POLICY STATEMENT:
Based upon our criteria and the lack of peer-reviewed literature, MRI guided focused ultrasonic (MRgFUS) tumor ablation (e.g., uterine fibroids; tumors of the breast, brain, liver, prostate and bone) has not been medically proven to be effective and is considered investigational.

Refer to Corporate Medical Policy #4.01.04 regarding Uterine Artery Occlusion in the Treatment of Uterine Fibroids.
Refer to Corporate Medical Policy #7.01.32 regarding Radiofrequency Tumor Ablation.
Refer to Corporate Medical Policy #7.02.03 regarding Cryosurgical Tumor Ablation.
Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:
The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:
Uterine fibroids, or leiomyomas, are benign tumors that originate from the smooth muscle cells of the uterus and are one of the most common solid pelvic tumors affecting women during a woman’s reproductive years. Symptoms include menorrhagia, pelvic pressure, and/or pain. Hysterectomy and various myomectomy procedures are considered the gold standard of treatment for fibroids.

Recent research has focused on developing minimally invasive techniques for treating uterine fibroids. One such method utilizes high intensity focused ultrasound treatment guided by magnetic resonance imaging (MRI) as a noninvasive approach for ablation of uterine fibroids. In this procedure, an ultrasonic beam penetrates through the soft tissue, while guided and monitored by MRI. The ultrasound beam is focused on targeted sites and causes a local increase in temperature in the target tissue, resulting in coagulation necrosis while sparing the surrounding normal structures.

In addition to providing guidance, MRI imaging can provide on-line thermometric imaging creating a temperature “map” that can confirm the therapeutic effect of the ablation treatment and allow for real time adjustment of the treatment parameters.

The ExAblate™ 2000, a focused ultrasonic device that is integrated with an MRI system, is approved by the U.S. Food and Drug Administration (FDA) for the treatment of uterine fibroids.

The ExAblate® System Model 2000/2100/2100 VI is FDA approved for palliative treatment of metastatic bone cancer.

RATIONALE:
On October 22, 2004 the FDA approved the Exablate™ 2000 device for the treatment of symptomatic uterine fibroids in pre- or peri-menopausal women with a uterine gestational size of less than 24 weeks, who have completed childbearing, and who desire a uterine sparing procedure. The treatment is contraindicated in women who intend to become pregnant in the future as the procedure could alter the composition and strength of the uterine tissue and the effects of the
MRgFUS is being investigated in other applications (e.g., tumors of the breast, brain, liver, prostate; low back pain); but has not receive FDA approval.

Uterine fibroids:

A case series (Stewart, et al. 2003) of 55 women with symptomatic uterine fibroids who either underwent high intensity focused ultrasound treatment or who underwent a planned hysterectomy within 1 month after the ultrasound treatment has been published in the peer-reviewed literature. In this study, hysterectomy specimens provided pathologic correlation of treatment, only 1 fibroid was targeted for treatment, no attempt was made to target the fibroid that was the most likely to cause symptoms, and fibroids that would require the ultrasound beam to pass through the bowel or bladder were excluded from treatment. While the procedure was well tolerated, there was no attempt to assess mid or long-term outcomes.

A multi-center comparative study (Hindley, et al. 2004) was undertaken to explore the hypothesis that MRI guided ultrasound ablation of uterine fibroids would lead to a significant reduction in symptoms and improvement in quality of life. In this study of 109 patients, the authors concluded although volume reduction was moderate, MRI guided ultrasound ablation of uterine fibroids resulted in marked symptomatic improvement in most patients at 6 month follow-up.

A June 2005 TEC Assessment by the BlueCross BlueShield Association compared MRI guided ultrasound ablation to conventional therapies (e.g., hysterectomy, myomectomy, uterine artery embolization). The assessment states the available evidence is insufficient to permit conclusions regarding the effect on health outcomes and that the available evidence is limited and raises concerns regarding the reliability and validity of the reported findings. Therefore, MRI guided ultrasound ablation of uterine fibroids does not meet the TEC criteria and is considered investigational.

A 2007 Technology Assessment published by the Agency for Healthcare Research and Quality (AHRQ) addressing uterine fibroids states the strength of evidence about MRI-guided ultrasound ablation of fibroids is weak, although one carefully conducted prospective case series was identified (Stewart, et al. 2006). Overall, the study suggested reasonable tolerance (16% of women reported severe pain at some point during the treatment, 8% reported severe to moderate pain after the procedure), improvement in quality of life (71% improved), and modest changes in fibroid size (13% decrease). During more than a year of follow-up, 11% of women experienced worsened symptoms; 28% elected further treatment including myomectomy and hysterectomy. The authors concluded MRgFUS treatment results in short term symptom reduction for women with symptomatic uterine fibroids with an excellent safety profile but that additional studies are needed to further define the reason for treatment failures and to compare MRgFUS with other treatment modalities.

