Endometrial Ablation

Description

Endometrial ablation is a potential alternative to hysterectomy for abnormal uterine bleeding. A variety of approaches are available; these are generally classified into hysteroscopic techniques (eg, Nd:YAG laser and electrosurgical rollerball) and non-hysteroscopic techniques (eg, cryosurgical and radiofrequency (RF) ablation).

Background

Ablation or destruction of the endometrium is used to treat menorrhagia in women who failed standard therapy. It 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.

Multiple energy sources have been used. These include: the Nd-YAG laser; a resecting loop using electric current; electric rollerball; and thermal ablation devices. Endometrial ablation is typically preceded by hormonal treatment to thin the endometrium.

Techniques for endometrial ablation are generally divided into 2 categories: those that do and do not require hysteroscopic procedures. (Other terminology for these categories of techniques include first-generation versus second-generation procedures and resectoscopic versus non-resectoscopic endometrial ablation methods). Hysteroscopic techniques were developed first; the initial technique was photovaporization of the endometrium using an Nd-YAG laser, and 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). Hydrothermal ablation also involves hysteroscopy. 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.

Nonhysteroscopic 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.
There are concerns about maternal and fetal morbidity and mortality associated with pregnancy after endometrial ablation. Thus, U.S. Food and Drug Administration (FDA) approval of endometrial ablation devices includes only women for whom childbearing is complete.

**Regulatory Status**

The FDA indicates 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 Genesys HTA™ system (Boston Scientific): The system involves the instillation and circulation of heated saline into the uterus using hysteroscopic guidance and includes features such as a smaller console and simplified set-up requirements, was approved by FDA in May 2010.
- The Microwave Endometrial Ablation (MEA) system (Microsulis Medical, U.K.): 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, Somerville, NJ): 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 (Cytyc Corp, Marlborough, MA): 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, Minnetonka, MN): 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. FDA Product Code: HHR

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Endometrial ablation, with or without hysteroscopic guidance, using a U.S. Food and Drug Administration–approved device may be considered **medically necessary** in women with abnormal uterine bleeding who are not candidates for, or who are unresponsive to, hormone therapy and would otherwise be considered candidates for hysterectomy.

Endometrial ablation is considered **not medically necessary** for all other indications.
Policy Guidelines

Intrauterine ablation or resection of the endometrium should not be confused with laparoscopic laser ablation of intraperitoneal endometriosis. This policy does not address laparoscopic intraperitoneal ablation.

Contraindications for intrauterine ablation or resection of the endometrium include:

- Patient who is pregnant or desires pregnancy.
- History of endometrial cancer or pre-cancerous histology.
- Patient with an active genital or urinary tract infection at the time of the procedure.
- Patient with active pelvic inflammatory disease.
- Patient with an intrauterine device (IUD) currently in place.
- Patient with any anatomic or pathologic condition in which weakness of the myometrium could exist, such as history of previous classical cesarean sections or transmural myomectomy.

Other contraindications for microwave ablation include myometrial thickness less than 10 mm, and uterine sounding length less than 6 cm.

In February 2013, the FDA downgraded its contraindication of NovaSure for women with Essure® contraceptive micro-inserts to a warning. The warning states that a health hazard may exist when a NovaSure procedure is performed in women with improperly positioned Essure® micro-inserts. To verify proper placement, a report of the Essure Confirmation Test (ECT) should be obtained prior to performing the NovaSure procedure. The labeling change also includes the requirement for a post-approval study.¹

Benefit Application

The BCBS FEP contract stipulates that FDA-approved biologics, drugs and certain devices may not be considered investigational when used for their intended purpose and thus these products may only be assessed based on medical necessity.

