

# Health Quality Ontario

The provincial advisor on the quality of health care in Ontario

## **Levonorgestrel-Releasing Intrauterine System (52 mg) for Idiopathic Heavy Menstrual Bleeding: OHTAC Recommendation**

### **ONTARIO HEALTH TECHNOLOGY ADVISORY COMMITTEE RECOMMENDATION**

The Ontario Health Technology Advisory Committee (OHTAC) recommends publicly funding the 52-mg levonorgestrel-releasing intrauterine system for the treatment of idiopathic heavy menstrual bleeding.

### **RATIONALE FOR THE RECOMMENDATION**

There was consensus among OHTAC members that the intervention provides clinical benefit and represents good value for money for two key reasons: it offers similar or superior improvement on patient-important outcomes compared with other available treatment options, and it costs less compared with surgery.<sup>1</sup>

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**Public Comment:** Held June 17 to July 8, 2016

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## Decision Determinants for Levonorgestrel-Releasing Intrauterine System (52 mg) for Idiopathic Heavy Menstrual Bleeding

Decision Criteria	Subcriteria	Decision Determinants Considerations
<b>Overall clinical benefit</b> How likely is the health technology/intervention to result in high, moderate, or low overall benefit?	<b>Effectiveness</b> How effective is the health technology/intervention likely to be (taking into account any variability)?	Based on evidence that ranged from very low to moderate quality, the LNG-IUS appears to be an effective treatment option for idiopathic heavy menstrual bleeding. It improves quality of life and menstrual blood loss and is well tolerated compared with endometrial ablation, hysterectomy, or usual medical therapies.
	<b>Safety</b> How safe is the health technology/intervention likely to be?	The most common side effects of the LNG-IUS were mild hormonal side effects related to the use of progestogens. Studies also found some patients using the LNG-IUS developed benign ovarian cysts, which are known to be more likely with this treatment. The cysts were mild and are known to resolve when treatment stops.
	<b>Burden of illness</b> What is the likely size of the burden of illness pertaining to this health technology/intervention?	Self-reported data suggest prevalence of heavy menstrual bleeding is about 30%; local experts estimated that 15% to 20% of women of reproductive age (15 to 55 years old) in Ontario are affected.
	<b>Need</b> How large is the need for this health technology/intervention?	The Mirena 52-mg LNG-IUS is the only LNG-IUS product currently licensed in Canada for both contraception and treatment of idiopathic menorrhagia (heavy menstrual bleeding).
<b>Consistency with expected societal and ethical values<sup>a</sup></b> How likely is adoption of the health technology/intervention to be congruent with societal and ethical values?	<b>Societal values</b> How likely is the adoption of the health technology/intervention to be congruent with expected societal values?	Heavy menstrual bleeding can have a large impact on quality of life; its effects are biopsychosocial and can include pain, iron-deficiency anemia, inconvenience, self-consciousness, embarrassment, worry, activity limitations, sexual dysfunction, depression, and lost earnings due to absence from work. A patient's perception of bleeding and impact on quality of life is most important to clinical management and the degree of intervention. The LNG-IUS offers a reversible, fertility-preserving, minimally invasive treatment option.
	<b>Ethical values</b> How likely is the adoption of the health technology/intervention to be congruent with expected ethical values?	Access to the LNG-IUS (the device costs approximately \$350) is largely dependent on patients' ability to purchase the product from the pharmacy entirely out-of-pocket or through private health insurance, if covered. Ontario Drug Benefit coverage is available for women with significant economic disadvantage (Trillium Drug Program or Social Assistance) and senior women (> 65 years of age). The LNG-IUS is not publicly funded for most Ontario women.
<b>Value for money</b> How efficient is the health technology/intervention likely to be?	<b>Economic evaluation</b> How efficient is the health technology/intervention likely to be?	The LNG-IUS appears to result in lower costs and similar or better outcomes versus treatment comparators.
<b>Feasibility of adoption into health system</b> How feasible is it to adopt the health technology/intervention into the Ontario health care system?	<b>Economic feasibility</b> How economically feasible is the health technology/intervention?	Cost savings to the health care system could be between \$0.1 million and \$23 million per year, if the LNG-IUS replaces hysterectomies for treatment of heavy menstrual bleeding. Cost savings to the health care system could be between \$3 million and \$9 million per year, if the LNG-IUS replaces endometrial ablation procedures for treatment of heavy menstrual bleeding.

Decision Criteria	Subcriteria	Decision Determinants Considerations
	<b>Organizational feasibility</b> How organizationally feasible is it to implement the health technology/intervention?	There are no major organizational feasibility challenges.

Abbreviations: LNG-IUS, levonorgestrel-releasing intrauterine system.

<sup>a</sup>The anticipated or assumed common ethical and societal values held in regard to the target condition, target population, and/or treatment options. Unless there is evidence from scientific sources to corroborate the true nature of the ethical and societal values, the expected values are considered.

## REFERENCES

- (1) Health Quality Ontario. Levonorgestrel-releasing intrauterine system (52 mg) for idiopathic heavy menstrual bleeding: a health technology assessment. Ont Health Technol Assess Ser [Internet]. 2016 November;16(18):1-119. Available from: <http://www.hqontario.ca/evidence-to-improve-care/journal-ontario-health-technology-assessment-series>

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