MEDICAL POLICY

POLICY TITLE	NONCONTRACEPTIVE USE OF INTRAUTERINE DEVICES (IUDS)
POLICY NUMBER	MP-7.026

Original Issue Date (Created):	**2/7/2005**
Most Recent Review Date (Revised):	**5/13/2020**
Effective Date:	**8/1/2020**

I. POLICY

NOTE: For the use of intrauterine devices for contraceptive purposes - refer to the Certificate of Coverage and Preventive Benefits.

Intrauterine devices (IUDs) may be **medically necessary** for non-contraceptive uses for the following indications:

- As indicated by the Food and Drug (FDA) label information, use of levonorgestrel intrauterine systems (LNG IUS) devices containing 52 mg levonorgestrel (Mirena®) may be considered **medically necessary** to treat heavy menstrual bleeding in women who use intrauterine contraception as their method of pregnancy prevention.
- Off-label use of levonorgestrel intrauterine systems (LNG IUS) devices containing 52 mg levonorgestrel (Mirena®, Liletta®) for conditions other than specified in the FDA label information above may be considered **medically necessary** for the following**.**
    - As an alternative to other hormonal regimens (oral contraceptives, cyclic or continuous progestin's, etc.) or as a treatment option to surgical interventions in an individual who has excessive or irregular bleeding defined as one of the following:
        - Idiopathic menorrhagia: Excessively heavy, regular menses in the absence of intracavitary pathology or coagulopathy; or
        - Menometrorrhagia: Bleeding that is excessive in amount, is prolonged in duration, and may occur at regular or irregular intervals.
    - As an alternative delivery system to protect against endometrial hyperplasia in women who are currently receiving selective estrogen receptor modulators.
    - Management of recurrent pelvic pain secondary to multi-treated endometriosis.

Levonorgestrel intrauterine systems (LNG IUS) devices containing less than 52 mg levonorgestrel (Skyla™, Kyleena™) for off-label non-contraceptive use are considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

The non-contraceptive use of IUDs for indications other than those described in the policy criteria are considered **investigational** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

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Removal of an IUD for medical conditions such as unexplained abnormal uterine bleeding or pregnancy may be considered **medically necessary**.

Cross-references:

MP-2.103 Off Label Use of Medications
MP-7.013 Endometrial Ablation

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

Note* - The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services.

III. DESCRIPTION/BACKGROUND

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Intrauterine devices (IUDs) are devices that are inserted in the uterus to prevent effective conception. IUDs can be classified as non-hormonal (e.g. ParaGard® copper IUD) or hormonal (e.g. Mirena® levonorgestrel intrauterine systems [LNG IUS] or Skyla™ levonorgestrel-releasing intrauterine system).

The Mirena® LNG IUS device received U. S. Food and Drug Administration (FDA) approval in December 2000 for intrauterine contraceptive use for up to five years. On October 1, 2009, the FDA approved the Mirena® (levonorgestrel intrauterine system 52 mg) to treat heavy menstrual bleeding in women who use intrauterine contraception as their method of pregnancy prevention.

The major advantage of this IUD is that it is progestin-only, avoiding estrogen contraindications. The use of LNG IUS devices for dysfunctional uterine bleeding may allow women to avoid more invasive procedures such as hysterectomy or endometrial ablation.

January 9, 2013 the U.S. Food and Drug Administration (FDA) approved Skyla™ (levonorgestrel-releasing intrauterine system) 13.5 mg, a hormone-releasing system that is placed in the uterus for the prevention of pregnancy for up to three years. No studies have been completed for the use of Skyla™ for the treatment of heavy menstrual bleeding.

February 27, 2015 the U.S. Food and Drug Administration (FDA) approved Liletta® (levonorgestrel-releasing intrauterine system) 52 mg, a hormone-releasing system to prevent pregnancy for up to 4 years. On October 28, 2019, the FDA extended its approval of Liletta® (LNG-IUS) for prevention of pregnancy for up to 6 years. No studies have been completed for the use of Liletta® for the treatment of heavy menstrual bleeding.

September 16, 2016 the U.S. Food and Drug Administration (FDA) approved Kyleena® (levonorgestrel-releasing intrauterine system) 19.5 mg, a hormone-releasing system to prevent

pregnancy for up to 5 years. No studies have been completed for the use of Liletta® for the treatment of heavy menstrual bleeding.

IV. RATIONALE

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For information on clinical studies for Mirena® LNG IUS, refer to the Prescribing Information.

