

VHA Office of Integrated Veteran Care Clinical Determination and Indication Magnetic Resonance-Guided Focused Ultrasound Thalamotomy

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I. Disclaimer

This document is currently in draft and is intended to be used as a reference for non-VA providers and not intended to replace clinical judgment when determining care pathways. These guidelines do not guarantee benefits or constitute medical advice.

II. Clinical Determinations and Indications

a. Indications for Magnetic Resonance-Guided Focused Ultrasound Thalamotomy

Magnetic resonance-guided focused ultrasound (MRgFUS) thalamotomy is indicated for the following:

- Idiopathic essential tremor with medication-refractory tremor
- Tremor-dominant Parkinson's disease with medication-refractory tremor

It will be considered **medically necessary** when **ALL** the following criteria are met:

- Diagnosis of **ONE** of the following medical conditions:
 - Idiopathic essential tremor with medication-refractory tremor
 - The patient has had at least three trials of medical therapy, including at least one first-line agent (unless contraindicated)
 - Tremor-dominant Parkinson's disease with medication-refractory tremor
 - Refractory (or intolerant) to levodopa or levodopa equivalent daily dosage (LEDD) \geq 1200 mg
- Must meet **ALL** the following clinical criteria to allow for treatment of patients with mild but disabling tremor:
 - Tremor is disabling:

- Score ≥ 2 on any of the eight items in the disability subsection of the CRST or another nationally accepted clinical measure of tremor severity
- Not a candidate for deep brain stimulation (DBS) due to comorbidities or patient refusal for DBS after informed consent including discussion of surgical process, device programming, and device maintenance
 - It is strongly recommended to have an evaluation from a movement disorder specialist (face-to-face, telemedicine, or via e-consult)

b. Limitations/Exclusions

MRgFUS thalamotomy is **not indicated** if any of the following are applicable:

- Untreated coagulopathy
- Severe cognitive impairment (score of <24 on the Mini-Mental State Examination)
- A history of previous brain procedure (e.g., DBS, stereotactic lesioning) or conditions that affect the safety of the procedure
- A skull density ratio (SDR) <0.45
- Contraindications to magnetic resonance imaging (MRI) are present (e.g., metallic foreign body in eye, pacemaker, unable to lay flat for study, severe claustrophobia, etc.)

Conditions/indications for which MRgFUS thalamotomy is **not medically necessary** include, but are not limited to, the following:

- Treatment of head or voice tremor
- Performing bilateral thalamotomy in one procedure

For all conditions/indications not listed in section II.a. of this document, MRgFUS thalamotomy is considered **not medically necessary** due to insufficient evidence of efficacy and safety.

c. Description of Treatment

Magnetic resonance-guided focused ultrasound (MRgFUS) is an incisionless procedure that combines MRI and ultrasound to heat and destroy targeted tissue at the focal point without injuring surrounding structures. Real-time MRI allows visualization during the ablation process using thermographic imaging which allows precision control by continuously monitoring the tissue temperature. Magnetic resonance-guided focused ultrasound is an incisionless thermal ablation technique comparable to radiofrequency ablation and avoids the need for open brain surgery. During the procedure, patients

are awake to provide feedback, allowing for assessment of tremor reduction and potential occurrence of adverse effects.

Magnetic resonance-guided focused ultrasound for the treatment of medication-refractory tremors in idiopathic essential tremor and tremor-dominant Parkinson's disease, specifically targets the ventralis intermedius of the thalamus in the brain, an area that relays cerebello-motor information. Heat created from high intensity ultrasound beam technology targets specific areas of the thalamus, resulting in a tiny burn or lesion on the targeted spot responsible for the tremor. The goal is to ablate the tissue interrupting the activity responsible for the tremor and relieve the associated symptoms.

