Clinical Policy Title: Endometrial ablation

Effective Date: April 1, 2015
Initial Review Date: November 15, 2014
Most Recent Review Date: November 16, 2016
Next Review Date: November 2017

Policy contains:
- Endometrial ablation (EA).
- Menorrhagia.

ABOUT THIS POLICY: AmeriHealth Caritas Northeast has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Northeast’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas Northeast when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Northeast’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Northeast’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Northeast will update its clinical policies as necessary. AmeriHealth Caritas Northeast’s clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas Northeast considers the use of endometrial ablation (EA) to be clinically proven and, therefore, medically necessary when the following criteria are met:

- A history of menorrhagia (heavy menstrual bleeding [HMB]) as evidenced by:
  - Profuse bleeding or repetitive periods longer than eight days.
  - Anemia due to acute or chronic blood loss.
- Unresponsiveness to at least three months of hormonal therapy (if not contraindicated).
- Review of endometrial histopathological and endometrial sampling results before EA (i.e., EA is not appropriate in women with endometrial hyperplasia or cancer).
- Diagnostic evaluation of the endometrium within the past 12 months by endometrial biopsy or dilatation and curettage (D and C) to show no evidence of remediable pathology.
- Endometrial and cervical pre-cancers or cancers have been ruled out.

AmeriHealth Caritas Northeast considers the following methods for performing EA to be clinically proven and, therefore, medically necessary (definitions of each method can be found in the glossary):

- Radiofrequency.
- Freezing (cryoablation).
- Heated fluid (hydrothermal).
- Heated balloon (thermal).
- Microwave energy.
- Electrosurgery.
- Laser.

Limitations:

- All other techniques used for EA are not medically necessary.
- EA is an ambulatory procedure unless the patient requires hospitalization for other indications.
- EA should not be done in women past menopause.
- EA is not recommended for women with certain medical conditions, including the following:
  - Other disorders of the uterus or endometrium or structural abnormalities that require surgery.
  - Endometrial hyperplasia.
  - Cancer of the uterus.
  - Recent pregnancy.
  - Current or recent infection of the uterus.
- Contraindications to EA include:
  - Known or suspected endometrial carcinoma or pre-malignant change of the endometrium (e.g., unresolved adenomatous hyperplasia).
  - Presence of enlarged uterus (e.g., greater than 10 cm in length or comparable to 12 weeks’ gestation or more).
  - Any anatomic or pathologic condition in which weakness of the myometrium could exist (e.g., history of previous classical cesarean sections or transmural myomectomy).
  - Uterine prolapse.
  - Submucosal myomas.
  - Active genital or urinary tract infection (e.g., cervicitis, vaginitis, endometritis, salpingitis, or cystitis).
  - Pregnancy or desire to become pregnant in the future.
  - Presence of intrauterine device (IUD).
  - Active pelvic inflammatory disease.

Alternative covered services:

- Conservative medical treatment as prescribed by treating specialist.
- Analgesics, antibiotics, antiprostaglandins, oral contraceptives, and gonadotropin-releasing hormone (Gn-RH) agonists (e.g., danazol).
- Non-steroidal anti-inflammatory drugs (NSAIDs).
• D and C.
• Endometrial biopsy.
• Hysterectomy for members who are candidates, based on the assessments and treatment failures of their treating providers.

Background

HMB, also known as menorrhagia, is defined as excessive menstrual blood loss that interferes with a woman's physical, social, emotional, or material quality of life (National Institute for Health and Care Excellence [NICE], 2016). HMB is a very common problem and can occur alone or in combination with other symptoms. The American Congress of Obstetricians and Gynecologists (ACOG; 2016) considers any of the following to be HMB:

• Bleeding that lasts more than seven days.
• Bleeding that soaks through one or more tampons or pads every hour for several hours in a row.
• Needing to wear more than one pad at a time to control menstrual flow.
• Needing to change pads or tampons during the night.
• Menstrual flow with blood clots that are quarter-sized or larger.

