Clinical Policy Title: Endometrial ablation

Clinical Policy Number: 12.03.03

Effective Date: April 1, 2015
Initial Review Date: November 15, 2014
Most Recent Review Date: November 16, 2017
Next Review Date: November 2018

Related policies:
CP# 12.03.02 Uterine artery embolization
CP# 12.03.04 Radiofrequency ablation of uterine fibroids
CP# 13.01.02 Transvaginal and transabdominal ultrasound

About this policy: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ 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 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’ 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’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers the use of endometrial ablation (EA) with or without resectoscopic guidance to be clinically proven and, therefore, medically necessary to treat premenopausal members with normal uterine cavities, when all of the following criteria are met (American Congress of Obstetricians and Gynecologists [ACOG], 2015):

- A history of heavy menstrual bleeding (HMB) as evidenced by either:
  - Profuse bleeding or repetitive periods longer than eight days.
  - Anemia due to acute or chronic blood loss.
- Unresponsive to at least three months of hormonal therapy (unless contraindicated or not tolerated). See limitations section.
- No desire for future fertility.
- No evidence of endometrial hyperplasia or malignancy based on histopathological sampling.
- Willingness to accept normalization of menstrual flow, not ammenorhea, as an outcome.
AmeriHealth Caritas considers the following methods for performing EA to be clinically proven and, therefore, medically necessary when used in accordance with U.S. Food and Drug Administration (FDA)-approved indications for use (FDA, 2017):

- 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.

Although failure of medical therapy is not an absolute prerequisite for the procedure, it is an important consideration (ACOG, 2015).

**Absolute contraindications to EA include the following (ACOG, 2017; ACOG, 2015):**

- Recent or current pregnancy, or a desire for future pregnancy.
- Post menopause.
- Other disorders of the uterus or endometrium or structural abnormalities that require surgery.
- Suspected or documented premalignant or malignant conditions of the endometrium or uterus.
- Presence of an intrauterine device.
- Active urogenital or pelvic infection (e.g., cystitis, vaginitis, cervicitis, endometritis, salpingitis, pelvic inflammatory disease, or tubo-ovarian abscess).

**Relative contraindications to non-resectoscopic EA depend on the member’s condition, medical history, and preferences, and the device used, and include select disorders of uterine structure that may unduly enhance the risks associated with the procedure or make success unlikely, for example (ACOG, 2015):**

- Previous uterine surgery such as abdominal or laparoscopic myomectomy, cesarean delivery (in particular classic cesarean delivery).
- Extreme uterine version or flexion.
- Prior endometrial ablation.
- Mullerian fusion disorders.
Resectascopic EA is generally preferred for members with abnormal uterine bleeding and a sounded cavity length or submucosal myomata outside the parameters of the devices available to the surgeon (ACOG, 2015).

EA is not recommended as a first-line therapy for abnormal uterine bleeding associated with ovulatory dysfunction (ACOG, 2013).

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).
- Dilatation and curettage (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. 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 (ACOG, 2016; NICE, 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 (ACOG, 2016; NICE, 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 hysteroscopic visualisation of the endometrium. 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, faster, and less operator-dependent than first-generation EA techniques (Bongers, 2004; ACOG, 2013). They may or may 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 hysteroscopic guidance (ACOG, 2013). The FDA has approved several devices for EA (FDA, 2017).

**Searches**

AmeriHealth Caritas 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 13, 2017. Search terms were: "Menorrhagia" (MeSH) and "Endometrial Ablation Techniques" (MeSH), and free text terms "menorrhagia," "endometrial ablation," and “heavy menstrual 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 hysteroscopy-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 (ACOG, 2013; Singh, 2013; Matteson, 2012; ACOG, 2007). 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, when 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.

In 2017, we added no new information to the policy, but the policy statements were clarified to reflect ACOG (2015) positions. Otherwise, no substantive changes were made to the policy.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
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<tbody>
<tr>
<td>Marjoribanks (2016) Cochrane review Surgery (hysterectomy, EA or endometrial resection) vs. medical therapy (oral medication or LNG-IUS for HMB)</td>
<td>Key points:</td>
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<tr>
<td></td>
<td>• Systematic review and meta-analysis of 15 parallel-group randomized controlled trials (RCTs) (1,289 women).</td>
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<td></td>
<td>• Overall quality: very low to moderate with high risk of bias, and many women randomized to medical interventions subsequently underwent surgery.</td>
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<td></td>
<td>• 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.</td>
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<tr>
<td></td>
<td>• Surgery, especially hysterectomy, reduces HMB more than medical treatment at one year, but hysterectomy can cause serious complications for a minority of women.</td>
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<td>• 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.</td>
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<td></td>
<td>• 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.</td>
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| Laberge (2015) for the SOGC EA in the management of abnormal uterine bleeding (AUB) | Key points: |
| | • Systematic review and evidence-based guidelines generally concur with other guidelines. |
| | • EA is safe and effective for the treatment of AUB of benign etiology. |
| | • The choice of device depends primarily on surgical judgment, available resources, and patient preferences. |
| | • Low-risk patients with satisfactory pain tolerance are good candidates to undergo EA in settings outside the operating room or in free-standing surgical centers. |
Both resectoscopic and non-resectoscopic EA are relatively safe procedures with low complication rates. The complications include perforation with potential injury to contiguous structures, hemorrhage, and infection.

For resectoscopic EA, a strict protocol should be followed for fluid monitoring and management, to minimize the risk of complications of distension medium overload.

Lethaby (2013) Cochrane review Endometrial resection and ablation techniques for HMB. 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) Cochrane review TCRE and EA vs. hysterectomy for HMB. 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 cost of endometrial destruction is significantly lower than that of hysterectomy, but over time the difference narrows, because retreatment is often necessary.

Daniels (2012) Relative effectiveness of Key points:
second generation EA techniques for HMB

- 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, 1.07 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.

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.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<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</td>
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<td>curettage, when performed</td>
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<tr>
<td>58563</td>
<td>Hysteroscopy, surgical; with endometrial ablation (e.g., endometrial resection,</td>
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<td>electrosurgical ablation, thermoablation)</td>
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<tr>
<td>D50.0</td>
<td>Iron deficiency anemia secondary to blood loss (chronic)</td>
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<tr>
<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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