
Medical Policy



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(See policy history boxes for previous effective dates)

Title: Endometrial Ablation

Description/Background

Ablation or destruction of the endometrium is used to treat abnormal uterine bleeding in women who have failed standard therapy. It is considered a less invasive alternative than hysterectomy; however, as with hysterectomy, the procedure is not recommended for women who want to preserve fertility.

Endometrial ablation has become an increasingly popular treatment for women beyond parity who are experiencing abnormal uterine bleeding. It is a minimally invasive surgical destruction of the uterine lining, which is accomplished under hysteroscopic visualization, using resectoscopic instruments. It can also be performed with a non-resectoscopic ablation device, which is inserted into the uterine cavity and delivers energy to uniformly destroy the uterine lining.

Multiple energy sources have been used, which include: a Nd-YAG laser; a resecting loop using electric current; microwave therapy; electrode array; cryosurgical device; minitouch 3.8 Era System; an 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 require hysteroscopic procedures and those that do not (other terminology for these categories of techniques includes first-generation versus second-generation procedures and resectoscopic versus nonresectoscopic endometrial ablation methods). Hysteroscopic techniques were developed first; the initial technique was photo-vaporization 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, the 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 which requires very accurate fluid monitoring.

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 radiofrequency ablation.

There are concerns about morbidity and mortality for both the mother and the fetus when becoming pregnant after endometrial ablation. Thus, Food and Drug Administration (FDA) approval of endometrial ablation devices includes only women for whom childbearing is complete.

NOTE: 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.

Regulatory Status:

Endometrial devices have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for use in premenopausal women with abnormal uterine bleeding due to benign causes in whom childbearing is complete. These devices 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:

- AEGEA Vapor System™ (AEGEA Medical Inc., Redwood City, CA): A slender probe is inserted into the uterine cavity, and 3 balloons are inflated to secure the probe and seal the uterus. The system conducts safety tests before delivering vapor to the uterine lining for 2 minutes. The balloons automatically deflate and the probe is removed. Name changed to the Mara Water Vapor Ablation System (11/4/19).
- Cerene® Cryotherapy Device (Channel Medsystems, Inc., Emeryville, CA): The Cerene Cryotherapy Device uses nitrous oxide (N₂O) to freeze and ablate the endometrium to reduce future menstrual bleeding. (2019; P180032).
- Genesys HTA™ system (Boston Scientific, Natick, MA) AKA Hydro ThermAblator® Endometrial Ablation System (BEI Medical Systems Co, Inc., Teterboro, NJ; 2001): The device is a closed loop system designed to ablate the endometrial lining of the uterus by recirculating heated saline within the uterus. The saline is heated to a temperature of 90 °C by a heating element located in the external heater canister, fed to the uterus by gravity and recirculated via an aspiration pump. The system includes various alarms and sensors to monitor the 10-minute treatment cycle. (2010; P00040)
- Her Option Office Cryoablation Therapy System (Cooper Surgical, Inc., Trumbull, CT) AKA Her Option™ Uterine Cryoablation Therapy™ System (American Medical Systems, Minnetonka, MN; 2001): 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. (2018; P000032).

- Hydro ThermAblator® Endometrial Ablation System (BEI Medical Systems: Teterboro NJ): The system involves the instillation and circulation of heated saline into the uterus using hysteroscopic guidance. The Genesys HTA™ system (also Boston Scientific) is a newer version of this technology that includes features, such as a smaller console and simplified set-up requirements. (2001; P0000400)
- Mara Water Vapor System (Cooper Surgical, Inc.; Trumbull, CT) AKA AEGEA Vapor System™ (AEGEA Medical, Inc., Redwood City, CA; 2017): This system uses an AC powered vapor generator which receives water from a de-ionized water supply and delivers vapor to the endometrium for 120 seconds. (2019; P160047).
- MicrosulisThe Microwave Endometrial Ablation (MEA) system (Microsulis Medical, Riverview, FL): This system delivers fixed-frequency microwave energy and may be performed in a physician's office and requires use of the hysteroscope. (2003; P020031).
- Minitouch 3.8 Era System (Minitouch System) MicroCube, LLC: used to treat heavy menstrual bleeding. These types of devices use a cold or heat energy source to destroy (thermally ablate) the lining of the uterus (endometrium) as a whole. (2023; P230002)
- Minerva™ Endometrial Ablation System (Minerva Surgical, Redwood City, CA): This device utilizes thermal heat. A sealed silicone membrane is deployed and conforms to the uterus. An electrical current ionizes argon gas, converting it to plasma which heats the silicone membrane and the uterine lining. (2015; P140013).
- The NovaSure™ Impedance-Controlled Endometrial Ablation System (Hologic, Inc., 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. (2001; P010013).
- The ThermoChoice® 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, women 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 manufacturer elected to discontinue this device in 2016. (1997; P970021)

Product code: MNB

Medical Policy Statement

The safety and effectiveness of endometrial ablation has been established. It may be considered a useful therapeutic option when indicated and using an FDA approved device, in individuals who are NOT candidates for, or are unresponsive to, hormone therapy and would otherwise be considered candidates for hysterectomy.

