

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

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I. POLICY

Intrauterine devices (IUDs) may be **medically necessary** 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®) 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 progestins, 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™) 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.

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The noncontraceptive 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.

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

Cross-reference:

MP-2.103 Off-label use of Prescription Drugs
 MP-7.013 Endometrial Ablation

II. PRODUCT VARIATIONS

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[N] = No product variation, policy applies as stated

[Y] = Standard product coverage varies from application of this policy, see below

- | | |
|--------------------------|-----------------|
| [N] Capital Cares 4 Kids | [N] Indemnity |
| [N] PPO | [N] SpecialCare |
| [N] HMO | [N] POS |
| [N] SeniorBlue HMO | [N] FEP PPO |
| [N] SeniorBlue | |

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.

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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

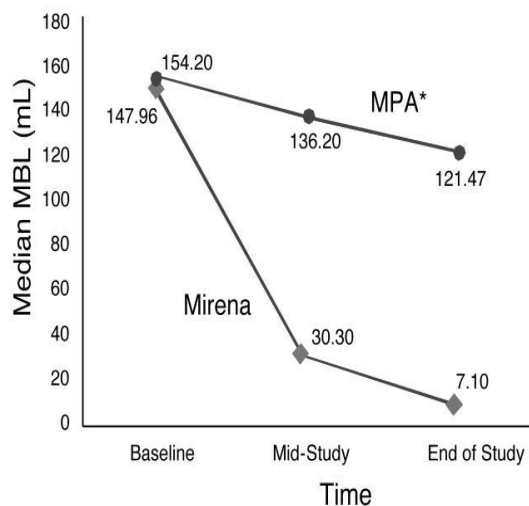
IV. RATIONALE

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Heavy Menstrual Bleeding

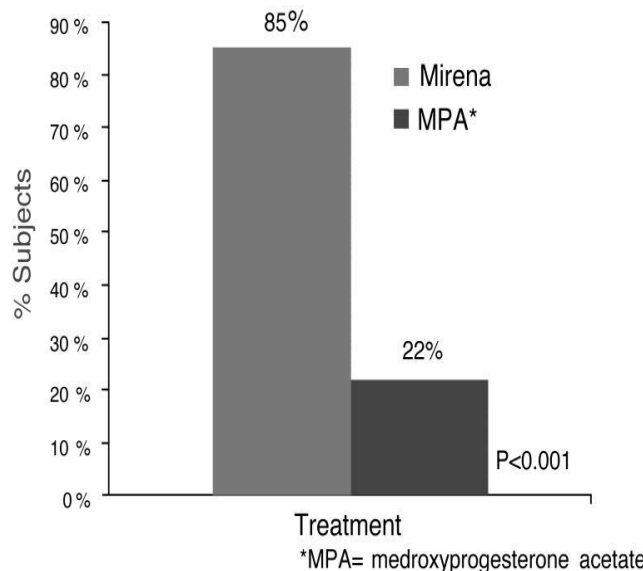
The efficacy of Mirena in the treatment of heavy menstrual bleeding was studied in a randomized, open-label, active-control, parallel-group trial comparing Mirena (n=79) to an approved therapy, medroxyprogesterone acetate (MPA) (n=81), over 6 cycles. The subjects included reproductive-aged women in good health, with no contraindications to the drug products and with confirmed heavy menstrual bleeding (≥ 80 mL menstrual blood loss [MBL]) determined using the alkaline hematin method. Excluded were women with organic or systemic conditions that may cause heavy uterine bleeding (except small fibroids, with total volume not > 5 mL). Treatment with Mirena showed a statistically significantly greater reduction in MBL (see **Figure 10**) and a statistically significantly greater number of subjects with successful treatment (see **Figure 11**). Successful treatment was defined as proportion of subjects with (1) end-of-study MBL < 80 mL and (2) a $\geq 50\%$ decrease in MBL from baseline to end-of-study.

Figure 10. Median Menstrual Blood Loss (MBL) by Time and Treatment



*MPA=medroxyprogesterone acetate

Figure 11. Proportion of Subjects with Successful Treatment



*MPA= medroxyprogesterone acetate

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There were no clinical trials for use of Skla for the treatment of heavy menstrual bleeding.

Endometrial hyperplasia; Prophylaxis - Tamoxifen adverse reaction; Prophylaxis

Intrauterine levonorgestrel was effective in protecting against uterine effects of tamoxifen in a controlled trial. Postmenopausal women (n=122) who had received at least 1 year of tamoxifen adjuvant treatment were randomized to treatment with levonorgestrel (20 mcg/day) and endometrial surveillance or to the control group, which consisted only of endometrial surveillance. Baseline assessment indicated only benign uterine changes in all women. At the end of 12 months, hysteroscopies indicated a uniform decidualization of the endometrium in all women using levonorgestrel. In addition, these women developed no new polyps and 13% had fewer fibroids compared to the control group. The intrauterine system was well tolerated with an excess of bleeding reported which resolved to baseline similar to the control group.

