Molina Clinical Policy
Magnetic Resonance Guided Focused Ultrasound (MRgFUS) Ablation for Essential Tremor: Policy No. 312

Last Approval: 02/12/2025
Next Review Due By: February 2026

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Essential tremor (ET) is a neurological disorder characterized by involuntary, rhythmic, and oscillatory movement most commonly affecting the hands and arms. Other areas such as the head and vocal cords may also be involved. According to the revised classification by the International Parkinson and Movement Disorder Society, ET is defined as an isolated tremor syndrome of bilateral upper limb action tremor, persisting for at least three years in the absence of other neurological signs, such as dystonia, ataxia, or parkinsonism. There are no recommended biomarkers, imaging signs, or genetic test to diagnose ET, but they may be used to rule out other disorders. Diagnosis relies on patient history, clinical presentation, neurological examination, and tremor characterization to differentiate ET from other movement disorders. (Bhatia et al. 2017; Hayes 2024). First-line treatment includes propranolol, the only FDA approved drug indicated for ET, and primidone. Both drugs are supported by double-blinded, placebo-controlled trials that meet criteria for Class I evidence. Second-line treatment includes other oral pharmacotherapies that are supported by double-blinded, placebo-controlled trials but do not meet Class I criteria, such as gabapentin, benzodiazepines (clonazepam, alprazolam), other beta-blockers (atenolol and metoprolol), pregabalin, topiramate, and zonisamide. Third-line treatments include pharmacotherapies supported by open-label or case series (nimodipine and clozapine), and more invasive treatments, such as magnetic resonance-guided focused ultrasound, deep brain stimulation, radiofrequency ablation, and gamma knife radiosurgery ablation (Agarwal and Biagioni 2023; Hayes 2024).

Magnetic resonance-guided focused ultrasound (MRgFUS) is a minimally invasive, incisionless procedure for unilateral thermoablation of the ventral intermediate nucleus of the thalamus, a key brain structure that regulates motor signaling and other sensory information. Bilateral treatment may cause permanent and/or severe adverse effects and is not cleared by the FDA or recommended by professional guidelines. Patients may be premedicated but must be able to communicate with treatment staff if they begin to experience adverse effects from a sonication that may not be visually apparent with monitoring tools while inside the MRI tunnel. MRgFUS is irreversible and produces a permanent thalamic lesion using high-intensity focused ultrasound. Due to the progressive nature of ET, relief of tremor symptoms may wane over time (Agarwal and Biagioni 2023; Hayes 2024).

Regulatory Status

In 2016, the FDA granted premarket approval for the ExAblate Model 4000 Type 1.0 System (ExAblate Neuro). The MRgFUS device is indicated for unilateral thalamotomy for idiopathic ET patients, age 22 or older, with medication-refractory tremor. The designated area in the brain responsible for the movement disorder symptoms (ventralis intermedius) must be identified and accessible for targeted thermal ablation.

In 2021, the FDA granted premarket approval for the ExAblate Neuro indicated for unilateral thalamotomy of tremor-dominant Parkinson's disease with medication-refractory tremor and for unilateral pallidotomy of patients with advanced, idiopathic Parkinson's disease with medication-refractory moderate to severe motor complications. However, evidence is lacking to support long-term safety and efficacy. More research, including randomized controlled trials with larger sample sizes, is needed (Monteiro et al. 2024; Tian et al. 2023).

