# Magnetic Resonance-guided Focused Ultrasound Surgery (MRgFUS)

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**INSTRUCTIONS FOR USE:** Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

**SCOPE:** Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

## *PLAN PRODUCT AND BENEFIT APPLICATION*

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

*Oregon*: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

MRgFUS: Guideline Note 173

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

## COVERAGE CRITERIA

Note: For the treatment of prostate cancer, please see Company Medical Policy, High-Intensity Focused Ultrasound (HIFU).

I. Magnetic Resonance-guided Focused Ultrasound (MRgFUS) unilateral thalamotomy may be considered **medically necessary** as a treatment of essential tremor when **all** of the following criteria (A.-D.) are met:

   A. Essential tremor is medication refractory (defined as refractory to at least two trials of medication therapy); **and**
   B. There is clinical documentation of quantifiable testing [e.g., Clinical Rating Scale for Tremor (CRST)] that indicates the patient is experiencing essential tremor that affects the patient's activities of daily living; **and**
   C. The patient is not a candidate for Deep Brain Stimulation (DBS) (e.g., advanced age, anticoagulant therapy, surgical comorbidities), or has failed DBS, but has no retained cranial implants; **and**
   D. The patient has undergone evaluation by a multidisciplinary team and is determined to be an appropriate candidate for MRgFUS.

II. MRgFUS may be considered **medically necessary** for pain palliation in adult patients with metastatic bone cancer who failed or are not candidates for radiotherapy

III. MRgFUS is considered **not medically necessary** for all other conditions not listed above. This includes, but is not limited to, the following conditions:

A. Essential tremor when criterion I. is not met
B. Treatment of head or voice tremor
C. Bilateral thalamotomy
D. Uterine fibroids
E. Treatment of chronic neuropathic pain
F. All tumors, including but not limited to brain, breast, and renal.
G. Treatment of pain palliation for patients with metastatic bone cancer except as indicated in criterion II.
H. Blood-brain barrier disruption using microbubbles for biomarker enhancement.
I. Any contraindications as defined by manufacturer (Please see Regulatory Status).

Link to Evidence Summary

## POLICY CROSS REFERENCES

- High-Intensity Focused Ultrasound (HIFU), MP199

**The full Company portfolio of current Medical Policies is available online and can be accessed here.**

## POLICY GUIDELINES

**DEFINITIONS**

The Clinical Rating Scale for Tremor (CRST) is a tremor assessment scale ranging from 0-160 points, with higher scores indicating greater disability.[1]

**BACKGROUND**

**Magnetic Resonance guided Focused Ultrasound Surgery (MRgFUS)**

Magnetic Resonance-guided Focused Ultrasound Surgery (MRgFUS), sometimes also referred to as MRI-guided focused ultrasound, magnetic resonance guided focused ultrasound, combines two technologies (focused ultrasound and MRI) to non-invasively target and ablate tissues.[2] The high-intensity focused ultrasound energy heats the area to 85°C to ablate tissue in the targeted area, causing cell death and coagulative necrosis of the targeted tissue while sparing surrounding organs/tissues. [3,4]

Essential Tremor

Tremor is defined as an involuntary, rhythmic, and oscillatory movement of a body part with a relatively constant frequency and variable amplitude.[5] Tremor is the most common type of movement disorder and essential tremor (ET) is the most common neurologic tremor disorder. ET is a clinical syndrome characterized by an action tremor involving both upper limbs of at least three years' duration. The tremor is typically confined to the upper limbs but may or may not also be present in other locations, such as the head, voice, and uncommonly, the legs. This condition is slowly progressive and disability and impact on activities of daily living can be significant.[6] While pharmacological treatment continues to

be the first line treatment for ET, there are two surgical options for patients with medication refractory limb tremor due to ET: thalamic ventral intermediate (VIM) nucleus deep brain stimulation (DBS) and unilateral thalamotomy (conventional thalamotomy, gamma knife, or MRgFUS).[5] Thalamotomy procedure completed by MRgFUS uses high-energy ultrasound beams to create a permanent lesion in the (VIM) nucleus of the thalamus. This procedure is unilateral as bilateral thalamotomy is no longer performed for ET as it is associated with an unacceptably high rate of side effects, particularly impairment of speech articulation.[7]

