

## Clinical Policy: Endometrial Ablation

Reference Number: CP.MP.106

Date of Last Revision: 03/23

<u>Revision Log Coding Implications</u>

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.

#### Policy/Criteria

- I. It is the policy of 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 at least three months of hormonal or medical therapy (unless contraindicated to such therapy);
    - 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;
  - B. Cervical cytology or human papillomavirus (HPV) testing and gynecological exam excludes significant cervical disease;
  - C. Endometrial sampling prior to the procedure has excluded malignancy or hyperplasia;
  - 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;
  - 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;
    - 2. Untreated disorders of hemostasis;
    - 3. Pregnancy at time of procedure;
    - 4. Intrauterine device at time of procedure;
    - 5. Active pelvic infection;
- **II.** It is the policy of 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 people at some time during their reproductive years.<sup>4</sup> 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. <sup>21,24,29</sup> Endometrial ablation can offer an alternative to the more invasive hysterectomy treatment option.<sup>9</sup>

Endometrial ablation can also be used to treat residual menstrual bleeding in transgender men.<sup>23</sup> Generally, masculinizing hormones cause cessation of menses within two to six months of initiation. The addition of a progestational agent or endometrial ablation may be considered for those wishing to completely cease menses.<sup>17</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; 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 who return for hysterectomy after failure of endometrial ablation, adenomyosis, leiomyomata and endometriosis are the most common contributing diagnoses.

Pregnancy following endometrial ablation can occur, and premenopausal patients should be counseled that an appropriate contraception method should be used. Endometrial ablation is predominately indicated for patients who have no desire for future fertility.<sup>20</sup> 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.<sup>13,21</sup> 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 Approved For Endometrial Ablation

Procedure <sup>1,2,3</sup>	System <sup>1,2,13</sup>	Device	Treatment	
Resectoscopic Ablation				
Laser Vaporization				37%



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>
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	

<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 2020 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.

<b>CPT® Codes</b>	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



Reviews, Revisions, and Approvals		Approval Date
Policy developed, reviewed by specialist	Date 12/15	01/16
Added "previous transmyometrial uterine surgery" in I.D. References		07/18
reviewed and updated.		
Added additional FDA approved devices (i.e., Mara, Minerva) to table		07/19
1. References reviewed and updated. Specialist review.		
Added "abnormal uterine bleeding" as an indication and combined this	10/19	11/19
with the residual menstrual bleeding after androgen therapy in a female		
to male transgender person indication. Removed reference to criteria in		
CP.MP.95 Gender Affirming Procedures. Added the following codes		
as medically necessary: N92.5, N92.6, N93.8, N93.9.		
References reviewed and updated.	07/20	07/20
Annual review completed. References reviewed and updated and	07/21	07/21
reformatted for AMA style. Changed "members" to		
"members/enrollees." Removed "experimental and investigation"		
from II, changing to "insufficient evidence." Changed "review date" in		
the header to "date of last revision" and "date" in the revision log		
header to "revision date." Specialty review completed. Added		
ThermaChoice to Table 1 per UpToDate reference "3".		
Annual review completed. Added "or HPV testing" to I.B. References	03/22	03/22
reviewed and updated. Background updated with no impact to criteria.		
Changed criteria I.D. from "no structural anomalies, such as fibroids or	04/22	04/22
polyps that require surgery or represent a contraindication to an		
ablation procedure, or previous transmyometrial uterine surgery		
(including classical cesarean)" to "no structural anomalies, such as		
fibroids or polyps that require transmural surgery or represent a		
contraindication to an ablation procedure." Added contraindication		
criteria I.F.6. "Previous classical cesarean or other transmural surgery."		
In I.A.2, reworded portion pertaining to abnormal bleeding in	09/22	
transgender members from "female to male transgender person" to		
"member/enrollee with a female reproductive system undergoing		
treatment for gender affirmation."		
Annual review completed. Added requirement in I.F. that thyroid	03/23	03/23
disorders have been treated or ruled out. Removed contraindication		
"previous classic cesarean or other transmural surgery" from I.G.		
Background and Table 1 updated. Minor rewording with no clinical		
significance. References reviewed and updated. Internal specialist		
reviewed.		

#### 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 January 27, 2023.

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#### CLINICAL POLICY Endometrial Ablation

- 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="www.acog.org">www.acog.org</a>. Published April 2013 (reaffirmed 2020). Accessed January 27, 2023.
- 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
- 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">www.acog.org</a> Published July 2012 (reaffirmed 2021). Accessed January 27, 2023.
- 7. Munro MG, Critchley HO, Broder MS, et al. FIGO classification system (PALM-COEIN) for causes of abnormal uterine bleeding in non-gravid women of reproductive age. *Int J Gynaecol Obstet*. 2011 Apr;113(1):3 to 13.
- 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 February 23, 2021. 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 to 379. doi:10.1016/s1701-2163(15)30288-7
- 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. <a href="https://www.uptodate.com">www.uptodate.com</a>. Updated October 17, 2022. Accessed January 27, 2023.
- 13. Sharp HT. Endometrial ablation: postoperative complications. *Am J Obstet Gynecol*. 2012;207(4):242 to 247. doi:10.1016/j.ajog.2012.04.011
- 14. El-Nashar SA, Hopkins MR, Creedon DJ, St Sauver JL, Weaver AL, McGree ME, Cliby WA, Famuyide AO. Prediction of treatment outcomes after global endometrial ablation. Obstet Gynecol. 2009 Jan;113(1):97 to 106. doi: 10.1097/AOG.0b013e31818f5a8d. Erratum in: Obstet Gynecol. 2010 Mar;115(3):663. PMID: 19104365; PMCID: PMC2977517.
- 15. 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 January 27, 2023.
- 16. 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] [published correction appears in J Clin Endocrinol Metab. 2018 Jul 1;103(7):2758-2759]. J Clin Endocrinol Metab. 2017;102(11):3869 to 3903. doi:10.1210/jc.2017-01658

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# **CLINICAL POLICY Endometrial Ablation**

- 17. The World Professional Association for Transgender Health Inc. (WPATH). Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 8<sup>th</sup> version. https://www.wpath.org/publications/soc. Accessed January 27, 2023.
- 18. 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/ijgo.12259.
- 19. 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.
- 20. 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.
- 21. Sharp HT. Overview of endometrial ablation. UpToDate. <a href="www.uptodate.com">www.uptodate.com</a>. Updated November 28, 2022. Accessed January 27, 2023.
- 22. National Institute for Clinical Excellence (NICE). Photodynamic endometrial ablation. Interventional Procedure Guidance 47. London, UK: NICE; 2004.
- 23. 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 January 27, 2023.
- 24. Kaunitz AM. Abnormal uterine bleeding: Management in premenopausal patients. UpToDate. <a href="www.uptodate.com">www.uptodate.com</a>. Updated January 11, 2023. Accessed January 27, 2023.
- 25. 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
- 26. 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
- 27. 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 January 27, 2023.
- 28. 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 2, 2022. Accessed January 30, 2023.
- 29. 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
- 30. Zacur H. Managing an episode of acute uterine bleeding. UpToDate. <a href="www.uptodate.com">www.uptodate.com</a>. Updated November 14, 2022. Accessed February 10, 2023.
- 31. Stevens KYR, Meulenbroeks D, Houterman S. et al. Prediction of unsuccessful endometrial ablation: a retrospective study. *Gynecol Surg* **16**, 7 (2019). https://link.springer.com/article/10.1186/s10397-019-1060-1. Accessed February 10, 2023.

#### **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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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.

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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