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COVERAGE POLICY

Magnetic resonance-guided focused ultrasound (MRgFUS) unilateral thalamotomy may be **considered medically necessary** for treatment of essential tremor (ET) when ALL the following clinical criteria are met:

1. Confirmed diagnosis of ET
2. Moderate to severe appendicular tremor that interferes with quality of life, as documented by quantifiable testing such as the Clinical Rating Scale for Tremor (e.g., score ≥ 2) or another nationally accepted clinical measure
3. Failure of at least TWO medications for ET, including at least one first-line agent (e.g., propranolol or primidone), with failure defined as persistent moderate to severe tremors despite adequate dosing and duration of therapy, intolerable side effects, or contraindications
4. For patients receiving concurrent medical therapy, medication doses should be stable for 30 days
5. Member is 22 years of age or older
6. Member is not a surgical candidate for deep brain stimulation (e.g., advanced age, surgical comorbidities), or deep brain stimulation has failed, and there are no retained cranial implants that would contraindicate MRgFUS
7. Absence of ALL the following contraindications:
   a. Planned bilateral MRgFUS thalamotomy
   b. Planned MRgFUS contralateral to a previous thalamotomy
   c. Overall skull density ratio ≤ 0.45 (± 0.05)
   d. Contraindications to MRI (e.g., non-MRI compatible implant, contrast allergy, size limitations)
   e. Unstable cardiac status, severe hypertension, or cerebrovascular disease
   f. History of abnormal bleeding, hemorrhage, and/or coagulopathy
   g. Taking anticoagulants, or drugs known to increase risk or hemorrhage, within one month prior to the procedure
   h. Pregnancy
   i. Advanced kidney disease or on dialysis
   j. Brain tumor
   k. Documented substance abuse
   l. Unable or unwilling to tolerate the required prolonged stationary position during treatment (approximately two hours)

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Randomized Controlled Trials

Elias et al. (2016) evaluated the ExAblate transcranial magnetic resonance-guided focused ultrasound (MRgFUS) thalamotomy system in a pivotal randomized, double-blind, sham-controlled trial to assess its efficacy and safety in treating medication refractory essential tremor (ET). The multicenter study enrolled 76 patients, randomizing them in a 3:1 ratio to undergo either MRgFUS or a sham procedure. The primary outcome was the change in hand tremor severity at three months, assessed using the Clinical Rating Scale for Tremor (CRST). Secondary outcomes included disability reduction and quality-of-life improvements assessed up to 12 months. Patients in the sham group were

eligible to crossover for active treatment after three months. Results demonstrated a significant reduction in hand tremor severity in the MRgFUS group, with a mean CRST hand tremor score improvement by 47% from baseline, compared to no significant change in the sham group (mean difference: 8.3 points on the CRST; 95% CI, 5.9 to 10.7; $p < 0.001$). This improvement was sustained at 12 months, with the active treatment group maintaining a 40% reduction in tremor severity. Functional disability scores decreased by 62% in the MRgFUS group compared to 3% in the sham group at three months, while quality-of-life scores showed a 46% improvement. Adverse events were common but generally mild to moderate. Sensory disturbances, including numbness and paresthesia, were reported in 38% of patients, with persistence at 12 months in 14% of patients. Gait disturbances occurred in 36% of patients, persisting in 9% at 12 months. Serious adverse events were rare but included one case of permanent sensory loss and two cases of transient ischemic attacks. The study supports that MRgFUS thalamotomy reduces tremor severity and improves quality of life in medication-refractory ET with manageable adverse effects, offering an alternative to traditional surgical options.

Chang et al. (2018) published the two-year follow-up results of the pivotal trial, with a total of 67 patients continuing into this extension phase of the study (n = 67). Tremor suppression and functional disability were assessed using the CRST at six months, one year, and two years post-treatment. Hand tremor scores improved by 55% at six months (mean reduction from 19.8 ± 4.9 to 8.6 ± 4.5), 53% at one year, and 56% at two years, while disability scores showed a 64% reduction at six months (mean reduction from 16.4 ± 4.5 to 5.4 ± 4.7), sustained at one and two years. Adverse events, primarily paresthesia and gait disturbances, occurred in a subset of patients (10 cases each at one year) but showed no worsening over time, with some resolving entirely. The study found no new delayed complications over the two-year follow-up, highlighting the durability and stability of tremor suppression achieved with MRgFUS.