V. DEFINITIONS

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DYSFUNCTIONAL UTERINE BLEEDING (DUB) is abnormal bleeding from the uterus not caused by tumor, inflammation or pregnancy.

MENORRHAGIA is excessive uterine bleeding occurring at the regular intervals of menstruation, the period of flow being of greater than usual duration.

OFF-LABEL USE is the use of a prescription drug or medical device in the treatment of an illness or injury for which it has not been specifically approved by the FDA.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered when used for any indication other than contraception:

HCPCS Code	Description
J7296	Levonorgestrel-releasing intrauterine contraceptive system (Kyleena), 19.5 mg
J7301	Levonorgestrel-Releasing Intrauterine Contraceptive System (Skyla), 13.5 mg

Covered when medically necessary:

CPT Codes®								
58300	58301							

HCPCS Code	Description
J7297	Levonorgestrel-releasing intrauterine contraceptive system (Liletta), 52 mg
J7298	Levonorgestrel-releasing intrauterine contraceptive system (Mirena), 52 mg
S4981	Insertion of levonorgestrel-releasing intrauterine system

ICD-10-CM Diagnosis Codes	Description
N80.0	Endometriosis of uterus
N80.1	Endometriosis of ovary
N80.2	Endometriosis of fallopian tube
N80.3	Endometriosis of pelvic peritoneum
N80.4	Endometriosis of rectovaginal septum and vagina
N92.0	Excessive and frequent menstruation with regular cycle
N92.1	Excessive and frequent menstruation with irregular cycle
N92.4	Excessive bleeding in the premenopausal period
Z30.430	Encounter for insertion of intrauterine contraceptive device
Z30.431	Encounter for routine checking of intrauterine contraceptive device
Z30.432	Encounter for removal of intrauterine contraceptive device
Z30.433	Encounter for removal and reinsertion of intrauterine contraceptive device

IX. REFERENCES

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X. POLICY HISTORY

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MP 7.026	**CAC 10/26/04**
	CAC 10/25/05
	CAC 9/26/06
	CAC 1/30/07
	CAC 2/27/07
	CAC 5/27/08
	CAC 5/26/09
	CAC 5/25/10 Consensus review
	CAC 4/26/11 Consensus review
	CAC 6/4/13 Major review. No changes to policy statements. Retirement recommended.
	CAC 11/26/13 Minor review. Policy was not retired. Added information related to Skyla™. Also, added medically necessary policy statement for use of levonorgestrel releasing IUD 52 mg in the treatment of idiopathic menorrhagia, menometrorrhagia, protection against endometrial hyperplasia in women who are currently receiving selective estrogen receptor modulators and for management of recurrent pelvic pain secondary to multi-treated endometriosis. Added the statement "Levonorgestrel intrauterine systems (LNG IUS) devices containing less than 52 mg levonorgestrel (Skyla™) for off-label non-contraceptive use are considered **investigational**." Deleted the following statement "The use of IUDs for contraception is generally non-covered. Individual plan contracts may allow coverage''. Deleted Medicare and Sr. Blue variations – benefits address coverage. New 2014 code added.
	09/26/2014- **Admin** coding review. Added diagnosis 617.0-617.4.
	CAC 11/25/14. **Consensus review**. No change to policy statements. References updated**.** Coding reviewed 11/07/2014
	CAC 11/24/15 Consensus review. No change to the policy statements. References updated. Coding reviewed.
	Administrative 1/15/16: New 2016 codes J7297 & J7298 added; removed end dated code J7302.

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	CAC 9/27/2016: Consensus review. No change to the policy statements. References updated. Coding reviewed. Variation section reformatted.
	Admin Update 1/1/17: New diagnosis codes added effective 10/1/16
	Administrative Update 7/3/17: New code (Q9984) for Kyleena™ 19.5mg added; effective 7/1/17.
	CAC 9/26/17 Consensus review. Policy statements unchanged. References updated. Coding reviewed.
	Admin Update 1/1/18: Added new code J7296 and removed end dated code Q9984; effective 1/1/18.
	6/8/18 Consensus review. No changes to the policy statements. Background revised to address Liletta® (levonorgestrel-releasing intrauterine system) 52 mg. References updated. Rationale revised to refer to the prescribing information for clinical studies.
	Admin Update 8/27/18 A note was added to the policy for clarification which states: For the use of intrauterine devices for contraceptive purposes - refer to the Certificate of Coverage and Preventive Benefits.
	5/30/19 Consensus review. No change in literature. No changes to the policy statements. References updated.
	5/13/2020 Consensus review. Background updated. References and FEP language added. No change to policy statement.

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