

Medical Policy Manual

Topic: Endometrial Ablation

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Section: Surgery

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Ablation or destruction of the endometrium is used to treat abnormal uterine bleeding in premenopausal women who fail standard medical therapy. Standard medical management typically includes a trial of nonhormonal therapy with adequate doses of nonsteroidal anti-inflammatory medication and oral tranexamic acid. If this fails, management with hormonal treatment to thin the endometrium may be tried. Ablation is considered a less invasive alternative to hysterectomy; however, as with hysterectomy, the procedure is not recommended for women who wish to preserve their fertility.

Techniques for endometrial ablation are generally divided into two categories:

Hysteroscopic Techniques

Hysteroscopic techniques require skilled surgeons and, due to the requirement for cervical dilation, use of general or regional anesthesia. In addition, the need for the instillation of hypotonic distension media creates a risk of pulmonary edema and hyponatremia such that very accurate monitoring of fluids is required.

The initial hysteroscopic technique involved photovaporization of the endometrium using an Nd-YAG laser. This was followed by electrosurgical ablation using an electrical rollerball or electrical wire loop.

(The latter technique is also known as transcervical resection of the endometrium or TCRE). Hydrothermal ablation is another technique involving hysteroscopy.

Non-Hysteroscopic Techniques

Non-hysteroscopic techniques can be performed without general anesthesia and do not involve use of a fluid distention medium. Techniques include thermal fluid-filled balloon, cryosurgical endometrial ablation, instillation of heated saline, and RF ablation.

Regulatory Status

The U.S. Food and Drug Administration (FDA) indicated that endometrial devices are for use in premenopausal women with menorrhagia due to benign causes for whom childbearing is complete. FDA-approved devices for endometrial ablation include, but may not be limited to, laser therapy, electrical wire loop, rollerball using electric current, and thermal ablation using a liquid-filled balloon, microwave, electrode array, or a cryosurgical device. Examples of devices for endometrial ablation are:

- The Hydro ThermAblator® system (Boston Scientific): This involves the instillation and circulation of heated saline into the uterus using hysteroscopic guidance.
- The Genesys HTA™ system (Boston Scientific), a newer version of this technology that includes features such as a smaller console and simplified set-up requirements, was approved by the FDA in May 2010.
- The Microwave Endometrial Ablation (MEA) system (Microsulis Medical): This delivers fixed-frequency microwave energy and may be performed in a physician's office but does require use of the hysteroscope.
- The ThermaChoice® device (J&J Ethicon Gynecare): This device ablates endometrial tissue by thermal energy heating of sterile injectable fluid within a silicone balloon. Endometrial ablation will only work when there is direct contact between the endometrial wall and the fluid-filled balloon. Therefore, patients with uteri of abnormal shape, resulting from tumors such as myomas or polyps, or large size, due to fibroids, are generally not considered candidates for this procedure.
- The NovaSure™ impedance-controlled endometrial ablation system (Cytac Corp): The system delivers RF energy to the endometrial surface. The device consists of an electrode array on a stretchable porous fabric that conforms to the endometrial surface.
- Her Option™ Uterine Cryoablation Therapy™ system (American Medical Systems): The system consists of, in part, a cryoprobe that is inserted through the cervix into the endometrial cavity. When cooled, an ice ball forms around the probe, which permanently destroys the endometrial tissue. Cryoablation is typically monitored by abdominal ultrasound.

MEDICAL POLICY CRITERIA

- I. Endometrial ablation, with or without hysteroscopic guidance, may be considered **medically necessary** when the clinical records document all of the following criteria are met:
 - A. There is a diagnosis of either premenopausal* acute or chronic bleeding:
 1. *Acute menstrual bleeding*, defined as bleeding that is abnormal in regularity, volume, frequency and is of sufficient quantity to require intervention to prevent further blood

