

4.01.04	Endometrial Ablation	
Section 4.0 OB/Gyn/Reproduction	Effective Date September 30, 2014	
Subsection	Original Policy Date September 30, 2014	Next Review Date September 2015

Description

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, electrosurgical rollerball) and nonhysteroscopic techniques (e.g., cryosurgical, radiofrequency [RF] ablation).

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

Related Policies

- N/A

Policy

Endometrial ablation, with or without hysteroscopic guidance, using an FDA-approved device may be considered **medically necessary** 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 is considered **investigational** for all other indications.

Policy Guidelines

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

Microwave ablation, thermal ablation, and cryoablation may be performed in an office setting.

Coding

There are specific CPT codes for this procedure:

- **58353:** Endometrial ablation, thermal, 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)

Benefit Application

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)) prohibit 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.

Rationale

Background

Ablation or destruction of the endometrium is used to treat menorrhagia in women who failed standard therapy. It is considered a less invasive alternative to hysterectomy; however, as with hysterectomy, the procedure is not recommended for women who wish to preserve their fertility.

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

Techniques for endometrial ablation are generally divided into 2 categories: those that do and do not require hysteroscopic procedures. (Other terminology for these categories of techniques include first- generation versus second-generation procedures and resectoscopic versus nonresectoscopic endometrial ablation methods).

Hysteroscopic techniques were developed first; the initial technique was photovaporization of the endometrium using an Nd-YAG laser, and this was followed by electrosurgical ablation using an electrical rollerball or electrical wire loop. (The latter

technique is also known as transcervical resection of the endometrium). Hydrothermal ablation also involves hysteroscopy. Hysteroscopic techniques require skilled surgeons and, due to the requirement for cervical dilation, use of general or regional anesthesia. In addition, the need for the instillation of hypotonic distension media creates a risk of pulmonary edema and hyponatremia such that very accurate monitoring of fluids is required.

Nonhysteroscopic techniques can be performed without general anesthesia and do not involve use of a fluid distention medium. Techniques include thermal fluid-filled balloon, cryosurgical endometrial ablation, instillation of heated saline, and radiofrequency(RF) ablation.

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

Regulatory Status

The FDA indicates that endometrial devices are for use in premenopausal women with menorrhagia due to benign causes for whom childbearing is complete. FDA-approved devices for endometrial ablation include, but may not be limited to, laser therapy, electrical wire loop, rollerball using electric current, and thermal ablation using a liquid-filled balloon, microwave, electrode array, or a cryosurgical device. Examples of devices for endometrial ablation are:

- The 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 ThermoChoice[®] device (J&J Ethicon Gynecare, Somerville, NJ): This device ablates endometrial tissue by thermal energy heating of sterile injectable fluid within a silicone balloon. Endometrial ablation will only work when there is direct contact between the endometrial wall and the fluid-filled balloon. Therefore, 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 (Cytoc Corp, Marlborough, MA): The system delivers RF energy to the endometrial surface. The device consists of an electrode array on a stretchable porous fabric that conforms to the endometrial surface.
- Her Option[™] Uterine Cryoablation Therapy[™] system (American Medical Systems, Minnetonka, MN): The system consists of, in part, a cryoprobe that is inserted through the cervix into the endometrial cavity. When cooled, an ice ball forms around the probe, which permanently destroys the endometrial tissue. Cryoablation is typically monitored by abdominal ultrasound.

FDA Product Code: HHR.

Comparison Between Endometrial Ablation and Hysterectomy

A 2012 systematic review of randomized controlled trials (RCTs) by Matteson et al. compared the efficacy of hysterectomy and less invasive techniques for controlling abnormal uterine bleeding.⁽³⁾ The authors identified 9 trials directly comparing hysterectomy with another intervention and reporting health outcomes; 7 of these studies compared hysterectomy with endometrial ablation. The 7 studies included a total of 1167 women, and follow-up ranged from 4 to 48 months. Due to the heterogeneity of outcome 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 postoperative period. The authors judged the quality of evidence on pain to be low but that results favored hysterectomy over ablation. Three studies reported that pelvic pain was less prevalent in the hysterectomy group than the ablation group; however, only 1 study compared rates statistically, and this study found a significantly lower rate of pain at 2- to 3-year follow-up in the group receiving hysterectomy. All 7 trials reported additional treatments obtained by participants after the initial intervention. At 1- to 4-year 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.⁽⁴⁾ They identified data on 1127 women from 7 trials comparing first-generation devices with 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-month follow-up, 7.3% (57/454) of women treated with first-generation endometrial ablation devices and 5.3% (23/432) of women who had a hysterectomy were dissatisfied with their treatment outcome. This difference was statistically significant, favoring hysterectomy (odds ratio [OR], 2.46; 95% confidence interval [CI], 1.54 to 3.93; $p < 0.001$).

