CONSULTATION

PHARMAC
Pharmaceutical Management Agency

23 July 2015

Proposal to fund preservative free Minims® prednisolone sodium phosphate 0.5% eye drops

PHARMAC is seeking feedback on a proposal to fund preservative free prednisolone sodium phosphate 0.5% eye drops, resulting from a provisional agreement formed between Bausch & Lomb (New Zealand) Limited and PHARMAC.

In summary, this proposal would result in Listing of Minims® prednisolone sodium phosphate 0.5% eye drops in Section B and pricing being added to the existing listing in Part II of Section H of the Pharmaceutical Schedule from 1 October 2015. Funding would be restricted to the treatment of patients with severe eye inflammation who are allergic to the preservative used in eye drops.

Details of the proposal are set out on the following page.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Thursday, 6 August 2015,** to:

An-Ruo Bian
Therapeutic Group Manager
PHARMAC
PO Box 10 254
Wellington 6143

Email: an-ruo.bian@pharmac.govt.nz

Fax: 04 460 4995

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.

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

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Details of the proposal

From 1 October 2015:

- Minims® prednisolone sodium phosphate 0.5% eye drops would be listed in Section B of the Pharmaceutical Schedule at the following price and subsidy (ex-manufacturer, exclusive of GST) :

Chemical	Presentation	Brand	Pack size	Subsidy and price
Prednisolone sodium phosphate	Eye drops 0.5%, single dose	Minims Prednisolone	20 dose	$38.50

- Minims® prednisolone sodium phosphate 0.5% eye drops would also be listed in Part II of Section H of the Pharmaceutical Schedule at the pricing set out above with no changes to current restrictions.

- Minims® prednisolone sodium phosphate 0.5% eye drops would be protected from subsidy reduction or delisting until 1 October 2018.

- Minims® prednisolone sodium phosphate 0.5% eye drops would be listed in Section B of the Pharmaceutical Schedule, subject to the following Special Authority criteria:

  Special Authority for Subsidy
  Initial application from an ophthalmologist. Approvals valid for 6 months for applications meeting the following criteria:
  Both:
  1. Patient has severe inflammation; and
  2. Patient has a confirmed allergic reaction to preservative in eye drops;

  Renewal from any relevant practitioner. Approvals valid for 6 months where the treatment remains appropriate and the patient is benefiting from treatment.

Background

Prednisolone is a corticosteroid that binds with glucocorticoid receptors (GR) alpha and beta, which leads to suppression of the inflammation. Prednisolone sodium phosphate 0.5% eye drops are preservative free corticosteroid eye drops, and can be used long-term and in high frequency for patients with severe inflammation without damage to the cornea. Currently, the only formulations of ocular corticosteroids listed on the Pharmaceutical Schedule contain benzalkonium chloride as a preservative, and prolonged exposure may cause some patients to experience an allergic reaction to benzalkonium chloride.

The HML has prednisolone sodium phosphate 0.5% eye drops listed, but with no particular brand or pricing; if this proposal is approved the provisional agreement with Bausch & Lomb would secure hospital supply of the product.

Minims® prednisolone sodium phosphate 0.5% eye drops is indicated for the treatment of non-infected inflammatory conditions of the eye.

The Ophthalmology Subcommittee of PHARMAC's Pharmacology and Therapeutics Advisory Committee (PTAC) first considered the funding of preservative free prednisolone sodium eye drops in 2012 and again in late 2014. The Subcommittee recommended that it be funded, with a high priority for patients who experience severe inflammation subject to initiation criteria similar to the proposed Special Authority restriction in this proposal. PTAC endorsed that recommendation in May 2015. PHARMAC proposes to allow any relevant practitioner[1] to apply for Special Authority Renewal. Further details, including copies of PTAC and the Subcommittee's minutes, can be found on the Application Tracker on PHARMAC's website.

PHARMAC has received a significant number of Named Patient Pharmaceutical Assessment (NPPA) funding applications, and applications under the earlier Exceptional Circumstances scheme for funding of Minims prednisolone eye drops. The vast majority of these have been approved. If this proposal is approved, then current patients funded under NPPA would automatically be transferred to Special Authority approvals, and it would eliminate the need for NPPA applications for Minims® prednisolone sodium phosphate 0.5% eye drops.

[1] Practitioner is defined in Section A: General Rules of the Pharmaceutical Schedule as "a Doctor, a Dentist, a Dietitian, a Midwife, a Nurse Prescriber, an Optometrist, a Quitcard Provider, or a Pharmacist Prescriber as those terms are defined in the Pharmaceutical Schedule"