III. Background and Supporting Information

The following information is for reference purposes only in accordance with the medical benefits package outlined in 38 C.F.R. § 17.38 (b). Each subsection supports VA's determinations for medical necessity and alignment with generally accepted standards of medical practice.

a. Background Information

Patients with medication refractory tremors, due to essential tremor or tremor-dominant Parkinson's disease, may be candidates for various treatment options. These include deep brain stimulation (DBS), radiofrequency ablation, and magnetic resonance-guided focused ultrasound (MRgFUS) ablation. The incisionless technique to ablate an intracranial target, while the patient is awake, has made MRgFUS a reasonable outpatient treatment option for patients who are not candidates for or have failed DBS. Patients that are not suitable to undergo a surgical procedure are potential candidates for MRgFUS thalamotomy for treatment of medication-refractory tremors in idiopathic essential tremor and tremor-dominant Parkinson's disease.

Essential Tremor

Essential tremor is a neurological (nervous system) disorder which causes involuntary shaking or trembling of parts of the body. Essential tremor may also be called benign essential tremor and is the most common type of tremor which can occur at any age but is most common in people who are 40 years and older. There is no known cause for essential tremor, but 50% of the cases are associated with a genetic risk factor. Studies suggest that the cerebellum, thalamus, and cortex (components of the brain structure) are involved in the mechanism of essential tremor. Symptoms may include a shaky/quivering voice, head nodding, and hand shaking impacting the ability to write, hold objects or use tools. Symptoms may be triggered by certain medications, emotions, fatigue, caffeine, or temperature changes.

Essential tremor is not a life-threatening condition and does not decrease life expectancy. Essential tremor can be severely debilitating, affecting the ability to manage emotions, work or social requirements, and activities of daily living (ADLs). There is no known cure, but essential tremor may be managed with beta blockers, anticonvulsants, or surgery.

Tremor-dominant Parkinson's Disease

Parkinson's disease is a progressive neurodegenerative disorder defined by a constellation of cardinal features that include tremor, bradykinesia, rigidity, and postural instability. The spectrum of motor and non-motor manifestations of the disease is further expanding. Tremor is one of the most common motor symptoms of Parkinson's disease and is reported to affect up to 75% of patients during their disease course. Both kinetic and re-emergent postural forms can also coexist, which may result in substantial functional impairment.

Parkinson's disease is recognized to be heterogeneous, and growing evidence of clinical subgroups has emerged based on the predominant symptom associated with each subtype. In comparison to other Parkinson's disease subtypes, tremor-dominant Parkinson's disease tends to have a slower disease progression, less debilitating non-motor symptoms, decreased probability of developing levodopa-induced dyskinesia, and potential resistance to dopaminergic agents.

b. Research, Clinical Trials, and Evidence Summaries

i. MRgFUS Thalamotomy for Medication-Refractory Essential

Tremor

Research evidence and clinical trials support MRgFUS as a safe and effective treatment option for medication-refractory essential tremor. Magnetic resonance-guided focused ultrasound has proved to be more effective than the sham procedure and a viable treatment option for patients who are not candidates for DBS. Magnetic resonance-guided focused ultrasound has proven to reduce tremor severity, improve quality of life, and increase the ability to perform activities of daily living.

Cosgrove et al. (2022) evaluated the long-term safety and efficacy of unilateral MRgFUS thalamotomy for the treatment of medication-refractory essential tremor from a cohort of patients in a multicenter clinical trial. The study used the Clinical Rating Scale for Tremor (CRST) to assess outcomes and results measured by a qualified neurologist. The team found that unilateral MRgFUS thalamotomy is an effective treatment for patients with medication-refractory essential tremor and showed significant tremor improvement at 5 years with an

overall improvement in quality-of-life without any progressive or delayed complications.

Hand-tremor scores (based on CRST) showed greater improvement after focused ultrasound thalamotomy (from 18.1 points at baseline to 9.6 at 3 months) than after the sham procedure (from 16.0 to 15.8 points). The improvement in the thalamotomy group was maintained at 12 months. Secondary outcome measures assessing disability and quality of life also improved with active treatment (the blinded thalamotomy cohort) as compared with the sham procedure. Adverse events in the thalamotomy group included gait disturbance in 36% of patients and paresthesia or numbness in 38%; these adverse events persisted at 12 months; in 9% and 14% of patients, respectively. MRgFUS thalamotomy reduced hand tremor in patients with essential tremor.

