

MRI Guided Focused Ultrasound (MRgFUS)

Policy MP-039

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Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, CHIP and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. **This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.**

Description:

Magnetic resonance guided focused ultrasound (MRgFUS) is a noninvasive treatment that combines focused ultrasound and magnetic resonance imaging (MRI). The ultrasound beam penetrates through soft tissues to targeted sites, while using MRI for guidance and monitoring. 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 sonic blast is directed at a focal point causing a rapid rise in temperature (i.e., to 65°C-85°C), which is sufficient to kill tissue at the focal point. In addition to providing guidance, the 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.

MRgFUS is used in many settings. It has been applied to prostate tissue in the treatment of prostate cancer, for uterine fibroids and essential tremor and for skeletal metastases. Other uses are continuing to be investigated

MRgFUS is being investigated for the treatment of other tumors, including breast, prostate, brain, and desmoid tumors as well as non-spinal osteoid osteoma, however, there has been no clinically proven effectiveness yet.

In the case of essential tremor (ET), unilateral MRgFUS thalamotomy is considered a less invasive alternative to current open neurologic procedures. MRgFUS takes approximately 2 hours to perform, the patient is awake, and from the procedure does not require any incisions, burr holes in the scalp, or the insertion of electrodes.

Policy Statement and Criteria

1. Commercial Plans/CHIP

U of U Health Plans COVERS magnetic resonance guided high-intensity ultrasound (MRgFUS) for the treatment of idiopathic essential tremor in *limited circumstances* when coverage criteria are met.

Coverage Criteria: **(Must meet ALL)**

- A. Documented diagnosis of disabling essential tremor;
- B. The tremor is refractory to medical therapy which is defined as a trial and failure or intolerance to medications alone or in combination from the all of the following categories:
 - i. Beta blockers (e.g., propranolol)
 - ii. Anticonvulsants (e.g., primidone, Gabapentin or topiramate)
 - iii. Benzodiazepines (e.g., clonazepam or diazepam)
- C. Member has failed or is not a surgical candidate for deep brain stimulation (DBS) (e.g., advanced age, anticoagulant therapy, or surgical comorbidities).
- D. Member does NOT have any of the following limitations or conditions:
 - i. Treatment of head or voice tremor
 - ii. Bilateral thalamotomy
 - iii. A neurodegenerative condition
 - iv. Unstable cardiac disease
 - v. Coagulopathy
 - vi. Risk factors for deep-vein thrombosis
 - vii. Severe depression
 - viii. Cognitive impairment
 - ix. Previous brain procedure (e.g., transcranial magnetic stimulation, stereotactic lesioning, electroconvulsive therapy, DBS)
 - x. A skull density ratio < 0.45 (the ratio of cortical to cancellous bone)
 - xi. MRI contraindicated

U of U Health Plans considers magnetic resonance guided high-intensity ultrasound (MRgFUS) ablation investigational in all other situations including but not limited to: Treatment of uterine fibroids, pain palliation in adults with metastatic bone cancer and treatment of other tumors (e.g., brain cancer, prostate cancer, breast cancer, desmoid).

2. Medicaid Plans

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: <https://medicaid.utah.gov/utah-medicaid-official-publications/> or the [Utah Medicaid code Look-Up tool](#)

CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

Clinical Rationale

The evidence supporting magnetic resonance guided focal ultrasound as it relates to essential tremor (ET) is limited but supportive in general. This is demonstrated by a meta-analysis completed in 2018 to evaluate the literature and findings as it pertains to the use of MRgFUS to treat medicine refractory ETs by Mohammed et al. The literature search identified 9 studies (total N=160 patients) for inclusion, 8 of which were also included in the Ontario technology assessment. Side effects included nausea, vomiting, and ataxia which decreased during the 12 month follow-up. The authors found that with significant improvements in the mean percentage change in Clinical Rating Scale for Tremor (CRST) scores (62.2%) and Quality of Life in ET scores (46.5%), MRgFUS is a promising therapy in functional neurosurgery.

A complete double-blind, randomized sham-controlled trial evaluated MRgFUS for the treatment of ET in 2016 by Elias et.al. Patients were randomized into 2 groups, MRgFUS thalamotomy (n=56) or sham treatment (n=20), and the criteria included moderate-to-severe ET which had not responded to at least 2 trials of medical therapies. Mean score for hand tremor improved significantly from baseline in the treatment group (47%) compared with the sham group (0.1%) at 3 months. Change in mean functional improvement score from baseline differed significantly in the MRgFUS group (62%) compared with the sham group (3%) at 3 months. The Quality of Life in Essential Tremor Questionnaire scores also differed significantly in the treatment group compared with the sham group, with the largest improvements experienced in the psychosocial domain. The improvements in hand tremor score, functional improvement, and quality of life (QOL) were maintained at 12 months in the MRgFUS group. Side effects included sensory and gait disturbances. In conclusion, MRgFUS thalamotomy reduced hand tremor in patients with ET.

