



Medical Coverage Policy

Effective Date..... 2/15/2020
Next Review Date..... 2/15/2021
Coverage Policy Number 0013

Endometrial Ablation

Table of Contents

Overview	1
Coverage Policy.....	1
General Background.....	2
Coding/Billing Information.....	6
References	7

Related Coverage Resources

[Pelvic Denervation Procedures](#)
[Treatment of Gender Dysphoria](#)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses various techniques for ablation of the endometrium which may be indicated for excessive uterine bleeding.

Coverage Policy

Endometrial ablation is considered medically necessary as an alternative to hysterectomy when ALL of the following criteria are met:

- Menorrhagia or excessive anovulatory bleeding that meets ANY of the following criteria:
 - bleeding is causing anemia
 - bleeding is repeatedly profuse
 - repetitive periods are occurring at less than 21-day intervals
- Failure, intolerance or contraindication to hormonal treatment of at least three months' duration
- Diagnostic evaluation of the endometrium within the past 12 months by endometrial biopsy, or dilatation and curettage (D&C) failed to show evidence of remediable pathology
- Diagnostic evaluation of the uterine cavity within the past 12 months by ultrasound, sonohysterogram or hysteroscopy failed to show evidence of remediable pathology

- Uterus size is less than 12 weeks' gestation (i.e., uterine length is less than 13 centimeters [cm] and anterior-posterior width is less than 7 cm)
- Endometrial and cervical precancers or cancers have been ruled out
- The woman is premenopausal and has no desire for future childbearing

Endometrial ablation is considered medically necessary for residual menstrual bleeding after androgen treatment in an individual with confirmed gender dysphoria undergoing female to male hormonal sex reassignment* therapy.

***Coverage for treatment of gender dysphoria and/or gender reassignment surgery and related services, including pre and post-surgical hormonal therapy varies across plans. For information on treatment of gender dysphoria and/or gender reassignment surgery, refer to the Cigna Coverage Policy Treatment of Gender Dysphoria.**

Endometrial ablation is considered experimental, investigational or unproven for any other indication.

Photodynamic or chemoablation of the endometrium are considered experimental, investigational or unproven.

General Background

Menorrhagia is defined as prolonged, excessive uterine bleeding or heavy menstrual bleeding (HMB) that occurs at regular intervals, or, more strictly, as the loss of 80 milliliters or more of blood per menstrual cycle or bleeding that lasts for more than seven days. Although menorrhagia is usually idiopathic, it may also be associated with other conditions (e.g., thyroid, liver, or renal disease), an anatomical abnormality, hormonal imbalances, or the use of certain medications. Causes of abnormal uterine bleeding include: polyps, adenomyosis, leiomyomas, malignancy and premalignant conditions, coagulopathy, ovulatory disorders and endometrial disorders. Treatment depends on the underlying cause of the bleeding. If diagnostic testing and pelvic and physical examinations rule out underlying causes of menorrhagia, conservative treatments such as nonsteroidal anti-inflammatory drugs (NSAIDs), antifibrinolytic agents, progestins or oral contraceptives may be used for medical management. For patients who fail medical therapy or those who do not desire future fertility, surgical management is appropriate. Hysterectomy has traditionally been used as the definitive surgical treatment for HMB with up to a 100% high success and patient satisfaction rate (Sharp, 2019; Shaw, et al., 2018; Matteson, et al., 2012; American College of Obstetrics and Gynecologists [ACOG], 2012; Stovall, 2011; ACOG; 2007). Endometrial ablation (EA) is an established minimally invasive alternative to hysterectomy for HMB.

Endometrial ablation is also performed in some cases of transgender female to male reassignment. Although hormones such as testosterone are typically successful, the addition of an oral, injected, implanted, or intrauterine (IUD) progestogen may serve as an adjunct to inducing amenorrhea. EA can be considered for transgender men who do not desire future fertility and who also either decline hysterectomy or have surgical complications (Obedin-Maliver, 2016).

