Clinical Policy Bulletin:
Endometrial Ablation

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Policy

I. Aetna considers endometrial ablation medically necessary for women who meet all of the following selection criteria:

A. Menorrhagia* unresponsive to (or with a contraindication to) either:
   1. Dilation and curettage; or
   2. Hormonal therapy or other pharmacotherapy;

(Note: The degree of severity and persistence of the menorrhagia and the failure of prior treatment should be such that the member would otherwise be a candidate for a hysterectomy.); or

To stop residual menstrual bleeding after androgen treatment in a female to male transgender person who meet criteria for gonadectomy in CPB 615 - Gender Reassignment Surgery [Note: some plans exclude coverage of surgery for gender reassignment; please check benefit plan descriptions.]

and

B. Endometrial sampling or D&C has been performed within the year prior to the procedure to exclude cancer, pre-cancer or hyperplasia, and the results of the histopathological report have been reviewed before the ablation procedure is scheduled; and

C. Structural abnormalities (fibroids, polyps) that require surgery or represent a contraindication to an ablation procedure have been excluded; and

D. Pap smear and gynecologic examination have excluded significant cervical disease.

Aetna considers endometrial ablation experimental and investigational for all other indications because its effectiveness for other indications has not been established.
Aetna considers the following endometrial ablation approaches to be established for treatment of women who meet the selection criteria set forth above:

- Chemical ablation with trichloroacetic acid
- Cryoablation (freezing)
- Electrosurgical ablation (e.g., electric rollerball, resecting loop with electric current, triangular mesh with electrical current)
- Laser
- Microwave endometrial ablation
- Radiofrequency ablation
- Thermoablation (e.g., heated saline, thermal fluid-filled balloon).

II. Aetna considers photodynamic endometrial ablation experimental and investigational because there is insufficient scientific evidence to support its effectiveness.

See also CPB 0304 - Fibroid Treatment.

**Background**

Menorrhagia (excessive uterine bleeding) affects approximately 20% of women of reproductive age. It may be due to many causes, including hormonal disorders, fibroids, tumors, or other problems. Pharmacotherapy and surgery are the mainstay treatments. Most commonly, hormonal and non-hormonal medications are followed by dilatation and curettage, and ultimately, in many cases, hysterectomy.

Endometrial ablation techniques have evolved as an alternative to hysterectomy. Ablation techniques (e.g., laser, resecting loop with electric current, electric rollerball, thermal fluid-filled balloon, radiofrequency, freezing, heated saline) remove some of the lining of the uterus in an attempt to control excessive bleeding. After endometrial ablation, pregnancy is not likely to occur.

Current guidelines recommend an endometrial sampling procedure be done prior to the endometrial ablation. The ACOG Practice Bulletin on endometrial ablation (2007) states: “Endometrial sampling, typically with an outpatient technique, can be used to evaluate all women for hyperplasia or malignancy, and results should be reviewed before ablation is scheduled. Women with endometrial hyperplasia or uterine cancer should not undergo endometrial ablation.”

The early techniques of endometrial ablation, introduced in the 1980s and still used today involve the use of a hysteroscope with either a "rollerball" or wire loop through which electrical heat travels to remove (resection) the endometrial lining. After the uterus is filled with fluid to enlarge it for better viewing, the surgeon moves the rollerball back and forth across the lining or uses the wire loop to shave off the tissue. Potential risks of this ablation method include infection, perforation of the uterus, cervical laceration, and fluid overload.
Bren (2001) reviewed some of the new methods of endometrial ablation. In 1997, the Food and Drug Administration (FDA) approved ThermaChoice, the first non-hysteroscopic ablation device to treat excessive uterine bleeding (menorrhagia) due to benign (non-cancerous) causes. The ThermaChoice Uterine Balloon Therapy System (Gynecare, Somerville, NJ) consists of a balloon that is inserted through the neck of the cervix and into the uterus. Through a catheter connected to a controller console, the balloon is inflated with fluid and heated to 188°F (87°C) for 8 mins to destroy the uterine lining.