In another 2017 case study, Zaaroor et al. evaluated 30 patients with severe medication-resistant tremor that underwent unilateral ventral intermediate nucleus (VIM) thalamotomy using MRgFUS to determine the effectiveness in alleviating tremor in patients with essential tremor (ET) and Parkinson's disease (PD). Patients that underwent MRgFUS, included 18 with ET, 9 with PD, and 3 with ET-PD. The mean age of the study population was 68.9 ± 8.3 years (range 46–87 years). At 1 month post-treatment, the mean CRST score of the patients with ET decreased from 40.7 ± 11.6 to 9.3 ± 7.1 ($p < 0.001$) and was 8.2 ± 5.0 six months after treatment ($p < 0.001$, compared with baseline). In patients with PD, the mean score of the motor part of the UPDRS decreased from 24.9 ± 8.0 to 16.4 ± 11.1 ($p = 0.042$) at 1 month and was 13.4 ± 9.2 six months after treatment ($p = 0.009$, compared with baseline). During follow-up of 6–24 months, tremor reappeared in 6 of the patients, although it was a lesser degree than before the procedure in 5. Short-term adverse events that occurred during sonication included headache, dizziness, nausea, burning scalp sensation, vomiting and lip paresthesia. No adverse event lasted beyond 3 months. The authors concluded that MRgFUS VIM thalamotomy was safe and effective in patients with

ET, PD, and ET-PD to relieve medication-resistant tremor. However, large randomized studies are needed to assess prolonged efficacy and safety.

Lastly, in 2018 Chang et al., reported results from 67 patients who participated in the 2016 open-label extension of the double-blind, randomized sham-controlled trial. Because 9 patients from the original trial received additional treatment during the 2-year follow-up, they were excluded from the analysis. Paresthesias and gait disturbances were the most common adverse effects at 1 year—each observed in 10 patients with an additional 5 patients experiencing neurological adverse effects. None of the adverse events worsened over the period of follow-up, and 2 of these resolved. At the 2 year follow-up there were no new delayed complications and improvements in tremor and disability scores were maintained (tremor, 19.8 ± 4.9 [baseline] to 8.8 ± 5.0 [at 2 years]; disability, 16.4 ± 4.5 [baseline] to 6.5 ± 5.0 [at 2 years]).

For individuals with medicine-refractory essential tremors who receive magnetic resonance-guided focused ultrasound (MRgFUS), the evidence concluded that, overall, MRgFUS decreased tremor severity, improved QOL and resulted in meaningful improvement of net health outcomes.

Hayes conducted a research brief in September of 2022 to summarize the volume of publications and to determine if there was adequate, newly published literature to update their tech assessment on magnetic resonance-guided high-intensity focused ultrasound (MRgHIFU) for the treatment of essential tremor from 2019. Research found only 2 newly published studies that met inclusion for consideration. Consequently, no updates to the conclusions from the 2019 review occurred, and the conclusion that current evidence on the efficacy of unilateral MRgFUS thalamotomy for treatment-resistant essential tremor is limited in quantity, though no major safety concerns were identified.

In a 2024 health technology assessment, Hayes evaluated the effectiveness and safety of thermoablation of the ventral intermediate nucleus (VIM) of the thalamus (i.e., thalamotomy) via MRgFUS compared with thalamic deep brain stimulation (DBS), radiofrequency ablation, or gamma knife radiosurgery ablation thalamotomy to treat disabling tremor symptoms associated with moderate to severe medication-refractory essential tremor (ET). The literature search identified 14 relevant clinical studies. One study only evaluated adverse events, while the other 13 studies evaluated treatment effectiveness along with adverse events. One substantial topic of controversy is the fact that the effects of DBS are completely reversible upon stopping the stimulation, whereas MRgFUS is irreversible and leaves a permanent scar at the focal lesion site that carries the potential for lingering sensory dysfunction and, due to the progressive nature of ET, relief of tremor symptoms that may wane over time (tremor reduction generally decreases $\geq 30\%$ across ≥ 1 year follow-up). One study found no statistically significant differences in efficacy when comparing MRgFUS to DBS and radiofrequency (RF) thalamotomy. Another study looked at the safety of all 3 and found MRgFUS compared to DBS and had potentially fewer side effects than RF thalamotomy. The authors found an overall low-quality body of evidence that suggests MRgFUS VIM thalamotomy appears reasonably safe and improves symptoms, disability, and quality of life over the short term in patients with medication-refractory ET. However, further, more robust comparative studies are needed to confirm the safety and effectiveness of unilateral MRgFUS relative to current competing technologies as well as the efficacy of alternative anatomical targets for ET and explore the potential for retreatment to address relapse in tremor symptoms.

