Subject: Magnetic Resonance Guided Focused Ultrasound Ablation for Uterine Fibroids

Overview: Magnetic resonance (MR)-guided focused ultrasound (MRgFUS) has been proposed as a non-invasive technique used to ablate uterine fibroids. During the procedure, magnetic resonance imaging (MRI) is used to guide highly focused ultrasound energy directly to the fibroid, causing tissue temperature to rise. Thermal destruction of the fibroid is monitored to avoid damage to nearby tissue or structures.

Policy and Coverage Criteria:

HPHC does NOT cover MR-guided ultrasound ablation for uterine fibroids. It is considered investigational/experimental and unproven.

Exclusions: N/A

Supporting Information:

1. Technology Assessment: Magnetic resonance-guided focused ultrasound (MRgFUS) combines thermal effects from absorption of acoustic energy with real-time imaging for treatment of symptomatic uterine fibroids. Thermal ablation by MRgFUS causes cell death and coagulative necrosis of the targeted tissue, while sparing surrounding organs. MRgFUS ablation of uterine fibroids with the ExAblate is done on an outpatient basis.

2. Literature Review:

Studies evaluating MRgFUS have reported reductions in fibroid volume and symptom improvement. However, most studies have short follow-up periods and do not compare the results of the MRgFUS to more established fibroid treatments. Questions remain around the maximum size of fibroids that can be treated with this technique.

A 2012 review by Hesley et al. noted early and intermediate follow-up of patients treated with MRgFUS provided promising results on efficacy and symptom relief. Efficacy can be further evaluated as more long-term follow-up data are published comparing the procedure to other fibroid treatment options.

12-month follow-up results were published by Gorny et al. (2011). 130 women were treated. The cumulative incidence of additional surgical fibroid treatment was 7.4% at 12 months after treatment. The average symptom relief score trended up between 3 and 12 months, but the increase was not significant. The authors felt the data demonstrated MRgFUS to be effective in treating symptomatic fibroids. Symptoms relief occurs soon after the procedure and persists during a 12-month period.

LeBlang et al. (2010) recently reported on a study of 80 women with symptomatic leiomyomas. Qualitative and quantitative relations between fibroid volume, nonperfused volume ratio at treatment, and 6-month shrinkage were measured. Results showed immediately after treatment the average nonperfused volume ration was 55% +/- 25%. After six months, the average volume reduction was 31% +/- 28%. A linear regression model found significant correlation between post-treatment nonperfused volume ration and shrinkage at 6 months.
LeBlang et al. concluded the MRgFUS treatment can result in better results than shown in previous studies because treatment guidelines have been relaxed to allow for a greater amount of tissue ablation. They suggest that by ablating a larger area, greater shrinkage can occur and lead to improved symptom relief.

Morita et al. (2008) described their early experience using MRgFUS to treat uterine fibroids in 48 women. During the 12-month follow-up, 2 women required surgical intervention, and two required additional drug treatment. The average reduction in fibroid volume as determined by MRI, was 33% at 6 months. No serious complications were reported. The authors concluded that the technology can safely be used in the treatment of fibroids and helps avoid surgical intervention in the short-term. However, they caution that additional follow-up is needed to determine the long-term durability of the procedure.

Stewart, et al. (2006) assessed the outcomes of a single treatment session of Magnetic Resonance-guided Focused Ultrasound (MRgFUS), at 6 and 12 month intervals. They evaluated 109 women 6 months after treatment and 82 women 12 months following treatment. They concluded the treatment had short-term symptom reduction for women with symptomatic uterine leiomyomas. The study also noted the incidence of adverse events was low.

In another article, Stewart et al. (2007) analyzed follow-up results of women who participated in all clinical trials of magnetic resonance-guided focused ultrasound surgery for uterine leiomyomata. Data on 359 women completing 24-month follow-up were evaluated and the investigators found women undergoing magnetic resonance-guided focused ultrasound surgery for symptomatic uterine leiomyoma had durable symptom relief, as measured by the symptom severity score at 24 months, with significantly greater improvement with more complete ablation. Survival analysis demonstrated a significant reduction in the percentage of women undergoing additional leiomyoma treatment in women in the high non-perfused volume group. The mean shrinkage and mean residual non-perfused volume ratio were both significantly above zero at 6 months in the high non-perfused volume group. The incidence of adverse events is low. However, for women with minimal treatment, the risk of additional procedures is high. The authors concluded magnetic resonance-guided focused ultrasound surgery is an effective treatment for uterine leiomyomata and results in sustained symptomatic relief.

A 2014 review by Kim et al. focused on review of techniques to expand patient selection and improvement of outcomes. The study found issues are not completely resolved and more studies need to be done. Research should include addressing fibroid accessibility for locations beyond the reachable depth of the system and excessively thick subcutaneous fat of the abdominal wall, which attenuates acoustic energy and has a negative effect on the quality of the focus. Because of these limitations, some patients are not good candidates for MRI-guided HIFU therapy. The authors concluded there is room for further advancement in MRI-guided HIFU technology and room for improvement in its clinical application.

3. Professional/Governmental Agencies

CMS: No NCD

FDA: ExAblate® 2000 received Pre-market approval on October 22, 2004

CPT Codes
0071T – Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue
0072T – Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue
76999 – Unlisted ultrasound procedure

References:

Summary of Changes

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>4/17</td>
<td>Reviewed Policy. Removed Benchmarks and ICD-9 references</td>
</tr>
</tbody>
</table>