Medical Coverage Policy

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Endometrial Ablation

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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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. 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 for the treatment of menorrhagia or excessive anovulatory bleeding.

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 not covered or reimbursable for any other indication.

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

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Compared to individuals with normal menstrual bleeding, individuals with menorrhagia can experience worse quality of life, including physical, mental, emotional, and social health. People with heavy menstrual bleeding have decreased involvement in personal relationships, social activities, and work attendance. Individuals who live in a more socioeconomically deprived area and are presenting for their first outpatient gynecology visit, report more severe heavy menstrual bleeding symptoms and a reduced quality of life. Compared with non-Hispanic White women, Black people experience higher rates of heavy menstrual bleeding which could be attributed to an increased prevalence of uterine fibroids among Black people. Black women and those aged ≥ 40

years were less likely to have documentation of nonsurgical treatment and less likely to receive a laparoscopic hysterectomy compared to other modes of hysterectomy (Depke, 2024).

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. It affects approximately 20% of women each year and is the most commonly reported problem women report to their doctors. 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 (e.g., von Willebrand disease), ovulatory disorders and endometrial disorders. Left untreated, menorrhagia puts a woman at risk for anemia, pain during menstruation, hospitalizations, blood transfusions, limitations in daily activities, time lost from work or school, and reduced quality of life. 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 (CDC, 2024; Sharp, 2019; Shaw, et al., 2018, updated 2023; 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)
Several 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; FDA, 2024):

- 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:

- Cerene Cryotherapy Device (Channel Medsystems, Inc., Emeryville, CA) (P180032)
- Gynecare ThermaChoice® Uterine Balloon Therapy System (Gynecare, Inc., a division of Ethicon, Inc., Menlo Park, CA) (P970021)
- HerOption™ Uterine Cryoablation Therapy System (Cryogen, Inc., San Diego, CA) (P000032)
- Hta System (previously known as Hydro ThermAblator®) (BEI Medical Systems, Inc., Teterboro, NJ) (P000040)
- MARA Water Vapor System (previously known as Aegea Vapor System) (CooperSurgical, Inc., Turmbull, CT) (P160047)
- Microwave Endometrial Ablation (MEA) System (Microsulis Corporation, Riverview, FL) (P020031)
- Minerva™ Endometrial Ablation System (Minerva Surgical, Inc., Redwood City, CA) (P140013)
- Minitouch 3.8 Era System (Minitouch System) (MicroCube, LLC, Fremont, CA) (P230002)
- NovaSure® Impedance Controlled Endometrial Ablation System (Novacept Inc., Palo Alto, CA) (P010013)

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. Several 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., 2022; Bofill, et al., 2021; Bofill, 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 scored 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 ≥ 160ml pretreatment to ≤ 80ml 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 disproportionally 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 trichoralacetic 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 trichoralacetic 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 2020).

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 for Reproductive Medicine (ASRM): ASRM (2008) stated that endometrial ablation may be considered in premenopausal women for the treatment of menorrhagia. Before preforming 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 post-operative 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."

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No National Coverage Determination found	
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
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)

ICD-10-CM Diagnosis Codes	Description
	All other codes not listed in the Not Covered or Reimbursable section below

Not Covered or Reimbursable:

ICD-10-CM Diagnosis Codes	Description
D25.0	Submucous leiomyoma of uterus
D25.1	Intramural leiomyoma of uterus
D25.9	Leiomyoma of uterus, unspecified
N84.0	Polyp of corpus uteri
N84.1	Polyp of cervix uteri
N85.6	Intrauterine synechiae
N85.8	Other specified noninflammatory disorders of uterus
N92.5	Other specified irregular menstruation
N94.6	Dysmenorrhea, unspecified
R93.89	Abnormal findings on diagnostic imaging of other specified body structures
Z30.2	Encounter for sterilization

Photodynamic Endometrial Ablation or Chemoablation of the Endometrium

Considered Experimental/Investigational/Unproven:

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

***Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.**

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	Revised policy statement for endometrial ablation for the treatment of menorrhagia or excessive anovulatory bleeding.	2/15/2025
Annual Review	Revised the policy statement for endometrial ablation for any other indication.	2/15/2024