Laparoscopic and Percutaneous Techniques for the Myolysis of Uterine Fibroids

**Description**

Various minimally invasive treatments for uterine fibroids have been proposed as alternatives to surgery. Among these approaches are laparoscopic and percutaneous techniques to induce myolysis, which includes radiofrequency volumetric thermal ablation (RFVTA), laser and bipolar needles, cryomyolysis, and magnetic resonance imaging-guided laser ablation.

**OBJECTIVE**

The objective of this evidence review is to determine whether laparoscopic and/or percutaneous techniques to induce myolysis improves the net health outcome in individuals with uterine fibroids.
POLICY STATEMENT

Laparoscopic and percutaneous techniques of myolysis as a treatment of uterine fibroids are considered investigational.

POLICY GUIDELINES

In November 2014, the U.S. Food and Drug Administration published a safety communication on laparoscopic power morcellators used for myomectomy and hysterectomy in most women. (Morcellators are not otherwise addressed herein). The Administration recommended that manufacturers of these devices include in their product labels a boxed safety warning and wording on contraindications (see https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM424123.pdf).

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

In 2012, the Acessa™ System (Acessa Health, formerly Halt Medical) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for percutaneous laparoscopic coagulation and ablation of soft tissue and treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance (K121858). The technology was previously approved in 2010, at which time it was called the Halt 2000GI™ Electrosurgical Radiofrequency Ablation System. In 2014, the ultrasound guidance system received marketing clearance from the FDA (K132744), FDA product code: GEI. In 2018, the third-generation Acessa™ ProVu System was cleared for marketing by the FDA through the 510(k) process for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. (K181124). FDA product code: HFG.

Cryoablation is a surgical procedure that uses previously approved and available cryoablation systems; and as a surgical procedure, it is not subject to regulation by the FDA. Other products addressed in this review (eg, Nd:YAG lasers, bipolar electrodes) have long-standing FDA approval, and there are no products specifically approved for the treatment of uterine fibroids.

RATIONALE

Summary of Evidence

For individuals who have symptomatic uterine fibroids who receive radiofrequency volumetric thermal ablation (RFVTA), the evidence includes a randomized controlled trial (RCT) and systematic review. The relevant outcomes are symptoms, quality of life (QOL), and treatment-related morbidity. The meta-analysis found low rates of reintervention with RFVTA and QOL outcomes that were similar to uterine artery embolization and myomectomy at 12 months. Data on reintervention rates at 36 months were limited to 1 study and no studies reported reintervention rates at 60 months. The single RCT with a follow-up longer than three months found that RFVTA was noninferior to laparoscopic myomectomy on the trial's primary outcome: length of hospitalization. A number of secondary outcomes were reported at 12 and 24 months, including symptoms and QOL. None of the secondary outcomes demonstrated significant between-group differences in a subgroup analysis of 43 patients. Additional well-designed RCTs with longer follow-up are needed to determine the effect of RFVTA on health outcomes compared with other treatment options. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have symptomatic uterine fibroids who receive laser or bipolar needles, the evidence includes case series. The relevant outcomes are symptoms, QOL, and treatment-related morbidity. The case series were published in the 1990s, and the procedures used then may not reflect current practice. RCTs comparing laser or bipolar needles with alternative treatments for uterine fibroids are needed to evaluate the safety and efficacy of this technology adequately. The evidence is insufficient to determine the effects of the technology on health outcomes.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
For individuals who have symptomatic uterine fibroids who receive cryomyolysis, the evidence includes case series. The relevant outcomes are symptoms, QOL, and treatment-related morbidity. Among the few case series, sample sizes were small (≤20 patients). RCTs comparing cryomyolysis with alternative treatments for uterine fibroids are needed to evaluate the safety and efficacy of this technology adequately. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have symptomatic uterine fibroids who receive magnetic resonance imaging-guided laser ablation, the evidence includes a study with historical controls. The relevant outcomes are symptoms, QOL, and treatment-related morbidity. A single study with historical controls is not sufficiently robust to evaluate this technology. RCTs comparing magnetic resonance imaging-guided laser ablation with alternative treatments for uterine fibroids are needed to evaluate safety and efficacy adequately. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Obstetricians and Gynecologists

The American College of Obstetricians and Gynecologists (2019) reaffirmed its 2008 position on alternatives to hysterectomy in the management of leiomyomas. Recommendations based on good and consistent scientific evidence were that abdominal myomectomy is a safe and effective treatment for women with symptomatic leiomyomas and that uterine artery embolization is a safe and effective option for appropriately selected women who want to retain their uteri. The bulletin contained no recommendations on myolysis using laparoscopic or percutaneous techniques.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES


**POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:**

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<td>Replace policy</td>
<td>Policy updated with literature review; references 2, 4, and 15 added. Policy statement unchanged.</td>
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<td>September 2015</td>
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<td>Policy updated with literature review; references 2, 4, and 15 added. Policy statement unchanged.</td>
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<td>Replace policy</td>
<td>Policy updated with literature review; references 3-4 added. Policy statement unchanged.</td>
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