Anthem

Clinical UM Guideline

Subject: Endometrial Ablation
Guideline #: CG-SURG-15
Status: Revised

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Description

This document addresses endometrial ablation. Ablation or destruction of the endometrium is used to treat abnormal uterine bleeding. The U.S Food and Drug Administration (FDA) has approved devices for endometrial ablation which include, but may not be limited to: laser therapy, electrical wire loop, rollerball using electric current, thermal ablation using a liquid-filled balloon, microwave, electrode array, or a cryosurgical device.

Clinical Indications

Medically Necessary:

Endometrial ablation is considered **medically necessary** when the individual meets **all** of the following criteria (A through D):

A. Is premenopausal; **and**
B. Has abnormal uterine bleeding; **and**
C. Has **any one** of the following:
    1. Failed prior hormone therapy; **or**
    2. Declined hormone therapy; **or**
    3. Contraindications to hormone therapy;
    and
D. Has no evidence of polyps or other surgically correctable cause of bleeding on sonogram or hysteroscopy.

Endometrial ablation is considered **medically necessary** for treatment of residual menstrual bleeding resulting from medically necessary gender affirming androgen therapy.

Not Medically Necessary:

Endometrial ablation is considered **not medically necessary** when the criteria above have not been met.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
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 Procedure	
0U5B0ZZ	Destruction of endometrium, open approach
0U5B3ZZ	Destruction of endometrium, percutaneous approach
0U5B4ZZ	Destruction of endometrium, percutaneous endoscopic approach
0U5B7ZZ	Destruction of endometrium, via natural or artificial opening
0U5B8ZZ	Destruction of endometrium, via natural or artificial opening endoscopic
0UDB7ZZ	Extraction of endometrium, via natural or artificial opening
0UDB8ZZ	Extraction of endometrium, via natural or artificial opening endoscopic

ICD-10 Diagnosis	
	All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met.

Discussion/General Information

Endometrial ablation was originally performed using rollerball ablation. The FDA approval of subsequent devices, designed explicitly for the purpose of endometrial ablation, was at least partially based on results of randomized trials that compared outcomes from these newer devices with that of rollerball ablation techniques. In general, these studies have suggested equivalent outcomes, in terms of reduction of abnormal uterine bleeding.

There are two groups of techniques typically available for performing endometrial ablation: hysteroscopic procedures and non-hysteroscopic procedures. The following have been used for hysteroscopic endometrial ablation: Nd:YAG laser, resecting loop using electric current, and electrosurgical rollerball instruments. The following have been used for non-hysteroscopic endometrial ablation: thermal balloon devices, cryosurgical devices, radiofrequency devices, and microwave endometrial ablation systems.

Professional Organization Recommendations

Guidance on endometrial ablation has been issued from several U.S. organizations including theAmerican College of Obstetricians and Gynecologists (ACOG).

A 2013 (reaffirmed 2019) ACOG Committee Opinion for the management of acute abnormal uterine bleeding in non-pregnant reproductive-aged women stated:

> Endometrial ablation, although readily available in most centers, should be considered only if other treatments have been ineffective or are contraindicated, and it should be performed only when a woman does not have plans for future childbearing and when the possibility of endometrial or uterine cancer has been reliably ruled out as the cause of the acute abnormal uterine bleeding.

The Society for Gynecologic Surgeons (SGS) systematic review group (Wheeler, 2012) published a clinical practice guideline on treatment of abnormal uterine bleeding. The guideline recommends that for individuals with bleeding caused mainly by ovulatory disorders or endometrial hemostatic disorders, any of the following treatments may be chosen: hysterectomy, endometrial ablation, systemic medical therapies or levonorgestrel-releasing intrauterine systems. In choosing between endometrial ablation and hysterectomy, the authors note that if the preference is for amenorrhea, less pain or avoiding additional therapy, hysterectomy is suggested. If the preference is for lower operative and post-operative procedural risk and a shorter hospital stay, endometrial ablation is recommended.

An Endocrine Society Clinical Practice Guideline (Hembree, 2017) addresses endometrial ablation as a treatment for residual menstrual bleeding after androgen treatment in transgender males.

> Cessation of menses may occur within a few months with testosterone treatment alone, although high doses of testosterone may be required. If uterine bleeding continues, clinicians may consider the addition of a progestational agent or endometrial ablation.