Halpern et al. (2019) published the three-year follow-up results of the pivotal trial, with outcomes assessed using the CRST and Quality of Life in Essential Tremor Questionnaire (QUEST). Tremor-motor scores, including hand tremor (scale 0-32), functional disability (scale 0-32), and postural tremor (scale 0-4), showed improvements from baseline ranging between 38%-75% at 36 months (all $p < 0.0001$), with significant sustained benefits in quality of life (27%-42% improvement. However, mild degradation in hand tremor and disability scores was observed compared to the six-month results, with median score increases for hand tremor and disability (95% CI 0-2, $p = 0.0098$ and 1-4, $p = 0.0001$, respectively). Adverse events remained mild or moderate and stable throughout follow-up, with no worsening or new complications observed by year three.

Cosgrove et al. (2022) published the five-year follow-up results of the pivotal trial, with a total of 40 patients who completed the final extension phase of the study (n = 40). Clinical outcomes were assessed using the CRST and QUEST. Tremor severity, as measured by CRST Part A (postural tremor), showed sustained improvement, with a 73.1% reduction at five years compared to baseline ($p < 0.0001$). Combined tremor/motor scores (CRST Parts A and B) improved by 40.4% at five years ($p < 0.0001$), and functional disability scores (CRST Part C) exhibited at 44.5% reduction ($p < 0.0001$), though with slight attenuation over time. Quality of life, as assessed by QUEST, remained significantly improved at five years ($p < 0.0003$), particularly in physical and psychological domains. Adverse events, predominately paresthesia and gait disturbances, were reported as mild or moderate and showed no progression over the five-year period. No new or delayed complications emerged during follow-up. The study supports that MRgFUS thalamotomy provides sustained tremor suppression, functional improvement, and quality-of-life enhancement over five years, with a favorable safety profile.

Systematic Reviews and Meta-Analyses

Mortezaei et al. (2024) performed a systematic review and meta-analysis to evaluate the long-term safety and efficacy of unilateral MRgFUS thalamotomy for medication-refractory ET. The review included data from 43 studies, with a total of 1,818 patients, 71.2% male, with a mean symptom duration of 20.5 years. Follow-up durations ranged from 3 months to 8.4 years. Outcomes included CRST, QUEST, and hand tremor scores (HTS). The mean CRST score decreased significantly at 3 months (SMD -4.5, $p = 0.0069$), 6 months (SMD -4.9, $p = 0.0045$), and 12 months (SMD -2.95, $p = 0.0039$). Hand tremor scores also showed significant reductions at multiple intervals up to 36 months post-treatment. QEST scores, reflecting quality of life, improved significantly at 3 months (SMD -2.8, $p = 0.0025$), 6 months (SMD -4.1, $p = 0.04$), and up to 3 years post-procedure. Meta-regression suggested male sex was associated with greater improvements in tremor scores, though other factors like age and symptom duration were not significant predictors. Adverse events were predominately mild or moderate and included neurological symptoms (26.4%), sensory symptoms (22.1%), and nonspecific complaints like headache and dizziness (27.4%). Paresthesia was the most common long-term adverse event, persisting in 11% of patients at five years. No serious complications or progressive

adverse effects were noted. The review highlighted a moderate to high risk of bias across studies and publication bias favoring positive outcomes. Despite these limitations, the findings support MRgFUS as an effective and safe treatment for medication-refractory ET, with significant and sustained improvements in tremor severity and quality of life. Future research is needed to refine patient selection criteria, optimize procedural protocols, and directly compare MRgFUS with other treatment modalities to further validate and enhance its clinical utility.

