

Cigna Medical Coverage Policy



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Subject **Endometrial Ablation**

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. 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. Proprietary information of Cigna. Copyright ©2014 Cigna

Coverage Policy

Cigna covers endometrial ablation as 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

Cigna does not cover endometrial ablation for any other indication because it is considered experimental, investigational or unproven.

Cigna does not cover photodynamic or chemoablation of the endometrium, because these techniques 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 (Matteson, et al., 2012; Shaw, et al., 2012; American College of Obstetrics and Gynecologists [ACOG], 2012; ACOG; 2011; Stovall, 2011; Arici, 2006).

Endometrial Ablation (EA)

EA is an established minimally invasive alternative to hysterectomy for HMB. A number of techniques have been developed to ablate or remove the lining of the endometrium. The gold standard or first-generation techniques (e.g., laser, transcervical resection of the endometrium and rollerball) require hysteroscopy. Second-generation techniques require 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 (Sweet, et al., 2012; ACOG, 2011; Lipscomb, 2008; U.S. Food and Drug Administration [FDA], 2004b):

- 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 12 cm (i.e., equivalent to 10 weeks' gestational size), as this may cause uterine or endocervical canal injury. EA procedures carry about a 4% risk each of uterine perforation, hemorrhage, fluid overload or infection. Rates of amenorrhea vary according to the procedure that is conducted. Reported outcomes have included 15% with ThermaChoice®, 35% with rollerball and loop electrode, and 41% with Novasure™ (Manzi-Smith, 2003). Many patients require a second ablative procedure for bleeding or a hysterectomy for residual bleeding or dysmenorrhea (Arici, 2006).

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)

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 (Daniels, et al., 2012; Matteson, et al., 2012; Munro, et al., 2011; Penninx, et al., 2010; Lethaby, et al., 2009; Sambrook, et al., 2009; Kleijn, et al., 2008; Dickersin et al., 2007; Furst, et al., 2007; Bongers, et al., 2004; Van Zon-Rabelink, et al., 2004; Duleba, et al., 2003; Bain, et al., 2002).

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 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 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): In the 2011 ACOG Practice Bulletin for endometrial ablation, the following recommendations and conclusions are made based on good and consistent scientific evidence:

- 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 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.
- Nonresectoscope 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 (2009) on anovulatory bleeding stated that “the treatment of choice for anovulatory uterine bleeding is medical therapy with oral contraceptives. Cyclic progestins also are effective. Women who have failed medical therapy and no longer desire future childbearing are candidates for EA, which appears to be an efficient and cost-effective alternative treatment to hysterectomy for anovulatory uterine bleeding. However, EA may not be definitive therapy”. Although EA appears to be an effective option in controlling menorrhagia in women without leiomyomas, further studies are needed in women who have clinically significant leiomyomas.

American Society of Reproductive Medicine (ASRM): ASRM (2008) stated that “EA may be considered in premenopausal women for the treatment of menorrhagia. Significant uterine pathology and medical conditions that can cause menorrhagia should be excluded before performing the ablative procedures. 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 or 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.”

Use Outside of the US

National Institute for Health and Clinical Excellence (NICE): A NICE (2007) clinical guideline stated that EA should be considered when bleeding is having a severe impact on a woman’s quality of life, and she does not want to conceive in the future. All women considering endometrial ablation should have access to a second-generation ablation technique. Second-generation ablation techniques should be used where no structural or histological abnormality is present. The second-generation techniques recommended for consideration are:

- Fluid-filled thermal balloon endometrial ablation (TBEA)
- Microwave endometrial ablation (MEA)
- Free fluid thermal endometrial ablation

The 2004 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.

Summary

Evidence in the published peer-reviewed literature indicates that endometrial ablation procedures are safe and effective for a select group of patients with menorrhagia. There is insufficient evidence in the published, peer-reviewed, scientific literature to support chemoablation and photodynamic ablation of the endometrium for the treatment of menorrhagia. There are a limited number of published studies with small patient populations and short-term follow-ups investigating the safety and effectiveness of these other ablative therapies. Patient selection criteria and standard treatment protocols have not been established. Well-designed, randomized controlled trials with long-term outcomes comparing other ablative therapies to established treatment options for menorrhagia are needed.

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

Covered when medically necessary:

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-9-CM Diagnosis Codes	Description
218.0-218.9	Uterine leiomyoma
626.2	Excessive or frequent menstruation
626.4	Irregular menstrual cycle
626.6	Metrorrhagia
626.8	Other disorder of menstruation and other abnormal bleeding from female genital tract
626.9	Disorders of menstruation and other abnormal bleeding from female genital track, unspecified
627.0	Premenopausal menorrhagia

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
	All other codes

Photodynamic Endometrial Ablation or Chemoablation of the Endometrium

Experimental/Investigational/Unproven and Not Covered when used to report photodynamic or chemoablation of the endometrium:

CPT* Codes	Description
58579	Unlisted hysteroscopy procedure, uterus
58999	Unlisted procedure, female genital system

***Current Procedural Terminology (CPT®) © 2013 American Medical Association: Chicago, IL.**

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