

Evidence Based Guideline

Intrauterine Ablation or Resection of the Endometrium

File Name: intrauterine_ablation_or_resection_of_the_endometrium
Origination: 4/1993
Last CAP Review: 12/2006
Next CAP Review: 9/2012
Last Review: 3/2012

Description of Procedure or Service

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.

The following multiple energy sources have been developed to perform endometrial ablation:

1. the neodymium- yttrium aluminum garnet (Nd-YAG) laser;
2. a resecting loop using electric current;
3. electric rollerball;
4. thermal ablation devices using thermal energy (heat or cold), including high frequency radio frequency (RF) probes, cryoprobes, liquid filled balloons, multi-electrode balloons, hydrothermal ablation/circulating heated saline, and microwave energy.

Techniques for endometrial ablation are generally divided into two categories: those that do and do not require hysteroscopic procedures (also known as first- and second-generation procedures). 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. Intrauterine ablation or resection may be performed on an outpatient basis, with an overnight hospital stay, or in a physician's office depending on the method used.

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

Endometrial ablation is typically preceded by hormonal treatment to thin the endometrium. After treatment, scarring of the uterine cavity occurs and the endometrium is not expected to regenerate. Pregnancies that occur after ablation can be dangerous for both the fetus and the mother. Although women undergoing endometrial ablation or resection must be finished with childbearing, intrauterine ablation or resection should not be considered a means of sterilization. Sterility may occur after ablation or resection, but cannot be guaranteed.

Intrauterine Ablation or Resection of the Endometrium

The U.S. Food and Drug Administration (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 (Cytoc 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.

*****Note: This Evidence Based Guideline is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Evidence Based Guideline for Intrauterine Ablation or Resection of the Endometrium

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

Medical Evidence regarding Intrauterine Ablation or Resection of the Endometrium indicates it is not recommended in the following situations

Intrauterine ablation or resection of the endometrium is not recommended when **any** of the following medical contraindications are present:

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

Contraindications for microwave ablation include:

- Essure contraceptive micro-inserts are in place in the fallopian tubes;
- Myometrial thickness less than 10 mm;
- Uterine sounding length less than 6 cm.

Benefits Application

This evidence based guideline relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this evidence based guideline.

Billing/Coding/Physician Documentation Information

This guideline may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 58353, 58356, 58563

Scientific Background and Reference Sources

BCBSA - 12/95

BCBSA - 7/31/97

Meyer WR, Walsh BW, Grainger DA. Thermal balloon and rollerball ablation to treat menorrhagia: a multicenter comparison. *Obstetrics & Gynecology*. 1998;92(1):98-103.

Amso NN, Stabinski SA, McFaul P. Uterine thermal balloon therapy for the treatment of menorrhagia: the first 300 patients from a multi-centre study. *British Journal of Obstetrics & Gynaecology*. 1998;105:517-523.

Specialty Matched Consultant Advisory Panel - 11/99

Medical Policy Advisory Group - 12/2/99

Intrauterine Ablation or Resection of the Endometrium

Specialty Matched Consultant Advisory Panel - 9/2001

ECRI Hotline Response: Cryosurgical Endometrial Ablation for Menorrhagia, Updated on 5/23/02

ECRI Hotline Response: Hydrothermal Endometrial Ablation for Menorrhagia, Updated on 6/3/02

BCBSA Medical Policy Reference Manual - Policy 4.01.04 - Review date: 07/12/02

FDA New Device Approval: Hydro ThermAblator®, referenced 9/6/02

Specialty Matched Consultant Advisory Panel - 12/2002

BCBSA Medical Policy Reference Manual - Policy 4.01.04 - Review date: 12/18/02

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.04, 2/25/04.

National Institute for Clinical Excellence. Interventional Procedure Guidance 47 - Photodynamic endometrial ablation. Accessed on 10/14/2004 at <http://www.nice.org.uk/pdf/IPG047guidance.pdf>.

Specialty Matched Consultant Advisory Panel - 12/2004

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.04, 12/14/05.

Specialty Matched Consultant Advisory Panel - 12/13/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 4.01.04, 7/14/11.

Policy Implementation/Update Information

10/89	Evaluated: Investigational for laser ablation
11/91	Evaluated: Eligible for coverage for laser ablation, rollerball ablation and loop resection
6/96	Reaffirmed: National Association reviewed 12/95. No changes.
7/99	Added liquid-filled balloon devices that have been FDA approved to covered indications.
7/99	Reformatted, Medical Term Definitions added.
12/99	Reaffirmed, Medical Policy Advisory Group
12/00	58563 added as replacement code for 56356 which is a deleted code (CPT 1999). New 2001 CPT code added; 58353. System coding changes.
9/01	Specialty Matched Consultant Advisory Panel review. No changes in criteria.
4/02	Policy revised under when it is covered to include liquid-filled balloons that are FDA approved such as ThermaChoice®. Revised under when it is not covered to clarify other thermal ablation devices that are not covered. Clarified contraindications to include women that have not finished with childbearing. Format changes. Billing/Coding Section updated with revised coding language.
8/02	Implementation section for 4/02 clarified for system coding changes.
01/03	Specialty Matched Consultant Advisory Panel review 12/02/2002. Description of procedure section revised for clarity. Under "When Covered" section - #3 added two bullets. One for Cryosurgical devices that are approved by the FDA such as HerOption Uterine Cryoablation Therapy System and another for Hydrothermal devices that are approved by the FDA such as Hydro ThermAblator Endometrial Ablation System. Under "When Not Covered" section re: techniques, first bullet, removed (except FDA approved thermal devices for.....). 0009T added to Billing/Coding Section. System coding changes.
7/03	Corrected dates of last review and next review to 12/2002 and 12/2004 respectively (Specialty Matched Consultant Advisory Panel review was 12/2002, not 10/2002.) Benefits Application

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- section revised.
- 4/04 Billing/Coding section updated for consistency.
- 12/23/04 Specialty Matched Consultant Advisory Panel review 12/9/2004. Added microwave energy devices (such as MEA system) and radiofrequency energy devices (such as NovaSure system) that are approved by the FDA as covered. Under "When not covered" section: Added photodynamic endometrial ablation as non-covered (investigational); Listed VestaBlate with 12 RF electrodes as a multi-electrode balloon under second bullet; Removed "including high frequency radiofrequency (RF) probes" and "microwave energy"; Contraindications updated. CPT Code 0009T removed from Billing/Coding section-code will be deleted as of 12/31/04. To report 0009T effective 1/1/05 providers should use CPT code 58356. CPT code 58356 added. Sources added. Notice given 12/ 23/04. Effective 3/3/05.
- 8/21/06 Medical Policy changed to Evidence Based Guideline.
- 1/17/2007 Specialty Matched Consultant Advisory Panel - 12/12/2006. No changes to criteria. Billing/Coding section revised. Reference sources added. (pmo)
- 10/20/08 Evidence Based Guideline status changed to "Active guideline, no longer scheduled for routine literature review." (pmo)
- 6/22/10 Policy Guideline Number(s) removed (amw)
- 3/30/12 Guideline returned to active review. References updated. "Dilation and curettage" removed from guideline statement and "would otherwise be considered a candidate for hysterectomy" added. A statement was added for clarification that endometrial ablation is not recommended for all other indications. No changes to guideline intent. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.