Endometrial Ablation (EA)

A number of techniques have been developed to ablate or remove the lining of the endometrium, which include resectoscopic and non-resectoscopic endometrial ablation. Resectoscopic endometrial ablation, also known as standard or first generation ablation, is performed under hysteroscopic visualization with resectoscopic electrosurgical instruments (e.g., laser, transcervical resection of the endometrium and rollerball). The second technique is non-resectoscopic endometrial ablation, also known as global or second generation ablation, and requires the use of high-frequency radiofrequency (RF) probes, cryoprobes, liquid-filled balloons, multi-electrode balloons, microwave energy or instillation of saline. In general, indications and study patient selection criteria for EA as a treatment for menorrhagia include (Sharp, 2019; Sweet, et al., 2012; Lipscomb, 2008; ACOG; 2007; U.S. Food and Drug Administration [FDA], 2001b):

- uterus size of < 12 weeks' gestation (i.e., uterine length of less than 13 centimeters [cm] and anterior-posterior width of less than 7 cm)

- failure, intolerance or contraindication of hormonal treatment for at least three months
- endometrial evaluation by biopsy, dilatation and curettage (D&C) fails to show evidence of remediable pathology
- diagnostic evaluation of the uterine cavity by ultrasound, sonohysterogram or hysteroscopy failed to show evidence of remediable pathology
- intrauterine devices (IUD) removed, then medical evaluation and management has been used to control the bleeding
- endometrial and cervical precancers or cancers are ruled out
- patient has completed childbearing

EA may be preceded by a course of gonadotropin-releasing hormone (GnRH) analogue medication to thin the endometrial walls. Patient selection criteria are determined by the type of procedure planned and uterine size. Endometrial ablation devices have not been approved for use in women with uterine lengths of greater than 10–12 cm (i.e., equivalent to 10 weeks' gestational size), as this may cause uterine or endocervical canal injury. Complications associated with endometrial ablation include uterine perforation, hemorrhage, hematometra, and pelvic infection. Many patients require a second ablative procedure for bleeding or a hysterectomy for residual bleeding or dysmenorrhea (Sharp, 2019).

U.S. Food and Drug Administration (FDA): Devices used to perform endometrial ablation/resection for the treatment of menorrhagia are approved by the FDA premarket approval (PMA) process. Examples of approved devices include:

- ThermaChoice® Uterine Balloon Therapy System (Gynecare, Inc., a division of Ethicon, Inc., Menlo Park, CA)
- Hydro ThermAblator® (BEI Medical Systems, Inc., Teterboro, NJ)
- HerOption™ Uterine Cryoablation Therapy System (Cryogen, Inc., San Diego, CA)
- NovaSure® Impedance Controlled Endometrial Ablation System (Novacept Inc., Palo Alto, CA)
- Microwave Endometrial Ablation (MEA) System (Microsulis Corporation, Riverview, FL)
- Minerva™ Endometrial Ablation System (Minerva Surgical, Inc., Redwood City, CA)

Literature Review: Evidence from systematic reviews, meta-analysis and randomized controlled trials (RCTs) supports the safety and efficacy of EA for the management of menorrhagia. A number of studies (n=120–279) with up to ten years of follow-up have compared first-generation to second-generation techniques and found similar rates of effectiveness. When compared to hysterectomy, EA has been reported to result in lower rates of successful reduction in menstrual flow. However, adverse events have been reported to be greater post-hysterectomy (Bofill, et al., 2019; Fergusson, et al., 2019; Daniels, et al., 2012; Matteson, et al., 2012; Munro, et al., 2011; Penninx, et al., 2010; Sambrook, et al., 2009; Kleijn, et al., 2008; Dickersin, et al., 2007; Fürst, et al., 2007; Bongers, et al., 2004; Van Zon-Rabelink, et al., 2004; Duleba, et al., 2003; Bain, et al., 2002).

