

# Clinical Policy: Endometrial Ablation

Reference Number: MC.CP.MP.106

Date of Last Revision: 09/24

Revision Log
Coding Implications

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

### **Description**

This policy describes the medical necessity guidelines for an endometrial ablation. Endometrial ablation is a minimally invasive surgical procedure used to treat premenopausal abnormal uterine bleeding. Although this procedure preserves the uterus, endometrial ablation is indicated for those who have no desire for future fertility. 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.

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<sup>®</sup> that endometrial ablation using an FDA approved device is **medically necessary** when all the following criteria are met:
  - A. One of the following indications:
    - 1. Menorrhagia unresponsive to hormonal or medical therapy (unless contraindicated to such therapy);<sup>24</sup>
    - 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;<sup>23</sup>
  - B. Cervical cytology or human papillomavirus (HPV) testing and gynecological exam excludes significant cervical disease;<sup>24</sup>
  - C. Endometrial sampling prior to the procedure has excluded malignancy or hyperplasia;<sup>25</sup>
  - 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;<sup>7</sup>
  - 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;<sup>26</sup>
    - 2. Untreated disorders of hemostasis;<sup>7</sup>
    - 3. Pregnancy at time of procedure;<sup>21</sup>
    - 4. Intrauterine device at time of procedure;<sup>26</sup>
    - 5. Active pelvic infection or recent uterine infection;<sup>26</sup>
    - 6. Endometrial hyperplasia or uterine cancer;<sup>21</sup>
    - 7. Recent pregnancy;
    - 8. Post-menopausal.



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- 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. 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. Endometrial ablation can offer an alternative to the more invasive hysterectomy treatment option.

Endometrial ablation can also be used to treat residual menstrual bleeding in transgender men.<sup>23</sup> Generally, testosterone or masculinizing hormone therapy causes cessation of menses within one to six months of initiation.<sup>17</sup> 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.<sup>23</sup>

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. 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. 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. Among patients who return for hysterectomy after failure of endometrial ablation, adenomyosis, leiomyomata and endometriosis are the most common contributing diagnoses. Among patients

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. Uterine perforation has been reported in 0.3 percent of non-resectoscopic endometrial ablation procedures and 1.3 percent of resectoscopic ablations or resections. <sup>21</sup>

**Table 1: FDA-Approved Techniques for Endometrial Ablation** 

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

<sup>\*</sup>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**

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023 American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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	Description
Code	
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

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Reviews, Revisions, and Approvals	Revision	Approval
	Date	Date
Policy developed.	08/23	08/23
Annual review. Updated criteria under I.A.1. by removing "at least	02/24	02/24
three months of". Expanded criteria under I.D. to include fibroids		
greater than 3cm in diameter. Added additional contraindications under		
I.G.5I.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.		
Annual review. Removed "greater than 3 cm in diameter" from	09/24	09/24
Criteria I.D. Background updated with no impact on criteria.		
References reviewed and updated.		

