

Corporate Medical Policy

MRI-Guided Focused Ultrasound (MRgFUS)

File Name: mri_guided_focused_ultrasound
Origination: 11/2004
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Description of Procedure or Service

Magnetic resonance-guided focused ultrasound (MRgFUS) is a non-invasive treatment that combines two technologies, focused ultrasound and magnetic resonance imaging. 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 directed at a focal point which has a maximum focal volume of 20 mm in diameter and 15 mm in height/length. This causes a rapid rise in temperature sufficient to achieve tissue ablation at the focal point. In addition to providing guidance, the associated MRI can provide on-line thermometric imaging that provides a temperature “map” that can further confirm the therapeutic effect of the ablation treatment and allow for real-time adjustment of the treatment parameters.

The U.S. Food and Drug Administration (FDA) has approved the ExAblate® MRgFUS system (InSightec, Inc., Haifa, Israel) for four indications; treatment of uterine fibroids (leiomyomata), palliation of pain associated with tumors metastatic to bone, medication refractory essential tremor, and tremor-dominant Parkinson disease. The ultrasound equipment is specifically designed to be compatible with MR magnets and is integrated into standard clinical MRI units. It includes a patient table with 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 the palliation of pain associated with metastatic bone cancer.

Uterine fibroids (leiomyomata) are one of the most common conditions affecting individuals in the reproductive years. Symptoms of uterine fibroids include menorrhagia, pelvic pressure, or pain. 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.

For treating pain associated with bone metastases, the aim of MRgFUS treatment is to destroy nerves in the bone surface surrounding the tumor. Metastatic bone disease is one of the most common causes of cancer pain. Existing treatments include conservative measures (e.g., massage, exercise) and pharmacologic agents (e.g., analgesics, bisphosphonates, corticosteroids). For patients who do not respond to these treatments, standard care is external beam radiotherapy (EBRT). However, a substantial proportion of patients have residual pain after radiotherapy, and there is a need for alternative treatments for these patients.

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

Essential tremor is the most common movement disorder. It often affects the hands and arms, may affect head and voice, and rarely includes the face, legs and trunk. It is herogeneous among patients, varying in frequency, amplitude, causes of exacerbation and association with other neurologic deficits. The neuropathology of essential tremor is uncertain, with some evidence suggesting that it is localized in the brainstem and cerebellum. If patients experience intermittent or persistent disability due to the tremors, initial therapy is with drugs (beta 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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Regulatory Status

In October 2004, the FDA approved the ExAblate[®] 2000 System (InSightec) through the premarket approval process for “ablation of uterine fibroid tissue in pre- or peri-menopausal 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 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[®] Neuro System for the treatment of essential tremors in patients who have not responded to medication (beta blockers or anticonvulsants) through the premarket approval process. In December 2018, the FDA approved the use of the ExAblate Model 4000 (Neuro) for the treatment of tremor-dominant PD with medication-refractory tremor through the premarket approval process.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for MRI-Guided Focused Ultrasound when the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When MRI-Guided Focused Ultrasound is covered

Magnetic resonance imaging (MRI) –guided high-intensity ultrasound ablation may be considered medically necessary for the following:

- pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy
- treatment of medicine-refractory essential tremors.

When MRI-Guided Focused Ultrasound is not covered

MRI-Guided High Intensity Ultrasound Ablation is considered **investigational** in all other situations, including, but not limited to:

- Treatment of uterine fibroids;
- Treatment of other tumors (e.g., brain cancer, prostate cancer, breast cancer, desmoid).
- Treatment of medication-refractory tremor dominant Parkinson disease.