loss, OR

2. *Chronic menstrual bleeding*, defined as bleeding that is abnormal in regularity, volume, frequency and is present for most of the last six months.
- B. Hysteroscopy, sonohysterography, or pelvic ultrasound has been performed.
- C. Hormonal therapy, which may include oral contraceptives or progestins**, cannot be used because of one or more of the following:
1. There is a documented contraindication (see Appendix I) or documented intolerance to prior hormonal therapy; or
 2. Documented intolerance develops during treatment; or
 3. A trial of at least 3 months of hormonal therapy did not adequately treat the patient's condition; or
 4. A trial of hormonal therapy is not appropriate for the severity of the patient's condition (e.g., severe and persistent bleeding); or
 5. Endometrial ablation is to be performed concomitantly with surgical treatment of a uterine intracavitary abnormality.
- D. Pre-procedural endometrial sampling has been completed and histopathology shows no evidence of endometrial hyperplasia or uterine cancer. Exceptions to pre-procedural endometrial sampling include any one of the following:
1. Patients younger than 45 years without a history of unopposed estrogen exposure; or
 2. Attempted but unsuccessful sampling; or
 3. Thin endometrial lining (<3mm) on ultrasound and a documented history of >6 months of continuous/cyclic oral contraceptives or progestins**
- II. Repeat endometrial ablation may be considered **medically necessary** when the clinical records document persistent cyclic pelvic pain, or recurrent premenopausal heavy menstrual bleeding following an initial endometrial ablation procedure.
- III. Endometrial ablation using *any* technique is considered **not medically necessary** for all other indications not meeting the criteria in I. A-D, or II.

Notes:

For the purposes of this policy the following definitions apply:

* Premenopausal is defined as age 35 to menopause (typically 1 year after the final menstrual cycle).

** Progestin includes oral progestins, progestin-releasing intrauterine devices (IUDs), or DepoProvera.

SCIENTIFIC BACKGROUND

Several published systematic reviews have evaluated the accumulated evidence for endometrial ablation. These reviews address both first- generation techniques (laser ablation, electrical wire loop, rollerball, or vaporizing electrode procedure) and second-generation techniques (newer techniques that generally do not require hysteroscopy such as balloon ablation, microwave ablation, and electrode ablation).

- A 1991 BlueCross BlueShield Technology Assessment Center (TEC) Assessment concluded that endometrial ablation using either an Nd-YAG laser or a resecting loop was an effective treatment of menorrhagia unresponsive to hormone treatment or dilation and curettage.^[1]
- A Cochrane systematic review of studies comparing the efficacy and safety of different endometrial ablation techniques was published in 2005 and updated in 2009.^[2] The review included RCTs that compared 2 ablation techniques and assessed amenorrhea and patient satisfaction.

A total of 21 studies with 3,395 premenopausal women were eligible for the review. Five of the trials compared two “first generation” ablation methods (laser ablation, electrical wire loop, rollerball, or vaporizing electrode procedure). Two trials compared “second generation” techniques to one another. The remaining 14 trials compared first- to second-generation procedures. There were only 1 or 2 studies on any given comparison of techniques; the exception was balloon ablation versus rollerball for which there were 3 studies.

The investigators also conducted a meta-analysis that combined studies comparing first- and second-generation techniques. A pooled analysis of 12 studies (total n=2,085) did not find a significant difference in the rate of amenorrhea at 1 year (OR: 0.92; 95% CI: 0.62–1.37). Eleven studies (total n=1,690) reported satisfaction rates at 1 year, and there was not a significant difference between first-and second-generation techniques. The absolute rates of satisfaction were high in both groups; 88% among those who received first-generation techniques and 91% among those who received second-generation techniques.

In a pooled analysis of 7 studies (total n=1,058), there was no significant difference in the rate of additional surgeries within 1 year (OR: 0.74; 95% CI: 0.42–1.31). Data on fluid overload were available from 4 trials that compared first- and second-generation procedures. There was a total of 10/327 (3%) cases of fluid overload using first-generation techniques and 0/354 using second-generation techniques (OR=0.17; 95% CI: 0.04 to 0.77). Compared to first-generation techniques, second-generation techniques were also associated with a significantly lower risk of perforation (OR: 0.32; 95% CI: 0.10 to 1.0), cervical lacerations (OR: 0.22; 95% CI: 0.08-0.6), and hematometra (OR: 0.31; 95% CI: 0.11 to 0.85). In contrast, second-generation techniques were associated with a significantly increased risk of nausea and vomiting (OR: 2.4; 95% CI: 1.6 to 3.9) and uterine cramping (OR: 1.8; 95% CI: 1.1 to 2.8). The meta-analysis did not find evidence of significant differences in other complications rates or in secondary outcomes such as inability to work or need for additional surgery or hysterectomy.

The authors of the Cochrane review concluded that, overall, the existing evidence suggests that success rates and complications profiles of second-generation techniques compare favorably with the first generation hysteroscopic techniques.