Inclusionary and Exclusionary Guidelines

Endometrial ablation is appropriate for premenopausal individuals with abnormal uterine bleeding due to benign causes.

Inclusions (ALL criteria must be met):

- Individuals with documented history of abnormal uterine bleeding or patient-perceived heavy menstrual bleeding
- Individuals who have had a D&C or endometrial biopsy that fails to show evidence of endometrial cancer or pre-cancerous changes of the endometrium such as endometrium hyperplasia
- Individuals who have no submucosal fibroids larger than 3 cm in diameter in the non-resectoscope method
- Individuals with a uterine sound no greater than 10 cm in the non-resectoscope approach and 14 cm for microwave ablation
- Individuals for whom childbearing is complete
- In the presence of Essure® contraceptive micro-inserts, correct placement of the Essure micro-insert must be confirmed, (e.g., by obtaining the report of the Essure Confirmation Test), prior to performing the NovaSure procedure.

Exclusions:

Contraindications for endometrial ablation include:

- Individual who is pregnant or desires pregnancy
- Suspicion/history of endometrial carcinoma or precancerous histology
- Individuals with active genital or urinary tract infection at the time of the procedure
- Individuals with active pelvic inflammatory disease or hydrosalpinx
- Individuals with an intrauterine device currently in place
- Individuals with any anatomical or pathologic condition in which weakness of myometrium could exist, such as history of previous classic cesarean section or intramural myomectomy (structural abnormalities, polyps or fibroids) in the non-resectoscope approach

In addition, contraindications for *microwave* or radiofrequency ablation include:

- Myometrial thickness less than 10 mm
- Uterine sounding length less than 6 cm

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

58353

58356

58563

Other codes (investigational, not medically necessary, not a benefit, etc.):

N/A

Rationale

ENDOMETRIAL ABLATION

Minalt et al (2021) described 2 techniques for endometrial ablation: resectoscopic and non-resectoscopic. The first-generation technique (resectoscopic) is performed under hysteroscopic guidance using a rollerball, monopolar, or bipolar loop electrode. The endometrium is desiccated to the level of the basalis layer using thermal energy. The major disadvantage to resectoscopic endometrial ablation is operator expertise and safety. Second generation techniques (nonresectoscopic) include thermal fluid, microwave or bipolar radiofrequency electrical energy, laser thermotherapy, and cryoablation. These options have become popular due to the ease of use, safety, and similar outcomes to resectoscopic techniques. Appropriate patient selection for endometrial ablation was emphasized for the treatment of abnormal uterine bleeding. Women of reproductive age who have met their desired parity with heavy menstrual bleeding due to a benign cause that significantly impacts their quality of life were named as the ideal candidates. Contraindications listed included pregnancy or fertility preservation, endometrial hyperplasia or uterine malignancy, active pelvic infection, intrauterine device, history of transmyometrial uterine surgery including classical cesarean section or myomectomy, uterine anomaly such as septate, bicornuate, or unicornuate uterus, and relative contraindications included postmenopausal state, uterine cavity length greater than 10 cm to 12 cm, severe myometrial thinning, or severe uterine retroflexion or antelexion.

Endometrial Ablation versus Hysterectomy

Systematic Reviews

A systematic review of randomized controlled trials (RCTs) by Matteson et al (2012) compared the efficacy of hysterectomy and less invasive techniques for controlling abnormal uterine bleeding. Reviewers identified 9 trials reporting health outcomes, 7 of which compared hysterectomy with 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 measures, 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 postoperative period. Reviewers judged the quality of evidence on pain to be low, with results favoring 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 that study found a significantly lower rate of pain at 2- to 3-year follow-up in the group receiving hysterectomy. All 7 trials reported additional treatments obtained by participants after the initial intervention; between 1- to 4-year follow-up, the proportion of women in the ablation group who had an additional surgical procedure for bleeding ranged from 16% to 42%; of these, 10% to 29% were treated with hysterectomy.

Bhattacharya et al (2011) conducted a systemic review of individual patient data from RCTs evaluating second-line treatments for abnormal uterine bleeding via the Health Technology Assessment (HTA) program. Reviewers identified data on 1127 women from 7 trials comparing first-generation devices with hysterectomy (a limitation of this review is that individual patient data were not available for approximately 35% of women randomized in the trials). The most frequently measured outcome was patient satisfaction/dissatisfaction, and this was used as the primary outcome of the meta-analysis. After 12-month 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 program analyzed individual patient data from national databases in Scotland to evaluate long-term outcomes after hysterectomy or endometrial ablation. Reviewers identified 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 ablations 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 (0.5%) than after hysterectomy (1.1%; adjusted HR=0.55; 95% CI, 0.41 to 0.74).