Policy Guidelines

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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 controlled trial (RCT), a systematic review of RCTs and observational studies, and case series. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life and treatment related morbidity. The RCT found statistically 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. A substantial proportion of patients in the treatment group experienced adverse events, but most of these were not severe and were transient. Pooled efficacy data from a systematic review reported a treatment response to MRgFUS of 79%. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have uterine fibroids who receive MRgFUS, the evidence includes 2 small randomized controlled trials (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 trial did not have an active comparator, the clinical significance of the primary outcome was unclear, and there were no follow-up data beyond 1 year. The second RCT (N=49) had preliminary results at 6 weeks posttreatment, comparing MRgFUS with uterine artery embolization, and demonstrated 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 (UAE) group, as measured by time to return to work and time to normal activities. Long-term follow-up results reported that there was lower reintervention rate and greater improvement in symptoms after UAE compared to MRgFUS. A 2021 meta-analysis reported that, comparatively, myomectomy had the lowest re-intervention rate of the 3 regimens (myomectomy vs UAE vs MRgFUS) in all time points assessed while the MRgFUS had the highest re-intervention rate. In a 2013 comparative study, outcomes appeared to be better with UAE 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 that the technology results in an improvement in the net health outcome.

For individuals with medicine-refractory essential tremors who receive MRgFUS, the evidence includes a technology assessment, meta-analyses, and a double-blind, sham-controlled randomized trial. Relevant outcomes include symptoms, functional outcomes, quality of life, and treatment-related morbidity. The assessment did not pool study results but concluded that, overall, MRgFUS decreased tremor severity and improved quality of life. One meta-analysis reported significant improvements in hand tremor scores from baseline up to 24 months post-treatment, with evidence of a diminishing treatment benefit over time. Another meta-analysis found similar improvements in tremor severity with MRgFUS to unilateral deep brain stimulation (DBS), but improvements in both were inferior to bilateral DBS. The sham-controlled randomized trial found significant improvements in the treatment group in tremor severity, functional improvement, and quality of life after 3 months of follow-up. The improvements in hand tremor score, function, and quality of life were maintained at the 2-year follow-up. The evidence is sufficient to determine that the technology results in an 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 a nonrandomized, uncontrolled phase II trial and several case series. Relevant outcomes are symptoms, health status measures, and treatment related morbidity. A nonrandomized, uncontrolled phase II trial evaluating MRgFUS for prostate cancer reported a 93% success rate at 5 months. The use of MRgFUS for the treatment of nonspinal osteoid osteoma consists of several larger case series, including a propensity score-matched retrospective study that reported similar reductions in pain with radiofrequency ablation and MRgFUS. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with medicine-refractory tremor dominant Parkinson disease who receive MRgFUS, the evidence includes a pilot RCT. Relevant outcomes include symptoms, functional outcomes, quality of life, and treatment-related morbidity. The double-blind, sham-controlled, pilot randomized trial found significant improvements in the treatment group in tremor severity after 3 months of follow-up. The

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evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0071T, 0072T, 0398T, C9734

These CPT codes should not be used in conjunction with 51702 or 77022, since 0071T and 0072T describe the comprehensive service.

There are no specific CPT codes for the use of MRI-guided high-intensity ultrasound ablation in metastatic bone cancer. An unlisted code would be used based on the anatomic location of the metastasis being treated (e.g., 23929 for the clavicle) or perhaps one of the radiation oncology unlisted codes (e.g., 77299 or 77499).

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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Fennessy FM, Tempany CM, McDannold NJ, Minna JS, Hesley G, Gostout B. Uterine Leiomyomas: MR Imaging-guided Focused Ultrasound Surgery-Results of Different Treatment Protocols. *Radiology* 2007;243(3):885-893

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Taran FA, Tempany CM, Regan L, et al. Magnetic resonance-guided focused ultrasound (MRgFUS) compared with abdominal hysterectomy for treatment of uterine leiomyomas. *Ultrasound Obstet Gynecol* 2009; 34(5):572-8

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National Institute of Health and Care Excellence (NICE). Unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor [IPG617]. 2018; <https://www.nice.org.uk/guidance/ipg617>

