CONSULTATION

PHARMAC
Pharmaceutical Management Agency

14 June 2013

Proposal to list desmopressin tablets, progesterone capsules and mesalazine granules

PHARMAC is seeking feedback on a proposal for listings in Section B and Part II of Section H of the Pharmaceutical Schedule through a provisional agreement with Pharmaco (NZ) Ltd.

In summary, this proposal would result in:

- Desmopressin tablets being funded, subject to Special Authority restrictions, for patients who have primary nocturnal enuresis or cranial diabetes insipidus and where the subsidised nasal preparations are contraindicated and (in the case of nocturnal enuresis) an enuresis alarm cannot be used;

- Progesterone capsules being funded, subject to Special Authority restrictions, for the prevention of pre-term labour where the patient has a short cervix or has a history of pre-term birth; and

- Mesalazine granules being funded, under Special Authority restrictions, for patients who are under the age of 16 and unable to swallow tablets.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Friday, 28 June 2013** to:

Christine Chapman
Therapeutic Group Manager
PHARMAC
PO Box 10 254
Wellington 6143

Email: Christine.Chapman@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

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

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

Desmopressin tablets

It is proposed that, from 1 September 2013, desmopressin acetate tablets be listed in Section B and Part II of Section H of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Desmopressin acetate	Tab 100 mcg	Minirin	30	$36.40
Desmopressin acetate	Tab 200 mcg	Minirin	30	$93.60

In Section B desmopressin acetate tablets would be subject to the following Special Authority restrictions:

> **Special Authority for Subsidy**
> **Initial application** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
> Either:
> 1. The patient has primary nocturnal enuresis; and
> 1.1. Either
> 1.1.1. The nasal forms of desmopressin are contraindicated; or
> 1.1.2. An enuresis alarm is contraindicated; or
> 2. Both
> 2.1. The patient has cranial diabetes insipidus; and
> 2.2. The nasal forms of desmopressin are contraindicated
>
> **Renewal** from any relevant practitioner. Approvals valid for 12 months where the treatment remains appropriate and the patient is benefiting from treatment.

The initial application criteria set out above would also apply to initiation of treatment with desmopressin tablets under Part II of Section H.

Background

Desmopressin is a structural analogue of the natural pituitary hormone arginine vasopressin. Desmopressin is indicated for the treatment of central diabetes insipidus and for establishing renal concentration capacity testing. It is also indicated for the treatment of primary nocturnal enuresis in patients (from 5 years of age) with normal ability to concentrate urine.

Desmopressin nasal spray and nasal drops are available, fully funded, on the Pharmaceutical Schedule. The Food and Drug Administration (FDA) issued a black box warning on the use of intranasal formulations of desmopressin for the treatment of primary nocturnal enuresis in children following post marketing surveillance found that a small number of children using the nasal formulations of desmopressin were susceptible to severe hyponatremia and seizures.

Progesterone capsules

It is proposed that, from 1 August 2013, progesterone capsules be listed in Section B and Part II of Section H of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Progesterone	Cap 100 mg	Utrogestan	30	$16.50

In Section B progesterone capsules would be subject to the following Special Authority restrictions:

> **Special Authority for Subsidy**
> **Initial application** from an obstetrician or gynaecologist. Approvals valid for 12 months for applications meeting the following criteria:
> **Both:**
> 1. For the prevention of pre-term labour*; and
> 2. Either
> 2.1. The patient has a short cervix on ultrasound (defined as < 25 mm at 16 to 28 weeks) or
> 2.2. The patient has a history of pre-term birth at less than 28 weeks.
>
> Note: Indications marked with * are Unapproved Indications (refer to Section A: General Rules, Part I (Interpretations and Definitions) and Part IV (Miscellaneous Provisions) rule 4.6).

Progesterone tablets will be listed in Part II of Section H from 1 July 2013 under the same initial criteria as outlined above.

Background

Progesterone is a steroid hormone belonging to the class of hormones called progestogens. Progesterone is involved in the menstrual cycle, embryogenesis and supports gestation.

At its August 2012 meeting, PTAC recommended that progesterone capsules be listed with a high priority for the prevention of pre-term births, an off label use of progesterone. Progesterone is widely used in New Zealand for this indication and PHARMAC has been receiving a number of applications for funding under the Named Patient Pharmaceutical Assessment pathway.

Mesalazine modified-release granules

It is proposed that, from 1 September 2013, Pentasa modified-release granules be listed in Section B and Part II of Section H of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Mesalazine	Modified release granules 1 g	Pentasa	120 g OP	$141.72

In Section B mesalazine modified-release granules would be subject to the following Special Authority restrictions:

Special Authority for Subsidy
Initial application from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:
Both:
1 The patient is unable to swallow tablets; and
2 The patient is aged 16 years or below.

Renewal from any relevant practitioner. Approvals valid for 12 months for patients meeting the following criteria:
Both:
1 The treatment remains appropriate and the patient is benefiting from treatment; and
2 The patient is aged 16 years or below.

The initial application criteria above would also apply to initiation of treatment with mesalazine modified-release granules under Part II of Section H.

Background
Mesalazine is an intestinal anti-inflammatory agent used for the treatment of ulcerative colitis and Crohn's disease.

At its April 2012 meeting, the Gastrointestinal Subcommittee of PTAC considered that there is an unmet need for children who require treatment with mesalazine but who find the tablets difficult to take. The Subcommittee recommended that mesalazine sachets be listed in the Pharmaceutical Schedule as an alternative for these children.