

**Regence BlueCross BlueShield of Oregon • Regence BlueShield  
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**Medication Policy Manual**

**Policy No:** dru079

**Topic:** Mirena<sup>®</sup>, levonorgestrel-containing  
intrauterine system (LNG-IUS) for Medical  
Conditions

**Date of Origin:** January 10, 2003

**Revised/Effective Date:** April 7, 2009

**Next Review Date:** March 2010

**IMPORTANT REMINDER**

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

**Description**

The levonorgestrel-containing intrauterine system (LNG-IUS) is a device that is placed into the uterus by a healthcare professional and provides contraception for up to five years.

## Policy/Criteria

- I. Some contracts require prior authorization approval of levonorgestrel-containing intrauterine system (LNG-IUS) prior to coverage. LNG-IUS may be considered medically necessary in patients with the following conditions:

A. Heavy or abnormal uterine bleeding.

**OR**

B. Adjuvant therapy with tamoxifen to protect against uterine effects.

**OR**

C. Hormone replacement therapy.

II. Administration

Regence does not consider LNG-IUS to be a self-administered medication.

## Position Statement

- There is scientific literature suggesting that the LNG-IUS has specific non-contraceptive health benefits.<sup>[1]</sup>
- The strongest evidence shows that the LNG-IUS has potential benefit in a variety of gynecological disorders (anemia, menorrhagia), hormone replacement therapy, adjuvant therapy with tamoxifen, and as an alternative to hysterectomy in women with bleeding problems.<sup>[1]</sup>
- Some of these benefits are based on intermediate endpoint measurements.
- Further clinical trials are necessary to establish the impact on long-term health outcomes, morbidity and mortality.

### *Anemia associated with Intrauterine Bleeding (Level I Evidence; Class A Recommendation)<sup>[1]</sup>*

- The LNG-IUS demonstrated a net gain in hemoglobin concentrations depending on the length of follow-up, ranging from as little as 0.5 gm/dl after 2 years to as much as 1.6 gm/dl after 5 years.<sup>[2,3]</sup>

- Trials comparing the LNG-IUS to the copper IUD showed decreases in hemoglobin concentrations.<sup>[2,3]</sup>
- There are no data to evaluate long-term health outcomes associated with the observed hemoglobin changes.

*Menorrhagia (Level I Evidence; Class A Recommendation)<sup>[1,32-33]</sup>*

- Clinical trials that measured menstrual blood loss estimated reductions of 74% to 97% with the LNG-IUS.<sup>[4-11]</sup>
- One study reported that women using the LNG-IUS reduced their number of days of bleeding by approximately 50% after 12 months.<sup>[7]</sup>
- There were additional trials that showed LNG-IUS resulted in:
  - \* significantly less blood loss when compared with mefenamic acid for the treatment of menorrhagia (5ml vs. 100ml,  $p < 0.001$ ).<sup>[34]</sup>
  - \* similar efficacy to transcervical resection of the endometrium in the treatment of menorrhagia over three years.<sup>[36]</sup>
  - \* reducing blood loss in menorrhagic patients with at least one type II myoma.<sup>[37]</sup>

*Heavy Uterine Bleeding to Prevent Hysterectomy (Level I Evidence; Class B Recommendation)<sup>[11]</sup>*

- Two studies compared LNG-IUS to continued conservative medical treatments in women who were candidates for hysterectomy.<sup>[7,13]</sup>
- The proportion of women canceling their planned hysterectomy in the LNG-IUS arms of the two trials was 80% and 64% compared to 9% and 14%, respectively, of the women assigned to the medical treatments.

*Adjuvant therapy with Tamoxifen (Level I Evidence; Class B Recommendation)<sup>[11]</sup>*

- As adjuvant therapy with tamoxifen, the LNG-IUS causes a decidual response in the endometrium of all treated women and potentially provides protection against the uterine effects of tamoxifen.<sup>[14]</sup>

### *Hormone Replacement Therapy (Level I Evidence; Class A Recommendation) <sup>[1]</sup>*

- The LNG-IUS reduces bleeding, as measured by the number of menstrual days, spotting days, or induced amenorrhea.
- In randomized trials comparing the LNG-IUS with other progestin administration methods, the LNG-IUS was superior (in reducing bleeding) to the comparison methods in all but one study. <sup>[15-22]</sup>
- A prospective, open, outpatient clinical trial was conducted to assess the long-term efficacy (5 years) of the levonorgestrel-releasing intrauterine system (LNG-IUS) in protecting the endometrium from hyperplasia during estrogen replacement therapy in perimenopausal women (N=82). At the end of 5 years, no endometrial hyperplasias were confirmed throughout a period of 60 cycles. <sup>[35]</sup>

### *Pelvic Inflammatory Disease (Level I Evidence: Class C Recommendations) <sup>[1]</sup>*

- There is inconsistent evidence that LNG-IUS provides greater protection against pelvic inflammatory disease than the copper IUD. <sup>[23-26]</sup>

### *Uterine Fibroids (Level III Evidence; Class C Recommendations) <sup>[1]</sup>*

- There is not sufficient evidence that LNG-IUS reduces the fibroid size or decreases bleeding associated with this condition. <sup>[27-30]</sup>

### *Endometriosis*

- LNG-IUS was judged to be of similar efficacy to depot leuprolide in controlling endometriosis-related pain over a period of six-months. LNG-IUS users had a higher bleeding score than depot leuprolide users at all observation points. <sup>[38]</sup>
- In a non-controlled observational study, LNG-IUS resulted in improvement in endometriosis-related pain scores and blood loss in 34 women over 3 years. <sup>[39]</sup>

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<b>Cross References</b>		
Self-administered Contraceptives for Medical Conditions dru022		

<b>Codes</b>	<b>Number</b>	<b>Description</b>
CPT	No code	
HCPCS	J7302	Levonorgestrel-releasing intrauterine contraceptive system, 52mg
BCBSA	No code	