Clinical Outcomes

Brown and Blank (2012) analyzed adverse events associated with endometrial ablation procedures that were reported in the FDA's Manufacturer and User Facility Device Experience (MAUDE) database. A total of 829 adverse events were reported between 2005 and 2011. Nearly two-thirds of the adverse events (540 of 829, 65%) were genital tract or skin burns and 529 of these events (98%) were associated with hydrothermal endometrial ablation. The next 2 most frequent types of adverse events were thermal bowel injury (93 of 820, 11%) and transmural uterine thermal injury (89 of 820, 11%). Of the 182 thermal injuries, 140 (77%) were associated with radiofrequency endometrial ablation. Additionally, 47 cases of sepsis or bacteremia were reported, and 43 of the 47 cases (91%) were associated with radiofrequency endometrial ablation. Four deaths were reported, two associated with radiofrequency ablation and one each associated with thermal balloon ablation and cryoablation. A total of 66 of the 829 events (8%) occurred when endometrial ablation was performed outside of the labeled instructions for use of the procedure. The total number of endometrial ablations performed during this time period was not reported by the authors; therefore, the proportion of procedures with adverse events could not be determined from these data.

In 2014, Dood and colleagues investigated whether endometrial ablation carried an increased risk of endometrial cancer or delay in diagnosis, as compared to medically managed abnormal uterine bleeding. Data were collected from a population-based cohort that included a total of 234,721 individuals with abnormal bleeding, 4776 of whom underwent endometrial ablation. The remaining 229,945 underwent medical management. During a median follow-up time of 4.07 years, 3 participants with a history of endometrial ablation and 601 participants who were treated medically developed endometrial cancer. There was not a statistically significant difference in endometrial cancer rates between groups (age-adjusted hazard ratio [HR] 0.61; 95% confidence interval [CI], 0.20 to 1.89; p=0.17). Additionally, the median time to endometrial cancer diagnosis, (237 days after ablation and 299 days with medical management), did not differ significantly between groups. The authors concluded their study findings that the comparative effectiveness of medical management and endometrial ablation for abnormal uterine bleeding is similar with regard to endometrial cancer outcomes.

In a 2015 study, Laberge and colleagues evaluated the safety and efficacy of the Minerva® Endometrial Ablation System (Minerva Surgical, Redwood City, CA) against objective performance criteria (OPC), that is, an FDA-provided analysis of the success rates of five previously approved endometrial devices (Her Option™ Uterine Cryoablation Therapy™ System [CooperSurgical®, Trumbull, CT], Hydro ThermAblator® Endometrial Ablation System [Boston Scientific Corp., Marlborough, MA], Microsulis Microwave Endometrial Ablation System [Microsulis Medical, Waterloo, UK], NovaSure® Endometrial Ablation system [Hologic, Inc., Marlborough, MA] and the ThermaChoice® Uterine Balloon Therapy System [J &J Ethicon Gynecare, Somerville, NJ]) Using seven clinical locations, the researchers studied 105 menorrhagia subjects with a pictorial blood loss assessment score (PBLAC) > 150, who underwent the Minerva procedure. After 1 year, researchers found a ≤ 75 PBLAC score in 96.2% of subjects and amenorrhea in 69.5% of subjects. No serious adverse events from the device were reported. The Minerva device was found to be superior to the OPC (lower confidence bound 66%, p<0.0001; upper confidence bound 83.5%, p<0.0001).

In an industry-supported, double-arm, RCT multicenter study, Laberge and colleagues (2016) evaluated the safety and effectiveness of the Minerva Endometrial Ablation System compared to rollerball endometrial ablation. Prior to inclusion in the study, participants had to demonstrate a minimum menstrual blood loss of 160 mL by AH laboratory analysis. Using 13 clinical locations, researchers randomly assigned 153 subjects to receive the Minerva procedure (n=102) or the rollerball procedure (n=51). Blood loss was measured at 6 months and 12 months and success was considered ≤ 80 mL. After 1 year, the Minerva group had a 93.1% success rate compared to 80.4% for the rollerball group (p=0.02). Additionally, amenorrhea was achieved for 71.6% of the Minerva group and 49% for the rollerball group (p=0.01). The Minerva group had 5 serious adverse events (4.9%) compared to 3 for the rollerball group (6.0%). The most common adverse event for the Minerva group was abdominal pain and/or bloating (2.9%). Limitations of the study included a lack of subject diversity and short follow-up duration.

Kalampokas and colleagues (2017) reported on a retrospective study that evaluated the long-term incidence of hysterectomy after endometrial resection/endometrial ablation (ERA) for heavy menstrual bleeding. A total of 901 individuals underwent ERA with first- or second-generation methods between 1990 and 1997. The researchers found that 22.9% (206/901) of individuals had a post-ERA hysterectomy; 75.2% of individuals had the hysterectomy within 5 years of ERA. Only 4.4% (9 individuals) had a hysterectomy within 16-25 years of having ERA. The most common reasons for hysterectomy were fibroids, ovarian cysts, and prolapse. The researchers concluded that ERA is a successful long-term treatment for heavy menstrual bleeding as most individuals do not require a hysterectomy within 25 years of ERA.

