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

Endometrial ablation is considered investigational for all other indications.

Contraindications for intrauterine ablation or resection of the endometrium include:
- Patient who is pregnant or desires pregnancy
- History of endometrial cancer or precancerous histology
- Patient with active genital or urinary tract infection at the time of the procedure
- Patient with active pelvic inflammatory disease
- Patient with an intrauterine device currently in place
- Patient with anatomic or pathologic condition for 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.

Endometrial ablation is a potential alternative to hysterectomy for treatment of abnormal uterine bleeding. When considering treatment, 2 techniques present themselves: the hysteroscopic technique (e.g., Nd-YAG laser, electrosurgical rollerball) and the nonhysteroscopic techniques (e.g., cryosurgical, radiofrequency ablation).

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these
instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**Regulatory Status**

Endometrial devices have been approved by the Food and Drug Administration through the premarket approval process for use in premenopausal women who are no longer bearing children and experiencing abnormal uterine bleeding due to benign causes. 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. Table 1 provides examples of devices for endometrial ablation.

**Table 1. Endometrial Ablation Devices Approved by the Food and Drug Administration**

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Method/ Energy Source</th>
<th>Date Cleared</th>
<th>PMA No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ThermaChoice® Uterine Balloon Therapy</td>
<td>Gynecare</td>
<td>Nonhysteroscopic/heated 5% dextrose in water filled balloon</td>
<td>12/12/97</td>
<td>P970021</td>
</tr>
<tr>
<td>HydroThermAblator® Endometrial Ablation System</td>
<td>Boston Scientific</td>
<td>Hysteroscopic/closed loop/heated saline</td>
<td>04/20/01</td>
<td>P000040</td>
</tr>
<tr>
<td>Genesys HTA™ System</td>
<td>Cooper Surgical</td>
<td>Nonhysteroscopic/cryoablation</td>
<td>04/23/10</td>
<td>P000040 S014</td>
</tr>
<tr>
<td>NovaSure Impedance Controlled Endometrial Ablation System</td>
<td>Hologic</td>
<td>Nonhysteroscopic/radiofrequency</td>
<td>09/28/01</td>
<td>P010013</td>
</tr>
<tr>
<td>Microsulis Microwave Endometrial Ablation (MEA) System</td>
<td>Microsulis Medical</td>
<td>Nonhysteroscopic/microwave</td>
<td>09/23/03</td>
<td>P020031</td>
</tr>
<tr>
<td>Minerva Endometrial Ablation System</td>
<td>Minerva Surgical</td>
<td>Nonhysteroscopic/radiofrequency</td>
<td>07/27/15</td>
<td>P140013</td>
</tr>
<tr>
<td>AEGEA Vapor System™</td>
<td>AEGEA Medical</td>
<td>Nonhysteroscopic/heated water vapor</td>
<td>06/14/17</td>
<td>P160047</td>
</tr>
</tbody>
</table>

PMA: premarket approval.

Heated Fluid Devices:
- The ThermaChoice® 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 Genesys HTA™ 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.

Cryoablation Devices:
- Her Option™ Uterine Cryoablation Therapy 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 endometrial tissue. Cryoablation is typically monitored by abdominal ultrasound.

Radiofrequency Devices:
- The Microwave Endometrial Ablation (MEA) System delivers fixed-frequency microwave energy, may be performed in a physician’s office, and requires the use of the hysteroscope.
4.01.04 Endometrial Ablation

- The NovaSure™ Impedance Controlled Endometrial Ablation System consists of an electrode array on a stretchable porous fabric that conforms to the endometrial surface.

Food and Drug Administration product code: MNB.

**Rationale**

**Background**

**Abnormal Uterine Bleeding**

A number of conditions cause abnormal uterine bleeding, including fibroids, polyps, and endometrial hyperplasia. Prevalence estimates for abnormal uterine bleeding range between 10% and 30%, varying by population and condition definition.¹

**Treatment**

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.

Multiple energy sources have been used, which include: an Nd-YAG laser; a resecting loop using electric current; 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 vs second-generation procedures and resectoscopic vs 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.

Nonhysteroscopic techniques can be performed without general anesthesia and do not involve the use of a fluid distention medium. Techniques include a 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, the Food and Drug Administration approval of endometrial ablation devices includes only women for whom childbearing is complete.

**Literature Review**

This review was informed by a Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment (1991).²

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.
To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

**Endometrial Ablation**

**Clinical Context and Therapy Purpose**

The purpose of endometrial ablation in patients who have abnormal uterine bleeding and have failed hormonal treatment is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does endometrial ablation improve the net health outcome in women with abnormal uterine bleeding?

The following PICOTS were used to select literature to inform this review.

**Patients**

The relevant population of interest is women with abnormal uterine bleeding who have failed standard medical and hormonal therapy.

**Interventions**

The therapy being considered is endometrial ablation using an energy source. Energy sources include an Nd-YAG laser; a resecting loop using electric current; an electric rollerball; and thermal ablation devices.

Endometrial ablation is considered a less invasive alternative than hysterectomy. Endometrial ablation is not recommended for women who want to preserve fertility. Endometrial ablation is typically preceded by hormonal treatment to thin the endometrium.

