MEDICAL POLICY

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Medical Policy Title	**Endometrial Ablation**
Policy Number	**4.01.01**
Current Effective Date	February 20, 2025
Next Review Date	February 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Endometrial ablation is considered **medically appropriate** when **ALL** of the following criteria are met:

- A. The patient has experienced menorrhagia/menometrorrhagia ("abnormal uterine bleed") for greater than three (3) menstrual cycles;
- B. The patient has been treated with and has failed to respond to hormone therapy (contraceptives, progestin) for three consecutive menstrual cycles, or there is a contraindication to hormone therapy;
- C. The symptoms are severe enough to warrant surgical intervention (e.g., hysterectomy);
- D. The symptoms interfere with activities of daily living (ADLs) or results in anemia that is unresponsive to treatment;
- E. The results of a Pap smear within the past 12 months are within normal limits;
- F. Endometrium is normal within the last six (6) to 12 months, as evidenced by **ONE** of the following:
  1. Hysteroscopy with dilation and curettage (D & C);
  2. Transvaginal ultrasound; or
  3. Sonohysterogram;
- G. The patient is not pregnant, and there is no desire for future pregnancy; **and**
- H. The device is approved by the U.S. Food and Drug Administration (FDA).

II. Endometrial ablation is considered **medically appropriate** to stop residual menstrual bleeding for those members with a diagnosis of gender dysphoria and meet criteria for a gonadectomy after hormone therapy, unless hormone therapy is medically contraindicated, or the patient identifies as nonbinary and/or elects not to pursue hormone therapy. (Refer to Corporate Medical Policy #7.01.84 Gender Affirming Surgery and Treatments for Commercial and Medicare Advantage Members and #7.01.105 Gender Reassignment/Gender Affirming Surgery and Treatments for Medicaid Managed Care Plan and Health and Recovery Plan Members).

III. Contraindications:

- A. Contraindications for endometrial ablation include:

1. Known or suspected endometrial carcinoma or pre-malignant change of the endometrium (e.g., pre-cancerous endometrial abnormalities);
2. Enlarged uterus (e.g., greater than 10 cm in length or comparable to 12 or more weeks of gestation;
3. Any anatomic or pathologic condition in which weakness of the myometrium could exist (e.g., history of previous classical cesarean section(s), transmural myomectomy, history of previous endometrial ablation procedure or endometrial resection);
4. The patient is on medications that could thin the myometrial muscles, such as long-term steroid use (except for inhaler or nasal therapy for asthma);
5. Uterine prolapse;
6. Submucosal myomas;
7. Active genital or urinary tract infection (e.g., cervicitis, vaginitis, endometritis, salpingitis, or cystitis);
8. Pregnancy or desire to become pregnant in the future;
9. Intrauterine device (IUD) in place; **or**
10. Active pelvic inflammatory disease.

B. Thermal balloon endometrial ablation is contraindicated in patients who have a history of latex allergy or who have demonstrated sensitivity to latex material.

C. Microwave ablation is contraindicated in patients who have **ALL** of the following:

1. Essure contraceptive micro-inserts in place;
2. Myometrial thickness less than 10 mm; **and**
3. Uterine sounding length less than 6 cm.

IV. Other methods of endometrial ablation (e.g., chemoablation, photodynamic endometrial ablation) are considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

#7.01.84 Gender Affirming Surgery and Treatments for Commercial and Medicare Advantage Member

#7.01.105 Gender Reassignment/Gender Affirming Surgery and Treatments for Medicaid Managed Care Plan (MMCP) and Health and Recovery Plan (HARP) Members

#11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Individuals with abnormal uterine bleeding (menorrhagia) should be screened for possible reasons for the condition, and, if results appear positive, further hematologic work-up should be performed. Examples of "red flags" indicating that further work-up should be completed for a patient include:

   A. a relative who has an inherited bleeding disorder,

   B. prolonged bleeding from small wounds or following dental procedures,

   C. heavy and prolonged bleeding following surgical procedures,

   D. easy bruising,

   E. spontaneous nosebleeds,

   F. blood in the stool or bleeding ulcer requiring urgent medical care,

   G. anemia requiring transfusion,

   H. heavy menses resulting in anemia,

   I. passing of large clots with menses or soaking more than one pad hourly, or

   J. heavy bleeding during or following childbirth.

DESCRIPTION

Endometrial ablation is a method of treating abnormal uterine bleed through destruction of the endometrial lining. Endometrial ablation is an alternative to hysterectomy for women with abnormal uterine bleed from benign causes, who have found medical therapy ineffective or contraindicated.

In addition, in order to exclude other conditions, thyroid stimulating hormone (TSH) and human chorionic gonadotropin (HCG) testing are often performed prior to endometrial ablation, to confirm that these are within normal limits.

Several devices have been developed that utilize various modalities to accomplish endometrial ablation, including, but not limited to laser therapy, resecting loop rollerball using electric current, thermal ablation using a liquid-filled balloon, microwave, electrode array or cryosurgical device.