In 2001, the FDA approved 3 more similar devices. These devices are to be used only in women who have not yet reached menopause and whose child-bearing is completed. The Hydro ThermAblator (BEI Medical Systems Inc, Teterboro, NJ) delivers heated saline solution into the uterus. The heated saline solution is delivered using hysteroscopic guidance. The heated solution destroys the uterine lining in about 10 mins.

The Her Option Uterine Cryoblation Therapy System (CryoGen Inc., San Diego, CA) uses a cryoprobe capable of producing temperatures down to minus 148°F (minus 100°C) at the tip. This extreme cold is applied to the tissue for 10 mins to freeze and destroy the uterine lining. Ultrasound is used to guide and monitor the procedure.

An assessment by the National Institute for Health and Clinical Excellence (NICE, 2006) found limited short-term evidence on the safety and effectiveness of endometrial cryotherapy for menorrhagia appears adequate to support the use of this procedure in carefully selected patients. Specialist advisors to NICE stated that the evidence from randomized controlled clinical trials is limited, and that this procedure was one of a number of ablation techniques that uses different energy. The specialist advisors to NICE stated that the procedure appears to be safe, but there are no data available on the incidence of major complications. The theoretical adverse events include thermal injury to the cervix and vagina. Anecdotal adverse events include persistent discharge and endometritis.

The NovaSure Impedance Controlled Endometrial Ablation System (Novacept, Palo Alto, CA) uses a metallic mesh triangular electrode that is expanded out of a slender tube into the uterus. A gentle suction brings the tissue into close contact with the triangular electrode, which delivers electrical current to the endometrial tissue, causing its destruction in about 90 seconds. With this method, there is no hysteroscope or ultrasound, so the physician can not view the uterus during the procedure.

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. It can often be carried out under local anesthetic on a day-case basis. An assessment conducted for the NICE (2003) concluded that current evidence on the safety and efficacy of photodynamic endometrial ablation does not appear adequate to support the use of this procedure outside formal research. The NICE's conclusions were based on the "extremely limited" evidence of the safety and effectiveness of this procedure.
An assessment conducted by the National Institute for Clinical Excellence (NICE, 2003) concluded that microwave endometrial ablation is an established method. In reaching this conclusion, NICE considered a Cochrane systematic review of endometrial destruction techniques. The systematic review concluded that women undergoing thermal ablation techniques had a similar reduction in bleeding and were as satisfied as women having hysteroscopic resection of the endometrium. The advantages of thermal ablation techniques were that general anesthesia was not required, and the procedures were quicker and easier to perform. The systematic review did not come to any conclusions about the relative advantages and disadvantages of the different thermal endometrial destruction techniques. The NICE assessment noted that other studies found that between 70 and 80% of women having microwave endometrial ablation were satisfied, and that 95% of women had returned to normal activities within 3 weeks of having the procedure.

Common side effects after endometrial ablation include nausea, vomiting, and a vaginal discharge that can last from days to weeks. Complications of ablation are rare, but may include blood loss requiring a transfusion, perforation of the uterus, or unintended damage to other internal organs.

A number of studies have compared the effectiveness of endometrial ablation techniques, several of which are described below. One randomized study found superior outcomes with electrosurgical ablation with triangular mesh (NovaSure) over balloon thermal ablation (ThermaChoice) for menorrhagia at long-term follow-up. Kleijn and colleagues (2008) evaluated amenorrhea rates, hysterectomy rate, and health-related quality of life (HRQol) associated with the bipolar impedance-controlled endometrial ablation technique (NovaSure) in comparison with balloon ablation technique (ThermaChoice) at 5-year after administration. A total of 126 pre-menopausal women suffering from menorrhagia with a pictorial blood loss assessment count greater than or equal to 150 without intra-cavitary abnormalities were included in this study. They were randomly allocated to bipolar radio-frequency ablation and balloon ablation in a 2:1 ratio. The main outcome measures were amenorrhea rate, hysterectomies, and HRQol as reported at 5-year follow-up. At 5 years of follow-up, the total response rate was 96% in the bipolar group and 90% in the balloon group. Amenorrhea was reported in the bipolar group by 48% of women and in the balloon arm by 32% (relative risk 1.6 [0.93 to 2.6]). There were 8 women in the bipolar group (9.8%) and 5 in the balloon group (12.9%) who had undergone a hysterectomy. Furthermore, there was a significant equal improvement of HRQol over time in both groups. The authors concluded that at 5-year follow-up, bipolar thermal ablation was superior over balloon ablation in the treatment of menorrhagia.