- In 2011, the Health Technology Assessment (HTA) program in the U.K. conducted a meta-analysis of individual patient data from RCTs evaluating second-line treatments for menorrhagia.^[3] They identified data on 2,448 women from 14 trials comparing first- and second-generation endometrial ablation devices and data on 1,127 women from 7 trials comparing first-generation devices to hysterectomy. A limitation of the review is that individual patient data were not available for approximately 35% of women randomized in the trials. The most frequently measured outcome in the studies was patient satisfaction/dissatisfaction and this was used as the primary outcome of the meta-analysis. After 12 months of follow-up, 7.3% (57/454)

of women treated with first-generation endometrial ablation devices and 5.3% (23/432) of women who had a hysterectomy were dissatisfied with their treatment outcome. This difference was statistically significant, favoring hysterectomy (OR: 2.46, 95% CI: 1.54 to 3.93, $p=0.0002$). Rates of dissatisfaction were similar among women treated with first-generation endometrial ablation devices (123/1,006 [12.2%]) and second-generation devices (110/1,034 [10.6%], $p=0.20$). The authors noted that rates of dissatisfaction were low for all treatments.

The HTA also conducted meta-analyses on several clinical outcomes. For example, when first- and second-generation endometrial ablation devices were compared, there was not a significant difference between groups in the rate of amenorrhea after 12 months. When findings from 13 studies were pooled, rates of amenorrhea were 326/899 (36%) with first-generation devices and 464/1,261 (37%) with second-generation devices (OR: 1.12; 95% CI: 0.93 to 1.35). There were insufficient data to conduct meta-analyses of longer-term amenorrhea rates. Similarly, the rates of menorrhagia after 12 months did not differ between groups. In a pooled analysis of 12 studies, rates were 111/899 (12.3%) with first-generation devices and 151/1,281 (11.8%) after second-generation devices (pooled OR: 0.97, 95% CI: 0.74 to 1.28). In addition, a pooled analysis of 6 studies did not find a significant difference in repeat endometrial ablations over 12 months after initial treatment with first-generation devices (4/589, 0.7%) or second-generation devices (4/880, 0.5%) (OR: 0.71, 95% CI: 0.17 to 2.94). The proportion of women requiring hysterectomy within 12 months after endometrial ablation did not differ significantly when first-generation devices (39/933 [4.2%]) or second-generation devices (35/1,343 [2.6%]) were used (OR: 0.77; 95% CI: 0.47 to 1.24 [11 studies]).

In addition to the meta-analyses of data from published studies, the HTA included an analysis of individual patient data from national databases in Scotland to evaluate long-term outcomes after hysterectomy or endometrial ablation. The investigators identified a total of 37,120 women who underwent hysterectomy and 11,299 women who underwent endometrial ablation for dysfunctional uterine bleeding between 1989 and 2006. Women who received endometrial ablation were significantly older (mean of 42.5 years) compared to those receiving hysterectomy (mean of 41.0 years). The type of endometrial ablation device could not be determined. The median duration of follow-up was 6.2 years in the endometrial ablation group and 11.6 years in the hysterectomy group. During follow-up, 962 (8.5%) women who received endometrial ablation had additional gynecologic surgery compared to 1,446 (3.9%) women who had hysterectomy; this difference was statistically significant (adjusted hazard ratio [HR]: 3.56, 95% CI: 3.26-3.89). The most common types of additional surgery after endometrial ablation were intrauterine procedures ($n=577$, 5.1%) and repeat endometrial ablation ($n=278$, 2.5%). However, women who had initial endometrial ablation procedures were significantly less likely than those with initial hysterectomies to have surgery for pelvic floor repair (0.9% vs. 2.2%, respectively, adjusted HR: 0.50 to 0.77). Women were also less likely to have tension-free vaginal tape surgery for stress urinary incontinence after endometrial ablation than after hysterectomy (0.5% vs. 1.1%, respectively, adjusted HR: 0.55, 95% CI: 0.41 to 0.74).

- In 2012, Daniels and colleagues compared first- and second-generation methods using 14 trials previously addressed in the HTA assessment.^[4] A pooled analysis of these studies yielded conclusions that were similar to the HTA group, in that no significant difference in amenorrhea rates was observed with the 2 types of techniques (OR: 0.72, 95% CI: 0.52-1.101). In addition, 3 studies compared the second-generation techniques, thermal balloon ablation and bipolar radiofrequency (RF) (total $n=264$). A pooled analysis showed a higher rate of amenorrhea with bipolar RF (OR: 4.56; 95% CI: 2.24-9.26).