Miller et al. (2022) performed a meta-analysis to evaluate the long-term efficacy and safety of MRgFUS for ET, noting that some studies highlight diminished treatment benefit over time. Twenty-one studies, including one RCT, were reviewed, for a total of 395 patients with data on HST, CRST, and QUEST, following Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. The mean pre-operative HTS was 19.2 ± 5.0, which improved to 7.4 ± 5 at three months post-treatment (61.5% improvement, $p < 0.001$). A reduction in efficacy was observed at 36 months, with HTS increasing to 9.1 ± 5.4 (8.8% reduction compared to the three-month mark). Meta-regression revealed a trend of diminishing effects over time, though this was not statistically significant. CRST scores, reported in 13 studies involving 250 patients, decreased by 46.2% at three months post-treatment ($p < 0.001$). QUEST scores improved significantly at three months, reflecting enhanced quality of life. However, data for CRST and QUEST scores beyond 12 months were scarce. CRST scores likely worsen with time, either due to diminished effect or disease progression. However, treatment benefit compared to pre-treatment symptoms is apparent at all follow-up times. Multiple studies also report diminished effects over time with deep brain stimulation (DBS). The most significant benefits of MRgFUS are its incisionless nature and reduced surgical risks compared to other treatments like DBS. The authors noted that there are no RCTs that compare MRgFUS and DBS.

Agrawal et al. (2021) performed a systematic review of 29 studies (n = 617) to analyze the efficacy and the safety profile of MRgFUS for ET. Studies that reported outcomes in patients with tremors secondary to any other causes, such as drug-induced tremor, trauma, psychogenic tremor, or co-morbid Parkinson disease and dystonia, were excluded. Of the 29 studies, one was a RCT and the remaining were observational studies. Pre and post procedure changes in the CRST score, hand score, disability, and quality of live scores were evaluated. A significant difference was observed in the pooled standard mean difference between pre and post-operative total CRST score, hand score, and disability at 12 months. Ataxia was the most common postoperative complication. All complications showed a decreasing trend over time. More than one third of patients developed sonication related complications, amongst which head pain and dizziness were the most common. No hemorrhage, seizure or trajectory related complications were reported. The authors noted the reliance on observational studies as a limitation, as there is only one clinical trial on the subject. The review concluded that currently, MRgFUS appears to be the procedure of choice for patients unable to tolerate an invasive procedure; however, for it to replace established surgical options like DBS, further research will be required to prove long-term clinical efficacy in both unilateral and bilateral procedures.

Giordano et al. (2020) performed a systematic review to compare unilateral MRgFUS versus unilateral and bilateral DBS for medication-refractory ET, including 45 studies between 1996 and 2019. DBS was analyzed in 37 trials (n = 1202), while MRgFUS was evaluated in 8 studies (n = 477). The average percentage improvement in tremor severity was higher in the pooled DBS group (60.1% ± 9.7%) than in the MRgFUS group (55.6% ± 8.2%). Subgroup analysis indicated that bilateral DBS (61.2% ± 5.2%) improved tremor severity significantly more than unilateral DBS (56.4% ± 9.7%) and MRgFUS, with no significant difference between unilateral DBS and MRgFUS. MRgFUS was associated with considerably better measures of average percentage increase in quality of life than DBS (61.9% ± 7.9% vs 52.5% ± 16.2%). There were 517 complications reported in the DBS group and 484 complications reported in the MRgFUS group. The most common adverse events associated with DBS were lead-related problems (11.4%) and speech difficulties (11.1%). The most common adverse effects associated with MRgFUS were sensory (36.7%) and gait disturbances/muscle difficulties (34.4%). Limitations of the analysis included the various scales used in studies to quantify tremor severity and quality of life. Only one retrospective study compared DBS and MRgFUS.