#### References

- 1. Apgar BS, Kaufman AH, George-Nwogu U, Kittendorf A. Treatment of menorrhagia. *Am Fam Physician*. 2007;75(12):1813 to1819.
- 2. Sharp HT. Endometrial ablation or resection: resectoscopic techniques. UpToDate. <a href="https://www.uptodate.com">www.uptodate.com</a>. Updated November 8, 2022. Accessed August 19, 2024.
- 3. American College of Obstetricians and Gynecologists. ACOG Committee Opinion No. 557: Management of Acute Abnormal Uterine Bleeding in Nonpregnant Reproductive-Aged Women. <a href="https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2013/04/management-of-acute-abnormal-uterine-bleeding-in-nonpregnant-reproductive-aged-women">https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2013/04/management-of-acute-abnormal-uterine-bleeding-in-nonpregnant-reproductive-aged-women</a>. Published April 2013 (reaffirmed 2024). Accessed August 30, 2024.
- 4. Matteson KA, Boardman LA, Munro MG, Clark MA. Abnormal uterine bleeding: a review of patient-based outcome measures. *Fertil Steril*. 2009;92(1):205 to 216. doi:10.1016/j.fertnstert.2008.04.023
- 5. Frick KD, Clark MA, Steinwachs DM, et al. Financial and quality-of-life burden of dysfunctional uterine bleeding among women agreeing to obtain surgical treatment. *Womens Health Issues*. 2009;19(1):70 to 78. doi:10.1016/j.whi.2008.07.002
- 6. American College of Obstetricians and Gynecologists. Committee on Practice Bulletins—Obstetrics. ACOG Practice Bulletin No. 128. Diagnosis of Abnormal Uterine Bleeding: in Reproductive-Aged Women. <a href="https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2012/07/diagnosis-of-abnormal-uterine-bleeding-in-reproductive-aged-women">https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2012/07/diagnosis-of-abnormal-uterine-bleeding-in-reproductive-aged-women</a>. Published July 2012 (reaffirmed 2021). Accessed January 27, 2023.
- 7. Munro MG, Critchley HO, Broder MS, Fraser IS; FIGO Working Group on Menstrual Disorders. FIGO classification system (PALM-COEIN) for causes of abnormal uterine bleeding in nongravid women of reproductive age. *Int J Gynaecol Obstet*. 2011;113(1):3-13. doi:10.1016/j.ijgo.2010.11.011
- 8. Sowter MC. New surgical treatments for menorrhagia. *Lancet*. 2003;361(9367):1456 to 1458. doi:10.1016/S0140-6736(03)13140-6
- 9. Bofill Rodriguez M, Lethaby A, Fergusson RJ. Endometrial resection and ablation versus hysterectomy for heavy menstrual bleeding. *Cochrane Database Syst Rev*. 2021;2(2):CD000329. Published 2021 Feb 23. doi:10.1002/14651858.CD000329.pub4
- 10. Laberge P, Leyland N, Murji A, et al. Endometrial ablation in the management of abnormal uterine bleeding. *J Obstet Gynaecol Can.* 2015;37(4):362-379. doi:10.1016/s1701-2163(15)30288-7

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- 11. Bofill Rodriguez M, Lethaby A, Grigore M, Brown J, Hickey M, Farquhar C. Endometrial resection and ablation techniques for heavy menstrual bleeding. Cochrane Database Syst Rev. 2019;1(1):CD001501. Published 2019 Jan 22. doi:10.1002/14651858.CD001501.pub5
- 12. Sharp HT. Endometrial ablation: non-resectoscopic techniques. UpToDate. www.uptodate.com. Updated April 08, 2024. Accessed August 30, 2024. Sharp HT. Endometrial ablation: postoperative complications. Am J Obstet Gynecol. 2012;207(4):242 to 247. doi:10.1016/j.ajog.2012.04.011
- 13. El-Nashar SA, Hopkins MR, Creedon DJ, et al. Prediction of treatment outcomes after global endometrial ablation [published correction appears in Obstet Gynecol. 2010 Mar;115(3):663]. *Obstet Gynecol*. 2009;113(1):97-106. doi:10.1097/AOG.0b013e31818f5a8d
- 14. Food and Drug Administration. Class 2 Device Recall Gynecare Thermachoice III. <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=142341">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=142341</a> Accessed August 20, 2024.
- Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline [published correction appears in J Clin Endocrinol Metab. 2018 Feb 1;103(2):699. doi: 10.1210/jc.2017-02548] [published correction appears in J Clin Endocrinol Metab. 2018 Jul 1;103(7):2758-2759. doi: 10.1210/jc.2018-01268]. J Clin Endocrinol Metab. 2017;102(11):3869-3903. doi:10.1210/jc.2017-01658
- 16. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. *Int J Transgend Health*. 2022;23(Suppl 1):S1-S259. Published 2022 Sep 6. doi:10.1080/26895269.2022.2100644
- 17. Kalampokas E, McRobbie S, Payne F, Parkin DE. Long-term incidence of hysterectomy following endometrial resection or endometrial ablation for heavy menstrual bleeding. *Int J Gynaecol Obstet*. 2017;139(1):61 to 64. doi:10.1002/jjgo.12259
- 18. Al-Shaikh G, Almalki G, Bukhari M, Fayed A, Al-Mandeel H. Effectiveness and outcomes of thermablate endometrial ablation system in women with heavy menstrual bleeding. *J Obstet Gynaecol.* 2017;37(6):770 to 774. doi:10.1080/01443615.2017.1292228
- 19. Riley KA, Davies MF, Harkins GJ. Characteristics of patients undergoing hysterectomy for failed endometrial ablation. *JSLS*. 2013;17(4):503 to 507.doi:10.4293/108680813X13693422520602
- 20. Sharp HT. Overview of endometrial ablation. UpToDate. <a href="www.uptodate.com">www.uptodate.com</a>. Updated January 29, 2024. Accessed August 20, 2024.
- National Institute for Health and Care Excellence. Photodynamic endometrial ablation. Interventional procedures guidance [IPG47].
   <a href="https://www.nice.org.uk/guidance/ipg47">https://www.nice.org.uk/guidance/ipg47</a>. Published March 24, 2004. Accessed August 30, 2024.
- 22. Obedin-Maliver J. Pelvic pain and persistent menses in transgender men. UCSF Transgender Care. <a href="https://transcare.ucsf.edu/guidelines/pain-transmen">https://transcare.ucsf.edu/guidelines/pain-transmen</a>. Published June 17, 2016. Accessed August 30, 2024.
- 23. Practice Committee of American Society for Reproductive Medicine. Indications and options for endometrial ablation. *Fertil Steril*. 2008;90(5 Suppl):S236 to S240. doi:10.1016/j.fertnstert.2008.08.059
- 24. Kumar V, Chodankar R, Gupta JK. Endometrial ablation for heavy menstrual bleeding. *Womens Health (Lond)*. 2016;12(1):45 to 52. doi:10.2217/whe.15.86
- 25. Food and Drug Administration (FDA). Endometrial ablation for heavy menstrual bleeding. <a href="https://www.fda.gov/medical-devices/surgery-devices/endometrial-ablation-heavy-menstrual-bleeding">https://www.fda.gov/medical-devices/surgery-devices/endometrial-ablation-heavy-menstrual-bleeding</a>. Published October 25, 2021. Accessed August 20, 2024.

