Policy Replaced with LCD L34555
Effective February 26, 2018

BlueCross BlueShield of Alabama

Name of the Blue Advantage Policy*:*
Magnetic Resonance Guided Focused Ultrasound (MRgFUS)

Policy #: 178
Category: Obstetrics/Gynecology

Latest Review Date: July 2017
Policy Grade: B

Background:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

Description of Procedure or Service:

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 for the treatment of other benign and malignant tumors.

Uterine Fibroids

Uterine fibroids are one of the most common conditions affecting women in the reproductive years. Symptoms of uterine fibroids include menorrhagia, pelvic pressure, or pain. Several approaches currently available to treat symptomatic uterine fibroids include: 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.

Metastatic Bone Disease

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, the standard care is to use 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.

Magnetic Resonance-Guided Focused Ultrasound

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 which 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 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 for two 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.

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

For coverage information regarding radiofrequency ablation of bone tumors, refer to medical policy #119- *Radiofrequency Ablation of Solid Tumors Excluding Liver Tumors.

***For coverage information regarding cryosurgical ablation of bone tumors, refer to medical policy #429- *Cryosurgical Ablation of Miscellaneous Solid Tumors other than Liver, Prostate, or Dermatologic Tumors*.**

***For coverage information regarding focal treatments of the prostate, refer to medical policy 596- *Focal Treatments for Prostate Cancer*.**

Policy:

Effective for dates of service on or after February 26, 2018 refer to LCD L34555

Effective for dates of service on or after July 6, 2013 and prior to February 26, 2018:
Blue Advantage will treat magnetic resonance imaging (MRI)-guided high-intensity ultrasound ablation as **non-covered** and as **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.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature search was performed through June2, 2017.

Assessment of efficacy for therapeutic interventions such as MRgFUS involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. The technology should be compared with the best alternative treatment when available, as is the case of MRgFUS for treating uterine fibroids. In the case of subjective outcomes such as pain or quality of life (QOL), a sham comparison is also appropriate. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes but are prone to biases such as selection bias (e.g., noncomparability of treatment groups) and observational bias (e.g., the placebo effect).

Uterine Fibroids
Evidence for the use of MRgFUS for the treatment of uterine fibroids consists of 2 small RCTs and many observational studies.

Randomized Controlled Trials
In 2017, Barnard et al published preliminary results from Fibroid Interventions: Reducing Symptoms Today and Tomorrow (FIRSTT) study, a parallel RCT and cohort study comparing MRgFUS with fibroid embolization for the treatment of uterine fibroids. For the RCT, patients were randomized to uterine artery embolization (UAE; n=22) or to MRgFUS (n=27). Patients and investigators were not blinded. Women who did not want to be randomized were enrolled in the cohort study; 16 underwent UAE and 16 underwent MRgFUS. Patients were instructed to keep diaries with the following information: medication use, return to normal activities, and symptoms. After 6 weeks of follow-up for the RCT patients, there were no differences between groups in symptoms such as fatigue, hot flashes, discomfort urinating, vaginal discharge, or constipation. Recovery was significantly faster in the MRgFUS group, as measured by the first day back to work and first day back to normal. Medication use (i.e., opioids, nonsteroidal anti-inflammatory drugs, acetaminophen or aspirin, nausea medication, bowel medication) was also significantly lower in the MRgFUS group. Analyses combining the RCT and cohort patients showed similar results. The MRgFUS procedure took significantly longer than the UAE procedure. A limitation of the trial was the inability to recruit more patients. Long-term follow-up results will be forthcoming.

In 2015, a pilot sham-controlled RCT with 20 patients was published by Jacoby et al. The study included 20 premenopausal women with symptomatic uterine fibroids. Women who were pregnant or had a desire for future fertility were excluded. Patients were randomized to MRgFUS with the ExAblate 2000 system (n=13) or a sham treatment in which no thermal energy was delivered (n=7). The investigators did not specify primary outcomes. The sample size was selected, not to have sufficient statistical power, but to assess the feasibility of a larger trial. All patients assigned to the MRgFUS group and six of seven in the placebo group received their allocated treatment and all treated patients completed three months of follow-up. (Patients were unblinded at three months and given the sham group was given the option of active treatment.)

QOL outcomes included the Uterine Fibroid Symptom and Health Related Quality of Life Questionnaire (UFS-QOL), which has subscales including the Symptom Severity Score (SSS) and Health Related Quality of Life (HRQL) score. Other measure was the Medical Outcomes Study (MOS), which has a Mental Component Summary (MCS) and Physical Component Summary (PCS). At both the four and 12-week follow-ups, there were no statistically significant differences (at the $p<0.05$ level) between the MRgFUS and sham groups in the SSS, HRQL, PCS, or MCS. Change in uterine and fibroid volume, however, differed significantly between groups at 12 weeks. Uterine volume decreased by 17% in the MRgFUS group and by 3% in the sham group ($p=0.04$). Total fibroid volume decreased 18% in the MRgFUS group and did not change in the sham group ($p=0.03$). The authors concluded that women are willing to participate in a sham-controlled RCT of MRgFUS and that larger trials are feasible.

