PROPOSED Local Coverage Determination (LCD): Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Essential Tremor (DL37761)

Please Note: This is a Proposed policy.
Proposed LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Proposed LCDs are not necessarily a reflection of the current policies or practices of the contractor.

Contractor Information

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**Proposed LCD Information**

**Document Information**

**Source LCD ID**
L37761

**Proposed LCD ID**
DL37761

**Proposed LCD Title**
Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Essential Tremor

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CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A) allows coverage and payment for only those services that are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, §1862 (a)(1)(D) research and experimental must be reasonable and necessary.

Title XVIII of the Social Security Act, §1833 (e) prohibits Medicare payment for any claim lacking the necessary documentation to process the claim.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity
This LCD addresses use of Magnetic Resonance Guided Focused Ultrasound Surgery System (MRgFUS) for the treatment of neurologic conditions.

**MRgFUS unilateral thalamotomy is considered medically reasonable and necessary in patients who have essential tremor and all of the following:**

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 (defined by a score of ≥2 on the Clinical Rating Scale for Tremor (CRST))
3. Disabling ET (defined by a score of ≥2 on any of the eight items in the disability subsection of the CRST)
4. Not able to tolerate the procedure

**MRgFUS unilateral thalamotomy is considered medically reasonable and necessary in patients who have Tremor-Dominant Parkinson’s disease and all of the following:**

1. Medication refractory Tremor-dominant Parkinson’s disease, defined as refractory (or intolerant) to levodopa or levodopa equivalent medications (LEDD) ≥ 900 mg
2. Parkinson’s disease with tremor dominant subtype. This should generally be reflected by administering the UPDRS in the on-medication state using the ratio of the mean score for tremor items (items 16, 20, and 21) to the mean postural instability/gait disorder score (items 13-15, 29, and 30). A ratio of ≥ 1.5 indicates tremor dominant Parkinson’s Disease
3. Severe and disabling tremor as indicated by documentation of specific activities in daily life that the patient is unable to perform or has substantial difficulty performing secondary to the tremor
4. Not able to tolerate the procedure

**Limitations (not covered):**

1. Treatment of head or voice tremor
2. Bilateral thalamotomy
3. Conditions
   1. unstable cardiac disease
   2. coagulopathy
   3. risk factors for deep-vein thrombosis
   4. severe depression (defined by a score ≥20 on Patient Health Questionnaire 9 (PHQ-9))
   5. cognitive impairment (defined by a score of <24 on the Mini–Mental State Examination)
   6. previous brain procedure (transcranial magnetic stimulation, DBS, stereotactic lesioning, or electroconvulsive therapy)
   7. a skull density ratio (the ratio of cortical to cancellous bone) <0.45
   8. MRI contraindicated

**Summary of Evidence**

Essential tremor (ET) is a most common movement disorder affecting roughly 0.9% of individuals over age 65 years, though it can have a large range of symptom severity ranging from mildly symptomatic to sufficiently severe as to render an individual unable to self-feed. Although there are no curative therapies, symptoms of ET are often managed medically using a variety of available oral or injected treatments. For patients whose tremor is not adequately controlled medically, surgical treatment options are also available including stereotactic thalamotomy with radiofrequency (RF) ablation and deep-brain stimulation (DBS). Radiosurgery has also been described, though
there is less data available on its efficacy. Both unilateral thalamotomy and deep brain stimulation are acceptable surgical interventions for medically refractory essential tremor, though deep brain stimulation is thought to have fewer adverse events.

Magnetic Resonance Guided Focused Ultrasound Surgery System (MRgFUS) has emerged as a potential non-invasive thalamotomy technique.

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, for which results were published in the peer reviewed literature. In this study investigators examined the impact of the ExAblate MRgFUS device in 76 patients with ET. There were 56 patients assigned to the treatment arm with ExAblate and 20 patients assigned to the sham control group. Patients in the sham group could cross-over to active treatment after 3 months, after initial effectiveness endpoints were assessed. The primary efficacy outcome measure was the change from baseline to 3 months in the on-medication upper-limb tremor subscore of the Clinical Rating Scale for Tremor (CRST A+B) for the treated limb. The baseline CRST A+B score was 18.4 in the treatment group and 16.0 in the sham group. The CRST A+B score improved 47% by 3 months in the treatment group and 0.01% in the sham group with a between group difference of 8.3 ($p < 0.001$). The between group difference persisted at 12 months. Following the initial 3 month outcome assessment 19 of the 20 patients originally randomized to the sham group and 2 patients randomized to MRgFUS in whom the procedure was not completed crossed-over to receive MRgFUS treatment. The mean baseline CRST A+B score at cross-over in this group was 16.5, but 3 months after the cross over, the mean dropped to 7.4 ($p < 0.001$), similar to the 3 months outcomes in the group originally allocated to treatment.

Following the FDA approval of MRgFUS for Essential Tremor, MRgFUS for unilateral thalamotomy was approved by the FDA for the treatment of medication-refractory tremor-dominant Parkinson’s disease (TDPD). Research has suggested that the pathophysiology of DDPD may be different from the pathophysiology of Parkinson’s disease in patients affected primarily by rigidity and bradykinesia. Additionally, a unique medication strategy is often indicated for TDPD, but for refractory patients, surgery may be considered.