In 2018, Ontario Health performed a systematic review of literature that examined MRgFUS neurosurgery alone compared to other interventions for the treatment of moderate to severe, medication-refractory essential tremor. Studies included in this review found MRgFUS neurosurgery had a favorable safety profile and should be considered a safe and effective option for moderate to severe, medication-refractory essential tremor. It provides a noninvasive option for all considering neurosurgery, including patients who are ineligible for invasive neurosurgery. Patients with essential tremor who had undergone MRgFUS neurosurgery reported a substantial reduction in tremor that resulted in an improvement in quality of life, and the ability to perform activities of daily living.

Chang et al. (2017) conducted a study reporting the results of MRgFUS thalamotomy for essential tremor at a 2-year follow-up point. Seventy-six patients with moderate-to-severe essential tremor, who had not responded to at least two trials of medical therapy, were enrolled in the original randomized study of unilateral thalamotomy and evaluated using the clinical rating scale for tremor. Sixty-seven patients continued in the open-label extension phase of the study with monitoring for 2 years. Mean hand tremor score at baseline improved by 55% at 6 months. The improvement in tremor score from baseline was durable at 1 year and at 2 years. The disability score at baseline improved by 64% at 6 months. This improvement was sustained after 1 year and 2 years of the procedure.

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 follow-up period, and two resolved. There were no new delayed complications at 2 years. Tremor suppression after MRgFUS thalamotomy for essential tremor was maintained at 2 years. Latent or delayed complications did not develop after treatment.

ii. MRgFUS Thalamotomy for Medication-Refractory Tremor in Tremor-Dominant Parkinson's Disease

Research evidence and clinical trials support MRgFUS as a safe and effective treatment option for medication-refractory tremor in Parkinson's Disease. Magnetic resonance-guided focused ultrasound thalamotomy has proven to be more effective in treating medication-refractory tremor in tremor-dominant Parkinson's Disease than the sham procedure and prevents the need to increase dopaminergic medications. Study results suggest conducting ongoing trials with larger cohorts to determine adverse events and long-term outcomes for the treatment of medication refractory tremor in tremor-dominant Parkinson's disease with MRgFUS.

Abusrain et al. (2022) conducted a structured literature review to highlight recent advances in the underlying pathogenesis and treatment modalities for tremor in Parkinson's disease. The purpose of the review was to highlight the underlying pathophysiological mechanisms of tremor in Parkinson's disease and recent advances in therapeutic options. Tremor is one of the most common symptoms associated with Parkinson's disease. The complexity of Parkinson's disease tremor and the wide and unpredictable response to therapeutic modalities remain challenging. Poor response to dopaminergic agents is common, reflecting the role of multiple underlying pathophysiologic processes. Evidence for advanced modalities is heterogeneous, with no sufficient comparative studies to address their efficacy in this specific group of Parkinson's disease patients. Despite promising results, authors suggested further investigation of long-term data for newer advanced modalities, such as MRgFUS, to ensure safety and sustained efficacy.

Andreasi et al. (2022) performed a study of patients diagnosed with early-stage idiopathic Parkinson's disease and tremor-dominant clinical phenotype who underwent MRgFUS ventralis intermedialis nucleus (Vim) thalamotomy and patients treated with oral dopaminergic medications. A total of 145 patients with tremor-dominant PD were initially evaluated. Ten patients in the MRgFUS group and 20 patients

receiving oral dopamine therapy met selection criteria. The study set out to prove that MRgFUS VIM thalamotomy in early-stage tremor-dominant PD prevented an increase in dopaminergic medications 6 months after treatment compared with matched Parkinson's disease control subjects on standard medical therapy. Patients had at least one follow-up visit ≥ 6 months after the procedure. Magnetic resonance-guided focused ultrasound thalamotomy, performed in patients with early-stage tremor-dominant Parkinson's disease, allowed them to maintain a low daily dosage of oral dopaminergic medications along with a good control of tremor for at least 6 months. Magnetic resonance-guided focused ultrasound was found to have an acceptable safety profile in patients with tremor-dominant Parkinson's disease presenting with unsatisfactory response to therapeutic dose of pharmacological approaches. In patients with early-stage tremor-dominant Parkinson's disease, MRgFUS thalamotomy may help decrease the tremor and avoid the need to increase dopaminergic medications. Authors concluded that MRgFUS thalamotomy is a safe and effective treatment for tremor in patients with Parkinson's disease.