Cooper et al. (2019) conducted a parallel-group, multicenter, open-label, randomized controlled trial that compared laparoscopic supracervical hysterectomy to endometrial ablation in women with heavy menstrual bleeding. Women were included in the study if they were age < 50 years with no desire for (further) children and were referred to a gynecologist for surgical treatment of heavy menstrual bleeding. Inclusion criteria were eligibility for endometrial ablation (fibroids < 3 cm, uterine cavity size < 11 cm, and absence of endometrial pathology on biopsy) and normal cervical cytology. Patients (n=660) were randomly assigned to a laparoscopic supracervical hysterectomy group (n=330) or a second generation endometrial ablation group (n=330). The co-primary clinical outcomes measured patient satisfaction and condition-specific quality of life, measured with the menorrhagia multi-attribute quality of life scale (MMAS), assessed at 15 months after randomization. The analysis was based on the intention-to-treat principle. At 15 months after randomization, significantly more women in the laparoscopic supracervical hysterectomy group were satisfied with their operation and had higher MMAS scores compared with those in the endometrial ablation group (p<0.0001 and p=0.00058, respectively). Adverse events between groups did not reach clinical significance (p=0.54). The authors concluded that there is a clear clinical benefit associated with both surgical techniques, however the measures of satisfaction, quality-of-life scores, and outcomes such as amenorrhea, residual menstrual bleeding, and pelvic pain were more positive for laparoscopic supracervical hysterectomy compared to endometrial ablation.

Laberge et al. (2017) performed a randomized, double-arm, multicenter, international controlled trial comparing the safety and efficacy of the Minerva Endometrial Ablation System compared to hysteroscopic rollerball ablation in the treatment of heavy menstrual bleeding (HMB) in premenopausal women. Patients were included if they were premenopausal, between 25 and 50 years of age, had completed childbearing, and had documented evidence of HMB using alkaline hematin (AH) test. The patients were randomized into two groups. The test group (n=102) received endometrial ablation using the Minerva Endometrial Ablation System and the control group (n=51) received rollerball ablation. The primary objectives were to evaluate the safety and effectiveness of the Minerva Endometrial Ablation System compared to hysteroscopic rollerball ablation in reducing menstrual blood loss and the occurrence of any adverse events (AEs). Study success was defined as a reduction in menstrual bleeding from ≥ 160 ml pretreatment to ≤ 80 ml at 12 months post-treatment. Secondary objectives included amenorrhea rate, treatment parameters (procedure time, anesthesia type) and patient satisfaction of treatment measured at 12 months. Menstrual blood loss was quantitatively measured for study inclusion and postoperatively at six and 12 months post-procedure. The success rate (alkaline hematin ≤ 80 mL) at one year was 93.1% for the Minerva test group compared to 80.4% for the rollerball control group indicating clinically significant success ($p=0.02$) in the Minerva test group. There was a significant difference ($p=0.01$) in the amenorrhea rate at one year between the groups, 71.6% for the Minerva group and 49% for the rollerball group. Procedure time for both procedures was short with mean procedure times of 3.1 minutes for Minerva and 17.2 minutes for rollerball. There were no intraoperative adverse events and/or complications reported. Patient satisfaction was assessed using a patient survey and a validated Menstrual Impact Questionnaire. Results indicated a significantly higher rate of satisfaction in the Minerva group at 91.9% versus 79.5% reported by the rollerball patients at one year post-procedure ($p<0.05$). Limitations of the study included the lack of core research on the underlying condition (HMB), a disproportionately small enrollment of African American population, short term follow-up and small patient population. The authors concluded that the Minerva procedure produced statistically significantly higher rates of success, amenorrhea, and patient satisfaction as well as a shorter procedure time. Safety results were excellent and similar for both procedures. Although the results of the current study demonstrated that the Minerva ablation procedure is more effective than rollerball ablation in treating HMB, additional, larger well-designed controlled trials with long-term follow-up are needed to support these results.

Other Ablative Therapies

Additional avenues of ablative therapy for the treatment of abnormal or heavy menstrual bleeding have been proposed. These procedures (i.e., chemoablation and photodynamic ablation) have been studied in a limited number of clinical trials.

Chemoablation of the Endometrium: Chemoablation of the endometrium requires the use of topically administered caustic agents, such as those used to destroy epithelial lesions secondary to human papillomaviral infection, into the uterine cavity. This technique is currently under investigation (Munro, 2006).

In a randomized clinical study (n=90), Kucuk et al. 2005 compared dysfunctional uterine bleeding (DUB) patients who received chemoablation with trichloroacetic acid (TCA) (n=45) to those who received a single dose of gonadotropin-releasing hormone analogue one month before the procedure. Amenorrhea, hypomenorrhea, and eumenorrhea rates at the end of one year were similar in both groups (26.7%, 31.1%, and 37.8%; 37.8%, 31.1% and 28.9%, respectively). Patients reported dysmenorrhea decreases of 73.3% and 75.5%, respectively.