Randomized Controlled Trials

Zupi et al (2015) published the 15-year results from the RCT with the longest follow-up. The trial, 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 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 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.

Subsection Summary: Endometrial Ablation versus Hysterectomy

The evidence suggests better outcomes (e.g., bleeding control, pelvic pain) and fewer additional surgeries in women who have hysterectomy than endometrial ablation. However, endometrial ablation is less invasive and involves retention of the uterus. Most of the studies comparing hysterectomy with endometrial ablation used first-generation techniques; there is less evidence comparing hysterectomy with second-generation techniques.

Different Endometrial Ablation Methods

Systematic Reviews

Numerous RCTs and several systematic reviews of RCTs have compared different methods of endometrial ablation. Angioni et al (2016) published a systematic review of published evidence on first- versus second-generation endometrial ablation techniques. Reviewers 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 (e.g., perforation and cervical laceration) were more common with first-generation techniques and others (e.g., uterine cramping and pain) were more common with second-generation techniques.

A Cochrane review by Lethaby et al (2013) 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. Twenty-five 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 women to have been unable to tolerate 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 was not reported.

There were only a few studies on any given comparison of techniques; the exception was balloon ablation (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 not a significant difference between groups in the satisfaction rate at 1 year (OR=0.99; 95% CI, 0.93 to 1.06).

Reviewers also conducted an overall analysis of studies comparing first- and second-generation techniques. A pooled analysis of 12 studies (total n=2085 patients) did not find a statistically significant difference in the rates 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, again 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 rate 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.

Daniels et al (2012) 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, reviewers 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 (total n=516). 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) (total n=264). 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. Reviewers 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 the number of 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 after endometrial ablation did not differ significantly when 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. For example, a double-blind RCT by Sambrook et al (2014) in the U.K. reported 5-year outcomes comparing microwave endometrial ablation and thermal balloon endometrial ablation (ThermaChoice). The trial included 320 women with heavy menstrual bleeding who were premenstrual 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 non-responders classified as treatment failures. Menstrual outcomes did not differ significantly between groups at 5 years. The rate 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).

Herman et al (2013) reported a 10-year follow-up of a double-blind RCT conducted in the Netherlands. The trial compared bipolar endometrial ablation RFA (NovaSure) with balloon endometrial ablation (ThermaChoice) 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, the 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, 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 five women in the balloon ablation group underwent a hysterectomy (relative risk, 1.0; 95% CI, 0.69 to 1.49).

Subsection Summary: 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 suggest 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 and Efficacy of Endometrial Ablation

Famuyide (2018) reviewed available literature with singular reference to nonresectoscopic endometrial ablation procedures. Multiple nonresectoscopic devices are approved for use in the United States in addition to resectoscopic techniques that rely on the skillful use of the operative hysteroscope. Authors determined that regardless of the technique used, endometrial ablation uniformly reduces menstrual blood loss, improves general and menstrual-related quality of life, and prevents hysterectomy in 4 of 5 women who undergo the procedure. When patients are appropriately selected, outcomes are optimized, and risks of serious complications are minimized.

Brown and Blank (2012) analyzed events associated with endometrial ablation procedures reported in the U.S. Food and Drug Administration's Manufacturer and User Facility Device Experience database. A total of 829 adverse events were reported between 2005 and 2011. Nearly two-thirds (540/829 [65%]) of the adverse events were genital tract or skin burns, and 529 (98%) of these events 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 endometrial RFA. In addition, 47 instances of sepsis or bacteremia were reported, and 43 (91%) of these 47 cases were associated with endometrial RFA. Four deaths were reported, 2 associated with RFA and 1 each associated with thermal balloon ablation and cryoablation. Sixty-six (8%) of the 829 events 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.

Dood et al (2012) examined whether women who undergo endometrial ablation are at increased risk of endometrial cancer compared with those with abnormal uterine bleeding managed with medication. Data were collected from a population-based cohort in the United States and included a total of 234,721 women with abnormal bleeding, 4776 of whom underwent endometrial ablation. During a median follow-up 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.

Subsection Summary: Safety

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

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 provided 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 (e.g., women retain their uterus and avoid a more invasive procedure). A meta-analysis of RCTs has 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.

Supplemental Information

PRACTICE GUIDELINES AND POSITION STATEMENTS

The Society of Obstetricians and Gynaecologists of Canada

The Society of Obstetricians and Gynaecologists of Canada (SCOG; 2013) published guidelines on management of abnormal uterine bleeding of benign origin. The group considered 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.” The Task Force noted: “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 judgment and the availability of resources.”