Thermal fluid-filled balloon, cryosurgical endometrial ablation, instillation of heated saline, and radiofrequency ablation can be performed without general anesthesia in a physician's office and do not require hysteroscopic guidance. Microwave ablation with the Microwave Endometrial Ablation System (MEA) may also be performed in a physician's office but does require use of the hysteroscope.

Methods that utilize direct hysteroscopic visualization include, but are not limited to:

I. Hydrothermal (e.g., Hydro ThermAblator, Genesys HTA System);

II. Neodymium-yttrium aluminum garnet (Nd-YAG) laser;

III. Resectoscope/resecting loop; and

IV. Rollerball.

Methods that do not utilize direct hysteroscopic visualization include, but are not limited to:

I. Cryoablation (e.g., Her Option);

II. Laser interstitial hyperthermy;

III. Microwave (e.g., MEA System, Minitouch 3.8);

IV. Radiofrequency (e.g., NovaSure); and

V. Thermal balloon (e.g., ThermaChoice).

SUPPORTIVE LITERATURE

Several first-generation hysteroscopically aided and second-generation non-hysteroscopically aided devices have been approved by the FDA as a safe and effective alternative to hysterectomy in premenopausal patients with heavy menstrual bleeding due to benign causes for whom childbearing is complete. In 2021, the FDA published guidelines listing contraindications for endometrial ablation which include, but are not limited to, pregnancy, previous endometrial ablation or endometrial resection, previous cesarean section, or infection at the time of treatment.

Several studies have been published that address the various techniques of endometrial ablation as an alternative to hysterectomy for the treatment of abnormal uterine bleed (menorrhagia). In summary, the studies show that endometrial ablation has become the surgical treatment of choice for dysfunctional uterine bleeding when hysterectomy is not desired. In the short-term, hysteroscopic and non-hysteroscopic endometrial ablation techniques have been proven to be safe and effective in reducing excessive menstrual bleeding, when specific criteria are met.

In a 2017 article by Klebanoff et al., the authors sought to determine the incidence and predictors of failed standard of care associated with second-generation endometrial ablation. "Failed" is defined as need for surgical re-intervention. The retrospective cohort study was conducted on subjects undergoing second-generation endometrial ablation between October 2003 and March 2016. Second-generation devices utilized during the study period included the radiofrequency ablation device (RFA), hydrothermal ablation device (HTA), and uterine balloon ablation system (UBA). Of the 5,936 women participating in the study, the surgical re-intervention rate was found to be 15.6%. Age, ethnicity, and radiofrequency ablation were significant risk factors for failed endometrial ablation, and menorrhagia was the leading indication for re-intervention.

In 2024, Deehan C et al. conducted a systematic review and meta-analysis to evaluate the clinical efficacy, safety, and cost-effectiveness of endometrial ablation or resection (E:A/R) compared to hysterectomy for the treatment of heavy menstrual bleeding. Twelve randomized controlled trials (RCTs) with 2,028 women (hystectomy: n=977 vs. n=1,051) were included in the analysis. Authors concluded that (E:A/R) offers alternatives to hysterectomy. Both procedures have high effectiveness rates, impact on QoL, and safety. Hysterectomy is associated with greater improvement in the bleeding symptoms, both subjectively and objectively, and higher patient-satisfaction up-to two

years. However, it has longer operating times, longer recovery periods, and higher rates of postoperative complications. On the other hand, (E:A/R) has lower initial cost than hysterectomy but the need for further surgery is common; therefore, there is no difference in the costs in the long-follow-up. These results should be interpreted with caution due to the heterogeneity of the trials included. An adequately powered and carefully-planned non-inferiority RCT comparing between the different methods of (E:A/R) to those of hysterectomy with long term follow-up periods is required to inform the surgeons, patients, and decision makers with the most clinically-effective and cost-effective surgical treatment for heavy menstrual bleeding.

Marchand G et al. (2024) conducted a network meta-analysis to determine the efficacy of first- and second-generation ablation techniques compared with medical treatment, invasive surgery and different modalities of the endometrial ablation (EA) techniques themselves. 49 RCTs that compared 8,038 premenopausal women with abnormal uterine bleeding (AUB) receiving the intervention of second-generation EA techniques were included in the study. The uterine balloon ablation had significantly higher amenorrhoea rates than other techniques in both short (hydrothermal ablation (risk ratio (RR)=0.51, 95%CI 0.37; 0.72), microwave ablation (RR=0.43, 95%CI 0.31; 0.59), first-generation techniques (RR=0.44, 95%CI 0.33; 0.59), endometrial laser intrauterine therapy (RR=0.18, 95%CI 0.10; 0.32) and bipolar radio frequency treatments (RR=0.22, 95%CI 0.15; 0.31)) and long-term follow-up (microwave ablation (RR=0.11, 95%CI 0.01; 0.86), bipolar radio frequency ablation (RR=0.12, 95%CI 0.02; 0.90), first generation (RR=0.12, 95%CI 0.02; 0.90) and endometrial laser intrauterine thermal therapy (RR=0.04, 95%CI 0.01; 0.36)). When calculating efficacy based only on calculated bleeding scores, the highest scores were achieved by cryoablation systems (p-score=0.98). Authors concluded that most second-generation EA systems were superior to first-generation systems but that there is no evidence at this time that any one of the examined second-generation systems is clearly superior to the others.

