MEDICAL POLICY

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

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**4/1/2025**

I. POLICY

NOTE: For the use of intrauterine devices for contraceptive purposes - refer to the Benefit Booklet 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®, Liletta®) may be considered **medically necessary** to treat heavy menstrual bleeding in individuals 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 individuals 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 general 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 general health outcomes or benefits associated with this procedure.

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 TOP

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

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND TOP

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. Hormonal devices include levonorgestrel-releasing intrauterine systems (LNG-IUS) like Mirena®, Liletta®, Skyla® and Kyleena®

The U.S. Food and Drug Administration (FDA) approved Mirena® (levonorgestrel-releasing intrauterine system) 52 mg, a hormone-releasing system to prevent pregnancy for up to 8 years and treatment of heavy menstrual bleeding for 5 years.

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.

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 8 years and treatment of heavy menstrual bleeding for 5 years.

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 Kyleena® for the treatment of heavy menstrual bleeding.

IV. RATIONALE

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Employing an IUD for heavy menstruation can reduce symptoms of cramping and pain and reduce associated comorbidities, such as anemia.

The use of LNG IUS devices for dysfunctional uterine bleeding may also allow women to avoid more invasive procedures such as hysterectomy or endometrial ablation.

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 are based on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits. These medical policies 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 Blue Cross' Provider Services or Member Services. Capital Blue Cross 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:

Procedure Codes								
J7296	J7301							

Covered when medically necessary:

Procedure Codes								
58300	58301	J7297	J7298	S4981				

ICD-10-CM Diagnosis Codes								
N80.00	N80.01	N80.02	N80.03	N80.101	N80.102	N80.103	N80.109	N80.111
N80.112	N80.113	N80.119	N80.121	N80.122	N80.123	N80.129	N80.201	N80.202
N80.203	N80.209	N80.211	N80.212	N80.213	N80.219	N80.221	N80.222	N80.223
N80.229	N80.30	N80.311	N80.312	N80.319	N80.321	N80.322	N80.329	N80.331
N80.332	N80.333	N80.339	N80.341	N80.342	N80.343	N80.349	N80.351	N80.352
N80.353	N80.359	N80.361	N80.362	N80.363	N80.369	N80.371	N80.372	N80.373
N80.379	N80.381	N80.382	N80.383	N80.389	N80.391	N80.392	N80.399	N80.3A1
N80.3A2	N80.3A3	N80.3A9	N80.3B1	N80.3B2	N80.3B3	N80.3B9	N80.3C1	N80.3C2
N80.3C3	N80.3C9	N80.40	N80.41	N80.42	N92.0	N92.1	N92.4	Z30.430
Z30.431	Z30.432	Z30.433						

IX. REFERENCES

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X. POLICY HISTORY

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MP 7.026	**05/13/2020 Consensus Review**. Background updated. References and FEP language added. No change to policy statement.
	08/05/2021 Consensus Review. No change to policy statement. Coding and references reviewed.
	03/23/2022 Consensus Review. No changes to the policy statement
	08/04/2022 Administrative Update. Removed ICD-10 codes that are deleted; N80.0, N80.1, N80.2, N80.3, N80.4 effective 10/01/2022. Added 77 new ICD-10 codes; N80.00-N80.42 effective 10/01/2022.
	06/28/2023 Consensus Review. No change to policy statement. Coding and references reviewed.

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	01/19/2024 Administrative Update. Clinical benefit added.
	03/29/2024 Consensus Review. No change to policy statement. Updated background, rationale and references.
	01/02/2025 Consensus Review. No changes to policy intent, administrative changes for clarity. References reviewed and updated. Coding reviewed.

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