Magnetic Resonance-Guided Focused Ultrasound

Policy # 00180
Original Effective Date: 09/22/2005
Current Effective Date: 11/15/2017

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.

When Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider magnetic resonance-guided high-intensity ultrasound ablation for pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy to be eligible for coverage.

When 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 magnetic resonance-guided high-intensity ultrasound ablation to be investigational in all other situations including but not limited to:

- Treatment of uterine fibroids; and
- Treatment of other tumors (eg, brain cancer, prostate cancer, breast cancer, desmoid).

Background/Overview

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 (eg, massage, exercise) and pharmacologic agents (eg, 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

Magnetic resonance–guided focused ultrasound (MRgFUS) is a noninvasive treatment that combines 2 technologies, focused ultrasound (US) and magnetic resonance imaging (MRI). The US beam penetrates through the soft tissues and, using MRI for guidance and monitoring, the beam can be focused on targeted sites. The US causes a local increase in temperature in the target tissue, resulting in coagulation necrosis while sparing the surrounding normal structures. The US 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 (ie, 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.

U.S. Food and Drug Administration (FDA) has approved the ExAblate MRgFUS system (InSightec Inc., Haifa, Israel) for 2 indications; treatment of uterine fibroids (leiomyomata) and palliation of pain associated with tumors metastatic to bone. The US 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 US 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. For treating pain associated with bone metastases, the aim of MRgFUS is to destroy nerves in the bone surface surrounding the tumor.

MRgFUS is also being investigated for the treatment of other tumors, including breast, prostate, brain, and desmoid tumors as well as nonspinal osteoid osteoma.

FDA or Other Governmental Regulatory Approval

FDA Approval

In October 2004, the ExAblate 2000 System (InSightec Inc., Haifa, Israel) was FDA approved via the premarket approval process 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 radiotherapy. 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.

FDA product code: NRZ.
Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source
Assessment of efficacy for therapeutic interventions such as MRgFUS involves the 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). The following is a summary of the literature to date.

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 2016, a pilot sham-controlled randomized trial evaluating MRgFUS for the treatment of uterine fibroids was published by Jacoby et al. The trial included 20 premenopausal women with symptomatic uterine fibroids (women who were pregnant or had a desire for future children were excluded). Patients were randomized to MRgFUS with the ExAblate 2000 System (n=13) or to a sham treatment not using thermal energy (n=7). The investigators did not specify primary outcomes. The sample size was calculated to assess the feasibility of a larger trial, not to provide sufficient statistical power. All patients were assigned to
the MRgFUS group and 6 of 7 in the placebo group received their allocated treatment; all patients who were treated completed 3 months of follow-up. Patients were unblinded at 3 months, and those in the sham group were given the option of active treatment.

QOL outcomes included the Uterine Fibroid Symptom and Quality of Life Questionnaire, which has subscales including the symptom severity score (SSS) and health related quality of life score. The 36-Item Short-Form Health Survey (SF-36), which includes the Mental Component Summary and Physical Component Summary, was also used. At 4- and 12-week follow-ups, there were no statistically significant differences (at the p<0.05 level) between the MRgFUS and the sham groups in the SSS, the health related quality of life score, and SF-36 Physical Component Summary or Mental Component Summary scores. 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 by 18% in the MRgFUS group and did not change in the sham group (p=0.03). The authors concluded that women would be willing to participate in a sham-controlled randomized trial of MRgFUS and that larger trials were feasible.

**Systematic Reviews**

The remaining published studies are nonrandomized. A systematic review, published by Gizzo et al in 2014, identified 38 uncontrolled studies with a total of 2500 patients who underwent MRgFUS for the treatment of uterine fibroids. All published studies included women 18 years or older 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 nonrandomized pivotal study included in the Gizzo systematic review, designed for U.S. FDA approval of the ExAblate 2000 device, evaluated 109 women treated with MRgFUS and 83 women treated with abdominal hysterectomy. The primary outcome was changed in SSS, part of the validated Uterine Fibroid Symptom and Quality of Life Questionnaire. Symptom severity was measured using 8 questions relevant to bulk and bleeding symptoms on a 0-to-100 scale, with the higher number representing greater symptom severity. Outcome data were initially reported for the MRgFUS group only. At 6-month 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. A threshold of more than 10 points was selected for the analysis, but this threshold is 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 2 variations on the MRgFUS procedure. Patients were treated with the original protocol (33% of fibroid volume with a 120-minute maximum treatment time, n=96) or modified protocol (50% treatment volume, 180-minute 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, SSS decreased from 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 the large loss to follow-up: 55 (57%) patients from the original treatment protocol completed follow-up. Only 21 (33%) patients 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 3 phase 3 trials and 1 postmarketing study (total N=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% 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 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 the treatment protocols.

