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MRI-Guided Focused Ultrasound (MRgFUS)

Policy # 00180
Original Effective Date: 09/22/2005
Current Effective Date: 10/16/2013

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of magnetic resonance imaging (MRI)-guided high-intensity ultrasound ablation, including, but not limited to the following situations, to be **investigational*:**

- 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.

Background/Overview

An integrated system providing MRI-guided focused ultrasound (MRgFUS) treatment is proposed as a noninvasive therapy for uterine fibroids and for pain palliation of bone metastases. Magnetic resonance imaging-guided focused ultrasound is also being investigated for the treatment of other benign and malignant tumors.

Magnetic resonance-guided focused ultrasound is a non-invasive treatment that combined 2 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 which has a maximum focal volume of 20nm in diameter and 15nm in height/length. This causes a rapid rise in temperature (i.e., to approximately 65°C to 85°C), which is 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 U.S. Food and Drug Administration (FDA) has approved the ExAblate®‡ MRgFUS system (InSightec, Inc., Haifa, Israel) for 2 indications; treatment of uterine fibroids and for 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

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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.

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.

Magnetic resonance-guided focused ultrasound is also being investigated for treatment of other tumors, including breast, prostate, and brain tumors.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration
In October 2004, the FDA approved via the premarket application (PMA) 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, the 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. The FDA required a post-approval study with 70 patients to evaluate the effectiveness of the system under actual clinical conditions.

Centers for Medicare and Medicaid Services (CMS)
No coverage determination.

Rationale/Source

A June 2005 TEC Assessment on MRgFUS therapy for symptomatic uterine leiomyomata found insufficient evidence of efficacy compared to convention therapies. The policy was updated regularly with literature searches. Following is a summary of the literature to date on high intensity focused ultrasound (HIFU) treatment that is guided by MRI; MRgFUS for the treatment of uterine fibroids and other conditions.

Uterine Fibroids

To date, no randomized controlled trials (RCTs) have been published using MRgFUS. There is one published non-randomized study comparing MRgFUS to another treatment for uterine fibroids; this is the "pivotal" study designed for FDA approval of the ExAblate 2000 device. The study included 109 women treated with MRgFUS and 83 women treated with abdominal hysterectomy. The primary outcome was change in the symptom severity score (SSS) that is part of the validated Uterine Fibroid Symptom Quality of Life. Symptom severity is measured by eight questions relevant to bulk and bleeding symptoms; it is a 0–100 scale, with the higher number representing greater severity of symptoms. Outcome data were initially

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reported for the MRgFUS group only. At six months' follow-up, 71% of the MRgFUS group achieved a 10-point or greater reduction in SSS, but this decreased to 51% at 12 months. It is unclear what represents a clinically meaningful change in SSS, the primary outcome measure. A threshold of greater than ten points was selected for the analysis, but this is somewhat arbitrary and not substantiated by other research. Twenty-one percent of those treated by MRgFUS needed additional surgical treatment, and 4% underwent a repeat MRgFUS by 12 months.

In 2009, Taran and colleagues reported outcomes for the hysterectomy group. The Taran article did not include the original primary outcome measure, SSS scores, and instead reported findings on a different quality of life (QOL) measure, the SF-36; also reported were safety data. A significantly higher proportion of women in the hysterectomy group (82 of 83, 99%) reported at least one adverse event compared to women in the MRgFUS group (88 of 109, 81%). Pain or discomfort, adverse events associated with the gastrointestinal tract, dermatological system, nervous system, and cardiovascular system were significantly more common in the hysterectomy group. However, a similar proportion reported a serious adverse event, 9 of 109 (8%) in the MRgFUS group and 8 of 83 (10%) in the hysterectomy group. At six months, there were significantly higher scores in the hysterectomy group on 2 of 8 subscales on the SF-36; scores on the remaining subscales did not differ significantly between groups. The SF-36 scores were subject to a multiple comparison bias; a large number of statistical comparisons were done for secondary outcomes and p-values were not adjusted. Moreover, it was not clear why the original primary outcome, the SSS, was not reported.

Another non-randomized comparative study compared two variations on the MRgFUS procedure. Patients were either treated with the original protocol (33% of fibroid volume with a maximum treatment time of 120 min, n = 96) or modified protocol (50% treatment volume, 180 min maximum treatment time, and a second treatment if within a 14-day period, n = 64). In the original group, the nonperfused (effectively treated) area was calculated at 17% of fibroid volume compared with 26% of fibroid volume with the modified protocol. Overall, 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%, respectively). Interpretation of these results was limited by 49% loss to follow-up; 55 patients (57%) from the original treatment protocol completed follow-up. Only 21 patients (33%) from the modified protocol group were evaluable at 12-month follow-up.

