsidy will be available via prescription endorsement in the community for patients with oral mucositis resulting from cancer treatment.
- Deferiprone: access will be widened to include acquired pure red cell aplasia.
- Gabapentin (Arrow-Gabapentin and Nupentin brands only): access will be widened to include uraemic pruritus and the requirement to trial a tricyclic antidepressant prior to gabapentin will be removed.
- Insulin pump and insulin pump consumables: access will be widened to include cystic fibrosis-related diabetes.
- Isotretinoin: some of the prescriber-related criteria will be amended or removed from the Special Authority, and the requirement for a trial of other available treatments prior to accessing isotretinoin will be removed.
- Midodrine: the requirement for a trial of fludrocortisone and other non-pharmacological treatments prior to accessing midodrine will be removed.
- Macrogol 3350 with potassium chloride, sodium bicarbonate and sodium chloride: the number of sachets funded on a prescription will increase from 60 to 90 and the initial

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Special Authority criteria will be amended as follows (similar changes will be made to the hospital restrictions):

> Initial application from any relevant practitioner. Approvals valid for 6 months **for applications meeting the following criteria:**
> **1.** ~~where~~ The patient has problematic constipation ~~requiring intervention with a per rectal preparation~~ despite an adequate trial of other oral pharmacotherapies including lactulose where lactulose is not contraindicated; **and**
> **2. The patient would otherwise require a per rectal preparation.**

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 8 August 2014 were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposals, and the following issues were raised in relation to specific aspects of the proposal/s:

Theme	Comment
Some submitters requested changes to the permitted applicant prescriber types for acitretin and isotretinoin.	We sought further advice on this from the Pharmacology and Therapeutics Advisory Committee (PTAC) at its most recent meeting this month. The minutes will be publicly available on PHARMAC's website in approximately 4-6 weeks.
Several submitters requested that fully funded access to benzydamine and gabapentin be widened to include other indications/patient groups.	We would welcome funding submissions for widened access to these pharmaceuticals. Submissions would need to include evidence of efficacy in the requested indications as well as evidence of benefit over funded alternatives. Information about making funding applications, and the funding application form, can be found on PHARMAC's website at www.pharmac.health.nz/medicines/how-medicines-are-funded/new-funding-applications/
Some submitters were concerned that widened access to some of the pharmaceuticals in the proposal would result in increased potential for adverse effects from inappropriate prescribing.	We note that responsibility for patient safety in relation to prescribed medicines lies with prescribers, who are regulated by their respective authorities (such as the Medical Council) in accordance with the Health Practitioners Competence Assurance Act 2003. However, in light of some of the concerns raised, we will be working with Best Practice Advocacy Centre (BPACnz) to determine whether further prescriber education may be useful in some areas.

More information

If you have any questions about this decision, you can email us at enquiry@pharmac.govt.nz or call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.