PROFESSIONAL GUIDELINE(S)

The American College of Obstetricians and Gynecologists (ACOG) 2008 practice bulletin addressing endometrial ablation considered the following recommendations and conclusions to be based on good and consistent scientific evidence (Level A):

1. For women with normal endometrial cavities, resectoscopic endometrial ablation and nonresectoscopic endometrial ablation systems appear to be equivalent with respect to successful reduction in menstrual flow and patient satisfaction at 1 year following index surgery.
2. Resectoscopic endometrial ablation is associated with a high degree of patient satisfaction but not as high as hysterectomy.

The World Professional Association for Transgender Health (WPATH) is a 501(c)(3) non-profit, interdisciplinary professional and educational organization that promotes evidence-based care, education, research, advocacy, public policy and respect in transgender health. WPATH publishes documents supporting medical necessary and appropriate care for transgender or transition-related treatments. These are known as the Standards of Care (SOC). WPATHs SOC states that menstrual suppression may impact gender dysphoria and can function as an initial step allowing for "…further

exploration of gender-related goals of care, prioritization of other mental health care, or both, especially for those who experience worsening gender dysphoria from unwanted uterine bleeding." Testosterone therapy typically causes cessation of menstruation within six months, but is impacted by the dose, route, frequency, body habitus, and other co-occurring medical conditions that may exist. Residual bleeding can occur after hormone therapy. Endometrial ablation can be offered for those that decline hysterectomy and/or hormone therapy (e.g., nonbinary) or in situations where those considerations may be contraindicated. The American College of Obstetricians and Gynecologists agrees with WPATHs statement regarding the impact of menstrual suppression to decrease gender dysphoria associated with menses, public restroom use for menstrual hygiene and its impact on individuals' attitudes and safety.

REGULATORY STATUS

In 1997, the U.S. Food and Drug Administration (FDA) approved ThermaChoice, the first non-hysteroscopic ablation device to treat excessive uterine bleeding (menorrhagia) due to benign (non-cancerous) causes. The ThermaChoice Uterine Balloon Therapy System (Gynecare) consists of a balloon that is inserted through the neck of the cervix and into the uterus.

In 2001, the FDA approved the Her Option Uterine Cryoblation Therapy System (CryoGen Inc.) uses a cryoprobe capable of producing temperatures down to minus 148˚F (minus 100˚C) at the tip. This extreme cold is applied to the tissue for 10 mins to freeze and destroy the uterine lining. Ultrasound is used to guide and monitor the procedure.

Also, in 2001, the FDA approved the NovaSure-Endometrial Alation System, which utilizes a metallized mesh electrode array that is introduced into the uterine cavity, applying bipolar electrical energy that creates heat to ablate the endometrium.

The Genesys HTA – Hydro-Thermal Ablation System, FDA approved in 2010, is a hysteroscopic thermal ablation device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia due to benign causes for whom childbearing is complete.

In 2003, the FDA approved the Microsulis Microwave Endometrial Ablation (MEA) System. The MEA system is a surgical device that uses microwave energy to treat excessive menstrual bleeding by destroying tissue lining the uterus (womb). Endometrial ablation is a minimally invasive surgery that can be a viable alternative to hysterectomy.

In 2023, the Minitouch 3.8 Era System (Minitouch System) received the Premarket approval (PMA) from the FDA. This device is intended for ablation of the endometrial lining of the uterus for the treatment of menorrhagia caused by non-malignant conditions in pre-menopausal women who do not wish to become pregnant in the future.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational

- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	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 (e.g., endometrial resection, electrosurgical ablation, thermoablation)

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HCPCS Codes

Code	Description
No specific code (s)	

ICD10 Codes

Medically Appropriate codes for when criteria are met under Policy Statement I:

Code	Description
F64.0-F64.9	Gender identity disorders (code range)
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
N93.8	Other specified abnormal uterine and vaginal bleeding
N93.9	Abnormal uterine and vaginal bleeding, unspecified
Z87.890	Personal history of sex reassignment

Contraindicated conditions under Policy Statement III (not an all-inclusive list of codes):

Code	Description
D07.0	Carcinoma in situ of endometrium
D25.0	Submucous leiomyoma of uterus
N81.2	Incomplete uterovaginal prolapse

Code	Description
N81.3	Complete uterovaginal prolapse
N81.4	Uterovaginal prolapse, unspecified
N85.00	Endometrial hyperplasia, unspecified
N85.02	Endometrial intraepithelial neoplasia [EIN]
N85.2	Hypertrophy of uterus

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based on our review, endometrial ablation is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

09/22/00, 05/18/05, 03/16/06, 03/15/07, 03/20/08, 03/19/09, 03/18/10, 04/21/11, 04/19/12, 03/21/13, 03/20/14, 03/19/15, 03/17/16, 03/16/17, 02/15/18, 02/21/19, 02/20/20, 02/18/21, 02/17/22, 02/16/23, 02/22/24, 02/20/25

Date	Summary of Changes
02/20/25	• Annual review, policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.

11/19/99	• Original effective date