Specialty Matched Consultant Advisory Panel review 5/2022

Medical Director review 5/2022

Specialty Matched Consultant Advisory Panel review 5/2023

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Policy Implementation/Update Information

- 11/11/04 New Policy issued. Reference added.
- 11/27/06 References updated. Specialty Matched Consultant Advisory Panel review 10/23/06. No changes to policy coverage criteria
- 6/16/08 References updated. Specialty Matched Consultant Advisory Panel review 5/15/08. No change to policy statement. (adn)
- 6/22/10 Policy Number(s) removed (amw)
- 9/28/10 Description section revised. Investigational statement reworded but intent remains unchanged. Policy Guidelines updated. Coding information added to Billing/Coding section. Specialty Matched Consultant Advisory Panel review 8/25/10. Draft approved as written. (adn)
- 7/19/11 Statement added to Description section regarding FDA status. Specialty Matched Consultant Advisory Panel review 6/29/11. Policy accepted as written. (adn)
- 6/29/12 Policy title changed to include “Other Tumors.” Related Guideline added to Description section. “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 investigational” added to When Not Covered section. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 6/20/12. (sk)

For Policy Re-named: MRI-Guided Focused Ultrasound (MRgFUS)

- 4/16/13 References added. Policy title changed from MRI-Guided High Intensity Ultrasound Ablation of Uterine Fibroids and Other Tumors to MRI-Guided Focused Ultrasound (MRgFUS). Description and Background sections updated to include information on palliative treatment of bony metastases. Regulatory Status section updated to include FDA information from 2012. HCPCS code C9734 added to Billing/Coding section. No change to policy statement. (sk)
- 10/1/13 Specialty Matched Consultant Advisory Panel review 6/19/13. No change to policy statement. (sk)

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- 4/15/14 Reference added. No change to policy statement. (sk)
- 3/31/15 Reference added. "Magnetic resonance imaging (MRI) –guided high-intensity ultrasound ablation may be considered medically necessary for pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy" added to the When Covered section. Policy guidelines updated. Billing/Coding section updated. Senior Medical Director review. (sk)
- 7/28/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. No change to policy statement. (lpr)
- 12/30/15 Added CPT code 0398T to Billing/Coding section for effective date 1/1/2016. (lpr)
- 4/1/16 Updated Policy Guidelines section. No change to policy intent. Reference added. (lpr)
- 7/26/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. No change to policy statement. (an)
- 12/30/16 Minor changes to description section. No change to policy statement. (an)
- 6/30/17 Minor changes to description section. Specialty Matched Consultant Advisory Panel review 5/31/2017. No change to policy statement. (an)
- 6/29/18 Minor changes to description section. Updated Policy Guidelines section. Reference added. Specialty Matched Consultant Advisory Panel review 5/23/2018. No change to policy statement. (an)
- 9/7/18 Description section updated to include information regarding essential tremors. Policy statement revised to include: **MRI-Guided High Intensity Ultrasound Ablation may be considered medically necessary for the treatment of medicine-refractory essential tremors.** This new indication also added to the "When Covered" section. Policy Guidelines updated. Reference added. (an)
- 6/11/19 Specialty Matched Consultant Advisory Panel review 5/15/2019. No change to policy statement. (an)
- 6/9/20 Specialty Matched Consultant Advisory Panel review 5/20/2020. No change to policy statement. (eel)
- 6/1/21 Reference added. Specialty Matched Consultant Advisory Panel review 5/2021. Medical Director review. No change to policy statement. (bb)
- 9/21/21 Reference added. Description updated. Regulatory Status updated. Related policy titled "Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors" removed. Policy Guidelines updated. (sk)
- 5/31/22 Policy statement updated for clarity. Investigational statement added on tremor-dominant Parkinson disease to when not covered section. References added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/2022. Medical Director review 5/2022. (tt)
- 5/30/23 References added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/2023. Medical Director review 5/2023. No change to policy statement. (tt)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational

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purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.