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>
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<tr>
<th>Populations</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 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>
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<tr>
<td>Individuals: • With miscellaneous tumors (e.g., brain cancer, prostate cancer, breast cancer)</td>
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<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 for pain palliation of bone metastases. MRgFUS is also being investigated as a treatment of other benign and malignant tumors.

Summary of Evidence

The evidence for magnetic resonance–guided focused ultrasound (MRgFUS) in individuals who have uterine fibroids includes a pilot randomized controlled trial (RCT), nonrandomized comparative studies, and case series. Relevant outcomes are symptoms, quality of life, resource utilization, and treatment-related morbidity. The pilot RCT (N=20 patients) 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 pivotal Food and Drug
Administration trial was not randomized, the clinical significance of the primary outcome was unclear, and there were no follow-up data beyond one year. In the 2013 comparative study, outcomes appeared to be better with uterine artery embolization than with MRgFUS. There are 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.

The evidence for MRgFUS in individuals who have metastatic bone cancer who failed or are not candidates for radiotherapy includes a sham-controlled randomized trial. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The RCT found statistically significant improvement after MRgFUS in a composite outcome comprised of 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 of these were not severe and were transient. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for MRgFUS in individuals who have miscellaneous tumors (e.g., brain cancer, prostate cancer, breast cancer) includes 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 adult patients with metastatic bone cancer who 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;
- Treatment of other tumors (e.g., brain cancer, prostate cancer and breast cancer)

Policy Guidelines

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

Background

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 focused 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 approximately 65° C-85° C), which is sufficient to achieve tissue ablation 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 U.S. Food and Drug Administration (FDA) has approved the ExAblate® MRgFUS system (InSightec, Haifa, Israel) 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 is integrated into standard clinical MRI units. It includes a patient table, which have a cradle housing the focused ultrasound transducer in a water or light oil bath. Some models of the device have a detachable cradle; only certain cradle types can be used for palliation of pain associated with metastatic bone cancer.

As noted, FDA has approved an MRgFUS for treatment of uterine fibroids, which is one of the most common conditions affecting women in the reproductive years. Symptoms of uterine fibroids include menorrhagia, pelvic pressure, or pain. Several approaches are currently available to treat symptomatic uterine fibroids: 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.

For treating pain associated with bone metastases, the other FDA-approved indication, the aim of MRgFUS is to destroy nerves in the bone surface surrounding the tumor. 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, standard care is use of 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).

MRgFUS is also being investigated for treatment of other tumors, including breast, prostate, and brain tumors.

Regulatory Status
In October 2004, the ExAblate® 2000 System (InSightec, Haifa, Israel) 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 less than 24 weeks who have completed childbearing.

In October 2012, the ExAblate® System, Model 2000/2100/2100 VI, was approved by FDA through the premarket approval process for pain palliation in adult patients with metastatic bone cancer who 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.

25. NGS Local Coverage Determination (LCD): Category III CPT® Codes (L33392), Revision Effective Date For services performed on or after 01/01/2017.