This protocol considers some applications of this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<tr>
<td>Individuals: • With uterine fibroids</td>
<td>Interventions of interest are: • Magnetic resonance–guided focused ultrasound</td>
<td>Comparators of interest are: • Alternative nonsurgical treatment • Surgery</td>
<td>Relevant outcomes include: • Symptoms • Quality of life • Resource utilization • Treatment-related morbidity</td>
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<tr>
<td>Individuals: • With metastatic bone cancer who have failed or are not candidates for radiotherapy</td>
<td>Interventions of interest are: • Magnetic resonance–guided focused ultrasound</td>
<td>Comparators of interest are: • Supportive care</td>
<td>Relevant outcomes include: • Symptoms • Functional outcomes • Health status measures • Quality of life • Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: • With other tumors (e.g., brain cancer, prostate cancer, breast cancer, desmoid, nonspinal osteoid osteoma)</td>
<td>Interventions of interest are: • Magnetic resonance–guided focused ultrasound</td>
<td>Comparators of interest are: • Standard care</td>
<td>Relevant outcomes include: • Symptoms • Health status measures • Treatment-related morbidity</td>
</tr>
</tbody>
</table>

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.

SUMMARY OF EVIDENCE

For individuals who have uterine fibroids who receive magnetic resonance–guided focused ultrasound (MRgFUS), the evidence includes two 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. This pivotal Food and Drug Administration (FDA) trial was not randomized, the clinical significance of the primary outcome was unclear, and there were no follow-up data beyond one year. The second RCT (N=49) is ongoing; it has provided preliminary results at six weeks posttreatment, comparing MRgFUS with uterine artery embolization (UAE). The two groups were comparable in medication use and symptom improvement following treatments. Patients in the MRgFUS group reported recovering significantly faster than patients in the UAE 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 UAE than with MRgFUS. We lack insufficient data on the long-term treatment effects, recurrence rates, and impact on future fertility and pregnancy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with painful 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 were not severe and were transient. The case series also reported reductions in pain following MRgFUS treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with other tumors (e.g., breast cancer, brain cancer, prostate cancer, or desmoid) or 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.

POLICY

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 is considered investigational in all other situations including but not limited to:

- Treatment of uterine fibroids; and
- Treatment of other tumors (e.g., brain cancer, prostate cancer and breast cancer, desmoid)

POLICY GUIDELINES

The procedure may be performed in a magnetic resonance imaging (MRI) suite with an open MRI scanner, which might not be available at many institutions. The procedure is performed in an outpatient setting, with the patient under conscious sedation.

BACKGROUND

UTERINE FIBROIDS

Uterine fibroids are one of the most common conditions affecting women in the reproductive years. Symptoms
of uterine fibroids include menorrhagia, pelvic pressure, or pain. Several approaches currently available to treat symptomatic uterine fibroids include: hysterectomy, abdominal myomectomy, laparoscopic and hysteroscopic myomectomy, hormone therapy, uterine artery embolization, and watchful waiting. Hysterectomy and various myomectomy procedures are considered the criterion standard treatment.

METASTATIC BONE DISEASE

Metastatic bone disease is one of the most common causes of cancer pain. Existing treatments include conservative measures (e.g., massage, exercise) and pharmacologic agents (e.g., analgesics, bisphosphonates, corticosteroids). For patients who fail the above treatments, the standard care is to use external-beam radiotherapy. However, a substantial proportion of patients have residual pain after radiotherapy, and there is a need for alternative treatments for these patients. (One option, radiofrequency ablation, is addressed in the Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors Protocol).

MAGNETIC RESONANCE–GUIDED FOCUSED ULTRASOUND

MRgFUS is a noninvasive treatment that combines two technologies: focused ultrasound and magnetic resonance imaging (MRI). The ultrasound beam penetrates through the soft tissues and, using MRI for guidance and monitoring, the beam can be focused on targeted sites. Ultrasound causes a local increase in temperature in the target tissue, resulting in coagulation necrosis while sparing the surrounding normal structures. Ultrasound waves from each sonication are directed at a focal point that has a maximum focal volume of 20 nm in diameter and 15 nm in height/length. This causes a rapid rise in temperature (i.e., to 65° C-85° C), which is sufficient to ablate tissue at the focal point. In addition to providing guidance, the associated MRI can provide online thermometric imaging that provides a temperature “map” to confirm the therapeutic effect of the ablation treatment and allow for real-time adjustment of the treatment parameters.

The FDA approved the ExAblate MRgFUS system (InSightec) for two indications: treatment of uterine fibroids (leiomyomata) and palliation of pain associated with tumors metastatic to bone. The ultrasound equipment is specifically designed to be compatible with magnetic resonance magnets, and it is integrated into standard clinical MRI units; it also includes a patient table, which has a cradle that houses the focused ultrasound transducer in water or a light oil bath. Some models have a detachable cradle; only certain cradle types can be used for palliation of pain associated with metastatic bone cancer. For treating pain associated with bone metastases, the aim of MRgFUS is to destroy nerves in the bone surface surrounding the tumor.

MRgFUS is also being investigated for the treatment of other tumors, including breast, prostate, brain, and desmoid tumors as well as nonspinal osteoid osteoma.

REGULATORY STATUS

In October 2004, the ExAblate® 2000 System (InSightec, Haifa, Israel) was approved by 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 less 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 adult patients with metastatic bone cancer who have failed or are not candidates for radiotherapy. The device was evaluated through an expedited review process. FDA required a postapproval study with 70 patients to evaluate the effectiveness of the system under actual clinical conditions.

FDA product code: NRZ.
RELATED PROTOCOLS

Occlusion of Uterine Arteries Using Transcatheter Embolization

Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


