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

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LCD Information

Document Information

Created on 04/11/2019. Page 1 of 9
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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CMS National Coverage Policy
Created on 04/11/2019. Page 2 of 9
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 ≥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
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. DBS is currently the intervention of choice, “because of its proven efficacy, reversibility, adjustability, and durability” (22), with thalamotomy “a reasonable alternative….if DBS is not available or practical”. This attribute of DBS in creating an adjustable “functional lesion” causes fewer adverse events than thalamotomy (24, 25), and resulted in a general shift away from ablation methods.

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 (0398T) 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.

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. 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. 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. 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”. 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 ± 4.8; 70 patients) and at 2 years (56%; 8.8 ± 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.

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. 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. 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 (1, 23) 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).

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

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Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

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CPT/HCPCS Codes

Group 1 Paragraph:

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ICD-10 Codes that Support Medical Necessity

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### Additional ICD-10 Information

N/A

### General Information

#### Associated Information

N/A

#### Sources of Information

N/A

#### Bibliography


8. Chang WS, Jung HH, Kweon EJ, Zadicario E, Rachmilevitch I, Chang JW. Unilateral magnetic resonance guided focused ultrasound thalamotomy for essential tremor: practices and clinicoradiological outcomes. *J Neurosurg*


15. Noridian LCD Non Covered Services (L36219).

16. First Coast Service Options LCD Noncovered Services (DL33777).

17. Palmetto GBA LCD Non-Covered Category III CPT Codes (DL34555).


20. UnitedHealthcare Guideline Number MPG043.05. Category III CPT Codes. UnitedHealthCareOnline.Category III Codes


thalamotomy for essential tremor: results of the 2-year follow-up. ANN NEUROL 2018;83:107-114.


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**Revision History Information**

N/A

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**Associated Documents**

**Attachments**

N/A

**Related Local Coverage Documents**

**Article(s)**

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

**LCD(s)**

DL37729 - Magnetic-Resonance-Guided Focused Ultrasound Surgery (MRgFUS) for Essential Tremor

**Related National Coverage Documents**

N/A

**Public Version(s)**

Updated on 02/07/2019 with effective dates 04/01/2019 - N/A

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- MRgFUS
- Essential Tremor
- Ultrasound Surgery