A 2007 publication reported 24-month follow-up from three Phase 3 trials and one postmarketing study (total of 416 patients). The study found a relationship between the nonperfused volume ratio and the probability of undergoing additional leiomyoma treatment. For nonperfused volume ratios of 20% to 50%, there was a 25% probability of additional treatment. Patients with a nonperfused 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 nonperfused volume ratios of 10% or less. Most women were found to have had limited treatments, with 57% of the patients having a nonperfused volume of 20% or less and 34% of the patients having a nonperfused volume between 30% and 70%. Fewer than 3% of women had a nonperfused volume ratio of 70% or greater. These results raise questions about the amount of nonperfusion achieved with current treatment protocols.

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Several case series have reported on the efficacy and safety of MRgFUS for treating uterine fibroids. For example, a 2011 case series included 40 women who were treated with MRgFUS for symptomatic uterine fibroids at one center in the U.S. The primary study endpoints were change from baseline in QOL and symptom severity. (Higher scores on the QOL measure and lower scores on the symptom severity measure indicated improvement). Twenty-nine of the 40 (73%) patients completed the three-year follow-up. The mean SSS was 64.8 at baseline and 17.0 at three years; this represents a mean reduction of 47.8 points. The mean baseline QOL score was 44.1 and the mean QOL at the 3-year follow-up was 83.9, a mean increase of 39.8 points. The improvement from baseline to three years was statistically significant for both outcome variables; however, there is no control group with which to compare results. Another 2011 single-center case series reported 12-month outcome data on 130 women treated with MRgFUS. Eight women had additional procedures to relieve symptoms within one-year of MRgFUS treatment; 7 underwent hysterectomy and 1 underwent endometrial ablation. Data on symptom relief at 12 months were available for 70 of 130 (54%) of patients. Fifty-one of the 70 (73%) reported excellent symptom relief. Conclusions about efficacy of MRgFUS cannot be drawn due to the lack of a comparison group and the large amount of missing data.

A prospective registry of pregnancies after MRgFUS had been maintained by the manufacturer of the ExAblate device. A 2010 article reported that there were 54 known pregnancies a mean of eight months after treatment. They included eight pregnancies from clinical trials designed for women who did not desire pregnancy, 26 pregnancies after commercial treatment, and 20 pregnancies in 17 patients from an ongoing study of MRgFUS in women trying to conceive. Twenty-two of the 54 pregnancies (42%) resulted in deliveries, 11 were ongoing beyond 20 weeks at the time the article was written. There were 14 miscarriages (26%) and 7 elective terminations (13%). Among the 22 live births, the mean birth weight of live births was 3.3kg, and the vaginal delivery rate was 64%. The article provides initial information on the impact of MRgFUS for uterine fibroids on pregnancy; findings suggest that fertility may be maintained but that the number of cases is too small to draw definitive conclusions. Moreover, the study does not address the possible impact of MRgFUS treatment on the ability to become pregnant.

Conclusions:
For the treatment of uterine fibroids, there are no RCTs and only one non-randomized study comparing MRgFUS to a different treatment. Limitations of the published comparative study include lack of randomization, data on the comparison group were not published until 5 years after data on the treatment group, the clinical significance of the primary outcome was unclear, and there were no follow-up data beyond 1 year. There is insufficient evidence on the long-term treatment effects, recurrence rates, and impact on future fertility and pregnancy.

Palliative Treatment of Bone Metastases
The FDA approval of the ExAblate device for palliative treatment of bone metastases was based on findings of an RCT described in the Summary of Safety and Effectiveness document. Study results have not been published in a peer-reviewed journal. The study includes patients with intractable pain associated with a well-defined bone tumor site (metastatic or multiple myeloma). To participate, patients needed to have a numeric rating scale (NRS) of at least 4 out of a maximum score of 10. Participants were randomized in a 3:1 ratio to active (n = 125) or sham (n = 41) MRgFUS treatment. Patients without a lesion that was

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accessible by the device or who received fewer than 3 of 4 planned sonications were considered a screen failure and exited from the study. Fifteen of 125 (12%) in the active treatment group and 4 of 41 (10%) in the sham group were screen failures. In addition, 8 other patients were excluded, 5 because they were found to have re-enrolled in the study. Thus, 104 patients in the active treatment group and 35 in the sham group (139 of 166, 84% of randomized patients) completed treatment and were included in the "intention to treat" efficacy analysis presented to the FDA. The study completed population consisted of 79 active treatment participants and 12 sham participants.

