IMPORTANT NOTE:

The purpose of this policy is to provide general information applicable to the administration of health benefits that Horizon Blue Cross Blue Shield of New Jersey and Horizon Healthcare of New Jersey, Inc. (collectively “Horizon BCBSNJ”) insures or administers. If the member’s contract benefits differ from the medical policy, the contract prevails. Although a service, supply or procedure may be medically necessary, it may be subject to limitations and/or exclusions under a member’s benefit plan. If a service, supply or procedure is not covered and the member proceeds to obtain the service, supply or procedure, the member may be responsible for the cost. Decisions regarding treatment and treatment plans are the responsibility of the physician. This policy is not intended to direct the course of clinical care a physician provides to a member, and it does not replace a physician’s independent professional clinical judgment or duty to exercise special knowledge and skill in the treatment of Horizon BCBSNJ members. Horizon BCBSNJ is not responsible for, does not provide, and does not hold itself out as a provider of medical care. The physician remains responsible for the quality and type of health care services provided to a Horizon BCBSNJ member.

Horizon BCBSNJ medical policies do not constitute medical advice, authorization, certification, approval, explanation of benefits, offer of coverage, contract or guarantee of payment.

Endometrial ablation is a less invasive alternative to hysterectomy in the treatment of women with menorrhagia who have failed standard therapy. However, as with hysterectomy, the procedure is not recommended for women who wish to preserve their fertility.

Multiple energy sources are used in endometrial ablation and these include: (1) the neodymium-yttrium aluminum garnet (Nd-YAG) laser; (2) a resecting loop using electric current; (3) electric rollerball; and (4) thermal ablation devices including high-frequency radiofrequency (RF) probes, cryoprobes, liquid-filled balloons, multi-electrode balloons, microwave energy, and installation of heated saline.

A variety of approaches/techniques for endometrial ablation are available and these are generally classified into hysteroscopic techniques (e.g., ND:YAG laser and electrosurgical rollerball) and non-hysteroscopic techniques (e.g., cryosurgical and radiofrequency ablation):

- Hysteroscopic techniques were developed first; the initial technique was photovaporization of the endometrium using a 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 trans cervical resection of the endometrium or TCRE). Hydrothermal ablation also involves hysteroscopy. Hysteroscopic techniques require skilled surgeons and, due to the requirement for cervical dilation, the 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 the use of a fluid distention medium. Techniques include thermal fluid-filled balloon, cryosurgical endometrial ablation, instillation of heated saline, and radiofrequency ablation.

Regulatory Status

The FDA indicates that endometrial devices are for use in pre-menopausal 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, roller ball using electric current, or thermal ablation using a liquid-filled balloon, microwave, electrode array or a cryosurgical device. Examples of FDA-approved devices for endometrial ablation are:

- **ThermaChoice** device manufactured by Gynecare, a division of Ethicon Inc. of Sommerville, NJ, has been approved by the U.S. Food and Drug Administration (FDA) as a technique for endometrial ablation; this device ablates endometrial tissue by thermal energy heating of sterile injectable fluid within a silicone balloon. This technique does not require a hysteroscope for guidance. 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, such as myomas, polyps, or large size due to fibroids, are generally not considered candidates for this procedure.

- **Hydro ThermAblator Endometrial Ablation System** manufactured by BEI Medical Systems Inc. of Teterboro, NJ, delivers hot saline solution into the endometrial cavity through a tube inserted into the cervix. The hot solution destroys the endometrial lining in about 10 minutes. A hysteroscope is used for viewing the uterus during the procedure. This technique may be useful in patients with abnormally shaped uterus in which a balloon system would not conform to the endometrial wall. The **Genesys HTA System**, a newer version of this technology including features such as a smaller console and simplified set-up requirements, was approved by the FDA in May 2010.

- **Her Option Uterine Cryoablation Therapy System** made by CryoGen Inc. of San Diego, CA, has also been FDA approved as a technique for endometrial ablation. The device consists in part of 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 but does not require a hysteroscope.

- **NovaSure Impedance Controlled Endometrial Ablation System** manufactured by Novacept of Palo Alto, CA, uses a bipolar electrode array that expands into a triangle-like shape when deployed in the uterus to deliver radio-frequency (RF) energy. Suction drawn through the device serves to maintain good contact between the endometrial tissue and the electrode during the ablation process, and also removes liquids, stem and other gases generated during the procedure. The actual RF treatment takes about 90 seconds. With this technique, a hysteroscope or ultrasound for guidance is not utilized.

- **Microwave Endometrial Ablation (MEA) System**, manufactured by Microsulis Medical Limited, received FDA approval for endometrial ablation by using fixed-frequency microwave energy. A
long slender tube that delivers microwave energy is inserted through the vagina into the uterus. A computer is used to deliver microwave energy which causes a rise in temperature where the tip of the applicator meets the tissue. The surgeon moves the applicator in a sweeping motion from side to side across the tissue while slowly pulling the applicator out of the uterus. Treatment typically lasts 3 ½ minutes.

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

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**Horizon BCBSNJ Medical Policy Development Process:**

This Horizon BCBSNJ Medical Policy (the “Medical Policy”) has been developed by Horizon BCBSNJ’s Medical Policy Committee (the “Committee”) consistent with generally accepted standards of medical practice, and reflects Horizon BCBSNJ’s view of the subject health care services, supplies or procedures, and in what circumstances they are deemed to be medically necessary or experimental/investigational in nature. This Medical Policy also considers whether and to what degree the subject health care services, supplies or procedures are clinically appropriate, in terms of type, frequency, extent, site and duration and if they are considered effective for the illnesses, injuries or diseases discussed. Where relevant, this Medical Policy considers whether the subject health care services, supplies or procedures are being requested primarily for the convenience of the covered person or the health care provider. It may also consider whether the services, supplies or procedures are more costly than an alternative service or sequence of services, supplies or procedures that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the relevant illness, injury or disease. In reaching its conclusion regarding what it considers to be the generally accepted standards of medical practice, the Committee reviews and considers the following: all credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician and health care provider specialty society recommendations, the views of physicians and health care providers practicing in relevant clinical areas (including, but not limited to, the prevailing opinion within the appropriate specialty) and any other relevant factor as determined by applicable State and Federal laws and regulations.

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**References:**


6. ECRI. Target Report #660: Hydrothermal endometrial ablation for excessive uterine bleeding. July
1998. (current version as of 08/31/07)


9. ECRI. Target Report #661: Cryosurgical endometrial ablation for excessive uterine bleeding. Content current as of: April, 2004. (current version as of 08/31/07)


