



**LEVONORGESTREL-RELEASING IUD (MIRENA®)**  
**FOR MENORRHAGIA**

**Effective Date: February 23, 2010**  
**Date Of Origin: November 17, 2004**

**Review Dates: 11/04, 10/05, 10/06, 10/07, 8/08, 8/09**  
**Status: Current**

**Summary of Changes**

Clarifications:

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Deletions:

- Pg. 3, Section II, A, the following language has been removed: when standard medical therapies for menorrhagia, including oral contraceptives, have failed.

Additions:

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**I. DESCRIPTION**

Menorrhagia is a significant worldwide health problem and is the major presenting symptom for women who undergo hysterectomy. The levonorgestrel-releasing intrauterine system (LNG-IUS) is an intrauterine system that slowly releases a steady amount of levonorgestrel. The LNG-IUS is currently being used outside of the United States for treatment of menorrhagia, but is approved in the United States only as a contraceptive device.

Priority Health's Technology Assessment Committee reviewed the literature on this device on September 3, 2004 and recommended coverage for menorrhagia when the criteria listed below are met.

**Background/Medical Literature Summary:**

The levonorgestrel-releasing intrauterine system (LNG-IUS) is currently being used in Finland for treatment of menorrhagia, but is approved in the United States only as a contraceptive device. A total of 236 Finnish women (mean age = 43 years) with complaints of menorrhagia were randomly assigned (concealed allocation assignment) to treatment with the LNG-IUS or hysterectomy. Follow-up was monitored for 96% of the patients for 5 years. Outcomes were self-assessed by patients not blinded to treatment assignment using pre-validated health questionnaires and surveys. Using intention-to-treat analysis, after 5 years there were no significant differences in health outcomes or overall satisfaction with care reported by the 2 groups. Although 42% of women initially assigned to the LNG-IUS group eventually underwent hysterectomy, both the direct and indirect costs were lower for patients assigned to the LNG-IUS group than for those in the assigned hysterectomy group (\$2817 vs. \$4660 per participant, respectively). Since the introduction of the LNG-IUS in Finland in 1998,



hysterectomy rates have fallen by 13%. Study design was randomized controlled trial (nonblinded).<sup>1</sup>

**Conclusions/Implications for Practice:**

The levonorgestrel-releasing intrauterine system results in a significant reduction from baseline in heavy menstrual bleeding (in both RCTs and non-randomised studies). It is more effective than cyclical norethisterone taken for 21 days but not as effective as TCRE (transcervical resection of the endometrium). It is uncertain if this objective change in blood loss is reflected in any significant improvement in subjective symptoms of heavy menstrual bleeding but the system is more acceptable to women than oral progestogens taken for 21 days. The levonorgestrel-releasing intrauterine system is associated with a greater rate of progestogenic adverse events and intermenstrual bleeding but rates of dysmenorrhoea do not appear to differ. We cannot comment on the risk of pelvic infection, ectopic pregnancy or cost effectiveness.<sup>2</sup>

**Conclusions:**

The evidence from the available published randomized controlled trials, nonrandomized controlled trials, and prospective case series indicates that the LNG-IUD is a relatively safe and effective minimally invasive therapy for DUB in premenopausal women with confirmed menorrhagia that is refractory to oral medications or for whom surgery has been recommended, who have no benign or malignant pelvic pathology that requires another type of therapy, who do not wish to undergo surgery or who are ineligible for surgery, who cannot tolerate the side effects from oral therapies, and/or who wish to retain their childbearing capacity. Overall, treatment with the LNG-IUD for 3 to 12 months resulted in significant reductions in MBL, improvement in menstrual bleeding patterns in the majority of patients, increases in blood hemoglobin (Hb) and iron levels, high levels of satisfaction, and improved QOL. Surgery was cancelled or postponed in approximately 70% of patients on surgical waiting lists whose menstrual bleeding improved during LNG-IUD therapy.

However, due to the small size of the study populations, the high attrition rate, and inadequate follow-up time, questions remain regarding the long-term safety and efficacy of LNG-IUD therapy. The nonrandomized and case series studies were limited by the lack of controls and/or randomization and interpretation of data from all of the studies, including randomized controlled trials, is hampered by the lack of placebo controls and blind assessment of the results. Additional, well-designed studies with longer follow-up are needed to evaluate the durability of the treatment effects, treatment discontinuation rates, and safety issues, as well as to compare the device with other medical and surgical therapies.

**II. POLICY/CRITERIA**

- A. The levonorgestrel-releasing intrauterine system (Mirena®) is a covered benefit for menorrhagia.
- B. IUDs for contraception *are* a covered benefit for Medicaid and MiCHILD members and for commercial groups who have purchased contraceptive riders.

**III. MEDICAL NECESSITY REVIEW**

- Required                       Not Required                       Not Applicable

**IV. APPLICATION TO PRODUCTS**

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS).*
- ❖ **MEDICAID:** *Coverage is determined by the Michigan Medicaid Provider Manual and the Michigan Medicaid Fee Schedule at: [http://www.michigan.gov/mdch/0,1607,7-132-2945\\_42542\\_42543\\_42546\\_42551-159815--,00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html).*
- ❖ **MICHILD:** *For MICHILD members, this policy will apply unless MICHILD certificate of coverage limits or extends coverage.*

**Special Note:** This policy is based on the recommendations of Priority Health's Technology Assessment Committee following their review on September 3, 2004.

**V. CODING INFORMATION****ICD-9 Diagnosis Codes**

*The device is covered for these diagnoses only:*

- 626.2      Excessive or frequent menstruation  
626.6      Metrorrhagia  
626.8      Other disorder of menstruation and other abnormal bleeding from female genital tract

**CPT/HCPCS Codes**

J7302	Levonorgestrel-releasing intrauterine contraceptive system, 52 mg
S4981	Insertion of levonorgestrel-releasing intrauterine system (Fully funded products only)
58300*	Insertion of intrauterine device (IUD)
58301*	Removal of intrauterine device (IUD)

(\*Payment for IUD insertion or removal is not covered when linked to contraceptive diagnosis or services, except for Medicaid/Mi-Child members and groups who have purchased contraceptive riders.)

**VI. REFERENCES**

- <sup>1</sup>Hurskainen R, Teperi J, Rissanen P, et al. Clinical outcomes and costs with the levonorgestrel-releasing intrauterine system or hysterectomy for treatment of menorrhagia. Randomized trial 5-year follow-up. JAMA 2004; 291:1456-63.
- <sup>2</sup>Levonorgestrel-releasing Intrauterine Device for Dysfunctional Uterine Bleeding, HAYES, Inc, May 2002, Updated Searches May 2004 and March 2006.
- <sup>3</sup>Lethaby, AE, Cooke, I, Rees, M. Progesterone/progestogen releasing intrauterine systems for heavy menstrual bleeding. The Cochrane Database of Systematic Reviews, November 2002

**AMA CPT Copyright Statement:**

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