Another RCT (n=90) by Kucukozkan et al. (2004) assessed the effectiveness of topically applied trichloroacetic acid (TCA) for endometrial ablation in patients with dysfunctional uterine bleeding. Patients in group one underwent dilatation and curettage prior to endometrial ablation. Danazol was administered to patients in group two before ablation. The patients in group three had goserelin acetate on the day of the procedure and 28 days after ablation. At six months post-procedure, endometrial thickness was decreased significantly in all treatment groups ($p<0.001$). Study results are limited by the short-term follow-up.

Well-designed randomized controlled clinical trials with adequate patient populations and follow-up are needed to support the safety and efficacy of this ablative technique.

Photodynamic Endometrial Ablation: Photodynamic endometrial ablation involves injecting a photosensitive chemical into the uterine cavity through a hysterosalpingography catheter. A probe inserted through the cervix

uses a laser to activate the photosensitive chemical, which destroys the endometrium. To date, there is limited data on the efficacy of this technique. The use of photodynamic endometrial ablation remains unproven at this time.

Professional Societies/Organizations

American College of Obstetrics and Gynecology (ACOG): The 2007 (reaffirmed 2018) ACOG Practice Bulletin for endometrial ablation included the following recommendations and conclusions based on good and consistent scientific evidence:

- 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.

Recommendations and conclusions based primarily on consensus and expert opinion included the following:

- Patients who choose endometrial ablation should be willing to accept normalization of menstrual flow, not necessarily amenorrhea, as an outcome.
- Non-resectoscopic endometrial ablation is not recommended in women with endometrial cavities that exceed device limitations.
- The endometrium of all candidates for endometrial ablation should be sampled, and histopathologic results should be reviewed before the procedure.
- Women with endometrial hyperplasia or uterine cancer should not undergo endometrial ablation.

The ACOG practice bulletin on the management of abnormal uterine bleeding associated with ovulatory dysfunction (AUB-O) stated that the choice of treatment is guided by the goals of therapy. The treatment goals may be to stop acute bleeding, avoid future irregular or heavy bleeding, simultaneously provide contraception, and prevent complications, such as anemia, unnecessary surgical intervention, and diminished quality of life. Failure of medical management requires further investigation which can include imaging or hysteroscopy. Furthermore, the practice bulletin stated that endometrial ablation is not recommended as a first line therapy for AUB-O (ACOG, 2013a; reaffirmed 2018). Additionally in 2013, ACOG published a committee opinion on the management of acute abnormal uterine bleeding in non-pregnant reproductive-aged women which stated that endometrial ablation, should be considered only if other treatments have been ineffective or are contraindicated. Additionally, EA should only be performed when a woman does not have plans for future childbearing and when the possibility of endometrial or uterine cancer has been reliably ruled out as the cause of the acute AUB (ACOG, 2013b; reaffirmed 2019).

Endocrine Society: According to the Endocrine Society guideline on gender-dysphoric/gender-incongruent persons, the cessation of menses may occur within a few months with testosterone treatment alone, although high doses of testosterone may be required. If uterine bleeding continues, the addition of a progestational agent or an endometrial ablation maybe considered. To stop menses prior to testosterone treatment clinicians may also use GnRH analogs or depot medroxyprogesterone. (Hembree, et al., 2017).

American Society of Reproductive Medicine (ASRM): ASRM (2008) stated that endometrial ablation may be considered in premenopausal women for the treatment of menorrhagia. Before performing an ablative procedure, significant uterine pathology and medical conditions that can cause menorrhagia-should be excluded. Ablative therapy may also be considered when medical treatments fail, are contraindicated, or are poorly tolerated. EA is not indicated in postmenopausal women, in women with endometrial cancer, hyperplasia, or in premenopausal women who wish to preserve their fertility. Hysteroscopic and non-hysteroscopic techniques offer similar rates of symptom relief and patient satisfaction.

