Protocol

Endometrial Ablation

(40104)

Medical Benefit		**Effective Date**: 01/01/14	**Next Review Date**: 09/14
Preauthorization	No	**Review Dates**: 09/13	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

Endometrial ablation is a potential alternative to hysterectomy for menorrhagia. A variety of approaches are available; these are generally classified into hysteroscopic techniques (e.g., Nd-YAG laser and electrosurgical rollerball) and non-hysteroscopic techniques (e.g., cryosurgical and radiofrequency [RF] ablation).

Background

Ablation or destruction of the endometrium is used to treat menorrhagia in women who failed standard therapy. It is considered a less invasive alternative to hysterectomy; however, as with hysterectomy, the procedure is not recommended for women who wish to preserve their fertility.

Multiple energy sources have been used. These include: the neodymium-yttrium aluminum garnet (Nd-YAG) laser, a resecting loop using electric current, electric rollerball, and thermal ablation devices. Endometrial ablation is typically preceded by hormonal treatment to thin the endometrium.

Techniques for endometrial ablation are generally divided into two categories: those that do and do not require hysteroscopic procedures. (Other terminology for these categories of techniques include first- generation versus second-generation procedures and resectoscopic versus non-resectoscopic endometrial ablation methods.) Hysteroscopic techniques were developed first; the initial technique was photovaporization of the endometrium using an Nd-YAG laser, and this was followed by electrosurgical ablation using an electrical rollerball or electrical wire loop. (The latter technique is also known as transcervical resection of the endometrium or TCRE.) Hydrothermal ablation also involves hysteroscopy. Hysteroscopic techniques require skilled surgeons and, due to the requirement for cervical dilation, use of general or regional anesthesia. In addition, the need for the instillation of hypotonic distension media creates a risk of pulmonary edema and hyponatremia such that very accurate monitoring of fluids is required.

Non-hysteroscopic techniques can be performed without general anesthesia and do not involve use of a fluid distention medium. Techniques include thermal fluid-filled balloon, cryosurgical endometrial ablation, instillation of heated saline, and radiofrequency (RF) ablation.

There are concerns about maternal and fetal morbidity and mortality associated with pregnancy after endometrial ablation. Thus, U.S. Food and Drug Administration (FDA) approval of endometrial ablation devices includes only women for whom childbearing is complete.

Regulatory Status

The FDA indicates that endometrial devices are for use in premenopausal women with menorrhagia due to benign causes for whom childbearing is complete. FDA-approved devices for endometrial ablation include, but

may not be limited to, laser therapy, electrical wire loop, rollerball using electric current, and thermal ablation using a liquid-filled balloon, microwave, electrode array, or a cryosurgical device. Examples of devices for endometrial ablation are:

- The Hydro ThermAblator® system (Boston Scientific, Natick, MA): This involves the instillation and circulation of heated saline into the uterus using hysteroscopic guidance. The Genesys HTA™ system (also Boston Scientific), a newer version of this technology that includes features such as a smaller console and simplified set-up requirements, was approved by the FDA in May 2010.
- The Microwave Endometrial Ablation (MEA) system (Microsulis Medical, U.K.): This delivers fixed-frequency microwave energy and may be performed in a physician's office but does require use of the hysteroscope.
- The ThermaChoice® device (J&J Ethicon Gynecare, Somerville, NJ): This device ablates endometrial tissue by thermal energy heating of sterile injectable fluid within a silicone balloon. Endometrial ablation will only work when there is direct contact between the endometrial wall and the fluid-filled balloon. Therefore, patients with uteri of abnormal shape, resulting from tumors such as myomas or polyps, or large size, due to fibroids, are generally not considered candidates for this procedure.
- The NovaSure™ impedance-controlled endometrial ablation system (Cytyc Corp, Marlborough, MA): The system delivers RF energy to the endometrial surface. The device consists of an electrode array on a stretchable porous fabric that conforms to the endometrial surface.
- Her Option™ Uterine Cryoablation Therapy™ system (American Medical Systems, Minnetonka, MN): The system consists of, in part, a cryoprobe that is inserted through the cervix into the endometrial cavity. When cooled, an ice ball forms around the probe, which permanently destroys the endometrial tissue. Cryoablation is typically monitored by abdominal ultrasound.

Corporate Medical Guideline

Endometrial ablation, with or without hysteroscopic guidance, using an FDA-approved device may be considered **medically necessary** in women with menorrhagia who are not candidates for, or who are unresponsive to, hormone therapy and would otherwise be considered candidates for hysterectomy.

Endometrial ablation is considered **investigational** for all other indications.

Policy Guideline

Intrauterine ablation or resection of the endometrium should not be confused with laparoscopic laser ablation of intraperitoneal endometriosis. This Protocol does not address laparoscopic intraperitoneal ablation.

Contraindications for intrauterine ablation or resection of the endometrium include:

- Patient who is pregnant or desires pregnancy
- History of endometrial cancer or pre-cancerous histology
- Patient with an active genital or urinary tract infection at the time of the procedure
- Patient with active pelvic inflammatory disease
- Patient with an intrauterine device (IUD) currently in place
- Patient with any anatomic or pathologic condition in which weakness of the myometrium could exist, such as history of previous classical cesarean sections or transmural myomectomy.

Other contraindications for microwave ablation include myometrial thickness less than 10 mm, and uterine sounding length less than 6 cm.

In February 2013, the FDA downgraded its contraindication of NovaSure for women with Essure® contraceptive micro-inserts to a warning. The warning states that a health hazard may exist when a NovaSure procedure is performed in women with improperly positioned Essure® micro-inserts. To verify proper placement, a report of the Essure Confirmation Test (ECT) should be obtained prior to performing the NovaSure procedure. The labeling change also includes the requirement for a post-approval study. (1)

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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17. National Institute for Health and Clinical Excellence (NICE). Heavy menstrual bleeding. Clinical guideline 44. 2007. Available online at: www.nice.org.uk/nicemedia/pdf/CG44NICEGuideline.pdf. Last accessed June, 2013.