Name of Policy:  
Endometrial Ablation

Policy #: 453
Category: Surgical
Latest Review Date: July 2014
Policy Grade: B

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
Endometrial ablation is a potential alternative to hysterectomy for menorrhagia. 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.

Policy:
Endometrial ablation, with or without hysteroscopic guidance, using an FDA-approved device meets Blue Cross and Blue Shield of Alabama’s medical criteria in women with menorrhagia who are not candidates for, or who are unresponsive to, hormone therapy and would otherwise be considered candidates for hysterectomy.

Endometrial ablation does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered 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 Cross and Blue Shield of Alabama 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 Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate 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 was originally created in 1995 following a 1991 TEC Assessment. The policy is regularly updated with searches of the MEDLINE database. The following is a summary of the key literature to date:

**Comparison between endometrial ablation and hysterectomy**
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 four 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=0.0002).

In addition to the meta-analyses of data from published studies, the HTA included an analysis of individual patient data from national databases in Scotland to evaluate long-term outcomes after hysterectomy or endometrial ablation. The investigators identified a total of 37,120 women who underwent hysterectomy and 11,299 women who underwent endometrial ablation for dysfunctional uterine bleeding between 1989 and 2006. Women who received endometrial 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).
Section Summary
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.

Comparison among different endometrial ablation methods
Numerous RCTs and several systematic reviews of RCTs have been published comparing different methods of endometrial ablation. Most recently, in 2013, an updated systematic review and meta-analysis by the Cochrane collaboration was published. The review included RCTs that compared two 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; six 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 two first-generation ablation techniques and five 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 one or two studies on any given comparison of techniques; the exception was balloon ablation (second generation) versus rollerball ablation (first generation) for which there were three studies (total n=352). A pooled analysis of these three studies found a statistically lower rate of amenorrhea at one 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).

The investigators 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 one 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 (eight studies), endometritis (five studies), or hemorrhage (five studies) using first-versus second-generation ablation techniques. Rates of fluid overload (four studies) and cervical lacerations (eight studies) and hematometra (five 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.
Previously, a 2012 review by Daniels et al identified 14 trials comparing first- and second-generation methods and five trials comparing two 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 one 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, three 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).

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 six 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]).

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

A 2014 study by Sambrook et al in the U.K. reported five-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 five years. The analysis was intention-to-treat, with nonresponders classified as treatment failures. Menstrual outcomes did not differ significantly between groups at five 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 seven 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).

In 2013, Herman et al reported 10-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 five in the balloon ablation group underwent a hysterectomy (RR=1.0, 95% CI, 0.69 to 1.49).

A 2010 study by Iglesias et al attempted to identify which women are most likely to fail treatment with endometrial ablation. This was a retrospective analysis of data on 142 women who were treated with hydrothermal ablation at a single institution. Patients had a median age of 40 years (range: 22–53 years) at the time of treatment. After a mean follow-up of 12 months, 97 women (68%) had a significant reduction in vaginal bleeding and were considered treatment successes, and the remaining 45 women (32%) were considered treatment failures. A total of 26 of the 142 women (18%) ultimately received a hysterectomy. Factors associated with treatment failure included younger age, tobacco use, and menometrorrhagia. Women who were at least age 45 years had a 16% treatment failure rate compared to a 38% rate in women younger than 45 years (p=0.014). The 35 women who smoked tobacco had a 46% treatment failure rate compared to a 27% failure rate in the 103 non-smokers (p=0.042). Sixty-five women reported menometrorrhagia and had a 42% treatment failure rate compared to the 75 women who reported only menorrhagia and had a 24% failure rate. Race (white versus other) and body mass index (BMI) (less than 30 or 30 and higher) were not significantly associated with treatment failure. These results have not been replicated in other studies.

**Section Summary**

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 two 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 four reported deaths, two 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, three 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
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
There is evidence from multiple randomized controlled trials that endometrial ablation improves the net health outcome in women who have failed prior treatment for menorrhagia and are otherwise eligible for hysterectomy. Moreover, meta-analyses of randomized controlled trials suggest similar benefits with first-generation (hysteroscopic) techniques and second-generation (mainly non-hysteroscopic) techniques. There is a lack of consistent evidence that any one ablation technique is superior to another. Thus, endometrial ablation using an FDA-approved device may be considered medically necessary in women with menorrhagia who have failed hormonal treatment and would be considered candidates for hysterectomy.

Practice Guidelines and Position Statements
Society for Gynecologic 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, ASRM reviewed their 2006 Practice Committee report and reissued their 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 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 and free fluid thermal endometrial ablation.

U.S. Preventive Services Task Force:
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

Approved by Governing Bodies:
The U.S. Food and Drug Administration (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 Hydro ThermAblator® system (Boston Scientific, Natick, MA): This involves the instillation and circulation of heated saline into the uterus using hysteroscopic guidance.
• The Genesys HTA™ system (also Boston Scientific), a newer version of this technology that includes features such as a smaller console and simplified set-up requirements, was approved by the FDA in May 2010.
• The Microwave Endometrial Ablation (MEA) system (Microsulis Medical, 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.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP: Special benefit consideration may apply. Refer to member’s benefit plan.

**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)

**References:**
4. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Intrauterine ablation or resection of the endometrium for menorrhagia. TEC Evaluations 1991; Volume 6, 296.

Policy History:
Medical Policy Group, December 1995 (3)
Medical Policy Group, November 1999 (3)
Medical Policy Group, October 2000 (3)
Medical Policy Group, July 2002 (2)
Medical Policy Panel, December 2005
Medical Policy Group, January 2006 (2)
Medical Policy Panel, July 2010
Medical Policy Group, October 2010 (2)
Medical Policy Administration Committee, October 2010
Available for comment October 21 through December 6, 2001
Medical Policy Group, July 2011(2): Updated Policy, Key Points, & References
Medical Policy Administration Committee, August 2011
Available for comment August 11 – September 26, 2011
Medical Policy Panel, July 2012
Medical Policy Group, July 2012 (2): Updated Key Points & References; no change to policy statement
Medical Policy Panel, July 2013
Medical Policy Group, September 2013 (1): Update to contradictions under policy section with FDA downgrade to warning for Essure contraceptive micro inserts; upgrade to Key Points and References; no change to policy statement
Medical Policy Panel, July 2014
Medical Policy Group, July 2014 (1): Update to Key Points and References; no change to policy statement

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.