



MASSACHUSETTS

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Medical Policy

Magnetic Resonance–Guided Focused Ultrasound

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Policy Number: 243

BCBSA Reference Number: 7.01.109 (For Plans internal use only)

Related Policies

- Occlusion of Uterine Arteries Using Transcatheter Embolization #[242](#)
- Radiofrequency Ablation of Miscellaneous Solid Tumors Excluding Liver Tumors #[259](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Magnetic resonance 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.

Magnetic resonance-guided high-intensity ultrasound ablation may be considered **MEDICALLY NECESSARY** for the treatment of medicine-refractory essential tremors.

Magnetic resonance-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 (eg, brain cancer, prostate cancer, breast cancer, desmoid)
- Treatment of medication-refractory tremor dominant Parkinson disease.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above **medical necessity criteria MUST** be met for the following codes to be covered for **Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

CPT Codes

CPT codes:	Code Description
0398T	Magnetic resonance image guided high intensity focused ultrasound (mrgfus), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed

The following ICD Diagnosis Code is considered medically necessary when submitted with the CPT code above if **medical necessity criteria** are met:

ICD-10 diagnosis coding

ICD-10 Diagnosis code	Description
G25.0	Essential tremor

The following CPT codes are considered investigational for **Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

CPT Codes

CPT codes:	Code Description
0071T	Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume 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

Description

Uterine Fibroids

Uterine fibroids are one of the most common conditions affecting women in the reproductive years. African American women have a greater lifetime incidence of uterine fibroids compared to other racial groups.¹ Symptoms of uterine fibroids include menorrhagia, pelvic pressure, or pain.

Treatment

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. (One option, radiofrequency ablation, is addressed in related evidence review 7.01.95).

Essential Tremors

Essential tremor (ET) is the most common movement disorder, with an estimated prevalence of 5% worldwide. Essential tremor most often affects the hands and arms, may affect head and voice, and rarely includes the face, legs, and trunk. Essential tremor 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 (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.

Tremor-Dominant Parkinson Disease

The 3 cardinal features of Parkinson disease (PD) are tremor, bradykinesia, and rigidity. The tremor in PD is a resting tremor that occurs when the body part is not engaged in purposeful activities. Major subtypes of PD include tremor-dominant, akinetic-rigid, and postural instability and gait difficulty. The progression of PD is highly variable and patients can change subtypes as the disease progresses.

Treatment

Dopaminergic therapy (ie, levodopa or a dopamine agonist) is the first-line treatment for PD, which improves tremor. Amantadine and anticholinergics (eg, trihexyphenidyl) can also be considered as initial treatment for tremor-dominant PD or as add-on therapy in patients who have persistent tremor despite dopaminergic therapy. For medication-refractory patients, surgery (deep brain stimulation or lesioning procedures) may be offered. Lesioning procedures include conventional unilateral thalamotomy and focused ultrasound thalamotomy. Deep brain stimulation is the most frequently performed surgical procedure for the treatment of PD.

Magnetic Resonance-Guided Focused Ultrasound

Magnetic resonance-guided focused ultrasound (MRgFUS) is a noninvasive treatment that combines 2 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 to 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 4 indications: treatment of uterine fibroids (leiomyomata), palliation of pain associated with tumors metastatic to bone, medication refractory ET, and tremor-dominant PD. 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.

Summary

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.

Summary of Evidence

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 metastatic bone cancer who have failed or are not candidates for radiotherapy who receive MRgFUS, the evidence includes a sham-controlled randomized trial, 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 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. 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 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 medication-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 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 evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
9/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
12/2021	Annual policy review. New investigational statement described for treatment of medication-refractory tremor dominant Parkinson disease. Effective 12/1/2021.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
9/2020	Annual policy review. Description, summary and references updated. Policy statements unchanged.
9/2019	Annual policy review. Description, summary and references updated. Policy statements unchanged.
2/2019	Annual policy review. New medically necessary statement added for MRgFUS ablation for treatment of medicine-refractory essential tremors. Clarified coding information. Effective 2/1/2019.
4/2018	Local Coverage Determination (LCD): Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Essential Tremor (L37421) added. Effective 4/1/2018.
8/2017	New references added from Annual policy review.
4/2016	Annual policy review. Policy statements unchanged. Global change to policy to remove "imaging" (eg, title, policy statement) to standardize terminology to magnetic resonance-guided focused ultrasound (MRgFUS).
1/2016	Clarified coding information.
7/2015	Annual policy review. New medically necessary indications described. Effective 7/1/2015.
5/2014	New references from Annual policy review.
8/2013	Annual policy review. Policy changed to single investigational statement; no change to intent of policy. Policy title changed to MRI-Guided Focused Ultrasound (MRgFUS). Effective 8/1/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/2011	Reviewed - Medical Policy Group - Obstetrics and Gynecology. No changes to policy statements.
10/2010	Reviewed - Medical Policy Group - Obstetrics and Gynecology. No changes to policy statements.
7/2010	New policy describing ongoing non-coverage. Effective 7/1/2010.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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