Medical treatment consists of anti-fibrinolytic tranexamic acid, NSAIDs, the combined contraception pill, progestogen, danazol, or GnRH agonists (NICE, 2016; ACOG, 2016). In women who refuse or fail medical management, D and C is an appropriate diagnostic step, as the addition of hysteroscopy will aid in the treatment of endometrial polyps or the performance of directed uterine biopsies. As a rule, D and C has not been shown to be very efficacious with dysfunctional uterine bleeding (DUB) and should not be used as a therapeutic treatment (NICE, 2016).

Abdominal or vaginal hysterectomy may be necessary in patients who have failed or declined hormonal therapy, have symptomatic anemia, and who experience a disruption in their quality of life from persistent, unscheduled bleeding (NICE, 2016; ACOG, 2016). Hysterectomy is the only treatment for HMB that guarantees complete cessation of menstrual periods, but it is associated with peri- and post-operative complications and long surgical times, hospital stays, and recovery times (Bongers, 2004). Minimally invasive procedures that destroy the endometrium are alternatives to hysterectomy.

EA:

First-generation EA techniques require direct visualisation of the endometrium using a hysteroscope. The most widely used first-generation EA techniques are transcervical resection of the endometrium (TCRE) using a loop diathermy electrode and rollerball ablation (RB) (Bongers, 2004).
Second-generation EA techniques are simpler and faster than first-generation EA techniques and hysterectomy (Bongers, 2004; ACOG, 2013). These techniques are less operator dependent, but they rely heavily on the devices themselves to ensure safety and efficacy. They do not require direct visualisation of the uterine cavity and can be carried out under either local or general anaesthesia. Second-generation EA techniques include fluid-filled thermal balloon EA (TBEA), radiofrequency (thermoregulated) balloon EA, hydrothermal EA, 3-D bipolar radiofrequency EA, diode laser hyperthermy, cryoablation, and photodynamic therapy. Microwave EA (MEA) may also be performed in a physician’s office but requires use of the hysteroscope (ACOG, 2013).

In 1997, the U.S. Food and Drug Administration (FDA) approved the ThermaChoice® Uterine Balloon Therapy System (Gynecare, Somerville, NJ), the first non-hysteroscopic ablation device to treat excessive uterine bleeding (menorrhagia) due to benign (non-cancerous) causes (FDA, 2016). ThermaChoice consists of a balloon that is inserted through the neck of the cervix and into the uterus. Through a catheter connected to a controller console, the balloon is inflated with fluid and heated to 188° F (87° C) for eight minutes to destroy the uterine lining.

In 2001, the FDA approved similar devices to be used only in women who have not yet reached menopause and whose childbearing is complete. The Hydro ThermAblator® (BEI Medical Systems Inc., Teterboro, NJ) delivers heated saline solution into the uterus (FDA, 2016). The heated saline solution is delivered using hysteroscopic guidance to destroy the uterine lining in about 10 minutes. The HerOption® Uterine Cryoblation Therapy System (CryoGen Inc., San Diego, CA) uses an ultrasound-guided 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 minutes to freeze and destroy the uterine lining. Since then, several devices have been approved for commercial use (FDA, 2016).

Searches

AmeriHealth Caritas Northeast searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on October 17, 2016. Search terms were: "Menorrhagia" [MeSH] and "Endometrial Ablation Techniques" [MeSH], and free text terms “menorrhagia,” “endometrial ablation,” and “heavy bleeding.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic
reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

EA techniques offer a less invasive surgical alternative to hysterectomy. While the rapid development of a number of new methods of endometrial destruction has made systematic comparisons between individual methods and first-generation techniques difficult, the existing evidence suggests success, satisfaction rates, and complication profiles of newer techniques of ablation compare favorably with hysteroscopic techniques (Lethaby, 2013; Daniels, 2012). The most frequently used second-generation EA techniques are fluid-filled TBEA and MEA.