Rationale

A review of the 1991 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.² Since the 1991 TEC Assessment, additional devices have been introduced, and randomized studies supporting the use of these devices have been published.
Comparison Between Endometrial Ablation and Hysterectomy

Systematic Reviews and Meta-Analyses

A 2012 systematic review of randomized controlled trials (RCTs) by Matteson et al compared the efficacy of hysterectomy and less invasive techniques for controlling abnormal uterine bleeding. The authors identified 9 trials directly comparing hysterectomy with another intervention and reporting health outcomes; 7 of these studies compared hysterectomy to endometrial ablation. The 7 studies included a total of 1167 women, and follow-up ranged from 4 to 48 months. Due to the heterogeneity of outcome measurement, study findings were not pooled. Following treatment, amenorrhea rates in the endometrial ablation groups ranged from 13% to 64% versus an implied 100% rate after hysterectomy. Five trials reported pain beyond the immediate post-operative period. The authors judged the quality of evidence on pain to be low but that results favored hysterectomy over ablation. Three studies reported that pelvic pain was less prevalent in the hysterectomy group than the ablation group; however, only 1 study compared rates statistically, and this study found a significantly lower rate of pain at 2-3 years’ follow-up in the group receiving hysterectomy. All 7 trials reported additional treatments obtained by participants after the initial intervention. At 1-4 years’ follow-up, the proportion of women in the ablation group who had an additional surgical procedure for bleeding was 16% to 42%; of these, 10% to 29% were treated with hysterectomy.

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. They identified data on 1127 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 (odds ratio [OR]: 2.46, 95% confidence interval [CI]: 1.54 to 3.93, p<0.001).

In addition, the HTA analyzed 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, 42.5 years) than those receiving hysterectomy (mean, 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 with 1446 (3.9%) women who had hysterectomy; this difference was statistically significant (adjusted hazard ratio [HR], 3.56; 95% CI, 3.26 to 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 range, 0.50-0.77). 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).

**Randomized Controlled Trials**
The RCT with the longest follow-up is that by Zupi et al, who published 15-year results in 2015. The study, which started in 1995, randomized 203 women with abnormal uterine bleeding who were unresponsive to medical therapy to endometrial ablation or laparoscopic supracervical hysterectomy. A total of 181 women underwent the assigned treatment, and 153 (85%) were included in the long-term follow-up analysis. After a mean of 14.4 years, the reoperation rate was significantly higher in the endometrial ablation group (20/71 [28.1%]) than in the hysterectomy group (0/71; p<0.001). All 20 women who had repeat surgery had second ablation procedures, and 15 of them had a hysterectomy for relapse of symptoms. Quality-of-life measures favored the hysterectomy group. Scores on both Physical and Mental Component Summary scores of the 12-Item Short-Form Health Survey were significantly higher in the hysterectomy group than in the endometrial ablation group (p<0.001). However, looking at the data from a different perspective, more than 70% of the women were spared a hysterectomy. Moreover, it is not known whether the lower quality-of-life scores were reported by all women in the endometrial ablation group or primarily by women who had reoperations; results were not stratified by reoperation status.

**Section Summary: Comparison of Endometrial Ablation and Hysterectomy**
The evidence suggests better outcomes (eg, bleeding control, pelvic pain) and fewer additional surgeries in women who have hysterectomy compared with those who have endometrial ablation. However, endometrial ablation is less invasive and involves retention of the uterus. Most studies comparing hysterectomy with endometrial ablation used first-generation techniques; there is less evidence comparing hysterectomy with second-generation techniques.

**Comparison Among Different Endometrial Ablation Methods**

**Systematic Reviews and Meta-Analyses**
Numerous RCTs and several systematic reviews of RCTs have been published comparing different methods of endometrial ablation. In 2016 Angioni et al published a systematic review of published evidence on first- versus second-generation endometrial ablation techniques. The authors did not find evidence that either group of techniques is clearly superior to the other; there were similar rates of efficacy and patient satisfaction. Moreover, some adverse effects (eg, perforation, cervical laceration) were more common with first-generation techniques and others (eg, uterine cramping, pain) were more common with second-generation techniques.