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#### **Endometrial Ablation**

- 26. European Society of Human Reproduction and Embryology (ESHRE). ESHRE Guideline Endometriosis. <a href="https://www.eshre.eu/Guidelines-and-Legal/Guidelines/Endometriosis-guideline.aspx">https://www.eshre.eu/Guidelines-and-Legal/Guidelines/Endometriosis-guideline.aspx</a>. Published February 02, 2022. Accessed August 20, 2024.
- 27. Bofill Rodriguez M, Dias S, Jordan V, et al. Interventions for heavy menstrual bleeding; overview of Cochrane reviews and network meta-analysis. *Cochrane Database Syst Rev.* 2022;5(5):CD013180. Published 2022 May 31. doi:10.1002/14651858.CD013180.pub2
- 28. Zacur HA. Managing an episode of acute uterine bleeding. UpToDate. <a href="www.uptodate.com">www.uptodate.com</a>. Updated August 23, 2024. Accessed August 30, 2024.
- 29. Stevens KYR, Meulenbroeks D, Houterman S. et al. Prediction of unsuccessful endometrial ablation: a retrospective study. *Gynecol Surg*. 2019;16(7):1-9. <a href="https://link.springer.com/article/10.1186/s10397-019-1060-1">https://link.springer.com/article/10.1186/s10397-019-1060-1</a>. Published May 01, 2019. Accessed August 30, 2024.
- 30. Middleton LJ, Champaneria R, Daniels JP, et al. Hysterectomy, endometrial destruction, and levonorgestrel releasing intrauterine system (Mirena) for heavy menstrual bleeding: systematic review and meta-analysis of data from individual patients. *BMJ*. 2010;341:c3929. Published 2010 Aug 16. doi:10.1136/bmj.c3929
- 31. American College of Obstetricians and Gynecologists. Endometrial ablation [FAQ134]. <a href="https://www.acog.org/womens-health/faqs/endometrial-ablation">https://www.acog.org/womens-health/faqs/endometrial-ablation</a>. Published January 2022. Accessed August 30, 2024.

### **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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.



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This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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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 <u>prior to</u> applying the criteria set forth in this clinical policy. Refer to the CMS website at <a href="http://www.cms.gov">http://www.cms.gov</a> for additional information.

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