In June and August 2007 studies from the MRgFUS study group were published. One of the studies (Fennessy, et al) compared results from patients treated with an original and modified protocol. In the original group, the non-perfused (effectively treated) area was calculated at 17% of fibroid volume compared with 26% of fibroid volume with the modified protocol. Symptom severity was reported to have decreased from a score of 62 at baseline to 33 at 12 months, with fewer patients in the modified group choosing alternative treatment (28% vs. 37%). Interpretation of these results is limited by a 49% loss to follow-up. The second study (Stewart, et al) reported 24-month follow-up from three Phase 3 trials and one post-marketing study with the total patient population of 416 patients. The study found a relationship
between the non-perfused volume ratio and the probability of undergoing additional treatment. For non-perfused volume ratios of 20% to 50% there was a 25% probability of additional treatment. Patients with a non-perfused volume ratio of less than 20% of fibroid volume had a 40% probability of additional treatment. No shrinkage, and a trend toward growth, was seen with non-perfused volume ratios of 10% or less. Most women were found to have had limited treatments, with 57% of the patients having a non-perfused volume of 20% or less and 34% of the patients having a non-perfused volume between 30% and 70%. Less than 3% of women had a non-perfused volume ratio of 70% or greater. The results raise questions regarding the amount of non-perfusion achieved with current treatment protocols. The studies lack concurrent control/comparison groups. Randomized, controlled trials are needed to compare the efficacy and durability of MRgFUS with alternative, standard treatment methods.

An August 2008 practice bulletin, published by the American College of Obstetricians and Gynecologists (ACOG), and reaffirmed in 2014, addresses alternatives to hysterectomy in the management of leiomyomas. The bulletin states whereas short-term studies show safety and efficacy, long-term studies are needed to discern whether the minimally invasive advantage of MRgFUS surgery will lead to durable results beyond 24 months. Protocols for treating larger leiomyoma volumes are being studied. And, case reports of pregnancy with term delivery have been reported after MRgFUS; however, larger experience is necessary before drawing conclusions.

Pain palliation in metastatic bone cancer:

FDA approval of the ExAblate® device for palliative treatment of bone metastases was based on findings of a randomized, controlled trial described in the FDA’s Summary of Safety and Effectiveness document. The study results submitted to the FDA showed benefit of MRgFUS compared to sham treatment for pain palliation of bone metastases but has limitations (e.g., incomplete follow-up and short-term length of follow-up). (Hurwitz, et al, 2014). Several manufacturer sponsored case series have been published but contain many limitations. No practice guidelines have been identified that address MRgFUS for pain palliation in metastatic bone metastases. Therefore, the evidence is insufficient to show that MRgFUS improves health outcomes in patients with painful bone metastases.

Breast:

A limited number of studies have been published that address the utilization of MRgFUS for breast cancer. The studies generally consist of very small populations, are of limited value, and call for further study utilizing this technique (Furusawa, et al. 2006 and 2007; Gianfelice, et al. 2003).

Prostate:

No studies on human subjects have been identified in the use of MRgFUS in prostate cancer.

Other tumors:

Studies have not been identified as being published in the peer-reviewed literature that address other tumors types under investigation.

CODEx:

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>0071T (E/I)</td>
<td>Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume of less than 200 cc of tissue</td>
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<tr>
<td>0072T (E/I)</td>
<td>total leiomyomata volume greater or equal to 200 cc of tissue</td>
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Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates. Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).
0398T (E/I) Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed

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HCPCS: C9734 (E/I) Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance

ICD9: 218 Uterine leiomyoma
   218.0 Submucous leiomyoma of the uterus
   218.1 Intramural or interstitial leiomyoma of the uterus
   218.2 Subserous leiomyoma of the uterus
   218.9 Leiomyoma of the uterus, unspecified

ICD10: D25.0-D25.9 Leiomyoma of uterus (code range)

REFERENCES:


**KEY WORDS:**

Exablate 2000; Focused ultrasonic ablation, uterine fibroids; MRgFUS; MRI guided ultrasonic ablation.

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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

Based on our review, MR guided focused ultrasonic ablation of tumors is not addressed in National or Local Medicare coverage determinations or policies.