MEDICAL POLICY

POLICY TITLE	ENDOMETRIAL ABLATION
POLICY NUMBER	MP-7.013

Original Issue Date (Created):	**5/9/2003**
Most Recent Review Date (Revised):	**2/8/2019**
Effective Date:	**4/1/2019**

I. POLICY

Endometrial ablation, with or without hysteroscopic guidance, using an FDA-approved device may be considered **medically necessary** in women with abnormal uterine bleeding who are not candidates for, or who are unresponsive to, hormone therapy and would otherwise be considered candidates for hysterectomy.

Endometrial ablation is considered **investigational** for all other indications. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

Intrauterine ablation or resection of the endometrium should not be confused with laparoscopic laser ablation of intraperitoneal endometriosis. This policy does not address laparoscopic intraperitoneal ablation.

Contraindications for intrauterine ablation or resection of the endometrium include:

- Patient who is pregnant or desires pregnancy
- History of endometrial cancer or pre-cancerous histology
- Patient with an active genital or urinary tract infection at the time of the procedure
- Patient with active pelvic inflammatory disease
- Patient with an intrauterine device (IUD) currently in place
- Patient with any anatomic or pathologic condition in which weakness of the myometrium could exist, such as history of previous classical cesarean sections or transmural myomectomy

Other contraindications for microwave ablation include myometrial thickness less than 10 mm, and uterine sounding length less than 6 cm.

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Cross-reference:
None

II. PRODUCT VARIATIONS TOP

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO: Refer to FEP Medical Policy Manual MP-4.01.04 Endometrial Ablation. The FEP Medical Policy Manual can be found at: www.fepblue.org

III. DESCRIPTION/BACKGROUND TOP

Endometrial ablation is a potential alternative to hysterectomy for abnormal uterine bleeding. A variety of approaches are available; these are generally classified into hysteroscopic techniques (e.g., Nd-YAG laser and electrosurgical rollerball) and non-hysteroscopic techniques (e.g., cryosurgical and radiofrequency [RF] ablation).

Ablation or destruction of the endometrium is used to treat abnormal uterine bleeding in women who have failed standard therapy. It is considered a less invasive alternative than hysterectomy; however, as with hysterectomy, the procedure is not recommended for women who want to preserve fertility.

Multiple energy sources have been used. These include: Nd-YAG laser, a resecting loop using electric current, electric rollerball, and thermal ablation devices. Endometrial ablation is typically preceded by hormonal treatment to thin the endometrium.

Techniques for endometrial ablation are generally divided into 2 categories: those that do and do not require hysteroscopic procedures. (Other terminology for these categories of techniques include first- generation versus second-generation procedures and resectoscopic versus nonresectoscopic endometrial ablation methods.) Hysteroscopic techniques were developed first; the initial technique was photovaporization of the endometrium using an Nd-YAG laser, and this was followed by electrosurgical ablation using an electrical rollerball or electrical wire loop. (The latter technique is also known as transcervical resection of the endometrium.) Hydrothermal ablation also involves hysteroscopy. Hysteroscopic techniques require skilled surgeons and, due to the requirement for cervical dilation, use of general or regional anesthesia. In addition, the need for the instillation of hypotonic distension media creates a risk of pulmonary edema and hyponatremia such that very accurate monitoring of fluids is required.

Nonhysteroscopic techniques can be performed without general anesthesia and do not involve use of a fluid distention medium. Techniques include thermal fluid-filled balloon, cryosurgical endometrial ablation, instillation of heated saline, and radiofrequency ablation.

There are concerns about maternal and fetal morbidity and mortality associated with pregnancy after endometrial ablation. Thus, Food and Drug Administration approval of endometrial ablation devices includes only women for whom childbearing is complete.

Regulatory Status

The FDA indicates that endometrial devices are for use in premenopausal women with menorrhagia due to benign causes for whom childbearing is complete. FDA-approved devices for endometrial ablation include, but may not be limited to, laser therapy, electrical wire loop, rollerball using electric current, and thermal ablation using a liquid-filled balloon, microwave, electrode array, or a cryosurgical device. Examples of devices for endometrial ablation are:

- The Genesys HTA™ system (Boston Scientific): The system involves the instillation and circulation of heated saline into the uterus using hysteroscopic guidance and includes features such as a smaller console and simplified set-up requirements, was approved by FDA in May 2010.
- The Microwave Endometrial Ablation system (Microsulis Medical, U.K.): This system delivers fixed-frequency microwave energy and may be performed in a physician's office but does require use of the hysteroscope.
- The ThermaChoice® device (J&J Ethicon Gynecare, Somerville, NJ): This device ablates endometrial tissue by thermal energy heating of sterile injectable fluid within a silicone balloon. Endometrial ablation will only work when there is direct contact between the endometrial wall and the fluid-filled balloon. Therefore, patients with uteri of abnormal shape, resulting from tumors such as myomas or polyps, or large size, due to fibroids, are generally not considered candidates for this procedure.
- The NovaSure™ impedance-controlled endometrial ablation system (Hologic, Marlborough, MA): The system delivers radiofrequency energy to the endometrial surface. The device consists of an electrode array on a stretchable porous fabric that conforms to the endometrial surface.
- Her Option™ Uterine Cryoablation Therapy™ system (American Medical Systems, Minnetonka, MN): The system consists of, in part, a cryoprobe that is inserted through the cervix into the endometrial cavity. When cooled, an ice ball forms around the probe, which permanently destroys the endometrial tissue. Cryoablation is typically monitored by abdominal ultrasound.

FDA Product Code: MNB.

IV. RATIONALE

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Summary of Evidence

For individuals who have abnormal uterine bleeding and have failed hormonal therapy who receive endometrial ablation, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, quality of life, resource utilization, and treatment-related morbidity.

RCTs and systematic reviews of RCT data have found that hysterectomy provided greater symptom relief and fewer reoperations than endometrial ablation, but that endometrial ablation resulted in a reasonable level of symptom control and the procedure has some advantages over hysterectomy (e.g., women retain their uterus and avoid a more invasive procedure). A meta-analysis of RCTs has suggested similar benefits with first-generation (hysteroscopic) techniques and second-generation (mainly nonhysteroscopic) techniques. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

V. DEFINITIONS

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ADENOMYOSIS is the benign invasive growth of the endometrium into the muscular layer of the uterus.

DILATION AND CURETTAGE is a surgical procedure that expands the cervical canal of the uterus (dilation) so that the surface of the lining of the uterus can be scraped (curettage).

HYSTERECTOMY is the surgical removal of the uterus.

MYOMECTOMY is the removal of a portion of muscle or muscular tissue.

NULLIPARITY refers to the condition of not having given birth.

SUBMUCOSAL refers to the layer of connective tissue below the mucosa.

TRANSMURAL refers to a condition affecting the entire thickness of the wall of an organ or cavity.

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

VII. DISCLAIMER

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Capital BlueCross'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 BlueCross 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®								
58353	58356	58563						

ICD-10-CM Diagnosis 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
N93.0	Abnormal uterine and vaginal bleeding, unspecified
N93.8	Other specified abnormal uterine and vaginal bleeding
N93.9	Abnormal uterine and vaginal bleeding, unspecified
N95.0	Postmenopausal bleeding

IX. REFERENCES

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1. *Blue Cross Blue Shield Association Technology Evaluation Center. Intrauterine ablation or resection of the endometrium for menorrhagia. 1991.*
2. *Matteson KA, Abed H, Wheeler TL, 2nd, et al. A systematic review comparing hysterectomy with less-invasive treatments for abnormal uterine bleeding. J Minim Invasive Gynecol. Jan-Feb 2012;19(1):13-28. PMID 22078015*
3. *Bhattacharya S, Middleton LJ, Tsourapas A, et al. Hysterectomy, endometrial ablation and Mirena(R) for heavy menstrual bleeding: a systematic review of clinical effectiveness and*

cost-effectiveness analysis. Health Technol Assess. Apr 2011;15(19):iii-xvi, 1-252. PMID 21535970