Uterine Fibroids

Uterine fibroids (UF), also called leiomyomata or myomas, are benign tumors of the myometrium, the smooth muscle layer of the uterus.[4] Uterine fibroids are very common in reproductive age females, with approximately 25% of them being symptomatic. The four common symptom categories that are associated with uterine fibroids include: heavy or prolonged menstrual bleeding; bulk symptoms (abdominal protrusion, bowel or bladder dysfunction, early satiety); reproductive dysfunction (infertility or recurrent pregnancy loss); pain, including pain menses or non menstrual pain.[8] This noninvasive, atheroablative technique applies multiple waves of ultrasound energy through the abdominal wall, causing coagulative necrosis of the fibroids while leaving surrounding organs unharmed. Ideal treatment candidates have three or fewer fibroids, size less than 10 centimeters in maximal dimension, homogenous and dark on T2-weighted images, and well-vascularized without calcification.

Bone Metastases

Bone metastases are a common manifestation of distant relapse from many types of solid cancers, especially those with primary sites in the lung, breast, and prostate.[9] Bone involvement can also occur in patients with multiple myeloma and lymphoma. These metastases represent a prominent source of morbidity due to pain, dysfunction, pathologic fracture, and neurovascular compromise. Bone-related cancer pain is frequently undertreated, with nearly 80 percent of patients experiencing severe pain before a sufficient palliative treatment plan is initiated. Treatment of bone metastases usually requires a multipronged approach that may include analgesics, external beam radiation therapy (EBRT), surgical management, and/or vertebroplasty/kyphoplasty.

EBRT is the current standard local therapy for painful bone metastases and can reduce pain for approximately 60–70% of patients. However, local radiotherapy for painful bone metastases has been associated with delayed side effects and the remaining 30–40% of patients do not have significant improvement in pain. Re-irradiation is an available option but can also increase the risk of radiation-induced adverse effects like pathologic fractures and myelopathy. Given the limited life expectancy of many of these patients and their coexisting morbidity, minimally invasive methods for local ablation of skeletal metastases have been developed, including radiofrequency ablation, cryoablation, and focused ultrasound (typically with MRI guidance: MRgFUS).

MRgFUS uses focused ultrasound energy directed at the target lesion, raising the temperature at the imaged focal point, producing thermal tissue ablation and tissue destruction. The high acoustic absorption of bone makes it particularly amenable to this technology, and osteoblastic as well as osteolytic metastases can be similarly treated.

Microbubbles

Magnetic Resonance-guided Focused Ultrasound (MRgFUS) with microbubbles is a noninvasive technique used to temporarily open the blood-brain barrier (BBB). By injecting microbubble contrast agents into the bloodstream and applying low-intensity ultrasound waves, the BBB can be safely and reversibly disrupted in targeted brain regions. This process purports to enhance the delivery of therapeutic agents or facilitates the detection of biomarkers that would otherwise be blocked by the BBB. This technique is primarily used in clinical trials for conditions like brain tumors and neurodegenerative diseases

## *REGULATORY STATUS*

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

**Essential Tremor**

The Food and Drug Administration (FDA) granted Premarket Approval (PMA) to ExAblate Neuro (InSightec Ltd.) initially in 2016 for the use in unilateral Thalamotomy treatment of idiopathic Essential Tremor patients with medication-refractory tremor.[10] Patients must be at least 22. This treatment is contraindicated for the use in the following:

- Patients with standard contraindications for MRI such as non-MRI-compatible implanted metallic devices, including cardiac pacemakers, size limitations, and allergies to MR contrast agent, etc.
- Women who are pregnant
- Patients with advanced kidney disease or on dialysis
- Subjects with unstable cardiac status or severe hypertension
- Subjects exhibiting any behavior(s) consistent with ethanol or substance abuse
- History of abnormal bleeding, hemorrhage, and/or coagulopathy
- Subjects receiving anticoagulant or drugs known to increase risk or hemorrhage within one month of focused ultrasound procedure
- Subjects with cerebrovascular disease
- Subjects with brain tumors
- Individuals who are not able or unwilling to tolerate the required prolonged stationary position during treatment (approximately two hours)
- Subjects who have an Overall Skull Density Ratio of 0.45 (± 0.05) or less as calculated from the screening Computed Tomography (CT)