A 2013 Cochrane review included RCTs that compared 2 ablation techniques or compared first- and second-generation techniques. Primary outcomes were change in menstrual bleeding and rates of patient satisfaction. A total of 25 studies (total N=4056 premenopausal women) were eligible for the review. Seven of the studies were multicenter; 6 of these were based in the United States. Nineteen of the trials required women to have completed their families, 12 excluded women with fibroids, and 14 required that women had not tolerated or failed to respond to medical therapy. Five of the trials compared 2 first-generation ablation techniques and 5 compared second-generation techniques. Fourteen trials compared second-generation with first-generation methods. Sixteen trials had adequate randomization methods, but, in most trials, blinding was not performed or not reported.
There were only 1 or 2 studies on any given comparison of techniques; the exception was balloon (second generation) versus rollerball (first generation) ablation (3 studies; n=352 patients). A pooled analysis of these 3 studies found a statistically lower rate of amenorrhea at 1 year with rollerball than with balloon ablation (OR=0.63; 95% CI, 0.41 to 0.97); the absolute rates of amenorrhea were 16% in the balloon ablation group and 24% in the rollerball group. However, there was no significant difference in the satisfaction rate at 1 year (OR=0.99; 95% CI, 0.93 to 1.06).

The investigators also conducted an overall analysis of studies comparing first- and second-generation techniques. A pooled analysis of 12 studies (n=2085 patients) did not find a statistically significant difference in the rate of amenorrhea at 1 year (OR=0.94; 95% CI, 0.74 to 1.20). The absolute rates of amenorrhea were 38% with first-generation procedures and 37% with second-generation procedures. Eleven studies reported satisfaction rates at 1 year, with no statistically significant difference between first-and second-generation techniques (OR=1.00; 95% CI, 0.97 to 1.02). The absolute rates of satisfaction were high in both groups. Pooled analysis of adverse effects did not find any significant differences in the rates of perforation (8 studies), endometritis (5 studies), or hemorrhage (5 studies) using first- versus second-generation ablation techniques. Rates of fluid overload (4 studies), cervical lacerations (8 studies), and hematometra (5 studies) were significantly higher with first-generation techniques than with second-generation techniques. Cochrane reviewers concluded that, overall, the existing evidence suggested that success and complication rate profiles of second-generation techniques compare favorably with the first-generation hysteroscopic techniques.

In a 2012 network meta-analysis, Daniels et al identified 14 trials comparing first- and second-generation methods and 5 trials comparing 2 second-generation methods of endometrial ablation for women with heavy menstrual bleeding who were unresponsive to medical therapy. In their analysis, the investigators compared the efficacy of each pair of techniques; only a few pooled comparisons included data from more than 1 trial. Eight studies compared a first-generation technique with thermal balloon ablation (n=516 patients). A pooled analysis of these studies did not find a significant difference in amenorrhea rates with the 2 techniques (OR=0.72; 95% CI, 0.52 to 1.101). In addition, 3 studies compared the second-generation techniques, thermal balloon ablation and bipolar radiofrequency ablation (RFA; n=264 patients). A pooled analysis of showed a higher rate of amenorrhea with bipolar RFA (OR=4.56; 95% CI, 2.24 to 9.26).

The 2011 assessment from HTA (described earlier) also compared different first- and second-generation endometrial ablation devices. The investigators identified data on 2448 women from 14 trials. When first- and second-generation endometrial ablation devices were compared, there was no significant difference between groups in the rates of amenorrhea after 12 months. When findings from 13 studies were pooled, rates of amenorrhea were 326 (36%) in 899 with first-generation devices and 464 (37%) in 1261 with second-generation devices (OR=1.12; 95% CI, 0.93 to 1.35). Data were insufficient to conduct meta-analyses of longer term amenorrhea rates. Similarly, the rates of abnormal uterine bleeding after 12 months did not differ between groups. In a pooled analysis of 12 studies, rates were 111 (12.3%) in 899 with first-generation devices and 151 (11.8%) in 1281 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 (4/589 [0.7%]) or second-generation (4/880 [0.5%]) devices (OR=0.71; 95% CI, 0.17 to 2.94). The proportion of women requiring hysterectomy within 12 months of endometrial ablation did not differ significantly for first-generation (39/933 [4.2%]) or second-generation (35/1343 [2.6%]) devices were used (11 studies; OR=0.77; 95% CI, 0.47 to 1.24).
Randomized Controlled Trials
Representative RCTs with relatively long-term follow-up are described next. A 2014 double-blind RCT by Sambrook et al in the U.K. reported 5-year outcomes comparing microwave endometrial ablation and thermal balloon endometrial ablation (TheraChoice). The trial included 320 women with heavy menstrual bleeding who were premenopausal and had completed their families. A total of 217 (59%) of 370 women responded to a written questionnaire at 5 years. Analysis was intention-to-treat, with nonresponders classified as treatment failures. Menstrual outcomes did not differ significantly between groups at 5 years. The rates of amenorrhea were 51% in the microwave ablation group and 45% in the thermal ablation group (mean difference [MD], 6.4; 95% CI, -4.7 to 17.4). Moreover, the proportion of patients with light menstrual bleeding was 27% in the microwave ablation group and 33% in the thermal ablation group (MD = -5.8; 95% CI, -18.0 to 6.4). Ten (8.8%) women in the microwave ablation group and 7 (6.8%) women in the thermal ablation group subsequently had a hysterectomy. The between-group difference in the hysterectomy rate was not statistically significant (MD=2.0; 95% CI, -5.1 to 9.1).

