

(40104)

Medical Benefit		Effective Date: 01/01/14	Next Review Date: 09/17
Preauthorization	No	Review Dates: 09/13, 09/14, 09/15, 09/16	

Preauthorization is not required.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Patients/individuals with: <ul style="list-style-type: none"> • With abnormal uterine bleeding and have failed hormonal therapy 	Interventions of interest are: <ul style="list-style-type: none"> • Endometrial ablation 	Comparators of interest are: <ul style="list-style-type: none"> • Hysterectomy • Another endometrial ablation device 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Quality of life • Resource utilization • Treatment-related morbidity

Description

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

Summary of Evidence

For individuals who have abnormal uterine bleeding and have failed hormonal therapy who receive endometrial ablation, the evidence includes randomized controlled trials (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 resulted in greater symptom relief and fewer reoperations than endometrial ablation, but 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 suggested similar benefits with first-generation (hysteroscopic) techniques and second-generation (mainly nonhysteroscopic) techniques. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Policy

Endometrial ablation, with or without hysteroscopic guidance, using a U.S. Food and Drug Administration (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.

Policy Guidelines

Microwave ablation, thermal ablation, and cryoablation may be performed in an office setting.

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

Background

Ablation or destruction of the endometrium is used to treat abnormal uterine bleeding in women who failed standard therapy. It is considered a less invasive alternative to hysterectomy; however, as with hysterectomy, the procedure is not recommended for women who wish to preserve their 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 two 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, FDA approval of endometrial ablation devices includes only women for whom childbearing is complete.

Regulatory Status

Endometrial devices have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for use in premenopausal women with abnormal uterine bleeding due to benign causes in whom childbearing is complete. These devices 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, Natick, MA): 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. It was approved by FDA in 2010.
- The Microwave Endometrial Ablation (MEA) system (Microsulis Medical, Riverview, FL): This system delivers fixed-frequency microwave energy and may be performed in a physician's office and requires use of the hysteroscope. It was approved in 2003.
- 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. It was approved in 1997.
- 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. It was approved in 2001.
- 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. It was approved in 2001.

FDA Product Code: MNB.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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 19007637
15. American Society for Reproductive Medicine (ASRM). Fact Sheet: Endometrial Ablation. 2011; http://www.asrm.org/Endometrial_Ablation_factsheet/. Accessed July, 2016.
16. American College of Obstetricians and Gynecologists (ACOG). Management of Acute Abnormal Uterine Bleeding in Non-Pregnant, 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 July 2016.
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; www.nice.org.uk/nicemedia/pdf/CG44NICEGuideline.pdf. Accessed July, 2016.