CONSULTATION

PHARMAC
Pharmaceutical Management Agency

10 October 2013

Proposal to widen access to levonorgestrel intrauterine system in DHB hospitals

PHARMAC is seeking feedback on a proposal to widen access to levonorgestrel intra-uterine system, 20 mcg per day (levonorgestrel IUS).

In summary, this proposal would result in the restrictions on use of levonorgestrel IUS being widened to include endometriosis, as well as amending the restriction relating to use in heavy menstrual bleeding in hospital only.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Thursday 24 October 2013** to:

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

Email: levonorgestrel@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.

Details of the proposal

Levonorgestrel intrauterine system (IUS) is currently listed in Part II of Section H of the Pharmaceutical Schedule (the HML) restricted to heavy menstrual bleeding.

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

From 1 December 2013 we propose the restrictions applying to levonorgestrel IUS in Part II of Section H of the Pharmaceutical Schedule would be amended as follows (additions in bold deletions in strikethrough):

Restricted
Obstetrician or gynaecologist
Initiation – heavy menstrual bleeding
All of the following:
1 The patient has a clinical diagnosis of heavy menstrual bleeding; and
2 The patient has failed to respond to or is unable to tolerate other appropriate pharmaceutical therapies as per the Heavy Menstrual Bleeding Guidelines; and
3 ~~Either~~ **Any of the following:**
  3.1 Serum ferritin level < 16 mcg/l (within the last 12 months); or
  3.2 Haemoglobin level < 120 g/l; or
  3.3 The patient has had a uterine ultrasound and either a hysteroscopy or endometrial biopsy.

Continuation – heavy menstrual bleeding
Either:
1 Patient demonstrated clinical improvement of heavy menstrual bleeding; or
2 Previous insertion was removed or expelled within 3 months of insertion.

Initiation – endometriosis
The patient has a clinical diagnosis of endometriosis confirmed by laparoscopy.

Continuation – endometriosis
Either:
1 Patient demonstrated satisfactory management of endometriosis; or
2 **Previous insertion was removed or expelled within 3 months of insertion**.

Note: endometriosis is an unregistered indication

Background

PHARMAC is aware that the levonorgestrel intrauterine system, Mirena, has historically been used more widely in hospitals than the current restrictions allow. Following discussions with the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and relevant members of subcommittees of the Pharmacology and Therapeutics Advisory Committee, PHARMAC is proposing to widen access to levonorgestrel IUS.

PHARMAC is aware that the levonorgestrel intrauterine system is also used for contraception however there are a number of other less expensive options available including the levonorgestrel implant (Jadelle) that offers five years of contraceptive protection. At this stage, we are not proposing funding the levonorgestrel intrauterine system available for use as a contraceptive.

PHARMAC is not considering making changes to the Special Authority criteria that currently apply in the Community.