A study found equivalent outcomes from balloon ablation and rollerball ablation for treatment of menorrhagia. Loffer and Grainger (2002) collected long-term follow-up data from women who participated in a randomized trial comparing uterine balloon therapy (UBT) with rollerball ablation for treatment of menorrhagia. Women treated with endometrial ablation for menorrhagia who were available for 5-year follow-up were included in the analysis. Of 255 women treated under the original protocol, 147 were available to be interviewed 5 years after the procedure. Of these, 25 patients reported hysterectomy, repeat ablation, or dilatation and curettage (D&C) between years 3 and 5, leaving 122 eligible for
analysis (61 UBT, 61 rollerball). Of these 122 patients, 58 (95 %) having UBT and 59 (97 %) having rollerball ablation reported normal or less bleeding. Similarly, 93 % and 100 %, respectively, were satisfied with the procedure. Among the total population of 255 women, 42 hysterectomies (21 UBT, 21 rollerball), 5 repeat ablations (3 UBT, 2 rollerball), and 1 D&C (rollerball) were reported by year 5. Thirty-five hysterectomies (83 %) were performed because of bleeding and/or pelvic pain; 1/3 of them were associated with myomas. Nearly 7 of 10 women were cured of menorrhagia without additional intervention 5 years after ablation. The authors concluded that UBT continues to be an effective, simple treatment of menorrhagia, with clinical outcomes similar to those of rollerball ablation at 5-year follow-up.

A randomized trial found radiofrequency ablation superior to thermoablation for treatment of menorrhagia. In a double-blind, randomized controlled trial, Penninx and colleagues (2010) compared the effectiveness of 2 second-generation ablation techniques, bipolar RF impedance-controlled endometrial ablation and hydro-thermablation in the treatment of menorrhagia. Women with menorrhagia were randomly allocated to bipolar RF ablation (bipolar group) and hydro-thermablation (hydro-therm group). At follow-up, both women and observers remained unaware of the type of treatment that had been performed. The primary outcome was amenorrhea; secondary outcome measures were patient satisfaction and reintervention. A total of 160 women were included in the study, of which 82 were allocated to the bipolar group and 78 to the hydro-therm group. No complications occurred in either of the treatment groups. After 12 months, 87 % (65 of 75) of the patients in the bipolar group were completely satisfied with the result of the treatment compared with 68 % (48 of 71) in the hydro-therm group (relative risk 1.3, 95 % confidence interval [CI]: 1.03 to1.6). The amenorrhea rates were 47 % (35 of 75) in the bipolar group and 24 % (17 of 71) in the hydro-therm group (relative risk 2.0, 95 % CI: 1.2 to 3.1). The relative risks for a re-intervention in the bipolar group compared with the hydro-therm group was 0.29 (95 % CI: 0.12 to 0.67), whereas for hysterectomy, this was 0.49 (95 % CI: 0.15 to1.5). The authors concluded that in the treatment of menorrhagia, bipolar RF endometrial ablation system is superior to hydro-thermablation.