Society for Gynecologic Surgeons (SGS): SGS conducted a systematic review (Matteson, et al., 2012) of randomized controlled trials to compare outcomes of hysterectomy to less-invasive alternatives, including endometrial ablation, for abnormal uterine bleeding. Seven randomized controlled trials, with 4–48 months follow-up, using resectoscopic methods of endometrial ablation met inclusion criteria. Overall quality of the

evidence was low to moderate. The seven studies reported 13%–64% amenorrhea following endometrial ablation vs. an implied 100% following hysterectomy. Five trials assessed pain beyond the immediate postoperative period. Outcomes were conflicting but favored less pain following hysterectomy. There were no significant differences between EA and hysterectomy in postoperative quality of life, sexual health outcomes and overall satisfaction. Based on the systematic review, SGS developed clinical practice guidelines for uterine bleeding (Wheeler, et al., 2012). SGS published the following “weak” recommendations for EA:

- “If the patient’s main preference is for amenorrhea or avoiding additional therapy or experiencing less pain, we suggest hysterectomy rather than endometrial ablation.”
- “If the patient’s main preference is for shorter hospitalization and for lower operative and postoperative procedural risk, we suggest endometrial ablation rather than hysterectomy.”
- “If the patient’s main preference is for improvement in overall quality of life or sexual health, we suggest that either hysterectomy or endometrial ablation may be chosen and that the selection of treatment be based on additional patient preferences.”

Centers for Medicare & Medicaid Services (CMS)

- National Coverage Determinations (NCDs): No NCD found
- Local Coverage Determinations (LCDs): No LCD’s found

Use Outside of the US

The National Institute for Health and Clinical Excellence (NICE, 2018) clinical guideline on the assessment and management of heavy menstrual bleeding stated that when considering treatment options for heavy menstrual bleeding the woman’s preferences, comorbidities, the presence of fibroids, polyps, endometrial pathology or adenomyosis and symptoms such as pressure and pain should be considered. The first choice of treatment for women without identified pathology, fibroids less than 3 cm in diameter or suspected/diagnosed adenomyosis is levonorgestrel-releasing intrauterine system (LNG-IUS). If this is not suitable, non-hormonal treatment such as tranexamic acid and NSAID’s may be considered as well as hormonal treatment such as combined hormonal contraception and cyclical oral progestogens. If pharmacological treatment is unsuccessful alternative surgical treatment choices include endometrial ablation and hysterectomy.

The NICE guidance on the use of photodynamic endometrial ablation for the treatment of menorrhagia stated that the current evidence on safety and efficacy does not appear adequate to support the use of this procedure outside of formal research. It is suitable for use only within good quality research studies approved by a research ethics committee and with explicit patient consent. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty (NICE, 2004; updated 2012).

The 2013 Society of Obstetricians and Gynaecologists of Canada (SOGC) clinical practice guideline on abnormal uterine bleeding in pre-menopausal women stated that after malignancy and significant pelvic pathology have been ruled out, the first line therapeutic option for abnormal uterine bleeding is medical treatment. Medical treatment for heavy menstrual bleeding that is mainly cyclic or predictable in timing consists of non-hormonal options such as non-steroidal anti-inflammatory drugs and antifibrinolytics. Hormonal treatment options include combined oral contraceptive pills, depot medroxyprogesterone acetate, and levonorgestrel-releasing intrauterine systems which significantly reduces menstrual bleeding and should be used to treat women with abnormal uterine bleeding who desire contraception. To encourage compliance and maximize likelihood of treatment success, medical treatment should be tailored to the individual woman’s therapeutic goals, desire for contraception, underlying medical conditions, and tolerance of side effects. Other medical treatment options include danazol and gonadotropin-releasing hormone agonists and may be used for scenarios in which other medical or surgical treatments have failed or are contraindicated. In appropriate candidates, non-resectoscopic ablation techniques (second generation) should be the ablation methods of choice in view of their higher efficacy and safety than resectoscopic techniques (Singh et al., 2013; reaffirmed 2018).

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible

for reimbursement.

Endometrial Ablation

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
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)

Photodynamic Endometrial Ablation or Chemoablation of the Endometrium

Considered Experimental/Investigational/Unproven when used to report photodynamic or chemoablation of the endometrium:

CPT®* Codes	Description
58579	Unlisted hysteroscopy procedure, uterus
58999	Unlisted procedure, female genital system (non-obstetrical)

***Current Procedural Terminology (CPT®) ©2019 American Medical Association: Chicago, IL.**

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