



# Louisiana

## Magnetic Resonance-Guided Focused Ultrasound

**Policy #** 00180

**Original Effective Date:** 09/22/2005

**Current Effective Date:** 05/11/2020

*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.*

*Note: Occlusion of Uterine Arteries Using Transcatheter Embolization or Laparoscopic Occlusion is addressed separately in medical policy 00130.*

*Note: Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors is addressed separately in medical policy 00175.*

### 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**.\*\*

Based on review of available data, the Company may consider magnetic resonance-guided high-intensity ultrasound ablation for the treatment of medicine-refractory essential tremors 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).

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## **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.

### **Treatment**

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 treatments.

### **Metastatic Bone Disease**

Metastatic bone disease is one of the most common causes of cancer pain.

### **Treatment**

Existing treatments include conservative measures (eg, massage, exercise) and pharmacologic agents (eg, analgesics, bisphosphonates, corticosteroids). For patients who do not respond to these treatments, standard care is 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.

### **Essential Tremors**

ET is the most common movement disorder, with an estimated prevalence of 5% worldwide. ET most often affects the hands and arms, may affect head and voice, and rarely includes the face, legs, and trunk. ET is heterogeneous among patients, varying in frequency, amplitude, causes of exacerbation, and association with other neurologic deficits.

### **Treatment**

The neuropathology of ET is uncertain, with some evidence suggesting that ET is localized in the brainstem and cerebellum. If patients with ET experience intermittent or persistent disability due to the tremors, initial therapy is with drugs (b-blockers or anticonvulsants). For medicine-refractory patients, surgery (deep brain stimulation or thalamotomy) may be offered, though high rates of adverse events have been observed.

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### **Magnetic Resonance-Guided Focused Ultrasound**

MRgFUS is a noninvasive treatment that combines two technologies: focused ultrasound and magnetic resonance imaging (MRI). The ultrasound beam penetrates through the soft tissues and, using MRI for guidance and monitoring, the beam can be focused on targeted sites. Ultrasound causes a local increase in temperature in the target tissue, resulting in coagulation necrosis while sparing the surrounding normal structures. Ultrasound waves from each sonication are directed at a focal point that has a maximum focal volume of 20 mm in diameter and 15 mm in height/length. This causes a rapid rise in temperature (ie, to 65°C-85°C), which is sufficient to ablate tissue at the focal point. In addition to providing guidance, the associated MRI can provide online thermometric imaging, a temperature "map", to 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) approved the ExAblate MRgFUS system (InSightec) for two indications: treatment of uterine fibroids (leiomyomata) and palliation of pain associated with tumors metastatic to bone. The ultrasound equipment is specifically designed to be compatible with magnetic resonance magnets, and it is integrated into standard clinical MRI units; it also includes a patient table, which has a cradle that houses the focused ultrasound transducer in water or a light oil bath. Some models 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**

### **U.S. Food and Drug Administration (FDA)**

In October 2004, the ExAblate<sup>®</sup> 2000 System (InSightec) was approved by the FDA through 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 fewer than 24 weeks who have completed childbearing.

In October 2012, the ExAblate System, Model 2000/2100/2100 VI, was approved by the FDA through the premarket approval process for pain palliation in adults with metastatic bone cancer who

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have failed or are not candidates for radiotherapy. 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.

In July 2016, the FDA approved the use of the ExAblate<sup>®</sup> Neuro System for the treatment of ET in patients who have not responded to medication (b-blockers or anticonvulsant drugs) through the premarket approval process.

FDA product codes: NRZ, POH.

### **Rationale/Source**

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

For individuals who have uterine fibroids who receive MRgFUS, the evidence includes two small randomized controlled trials (RCTs), nonrandomized comparative studies, and case series. The relevant outcomes are symptoms, quality of life (QOL), 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 QOL outcomes between active and sham treatment groups but it did find lower fibroid volumes after active treatment. This trial did not have an active comparator, the clinical significance of the primary outcome was unclear, and there were no follow-up data beyond one year. The second RCT (n=49) is ongoing; preliminary results at 6 weeks post treatment, comparing MRgFUS with uterine artery embolization have shown that the 2 groups are comparable in medication use and symptom improvement following treatments. Patients in the MRgFUS group reported recovering significantly faster than patients in the uterine artery embolization 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 uterine artery embolization than with MRgFUS. Long-term data on the treatment effects, recurrence rates, and impact on future fertility and pregnancy are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

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For individuals with 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. The relevant outcomes are symptoms, functional outcomes, health status measures, QOL, 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 events were transient and not severe. The case series reported reductions in pain following MRgFUS treatment, consistent with the RCT. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with other tumors (eg, breast cancer, brain cancer, prostate cancer, desmoid, nonspinal osteoid osteoma) who receive MRgFUS, the evidence includes small case series. The 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.