The success rates of hysterectomy-based EA depend heavily on the skills and experience of the operator. Possible perioperative adverse effects with first-generation EA techniques include electrosurgical burns, uterine perforation, hemorrhage, infection, and fluid overload, which may cause congestive cardiac failure, hypertension, hemolysis, coma, and death. The Minimally Invasive Surgical Techniques-Laser, EndoThermal or EndoResection (MISTLETOE) study (of more than 10,000 women) in England and Wales and the Scottish Audit of Hysteroscopic Surgery study (SAHS) (of about 1,000 women) reported mortality rates of 0.26 deaths per 1,000 procedures (Overton, 1997; SAHS, 1997).

Most of the newer techniques are technically easier to perform than traditional hysteroscopy-based methods. Although equipment failures for MEA and TBEA were reported in early usage, the devices have been improved, and these failures are now much less common. Adverse events with second-generation EA techniques include uterine infection, perforation, visceral burn, bleeding, hematometra, laceration, intra-abdominal injury, and cyclical pain. Women who do not respond to initial EA may require further ablations or, eventually, hysterectomy.

Evidence-based guidelines agree that for premenopausal patients who choose EAs, childbearing is complete, a form of contraception is required, underlying uterine pathology is ruled out (i.e., hyperplasia or malignancy), expectations are clearly outlined (patient satisfaction, not amenorrhea), and risk of requiring a future hysterectomy is discussed (Matteson, 2012; ACOG, 2007 and 2013; Singh, 2013). In women with HMB caused mainly by ovulatory disorders or endometrial hemostatic disorders, any of the following treatments may be chosen: hysterectomy, EA, systemic medical therapies, or levonorgestrel-releasing intrauterine systems (LNG-IUS). In choosing between EA and hysterectomy, if a woman’s preference is for amenorrhea, less pain, or avoiding additional therapy, hysterectomy is suggested. If her preference is for lower operative and postoperative procedural risk and a shorter hospital stay, EA is recommended. Premenopausal patients undergoing EA should be counseled to use appropriate contraception.
The most common contraindications to EA include recent pregnancy, the presence of active or recent uterine infection, endometrial malignancy or hyperplasia, or endometrial cavities that exceed device limitations. In cases of suspected uterine displacement, clinicians should verify the correct placement using ultrasound before the device is activated. In addition to ultrasound, the use of hysteroscopy prior to the insertion of the ablation device is recommended, if the device is not a balloon. The concurrent use of diathermy during such procedures should not be undertaken, because of the risk of the ablation device as a source of alternate site burns.

Policy updates:

We identified one new evidence-based guideline produced by the Society of Obstetricians and Gynaecologists in Canada (SOGC) (Laberge, 2015). Their results are in agreement with the original policy. Therefore, no changes to the policy are warranted.

