Clinical Policy Title: Endometrial ablation

Clinical Policy Number: CCP.1145

Effective Date: April 1, 2015
Initial Review Date: November 15, 2014
Most Recent Review Date: November 6, 2018
Next Review Date: November 2019

Related policies:

CCP.1139 Uterine artery embolization
CCP.1166 Radiofrequency ablation of uterine fibroids
CCP.1116 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 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 College of Obstetricians and Gynecologists, 2018a):

- A history of heavy menstrual bleeding 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 amenorrhea, as an outcome.

AmeriHealth Caritas considers the following methods for performing endometrial ablation to be clinically proven and, therefore, medically necessary when used in accordance with U.S. Food and Drug Administration-approved indications (2018):

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

Limitations:

All other techniques used for endometrial ablation are not medically necessary.

Endometrial ablation 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 (American College of Obstetricians and Gynecologists, 2018a).

Absolute contraindications to endometrial ablation include the following (American College of Obstetricians and Gynecologists, 2018a and b):

• 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 endometrial ablation 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 (American College of Obstetricians and Gynecologists, 2018a):
• 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.

Resectoscopic endometrial ablation 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 (American College of Obstetricians and Gynecologists, 2018a).

Endometrial ablation is not recommended as a first-line therapy for abnormal uterine bleeding associated with ovulatory dysfunction (American College of Obstetricians and Gynecologists, 2018b).

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.
• Dilatation and curettage.
• Endometrial biopsy.
• Hysterectomy for members who are candidates, based on the assessments and treatment failures of their treating providers.

Background

Heavy menstrual bleeding, 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, 2018). Heavy menstrual bleeding is a very common problem and can occur alone or in combination with other symptoms. The American College of Obstetricians and Gynecologists (2016) considers any of the following to be heavy menstrual bleeding:

• 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, non-steroidal anti-inflammatory drugs, the combined contraception pill, progestogen, danazol, or GnRH agonists (National Institute for Health and Care Excellence, 2018; American College of Obstetricians and Gynecologists, 2016). In women who
refuse or fail medical management, dilatation and curettage 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, dilatation and curettage has not been shown to be very efficacious with dysfunctional uterine bleeding and should not be used as a therapeutic treatment (National Institute for Health and Care Excellence, 2018).

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 (National Institute for Health and Care Excellence, 2018; American College of Obstetricians and Gynecologists, 2016). Hysterectomy is the only treatment for heavy menstrual bleeding 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. Minimally invasive procedures that destroy the endometrium are alternatives to hysterectomy.

**Endometrial ablation:**

First-generation endometrial ablation techniques require direct hysteroscopic visualisation of the endometrium. The most widely used first-generation techniques are transcervical resection of the endometrium using a loop diathermy electrode and rollerball ablation. Second-generation endometrial ablation techniques are simpler, faster, and less operator-dependent than first-generation endometrial ablation techniques (American College of Obstetricians and Gynecologists, 2017). 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 endometrial ablation techniques may apply fluid-filled thermal balloons, radiofrequency (thermoregulated) balloons, hydrothermy, 3-dimensional bipolar radiofrequency, diode laser hyperthermy, cryoablation, and photodynamic therapy. Microwave endometrial ablation may also be performed in a physician’s office but requires hysteroscopic guidance. The U.S. Food and Drug Administration (2018) has approved several devices for endometrial ablation.

**Searches**

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.

We conducted searches on September 19, 2018. 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**

Endometrial ablation 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 endometrial ablation techniques apply fluid-filled thermal balloons and microwaves.

The success rates of hysteroscopy-based endometrial ablation depend heavily on the skills and experience of the operator. Possible perioperative adverse effects with first-generation endometrial ablation 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 study (of more than 10,000 women) in England and Wales (Overton, 1997) and the Scottish Audit of Hysteroscopic Surgery study (1997) (of about 1,000 women) reported mortality rates of 0.26 deaths per 1,000 procedures.

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

Evidence-based guidelines agree that for premenopausal patients who choose endometrial ablation, childbearing must be 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 (American College of Obstetricians and Gynecologists, 2013; Singh, 2013; Matteson, 2012; American College of Obstetricians and Gynecologists, 2007). In women with heavy menstrual 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, 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, endometrial ablation is recommended.

The most common contraindications to endometrial ablation 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 (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 (National Institute for Health and Care Excellence, 2016) to this policy. Oral medications, levonorgestrel-releasing intrauterine systems devices, endometrial resection, and endometrial ablation are safe, effective alternatives to hysterectomy for treatment of heavy menstrual bleeding. Each option has advantages and disadvantages; surgical judgment, available resources, and patient preferences play important roles in choice of treatment. National Institute for Health and Care Excellence (2016) guidance suggests consideration of endometrial ablation 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. 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 American College of Obstetricians and Gynecologists (2015) positions. Otherwise, no substantive changes were made to the policy.