For individuals with medicine-refractory essential tremors who receive MRgFUS, the evidence includes two systematic reviews that identified an RCT and several observational studies. The relevant outcomes include symptoms, functional outcomes, QOL, and treatment-related morbidity. The assessment did not pool study results but concluded that, overall, MRgFUS decreased tremor severity and improved QOL. The sham-controlled randomized trial found significant improvements in the treatment group in tremor severity, functional improvement, and QOL after three months of follow-up. The improvements in hand tremor score, function, and QOL were maintained at the two-year follow-up. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

## **Supplemental Information**

### **Practice Guidelines and Position Statements**

#### **American Society for Radiation Oncology**

The American Society for Radiation Oncology (2017) 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 guidelines did not mention

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magnetic resonance-guided focused ultrasound. If patients experience persistent or recurrent pain more than 1 month after initial treatment, the guidelines recommended retreatment with external-beam radiotherapy. As for advanced radiotherapy such as stereotactic body radiotherapy for retreatment of recurrent pain in spine bone lesions, these "may be feasible, effective, and safe, but the panel recommends that this approach should be limited to clinical trial participation or on a registry given limited data supporting routine use."

### National Comprehensive Cancer Network

Guidelines from the National Comprehensive Cancer Network on bone cancer (v. 2.2019), breast cancer (v.1.2019), brain cancer (v.1.2019), and prostate cancer (v.2.2019) do not mention magnetic resonance-guided ultrasound as a treatment option.

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT00981578 <sup>a</sup>	A Feasibility Study to Evaluate the Safety and Initial	50	Jun 2019

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NCT No.	Trial Name	Planned Enrollment	Completion Date
	Effectiveness of ExAblate MR Guided Focused Ultrasound Surgery in the Treatment of Pain Resulting from Metastatic Bone Tumors with the ExAblate 2100 Conformal Bone System		(ongoing)
NCT01833806 <sup>a</sup>	A Phase IV Post Approval Clinical Study of ExAblate Treatment of Metastatic Bone Tumors for the Palliation of Pain	70	Oct2020
NCT01473485 <sup>a</sup>	A Study to Evaluate the Safety and Feasibility of Transcranial MRI-Guided Focused Ultrasound Surgery in the Treatment of Brain Tumors	10	Dec2022
NCT00147056 <sup>a</sup>	A Study to Evaluate the Safety and Feasibility of Transcranial MRI-Guided Focused Ultrasound Surgery in the Treatment of Brain Tumors	10	Dec2022
NCT02252380 <sup>a</sup>	A Feasibility Clinical Trial of the Magnetic Resonance Guided	10	Dec2020

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NCT No.	Trial Name	Planned Enrollment	Completion Date
	Focused Ultrasound (MRgFUS) for the Management of Treatment-Refractory Movement Disorders		
NCT02260752	Comparing Options for Management: Patient-Centered Results for Uterine Fibroids	10,000	Apr 2020
NCT02968784 <sup>a</sup>	Focal ExAblate MR Guided Focused Ultrasound Treatment for Management of Organ-Confining Intermediate Risk Prostate Cancer: Evaluation of Safety and Effectiveness	68	Jun 2020
NCT01657942 <sup>a</sup>	Focal MR Guided Focused Ultrasound Treatment of Localized Low and Intermediate Risk Prostate Lesions	100	Oct 2020
NCT02794558 <sup>a</sup>	A Clinical Study to Evaluate the Safety and Effectiveness of MR Guided Focused Ultrasound Surgery in the Treatment of Early Breast Carcinomas	100	Apr 2021

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NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Unpublished</i>			
NCT01285960 <sup>a</sup>	A Clinical Study to Evaluate Safety of the ExAblate Model 2100 Type 1.1 System in the Treatment of Symptomatic Uterine Fibroids	106	Apr 2016 (completed)
NCT01620359 <sup>a</sup>	Study of ExAblate Focused Ultrasound Ablation of Breast Cancer under MR Guidance and MRI Evaluation of Ablation	14	Jul 2016 (completed)
NCT01834937 <sup>a</sup>	A Post Approval Registry: ExAblate Treatment of Metastatic Bone Tumors for the Palliation of Pain	17	Apr 2017 (completed)
NCT01091883 <sup>a</sup>	Phase IIIA Study Comparing the Safety and Effectiveness of MR Guided Focused Ultrasound and External Beam Radiation for Treatment of Metastatic Bone Tumors and Multiple Myeloma	60	Mar 2018 (unknown)

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NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01226576 <sup>a</sup>	Focal MR Guided Focused Ultrasound Treatment of Localized Low-Intermediate Risk Prostate Cancer: Feasibility Study	8	Dec 2018

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

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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.
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.

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- 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.
  - 11/08/2018 Medical Policy Committee review
  - 11/21/2018 Medical Policy Implementation Committee approval. A policy statement added that MRgFUS ablation may be considered eligible for coverage for the treatment of medicine-refractory essential tremors.
  - 11/07/2019 Medical Policy Committee review
  - 11/13/2019 Medical Policy Implementation Committee approval. No change to coverage.
  - 04/02/2020 Medical Policy Committee review
  - 04/08/2020 Medical Policy Implementation Committee approval. No change to coverage.
- Next Scheduled Review Date: 04/2021

### **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®)‡, copyright 2019 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*

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# Louisiana

## Magnetic Resonance-Guided Focused Ultrasound

Policy # 00180

Original Effective Date: 09/22/2005

Current Effective Date: 05/11/2020

*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:

Code Type	Code
CPT	0071T, 0072T, 0398T
HCPCS	C9734
ICD-10 Diagnosis	All related diagnoses

\*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. Food and Drug Administration (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 technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);

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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:** If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**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.

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