Soini and colleagues (2017) conducted a retrospective cohort study to determine the risk of cancer and the hysterectomy rate after endometrial ablation for abnormal uterine bleeding. The researchers collected data on 5484 female individuals between 1997 and 2014 who had an endometrial ablation and who had never been diagnosed with cancer. They compared the cohort to a control group of 26,938 females. A total of 154 individuals in the endometrial ablation cohort were diagnosed with cancer during 39,892 women-years at risk. The standard incidence ratio for all cancers was 0.96 (95% CI, 0.82 to 1.13). The standard incidence ratio for

endometrial cancer was 0.56 (95% CI, 0.12 to 1.64) and for breast cancer was 0.86 (95% CI, 0.67 to 1.09). A total of 1086 individuals (19.8%) had hysterectomies post-endometrial ablation, compared to 2521 (9.4%) in the control group. The adjusted hazard risk for hysterectomy in the endometrial ablation cohort was 3.63 (95% CI, 3.32 to 3.96; p<0.001). The authors found that endometrial ablation was not associated with an increased risk for endometrial or breast cancer, and endometrial ablation is an effective alternative to hysterectomy in selected women with heavy menstrual bleeding.

In a monocentric, longitudinal cohort study, Philip and colleagues (2018) evaluated the efficacy of the NovaSure Endometrial Ablation system in individuals with adenomyosis. A total of 43 individuals with a median age of 46.7 years were included. The NovaSure procedure was performed as outpatient surgery under general or locoregional anesthesia, with a hysteroscopy performed at the end of the procedure to verify the quality of destruction. A validated questionnaire on gynecological symptoms (dysmenorrhea and abnormal uterine bleeding) was sent to each participant preoperatively and followed up with a phone call at 6 months and 3 years. At 3 years, there was a significant reduction in abnormal uterine bleeding in 29 subjects (–67.4%; 95% CI, 53.3 to 81.6; p<0.00001) and amenorrhea in 16 subjects (37.2%; 95% CI, 22.6 to 51.8, p<0.00001). However, 11 subjects experienced significant recurrence of abnormal uterine bleeding between 6 months and 3 years. No major complications were reported, and the overall satisfaction rate was 92%. The researchers concluded that NovaSure is effective in treating adenomyosis, but efficacy may decrease over time in some individuals.

Levie and colleagues (2019) performed a prospective, multicenter study to evaluate the safety and effectiveness of the AEGEA Vapor System™ (currently known as the Mara™ Water Vapor Ablation System [CooperSurgical®, Trumbull, CT]) for the treatment of heavy menstrual bleeding. A minimum of two imaging modalities were used to verify eligibility, and validated questionnaires were given at baseline and at 3-, 6- and 12-months post-treatment. The intention-to-treat group included 155 subjects, and the primary endpoint was the reduction of menstrual blood loss in a PBLAC score of ≤ 75. At 12 months post-procedure, the primary endpoint was achieved in 78.7% of subjects. At total of 90.8% of subjects were satisfied or very satisfied with the procedure. No serious adverse events related to the procedure were reported. The most common adverse event was uterine cramping, which decreased with time.

In a 2019 Cochrane review, Bofill and colleagues compared the efficacy, safety and acceptability of endometrial destruction techniques (first, second and third generation) to reduce heavy menstrual bleeding in premenopausal women. The researchers included 28 studies (n=4287), and the quality of evidence was deemed very low to moderate. They found equivalent efficacy between first-generation techniques (endometrial laser ablation, transcervical resection of the endometrium, and rollerball endometrial ablation) and second-generation techniques (thermal balloon endometrial ablation, microwave endometrial ablation, hydrothermal ablation, bipolar radiofrequency endometrial ablation, and endometrial cryotherapy) for heavy menstrual bleeding. However, second-generation techniques were associated with a shorter procedure time and were more often performed under local anesthetics. The evidence was insufficient to show superiority of specific second-generation techniques or for the safety and efficacy of third-generation techniques compared to first- and second-generation techniques.

In 2021, Curlin and colleagues conducted a prospective, single-arm, non-randomized study to evaluate the safety and effectiveness of the Cerene® Cryotherapy Device (Channel Medsystems, Inc. Emeryville, CA). The study consisted of 242 subjects who were premenopausal with heavy menstrual bleeding due to benign causes for whom childbearing was complete. Follow-up visits were performed at 1-3 days postoperative, 2-4 weeks postoperative, and at 3-, 6-, and 12-months (±4 weeks) postoperative. The outcomes measured were PBLAC score, the Menorrhagia Impact Questionnaire (MIQ), Premenstrual Symptoms Impact Survey (PMSIS), and uterine cavity access. Uterine cavity access was assessed via hysteroscopic evaluation at 12 months post-procedure. A total of 230 subjects (95%) were available for data analysis at the 12-month follow-up. The primary safety end points were serious device-related adverse events and serious adverse events at 12 months. There were no serious device-related adverse events. There were seven serious adverse events that occurred in 6 subjects. These events were reviewed by a Clinical Events Committee and were not determined to be device-related or procedure-related. A total of 4 subjects exited the study due to a medical or surgical intervention for menstrual bleeding after treatment with the Cerene Cryotherapy Device, and no subjects exited the study due to an adverse event. The MIQ results showed statistically significant improvement in all metrics (p<0.001) at 12 months post-procedure. The PMSIS results also showed statistically significant improvement (p<0.001) indicating reduction in premenstrual syndrome and premenstrual dysphoric disorder symptoms. At the month 12 follow-up appointment, over 90% of subjects reported they had a normal or lighter than normal period or that they no longer got their period. At the 12-month appointment, the uterine cavity was evaluated in 220 subjects and could be fully visualized in 204 (93%) subjects. These results appear to support the safety and efficacy of the Cerene device.