**Uterine Fibroids**

The Food and Drug Administration (FDA) granted Premarket Approval (PMA) to ExAblate Ablation System, High Intensity Focused Ultrasound (HIFU), MR-Guided (InSightec Ltd.) in 2005 for ablation of uterine fibroid tissue in pre- or peri-menopausal women with symptomatic uterine fibroids who desire a

uterine sparing procedure.[11] Patients must have uterine size of less than 24 weeks and have completed childbearing. This treatment is contraindicated for the use in the following:

- Women who should not undergo magnetic resonance imaging (MRI) (e.g., women who have metallic implants that are incompatible with MRI or sensitivity to MRI contrast agents). ces, including cardiac pacemakers, size limitations, and allergies to MR contrast agent, etc.
- The ExAblate treatment is contraindicated if the clinician is unable to avoid important structures [e.g., scar, skin fold or irregularity, bowel, pubic bone, IUD (intrauterine device), surgical clips, or any hard implants) in the path of the ultrasound beam]

**Bone Metastases**

The Food and Drug Administration (FDA) granted Premarket Approval (PMA) to ExAblate Ablation System, High Intensity Focused Ultrasound (HIFU) MR- Guided (InSightec Ltd.) in 2012 for pain palliation of Metastatic Bone Cancer in patients 18 years of age or older who are suffering from bone pain due to metastatic disease and who are failures of standard radiation therapy, or are not candidates for, or refused radiation therapy.[2] The bone tumor to be treated must be visible on non-contrast MR and device accessible. The device description states this magnetic resonance image guided focused ultrasound surgery (MRgFUS) device combines two technologies (focused ultrasound and MRI) to non-invasively target and ablate tissues. This treatment is contraindicated for the use in the following:

- Patients with standard contraindications for MRI such as non-MRI-compatible implanted metallic devices, including cardiac pacemakers, size limitations, and allergies to MR contrast agent, etc.
- Patients who need pre-treatment surgical stabilization of the affected bony structure or targeted tumor is in impending fracture, or have been stabilized with metallic implants
- Women who are pregnant
- Patient with extensive scarring in an area in the path of energy planned passage to the treatment area
- The ExAblate treatment is contraindicated if the clinician is unable to avoid important structures [e.g., scar, skin fold or irregularity, bowel, other bone, surgical clips, or any hard implants) in the path of the ultrasound beam]
- Targeted tumor is in the skull or less than 1 cm from the skin surface
- Patients with advanced kidney disease or on dialysis
- Individuals who are not able or unwilling to tolerate the required prolonged stationary position during treatment (approximately two hours)

## *CLINICAL EVIDENCE AND LITERATURE REVIEW*

**EVIDENCE REVIEW**

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of Magnetic Resonance guided Ultrasound Surgery. Below is a summary of the available evidence identified through July 2024.

**Essential Tremor**

Systematic Reviews

- In 2022, Miller and colleagues completed a meta-analysis on the sustained efficacy of Magnetic resonance-guided focused ultrasound treatment for essential tremor.[12] Twenty-one articles reviewing hand tremor scores (HTS) totalling 395 patients were included. Mean HTS at three months post-treatment showed a 61.5% improvement, with a mild decrease at 36 months by 8.8%. Only four studies included follow-up of at least 24 months. The authors also reviewed thirteen articles that reported total Clinical Rating Scale for Tremor (CRST) scores with standardized follow-up for 250 patients. Mean pre-operative total CRST score decreased by 46.2% at the 3 months post-treatment mark. Quality of Life in Essential Tremor Questionnaire (QUEST) score were also reviewed with significant improvement compared to baseline ($p <$ 0.001). Additional studies with longer follow-up periods are needed to review the long-term efficiency of MRgFUS.