In 2018, SOGC released updated guidelines indicating that non-hysteroscopic ablation techniques offer similar patient satisfaction results with fewer risks of complications and less anesthetic requirement than traditional hysteroscopic ablation. Recommendations were made for non-hysteroscopic ablation techniques to be the method of choice in appropriate candidates as they have shown a higher efficacy and safety rates than hysteroscopic techniques.

Society for Gynecologic Surgeons

The Society for Gynecologic Surgeons (2012) published clinical practice guidelines on treatment of abnormal uterine bleeding. The guidelines recommended 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 postoperative procedural risk, and a shorter hospital stay, endometrial ablation is recommended.

American Society for Reproductive Medicine

The Practice Committee of the American Society for Reproductive Medicine (2008) issued a statement on indications and options for endometrial ablation. Conclusions were:

- “Endometrial ablation is an effective therapeutic option for the management of menorrhagia (abnormal uterine bleeding).
- 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 Society stated 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

Health Care for Transgender Individuals - Committee Opinion No. 823; March 2021.

The American College of Obstetricians and Gynecologists opposes discrimination on the basis of gender identity, urges public and private health insurance plans to cover necessary services for individuals with gender dysphoria, and advocates for inclusive, thoughtful, and affirming care for transgender individuals.

- Patients should be counseled that menses likely will cease within a few months after initiating hormone therapy. If bleeding continues, the obstetrician–gynecologist may

consider adding progesterone therapy to facilitate amenorrhea for patients who wish to avoid hysterectomy or endometrial ablation.

Endometrial ablation - Committee Opinion No. 81; 2007

The American College of Obstetricians and Gynecologists (ACOG-2013) issued an opinion on the management of acute abnormal uterine bleeding in nonpregnant women of reproductive age. ACOG 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 a surgical option, along with dilation and curettage, uterine artery embolization, and hysterectomy. ACOG stated that endometrial ablation only should be considered for patients who have failed 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. (Reaffirmed 2019)

ACOG (2007) published a guideline on endometrial ablation. The guidelines, reaffirmed in 2018, made recommendations assessed as being based on good and consistent evidence included:

- 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.

Endocrine Society

According to the Endocrine Society guideline on gender-dysphoric/gender-incongruent persons, the cessation of menses may occur within a few months with testosterone treatment alone, although high doses of testosterone may be required. If uterine bleeding continues, the addition of a progestational agent or an endometrial ablation maybe considered. To stop menses prior to testosterone treatment clinicians may also use gonadotropin-releasing hormone analogs or depot medroxyprogesterone.

National Institute for Health and Clinical Excellence

The National Institute for Health and Clinical Excellence's (2018; updated 2021) guidance on heavy menstrual bleeding included the following recommendations on endometrial ablation:

- Endometrial ablation should be considered in women with heavy menstrual bleeding (HMB who have a normal uterus and also those with small uterine fibroids (less than 3 cm in diameter).
- In women with heavy menstrual bleeding alone, with 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.
- The second-generation techniques recommended for consideration are as follows:

- Impedance-controlled bipolar radiofrequency ablation...
- Fluid-filled thermal balloon endometrial ablation...
- Microwave endometrial ablation
- Free fluid thermal endometrial ablation.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

A search of ClinicalTrials.gov did not identify any ongoing or unpublished trials that would likely influence this review.

Government Regulations

National:

There is no national or local coverage determination.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Gender Affirming Services

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 5/1/24, the date the research was completed.

BCN Medical Policy History

Date	Rationale
3/31/10	BCN policy established
4/20/11	Routine maintenance
5/16/12	Routine maintenance
6/19/13	Removed exclusion “The presence of Essure contraceptive micro-inserts” and added the inclusion: “In the presence of Essure contraceptive micro-inserts, correct placement of the Essure micro-insert must be confirmed, e.g., by obtaining the report of the Essure Confirmation Test (ECT), prior to performing the NovaSure procedure”; no change in policy position.
7/16/14	Routine maintenance
8/19/15	Routine maintenance; references updated
8/17/16	• Routine maintenance; rationale, background, MPS and references updated • Policy in line with BCBSA; JUMP inclusions/exclusions provide further clarification
8/23/17	• Routine maintenance
7/18/18	• Routine maintenance
7/17/19	• Routine maintenance
7/9/20	• Routine maintenance
7/15/21	• Routine maintenance
7/7/22	• Routine maintenance
7/13/23	• Routine maintenance (slp); Vendor managed: N/A
7/11/24	• Routine maintenance (slp); Vendor managed: N/A; Policy RETIRED

Next Review: Policy retired. This is an established procedure and no longer requires routine review.

MEDICAL POLICY TITLE: ENDOMETRIAL ABLATION
BCN BENEFIT ADMINISTRATION

I. Coverage Determination

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; policy criteria apply.
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.