MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**ENDOMETRIAL ABLATION**
Policy Number	**4.01.01**
Category	**Technology Assessment**
Effective Date	**10/18/01**
Revised Date	**10/18/01, 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**
Archived Date	**(12/20/01-05/18/05), 02/21/19**
Edited Date	**02/20/20**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare 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.*

POLICY STATEMENT

I. Based upon our criteria and review of the peer-reviewed literature, endometrial ablation, with devices approved by the U.S. Food and Drug Administration (FDA), is considered **medically appropriate** and may be a treatment option for menorrhagia/menometrorrhagia ("abnormal uterine bleed") in women for whom child bearing is complete and symptoms are severe enough to warrant surgical intervention (e.g., hysterectomy).
ALL the following criteria must be met:
   A. Abnormal uterine bleed for greater than three (3) menstrual cycles that interferes with activities of daily living (ADLs) or results in anemia unresponsive to treatment;
   B. Pap smear in the past 12 months within normal limits;
   C. Treatment with and failure to respond to hormone therapy (contraceptives, progestin) for 3 consecutive menstrual cycles or contraindication to hormone therapy; and
   D. Endometrium normal within the last 6-12 months by one of the following:
      1. Hysterectomy with dilation and curettage (D & C); or
      2. Transvaginal ultrasound; or
      3. Sonohysterogram

II. 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 weeks gestation or more
      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);
      4. Uterine prolapse;
      5. Submucosal myomas;
      6. Active genital or urinary tract infection (e.g., cervicitis, vaginitis, endometritis, salpingitis, or cystitis);
      7. Pregnancy or desire to become pregnant in the future;
      8. Intrauterine device (IUD) in place; or
      9. 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.

III. Based upon our criteria and review of the peer-reviewed literature, all other methods of endometrial ablation (e.g., chemoablation, photodynamic endometrial ablation) have not been medically proven to be effective and are considered **investigational**.

POLICY GUIDELINES

I. Women with abnormal uterine bleed (menorrhagia) should be screened for possible reasons of the condition, and if results appear positive, further hematologic work-up should be performed. Examples of "red flags" indicating further work-up should be completed for a patient include a relative who has an inherited bleeding disorder, prolonged bleeding from small wounds or following dental procedures, heavy and prolonged bleeding following surgical procedures, easy bruising, spontaneous nosebleeds, blood in the stool or bleeding ulcer requiring urgent medical care, anemia requiring transfusion, heavy menses resulting in anemia, passing of large clots with menses or soaking more than one pad hourly, or heavy bleeding during or following childbirth.

II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the FDA may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

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 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 a 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 MEA System 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),
IV. Radiofrequency (e.g. NovaSure®), and
V. Thermal balloon (e.g. ThermaChoice®).

RATIONALE

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 select patients.

Several studies have been published addressing 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.

The American College of Obstetricians and Gynecologists (ACOG) practice bulletin addressing endometrial ablation has stated "the following recommendations and conclusions are based on good and consistent scientific evidence (Level A):

I. 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.
II. Resectoscopic endometrial ablation is associated with a high degree of patient satisfaction but not as high as hysterectomy."

In the 2017 article (Klebanoff, et. al.), the authors sought to determine the incidence and predictors of failed standard of care, 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.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

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 (eg, endometrial resection, electrosurgical ablation, thermoablation)

HCPCS Codes

Code	Description
No specific code(s)	

ICD10 Codes

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

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
N93.8	Other specified abnormal uterine and vaginal bleeding
N93.9	Abnormal uterine and vaginal bleeding, unspecified

Contraindicated conditions Policy Statement II (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
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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*Key Article

KEY WORDS

Endometrial ablation, Her Option™, Hydro ThermAblator®, MEA System, Novasure™, Resectoscope, Resecting loop, Rollerball, ThermaChoice®, Thermal balloon therapy.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, endometrial ablation is not addressed in a National or Local Medicare coverage determination or policy.