NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

15 November 2013

Decision to widen access to levonorgestrel intrauterine system in DHB hospitals

PHARMAC is pleased to announce the approval of a proposal to widen access to levonorgestrel intra-uterine system, 20 mcg per day (levonorgestrel IUS) in the hospital setting.

This decision was the subject of a consultation letter dated 10 October 2013 which can be found on PHARMAC's website at http://www.pharmac.health.nz/news/item/intrauterine-levonorgestrel-proposal

Details of the decision

From 1 December 2013 the restrictions applying to levonorgestrel IUS in Part II of Section H of the Pharmaceutical Schedule will 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

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 24 October 2013 were considered in their

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entirety in making a decision on the proposed changes. Most responses were supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) endorsed the proposal as it is in accord with their NZ Committee suggestions.	Noted.
The majority of clinician responses supported the proposal. Some clinicians stated they would like Mirena to be a contraceptive option. Some clinicians stated that they would like the indications for use extended to manage adenomyosis, menorrhagia where guideline criteria are not met, painful periods, polycystic ovaries and as a treatment option for intellectually and physically disabled clients.	There are a number of alternative fully funded contraceptive options currently listed on the Schedule that are significantly more cost-effective than Mirena. There are a number of alternative treatment options listed on the Schedule which are more cost-effective and available for these other indications. Applications for funding for Mirena for uses not listed in the Scehdule may be made under the NPPA Policy

Named Patient Pharmaceutical Assessment (NPPA)

During a time of transition since the 1 July 2013 implementation of Part II of Section H of the Pharmaceutical Schedule (the Hospital Medicines List), PHARMAC has received some applications for in hospital use of levonorgestrel IUS and these have been managed under the NPPA Policy. Applications under the NPPA Policy for usage outside of the HML Restrictions can still be submitted for consideration post 1 December 2013.

More information

If you have any questions about this decision, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.