In addition 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 ablation were significantly older (mean, 42.5 years) compared with those receiving hysterectomy (mean, 41.0 years). The type of endometrial ablation device could not be determined. The median duration of follow-up was 6.2 years in the endometrial ablation group and 11.6 years in the hysterectomy group. During follow-up, 962 (8.5%) women who received endometrial ablation had additional gynecologic surgery compared with 1446 (3.9%) women who had hysterectomy; this difference was statistically significant (adjusted hazard ratio [HR], 3.56; 95% CI, 3.26 to 3.89). The most common types of additional surgery after endometrial ablation were intrauterine procedures ($n=577$, 5.1%) and repeat endometrial ablation ($n=278$, 2.5%). However, women who had initial endometrial ablation procedures were significantly less likely than those with initial hysterectomies to have surgery for pelvic floor repair (0.9% vs 2.2%, respectively; adjusted HR range, 0.50-0.77). Women were also less likely to have tension-free vaginal tape surgery for stress urinary incontinence after endometrial ablation than after hysterectomy (0.5% vs 1.1%, respectively; adjusted HR=0.55; 95% CI, 0.41 to 0.74).

Section Summary

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

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.⁽⁵⁾ The 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 1 or 2 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 1 year (OR=0.99; 95% CI, 0.93 to 1.06).

The investigators also conducted an overall analysis of studies comparing first- and second-generation techniques. A pooled analysis of 12 studies (total N=2085) did not find a statistically significant difference in the rate of amenorrhea at 1 year (OR=0.94; 95% CI, 0.74 to 1.20). The absolute rates of amenorrhea were 38% with first-generation procedures and 37% with second-generation procedures. Eleven studies reported satisfaction rates at 1 year, 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.

Previously, 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.⁽⁶⁾ 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 2 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 showed a higher rate of amenorrhea with bipolar RF (OR=4.56; 95% CI, 2.24 to 9.26).

The 2011 assessment from HTA, described earlier, also included comparisons of different endometrial ablation methods.(4) The investigators identified data on 2448 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 in 899 (36%) with first-generation devices and 464 in 1261 (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 in 899 (12.3%) with first-generation devices and 151 in 1281 (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 (4/589 [0.7%]) or second-generation (4/880 [0.5%]) devices (OR=0.71; 95% CI, 0.17 to 2.94). The proportion of women requiring hysterectomy within 12 months after endometrial ablation did not differ significantly when first-generation (39/933 [4.2%]) or second-generation (35/1343 [2.6%]) devices were used (11 studies; OR=0.77; 95% CI, 0.47 to 1.24).

Representative RCTs with relatively long-term follow-up are described next.

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).(7) 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).

In 2013, Herman et al. reported 10-year follow-up of a double-blind RCT conducted in the Netherlands.(8) 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 2010 study by Iglesias et al. attempted to identify which women are most likely to fail treatment with endometrial ablation.(9) 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 underwent 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 with 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 with a 27% failure rate in the 103 nonsmokers ($p=0.042$). Sixty-five women reported menometrorrhagia and had a 42% treatment failure rate compared with the 75 women who reported only menorrhagia and had a 24% failure rate. Race (white versus other) and body mass index (<30 or ≥ 30) 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 with 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 FDA's Manufacturer and User Facility Device Experience database.(10) There were a total of 829 reported adverse events between 2005 and 2011. Nearly two-thirds of the adverse events (540/829 [65%]) were genital tract or skin burns, and 529 of these events (98%) were associated with hydrothermal endometrial ablation. The next 2 most frequent types of adverse events were thermal bowel injury (93/820 [11%]) and transmural uterine thermal activity (89/820 [11%]). Of the 182 thermal injuries, 140 (77%) were associated with RF endometrial ablation. In addition, 47 instances of sepsis or bacteremia were reported, and 43 of the 47 cases (91%) were associated with RF endometrial ablation. There were 4 reported deaths, 2 associated with RF ablation and 1 each associated with thermal balloon ablation and cryoablation. Sixty-six of the 829 events (8%) occurred when endometrial ablation was performed outside of the labeled instructions for use of the procedure. The authors did not report the total number of endometrial ablation performed during this time period, so the proportion of procedures with adverse events cannot be determined from these data.

