

AMERICAN ASSOCIATION OF  
NEUROLOGICAL SURGEONS

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American  
Association of  
Neurological  
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Congress of  
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CONGRESS OF  
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Debra L. Patterson, MD, Vice President, Clinical Affairs  
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Submitted electronically via [debra.patterson@novitas-solutions.com](mailto:debra.patterson@novitas-solutions.com)

**SUBJECT: LCD DL35094, Non-coverage for MRgFUS for Essential Tremor**

Dear Dr. Patterson:

The American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS) and American Society for Stereotactic and Functional Neurosurgery (ASSFN) appreciate the opportunity to comment on the proposed local coverage determination (LCD) titled "Services That are not Reasonable and Necessary: L35094." In particular, we are concerned about the inclusion on this list of Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Essential Tremor, reported with CPT Category III Code 0398T. We strongly urge Novitas to remove this procedure from the non-covered list and to begin the process of issuing a positive coverage policy for MRgFUS for the treatment of idiopathic essential tremor (ET) patients with medication-refractory tremor.

Novitas is an outlier among other Medicare payors regarding coverage for this important procedure. Currently, six Medicare Administrative Contractors (MACs) provide coverage for MRgFUS. Neurosurgery has actively participated with several MACs to support coverage for MRgFUS for appropriately selected patients and provided guidance regarding details of their policies. We welcome the opportunity to share our expertise on this subject.

We understand that Novitas has cited as a concern the fact that the FDA approval for MRgFUS included a requirement for five years of follow-up data. Post-market data requirements of five years for post-approval review is becoming increasingly common for many new technologies cleared by the FDA. The FDA has approved the device as safe and effective based on the data submitted in the pre-market application (PMA) initially submitted. The post-market requirement for additional data should not be a barrier to coverage and has not been with other MACs. For patients with essential tremor that is refractory to medical treatment, MRgFUS is an alternative to open surgical treatment methods that involve incising the skin, opening the skull and passing surgical instruments through brain tissue.

The AANS, CNS and ASSFN appreciate the opportunity to comment on this issue. We are eager to understand the Novitas rationale, as we believe that Novitas' policy is limiting our patients' access to the highest quality of care. For this reason, we strongly recommend that Novitas change its coverage policy to reflect the best available literature and remove MRgFUS from the non-coverage list. Our clinical and coding experts would welcome an opportunity to have a conference call regarding this matter with members of your coverage policy team, and Catherine Hill on our staff can help with these

arrangements. In the meantime, if you have any questions or need further information, please feel free to contact us.

Thank you for considering our comments.

Sincerely,



Shelly D. Timmons, MD, PhD, President  
American Association of Neurological Surgeons



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



Robert Gross, MD, President  
American Society for Stereotactic and Functional Neurosurgery

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