Clinical Policy: Endometrial Ablation

Reference Number: MC.CP.MP.106
Date of Last Revision: 12/25

Revision Log
Coding Implications

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

This policy describes the medical necessity guidelines for an endometrial ablation given the absence of coverage criteria provided by the Centers for Medicare and Medicaid Services (CMS) and the applicable Medicare Advantage Contractors. Endometrial ablation is a minimally invasive surgical procedure used to treat premenopausal abnormal uterine bleeding.[2,12,21] Although this procedure preserves the uterus, endometrial ablation is indicated for those who have no desire for future fertility.[11] The two major classifications of endometrial ablation procedures are first generation resectoscopic techniques and second generation non-resectoscopic methods. Quality of life resulting from reduced bleeding and amenorrhea may improve following endometrial ablation procedures.

The policy criteria are sourced from the American College of Obstetricians and Gynecologists (ACOG) practice committee opinions as well as guidance from the American Society for Reproductive Medicine (ASRM) practice committee.[3,6,32] The criteria below are derived from professional guidelines that experts in the field developed by systematically examining current evidence regarding the risks and benefits of endometrial ablation. Thus, criteria sourced from such guidelines presents clinical scenarios in which endometrial ablation would most benefit the patient and minimizes the risks of the criteria. Endometrial ablation is a beneficial procedure for patients who have no desire for future fertility since it is minimally invasive and preserves the uterus with most patients experiencing a significant reduction in menstrual bleeding, resulting in improved quality of life.[32] Risks of an endometrial ablation include infection, bleeding, uterine perforation, fluid volume overload, and burns to the vagina, vulva, and/or bowel. Additionally, pregnancy after endometrial ablation, although rare, is still possible and can cause serious fetal and maternal complications.[32] Overall, endometrial ablation is considered medically appropriate when the patient has received counseling on required post-procedure contraception, meets established clinical selection criteria, and when the anticipated therapeutic benefits outweigh the potential risks.

Note: For criteria applicable to non-Medicare plans, please see CP.MP.106 Endometrial Ablation.

Policy/Criteria

I. It is the policy of Medicare health plans affiliated with Centene Corporation® that endometrial ablation using an FDA approved device is **medically necessary** when all the following criteria are met[3,6,32]:

A. One of the following indications:

1. Menorrhagia unresponsive to hormonal or medical therapy (unless contraindicated to such therapy);[24]
2. Abnormal uterine bleeding, including residual menstrual bleeding after at least six months of androgen therapy in a member/enrollee with a female reproductive system undergoing treatment for gender affirmation;[23]

B. Cervical cytology or human papillomavirus (HPV) testing and gynecological exam excludes significant cervical disease;[24]
C. Endometrial sampling prior to the procedure has excluded malignancy or hyperplasia;[25]
D. No structural anomalies, such as fibroids or polyps that require transmural surgery or represent a contraindication to an ablation procedure;
E. If anatomic or pathologic conditions exist that may result in a weakened myometrium, only a resectoscopic endometrial ablation is appropriate;[7]
F. Thyroid disorders have been treated or ruled out;
G. Does not have any of the following contraindications:
    1. Premenopausal with future desire for fertility;[26]
    2. Untreated disorders of hemostasis;[7]
    3. Pregnancy at time of procedure;
    4. Intrauterine device unless device will be removed during procedure;[26]
    5. Active pelvic infection or recent uterine infection;[26]
    6. Endometrial hyperplasia or uterine cancer;
    7. Post-menopausal.

II. It is the policy of Medicare health plans affiliated with Centene Corporation that there is insufficient scientific evidence to support effectiveness for the following:
A. Photodynamic endometrial ablation procedures;
B. Endometrial ablation for the treatment of all other conditions than those specified above.

Background

Menstrual disorders are among the most prevalent gynecological health problems in the United States, and abnormal menstrual bleeding affects up to 30% of individuals with a female reproductive system at some time during their reproductive years.[4] Traditionally, medication therapy has been the initial treatment of choice, followed by hysterectomy, when medication does not provide the desired outcome. The levonorgestrel-releasing intrauterine device (e.g., Mirena or Liletta; referred to as LNG 52 mg IUD) is an option in patients who do not desire pregnancy. Both the LNG 52 mg IUD and endometrial ablation are effective in reducing menstrual blood loss. The decision to use the LNG 52 mg IUD or endometrial ablation depends on a patient's preferences regarding treatment factors, such as plans for fertility and contraception, convenience, and risks of anesthesia.[21,28] Endometrial ablation can offer an alternative to the more invasive hysterectomy treatment option.[9]