Systematic Reviews

The remaining published studies are nonrandomized. A systematic review, published by Gizzo et al in 2013, identified 38 uncontrolled studies with a total of 2500 patients who underwent MRgFUS for treatment of uterine fibroids. All of the published studies included women older than age 18 years with symptomatic uterine fibroids, and most excluded patients who desired future pregnancies. Reviewers did not pool study findings but concluded that, overall, MRgFUS appeared to be a safe, noninvasive option for treating uterine fibroids. Future research was recommended to compare MRgFUS with other noninvasive procedures and to explore the fertility-sparing potential further.

Nonrandomized Studies

A "pivotal" study designed for FDA approval of the ExAblate® 2000 device was nonrandomized and 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 to 100 scale, with the higher number representing greater severity of symptoms. Outcome data were initially reported for the MRgFUS group only. At six month follow-up, 71% of the MRgFUS group achieved a ten 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 10 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.

Fennessy et al (2007) 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.

In 2009, Taran et al reported on outcomes between MRgFUS and hysterectomy in women with uterine fibroids. The main outcome measure was SF-36 scores. Safety data were also presented. A significantly higher proportion of women in the hysterectomy group (82/83 [99%]) reported at least 1 adverse event compared with women in the MRgFUS group (88/109 [81%]). Pain or discomfort as well as adverse events associated with the gastrointestinal tract, dermatologic system, nervous system, and cardiovascular system were significantly more common in the hysterectomy group. However, a similar proportion reported a serious adverse event, 9 (8%) of 109 in the MRgFUS group and 8 (10%) of 83 in the hysterectomy group. At 6 months, there were significantly higher scores in the hysterectomy group on 2 of 8 SF-36 subscales; scores on the remaining subscales did not differ significantly between groups. SF-36 subscale 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.

A 2007 publication reported 24-month follow-up from three Phase III trials and one postmarketing study (total of 416 patients). The study found a relation between the nonperfused fibroid 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.

A 2011 case series included 40 women treated with MRgFUS for symptomatic uterine fibroids at one center in the U.S. The primary study end points 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). The mean symptom severity score in the 29 (73%) of patients who completed the three-year follow-up was 64.8 at baseline and 17.0 at 3 years; this represents a mean reduction of 47.8 points. The mean baseline QOL score was 44.1 and the mean QOL at the three-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. Another representative case series (2011) 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; seven underwent hysterectomy and one 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.

The following studies were published after the Gizzo systematic review:
In 2016, Chen et al evaluated 107 women undergoing MRgFUS for the treatment of uterine fibroids. Efficacy was defined as the proportion of patients with at least 10% fibroid shrinkage from baseline, as measured by MRI. At the 6-month follow-up, 93% efficacy was reported.

In 2013, Froeling et al reported on 121 women with symptomatic uterine fibroids who were equally eligible for treatment with MRgFUS and uterine artery embolization (UAE). Forty-four (36%) women were lost to follow-up. Follow-up data at approximately 60 months were available on 77 women, 41 in the UAE group and 36 in the MRgFUS group. The primary study outcome was the rate of reintervention (e.g., repeat MRgFUS, myomectomy, hysterectomy, endometrial ablation). During follow-up, five (12%) women in the UAE group and 24 (67%) women in the MRgFUS group experienced a reintervention (statistical comparison not reported).Healthcare QOL scores, secondary outcomes, were significantly better in the UAE group compared with the MRgFUS group at follow-up.

Fertility Following MRgFUS for Treatment of Uterine Fibroids

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 seven elective terminations (13%). Among the 22 live births, the mean birth weight of live births was 3.3 kg, 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.

Section Summary: Uterine Fibroids

For the treatment of uterine fibroids, there are 2 small RCTs, one with 49 women that compared MRgFUS with UAE and one with 20 women that had a sham control. Several non-randomized studies have also compared MRgFUS with a different treatment. The sham controlled RCT determined that a larger trial is feasible. The trial reported significantly lower fibroid volumes in the active treatment group; however, there were no statistically significant differences in QOL between the groups. The other RCT reported no significant differences in medication use or symptoms between the MRgFUS and UAE groups. Recovery was significantly faster in the MRgFUS group than in the UAE group. The pivotal FDA trial had several limitations: no randomization, data on the comparison group were not published until 5 years after data on the treatment group, unclear clinical significance of primary outcome, and no follow-up data beyond 1 year. In the 2013 comparative study, outcomes appeared to be better with UAE than with MRgFUS. There is insufficient evidence on the long-term treatment effects, recurrence rates, and impact on future fertility and pregnancy of this therapy.