In a study patterned off of the study used to FDA approval of MRgFUS for Essential Tremor, investigators studied the impact of the ExAblate MRgFUS device in 27 patients with TDPD. There were 20 patients assigned to the treatment arm and 7 patients assigned to the sham control group. Patients in the sham group could cross-over to active treatment after 3 months, after initial effectiveness endpoints were assessed. The patients in the treatment arm received a unilateral MRgFUS thalamotomy. The primary efficacy outcome measure was the change from baseline to 3 months in the on-medication upper-limb tremor subscore of the Clinical Rating Scale for Tremor (CRST A+B) for the treated limb. The baseline CRST A+B score was 17 (range of 10.5-27.5) in the treatment group and 23 (range of 14-27) in the sham group. The CRST A+B score improved 62% by 3 months in the treatment group and 22% in the sham group ($p = 0.04$). The investigators also noticed improvements in efficacy secondary outcome measures at 3 months including the CRST, Unified Parkinson’s Disease Rating Scale, and Parkinson’s disease Questionnaire-39 in the treatment group. Following the initial 3 month outcome assessment 6 of the 7 patients originally randomized to the sham group crossed-over to receive MRgFUS treatment. The median baseline CRST A+B score at cross-over in these 6 was 21, but 3 months after the sham group crossed over, the median dropped to 5.5, similar to the 3 months outcomes in the group originally allocated to treatment. The investigators also considered the 1 year outcome of response in on-medication CRST A+B score. Of the 20 patients enrolled in the treatment group, 14 were unblended for 1 year assessments, and the median CRST was 5. Among the sham patients who crossed over, the median CRST was 6 at 1 year.

Additionally, MRgFUS is currently being studied for use in medically-refractory dyskinesia symptoms or motor fluctuations of advanced Parkinson's Disease as part of a study registered at clinicaltrials.gov. This study does not
yet have results available, so evidence from it was not reviewed.

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

When making coverage determinations, CMS and Medicare Administrative Contractors generally evaluate relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for beneficiaries. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

MRgFUS is a treatment approach that relies on high-intensity focused ultrasound delivered with MR guidance. It can be used to ablate specific deep brain structures non-invasively. While, long term effectiveness and safety have not been studied, the use of this technology to non-invasively ablate structures for which surgical ablation is considered an accepted treatment approach suggests that this technology would have a similar therapeutic effect as surgical approaches to the ablation of these regions of the brain. In the background of this bioplausibility, clinical trials have been performed to study the outcomes achieved from treating of patients with neurological conditions with MRgFUS. Efficacy of this therapeutic technique has been specifically demonstrated when MRgFUS is used for unilateral thalamotomy (ventralis intermedius) for Essential Tremor and for Tremor-dominant Parkinson's disease. We did not find any high quality head-to-head studies comparing MRgFUS to existing surgical techniques, so we are unable to definitively conclude how it compares to these treatment methods.

This appears to be an evolving area of research with at least one other ongoing study for the use of this technology in neurologic disease. Palmetto GBA will continue to monitor scientific developments, and may adjust this coverage policy in accordance.

### Proposed Process Information

**Synopsis of Changes**

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<th>CHANGES</th>
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<td>This LCD is being presented for comment due to receipt of a reconsideration request. Coverage for tremor dominant Parkinson’s disease was added; therefore, ICD-10 code G20 Parkinson’s disease will be added to the related Billing and Coding: Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Essential Tremor A56690 article when this proposed LCD becomes effective.</td>
<td>Coverage Indications, Limitations and/or Medical Necessity Sources of Information and Basis for Decision ICD-10 Codes that Support Medical Necessity</td>
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**Associated Information**

**Documentation Requirements**
Documentation supporting medical necessity should be legible, maintained in the patient’s medical record and made available to the A/B MAC upon request.

ICD-10-CM diagnosis codes supporting medical necessity must be submitted with each claim. Claims submitted without such evidence will be denied as not medically necessary.

Any diagnosis submitted must have documentation in the patient’s record to support coverage and medical necessity.

Sources of Information

N/A

Bibliography


Open Meetings/Contractor Advisory Committee (CAC) Meetings

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MAC Meeting Information URL(s)

N/A

Proposed LCD Posting Date

N/A

Comment Period Start Date

10/07/2019

Comment Period End Date

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Proposed Contact
Part B Policy
PO Box 100238 (JM) or PO Box 100305 (JJ)
AG-275
Columbia, South Carolina 29202-
B.Policy@PalmettoGBA.com

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.
N/A

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.
N/A

CPT/HCPCS Codes
Group 1 Paragraph:
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Group 1 Codes:

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ICD-10 Codes that Support Medical Necessity

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ICD-10 Codes that DO NOT Support Medical Necessity
N/A

Additional ICD-10 Information
N/A

-associated_documents

Associated Documents

Attachments
N/A

Related Local Coverage Documents
Article(s)
A56690 - Billing and Coding: Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Essential Tremor

Related National Coverage Documents
N/A

Public Version(s)
N/A

Keywords

- MRgFUS