New methods of endometrial ablation are being investigated. In a prospective, randomized, controlled study, Kucuk and Okman (2005) assessed the effectiveness of trichloroacetic acid (TCA) instillation into uterine cavity for the treatment of patients with dysfunctional uterine bleeding (DUB). A total of 90 women were randomized to receive only TCA or receive a single dose of gonadotropin-releasing hormone analog 1 month before the procedure. All subjects underwent an evaluation that included cycle history, body mass index measurement, and trans-vaginal ultrasonography of pelvis, diagnostic hysteroscopy and endometrial biopsy. At the end of 12 months, amenorrhea rates in group 1 and group 2 were 26.7 % versus 31.1 %, with pooled amenorrhea, hypomenorrhea, and eumenorrhea rates of 95.6 % versus 97.8 %, respectively. There was no significant difference between the groups’ vis-à-vis post-procedure results. More than 90 % of women who had this procedure were satisfied with the results. There were no observed negative effects or related complications with this treatment. These investigators concluded that an instillation of TCA into uterine cavity produced acceptable results and provided conservative management of DUB. This is in agreement with the findings of a randomized
controlled trial by Kucukozkan et al (2004) who reported that endometrial ablation by TCA may readily be performed as an alternative method in the treatment of DUB. These investigators also noted that suppression of endometrium with danazol or especially with goserelin acetate before chemical ablation with TCA resulted in significant success rate.

In a meta-analysis, Daniels et al (2012) examined the relative effectiveness of second generation ablation techniques in the treatment of heavy menstrual bleeding. A total of 19 randomized controlled trials (RCTs; involving 3,287 women) were identified through electronic searches of the Cochrane Library, Medline, Embase and PsycINFO databases from inception to April 2011. The reference lists of known relevant articles were searched for further articles. Two reviewers independently selected articles without language restrictions.

Randomized controlled trials involving second generation endometrial destruction techniques for women with heavy menstrual bleeding unresponsive to medical treatment were selected for analysis. Of the 3 most commonly used techniques, network meta-analysis showed that bipolar radiofrequency and microwave ablation resulted in higher rates of amenorrhea than thermal balloon ablation at around 12 months (odds ratio 2.51, 95 % CI: 1.53 to 4.12, p < 0.001; and 1.66, 1.01 to 2.71, p = 0.05, respectively), but there was no evidence of a convincing difference between the 3 techniques in the number of women dissatisfied with treatment or still experiencing heavy bleeding. Compared with bipolar radio frequency and microwave devices, an increased number of women still experienced heavy bleeding after free fluid ablation (95 % CI: 2.19: 1.07 to 4.50, p = 0.03; and 95 CI: 2.91: 1.23 to 6.88, p = 0.02, respectively). Compared with radiofrequency ablation, free fluid ablation was associated with reduced rates of amenorrhea (95 % CI: 0.36, 0.19 to 0.67, p = 0.004) and increased rates of dissatisfaction (95 % CI: 4.79, 1.07 to 21.5, p = 0.04). Of the less commonly used devices, endometrial laser intra-uterine thermotherapy was associated with increased rates of amenorrhea compared with all the other devices, while cryoablation led to a reduced rate compared with bipolar radiofrequency and microwave. The authors concluded that bipolar radiofrequency and microwave ablative devices are more effective than thermal balloon and free fluid ablation in the treatment of heavy menstrual bleeding with second generation endometrial ablation devices.

Endocrine Society Guidelines (Hembree, et al., 2009) indicate endometrial ablation in female to male transgender individuals with residual bleeding after testosterone treatment. These guidelines state that 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, addition of a progestational agent or endometrial ablation may be considered.

CPT Codes / HCPCS Codes/ ICD-9 Codes

CPT codes covered if selection criteria are met:

58353
58356
Other CPT codes related to the CPB:

57558
57800
58100 - 58294
58558

Other HCPCS codes related to the CPB:

C1886 Catheter, extravascular tissue ablation, any modality (insertable)

ICD-9 codes covered if selection criteria are met:

626.2 Excessive or frequent menstruation
626.3 Pubertal bleeding
627.0 Premenopausal menorrhagia
627.1 Postmenopausal bleeding

Other ICD-9 codes related to the CPB:

182.0 Malignant neoplasm of corpus uteri, except isthmus
218.0 - 218.9 Uterine leiomyoma
219.1 Other benign neoplasm of corpus uteri
621.0 Polyp of corpus uteri

The above policy is based on the following references:


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