- In 2021, Agrawal and colleagues completed a systematic review and meta-analysis on outcome and complications of MR guided focused ultrasound for essential tremor.[13] Twenty-nine studies evaluating 617 patients were included in the review, including one RCT, fourteen prospective studies, eight retrospective studies, and three case reports. Disability, measured by change from Clinical Rating Scale for Tremor (CRST) baseline scores, showed statistically significant improvement at 3- and 12-months post-procedure. In studies that compared with MRgFUS with DBS, outcome differences between the two groups were found to not be statistically different. However, the RCT did find a greater percentage improvement with DBS, although the patients in the DBS group had worse baseline tremor scores. The use of diffusion tensor imaging (DTI) targeting revealed a significant reduction in post procedure ataxia related complications as compared to traditional targeting techniques. There were no hemorrhage, seizure, or trajectory related complications noted with MRgFUS for ET. The authors concluded that MRgFUS for ET seems to be an effective procedure for relieving unilateral tremor, while they urge for additional studies, particularly RCTs.

- In 2024, Hayes conducted an evidence evaluation and gave a rating of "C" for the use of MRgFUS thalamotomy for the treatment of moderate-to-severe treatment-resistant essential tremor. [14] The rating reflects "an overall low-quality body of evidence suggesting that MRgFUS has an acceptable safety profile and has clinically significant beneficial effects on tremor symptoms, disability, and quality of life; however, these effects wane over time." The main reasons for this overall quality rating are individual study limitations, differences in how studies reported the same outcome (i.e., tremor symptoms), and the very small number of comparative studies. However, good-quality randomized controlled trials (RCTs) comparing DBS, RF thalamotomy, and gamma knife radiosurgery may not be feasible due to individual patient considerations and suitability that drive the selection of third-line therapies.

- In 2020, ECRI published a review on ExAblate Neuro (InSightec, Inc.) for Treating Essential Tremor.[3] The ExAblate Neuro System is a MRgFUS system intended to treat medically refractory essential tremor (ET) in an outpatient setting via unilateral MRgFUS thalamotomy. The initial ECRI review included a small, double-blind, multicenter, randomized controlled trial (RCT); two retrospective comparative studies, two retrospective analyses of 5 unpublished case series, and one additional case series. The update in 2020 added one RCT, one nonrandomized comparative study, and two case series as well as the abstract of one nonrandomized comparative study

reporting on 474 patients. The review concluded that unilateral MRgFUS thalamotomy reduced symptoms and improved function and Quality of Life (QOL) at one year follow-up in patients. One study reported a QOL improvement score improvement of 43% when compared to sham procedure at 3%. The other studies that reviewed QOL showed similar improvement. The authors noted that the improvement may be comparable or equal to results achieved with deep brain stimulation (DBS), but all studies urged additional RCTs are needed to confirm results on direct comparative effectiveness. All studies except the RCTs were at high risk of bias due to three or more of the following: retrospective design, single-center focus, small sample size of randomization, controls, and blinding. The RCTs also had small sample sizes. More RCTs comparing MRgFUS to other treatments and reporting on tremor and QOL at follow-up times longer than one year are needed. ECRI listed the evidence bar as evidence is somewhat favorable.

**Uterine Fibroids**

Systematic Reviews

- In 2022, Hayes with an annual review on MRgFUS therapy for treatment of uterine fibroids.[4] This report gave an evidence rating of "C" for the use of MRgFUS to treat uterine fibroids. The review included six studies (published in 8 articles) that evaluated patients with symptomatic uterine fibroids and used comparative groups of abdominal hysterectomy, laparoscopic myomectomy, uterine artery embolization (UAE), and sham. In three poor-quality studies, it was found that uterine artery embolization was favored over MRgFUS in terms of effectiveness and quality of life, while no difference was found between MRgFUS and laparoscopic myomectomy for effectiveness or quality of life in one poor-quality study. Rates of reintervention for women treated with MRgFUS ranged from 13-67% with a reduction in fibroid volume ranging from 17-36%. UAE was found to be favored over MRgFUS in both outcome measurements (three poor-quality studies). The review concluded that a low-quality body of evidence suggests that MRgFUS may reduce symptom severity, result in improved recovery times, improve quality of life, and be associated with few adverse events following treatment. However, substantial uncertainty remains regarding the comparative effectiveness of MRgFUS due to inconsistent results across comparative studies that suggest that MRgFUS did not perform as well as alternatively minimally invasive treatments and did not improve outcomes in comparison with hysterectomy (with the exception of adverse events). Additionally, none of the eligible studies reviewed adequately evaluated fertility outcomes.