The conclusion of the only systematic review identified is further supported in several studies. In 2009, Liberman et al. directed a multicenter prospective study on 3 medical centers 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 non-opioid analgesics and 6 of 10 who used opioids decreased medication use after treatment. Neither group reported treatment-related adverse events. The authors found that this study demonstrates potential for MRgFUS in treating painful bone metastases, however, larger studies are needed to better understand as to what extent the treatment actually affected the lesions.

Zulkifli et al performed a retrospective study to evaluate "the role of high-intensity focused ultrasound (HIFU) ablative therapy in treating primary breast cancer. Further exploration is needed to establish the accurate ablation margin with a reliable radiological modality for treatment and follow-up. HIFU therapy is currently limited to single, palpable breast tumors. More extensive and randomized clinical trials are needed to evaluate HIFU therapy for breast cancer, especially where the tumor is left in situ." Therefore a review of recent literature indicates that MRI-guided focused ultrasound is promising for several indications but more analysis is needed to determine longer term success rates and outcomes.

Arrigoni et al., assessed the use of MRgFUS in a case series of 14 patients, who were followed for 12 months, with intra-articular benign bone lesions as an alternative to surgery. Pain was measured by a visual analog scale and all patients received CT and MRI images to monitor the success of the treatment. 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.

Ehdaie et al treated 101 patients as part of a "single-arm, multicenter, phase 2b study conducted at eight health-care centers in the USA (involving) men aged 50 years and older with unilateral, MRI-visible, primary, intermediate-risk, previously untreated prostate adenocarcinoma (prostate-specific antigen ≤ 20 ng/mL, grade group 2 or 3; tumor classification $\leq T2$) confirmed on combined biopsy (combining MRI-targeted and systematic biopsies). The authors concluded that "24-month biopsy outcomes show that MRI-guided focused ultrasound focal therapy is safe and effectively treats grade group 2 or 3 prostate cancer. These results support focal therapy for select patients and its use in comparative trials to determine if a tissue-preserving approach is effective in delaying or eliminating the need for radical whole-gland treatment in the long term."

In the study by Dux et al, "105 patients with desmoid fibromatosis (79 females, 26 males; 35 ± 14 years) were treated with MRgFUS between 2011 and 2021 in three centers. "MRgFUS reduced tumor volume, reduced pain, and improved quality of life in this series of 105 patients with extra-abdominal desmoid fibromatosis." The authors recommended more research to further investigate the clinical outcomes.

In a recent paper by Zhou et al, the authors performed a study "to evaluate the long-term efficacy of fibroid devascularization with ultrasound-guided HIFU (USgHIFU) and the effects of treatment on the ovarian reserve endometrial injury. The authors concluded that "For patients with uterine fibroids, USgHIFU-induced devascularization is a safe and effective treatment option. It has little effect on ovarian function and the endometrial injury is reversible, which could be attractive for patients who plan to become pregnant", and recommended further investigation to evaluate longer term outcomes and complications.

FDA approvals:

In October 2004, the ExAblate® 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 FDA through the premarket approval process for pain palliation in adults with metastatic bone cancer who have failed or are not candidates for radiotherapy. The device was evaluated through an expedited review process. FDA required a post-approval study with 70 patients to evaluate the effectiveness of the system under actual clinical conditions the results of which are not yet available.

In July 2016, the FDA provided a premarket approval for the use of the ExAblate® Neuro System for the treatment of essential tremors in patients who have not responded to medication (β -blockers or anticonvulsant drugs).

Applicable Coding

CPT Codes

Possibly Covered CPT Codes

- 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 (**Deleted Code as of 01/01/2025**)
- 61715** Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation of target, intracranial, including stereotactic navigation and frame placement, when performed (**New Code as of 01/01/2025**)

Non-Covered CPT Codes

- 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
- 0947T** Magnetic resonance image guided low intensity focused ultrasound (MRgFUS), stereotactic blood-brain barrier disruption using microbubble resonators to increase the concentration of blood-based biomarkers of target, intracranial, including stereotactic navigation and frame placement, when performed (**New Code as of 01/01/2025**)

HCPCS Codes

Non-Covered HCPCS Codes

- C9734** Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance

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