

# Local Coverage Determination (LCD): Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor (L37729)

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## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

## LCD Information

## Document Information

**LCD ID**

L37729

**LCD Title**

Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor

**Proposed LCD in Comment Period**

N/A

**Source Proposed LCD**

DL37729

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N/A

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N/A

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02/14/2019

**Notice Period End Date**

03/31/2019

**CMS National Coverage Policy**

Language quoted from Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals is italicized throughout the policy. NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See Section 1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

Title XVIII of the Social Security Act (SSA):

Section 1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Section 1862(a)(1)(D) refers to limitations on items or devices that are investigational or experimental.

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

## **Coverage Guidance**

### **Coverage Indications, Limitations, and/or Medical Necessity**

This LCD addresses use of Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for the treatment of idiopathic essential tremor (ET) patients with medication-refractory tremor.

MRgFUS unilateral thalamotomy is considered medically reasonable and necessary in patients with all four of the following criteria:

1. medication refractory ET (defined as refractory to at least two trials of medical therapy, including at least one first-line agent)
2. moderate to severe postural or intention tremor of the dominant hand or another nationally accepted clinical measure of tremor severity
3. disabling ET (defined by a score of  $\geq 2$  on any of the eight items in the disability subsection of the CRST or another nationally accepted clinical measure of tremor severity)
4. not a candidate for DBS (e.g., advanced age, anticoagulant therapy, surgical comorbidities, or has failed Deep Brain Stimulation (DBS), but has no retained cranial implants)

Limitations (not covered):

1. Treatment of head or voice tremor
2. Bilateral thalamotomy
3. An advanced neurodegenerative condition
4. Unstable cardiac disease
5. Depression sufficiently severe to compromise beneficiary's ability to provide informed consent and limit likely clinical benefit of the treatment
6. Severe cognitive impairment (such as may be defined by a score of  $< 24$  on the Mini-Mental State

Examination)

7. A skull density ratio (SDR) (the ratio of cortical to cancellous bone) <0.40

8. MRI contraindicated

## Summary of Evidence

Essential tremor (ET) is the most common movement disorder as well as one of the most treated surgically. The prevalence of ET has been estimated at approximately 3% or 10 million people in the United States. While ET does not shorten life expectancy, the associated disabling symptoms, such as hand tremor, can greatly impact quality of life (functional ADLs, work activities, mood, and socialization).

Although there are no curative therapies, symptoms of ET are well managed medically in up to 70% of patients, with surgery reserved for medication-refractory severe impairments. Current surgical options include thalamotomy with radiofrequency (RF) ablation and deep-brain stimulation (DBS); both effectively suppress tremor but require intracranial surgery. Stereotactic radiosurgery (SRS), while non-operative, suffers from delay in tremor reduction (making intraoperative validation impossible), a greater than 10% cumulative risk of adverse events, and theoretical concerns about radiation side effects.<sup>(6, 22)</sup> DBS is currently the intervention of choice, "because of its proven efficacy, reversibility, adjustability, and durability" <sup>(22)</sup>, with thalamotomy "a reasonable alternative...if DBS is not available or practical".<sup>(1)</sup> This attribute of DBS in creating an adjustable "functional lesion" causes fewer adverse events than thalamotomy <sup>(24, 25)</sup>, and resulted in a general shift away from ablation methods. <sup>(23)</sup>

Neuromodulation with ultrasound energy also required craniotomy until recently; advances in ultrasound transducer design and high-resolution magnetic resonance imaging now allow precise transcranial delivery of high-intensity focused ultrasound. The ultrasound causes a local increase in temperature in the target tissue, resulting in coagulation necrosis while sparing the surrounding normal structures. In addition to providing location guidance, MRI provides real-time clinical monitoring of treatment intensity via thermal imagery. On 1/1/16, a CPT Category III tracking code specific to MRgFUS treatment of movement disorder became effective. FDA PMA approval for the Magnetic-Resonance-Guided Focused Ultrasound Surgery System (MRgFUS) (ExAblate Model 4000, InSightec, Inc.) "for the unilateral thalamotomy treatment of idiopathic essential tremor patients with medication-refractory tremor" came on 7/11/16.<sup>(3)</sup>

Among the peer-reviewed clinical studies of MRgFUS for the treatment of medication-refractory ET, all but one were small, uncontrolled, pilot studies with short follow-up.<sup>(4-11)</sup> FDA approval for MRgFUS treatment of ET was based on its pivotal study, a prospective, double-blind, randomized, sham-controlled trial (RCT) of MRgFUS to create a unilateral thalamic ablation for the treatment of ET.<sup>(12)</sup> Seventy-six patients with moderate-to-severe essential tremor refractory to at least two trials of medical therapy were randomized in a 3:1 ratio to either MRgFUS or a sham procedure. The primary endpoint, the CRST at 3 months, was significantly improved in the MRgFUS group ( $p < 0.001$ ). Secondary outcome measures, including disability and quality of life, were also significantly improved.