In 2013, Herman et al reported 10-year follow-up of a double-blind RCT conducted in the Netherlands. The trial compared bipolar endometrial RFA (NovaSure) with balloon endometrial ablation (TheraChoice) in 126 women who had heavy menstrual bleeding. The 10-year follow-up rate was 69 (69%) of 83 in the RFA group and 35 (81%) of 43 in the balloon ablation group. At 10 years, rate of amenorrhea (the primary outcome) was 50 (73%) of 69 in the RFA group and 23 (66%) of 35 in the balloon ablation group (relative risk [RR], 1.1; 95% CI, 0.83 to 1.50). The long-term analysis was not intention-to-treat. Over the 10 years, 10 women in the RFA group and 5 in the balloon ablation group underwent a hysterectomy (RR=1.0; 95% CI, 0.69 to 1.49).

Section Summary: Comparison of Different Endometrial Ablation Methods
There is no clear evidence that the net health benefit is superior with any method of endometrial ablation compared with any other method. Rates of abnormal uterine bleeding and patient satisfaction were generally similar after treatment with first- and second-generation devices. Meta-analyses of the available data from RCTs have suggested that there are higher rates of certain adverse events with first-generation techniques and higher rates of other adverse events with 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. There were a total of 829 reported adverse events between 2005 and 2011. Nearly two-thirds of the adverse events (540/829 [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 (93/820 [11%]) and transmural uterine thermal activity (89/820 [11%]). Of the 182 thermal injuries, 140 (77%) were associated with RF endometrial ablation. In addition, 47 instances of sepsis or bacteremia were reported, and 43 of the 47 cases (91%) were associated with RF endometrial ablation. There were 4 reported deaths, 2 associated with RF 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 ablation performed during this time period so the proportion of procedures with adverse events cannot be determined from these data.

A 2014 study by Dood et al in the U.K. examined whether women who undergo endometrial ablation are at increased risk of endometrial cancer compared with those with abnormal uterine bleeding that is managed with medication. The data were collected from a population-based cohort in the U.S. and included a total of 234,721 women with abnormal bleeding, 4776 of whom underwent endometrial ablation. During a median follow-up period of 4.1 years, 3 women with a history of endometrial ablation and 601 women who were treated medically developed endometrial cancer. There was not a statistically significant difference in endometrial cancer rates between groups (age-adjusted HR=0.61; 95% CI, 0.20 to 1.89; p=0.17). Moreover, the median time to endometrial cancer diagnosis, 237 days after ablation and 299 days with medical management, did not differ significantly between groups.

Section Summary: Safety
Adverse events have been associated with endometrial ablation procedures. Certain types of adverse events are more likely to occur with particular 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 procedures. Endometrial ablation does not appear to increase the risk of subsequent endometrial cancer.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in July 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

Practice Guidelines and Position Statements

Canadian Task Force on Preventive Health Care: In 2015, the Canadian Task Force (CTF) published a guideline on management of abnormal uterine bleeding of benign origin. The group considers endometrial ablation a "safe and effective minimally invasive surgical procedure that has become a well-established alternative to medical treatment or hysterectomy to treat abnormal uterine bleeding in select cases." CTF notes: “All non-resectoscopic endometrial ablation devices available in Canada have demonstrated effectiveness in decreasing menstrual flow and result in high patient satisfaction. The choice of which device to use depends primarily on surgical judgement and the availability of resources.”

