BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Levonorgestrel-releasing Intrauterine System (LNG-IUS) (Mirena®) for Heavy Menstrual Bleeding

Policy #: 209
Category: OB/GYN Reproductive

Latest Review Date: April 2020
Policy Grade: A

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

For dates of service on or after March 24, 2020:

Blue Advantage will treat **levonorgestrel-releasing intrauterine system (LNG-IUS (Mirena®)** as a **covered benefit** for the following medical conditions:

- Idiopathic menorrhagia
- Dysfunctional uterine bleeding
- Premenopausal menorrhagia
- Adenomatous hyperplasia
- Metrorrhagia

Blue Advantage will treat **the use of any other levonorgestrel intrauterine systems (LNG IUS) devices, other than Mirena®, for non-contraceptive use** as a **non-covered benefit** and **investigational.**

Effective for dates of service February 26, 2018, through March 23, 2020, refer to LCD L36954.

Effective for dates of service prior to February 26, 2018:

Blue Advantage will treat **Levonorgestrel-releasing intrauterine system (LNG-IUS (Mirena®)** as a **covered** benefit for the following medical conditions:

- Idiopathic menorrhagia
- Dysfunctional uterine bleeding
- Premenopausal menorrhagia
- Adenomatous hyperplasia
- Metrorrhagia

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVCIE:

Levonorgestrel-releasing intrauterine system (LNG-IUS), (Mirena®), is a device that releases levonorgestrel into the uterine cavity at a rate of approximately 20mcg per day for five years. It is indicated for intrauterine contraception for up to five years. It may also cause significant reduction in menstrual blood loss, thus it has been used for the treatment of menorrhagia and

dysfunctional uterine bleeding. It has also been used to treat endometrial hyperplasia, as an effective method for suppression of the endometrium and as an alternative to hysterectomy.

KEY POINTS:

The most recent literature search was conducted through April 2, 2020.

Summary of Evidence

For women who are experiencing heavy menstrual bleeding and receive a levonorgestrel releasing IUS (i.e. Mirena), the evidence consists of meta-analyses and randomized controlled trials. The primary endpoints were quality of life, safety, and surgical reinterventions. Overall, studies have shown more patient satisfaction with LNG-IUDs compared to medical treatment. In a systematic review and meta-analysis conducted, the LNG-IUS was superior to conventional medical treatment in reducing menstrual blood loss and more women were satisfied with the LNG-IUS than with the use of conventional medical treatment. In other trials, the LNG-IUS group was more satisfied compared to medical treatment. The evidence is sufficient to determine that the device results in a meaningful improvement in the net health outcome.

Practice and Position Statements

In January 2010 (reaffirmed in 2018), the American College of Obstetricians and Gynecologist (ACOG) replaced Committee Opinion number 337 (Noncontraceptive uses of the Levonorgestrel Intrauterine System) with a Practice Bulletin (Number 110), "Noncontraceptive uses of Hormonal Contraception." Per the bulletin, "The levonorgestrel intrauterine system is a highly effective contraceptive method with significant noncontraceptive benefits in women with excessive menstrual bleeding and dysmenorrhea. Numerous studies have confirmed the effectiveness of the levonorgestrel intrauterine system for reduction of menstrual blood loss from idiopathic menorrhagia, adenomyosis, leiomyomas, pain due to endometriosis and hemostatic disorders with commensurate reduction in dysmenorrhea and anemia."

KEY WORDS:

Mirena®, levonorgestrel-releasing intrauterine system, LNG-IUS, menorrhagia, premenopausal menorrhagia, endometrial hyperplasia, adenomatous hyperplasia, dysfunctional uterine bleeding, hysterectomy, IUS, menstrual bleeding, heavy menstrual bleeding

APPROVED BY GOVERNING BODIES:

The FDA approved Mirena® (levonorgestrel-releasing intrauterine device) in December 2000 as a hormone-releasing system for intrauterine contraception.

The FDA approved Mirena® (levonorgestrel-releasing intrauterine device) October 1, 2009 for the treatment of heavy menstrual bleeding in women who use intrauterine contraception as a method of pregnancy prevention.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. The use of this device for contraceptive management is a group specific benefit.

CURRENT CODING:

CPT codes:

58300	Insertion of intrauterine device (IUD)

HCPCS codes:

J7298	Levonorgestrel-releasing intrauterine contraceptive system (Mirena), 52mg
S4981	Insertion of levonorgestrel-releasing intrauterine system

REFERENCES:

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POLICY HISTORY:

Adopted for Blue Advantage, March 2005
Available for comment May 1-June 14, 2005

Medical Policy Group, October 2007
Medical Policy Group, January 2009
Available for comment January 14-February 27, 2009
Medical Policy Group, October 2009
Medical Policy Group, January 2013
Medical Policy Group, February 2016
Medical Policy Group, April 2016
Medical Policy Group, February 2018
Medical Policy Group, April 2020: Reinstated policy effective March 24, 2020.