A 2014 study by Dood et al. in the U.K. examined whether women who undergo endometrial ablation are at increased risk of endometrial cancer compared with those with abnormal uterine bleeding that is managed with medication.(11) 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

Adverse events have been associated with endometrial ablation procedures. Certain types of adverse events are more likely to occur with particular approaches to endometrial ablation. Due to lack of information about the total number of procedures and the number of each type of endometrial ablation procedure performed, conclusions cannot be drawn from these data about the relative safety of different types of procedures. Endometrial ablation does not appear to increase the risk of subsequent endometrial cancer.

Ongoing Clinical Trials

Medical therapy versus radiofrequency endometrial ablation in the initial treatment of menorrhagia (iTOM) (NCT01165307)(12): This RCT is comparing medical therapy (oral contraceptives) with endometrial ablation using NovaSure as a treatment of heavy menstrual bleeding. Efficacy outcomes will be assessed at 12 months. The investigators plan to enroll 120 patients, and the estimated completion date is September 2014.

Levonorgestrel intra-uterine system versus radiofrequency endometrial ablation in women with menorrhagia (Dutch trial register, NTR2984)(13): This noninferiority RCT is comparing the levonorgestrel intra-uterine system (Mirena) with endometrial ablation using NovaSure as a treatment of heavy menstrual bleeding. Efficacy outcomes will be assessed at 24 months. The investigators plan to enroll 256 patients; an estimated completion date is not reported.

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 nonhysteroscopic) techniques. There is a lack of consistent evidence that any 1 ablation technique is superior to another. Thus, endometrial ablation using a Food and Drug Administration–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 systematic review group: In 2012, they published a clinical practice guideline on treatment of abnormal uterine bleeding.(14) 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 postoperative procedural risk, and a shorter hospital stay, endometrial ablation is recommended.

Practice Committee of the American Society for Reproductive Medicine: In 2008, American Society for Reproductive Medicine (ASRM) issued a statement on indications and options for endometrial ablation.(15) 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.”

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.” (16)

American College of Obstetricians and Gynecologists: In 2007, the American College of Obstetricians and Gynecologists published a guideline on endometrial ablation.(17) Recommendations they assessed as being based on good and consistent evidence include:

- “For women with normal endometrial cavities, resectoscopic endometrial ablation and nonresectoscopic endometrial ablation systems appear to be equivalent with respect to successful reduction in menstrual flow and patient satisfaction at 1 year following index surgery.
- Resectoscopic endometrial ablation is associated with a high degree of patient satisfaction but not as high as hysterectomy. ”

National Institute for Health and Clinical Excellence, United Kingdom: The 2007 National Institute for Health and Clinical Excellence guidance on heavy menstrual bleeding includes the following recommendations regarding endometrial ablation(18):

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

endometrial ablation, microwave endometrial ablation, and free fluid thermal endometrial ablation.

U.S. Preventive Services Task Force Recommendations

Endometrial ablation is not a preventive service.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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 17. American College of Obstetricians and Gynecologists (ACOG). Endometrial ablation: 2007 ACOG Practice Bulletin No. 81. 2007. Available online at: <http://www.acog.org/Search?Keyword=Endometrial+Ablation>. Last accessed May, 2014.
 18. National Institute for Health and Clinical Excellence (NICE). Heavy menstrual bleeding. Clinical guideline 44. 2007. Available online at: www.nice.org.uk/nicemedia/pdf/CG44NICEGuideline.pdf. Last accessed May, 2014.
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Documentation Required for Clinical Review

- 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 benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following service/procedure may be considered medically necessary in certain instances and investigational in others. Services may be medically necessary when policy criteria are met. Services are 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.

Type	Code	Description
CPT®	58353	Endometrial ablation, thermal, 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)
HCPC	None	
ICD-9 Procedure	68.23	Endometrial ablation
ICD-10 Procedure	<i>For dates of service on or after 10/01/2015</i>	
	0U5B0ZZ	Destruction of Endometrium, Open Approach
	0U5B3ZZ	Destruction of Endometrium, Percutaneous Approach
	0U5B4ZZ	Destruction of Endometrium, Percutaneous Endoscopic Approach
	0U5B7ZZ	Destruction of Endometrium, Via Natural or Artificial Opening
	0U5B8ZZ	Destruction of Endometrium, Via Natural or Artificial Opening Endoscopic
ICD-9 Diagnosis	All Diagnoses	
ICD-10 Diagnosis	<i>For dates of service on or after 10/01/2015</i>	
	All Diagnoses	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
9/30/2014	BCBSA Medical Policy adoption	Medical Policy Committee

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 governmental 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

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

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 also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.