However, both hand and total tremor scores steadily deteriorated over the year, 23% and 38% respectively. In fact, this drop in efficacy and the limited follow-up period were cited as major concerns in the accompanying editorial which advocates for much longer follow-up (2-5 years or more) to demonstrate sustained benefit.<sup>(2)</sup> Another concern was persistent adverse neurologic effects in the MRgFUS group at 12 months, including gait disturbance (9%) or numbness (14%).

The editorial concludes that "A head-to-head comparison with DBS would facilitate the direct comparison of the two approaches." Some contend that a direct comparative trial between MRgFUS and DBS will be unlikely "due to the significant differences in invasiveness of the two procedures." Interestingly, a letter to the editor agrees a direct comparative study isn't warranted, but apparently for the opposite ethical reason, noting "that the high rate of adverse events that is consistently reported with thalamotomy of any kind suggests that equipoise does not exist".<sup>(13)</sup> While it is true that MRgFUS is less invasive than DBS in terms of not requiring cranial penetration with hardware, it is more invasive than DBS in the creation of a fixed thalamic brain lesion, which can result in permanent neurologic deficit.

More recently, follow-up on this same cohort of seventy-six patients with refractory moderate-to-severe essential tremor has been reported on sixty-seven of the patients continued with monitoring for two years. The improvement in tremor was durable at 1 year (53%;  $8.9 \pm 4.8$ ; 70 patients) and at 2 years (56%;  $8.8 \pm 5.0$ ; 67 patients). Disability score improved throughout this period, none of the adverse effects worsened, two resolved and there were no new delayed complications.<sup>(27)</sup>

A recently published meta-analysis is meant to provide "an approximation of an RCT" head-to-head comparison between MRgFUS, DBS, and SRS; the authors claim an actual RCT is unlikely.<sup>(22)</sup> Pre- and postoperative tremor-related disability scores were collected from 32 studies involving 83 MRgFUS, 615 DBS, and 260 SRS cases. MRgFUS thalamotomy resulted in significantly higher utility scores (defined as quality of life and derived from percent change in functional disability) compared with DBS ( $P < 0.001$ ) or SRS ( $P < 0.001$ ). The authors conclude that "preliminary experience with MRgFUS supports its broad adoption for medically refractory ET."

A retrospective analysis of 59 patients who underwent unilateral treatment for drug-resistant ET with RF thalamotomy ( $n=17$ ), DBS ( $n=19$ ), and MRgFUS ( $n=23$ ) showed no statistical differences in tremor severity improvement at 1 month or 1 year follow-up.<sup>(23)</sup> However, MRgFUS had a significantly lower complication rate ( $p < 0.01$ ) at 1 year (4.4%) compared with RF (11.8%) and DBS (21.1%). The authors conclude that "MRgFUS is a promising therapy with the potential to replace DBS for patients who cannot tolerate DBS, the standard surgical treatment for ET," but that "the long-term effects of MRgFUS should be systematically evaluated in a future prospective, randomized study in order to demonstrate whether MRgFUS provides superior management of ET symptoms."

## **Analysis of Evidence (Rationale for Determination)**

In summary, MRgFUS is a promising new treatment approach that has attributes, positive and negative, distinct from both traditional thalamotomy and DBS. However, long-term effectiveness and safety remain uncertain<sup>(1, 23)</sup> and warrant a direct comparison with DBS, the current surgical standard. Widespread non-coverage by both Medicare (14-17) and commercial payers (18-21) supports this interpretation.

However, given the support for traditional thalamotomy, generally, as an alternative "if DBS is not available or practical", and the support for MRgFUS thalamotomy, specifically, as an alternative in patients "who are not a

candidate for DBS” by the American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS) and the American Association of Stereotactic and Functional Neurosurgery (ASSFN), Noridian considers MRgFUS reasonable and necessary in that context. Patient selection criteria will largely mirror those used in the pivotal study (see Coverage and Limitations section for details).

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## General Information

### Associated Information

N/A

### Sources of Information

N/A

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## Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
11/01/2019	R2	<p>The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.</p> <p>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</p>	<ul style="list-style-type: none"> <li>Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)</li> </ul>
11/01/2019	R1	<p>11/1/19: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage.</p> <p>As requested by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD.</p>	<ul style="list-style-type: none"> <li>Provider Education/Guidance</li> <li>Revisions Due To Code Removal</li> </ul>

## Associated Documents

### Attachments

N/A

### Related Local Coverage Documents

Article(s)

A57512 - Billing and Coding: Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor

A56253 - Response to Comments: Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor

LCD(s)

DL37729

- (MCD Archive Site)

### Related National Coverage Documents

N/A

### Public Version(s)

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