Chua et al. (2023) evaluated the clinical outcomes of 48 patients with medically refractory tremor-dominant Parkinson's disease who underwent MRgFUS thalamotomy and assess tremor outcomes and adverse effects at various intervals. The team's objective was to report the largest prospective experience of unilateral MRgFUS thalamotomy for the treatment of medically refractory tremor-dominant Parkinson's disease. Results from the study found significant tremor control persisted at all follow-ups, which were statistically significant. The most commonly observed adverse events after MRgFUS thalamotomy were gait imbalance and sensory defects. Gait imbalance was reported at 59.18% on day 1 and decreased to 20% at 2 years. Sensory deficits were reported at 14.29% on day 1 and 13.64% at 1 year. Motor weakness, dysgeusia, and dysarthria were also noted in patients. The majority of adverse events improved over time, particularly after the 3-month follow-up point. The team concluded that MRgFUS thalamotomy is an effective treatment for sustained tremor control in patients with medically refractory tremor-dominant Parkinson's disease with a 78.6% reduction at 1 year.

Bond et al. (2019) conducted a clinical trial designed to explore the safety and initial efficacy of unilateral MRgFUS for symptom management in patients with tremor dominant Parkinson's disease. Although it was a pilot study, it incorporated a randomized clinical trial design controlled with sham procedures to account for placebo effects that often confound research on Parkinson's disease treatments. Adult

patients with idiopathic tremor dominant Parkinson’s disease were included if the disease was deemed medication-refractory, severe, and disabling. Twenty patients were randomized to unilateral FUS thalamotomy and 7 to sham procedure. The clinical trial of unilateral MRgFUS thalamotomy for patients with tremor dominant Parkinson’s disease demonstrated a 62% median improvement in contralateral hand tremor CRST sub-scores in the FUS thalamotomy group. There was a 22% median improvement in the sham group. A notable placebo response was observed with the sham procedures, necessitating a larger study to prove efficacy. Adverse events were similar to other thalamotomy procedures and will likely improve as the technology for monitoring the MRgFUS thalamotomy procedure improves.

Ge et al. (2021) conducted a search database of Medline, EMBASE, and the Cochrane Library for eligible randomized controlled trials comparing magnetic resonance-guided focused group vs. sham procedure group in Parkinson’s disease. The purpose of the research was to evaluate the safety and efficacy of MRgFUS to improve limb tremor in the treatment of Parkinson’s disease. Data obtained from two small randomized clinical trials found the MRgFUS group showed significant improvement in limb tremor on the treated side and a greater ability to perform daily activities compared to the sham group. Authors concluded the studies demonstrated the beneficial effects of MRgFUS in Parkinson’s disease patients with no serious side effects or adverse events.

c. U.S. Food & Drug Administration (FDA) Information

VA generally only approves use of medical devices that have received at least FDA clearance for 510(k) Premarket Notification. The following device has received Premarket Approval from the FDA and is indicated for use in patients with above knee amputations.

To search for devices that have received FDA 510(k) clearance or Premarket Approval (PMA), please visit the [FDA Devices database](#).

| Information | Description |
|---------------|---|
| Product Name | Exablate Model 4000 Type 1.0 and 1.1 System (“Exablate Neuro”) – P150038/S014 |
| PMA Applicant | INSIGHTEC, Inc |
| Address | 4851 LBJ Freeway, Suite 400 Dallas, TX 75244 |
| Approval Date | 10/29/2021 |

| Information | Description |
|-----------------|---|
| Approval Letter | Premarket Approval Letter |

d. Medicare Coverage Determinations

Available Medicare coverage determinations are listed below as a resource. VA and Medicare are governed by separate laws and regulations; thus, VA coverage determinations may be different.

| NCD Number | Name | Effective Date |
|------------|------|----------------|
| None | N/A | N/A |

| LCD Number | Contractor | Revision Effective Date |
|------------------------|------------------------------------|-------------------------|
| L38506 | First Coast Service Options, Inc. | 07/12/2020 |
| L37729 | Noridian Healthcare Solutions, LLC | 07/30/2023 |
| L37738 | Noridian Healthcare Solutions, LLC | 07/30/2023 |
| L38495 | Novitas Solutions, Inc. | 07/12/2020 |