**Comparators**

The following practice is currently being used to treat abnormal uterine bleeding: hysterectomy.

**Outcomes**

The general outcomes of interest are level of bleeding (e.g., light, moderate, heavy), amenorrhea, quality of life due to bleeding, as well as acute and long-term adverse events of the treatment and subsequent need for hysterectomy.

**Timing**

Morbidity due to the procedure should be assessed in the first month. Follow-up is needed for a minimum of 1 year.

**Setting**

Endometrial ablation is administered in an outpatient care by a specialist.

**Endometrial Ablation vs Hysterectomy**

**Systematic Reviews**

A systematic review of RCTs by Matteson et al (2012) compared the efficacy of a hysterectomy with less invasive techniques for controlling abnormal uterine bleeding. Reviewers identified 9
trials reporting health outcomes, seven of which compared a hysterectomy with endometrial ablation. For the 7 studies selected (total N=1167 women), 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% vs an implied 100% rate after a hysterectomy. Five trials reported pain beyond the immediate postoperative period. Reviewers judged the quality of evidence on pain to be low, with results favoring a hysterectomy over ablation. Three studies reported that pelvic pain was less prevalent in the hysterectomy group than in the ablation group; however, only 1 study compared rates statistically, and that study found a significantly lower rate of pain at between 2-year and 3-year follow-up in the group receiving a hysterectomy. All 7 trials reported additional treatments obtained by participants after the initial intervention. At between 1-year and 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 a hysterectomy.

Bhattacharya et al (2011) conducted a systematic review of individual patient data from RCTs evaluating second-line treatments for abnormal uterine bleeding on behalf of the U.K. Health Technology Assessment program. Reviewers identified data on 1127 women from 7 trials comparing first-generation ablative devices with a 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 measure 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 a hysterectomy (odds ratio [OR], 2.46; 95% confidence interval [CI], 1.54 to 3.93; p<0.001).

Additionally, Bhattacharya et al (2011) analyzed individual patient data from national databases in Scotland to evaluate long-term outcomes after a hysterectomy or endometrial ablation. Reviewers identified 37,120 women who underwent a hysterectomy and 11,299 women who underwent endometrial ablation for dysfunctional uterine bleeding between 1989 and 2006. Women who received endometrial ablation were significantly older (mean, 42.5 years) than those receiving hysterectomy (mean, 41.0 years). The type of endometrial ablation device used 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 a 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 (0.1%; adjusted HR=0.55; 95%CI, 0.41 to 0.74).

Randomized Controlled Trials

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

Subsection Summary: Endometrial Ablation vs Hysterectomy
The evidence has suggested better outcomes (e.g., bleeding control, pelvic pain) and fewer
additional surgeries in women who have a hysterectomy than endometrial ablation. However,
endometrial ablation is less invasive and involves retention of the uterus. Most studies comparing
hysterectomy with endometrial ablation used first-generation ablative 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 comparing first- with
second-generation endometrial ablation techniques.6 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 events (e.g., perforation, cervical laceration) were
more common with first-generation techniques and others (e.g., uterine cramping, 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- with second-generation techniques.7 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
them 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 to have failed to respond to medical therapy. Five of the trials compared 2 first-
generation ablation techniques, and 5 compared second-generation techniques. Fourteen trials
compared second-generation with first-generation methods. Sixteen trials had adequate
randomization methods, but, in most trials, blinding was not performed or not reported.

There were only a few studies on any given comparison of techniques; the exception was
balloon (second-generation) vs rollerball (first-generation) ablation (3 studies; n=352 patients). A
pooled analysis of these 3 studies found a statistically significant lower rate of amenorrhea at 1
year with rollerball than with balloon ablation (OR=0.63; 95% CI, 0.41 to 0.97); the absolute rates
of amenorrhea were 16% in the balloon ablation group and 24% in the rollerball group. However,
there was no significant difference 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- with second-generation
techniques. A pooled analysis of 12 studies (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
events did not find any significant differences in the rates of perforation (8 studies), endometritis
(5 studies), or hemorrhage (5 studies) using first- vs 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.
Reviewers concluded that, overall, the existing evidence suggested that success and
complication rate profiles of second-generation techniques compared favorably with the first-
generation hysteroscopic techniques.
In a network meta-analysis, Daniels et al (2012) identified 14 trials comparing first- with second-generation methods and 5 trials comparing 2 second-generation methods of endometrial ablation for women who had heavy menstrual bleeding 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 (n=516 patients). A pooled analysis of these studies did not find a significant difference in amenorrhea rates with the 2 techniques (OR=0.72; 95% CI, 0.52 to 1.101). In addition, 3 studies compared the second-generation techniques, thermal balloon ablation and bipolar radiofrequency ablation (RFA; n=264 patients). A pooled analysis showed a higher rate of amenorrhea with bipolar RFA (OR=4.56; 95% CI, 2.24 to 9.26).