A continuation study was performed by Curlin and reported in 2022 to examine the long-term outcomes of treatment with the Cerene Cryotherapy Device. This study conducted long-term follow-up visits for the original subjects at 24- and 36-months post-procedure. At 24 months post-procedure, 210 subjects (87%) were available for follow-up and at 36 months post-procedure, 201 subjects (83%) were available for follow-up. The subjects' menstrual bleeding remained stable throughout the long-term follow-up. The statistically significant improvements in the MIQ and PMSIS scores were sustained for 3 years after treatment. There were 52 gynecologic adverse events reported between 12- and 36-months post-procedure, including 1 incidence of postcoital bleeding determined to be procedure-related, 12 hysterectomies, and 5 pregnancies. Of the pregnancies, 1 pregnancy was ectopic, 1 pregnancy was terminated, and 3 pregnancies resulted in preterm (35-36 weeks) cesarean births. A total of 2 subjects underwent endometrial ablations with different devices. A total of 10 subjects who underwent hysterectomies elected to have hysterectomies despite a decrease in post-ablation menstrual bleeding recorded at the 12-month follow-up visit. The authors concluded that the risks associated with the Cerene Cryotherapy Device and procedure are low and the positive effects after treatment are sustained through 36 months post-procedure.

Some of the above studies involve the use of the ThermaChoice Uterine Balloon Therapy System and the Microwave Endometrial Ablation System. It should be noted that these devices are no longer available in the United States.

References

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Government Agency, Medical Society, and Other Authoritative Publications:

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Genesys HTA™ System

Her Option Uterine Cryoablation Therapy System
Hydro ThermAblator System
Intrauterine Ablation
Laser Ablation of the Endometrium
Mara Water Vapor Ablation System
Minerva Endometrial Ablation System
Minitouch System
NovaSure Impedance Controlled Endometrial Ablation System
Rollerball Ablation of the Endometrium

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Reformatted Clinical Indications section. Revised statement regarding residual menstrual bleeding. Revised Discussion/General Information, References, and Index sections.
Reviewed	08/11/2022	MPTAC review. References section updated.
Revised	08/12/2021	MPTAC review. The NMN statement has been clarified to include all other conditions not listed as MN. Updated Coding and References sections.
Revised	08/13/2020	MPTAC review. The language, "…using an FDA approved device" was removed from the MN statements. The Discussion, References and Index sections were updated. Reformatted Coding section.
Reviewed	08/22/2019	MPTAC review. Discussion and References sections updated.
Revised	09/13/2018	MPTAC review. MN criteria clarified in Clinical Indications section. Discussion, References, and Index sections updated.
Reviewed	11/02/2017	MPTAC review. Discussion, References and Index sections updated. The document header wording updated from "Current Effective Date" to "Publish Date."
Revised	11/03/2016	MPTAC review. Medically Necessary criteria added for residual menstrual bleeding after androgen treatment in a female to male transgender person. Description, Discussion and References sections updated.
Reviewed	11/05/2015	MPTAC review. Discussion and References sections updated. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Discussion and References sections updated.
Reviewed	11/14/2013	MPTAC review. Discussion and References sections updated.
Reviewed	11/08/2012	MPTAC review. Discussion and References sections updated.
Reviewed	11/17/2011	MPTAC review. Coding, Discussion and References sections updated.
Reviewed	11/18/2010	MPTAC review. Description, Discussion, References, and Index updated.
Reviewed	11/19/2009	MPTAC review. Removed place of service. References updated.
Reviewed	11/20/2008	MPTAC review. References updated.
Reviewed	11/29/2007	MPTAC review. References updated.
Reviewed	12/07/2006	MPTAC review. References and discussion updated.
Revised	12/01/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.			None
Anthem BCBS			None
WellPoint Health Networks, Inc.	06/24/2004	3.09.06	Endometrial Ablation
	06/24/2004	Clinical Guideline	Endometrial Ablation