Palliative Treatment of Bone Metastases

Evidence for the use of MRgFUS for the treatment of painful bone metastases consists of a large RCT and many observational studies.

An industry sponsored RCT evaluating the ExAblate System for the treatment of painful bone metastases was published by Hurwitz et al in 2014. Findings from this trial were available on the FDA website, because this trial was used as evidence for FDA approval. The trial included patients with at least 3 months of life expectancy who had bone metastases that were painful, despite radiotherapy, or who were unsuitable for or declined radiotherapy. Patients rated tumor pain on a numeric rating scale (NRS) at 4 or higher on a 10-point scale. While they could have up to 5 painful lesions, only 1 lesion was treated, and it had to cause at least 2 points greater pain on the NRS than any other lesion. Also targeted tumors needed to be device-accessible.

Study participants were randomized in a 3:1 ratio to active (n=122) or sham (n=39) MRgFUS treatment. Ten patients in the treatment group and four in the sham group did not receive the allocated treatment. An additional 26 patients in the treatment group and 23 in the sham group did not complete the three month follow-up. A much larger proportion of the placebo group

dropped out; 17 of 35 who were treated (49%) decided to have rescue MRgFUS treatment after lack of response to placebo. A modified intention-to-treat analysis was used that included patients who had at least one MRgFUS or placebo sonication. Missing values were imputed using the last observation carried forward method.

The primary efficacy outpoint, assessed at three months, was a composite outcome comprised of change in baseline in worst NRS score and morphine equivalent daily dose (MEDD) intake. Patients were considered responders if their worst NRS score decreased by at least two points and if their MEDD intake did not increase more than 25% from baseline to three months. NRS score and MEDD intake separately were reported as secondary outcomes.

Seventy-two of 112 (64.3%) patients in the MRgFUS group and seven of 35 patients (20%) in the control group were considered responders, as previously defined. The difference between groups was statistically significant (p=0.01), favoring active treatment. When the two measures that made up the primary end point were analyzed separately, there was a statistically significant difference between groups in change in worst NRS score and a nonsignificant difference in change from baseline in pain medication. The NRS score decreased by a mean of 3.6 points (SD=3.1) in the MRgFUS group and a mean of 0.7 (SD=2.4) in the placebo group (p<0.01). Change in MEDD from baseline was 3.7 in the MRgFUS group and 15.3 in the placebo group. Fifty-one patients (45.5%) in the MRgFUS group and one (2.9%) in the placebo group experienced at least one AE. Most AEs were transient, and the most common was sonication pain, experienced by 36 patients (32.1%) in the MRgFUS group. In 17 patients (15.2%), sonication pain was severe; three patients did not complete treatment due to pain. The most clinically significant AEs that lasted more than a week were third-degree skin burns in one patient (associated with noncompliance with the treatment protocol) and fracture in two patients (one of which was outside the treatment location). Potential limitations of the trial include a nonconventional primary outcome measure and, the small initial size of the sham group. Moreover, a large number of sham patients (66%) did not complete the three month follow-up; however, the authors stated that this low completion rate was due to lack of response to placebo treatment.

In addition to the single RCT, several manufacturer-sponsored case series have evaluated MRgFUS for pain palliation in bone metastases. In 2009, Liberman et al 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 three-month follow-up. The mean visual analog scale score decreased from 5.9 before treatment to 1.8 three months after treatment. Thirteen of 25 patients who used nonopioid analgesics and six of ten who used opioids decreased medication use after treatment. Neither group reported any treatment-related adverse events.

In a 2017 recent case series, Arrigoni et al evaluated use of MRgFUS in 14 patients with intra-articular benign bone lesions who were followed for 12 months. Pain was measured by visual analog scale and all patients underwent computed tomography and magnetic resonance imaging. Mean pain scores decreased from 7.8 pretreatment to 2.0 at 6-month follow-up to 0.6 at 12-month follow-up (p<0.001). No patients reported worse symptoms and none reported the

procedure unsuccessful. Diagnostic imaging supported the clinical findings and showed calcification of the lesion, lack of contrast enhancement, and resolution of bone edema.

Section Summary: Palliative Treatment of Bone Metastases
The evidence base consists of a single industry-sponsored RCT which found 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 AEs, but most of these were nonsevere and transient. Although results are promising for the palliation treatment of bone metastases, additional RCTs with appropriate sham controlled studies are needed.

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, prostate cancer, and nonspinal osteoid osteoma.

