



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject **Endometrial Ablation**

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 Uterine Artery Embolization

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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 (sufficient to cause anemia, **OR** bleeding is repeatedly profuse, **OR** repetitive periods are occurring at less than 21-day intervals).
- Hormonal treatment of at least three months' duration has failed, has produced adverse or intolerable effects, or was contraindicated; or the individual was not a candidate for hormonal therapy.
- Diagnostic evaluation of the endometrium by endometrial biopsy, or dilatation and curettage (D&C) failed to show evidence of remediable pathology.
- Diagnostic evaluation of the uterine cavity by ultrasound, sonohysterogram or hysteroscopy failed to show evidence of remediable pathology.
- Uterus size is < 12 weeks' gestation (i.e., uterine length of less than 13 centimeters [cm] and anterior-posterior width of less than 7 cm).
- Endometrial and cervical precancers or cancers are ruled out.
- The woman 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 by the American College of Obstetrics and Gynecologists (Arici, 2006; ACOG, 2001) as prolonged, excessive uterine bleeding or heavy menstrual bleeding (HMB) that occurs at regular intervals, or, more strictly, as the loss of 80 milliliters (mL) 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. If diagnostic testing, and pelvic and physical examinations rule out underlying causes of menorrhagia, conservative treatments such as nonsteroidal anti-inflammatory drugs (NSAIDs), mefenamic acid (Ponstel), antifibrinolytic agents 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 a high success (100%) and patient satisfaction rate (Arici, 2006).

Endometrial Ablation (EA)

EA has developed as a 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, patient selection criteria for EA as a treatment for menorrhagia include:

- 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) were 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 also vary according to the procedure that is conducted, with reports ranging from 15% with ThermaChoice[®]; 35% with rollerball and loop electrode; to 41% with Novasure[™] (Manzi-Smith, 2003). Many patients require another ablative procedure for bleeding or a hysterectomy for residual bleeding or dysmenorrhea (Arici, 2006).

U.S. Food and Drug Administration (FDA)

The FDA has approved several devices for endometrial ablation/resection for the treatment of menorrhagia only (this list may not be all-inclusive):

- 1997: ThermaChoice Uterine Balloon Therapy System, manufactured by Gynecare, a division of Ethicon, Inc., Somerville, NJ
- 2001: Hydro ThermAblator[®], manufactured by BEI Medical Systems, Inc., of Teterboro, NJ
- 2001: Her Option[™] Uterine Cryoablation Therapy System, manufactured by Cryogen, Inc., of San Diego, CA. In December, 2002, Cryogen, Inc., was acquired by American Medical Systems, of Minnetonka,

MN. Prior to the acquisition of Cryogen, Inc., the company's first-generation endometrial probe device, First Choice, did not receive FDA approval for the ablation of endometrial tissue or treatment of menorrhagia (FDA, 1999, Warning Letter).

- 2001: NovaSure Impedance Controlled Endometrial Ablation System, manufactured by Novacept, of Palo Alto, CA
- 2003: Microsulis Microwave Endometrial Ablation (MEA) System, manufactured by Microsulis Corporation, of Riverview, FL.

Literature Review

There is evidence in the form of randomized controlled trials (RCTs) to support 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 (Sambrook, et al., 2009; Kleijn, et al., 2008; Furst, et al., 2007; Bongers, et al., 2004; Van Zon-Rabelink, et al., 2004; Duleba, et al., 2003; Bain, et al., 2002). 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 Dickersin et al. (2007).

A Cochrane meta-analysis by Lethaby et al. (2009) compared the newer EA techniques (i.e., second generation) with the gold standard hysteroscopic ablative techniques (i.e., first generation), and concluded there was no evidence of overall differences in the improvement in HMB or patient satisfaction. Overall, the existing evidence suggests that success rates and complication profiles of newer techniques of ablation compare favorably with hysteroscopic techniques.

A 2004 ECRI Emerging Technology Evidence Report found cryosurgical endometrial ablation appears to be safe and as effective as rollerball electroablation based on the results of an RCT (ECRI, 2004a). Another ECRI report found evidence from RCTs to indicate that impedance-controlled RF endometrial ablation significantly reduces menorrhagia in 70% to 90% of patients for at least one year; results are similar to those achieved with some other endometrial ablation techniques (i.e., rollerball ablation, endometrial hydrothermal balloon ablation) (ECRI, 2004b).

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) are currently being studied.

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 DUB. 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 Society of Reproductive Medicine (ASRM): The ASRM states 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” (Practice Committee of the ASRM, 2008).

American College of Obstetrics and Gynecology (ACOG): In the 2007 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 include 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.

A 2001 ACOG Practice Bulletin states that 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 (ACOG, 2001).

National Institute for Health and Clinical Excellence (NICE): A clinical guideline issued by NICE states that EA should be considered where 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 as follows (NICE, 2007):

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

The NICE guidance on the use of photodynamic endometrial ablation for the treatment of menorrhagia states 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).

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 the use of chemoablation or photodynamic ablation of the endometrium

for the treatment of menorrhagia. Patient selection criteria, standard protocols of treatment applications, and long-term effects of these techniques on patient safety need to be determined through well-designed clinical trials.

Coding/Billing Information

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

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, electro-surgical ablation, thermoablation)

ICD-9-CM Diagnosis Codes	Description
626.2	Excessive or frequent menstruation
626.4	Irregular menstrual cycle
626.6	Metrorrhagia
627.0	Premenopausal menorrhagia

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

ICD-9-CM Diagnosis Codes	Description
	All codes

*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	1/15/2008	0013	Endometrial Ablation
Great-West Healthcare	10/13/2005	05.300.02	Hysteroscopic Endometrial Ablation

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