Society for Gyneologic Surgeons (SGS) systematic review group: In 2012, they published a clinical practice guideline on treatment of abnormal uterine bleeding. 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.

Practice Committee of the American Society for Reproductive Medicine (ASRM):
In 2008, the practice committee of the American Society for Reproductive Medicine (ASRM) issued a statement on indications and options for endometrial ablation. 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 overloads 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.”

American College of Obstetricians and Gynecologists

In 2013, the American College of Obstetricians and Gynecologists (ACOG) issued a committee opinion on the management of acute abnormal uterine bleeding in nonpregnant reproductive-aged women. The committee recommended medical management as first-line treatment and stated that surgical management be considered for patients who failed or are not suitable for medical management, or who are not clinically stable. Endometrial ablation was listed as one of the other surgical options, along with dilation and curettage, uterine artery embolization, and hysterectomy. The document stated that endometrial ablation only should be considered for patients who fail other treatments or have a contraindication, when women have no plans for future childbearing, and when endometrial and uterine cancer have been ruled out as the cause of acute uterine bleeding.

In 2007, ACOG published a guideline on endometrial ablation. Recommendations they assessed as being based on good and consistent evidence include:
Endometrial Ablation

- “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.”

National Institute for Health and Clinical Excellence (NICE), United Kingdom: The 2007 NICE guidance on heavy menstrual bleeding includes the following recommendations regarding endometrial ablation:

- Endometrial ablation should be considered in women with heavy menstrual bleeding who have a normal uterus and those with small uterine fibroids (less than 3 cm in diameter).
- In women with heavy menstrual bleeding alone and a uterus no bigger than a 10-week pregnancy, endometrial ablation is preferable to hysterectomy.
- Endometrial ablation may be offered as an initial treatment for heavy menstrual bleeding after full discussion of the risks and benefits, and other treatment options.
- First generation techniques are appropriate if hysteroscopic myomectomy is to be included in the procedure.
- Second generation techniques that can be recommended include,
  - impedance-controlled bipolar radiofrequency ablation,
  - fluid-filled thermal balloon endometrial ablation,
  - microwave endometrial ablation and
  - free fluid thermal endometrial ablation.

U.S. Preventive Services Task Force Recommendations

Endometrial ablation is not a preventive service.

Summary of Evidence

For individuals who have abnormal uterine bleeding and have failed hormonal therapy who receive endometrial ablation, the evidence includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, quality of life, resource utilization, and treatment-related morbidity. RCTs and systematic reviews of RCT data have found that hysterectomy resulted in greater symptom relief and fewer reoperations than endometrial ablation, but endometrial ablation resulted in a reasonable level of symptom control and the procedure has some advantages over hysterectomy (eg, women retain their uterus and avoid a more invasive procedure). A meta-analysis of RCTs suggested similar benefits with first-generation (hysteroscopic) techniques and second-generation (mainly nonhysteroscopic) techniques. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Medicare National Coverage

No national coverage determination.
References

8. Sambrook A, Elders A, Cooper K. Microwave endometrial ablation versus thermal balloon endometrial ablation (MEATBall): 5-year follow-up of a randomised controlled trial. BJOG. May 2014;121(6):747-753. PMID 24506529

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td></td>
</tr>
<tr>
<td>December 2012</td>
<td>Update Policy</td>
<td>Policy updated with literature review. References 2, 4 and 11 added; other references renumbered or removed. No change to policy statements.</td>
</tr>
</tbody>
</table>
Keywords

Endometrial Ablation
Her Option™ Uterine Cryoablation Therapy™ System
Intrauterine Ablation
Laser Ablation of the Endometrium
Liquid-Filled Balloons Used in Endometrial Ablation
Rollerball Ablation of the Endometrium
ThermChoice
Hydro ThermAblator
Microwave endometrial ablation
The NovaSure

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 16, 2016 and is effective October 15, 2016.

Signature on file
Deborah M. Smith, MD, MPH