Magnetic Resonance Imaging-Guided Focused Ultrasound

Description

An integrated system providing magnetic resonance-guided focused ultrasound (MRgFUS) treatment is proposed as a noninvasive therapy for uterine fibroids and pain palliation of bone metastases. MRgFUS is also being investigated as a treatment of other benign and malignant tumors as well as essential tremors.

OBJECTIVE

The objective of this evidence review is to evaluate whether MRgFUS improves the net health outcome in patients with uterine fibroids tumors, metastatic bone cancer, other tumors, or medication-refractory essential tumors.

POLICY STATEMENT

Magnetic resonance-guided high-intensity ultrasound ablation may be considered medically necessary for pain palliation in adults with metastatic bone cancer who have failed or are not candidates for radiotherapy.

Magnetic resonance-guided high-intensity ultrasound ablation may be considered medically necessary for the treatment of medicine-refractory essential tremors.

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Magnetic resonance-guided high-intensity ultrasound ablation is considered **not medically necessary** for the treatment of uterine fibroids.

Magnetic resonance-guided high-intensity ultrasound ablation is considered **investigational** in all other situations including but not limited to:

- Treatment of other tumors (eg, brain cancer, prostate cancer, breast cancer, desmoid).

**POLICY GUIDELINES**

None

**BENEFIT APPLICATION**

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

Magnetic resonance-guided high-intensity ultrasound ablation of uterine fibroids is currently performed at a limited number of institutions.

**FDA REGULATORY STATUS**

In October 2004, the ExAblate 2000 System (InSightec) was approved by the FDA through the premarket approval process for "ablation of uterine fibroid tissue in pre- or perimenopausal women with symptomatic uterine fibroids who desire a uterine sparing procedure." Treatment is indicated for women with a uterine gestational size of fewer than 24 weeks who have completed childbearing.

In October 2012, the ExAblate System, Model 2000/2100/2100 VI, was approved by the FDA through the premarket approval process for pain palliation in adults with metastatic bone cancer who have failed or are not candidates for radiotherapy. The device was evaluated through an expedited review process. The FDA required a post-approval study with 70 patients to evaluate the effectiveness of the system under actual clinical conditions.

In July 2016, the FDA approved the use of the ExAblate Neuro System for the treatment of ET in patients who have not responded to medication (b-blockers or anticonvulsant drugs) through the premarket approval process.

FDA product codes: NRZ, POH.

**RATIONALE**

**Summary of Evidence**

For individuals who have uterine fibroids who receive magnetic resonance-guided focused ultrasound (MRgFUS), the evidence includes 2 small randomized controlled trials (RCTs), nonrandomized comparative studies, and case series. Relevant outcomes are symptoms, quality of life, resource utilization, and treatment-related morbidity. One RCT (n=20) has reported some health outcomes but its primary purpose was to determine the feasibility of a larger trial. It did not find statistically significant differences in quality of life outcomes between active and sham treatment groups but it did find lower fibroid volumes after active treatment. The second RCT (n=49) is ongoing; preliminary results at 6 weeks post-treatment, comparing MRgFUS with uterine artery embolization have shown that the 2 groups are comparable in medication use and symptom improvement following treatments. Patients in the MRgFUS group reported recovering significantly faster than patients in the uterine artery embolization group, as measured by time to return to work and time to normal activities. In a separate 2013 comparative study, outcomes appeared to be better with uterine artery embolization than with MRgFUS. Long-term data on the treatment effects, recurrence rates, and impact on future fertility and pregnancy are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals with metastatic bone cancer who have failed or are not candidates for radiotherapy who receive MRgFUS, the evidence includes a sham-controlled randomized trial and several case series. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The RCT found statistically significant improvements after MRgFUS in a composite outcome comprised of a reduction in pain and morphine use, and in pain reduction as a stand-alone outcome. A substantial proportion of patients in the treatment group experienced adverse events but most events were transient and not severe. The case series reported reductions in pain following MRgFUS treatment, consistent with the RCT. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with other tumors (eg, breast cancer, brain cancer, prostate cancer, desmoid, nonspinal osteoid osteoma) who receive MRgFUS, the evidence includes small case series. Relevant outcomes are symptoms, health status measures, and treatment-related morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with medicine-refractory essential tremors who receive MRgFUS, the evidence includes 2 systematic reviews that identified an RCT and several observational studies. Relevant outcomes include symptoms, functional outcomes, quality of life, and treatment-related morbidity. The assessment did not pool study results but concluded that, overall, MRgFUS decreased tremor severity and improved quality of life. The sham-controlled randomized trial found significant improvements in the treatment group in tremor severity, functional improvement, and quality of life after 3 months of follow-up. The improvements in hand tremor score, function, and quality of life were maintained at the 2 year follow-up. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Society for Radiation Oncology

In 2017, the American Society for Radiation Oncology published guidelines on palliative radiotherapy for bone metastases, which stated that external-beam radiotherapy continues to be the primary therapy for treating painful uncomplicated bone metastases. The guidelines did not mention magnetic resonance-guided focused ultrasound. If patients experience persistent or recurrent pain more than 1 month after initial treatment, the guidelines recommended retreatment with external-beam radiotherapy. As for advanced radiotherapy such as stereotactic body radiotherapy for retreatment of recurrent pain in spine bone lesions, these "may be feasible, effective, and safe, but the panel recommends that this approach should be limited to clinical trial participation or on a registry given limited data supporting routine use."

National Comprehensive Cancer Network

Guidelines from the National Comprehensive Cancer Network on bone cancer (v.1.2020), breast cancer (v.4.2020), brain cancer (v.2.2020), and prostate cancer (v.1.2020) do not mention magnetic resonance-guided ultrasound as a treatment option.

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.

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REFERENCES


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

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>December 2011</td>
<td>New policy</td>
<td>Policy statement changed to not medically necessary. Related policy added. URL corrected in Reference 1. Policy updated with literature review; reference numbers 8, 18 added; references re-numbered.</td>
</tr>
<tr>
<td>June 2012</td>
<td>Replace policy</td>
<td>Policy updated with literature review and references. Policy changed to single not medically necessary statement; no change to intent of policy. Policy title changed to MRI-Guided Focused Ultrasound (MRgFUS).</td>
</tr>
<tr>
<td>June 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature review, References 2, 6, and 14 added; other references renumbered or removed. No change in policy statement.</td>
</tr>
<tr>
<td>June 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature review through December 15, 2015; references 2 and 23 added. Policy statements unchanged. Global change to policy to remove “imaging” (eg, title, policy statement) to standardize terminology to magnetic resonance guided focused ultrasound (MRgFUS).</td>
</tr>
<tr>
<td>June 2015</td>
<td>Replace policy</td>
<td>Policy statement added that MRgFUS may be considered medically necessary for pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy. Bullet point on bone metastases removed from not medically necessary statement. References 12 and 21-22 added.</td>
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<tr>
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<tr>
<td>September 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through May 7, 2018; references 23-26 and 28 added. A policy statement added that MRgFUS ablation may be considered medically necessary for the treatment of medicine-refractory essential tremors. Policy statement clarified that “treatment of other tumors...” is investigational (instead of not medically necessary) as this is a non-approved indication.</td>
</tr>
<tr>
<td>September 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through May 14, 2019; references on NCCN updated. Policy statements unchanged.</td>
</tr>
<tr>
<td>September 2020</td>
<td>Replace policy</td>
<td>Policy updated with literature review through May 18, 2020; no references added. Policy statements unchanged</td>
</tr>
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