A 2011 case series included 40 women treated with MRgFUS for symptomatic uterine fibroids at 1 center in the United States. The primary study end points were change from baseline in QOL and symptom severity scores. (Higher scores on the QOL measure and lower scores on the symptom severity measure indicated improvement.) Mean SSS in the 29 (73%) patients who completed the 3-year follow-up was 64.8 at baseline and 17.0 at 3 years, representing a mean reduction of 47.8 points. Mean QOL score at baseline was 44.1 and at the 3-year follow-up was 83.9, a mean improvement of 39.8 points. Both improvements were statistically significant. Another representative case series (2011) reported 12-month outcomes data on 130 women treated with MRgFUS. Eight women had additional procedures to relieve symptoms within 1 year of MRgFUS treatment; seven underwent a hysterectomy, and one underwent endometrial ablation. Data on symptom relief at 12 months were available for 70 (54%) of 130 patients. Fifty-one (73%) of the 70 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 eligible for treatment with MRgFUS and UAE. Forty-four (36%) women were lost to follow-up. Follow-up data at 60 months were available for 77 women, 41 in the UAE group, and 36 in the MRgFUS group. The primary outcome was rate of reintervention (eg, repeat MRgFUS, myomectomy, hysterectomy, endometrial ablation). During follow-up, 5 (12%) women in the UAE group and 24 (67%) women in the MRgFUS group experienced a reintervention (statistical comparison not reported). Health-related QOL scores (secondary outcomes) were significantly better in the UAE group than in 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 8 months after treatment. They included 8 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 (42%) of the 54 pregnancies resulted in deliveries and 11 were ongoing beyond 20 weeks at the time the article was written. There were 14 (26%) miscarriages and 7 (13%) elective terminations. Among the 22 live births, mean live birth weight was 3.3 kg, and the vaginal delivery rate was 64%. The article provided initial information on the impact of MRgFUS on uterine fibroids in pregnancy; findings suggested that fertility may be maintained but that the number of cases was too small to draw definitive conclusions. The study also did not address the possible impact of MRgFUS treatment on the future 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 nonrandomized studies have also compared MRgFUS with a different treatment. The sham-controlled randomized trial concluded that a larger trial would be 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 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 3:1 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 3-month follow-up. A larger proportion of the placebo group dropped out: 17 (49%) of 35 who were treated decided to have rescue MRgFUS treatment after a lack of response to placebo. A modified intention-to-treat analysis was used that included patients who had at least 1 MRgFUS or placebo sonication. Missing values were imputed using the last-observation carried forward method.

The primary efficacy end point, assessed at 3 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 2 points and if their MEDD intake did not increase more than 25% from baseline to 3 months. NRS scores and MEDD intake were reported separately as secondary outcomes.

Seventy-two (64%) of 112 patients in the MRgFUS group and 7 (20%) of 35 patients in the control group were considered responders, as previously defined. The difference was statistically significant (p=0.01), favoring active treatment. When the 2 measures comprising 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 (SD) of 3.6 (3.1) points in the MRgFUS group and by a mean of 0.7 (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 (46%) patients in the MRgFUS group and 1 (3%) in the placebo group experienced at least 1 adverse event. Most adverse events were transient, with the most common being sonication pain, experienced by 36 (32%) patients in the MRgFUS group. In 17 (15%) patients, sonication pain was severe; 3 patients did not complete treatment due to pain. The most clinically significant adverse events that lasted more than a week were third-degree skin burns in 1 patient (associated with noncompliance with the treatment protocol) and fracture in 2 patients (one of which was outside the treatment location). Potential limitations of the trial included 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 3-month follow-up; the authors indicated 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 (81%) patients were available for 3-month follow-up. Mean visual analog scale score decreased from 5.9 at baseline to 1.8 three months after treatment. Thirteen of 25 patients who used nonopioid analgesics and 6 of 10 who used opioids decreased medication use after treatment. Neither group reported 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 significantly 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 that found significant improvement after MRgFUS in a composite outcome comprised of reduction in pain and morphine use, and in pain reduction as a stand-alone outcome. This trial was appropriately sham-controlled. A substantial proportion of patients in the treatment group experienced adverse events, but most adverse events were transient and not severe. Several case series has also reported improvements in pain and patient satisfaction with MRgFUS.