National and Specialty Organizations

The **American Society for Stereotactic and Functional Neurosurgery (ASSFN)** position statement concludes that MRgFUS is a safe and effective treatment option for medically refractory ET, noting that it should be a treatment option for those who can provide informed consent, who understand the benefits, risks, and alternatives, in whom tremor results in significant functional impairments based on clinical history, and in whom treatment of unilateral tremor (whether dominant or non-dominant hand) is anticipated to result in significant functional improvement. The ASSFN also provides indications for the use of MRgFUS for ET, including all the following criteria:

1. Confirmed diagnosis of ET
2. Failure to respond to, intolerance of, or medical contraindication to use of at least two medications for ET, one of which must be a first line medication
3. Appendicular tremor that interferes with quality of life based on clinical history
4. Unilateral treatment

They also highlight the following contraindications for the use of MRgFUS:

1. Bilateral MRgFUS thalamotomy
2. Contralateral to a previous thalamotomy
3. Cannot undergo MRI due to medical reasons
4. Skull density ratio (ratio of cortical to cancellous bone) is <0.40

The ASSFN notes that indications and preferences for MRgFUS are distinct from that of DBS, and prospective comparative analyses are unlikely to support superiority of one therapy vs another (Pouratian et al. 2020).

The **International Parkinson and Movement Disorder Society (IPMDS)** published an evidence-based review of ET treatments. Propranolol, primidone, and topiramate (>200 mg/day) are the pharmacological interventions with the strongest evidence supporting efficacy and safety. MRgFUS was, for the first time, assessed and was considered possibly useful. Unilateral DBS and radiofrequency thalamotomy were also considered possibly useful. The authors note a need to improve study design in ET and overcome the limitation of small sample sizes, cross-over studies, short-term follow-up studies, and use of non-validated clinical scales (Ferreira et al. 2019).

The **National Institute for Health and Care Excellence (NICE)** issued guidance on unilateral MRgFUS thalamotomy in treatment-resistant ET, identifying no major safety concerns, but noting that current evidence of efficacy is limited in quantity. The guideline recommends MRgFUS not be used unless there are special arrangements for clinical governance, consent, and audit or research. Clinicians should also ensure patients understand that this procedure is only done to treat tremor on one side of the body, and that the effect of this on the functional ability and quality of life of patients with bilateral disease is uncertain. Patients should be informed about alternative treatments, including those that can be done bilaterally (National Institute for Health and Care Excellence 2018).

SUPPLEMENTAL INFORMATION

The **clinical rating scale for tremor (CRST)** is a scoring system for determining the severity of ET. The CRST is divided into three sections. Part A assesses the tremor, Part B assesses task performance, and Part C assesses the disability caused by the tremor. The three parts add up to a total of 160 points; higher scores indicate a more severe tremor. Part A is the primary clinical end point of interest, with a score range of 0 to 32 summarizing 8 items. The CRST scores at baseline and post-treatment are recorded. A score of two or more on the CRST's postural or action item (ranging from 0 - 4) and significant disability in at least two daily activities from the disability subsection indicate moderate to severe tremor (Mohammed et al. 2018).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
61715	Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation of target, intracranial, including stereotactic navigation and frame placement, when performed

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

02/12/2025	Policy revised. Removed criteria point requiring MRgFUS to be determined as best treatment option by a multidisciplinary team. Changed "tremor of the hand" to "appendicular tremor" and added "interferes with quality of life" in coverage criteria. Reorganized and clarified contraindications. IRO reviewed on January 13, 2025, by a practicing physician board certified in neurology.
02/14/2024	Policy reviewed, no changes to criteria. Updated overview, summary of evidence and references.
02/08/2023	Policy revised. Updated coverage position to medically necessary and added coverage criteria to 'Coverage Policy' section, and Updated 'Overview' and 'Summary of Evidence' section. Updated references. IRO Peer Review on January 23, 2023, by a practicing physician board-certified in Neurology, Neurology Vascular.
02/09/2022	Policy reviewed and updated. No changes in coverage position. Updated references.
02/08/2021	Policy reviewed, no changes to criteria; included guidelines from the American Society for Stereotactic and Functional Neurosurgeons (ASSFN) & Health Quality Ontario (HQO).
04/23/2020	Policy reviewed, no changes.
09/18/2019	Policy reviewed, no changes.
07/10/2018	New policy. IRO Peer Review 4/23/2018. Reviewed by practicing physician board-certified in Neurology.

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