

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS

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November 16, 2017

Craig Haug, MD, Medical Director
National Government Services, Inc.
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LCD Policy Comment Unit
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Submitted electronically via PartBLCDComments@anthem.com

SUBJECT: LCD DL37421-Draft LCD for MRgFUS for Essential Tremor

Dear Dr. Haug,

The American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS) and the American Association of Stereotactic and Functional Neurosurgery (ASSFN) appreciate the opportunity to comment on the proposed local coverage determination (LCD) titled "Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Essential Tremor: DL37421." Based on the current literature, we request that National Government Services (NGS), Inc., cover unilateral MRgFUS thalamotomy for patients with essential tremor (ET) who cannot be controlled with medication or who are not candidates for Deep Brain Stimulation (DBS) therapy.

Approved procedures for treatment of ET currently include:

- CPT 61720 *Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus;*
- CPT 61863 *Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array;*
- CPT 61867 *Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; first array, and the associated "additional array" codes (CPT +61864, CPT +61868).*

All of these codes require passing a probe through brain tissue, and in the case of CPT 61720, also require creating a lesion with a radiofrequency (RF) probe.

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A recent Level I double-blinded, randomized, sham-controlled trial published in the *New England Journal of Medicine* (Elias, Lipsman et al., 2016) demonstrated clinically meaningful benefit from MRgFUS thalamotomy for ET patients that were refractory to medical therapy. The major findings from this study, which led to FDA approval in July 2016, include:

- Contralateral upper limb tremor score (maximum 32 points), the primary study endpoint, was significantly improved following transcranial MRgFUS thalamotomy than from sham procedures at three months ($p < 0.001$). Mean contralateral hand tremor score improved by 47% following MRgFUS thalamotomy (18.1 ± 4.8 at baseline vs. 9.6 ± 5.1 at 3 months) and did not change in the control cohort who received sham procedure (16.0 ± 4.4 at baseline vs. 15.8 ± 4.9 at three months).
- The improvement from baseline resulting from MRgFUS persisted throughout the study period with mean, contralateral hand tremor score of 10.9 ± 4.9 ($p < 0.001$) at 12 months, a 40% improvement.
- An unblinded cohort of 21 subjects (19 sham crossover and two prior incomplete thalamotomies) was treated after the three month blinded assessment period. Their mean, contralateral hand tremor score improved by 55% at 3 months (16.5 ± 4.2 to 7.4 ± 3.9 , $p < 0.001$) and by 60% at 6 months (16.5 ± 4.2 to 8.0 ± 3.9 , $p < 0.001$).
- Regarding safety, there were no serious peri-procedural adverse events, and the one serious adverse event was a moderate thumb paresthesia that persisted. All other adverse events were categorized as mild or moderate with the majority being transient and the most common being sensory paresthesias (14% at 12 months) and gait disturbance (9% at 12 months).

Transcranial MRgFUS is an alternative to the current open surgical methods of treating ET; it differs from other surgical methods because it does not involve incising the skin, opening the skull, and passing surgical instruments through brain tissue. RF thalamotomy and MRgFUS thalamotomy both create a thermocoagulation lesion in the thalamus.

MRgFUS has similar clinical outcomes to RF thalamotomy and thalamic DBS. The safety profile is superior to RF thalamotomy. **To date, MRgFUS is the only surgical therapy for medication-refractory ET with class 1 evidence from a contemporary RCT.** We recommend NGS cover unilateral MRgFUS thalamotomy for patients with essential tremor who cannot be controlled with medication therapy or who are not candidates for DBS.

The AANS and CNS appreciate the opportunity to comment on this proposed LCD. If you have any questions or need further information, please feel free to contact us.

Sincerely,



Alex B. Valadka, MD, President
American Association of Neurological Surgeons



Ashwini D. Sharan, MD, President
Congress of Neurological Surgeons

Craig Haug, MD
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