The most recent case series on the use of MRgFUS for breast cancer ablation was published in 2016. Ten patients with early-stage invasive breast cancer underwent MRgFUS prior to surgical resection. Ablation was confirmed histopathologically in 6 of these patients. The investigators concluded that MRgFUS is safe and feasible. A noted limitation is the long procedure time (average, 145 minutes), due to waiting time after contrast injection and time to find a proper magnetic resonance navigator signal.

In addition, several case series have investigated the use of MRgFUS for desmoid tumors. One by Avedian et al (2016) used MRgFUS to treat 9 patients with desmoid tumors. Five patients were available for follow-up for at least 12 months. Mean decrease in tumor size was 36% (95% CI, 7% to 66%). Bucknor et al (2017) described the use of MRgFUS to treat 3 patients with large aggressive desmoid tumors within the posterior thigh. Each patient received multiple MRgFUS treatments. In this case series, the authors noted that the use of MRgFUS for desmoid tumors required different treatment parameters than those used for fibroids or bone lesions, due to differences in vascularity of the target tissue and the need for effective skin protection when using MRgFUS on extremities. Ghanouni et al (2017) used MRgFUS to treat 15 patients with extra-abdominal desmoid tumors. Treatment times ranged from 0.8 to 8 hours. Results were presented on 9 patients (3 were lost to follow-up before 6 months, 3 received additional treatments). Seven of 9 patients experienced durable clinical benefits, with a median reduction in tumor volume of 98%. Treatment-related adverse events included skin burns, nerve injury, and off-target heating.

Section Summary: Treatment of Other Tumors
Currently, evidence on the use of MRgFUS for the treatment of other tumors consists of small case series. There are several ongoing trials evaluating the safety and efficacy of MRgFUS for other tumors, with completion dates in later 2017 and in the coming years. Trials on several soft tissue tumors and breast cancer have been completed in the past year and have yet to be published.

Summary
For individuals who have uterine fibroids, metastatic bone cancer, or miscellaneous tumors, the evidence includes RCTs, nonrandomized comparative studies, and mostly small case series. Relevant outcomes are symptoms, quality of life, and treatment related morbidity. There is insufficient evidence from randomized controlled trials or nonrandomized controlled trials 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. MRgFUS is considered investigational for treatment of uterine fibroids, pain palliation in patients with bone metastases, and other applications.

Practice Guidelines and Position Statements
Society of Obstetricians and Gynaecologists of Canada
In 2015, the Society of Obstetricians and Gynaecologists of Canada published a clinical practice guideline entitled "Management of Uterine Fibroids in Women with Otherwise Unexplained Fertility." The guideline states that there are no studies comparing MRgFUS with myomectomy or in women with fibroids who have infertility as their primary complaint, and thus additional data are needed before the treatment is offered to this patient population.

American Society for Radiation Oncology
In 2011, the American Society for Radiation Oncology published guidelines on palliative radiotherapy for bone metastases, which stated that external beam radiotherapy continues to be the primary therapy for treating painful uncomplicated bone metastases. The guideline does not mention MRgFUS and does not have specific recommendations for patients who fail or are not candidates for radiotherapy.

National Comprehensive Cancer Network
Guidelines from the National Comprehensive Cancer Network on breast cancer (v.2.2017), brain cancer (v.1.2016), and prostate cancer (v.2.2017) do not mention MRgFUS as a treatment option.

U.S. Preventive Services Task Force Recommendations
Not applicable

Key Words:
Fibroids, ultrasound ablation, MRI-guidance, ultrasound ablation of uterine fibroids, ExAblate 2000, high intensity ultrasound ablation; uterine, leiomyoma; uterine; high intensity ultrasound ablation (HIFU), ExAblate, ultrasound ablation of breast tumors, ultrasound ablation of brain tumors, ultrasound ablation of prostate cancer, ultrasound ablation of bone metastasis, trans rectal high intensity focused ultrasound for prostate cancer, Ablatherm®, Sonablate 500®; MRgFUS

Approved by Governing Bodies:
In October 2004, the U.S. Food and Drug Administration (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.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

Current Coding:

CPT codes:

0071T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume of less than 200 cc of tissue
0072T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue

There is no specific code for MRgFUS in reference to bone cancer. This code may come in on unlisted code **20999** along with the appropriate radiology guidance code.

These CPT codes should not be used in conjunction with **51702** (insertion of temporary indwelling bladder catheter, simple) or **77022** (magnetic resonance imaging guidance for, and monitoring of, visceral tissue ablation). Prior to the introduction of the above codes, the procedure may have been coded for using several codes describing the individual components of the procedure. CPT codes **0071T-0072T** describe the comprehensive service.

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