



**BlueCross BlueShield
of Alabama**

Name of Blue Advantage Policy:
Endometrial Ablation

Policy #: 453
Category: Surgical

Latest Review Date: August 2017
Policy Grade: B

Background/Definitions:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

Description of Procedure or Service:

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

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 neodymium-yttrium aluminum garnet (Nd-YAG) laser; a resecting loop using electric current; electric rollerball; and thermal ablation devices, including high-frequency radiofrequency (RF) probes, cryoprobes, liquid-filled balloons, multi-electrode balloons, microwave energy, and installation of heated saline. Endometrial ablation is typically preceded by hormonal treatment to thin the endometrium.

Techniques for endometrial ablation are generally divided into two 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 or TCRE). 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.

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.

There are concerns about maternal and fetal morbidity and mortality associated with pregnancy after endometrial ablation. Thus, FDA approval of endometrial ablation devices includes only women for whom childbearing is complete.

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.

Policy:

Effective for dates of service on or after December 7, 2010:

Blue Advantage will treat endometrial ablation, with or without hysteroscopic guidance, using an FDA-approved device, as a covered benefit in women with ~~menorrhagia~~ abnormal uterine bleeding who are not candidates for, or who are unresponsive to, hormone therapy and would otherwise be considered candidates for hysterectomy.

Blue Advantage will treat endometrial ablation as non-covered and investigational 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.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

This policy is regularly updated with searches of the MEDLINE database. Most recently, the literature was reviewed through June 22, 2017. The following is a summary of the key literature to date.

Endometrial Ablation and Hysterectomy **Systematic Reviews and Meta-Analyses**

A 2012 systematic review of randomized controlled trials (RCTs) by Matteson and colleagues compared the efficacy of hysterectomy and less invasive techniques for controlling abnormal uterine bleeding. The authors identified nine trials directly comparing hysterectomy with another intervention and reporting health outcomes; seven of these studies compared hysterectomy to endometrial ablation. The seven studies included a total of 1,167 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 one study compared rates statistically, and this study found a significantly lower rate of pain at two to three years' follow-up in the group receiving hysterectomy. All seven trials reported additional treatments obtained by participants after the initial intervention. At one to four 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 1,127 women from seven 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<0.0001).

In addition, 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 ablations 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).

Randomized Controlled Trials

The RCT with the longest follow-up was 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 of these (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 than the hysterectomy group (20/71 women [28.1%] vs 0/71, p<0.001). The 20 women who had repeat surgery all 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.

Section Summary: Endometrial Ablation and Hysterectomy

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

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.

The 2011 assessment from the HTA, described above, also included comparisons of different endometrial ablation methods. The investigators identified data on 2,448 women from 14 trials comparing first- and second-generation endometrial ablation devices. 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]).

A 2012 review by 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 comparisons included 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 two types of 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 (RF) (total n=264). A pooled analysis of showed a higher rate of amenorrhea with bipolar RF (OR=4.56; 95% CI, 2.24 to 9.26).

A 2013 Cochrane review included RCTs that compared 2 ablation techniques, or compared first- and second-generation techniques. Primary outcomes of interest were change in menstrual bleeding and rates of patient satisfaction. A total of 25 studies with 4056 premenopausal women were eligible for the review. Seven of the studies were multicenter; 6 of these were based in the U.S. 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 was not reported.

There were only a few studies on any given comparison of techniques; the exception was balloon ablation (second generation) versus rollerball ablation (first generation) for which there were 3 studies (total n=352). 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 in the satisfaction rate at one 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) did not find a statistically significant difference in the rate of amenorrhea at one 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, and there was not a 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) and cervical lacerations (8 studies) and hematometra (5 studies) were significantly higher with first-generation techniques than with second-generation techniques. 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 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 efficacy and patient satisfaction rates. 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.

Randomized Controlled Trials

Representative RCTs with longer term follow-up are described below:

In 2013, Herman et al reported ten year follow-up of a double-blind RCT conducted in the Netherlands. The trial compared bipolar RF endometrial ablation (Novasure) with balloon endometrial ablation (Thermachoice) in 126 women who had heavy menstrual bleeding. The 10 year follow-up rate was 69 of 83 (69%) in the RF ablation group and 35 of 43 (81%) in the balloon ablation group. At 10 years, rate of amenorrhea, the primary outcome, was 50 of 69 (73%) in the RF ablation group and 23 of 35 (66%) 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 RF ablation group and 5 in the balloon ablation group underwent a hysterectomy (RR=1.0, 95% CI, 0.69 to 1.49).

A 2014 study by Sambrook et al in the U.K. reported 5-year outcomes of a double-blind RCT comparing microwave endometrial ablation and thermal balloon endometrial ablation (Thermachoice). The study included 320 women with heavy menstrual bleeding who were premenstrual and had completed their families. A total of 217 of 370 women (59%) responded to a written questionnaire at 5 years. The analysis was intention-to-treat, with nonresponders classified as treatment failures. Menstrual outcomes did not differ significantly between groups at 5 years. The rate of amenorrhea was 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 women (8.8%) in the microwave ablation group and 7 women (6.8%) in the thermal ablation group subsequently had a hysterectomy. The difference between groups in the hysterectomy rate was not statistically significant (MD, 2.0, 95% CI, -5.1 to 9.1).

Section Summary: Different Endometrial Ablation Methods

There is no clear evidence that the net health benefit is superior with any method of endometrial ablation compared to any other method. Rates of menorrhagia 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

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 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 the 47 cases (91%) were associated with radiofrequency endometrial ablation. There were 4 reported deaths, 2 associated with radiofrequency ablation and one 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.

Summary of Evidence

For individuals who have abnormal uterine bleeding who 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 e.g., women are able to retain their uterus and avoid a more invasive procedure. A meta-analysis of RCTs suggest similar benefits with first-generation (hysteroscopic) techniques and second-generation (mainly non-hysteroscopic) techniques. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

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 note: “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 Gynecologic Surgeons (SGS)

In 2012, the Society for Gynecologic Surgeons (SGS) systematic review group 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.

American Society for Reproductive Medicine (ASRM):

In 2008, the Practice Committee of the American Society for Reproductive Medicine 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 non-hysteroscopic 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 two 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.

- Non-hysteroscopic 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 (ACOG):

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:

- “For women with normal endometrial cavities, resectoscopic endometrial ablation and non-resectoscopic endometrial ablation systems appear to be equivalent with respect to successful reduction in menstrual flow and patient satisfaction at one 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
 - Free fluid thermal endometrial ablation.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Key Words:

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, ThermaChoice®, Hydro ThermAblator, HTA, Microwave endometrial ablation, NovaSure™, rollerball ablation, balloon ablation, microwave ablation, Genesys HTA™, endometrial cryoablation, hysteroscopy with endometrial ablation, electrosurgical ablation, thermoablation, abnormal uterine bleeding

Approved by Governing Bodies:

Endometrial devices have been approved by FDA through the premarket approval process 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 the 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.
- 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.
- The NovaSure™ impedance-controlled endometrial ablation system (Cytac 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.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

Current Coding:

CPT Codes:

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)

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Medical Policy Group, October 2010

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Medical Policy Group, July 2015

Medical Policy Group, August 2016

Medical Policy Group, August 2017

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.