- In 2021, Xu and colleagues completed a meta-analysis on the comparison of myomectomy, UAE, and MRgFUS in the treatment of uterine fibroids.[15] Thirty-one studies, totaling 42,103 patients were included during the review of re-intervention rates at 12, 24, 36, and 60 months. The 12-month re-intervention rates of myomectomy, UAE and MRgFUS for UFs were 0.06, 0.07, and 0.12 respectively. The 24-month re-intervention rates were 0.10, 0.08, and 0.14 respectively. The 36-month re-intervention rates were 0.09, 0.14, and 0.22 respectively. Additionally, the 60-month re-intervention rates were 0.19, 0.21, and 0.49 respectively. Overall, the myomectomy had the lowest re-intervention rate of the three treatment options in the short and long term, while MRgFUS has the highest in both. The rate of re-intervention for MRgFUS increased rapidly in the 60$^{th}$ month after treatment.

- In 2020, ECRI published a clinical evidence assessment on ExAblate Body System (InSightec, Inc.) MR-guided Focused Ultrasound for Treating Uterine Fibroids.[16] The review included one systematic review with meta-analysis (n=1,202), one multicenter RCT (n=83), one prospective nonrandomized study (n=154), two before-and-after-treatment studies (n=154; n=100), and two case series studies (n=201; n=238). Evidence from two before-and-after-treatment studies and the two case series suggest that MRgFUS reduces symptoms and improves quality of life up to three years after treatment in women with symptomatic uterine fibroids. However, findings in systematic review and two additional studies found the comparison of MRgFUS, uterine artery embolization (UAE) and laparoscopic myomectomy to be inconclusive. Additional studies are needed in multi-center settings with adequate samples sizes, particularly those that that compare MRgFUS to other uterine-sparing treatments (e.g., laparoscopic or robotic myomectomy, laser ablation, etc.). Study limitations included high risk of bias among several studies, single-center focus, high patient attrition, lack of control groups, retrospective design, and lack of randomization and blinding. ECRI listed the evidence bar as evidence is inconclusive-too few data on outcomes of interest.

**Bone Metastases**

Systematic Reviews

- In 2021, Baal and colleagues completed a systematic review and meta-analysis on the efficacy and safety of Magnetic Resonance-guided Focused Ultrasound for the treatment of painful bone metastases.[17] Thirty-three studies were included, with a total sample size of 1082 patients. The majority of studies were prospective with a reported follow-up period of three months. The pooled proportion of patients that achieved pain relief from MRgFUS, defined as at least a two-point improvement compared to baseline pain scores (10-point visual analogue scale or numerical rating scale), was 79%. Only five studies (n=102) reported on quality of life before and after MRgFUS treatment. Pooled data indicated a significant decrease in pain or symptom scale from baseline to 3-month follow-up after treatment. However, data from functional status were conflicting between different studies. The most frequent minor adverse effects (5.9%) found in this review was treatment-related pain, followed by low-grade skin burn or edema overlying the treatment site. The severe adverse event rate was only at 0.9% (one deep vein thrombosis, two grade III skin burns, and four fractures), which compares well with adverse event rates seen in radiotherapy. Lower grade adverse effects associated with radiotherapy include gastrointestinal disturbances, skin reactions, fatigue, and acute plain flare-specifically, post-radiotherapy acute pain flare is reported to have an incidence ranging from 40-68% compared to only 3% observed with MRgFUS. The authors noted limitations to study including heterogeneity of included studies with a variable study populations (varying age, primary cancer, variable morphology of treated bone metastases, etc.), reported data, and treatment details/planning. Additionally, the estimates of quality of life were limited by use of different questionnaires, and the data was only available from a small fraction of selected studies.

- In 2021, Han and colleagues completed a systematic review and meta-analysis on the role of MRgFUS in pain relief in patients with bone metastases.[18] Fifteen eligible studies with a total of 362 were selected for the review with the studies reporting data on quantitative pain assessments before/after treatment, response rate, and complication rate. When compared to baseline pain scores (average of 6.74 with 95% CI: 6.30-7.18), the pain improvement at 0-1 week

