

**NON-FORMULARY MEDICATION REQUEST**  
**PHOENIX INDIAN MEDICAL CENTER**

**Drug:** Levonorgestrel IUD (Mirena)

The LNG-IUD is a polyethylene T-frame surrounded by a levonorgestrel-containing cylinder. The cylinder is covered with a rate-controlling membrane. The release rate is 20 mcg of LNG per 24 hours. The approved duration of use of the LNG-IUD is 5 years.

**Safety:** The incidences of adverse events during prolonged use of the LNG-IUD and the Copper T 380A IUD were compared in a multicenter, prospective, 7- year, randomized study. In this study, accrued experience totaled 3416 years for women using the LNG-IUD and 3975 years for those using the Copper T 380A IUD. Findings of this study included the following:

- The LNG-IUD significantly decreased the number of bleeding and spotting days compared with users of the Copper T 380A and with historical data for noncontraceptors
- Dysmenorrhea, vaginitis, and myoma development were markedly decreased in women inserted with the LNG-IUD compared with those using the Copper T 380A
- Significantly higher rates of amenorrhea, skin and hair conditions (eg. Acne, hirsutism), and headache were observed with the LNG-IUD than with the Copper T380A
- Upper-genital-tract infection occurred at rates of 0.6-0.7 per 100 years of use, with no significant difference between the two IUDs; rates were higher in the first year of use than subsequently
- As with the Copper T 380A IUD, uterine perforation with the LNG-IUD is very rare when insertion is performed by trained clinicians.

Use of IUDs has been limited due to concerns about their association with upper-genital-tract infection. However, the biases of early observational studies tended to exaggerate this risk. A review of the evidence concerning IUD associated infection provides perspective. Not only do IUDs compare with sterilization in efficacy, they are much safer than previously thought.

**Tolerability:** The LNG-IUD was compared with a copper-bearing IUD having 200mm<sup>2</sup> surface area of copper in an open, randomized, multicenter study during 5 years of use. The 60-month cumulative termination rate for expulsion was 5.8 per 100 women for the LNG-IUD and 6.7 per 100 women for the copper IUD. The majority of expulsions in this study occurred during the first months after insertion. Although the removal rate for irregular bleeding or spotting did not differ significantly between the two study groups, termination for heavy and prolonged menstrual flow was significantly less with the LNG-IUD than with the copper IUD. Discontinuation due to hormonal side effects considered to be related to LNG were higher in the group of LNG-IUD users than in users of the copper IUD.

**Effectiveness:** In the same study, the rate of termination due to pregnancy was significantly lower for the LNG-IUD than the copper IUD (0.5 per 100 women versus 5.9 per 100 women). Numerous studies with more than 12,000 woman-years demonstrate a high effectiveness in preventing unintended pregnancies comparable to that of surgical sterilization (Pearl Index 0-0.3 per 100 women-years). Additional studies have shown the LNG-IUD to be useful in reducing excessive menstrual bleeding and increasing hemoglobin concentration, being effective and well tolerated and superior to other pharmacological treatments (NSAIDs).

**Price:** Government pricing available and should be comparable to the Paraguard. (\$235/unit)

**Simplicity:** The LNG-IUD is an extremely effective and reversible long-acting contraceptive. Because IUDs do not require daily or monthly decisions to continue use, their efficacy is not determined by a woman's frequent decision-making. The LNG-IUD is especially appropriate for nulliparous women with menorrhagia and/or dysmenorrhea. The LNG-IUD has also been shown as an effective measure to prevent endometrial hyperplasia in women on Tamoxifen treatment for breast cancer and can be used as an alternative to the regular endometrial sampling or ultrasonography procedures these women usually undergo.

**Bottom Line:** The LNG-IUD combines advantages of both hormonal and intrauterine contraception. A long-acting reversible contraceptive method with a pregnancy rate comparable to female sterilization, the LNG-IUD provides several therapeutic benefits, such as reduction of menstrual blood loss. Particularly for our patients who enjoy the menstrual benefits from DMPA but are concerned with the weight gain and possible increased incidence of Diabetes associated with its use, the LNG-IUD represents an excellent option for long acting, effective contraception that is not dependent on the frequency of a woman's decision to use it.

**References:**

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