In 2016, we added two new Cochrane reviews (Marjoribanks, 2016; Fergusson, 2013) and one update of an evidence-based guideline (NICE, 2016) to this policy. Oral medications, LNG-IUS devices, endometrial resection, and EA are safe, effective alternatives to hysterectomy for treatment of HMB. Each option has advantages and disadvantages; surgical judgment, available resources, and patient preferences play important roles in choice of treatment. NICE guidance suggests consideration of EA using a second-generation ablative technique, where bleeding is severely impacting a woman's quality of life, she has no desire to conceive in the future, and she has a normal uterus and small uterine fibroids (NICE, 2016). These results confirm previous findings. Therefore, no changes to the policy are warranted.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
<th>Key points:</th>
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| Marjoribanks (2016)    | Cochrane review Surgery (hysterectomy, EA or endometrial resection) vs. medical therapy (oral medication or LNG-IUS for HMB) | - Systematic review and meta-analysis of 15 parallel-group randomized controlled trials (RCTs) (1,289 women).  
- Overall quality: very low to moderate with high risk of bias, and many women randomized to medical interventions subsequently underwent surgery.  
- Conservative surgery (thermal balloon ablation [six RCTs] or radiofrequency EA [one RCT] versus LNG-IUS: At one year, the surgical group was more likely to have subjective control of bleeding and fewer adverse events, but differences in satisfaction rates at one year or two years were inconclusive or comparable, respectively.  
- Surgery, especially hysterectomy, reduces HMB more than medical treatment at one year, but hysterectomy can cause serious complications for a minority of women.  
- Oral medication suits a minority of women in the long term, and the LNG-IUS device provides a better alternative to surgery in most cases.  
- Authors' recommendations: Most women may be well advised to try a less radical treatment as first-line therapy. Both LNG-IUS and conservative surgery appear to be safe, acceptable, and effective. |
| Laberge (2015) for the SOGC | EA in the management of | Key points:  
- Systematic review and evidence-based guidelines generally concur with other guidelines. |
<table>
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<th>Content, Methods, Recommendations</th>
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| Lethaby (2013) | **Key points:**  
  - Systematic review of 25 trials (4,040 women) with sample sizes ranging from 20 to 372 women.  
  - Overall quality: low to moderate. Most had inadequate allocation concealment and were unblinded.  
  - Compared to first-generation techniques, second-generation techniques were associated with:  
    - Similar improvement in HMB (12 RCTs) and patient satisfaction (11 RCTs).  
    - Shorter procedure times (15 minutes on average) (mean difference [MD] 14.9, 95% confidence interval [CI] 10.1 to 19.7, nine RCTs; low-quality evidence).  
    - More frequent use of local anesthesia (relative risk [RR] 2.8, 95% CI 1.8 to 4.4, six RCTs; low-quality evidence).  
    - More equipment failure (RR 4.3, 95% CI 1.5 to 12.4, three RCTs; moderate-quality evidence).  
    - Fewer incidences of fluid overload, uterine perforation, cervical lacerations, and hematometra than women undergoing the more traditional EA and resection techniques (RR 0.18, 95% CI 0.04 to 0.79, four RCTs; RR 0.32, 95% CI 0.1 to 1.0, eight RCTs; RR 0.22, 95% CI 0.08 to 0.61, eight RCTs; and RR 0.32, 95% CI 0.12 to 0.85, five RCTs; all moderate-quality evidence).  
    - More nausea and vomiting and uterine cramping (RR 2.0, 95% CI 1.3 to 3.0, four RCTs; and RR 1.2, 95% CI 1.0 to 1.4, two RCTs; both moderate-quality evidence).  
    - A lower risk of requiring either further surgery of any kind or hysterectomy up to 10 years after surgery (RR 0.69, 95% CI 0.48 to 0.99, one RCT; and RR 0.60, 95% CI 0.38 to 0.96, one RCT; both moderate-quality evidence, respectively) but not at earlier follow-up. Additional research is required to confirm this finding.  
  - Insufficient evidence to suggest superiority of a particular technique in the pairwise comparisons between individual ablation and resection methods. |
| Fergusson (2013) | **Key points:**  
  - Systematic review and meta-analysis of eight RCTs with pre-menopausal women.  
  - Overall quality: moderate with low or unclear risk of bias.  
  - Improvement in bleeding symptoms and satisfaction rates were slightly higher with hysterectomy.  
  - Most adverse events, both major and minor, were significantly more likely to occur after hysterectomy during hospital stay.  
  - After discharge, there was a higher rate of infection after hysterectomy (RR 0.2, 95% CI 0.1 to 0.5, one RCT; 172 women).  
  - For some outcomes (e.g., a woman’s perception of bleeding and proportion of women requiring further surgery for HMB), further research in these areas is likely to change the estimates.  
  - Authors’ conclusions: TCRE and EA are alternatives to hysterectomy for HMB. The initial
<table>
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<tr>
<td>Daniels (2012)</td>
<td>The cost of endometrial destruction is significantly lower than that of hysterectomy, but over time the difference narrows, because retreatment is often necessary.</td>
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</table>