**TREATMENT OF OTHER TUMORS**
Only small case series have been published on the safety and/or efficacy of MRgFUS for treating tumors related to 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. 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 (see Table 1).

SUMMARY OF EVIDENCE
For individuals who have uterine fibroids who receive MRgFUS, the evidence includes 2 small RCTs, nonrandomized comparative studies, and case series. Relevant outcomes are symptoms, quality of life, resource utilization, and treatment-related morbidity. One RCT (N=20) has reported some health outcomes, but its primary purpose was to determine the feasibility of a larger trial. It did not find statistically significant differences in quality of life outcomes between active and sham treatment groups, but it did find lower fibroid volumes after active treatment. This pivotal FDA trial was not randomized, the clinical significance of the primary outcome was unclear, and there were no follow-up data beyond 1 year. The second RCT (N=49) is ongoing; it has provided preliminary results at 6 weeks posttreatment, comparing MRgFUS with uterine artery embolization (UAE). The 2 groups were comparable in medication use and symptom improvement following treatments. Patients in the MRgFUS group reported recovering significantly faster than patients in the UAE group, as measured by time to return to work and time to normal activities. In a separate 2013 comparative study, outcomes appeared to be better with UAE than with MRgFUS. We lack insufficient data on the long-term treatment effects, recurrence rates, and impact on future fertility and pregnancy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with painful metastatic bone cancer who have failed or are not candidates for radiotherapy who receive MRgFUS, the evidence includes a sham-controlled randomized trial and several case series. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The RCT found statistically significant improvements after MRgFUS in a composite outcome comprised of a 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 adverse events, but most were not severe and were transient. The case series also reported reductions in pain following MRgFUS treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Magnetic Resonance-Guided Focused Ultrasound

Policy #: 00180
Original Effective Date: 09/22/2005
Current Effective Date: 11/15/2017

For individuals with other tumors (e.g., breast cancer, brain cancer, prostate cancer, or desmoid) or nonspinal osteoid osteoma who receive MRgFUS, the evidence includes small case series. Relevant outcomes are symptoms, health status measures, and treatment-related morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

References

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Magnetic Resonance-Guided Focused Ultrasound

Policy # 00180
Original Effective Date: 09/22/2005
Current Effective Date: 11/15/2017


Policy History
Original Effective Date: 09/22/2005
Current Effective Date: 11/15/2017

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

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Magnetic Resonance-Guided Focused Ultrasound

Policy # 00180
Original Effective Date: 09/22/2005
Current Effective Date: 11/15/2017

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.

11/06/2014 Medical Policy Committee review

11/21/2014 Medical Policy Implementation Committee approval. No change to coverage. Title changed from MRI-Guided Focused Ultrasound (MRgFUS) to Magnetic Resonance Imaging-Guided Focused Ultrasound.

08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.

10/29/2015 Medical Policy Committee review

11/16/2015 Medical Policy Implementation Committee approval. Added “Based on review of available data, the Company may consider magnetic resonance imaging (MRI)–guided high-intensity ultrasound ablation for pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy to be eligible for coverage.”

11/03/2016 Medical Policy Committee review

11/16/2016 Medical Policy Implementation Committee approval. Title change, “imaging” removed from policy statements.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

11/02/2017 Medical Policy Committee review

11/15/2017 Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 11/2018

Coding
The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)2, copyright 2016 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>0071T, 0072T</td>
</tr>
</tbody>
</table>

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Magnetic Resonance-Guided Focused Ultrasound

Policy # 00180
Original Effective Date: 09/22/2005
Current Effective Date: 11/15/2017

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>C9734</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICD-10 Diagnosis</td>
<td>All related diagnoses</td>
</tr>
</tbody>
</table>

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

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:

1. Consultation with the Blue Cross and Blue Shield Association TEC or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;

B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.