- In 2013, Kroft and Liu also reported no difference in amenorrhea rates when comparing first- and second-generation methods as a treatment for menorrhagia in premenopausal women (11 randomized controlled trials^[5] were included in the review). However, authors did note a decrease in complication rates (7 studies with 1272 patients, rate ratio 0.52, 95% CI 0.35 to 0.76; $P < 0.001$), operating time (16.6 minutes 3 studies with 486 patients, 95% CI 12.1 to 21.2 minutes; $P < 0.001$) and improved compatibility with anaesthesia (3 studies with 558 patients, rate ratio 1.87, 95% CI 1.04 to 3.37; $P = 0.04$) in second-generation devices compared to first-generation methods. In addition, authors reported higher rates of amenorrhea in patients treated with Novasure compared to other second-generation devices (4 studies with 407 patients, rate ratio 2.60, 95% CI 1.63 to 4.14; $P < 0.001$).

Conclusion

Evidence from these large systematic reviews do not demonstrate that one ablation technique is superior to another. Overall, these studies continue to report similar amenorrhea rates in first-generation and second-generation techniques.

Safety

In 2012, Brown and Blank published an analysis of adverse events associated with endometrial ablation procedures that were reported in the U.S. Food and Drug Administration (FDA's) Manufacturer and User Facility Device Experience (MAUDE) database.^[6] There were a total of 829 reported adverse events between 2005 and 2011. Nearly two-thirds of the adverse events (540 of 829, 65%) were genital tract or skin burns and 529 of these events (98%) were associated with hydrothermal endometrial ablation. The next 2 most frequent types of adverse events were thermal bowel injury (93 of 820, 11%) and transmural uterine thermal activity (89 of 820, 11%). Of the 182 thermal injuries, 140 (77%) were associated with radiofrequency endometrial ablation. In addition, 47 instances of sepsis or bacteremia were reported, and 43 of these cases (91%) were associated with radiofrequency endometrial ablation. There were 4 reported deaths, 2 associated with radiofrequency ablation and 1 each associated with thermal balloon ablation and cryoablation. Sixty-six of the 829 events (8%) occurred when endometrial ablation was performed outside of the labeled instructions for use of the procedure. The authors did not report the total number of endometrial ablations performed during this time period, therefore the proportion of procedures with adverse events cannot be determined from these data.

Conclusion

Adverse events have been associated with endometrial ablation procedures. Certain types of adverse events are more likely to occur with specific approaches to endometrial ablation. Due to lack of information about the total number of procedures and the number of each type of endometrial ablation procedure performed, conclusions cannot be drawn from these data about the relative safety of different types of endometrial ablation procedures.

Practice Guidelines and Position Statements

Practice Committee of the American Society for Reproductive Medicine (ASRM)

In 2008, ASRM reviewed their 2006 Practice Committee report and reissued their statement on indications and options for endometrial ablation.^[7] Conclusions were:

- “Endometrial ablation is an effective therapeutic option for the management of menorrhagia.
- Hysteroscopic and nonhysteroscopic techniques for endometrial ablation offer similar rates of symptom relief and patient satisfaction.
- Later definitive surgery may be required in 6% to 20% of women after endometrial ablation.
- Women who undergo hysterectomy after a failed endometrial ablation report significantly more satisfaction after 2 years of follow-up.
- Endometrial ablation generally is more effective when the endometrium is relatively thin.
- Ideally, hysteroscopic methods for endometrial ablation should be performed using a fluid monitoring system to reduce the risks and complications relating to fluid overload and electrolyte imbalance.
- Nonhysteroscopic methods for endometrial ablation require less skill and operating time.”

A 2011 patient fact sheet from the ASRM states that women who meet the following criteria should not have endometrial ablation:

“Women who are pregnant, who would like to have children in the future, or have gone through menopause should not have this procedure.”^[8]

American Congress of Obstetricians and Gynecologists (ACOG)

ACOG published a guideline on endometrial ablation in 2007.^[9] Recommendations they assessed as being based on good and consistent evidence include:

- “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.
- Resectoscopic endometrial ablation is associated with a high degree of patient satisfaction but not as high as hysterectomy. “

In 2013, ACOG published guidelines regarding the management of acute abnormal uterine bleeding (AUB) in nonpregnant reproductive-aged women.^[10] Recommendations regarding laboratory testing and imaging of these patients are as follows:

- “Endometrial tissue sampling should be performed in patients with AUB who are older than 45 years as a first-line test. Endometrial sampling also should be performed in patients younger than 45 years with a history of unopposed estrogen exposure (such as seen in patients with obesity or polycystic ovary syndrome), failed medical management, and persistent AUB.”