was 2.54, at 1-5 weeks was 3.56, and at 5-14 weeks was 4.22. Changes in oral morphine equivalent dose (OMEDD) was also utilized to help evaluate pain response. Change from baseline in OMEDD at 2 weeks after treatment was -15.11, at 1 month after treatment was -10.87, and at 3 months after treatment was -5.53. The response rate used to quantitatively evaluate pain relief and included complete response, partial response, and no response. Complete response rate was defined as a pain score of 0 without medication increase; partial response was defined as a drop of 2 points on a 10-point scale without an increase in pain medications or a drop of 25% in pain medication without increase in the reported pain score; no response was defined as no drop of score and no changes in medication use. The overall complete response rate was 0.36 (95% CI: 0.24-0.48), partial response rate was 0.47 (95% CI: 0.36-0.58), and no response rate was 0.23 (95% CI: 0.13-0.34). Among 14 studies reporting complications (n=352), 93 (26.4%) patients with minor complications and 5 (1.42%) patients with major complications were recorded. The authors concluded that MRgFUS is a reliable therapeutic option to relieve cancer pain for patients with metastatic bone tumors with controllable related complications. The authors recommend additional studies with control arms and randomization as well as non-subjective evaluation indicators, such as biomarker evaluation, for pain relief evaluation.

- In 2020, ECRI published a review including one RCT (n=147), one nonrandomized comparison study (n=63), and nine small before-and-after treatment studies.[19] In the single-center RCT, the authors concluded that MRgFUS is a safe and effective, noninvasive treatment for alleviating pain resulting from bone metastases in patients that have failed standard treatments. In the retrospective, single-center nonrandomized controlled trial found that MRgFUS provides a similar overall treatment response rate but faster pain relief compared with conventional radiation therapy and has the potential to serve as the first-line treatment for painful bone metastases in selected patients. Evidence from the nine before-and-after studies also suggest that MRgFUS may reduce pain and improve quality of life up to one year after treatment in patients with bone metastases. However, all the studies were at risk of bias related to single-center focus and the RCT did not use QOL instruments that are specific to patients with bone metastases. The other studies also had small sample sizes, retrospective design, high patient attrition, lack of control groups, lack of randomization, and lack of blinding. Studies are also needed to compare MRgFUS to other minimally invasive treatments (e.g., radiofrequency ablation, cryoablation) and report on important patient-center outcomes. ECRI listed the evidence bar as evidence is inconclusive- too few data on outcomes of interest.

**Magnetic Resonance-guided Focused Ultrasound (MRgFUS) with Microbubbles**

No clinical utility studies were identified.

**CLINICAL PRACTICE GUIDELINES**

**Essential Tremor**

The American Academy of Neurology

The American Academy of Neurology published Update: Treatment of Essential Tremor guideline in 2011, replacing the guideline from 2005.[7] The guideline was last reaffirmed in July 2012. They

concluded: recommendations for the use of propranolol, primidone (Level A, established as effective); alprazolam, atenolol, gabapentin (monotherapy), sotalol, topiramate (Level B, probably effective); nadolol, nimodipine, clonazepam, botulinum toxin A, deep brain stimulation, thalamotomy (Level C, possibly effective); and gamma knife thalamotomy (Level U, insufficient evidence) are unchanged from the previous guideline. In the question of thalamotomy in patients with medically refractory ET, the guideline states:

- Deep Brain Stimulation (DBS) has fewer adverse events than thalamotomy (Level B). However, the decision to use either procedure depends on each patient's circumstances and risk for intraoperative complications compared to feasibility of stimulator monitoring and adjustments
- Unilateral thalamotomy may be used to treat limb tremor in ET that is refractory to medical management (Level C), but bilateral thalamotomy is not recommend due to adverse side effects (Level C)

National Institute for Health and Care Excellence (NICE)

In 2018, NICE published a guideline stating the evidence on the safety of unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor raises no major safety concerns.[20] However, it also stated the current evidence on the procedure's efficacy is limited in quantity. Therefore, the procedure should not be used unless there are special arrangements for clinical governance, consent, and audit or research.

**Uterine Fibroids**

American College of Obstetrics and Gynecology (ACOG)

The ACOG published a practice bulletin in 2021 on the Management of Symptomatic Uterine Leiomyomas.[21] This bulletin discussed MRgFUS and states that low-quality data suggests that MRgFUS and high-intensity focused ultrasound are associated with a reduction in leiomyoma and uterine size. However, there is also data that, compared with uterine artery embolization, MRgFUS is associated with less improvement in symptoms and QOL measures and a higher risk of reintervention. ACOG concludes that additional data is needed before recommendations can be made regarding the use of this treatment for uterine leiomyomas and MRgFUS was not included in the recommended treatment options at any level for uterine leiomyomas.

