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; supporting documentation must be submitted to Use Management.* 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. MRgFUS is also being investigated for the treatment of other benign and malignant tumors, including palliative treatment of painful bone metastases.

Background
Uterine fibroids (leiomyomata) are one of the most common conditions affecting women in the reproductive years; symptoms 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 gold standard treatment.

Recently, there has been interest in using high-intensity focused ultrasound (HIFU) treatment that is guided by magnetic resonance imaging (MRI; MRgFUS) as a totally noninvasive approach to the ablation of uterine fibroids. 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 can be focused into a maximum tissue volume of 4.3 cm³, causing a rapid rise in temperature sufficient to achieve tissue ablation at the focal point. In addition to providing guidance, the associated MRI can provide on-line 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 ultrasound equipment is specially designed to be compatible with MR magnets and is integrated into standard clinical MRI units. The ExAblate® System (InSightec, Inc., Dallas, TX) consists of a focused piezoelectric phased-array transducer, a computer-controlled positioning system, and a multichannel radiofrequency amplifier system. The array is located within a specially designed table in a water bath; imaging is performed with a custom receive-only pelvic coil. The ExAblate® System has received U.S. Food and Drug Administration (FDA) approval for treatment of uterine fibroids. MRI-guided high-intensity focused ultrasound ablation of other tumors, including breast, prostate, and brain tumors and for the treatment of tumors metastatic to bone for the palliation of pain is also being studied. However, the device approved by the FDA for MRI-guided ultrasound ablation is only for uterine fibroids.

Regulatory Status
In October 2004, the U.S. Food and Drug Administration (FDA) approved via the premarket application (PMA)
process, the ExAblate® 2000 System 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 December 2009, the ExAblate® 2100 System received premarket approval. It includes several modifications to the previous system including enhanced sonication and a detachable cradle. Approval remains limited to treatment of symptomatic uterine fibroids and is indicated in women with a uterine size of less than 24 weeks and those who have completed childbearing.

Related Protocol:
Occlusion of Uterine Arteries Using Transcatheter Embolization

Corporate Medical Guideline

Magnetic resonance imaging (MRI) guided high-intensity ultrasound ablation of uterine fibroids is considered investigational.

Magnetic resonance imaging (MRI)-guided high-intensity ultrasound ablation of other tumors, including but not limited to breast, brain, prostate cancer, and palliative treatment of bone metastasis, is considered investigational.

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.