4. *Zupi E, Centini G, Lazzeri L, et al. Hysteroscopic endometrial resection versus laparoscopic supracervical hysterectomy for abnormal uterine bleeding: long-term follow-up of a randomized trial. J Minim Invasive Gynecol. Jul-Aug 2015;22(5):841-845. PMID 25881883*
5. *Angioni S, Pontis A, Nappi L, et al. Endometrial ablation: first- vs. second-generation techniques. Minerva Ginecol. Apr 2016;68(2):143-153. PMID 26928420*
6. *Lethaby A, Penninx J, Hickey M, et al. Endometrial resection and ablation techniques for heavy menstrual bleeding. Cochrane Database Syst Rev. 2013;8:CD001501. PMID 23990373*
7. *Daniels JP, Middleton LJ, Champaneria R, et al. Second generation endometrial ablation techniques for heavy menstrual bleeding: network meta-analysis. BMJ. 2012;344:e2564. PMID 22529302*
8. *Sambrook A, Elders A, Cooper K. Microwave endometrial ablation versus thermal balloon endometrial ablation (MEATBall): 5-year follow up of a randomised controlled trial. BJOG. May 2014;121(6):747-753. PMID 24506529*
9. *Herman MC, Penninx JP, Mol BW, et al. Ten-year follow-up of a randomised controlled trial comparing bipolar endometrial ablation with balloon ablation for heavy menstrual bleeding. BJOG. Jul 2013;120(8):966-970. PMID 23759085*
10. *Brown J, Blank K. Minimally invasive endometrial ablation device complications and use outside of the manufacturers' instructions. Obstet Gynecol. Oct 2012;120(4):865-870. PMID 22996104*
11. *Dood RL, Gracia CR, Sammel MD, et al. Endometrial cancer after endometrial ablation vs medical management of abnormal uterine bleeding. J Minim Invasive Gynecol. Sep-Oct 2014;21(5):744-752. PMID 24590007*
12. *Laberge P, Leyland N, Murji A, et al. Endometrial ablation in the management of abnormal uterine bleeding. J Obstet Gynaecol Can. Apr 2015;37(4):362-376. PMID 26001691*
13. *Wheeler TL, 2nd, Murphy M, Rogers RG, et al. Clinical practice guideline for abnormal uterine bleeding: hysterectomy versus alternative therapy. J Minim Invasive Gynecol. Jan-Feb 2012;19(1):81-88. PMID 22078016*
14. *Practice Committee of American Society for Reproductive Medicine. Indications and options for endometrial ablation. Fertil Steril. Nov 2008;90(5 Suppl):S236-240. PMID 1900763715.*

    American Society for Reproductive Medicine (ASRM). Fact Sheet: Endometrial Ablation. 2011; https://www.reproductivefacts.org/globalassets/rf/news-and-publications/bookletsfact-sheets/english-fact-sheets-and-info-booklets/endometrial_ablation_factsheet.pdf. Accessed February 8, 2019.
16. *American College of Obstetricians and Gynecologists (ACOG). Management of Acute Abnormal Uterine Bleeding in Non-Pregant, Reproductive- Aged Women. Committee Opinion Number 557. 2013; http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Management-of-Acute-Abnormal-Uterine-Bleeding-in-Nonpregnant-Reproductive-Aged-Women. Accessed February 8, 2019.*

17. *American College of Obstetricians and Gynecologists (ACOG). Endometrial ablation: 2007 ACOG Practice Bulletin No. 81. 2007; http://www.acog.org/Search?Keyword=Endometrial+Ablation.*
18. *National Institute for Health and Clinical Excellence (NICE). Heavy menstrual bleeding. Clinical guideline 44. 2007; https://www.nice.org.uk/guidance/ng88Accessed February 8, 2019.*

X. POLICY HISTORY

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MP 7.013	**CAC 11/24/02**
	CAC 12/2/03
	CAC 5/31/05
	CAC 5/30/06
	CAC 4/24/07 Consensus
	CAC 5/27/08
	CAC 11/25/08
	CAC 11/24/09 Consensus Review
	CAC 04/24/12 Adopt BCBSA. No change to policy statements. Contraindications were moved to description/background. FEP variation added. Added diagnosis codes 9/11/12
	CAC 3/26/13 Consensus review. References updated but no changes to the policy statements. Coding reviewed.
	CAC 1/28/14 Consensus. No change to policy statements. References updated. Added rationale section and policy guidelines.
	CAC 1/27/15 Consensus review. References and rationale updated. No changes to the policy statements. Codes reviewed.
	CAC 1/26/16 Consensus review. References and rationale updated. No change to policy statements**.** Coding reviewed**.**
	Administrative Update 11/10/16 Variation reformatting.
	CAC 3/28/17 Consensus review**.** Changed the term "menorrhagia" to "abnormal uterine bleeding". Intent of policy statement unchanged. Updated rationale and references. Coding Reviewed.
	1/3/18 Consensus review. No changes to the policy statements. Rationale updated, references reviewed.
	10/22/18 Coding review completed. Diagnosis updated.
	02/09/2019 Consensus review. Condensed rational. Updated references.

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