In 2018, we added one single-site, randomized controlled trial and economic analysis (Famuyide, 2017) and one cost effectiveness analysis (Spencer, 2017) to the policy. The American College of Obstetricians and Gynecologists reaffirmed two practice bulletins in 2018—No. 81 Endometrial ablation (2007) and No. 136 Management of abnormal uterine bleeding associated with ovulatory dysfunction (2015). The National Institute for Health and Care Excellence Guideline updated and replaced their guideline on heavy menstrual bleeding (2018). The new information supports endothelial ablation as one of several
available primary or secondary treatment options for heavy menstrual bleeding. These results confirm previous findings, and no policy changes are warranted.

Policy ID changed from CP# 12.03.03 to CCP.1145.

Summary of clinical evidence:

<table>
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<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| Famuyide (2017)        | **Key points:**
|                        | • A randomized controlled trial and economic analysis of radiofrequency endometrial ablation (n = 34) versus medical therapy (n = 33) as initial therapy. Primary 12-month outcome measures included menstrual blood loss using pictorial blood loss assessment chart, patients’ satisfaction, and Menorrhagia Multi-Attribute Scale. Secondary outcomes were total costs including direct medical and indirect costs associated with healthcare use, patient out-of-pocket costs, and lost work days and activity limitations over 12 months.
|                        | • Compared to medical therapy, initial radiofrequency endometrial ablation offered superior reduction in menstrual blood loss and improvement in quality of life without significant differences in total costs of care. |
| Spencer (2017)         | **Key points:**
|                        | • Searches of articles published from 2006-2016 comparing at least two treatment modalities (hysterectomy, resectoscopic endometrial ablation, nonresectoscopic endometrial ablation, and the levonorgestrel-releasing intrauterine system) to evaluate complications, mortality, and treatment outcomes over a 5-year period, calculate cumulative quality-adjusted life years, and conduct probabilistic sensitivity analysis.
|                        | • The levonorgestrel-releasing intrauterine system was superior to both hysterectomy and endometrial ablation in terms of cost and quality of life.
|                        | • Hysterectomy is associated with a superior quality of life and fewer complications than either type of ablation but at a higher cost.
|                        | • For women who are unwilling or unable to choose the levonorgestrel-releasing intrauterine system as a first-course treatment for heavy menstrual bleeding, consideration of cost, procedure-specific complications, and patient preferences can guide the decision between hysterectomy and ablation. |
| Marjoribanks (2016)    | **Key points:**
|                        | • Systematic review and meta-analysis of 15 parallel-group randomized controlled trials (n= 1,289).
|                        | • 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 randomized controlled trials] or radiofrequency endometrial ablation [one randomized controlled trial] versus levonorgestrel-releasing intrauterine systems: 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 heavy menstrual bleeding 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 levonorgestrel-releasing intrauterine systems provide 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 levonorgestrel-releasing intrauterine systems and conservative surgery appear to be safe, acceptable, and effective.

Laberge (2015) for the Society of Obstetricians and Gynaecologists in Canada

Endometrial ablation in the management of abnormal uterine bleeding

Key points:
- Systematic review and evidence-based guidelines generally concur with other guidelines.
- Endometrial ablation is safe and effective for the treatment of abnormal uterine bleeding 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 endometrial ablation in settings outside the operating room or in free-standing surgical centers.
- For resectoscopic endometrial ablation, 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 heavy menstrual bleeding.

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 heavy menstrual bleeding.
  - Shorter procedure times (15 minutes on average).
  - More frequent use of local anesthesia.
  - More equipment failure.
  - Fewer incidences of fluid overload, uterine perforation, cervical lacerations, and hematometra than women undergoing the more traditional endometrial ablation and resection techniques.
  - More nausea and vomiting and uterine cramping.
  - A lower risk of requiring either further surgery of any kind or hysterectomy up to 10 years after surgery 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

Key points:
- Systematic review and meta-analysis of eight randomized controlled trials with premenopausal women.
Transcervical resection of the endometrium and endometrial ablation vs. hysterectomy for heavy menstrual bleeding

- 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 (risk ratio 0.2, 95% CI 0.1 to 0.5, one randomized controlled trial; 172 women).
- For some outcomes (e.g., a woman's perception of bleeding and proportion of women requiring further surgery for heavy menstrual bleeding), further research in these areas is likely to change the estimates.
- Authors' conclusions: transcervical resection of the endometrium and endometrial ablation are alternatives to hysterectomy for heavy menstrual bleeding. The initial cost of endometrial destruction is significantly lower than that of hysterectomy, but over time the difference narrows, because retreatment is often necessary.

References

Professional society guidelines/other:

American College of Obstetricians and Gynecologists:


Peer-reviewed references:


**Centers for Medicare& Medicaid Services National Coverage Determinations:**

No National Coverage Determinations identified as of the writing of this policy.

**Local Coverage Determinations:**

No Local Coverage Determinations 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>
<th>Comments</th>
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<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></td>
<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></td>
<td>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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