- NCD: National Coverage Determination
- LCD: Local Coverage Determination

IV. Definitions

| Term | Definition |
|---|---|
| Ablate/Ablation | A procedure where a type of energy is used to remove or destroy targeted tissue in the body |
| Anticonvulsants | A type of drug that can be used to prevent or treat seizures or convulsions by controlling abnormal electrical activity in the brain used to treat epilepsy and other seizure disorders. These medications have proven beneficial in a variety of other disorders, including essential tremor |
| Benign | Condition, tumor, or growth that is not cancerous |
| Beta Blockers | A class of medications used to help reduce blood pressure; act to block adrenergic receptors responsible for increased cardiac action. Beta blockers, most commonly propranolol, are first line medications for the treatment of essential tremor |
| Bradykinesia | Impairment of voluntary motor control and slow movements or freezing |
| Clinical Rating Scale for Tremor (CRST) | A tool used to rate the severity of the tremor |
| Comorbidity | Having two or more diseases at the same time |

| Term | Definition |
|------------------------------|--|
| Contralateral | Occurring on or acting in conjunction with a part on the opposite side of the body |
| Deep Brain Stimulation (DBS) | A surgical procedure that implants electrodes in certain areas of the brain to control abnormal brain activity |
| Dopaminergic Agents | Medications aimed to replace dopamine or prevent the degradation of dopamine |
| Dyskinesia | Uncontrolled, involuntary muscle movements ranging from shakes, tics and tremors to full-body movements |
| Essential Tremor | A neurological disorder that causes your hands, head, trunk, voice, or legs to shake rhythmically |
| Gait Disturbance | Disruption of the ability to walk |
| Heterogeneous | Consisting of or composed of dissimilar elements or ingredients; not having a uniform quality throughout |
| Kinetic | Occurs with voluntary movement |
| Levodopa-induced Dyskinesia | Involuntary, purposeless, predominantly choreiform movements due to long-standing chronic levodopa therapy |
| Medication Refractory | Not responding to or not able to be treated with medication, after consideration of or trial of at least 2 agents at adequate doses |
| Neurodegenerative | A type of disease in which cells of the central nervous system stop working or die; usually getting worse over time and having no cure |
| Paresthesia | Abnormal sensation, tingling or pricking felt in the hands, arms, or legs |
| Parkinsonism | General term that refers to a group of neurological disorders that cause movement problems similar to those seen in Parkinson's disease such as tremors, slow movement and stiffness |
| Phenotype | The observable characteristics or traits of a disease |
| Re-emergent postural form | Occurs when holding a body part motionless against the force of gravity and the tremor commences after a variable latency of one to several seconds |
| Refractory | Resistant to treatment or cure |
| Sham Procedure | Placebo surgery or treatment - intervention that omits the step thought to be therapeutically necessary |
| Skull Density Ratio (SDR) | The ratio of cortical to cancellous bone, which is used to estimate the density of the skull |
| Stereotactic | Involving a technique that targets a specific area with the assistance of image guidance |
| Superimposed | Combines the volume render features with a side by side visual of two chosen images |

| Term | Definition |
|-------------------------------------|---|
| Thalamotomy | A surgical procedure in which a lesion is made in the thalamus to improve the overall brain function in patients |
| Thalamus | A paired gray matter structure of the diencephalon near the brain's center that is responsible for several functions including the relay of different sensory signals to other parts of the brain |
| Thermographic | A procedure that uses a heat-sensing infrared camera to record the surface heat produced by different parts of the body |
| Ventralis Intermedius Nucleus (Vim) | A part of the thalamus, the Vim is centrally placed in the dentato-thalamo-cortical pathway (DTCp) and is a key surgical target in the treatment of severe medically refractory tremor |

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VI. CDI History/Revision Information

- Explanation of changes to the CDI

| Revision Type | Date of Revision | Update(s) Made to CDI |
|---------------|------------------|-----------------------|
| | MM/DD/YYYY | |
| | MM/DD/YYYY | |