FEP 4.01.19 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.

FDA REGULATORY STATUS
In November 2012, the Acessa™ System (Acessa Health, Austin, TX, 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. The technology was previously approved in 2010, at which time it was called the Halt 2000GI™ Electrosurgical Radiofrequency Ablation System. The intended use of the Halt 2000GI™ system was for percutaneous laparoscopic coagulation and ablation of soft tissue. Unlike FDA clearance of the Acessa™ System, the intended use statement for the Halt 2000GI™ system does not specifically mention the treatment of uterine fibroids. FDA product code: GEI.

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 FDA. Other products addressed in this review (eg, Nd:YAG lasers, bipolar electrodes) have long-standing FDA approval, and there are not products specifically approved for treatment of 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.
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(see http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm393809.htm).

**BENEFIT APPLICATION**

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

**RATIONALE**

**Summary of Evidence**

For individuals who have uterine fibroids who receive RFVTA, the evidence includes an RCT. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. The RCT 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 the clinically relevant outcomes (symptoms and quality of life), none of which demonstrated significant between-group differences. The RCT had a relatively small sample size (N=50), and only included 43 (86%) patients in 12- and 24-month analyses. A prospective case series with 3 years of follow-up reported positive outcomes (eg, increase in quality of life and low reintervention rate). Given the limitations in the RCT design and lack of significant benefit on clinically important outcomes, additional well-designed RCTs 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 uterine fibroids who receive laser or bipolar needles, the evidence includes case series. Relevant outcomes are symptoms, quality of life, 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.

For individuals who have uterine fibroids who receive cryomyolysis, the evidence includes case series. Relevant outcomes are symptoms, quality of life, 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 uterine fibroids who receive magnetic resonance imaging-guided laser ablation, the evidence includes a case series. Relevant outcomes are symptoms, quality of life, and treatment-related morbidity. A single case series (N=66) is insufficient for evaluating the technology. RCTs comparing magnetic resonance imaging-guided laser ablation 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.

**SUPPLEMENTAL INFORMATION**

**Practice Guidelines and Position Statements**

**Society of Obstetricians and Gynecologists of Canada**

In 2015, the Society of Obstetricians and Gynecologists of Canada published clinical guidelines on the management of uterine leiomyomas. The guidelines included the following summary statements:
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- “Of the conservative interventional treatments currently available, uterine artery embolization has the longest track record and has been shown to be effective in properly selected patients.”
- “Newer focused energy delivery methods are promising but lack long-term data.”

American College of Obstetricians and Gynecologists

In 2016, the American College of Obstetricians and Gynecologists reaffirmed its 2008 Practice Bulletin 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 (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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POLICY HISTORY

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<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tr>
<td>September 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 5 and 15 added. Policy statement unchanged.</td>
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<tr>
<td>September 2016</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 3-4 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>December 2017</td>
<td>Update Policy</td>
<td>Policy updated with literature review through 2017; references 7 and 18 added. Policy statement unchanged.</td>
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