The assessment by Bhattacharya et al (2011; described earlier) also compared different first- and second-generation endometrial ablation devices. They 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, 0.47 to 1.28). The proportion of women requiring hysterectomy within 12 months of endometrial ablation did not differ significantly for first-generation (39/933 (4.2%)) or second-generation (35/1343 (2.6%)) devices (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) reported on 5-year outcomes comparing microwave endometrial ablation with thermal balloon endometrial ablation (ThermaChoice). The trial included 320 premenopausal women with heavy menstrual bleeding who had completed childbearing. A total of 217 (59%) of 370 women 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 rates of amenorrhea were 51% in the microwave ablation group and 45% in the thermal ablation group (mean difference, 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 (mean difference, -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 (mean difference, 2.0%; 95% CI, -5.1% to 9.1%).

Herman et al (2013) reported on 10-year follow-up for a double-blind RCT conducted in the Netherlands. The trial compared bipolar endometrial RFA (NovaSure) with balloon endometrial ablation (ThermaChoice) in 126 women who had heavy menstrual bleeding. Ten-year follow-up data were available for 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 5 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 of a superior net health benefit with any method of endometrial ablation. Rates of abnormal uterine bleeding and patient satisfaction were generally similar after treatment with first- and second-generation devices. Meta-analyses of the available data from RCTs have suggested that there are higher rates of certain adverse events with first-generation techniques and higher rates of other adverse events with second-generation techniques.

Safety
Brown and Blank (2012) analyzed adverse 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, two associated with RFA and one 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 ablations performed during this period, so the proportion of procedures with adverse events cannot be determined from these data.

A study by Dood et al (2014) examined whether women who undergo endometrial ablation are at increased risk of endometrial cancer compared with those who had 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 treated medically developed endometrial cancer. There was no 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 vs 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 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 that 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 that the technology results in a meaningful improvement in the net health outcome.
Supplemental Information
Practice Guidelines and Position Statements

Society for Gynecologic Surgeons
The Society for Gynecologic Surgeons (2012) published clinical practice guidelines on the
treatment of abnormal uterine bleeding.13 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 a hysterectomy, if the
patient’s preference is for amenorrhea, less pain, or avoiding additional therapy, a
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 American Society for Reproductive Medicine (2008) issued a statement on indications and
options for endometrial ablation.14 Conclusions were:
• “Endometrial ablation is an effective therapeutic option for the management of
menorrhagia.
• Hysteroscopic and nonhysteroscopic techniques for endometrial ablation offer similar
rates of symptom relief and patient satisfaction.
• Later definitive surgery may be required in 6% to 20% of women after endometrial
ablation.
• Women who undergo hysterectomy after a failed endometrial ablation report
significantly more satisfaction after 2 years of follow-up.
• Endometrial ablation generally is more effective when the endometrium is relatively thin.
• Ideally, hysteroscopic methods for endometrial ablation should be performed using a
fluid monitoring system to reduce the risks and complications relating to fluid overload
and electrolyte imbalance.
• Nonhysteroscopic methods for endometrial ablation require less skill and operating time.”

American College of Obstetricians and Gynecologists
The American College of Obstetricians and Gynecologists (2013) issued an opinion on the
management of acute abnormal uterine bleeding in nonpregnant women of reproductive
age.15 The College 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. The
College stated that endometrial ablation should only 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.

The College (2007) guidelines on endometrial ablation, affirmed in 2018, made
recommendations assessed based on good and consistent evidence16:
• “For women with normal endometrial cavities, resectoscopic endometrial ablation and
nonresectoscopic endometrial ablation systems appear to be equivalent with respect to
successful reduction in menstrual flow and patient satisfaction at 1 year following index
surgery.
• Resectoscopic endometrial ablation is associated with a high degree of patient
satisfaction but not as high as hysterectomy.”

National Institute for Health and Care Excellence
The National Institute for Health and Care Excellence’s (2016) guidance on heavy menstrual
bleeding included the following recommendations on endometrial ablation17:
Endometrial Ablation

- “Endometrial ablation should be considered in women with HMB [heavy menstrual bleeding] who have a normal uterus and also those with small uterine fibroids (less than 3 cm in diameter).”
- “In women with HMB alone, with uterus no bigger than a 10-week pregnancy, endometrial ablation is preferable to hysterectomy.”
- “Endometrial ablation may be offered as an initial treatment for HMB....”
- “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....
  o Impedance-controlled bipolar radiofrequency ablation...
  o Fluid-filled thermal balloon endometrial ablation...
  o Microwave endometrial ablation...
  o Free fluid thermal endometrial ablation.”

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in July 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

References

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

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**Documentation for Clinical Review**

**Please provide the following documentation (if/when requested):**

- History and physical and/or consultation report including:
  - Reason for ablation procedure
  - Documentation of failure of hormone therapy or reason for non-candidacy of hormone therapy
  - Device used
  - Documentation of whether patient can undergo hysterectomy

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

**MN/IE**

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT®</td>
<td>58353</td>
<td>Endometrial ablation, thermal, without hysteroscopic guidance</td>
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<tr>
<td></td>
<td>58356</td>
<td>Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed</td>
</tr>
</tbody>
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### Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state government is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

### Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.