Endometrial ablation can also be used to treat residual menstrual bleeding in transgender men.[23] Generally, testosterone or masculinizing hormone therapy causes cessation of menses within one to six months of initiation.[17] Endometrial ablation may be considered for transgender men wishing to completely cease menses who do not desire future fertility and who also either decline hysterectomy or have surgical complications.[23]

Endometrial ablation encompasses several techniques of targeted destruction of the endothelial surface of the uterine cavity through a vast array of energy sources. While hysterectomies provide permanent relief from abnormal uterine bleeding, they are associated with longer recovery times, higher rates of postoperative complications, substantial convalescent time and morbidity.[8,9] Although endometrial ablation has a high success rate, there are specific cases of endometrial ablation failures in which the patient will return for repeat care, often for a hysterectomy.[9] The effectiveness of endometrial ablation was demonstrated in a report of 26 patients who underwent ablation. After one year, 25 of the 26 patients reported reduced bleeding with no further medical or surgical interventions, and one patient required a hysterectomy due to persistent uterine bleeding related to a leiomyoma.[29] Among patients who return for hysterectomy after failure of endometrial ablation, adenomyosis, leiomyomata and endometriosis are the most common contributing diagnoses.[21,30]

Pregnancy following endometrial ablation can occur, and premenopausal patients should be counseled that an appropriate contraception method should be used. Post-operative complications from endometrial ablation include: (1) pregnancy after endometrial ablation; (2) pain related to obstructed menses (hematometra, post ablation tubal sterilization syndrome); (3) failure to control menses; (4) risk from preexisting conditions (endometrial neoplasia, cesarean section; and (5) infection.[13,21] Uterine perforation has been reported in 0.3 percent of non-resectoscopic endometrial ablation procedures and 1.3 percent of resectoscopic ablations or resections.[21]

Table 1: FDA-Approved Techniques for Endometrial Ablation

Procedure[1,2,3]	System[1,2,13]	Device Size[1] (mm)	Treatment Time[1,13] (min)	Amenorrhea Rate[2]
Resectoscopic Ablation				
Laser Vaporization				37%
Electrosurgical Rollerball				25 to 60%
Transcervical resection of endometrium				26 to 40%
Radiofrequency Vaporization				N/A
Non-Resectoscopic Ablation				
Cryotherapy	Cerene	4.5	10 to 8	53%
Heated Free Fluid	Hydro ThermAblator	7.8	approx. 14*	71%
Vapor ablation	Mara		2.0	
Radiofrequency Electricity	NovaSure	7.2	1.5	41%
Combined thermal and bipolar radiofrequency ablation device	Minerva		2.0	

* Three minutes to heat the fluid to 90°C, 10 minutes to maintain that temperature to ablate the endometrium, and approximately one minute for the fluid to cool down allowing the device to be removed.

Coding Implications

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CPT® Codes	Description
58353	Endometrial ablation, thermal, without hysteroscopic guidance
58356	Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed
58563	Hysteroscopy, surgical; with endometrial ablation (eg, endometrial resection, electrosurgical ablation, thermoablation)

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
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
N92.5	Other specified irregular menstruation
N92.6	Irregular menstruation, unspecified
N93.8	Other specified abnormal uterine and vaginal bleeding
N93.9	Abnormal uterine and vaginal bleeding, unspecified

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed.	08/23	08/23
Annual review. Updated criteria under I.A.1. by removing "at least three months of". Expanded criteria under I.D. to include fibroids greater than 3cm in diameter. Added additional contraindications under I.G.5.-I.G.8. to include active pelvic infection or recent uterine infection, endometrial hyperplasia or uterine cancer, recent pregnancy, and post-menopausal. Updated wording in Table 1 under Background with no impact to criteria. References reviewed and updated. Reviewed by external specialist.	02/24	02/24
Annual review. Removed "greater than 3 cm in diameter" from Criteria I.D. Background updated with no impact on criteria. References reviewed and updated.	09/24	09/24
Annual review. Updated contraindication in Criteria I.G.4. regarding intrauterine device for clarity. Removed contraindication of recent pregnancy in Criteria I.G.7. Coding and descriptions reviewed. References reviewed and updated. Reviewed by external specialist.	09/25	09/25
Updated description to note the absence of coverage criteria from CMS and added where criteria are sourced and risk versus benefit information.	12/25	

References

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Important reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.