Protocol

Magnetic Resonance Imaging-Guided Focused Ultrasound

(701109)

(Formerly MRI-Guided Focused Ultrasound [MRgFUS])

Medical Benefit		**Effective Date**: 07/01/14	**Next Review Date**: 05/15
Preauthorization	No	**Review Dates**: 05/09, 05/10, 05/11, 05/12, 05/13, 05/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary.*** *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.*

Description

An integrated system providing magnetic resonance imaging (MRI)–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 for the treatment of other benign and malignant tumors.

Background

MRgFUS is a noninvasive treatment that combines two technologies, focused ultrasound and MRI. The ultrasound beam penetrates through the soft tissues and, using MRI for guidance and monitoring, the beam can be focused on targeted sites. The ultrasound causes a local increase in temperature in the target tissue, resulting in coagulation necrosis while sparing the surrounding normal structures. The 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" that can further 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 Inc., Haifa, Israel) for two indications; treatment of uterine fibroids and palliation of pain associated with tumors metastatic to bone. The ultrasound equipment is specially designed to be compatible with MR magnets and is integrated into standard clinical MRI units. It includes a patient table, which includes 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.

To date, the primary clinical application of MRgFUS has been treatment of uterine fibroids (leiomyomata), one of the most common conditions affecting women in the reproductive years. Symptoms of uterine fibroids include menorrhagia, pelvic pressure, or pain. There are several approaches that 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 aim of MRgFUS treatment 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), pharmacologic agents (e.g., analgesics, bisphosphonates, corticosteroids) and radiotherapy, especially conventional external beam radiotherapy (EBRT) for tumors that do not involve the nervous system.

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

Regulatory Status

In October 2004, FDA approved via the premarket application process, the ExAblate® 2000 System (Insightec, Inc., Haifa, Israel) 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, FDA approved the ExAblate® System, Model 2000/2100/2100 VI via the PMA process. The intended use of the device is for pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiation therapy. 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.

Related Protocol

Occlusion of Uterine Arteries Using Transcatheter Embolization

Policy (Formerly Corporate Medical Guideline)

Magnetic resonance imaging (MRI) guided high-intensity ultrasound is considered **investigational**. This includes, but is not limited to, its use in the following situations:

- Treatment of uterine fibroids;
- Pain palliation for patients with metastatic bone cancer;
- Treatment of other tumors, e.g., brain cancer, prostate cancer and breast cancer.

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.

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