MAGNETIC RESONANCE IMAGE GUIDED HIGH INTENSITY FOCUSED ULTRASOUND (MRGFUS) FOR ESSENTIAL TREMOR

Guideline Number: MPG374.02
Approval Date: April 10, 2019

Table of Contents

| Page | Table of Contents
|------|-------------------|
| 1   | POLICY SUMMARY
| 2   | APPLICABLE CODES
| 2   | PURPOSE
| 2   | REFERENCES
| 3   | GUIDELINE HISTORY/REVISION INFORMATION
| 3   | TERMS AND CONDITIONS

POLICY SUMMARY

Overview
Magnetic resonance image guided high intensity focused ultrasound (MRgFUS) stereotactic intracranial lesion ablation for movement disorders utilizes multiple elemental arrays of ultrasound transducers to focus thermal ablation to the specific target area as small as millimeters in size. This disturbs the blood-brain barrier, but is noninvasive allowing for an alternative treatment to current open neurologic procedures.

Guidelines
This policy guideline addresses the use of Magnetic Resonance Guided Focused Ultrasound Surgery System (MRgFUS) for the treatment of idiopathic essential tremor (ET) patients with medication-refractory tremor. Coverage is based upon the existing Local Coverage Determination (LCD) for the jurisdiction in which the procedure is performed.

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

- Medication refractory ET (defined as refractory to at least two trials of medical therapy, including at least one first-line agent)
- 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))
- Disabling ET (defined by a score of ≥2 on any of the eight items in the disability subsection of the CRST)
- Not a surgical candidate for Deep Brain Stimulation (DBS) (e.g., advanced age, anticoagulant therapy, or surgical comorbidities)

Limitations (not covered):
- Treatment of head or voice tremor
- Bilateral thalamotomy
- Conditions:
  - A neurodegenerative condition
  - Unstable cardiac disease
  - Coagulopathy
  - Risk factors for deep-vein thrombosis
  - Severe depression (defined by a score ≥20 on Patient Health Questionnaire 9 (PHQ-9))
  - Cognitive impairment (defined by a score of <24 on the Mini–Mental State Examination)
  - Previous brain procedure (transcranial magnetic stimulation, DBS, stereotactic lesioning, or electroconvulsive therapy)
  - A skull density ratio (the ratio of cortical to cancellous bone) <0.45
  - MRI contraindicated

Related Medicare Advantage Policy Guideline
- Category III CPT Codes

Related Medicare Advantage Coverage Summary
- Radiologic Therapeutic Procedures

Related Medicare Advantage Policy Guideline
- Radiologic Therapeutic Procedures
### APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0398T</td>
<td>Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed</td>
</tr>
</tbody>
</table>

**Coding Clarification:** This section lists code(s) for states where provisional coverage may be provided

<table>
<thead>
<tr>
<th>ICD-10 Diagnosis Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>G25.0</td>
<td>Essential tremor</td>
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</table>

### PURPOSE

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:
- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the **References** section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

### REFERENCES

**CMS Local Coverage Determinations (LCDs) - Provisional**

<table>
<thead>
<tr>
<th>Provisional Coverage LCD</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
</tr>
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<tbody>
<tr>
<td>L37421 (Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Essential Tremor) NGS</td>
<td>CT, IL, MA, ME, MN, NH, NY, RI, VT, WI</td>
<td>CT, IL, MA, ME, MN, NH, NY, RI, VT, WI</td>
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<tr>
<td>L37790 (Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Essential Tremor) CGS</td>
<td>KY, OH</td>
<td>KY, OH</td>
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<tr>
<td>L37761 (Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Essential Tremor) Palmetto</td>
<td>AL, GA, TN, NC, SC, VA, WV</td>
<td>AL, GA, TN, NC, SC, VA, WV</td>
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<tr>
<td>L35490 (Category III Codes) WPS</td>
<td>IA, IN, KS, MI, MO, NE</td>
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**CMS Local Coverage Determinations (LCDs) - Noncovered**

<table>
<thead>
<tr>
<th>Noncovered LCD</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
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<tbody>
<tr>
<td>L33777 (Noncovered Services) First Coast</td>
<td>FL, PR, VI</td>
<td>FL, PR, VI</td>
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<tr>
<td>L35094 (Services That Are Not Reasonable and Necessary) Novitas</td>
<td>AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA TX</td>
<td>AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA TX</td>
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</table>
UnitedHealthcare Commercial Policies

Omnibus Codes

GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<tbody>
<tr>
<td>04/10/2019</td>
<td>• Annual review</td>
</tr>
<tr>
<td></td>
<td>• Available CMS sources reviewed and updated</td>
</tr>
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</table>

TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member’s benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.