National Institute for Health and Care Excellence (NICE)

In 2011, NICE published a guideline stating the evidence on the safety of MRI-guided transcutaneous focused ultrasound for uterine fibroids in the short term is adequate, although further treatment may be required and the effect on subsequent pregnancy is uncertain.[22] There are well-recognized complications but the evidence on safety is adequate to support the use of this procedure provide that normal arrangements are in place for clinical governance and audit. NICE encourages further research into the efficacy, particularly regarding long-term outcomes, including the need for further treatment.

**Bone Metastases**

National Comprehensive Cancer Network NCCN

In 2024, the NCCN published clinical practice guidelines for adult cancer pain (v2.2024).[23] The guidelines do not include ultrasound ablation in pain management algorithms.

**EVIDENCE SUMMARY**

There is enough high-quality evidence to show that Magnetic Resonance guided Focused Ultrasound Surgery (MRgFUS) unilateral thalamotomy is an effective treatment for essential tremor that is medication refractory and for those patients that are not candidates, or have failed, DBS. Systematic reviews have found that MRgFUS is a safe and effective treatment, and the clinical practice guideline from the American Academy of Neurology recommends unilateral thalamotomy as a surgical option for medication refractory essential tremor along with DBS, the decision dependent on each patient's unique circumstances. Therefore, MRgFUS unilateral thalamotomy for the treatment of medication refractory essential tremor may be considered medically necessary.

There is also enough high-quality evidence to show that MRgFUS is an effective treatment for pain palliation in patients with metastatic bone cancer in patients that have failed, or are not a candidate, for radiotherapy. Systematic reviews have found that MRgFUS is a reliable therapeutic option to relieve cancer pain for patients with metastatic bone tumors with minimal severe adverse event rates that are comparable to those seen in radiation therapy. The clinical guideline from NCCN also states that image-guided ablation of bone lesions has proven successful in pain management, especially for those that have failed to achieve adequate pain relief. Therefore, MRgFUS for the pain palliation in patients with metastatic bone cancer may be considered medically necessary.

Evidence is insufficient to MRgFUS as effective treatments for any other indication, including, but not limited to, opening the blood-brain barrier, treatment of head or voice tremor, bilateral thalamotomy, uterine fibroids, treatment of chronic neuropathic pain, and ablation of all tumors (including but not limited to brain, breast, and renal). Further studies of good methodological quality are required in order to establish the safety, effectiveness, and medical necessity of this treatment. The clinical guideline on uterine fibroid treatment does not include MRgFUS as a treatment recommendation and MRgFUS was not identified in any other evidence-based clinical practice guidelines. Therefore, MRgFUS is considered not medically necessary as a treatment for any indication other than essential tremor or pain palliation in patients with metastatic bone cancer.

## *HEALTH EQUITY CONSIDERATIONS*

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.
The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly

reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online here.

## *BILLING GUIDELINES AND CODING*

| CODES* | | |
|---|---|---|
| **CPT** | 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 than or equal to 200 cc of tissue |
| | ~~0398T~~ | **TERMED 12/31/2024** ~~Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed~~ |
| | 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 |
| | 19499 | Unlisted procedure, breast [when specified as destruction of breast tissue by magnetic resonance-guided focused ultrasound] |
| | 20999 | Unlisted procedure, musculoskeletal system, general [when specified as magnetic resonance-guided focused ultrasound for pain palliation for bone metastases] |
| | 61715 | Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation of target, intracranial, including stereotactic navigation and frame placement, when performed |
| | 76999 | Unlisted ultrasound procedure (e.g. diagnostic, interventional) |
| **HCPCS** | C9734 | Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance |

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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## *POLICY REVISION HISTORY*

| DATE | REVISION SUMMARY |
|---|---|
| 2/2023 | Converted to new policy template. |
| 11/2023 | Annual review. Investigational denial updated to not medically necessary. |
| 9/2024 | Annual review. No changes to criteria and codes. |
| 1/2025 | Q1 code set update. |
| 7/2025 | Interim update. Code added to policy. |