Recommendations regarding surgical management of women who do not respond to medical management of symptoms are as follows:

- “Surgical options include dilation and curettage (D&C), endometrial ablation, uterine artery embolization, and hysterectomy.”
- “Endometrial ablation, although readily available in most centers, should be considered only if other treatments have been ineffective or are contraindicated, and it should be performed only when a woman does not have plans for future childbearing and when the possibility of endometrial or uterine cancer has been reliably ruled out as the cause of the acute AUB.”

Also in 2013, ACOG published a practice bulletin regarding the management of abnormal uterine

bleeding associated with ovulatory dysfunction (AUB-O).^[11] The following recommendation is made primarily based upon consensus and expert opinion:

“Endometrial ablation is not recommended as a first-line therapy for AUB-O. Physicians must provide thorough informed consent and adequate counseling to women with AUB-O who desire endometrial ablation.”

Society for Gynecologic Surgeons (SGS)

In 2012, SGS published a clinical practice guideline on treatment of abnormal uterine bleeding.^[12] The guideline recommends that, in women with bleeding caused mainly by ovulatory disorders or endometrial hemostatic disorders, any of the following treatments may be chosen depending on patient values and preferences: hysterectomy, endometrial ablation, systemic medical therapies or levonorgestrel-releasing intrauterine systems. In choosing between endometrial ablation and hysterectomy, if the patient’s preference is for amenorrhea, less pain or avoiding additional therapy, hysterectomy is suggested. If the patient’s preference is for lower operative and post-operative procedural risk, and a shorter hospital stay, endometrial ablation is recommended.

Summary

There is substantial evidence indicating that endometrial ablation improves the net health outcome in women who have failed prior treatment for menorrhagia and are otherwise considering hysterectomy; therefore endometrial ablation may be considered medically necessary when criteria are met. Meta-analyses of randomized controlled trials suggest similar benefits with first-generation (hysteroscopic) techniques and second-generation (mainly non-hysteroscopic) techniques. There is a lack of consistent evidence that any one ablation technique is superior to another.

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CROSS REFERENCES

None

CODES	NUMBER	DESCRIPTION
CPT	58353	Endometrial ablation, 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)
HCPCS	None	

APPENDIX I

Possible Relative Contraindications for Oral Contraceptive Pills (OCP):

- Breast feeding & <4 wks postpartum
- Current DVT/pulmonary embolism
- Current use of selected anticonvulsants: antiretroviral & antibiotics
- Diabetes with nephropathy, retinopathy or neuropathy
- Diabetes with other vascular disease and >20yrs duration
- DVT/Pulmonary embolism not anticoagulated and at low/high risk of recurrence

APPENDIX I

- DVT/Pulmonary embolism anticoagulated for at least 3 months and at low/high risk of recurrence
- Gallbladder disease -symptomatic and medically treated or current
- Heart disease: Ischemic heart disease, complicated valvular disease, or cardiomyopathy
- History of breast cancer
- History of CVA
- History or malabsorptive type bariatric surgery
- Hyperlipidemia
- Hypertension
- Increased risk for embolic event
- Known thrombogenic mutation
- Liver tumors- hepatocellular adenoma, or malignant
- Migraines with auras at any age
- Migraines without aura and age 35 or older
- Multiple cardiovascular risk factors(i.e. diabetes, hypertension, smoker, old age)
- Non breast feeding & 21days or less postpartum
- Non breast feeding > 21days and <30days and at risk for VTE events
- Peripartum cardiomyopathy irregardless of cardiac function
- Severe decompensated cirrhosis
- Smoking in women 35 years or older
- Solid organ transplantation-complicated only
- Systemic lupus erythematosus with positive or unknown autoantibodies
- Viral hepatitis-acute or flare

Possible Relative Contraindications for Progestins (Depo-Provera, progestin-eluting IUD):

- History of breast cancer
- History of CVA
- History or malabsorptive type bariatric surgery (unless using Mirena IUD)
- Liver tumors- hepatocellular adenoma, or malignant
- Migraines with auras at any age
- Severe decompensated cirrhosis