**Key points:**

- Bipolar radiofrequency EA and MEA resulted in higher rates of amenorrhea than thermal balloon ablation at around 12 months (odds ratio [OR] 2.51, 95% CI 1.53 to 4.12, \( p < 0.001 \); and OR 1.66, 95% CI 1.01 to 2.71, \( p = 0.05 \), respectively), but no significant difference between techniques in satisfaction with treatment or continued HMB.
- Compared with bipolar radiofrequency and MEA devices, free-fluid ablation had a higher number of women still experiencing HMB (95% CI 2.19 to 4.50, \( p = 0.03 \); and 95% CI 2.91, 1.23 to 6.88, \( p = 0.02 \), respectively).
- Compared with radiofrequency EA, free-fluid ablation was associated with reduced rates of amenorrhea (95% CI 0.36, 0.19 to 0.67, \( p = 0.004 \)) and increased rates of dissatisfaction (95% CI 4.79, 1.07 to 21.5, \( p = 0.04 \)).
- Of the less commonly used devices, endometrial laser intra-uterine thermotherapy was associated with increased rates of amenorrhea compared with all the other devices.
- Cryoablation led to a reduced rate compared with bipolar radiofrequency and MEA.
- Authors’ conclusions: Second-generation bipolar radiofrequency and MEA devices are more effective than thermal balloon and free-fluid ablation in the treatment of HMB.

**Glossary**

**Dilation and curettage (D and C)** — Procedure in which the cervix is dilated and a curette is used to scrape and remove uterine tissue.

**Electrosurgery** — Procedure using a resectoscope, which is a slender telescopic device that is inserted into the uterus. It has an electrical wire loop, rollerball, or spiked-ball tip that destroys the uterine lining. This method is usually performed in an operating room with general anesthesia. It is not as frequently used as the other methods.

**Endometrial ablation (EA)** — Procedure that destroys a thin layer of the lining of the uterus and stops menstrual flow in many women. In some women, menstrual bleeding does not stop, but is reduced to normal or lighter levels. If ablation does not control heavy bleeding, further treatment or surgery may be required.

**Endometrial hyperplasia** — Condition in which the lining of the uterus grows too thick. If left untreated over time, this condition may lead to cancer.

**Freezing (cryoablation)** — A thin probe is inserted into the uterus. The tip of the probe freezes the uterine lining. Ultrasound is used to help guide the procedure.

**Heated fluid (hydrothermal)** — Fluid is inserted into the uterus through a hysteroscope, a slender, light-transmitting device. The fluid is heated and stays in the uterus for approximately 10 minutes to destroy the endometrium.

**Heated balloon (thermal)** — A balloon is placed in the uterus with a hysteroscope. Heated fluid is injected into the balloon. The balloon expands until its edges touch the uterine lining. The heat destroys the endometrium.
**Hysterectomy** — Removal of the uterus.

**Intrauterine device (IUD)** — A small device that is inserted and left inside the uterus to prevent pregnancy.

**Laser (Nd:YAG laser)** — Surgical laser modified with a single channel thermometry unit, a computer, a printer, and a computer-controlled laser exposure shutter.

**Menopause** — The process in a woman’s life when ovaries stop functioning and menstruation stops.

**Microwave energy** — A special probe is inserted into the uterus through the cervix. The probe applies microwave energy to the uterine lining, which destroys it.

**Polyps** — Growths that develop from membrane tissue, such as the lining of the inside of the uterus.

**Radiofrequency** — An EA procedure in which a probe is inserted into the uterus through the cervix. The tip of the probe expands into a mesh-like device that sends radiofrequency energy into the lining. The energy and heat destroy the endometrial tissue, while suction is applied to remove it.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<th>CPT Code</th>
<th>Description</th>
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<td>58353</td>
<td>Endometrial ablation, thermal, without hysteroscopic guidance</td>
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<tr>
<td>58356</td>
<td>Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed</td>
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<tr>
<td>58563</td>
<td>Hysteroscopy, surgical; with endometrial ablation (e.g., endometrial resection, electrosurgical ablation, thermoablation)</td>
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<td>D50.0</td>
<td>Iron deficiency anemia secondary to blood loss (chronic)</td>
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<td>D62</td>
<td>Acute posthemorrhagic anemia</td>
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<tr>
<td>N92.0</td>
<td>Excessive and frequent menstruation with regular cycle</td>
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