Management of recurrent pelvic pain due to endometriosis

In a prospective, open-label, single-center study, insertion of levonorgestrel intrauterine device (IUD) led to significant improvements in pain in women with recurrent pelvic pain secondary to multi-treated endometriosis. Women (n=43; 60.5% nulliparous) aged 16 to 50 years (mean, 40.28 years) with histopathologically-confirmed endometriosis, and persistent or recurrent pain despite either 1 prior surgery plus 2 medical treatments or 2 prior surgeries plus 1 medical treatment received the levonorgestrel IUD which released 20 mcg levonorgestrel/day. Pain was assessed using both the visual analog scale (VAS; 0=no pain to 10=maximum pain) and the verbal descriptive scale (VDS; absent, mild, moderate, or severe). Assessments were conducted every 3 months during the first year and yearly thereafter, with a median follow-up of 22 months (range, 3 to 36 months). During the follow-up, patients still carrying the IUD with no pain or mild pain were considered as having a good response; removal of IUD for any reason or patients with persistent moderate to severe pain were considered as not having a good response. The cumulative rate of IUD removal was 27.1% after 3 years. Among women still carrying the IUD, there was a significant improvement in pain over time, with mean VAS scores of 8.07 +/- 2.2 at baseline dropping to 5.3 +/- 2.6 at 3 months and to 2 +/- 1.7 at 3 years (p less than 0.05); 67% and 87.5% of women reported an improvement in pain at 3 months and 3 years, respectively. Rates for good response, based on VAS scores, were 53.5% at 3 months, increasing steadily to 72.3% at 3 years. Similar results were obtained on the VDS. Additional therapies used by women during follow-up included NSAIDs (n=9), progestins (n=5), danazol (n=3), oral contraceptives (n=1), and tibolone (n=1). Analysis of trends in response rates suggested a better response in women who had endometriosis for less than 10 years compared with those who had endometriosis of greater than 10 years duration.

Levonorgestrel intrauterine system (IUS) was effective for treating symptomatic minimal to moderate endometriosis during a prospective, observational study. Women (n=34) with clinically suspected and laparoscopically confirmed symptomatic minimal to moderate endometriosis had levonorgestrel IUS (delivering 20 mcg/day) inserted for 6 months. Of the 34 women recruited,

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29 completed the study. There was a statistically significant fall in visual analogue scale (VAS) from 7.7 cm before therapy to 6.1 cm at 3 months post-IUS insertion (p less than 0.01) and to 4.6 cm after 6 months (p less than 0.01). The verbal rating score (VRS) for dysmenorrhea was also significantly improved with the proportion of patients experiencing moderate or severe dysmenorrhea falling from 96% before therapy to 68% at 3 months (p=0.001) and to 50% at 6 months (p less than 0.001). Noncyclical pain was not significantly reduced over 6 months. The number of days of pain experienced per month was significantly reduced from a mean of 15 to 10.7 after 6 months (p less than 0.05). Twenty-three cases elected to continue with the device after 6 months of therapy.

Intrauterine levonorgestrel 20 mcg/day was effective in alleviating pain and reducing size of endometrial lesions in 11 women with symptomatic rectovaginal endometriosis. The levonorgestrel intrauterine device was inserted for 12 months. Moderate to severe dysmenorrhea at baseline was absent in all 11 patients at the end of one year. Pelvic pain was also alleviated over a period of one year and moderate to severe dyspareunia improved to mild or was completely alleviated. Ultrasound revealed that lesions of the rectovaginal septum were significantly reduced after 6 months (p less than 0.05) and continued to decrease over the remaining 6 months of therapy. Use of levonorgestrel was associated with headache, breast tenderness, and an increase in body weight

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.

SELECTIVE ESTROGEN RECEPTOR MODULATORS (SERMs) - tamoxifen, raloxifen and toremifene are competitive inhibitors of estrogen binding to estrogen receptors (ERs); all have mixed agonist and antagonist activity, depending on the target tissue

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 contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded,

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and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VII. DISCLAIMER

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Capital’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. Capital 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.

Covered when medically necessary:

CPT Codes®							
58300	58301						

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HCPCS Code	Description
J7302	Levonorgestrel-releasing intrauterine contraceptive system, 52 mg
S4981	Insertion of levonorgestrel-releasing intrauterine system

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

HCPCS Code	Description
J7301	Levonorgestrel-Releasing Intrauterine Contraceptive System (SKYLA), 13.5 mg

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ICD-9-CM Diagnosis Code*	Description
617.0	Endometriosis of uterus
617.1	Endometriosis of ovary
617.2	Endometriosis of fallopian tube
617.3	Endometriosis of pelvic peritoneum
617.4	Endometriosis of rectovaginal septum and vagina
626.2	Excessive or frequent menstruation
626.6	Metrorrhagia
V25.42	Surveillance of previously prescribed intrauterine contraceptive device

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

The following ICD-10 diagnosis codes will be effective October 1, 2015:

ICD-10-CM Diagnosis Code*	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
Z30.431	Encounter for routine checking of intrauterine contraceptive device

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

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
	CAC 4/26/11 Consensus
	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

MEDICAL POLICY

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	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.

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