The primary efficacy outpoint was change in the NRS score. The investigators considered patients to be responders if they had at least a 2-point decrease in the NRS score from baseline to 3 months. The investigators stratified efficacy findings according to whether or not patients were in the Russian cohort or the non-Russian cohort (study sites in the U.S., Canada, Israel, and Europe). The investigators noted that ExAblate had already been marketed in Russia and that patient management there tended to involve deeper sedation/anesthesia which might make it easier for patients to achieve thermally ablative temperatures. In the non-Russian cohort (n = 83), the proportion of patients who had at least a 2-point decrease in the NRS was 35 of 64 (55%) in the active treatment group and 5 of 19 (26%) in the sham group, $p = 0.04$. In the Russian cohort (n = 56), 36 of 40 patients (90%) in the active treatment group were considered responders compared to 2 of 16 patients (13%) in the sham group, $p < 0.0001$. Among secondary outcomes was change in the QOL measure, the brief pain inventory (BPI). In the non-Russian cohort, mean change in the BPI score from baseline was 2.19 in the active treatment group and 0.74 in the sham group ($p = 0.048$). In the Russian cohort, mean change in BPI was 2.66 in the active treatment group and -0.48 (i.e. an increase in pain) in the sham group, $p < 0.0001$. Limitations of the study include the large number of randomized patients excluded from analysis, the small number of study completers in the sham group and potentially inconsistent protocols at different sites. In addition, patient follow-up was only 3 months.

Several manufacturer-sponsored case series on MRgFUS for pain palliation in bone metastases have been published. In 2009, Liberman and colleagues published findings of a multicenter prospective study conducted in Canada, Israel, and Germany. The study included 31 patients with painful bone metastases who had failed or refused other treatment options; 25 patients (81%) were available for 3-month follow-up. The mean visual analog scale (VAS) score decreased from 5.9 before treatment to 1.8 three months after treatment. Thirteen of 25 patients who used non-opioid analgesics and 6 of 10 who used opioids decreased medication use after treatment. Neither series reported any treatment-related adverse effects.

Conclusions:
The RCT 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 (3 months). No other studies comparing MRgFUS to another treatment for palliation of pain associated with bone metastases have been published. One RCT comparing MRgFUS to external beam radiation is underway (see section on ongoing clinical trials, below). Thus, the evidence is insufficient that MRgFUS improves health outcomes in patients with painful bone metastases.

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Treatment of Other Tumors
Only small case series have been published investigating the safety and/or efficacy of MRgFUS for treating other tumors, including breast cancer, brain cancer, and prostate cancer.

Ongoing Clinical Trials
The FIRSST: Comparing MRgFUS (MR guided Focused Ultrasound) versus UAE (Uterine Artery Embolization) (NCT00995878): This is a RCT comparing MRgFUS to UAE in pre-menopausal women at least 25 years of age who have symptomatic uterine fibroids. The study is sponsored by the Mayo Clinic. Estimated enrollment is 180 patients.

Study Comparing the Safety and Effectiveness of Magnetic Resonance Guided Focused Ultrasound (MRgFUS) and External Beam Radiation (EBRT) for Treatment of Metastatic Bone Tumors and Multiple Myeloma (NCT01091883): This RCT is comparing MRgFUS to EBRT in adult patients with painful bone metastasis (i.e., worse NRS pain score at least 4 out of 10). The study is sponsored by Insightec. Expected enrollment is 60 patients.

Summary
There is insufficient evidence from RCTs or non-RCTs that MRgFUS improves the net health outcome for any clinical application. Additional well-designed studies with sufficient numbers of patients, high rates of follow-up and sufficient lengths of follow-up are needed. Thus, MRgFUS is considered investigational for treatment of uterine fibroids, pain palliation in patients with bone metastases and other applications.

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Code Type	Code
CPT	0071T, 0072T
HCPCS	No code
ICD-9 Diagnosis	All diagnoses
ICD-9 Procedure	No code

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09/07/2005	Medical Director review
09/20/2005	Medical Policy Committee review
09/22/2005	Quality Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
09/05/2007	Medical Director review
09/19/2007	Medical Policy Committee approval. Coverage eligibility unchanged.
09/03/2009	Medical Policy Committee approval
09/16/2009	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/09/2010	Medical Policy Committee review
09/15/2010	Medical Policy Implementation Committee approval. Added that magnetic resonance imaging (MRI)-guided ablation of other tumors, including but not limited to breast, brain, prostate cancer, and palliative treatment of bone metastases, is considered to be investigational.
09/01/2011	Medical Policy Committee review
09/14/2011	Medical Policy Implementation Committee approval. Title changed from "MRI-Guided High Intensity Ultrasound Ablation of Uterine Fibroids" to "MRI-Guided Focused Ultrasound (MRgFUS) for the Treatment of Uterine Fibroids and Other Tumors." Coverage eligibility unchanged.
10/11/2012	Medical Policy Committee review
10/31/2012	Medical Policy Implementation Committee approval
10/03/2013	Medical Policy Committee review
10/16/2013	Medical Policy Implementation Committee approval. Policy title changed from "MRI-Guided Focused Ultrasound (MRgFUS) for the Treatment of Uterine Fibroids and Other Tumors" to "MRI-Guided Focused Ultrasound (MRgFUS)". Policy changed to a single investigational statement with no change to coverage eligibility.

Next Scheduled Review Date: 10/2014

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B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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