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December 19, 2018

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Subject: CMS Proposed Decision Memo for Vagus Nerve Stimulation (VNS) for Treatment-Resistant Depression (TRD) (CAG-00313R2)

Dear Ms. Jensen:

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 above referenced draft coverage decision memo regarding Medicare coverage for vagus nerve stimulation (VNS) for treatment-resistant depression (TRD), released on November 19, 2018.

As we mentioned in our comments submitted on June 29, 2018, when CMS announced their intention to review their non-coverage decision for VNS for TRD, we support coverage for this procedure. Despite decades of research, patients with TRD continue to have very limited options. We are pleased to see that CMS will be permitting some Medicare patients to have access to this important treatment option for their TRD. However, we question the decision to restrict Medicare coverage to patients enrolled in a clinical trial. We feel the current literature submitted as part of the initial request for review is robust and shows clear evidence of efficacy and cost-benefit for VNS for TRD. Medicare patients who meet the established criteria for this treatment should, therefore, have unfettered access to this life-changing and life-saving therapy. As part of the FDA approval process in 2005 and since that time, a strong body of evidence has been developed for VNS for TRD. With suicide continuing to be among the top ten causes of death in the United States, we urge CMS to make this potentially life-saving procedure available to appropriately selected patients without undue burden on the patient or the treating surgeon.

Rather than requiring a prospective randomized controlled trial that will duplicate pivotal studies that have already shown VNS for TRD to be safe and effective, we would urge the agency to consider less onerous options for further evidence development, such as participation in clinical registries. Gathering real world experience outside of the study setting would be more useful than restricting coverage to study populations. Given the current state of the evidence, withholding this effective treatment from appropriately selected patients that we know are good candidates for the procedure and likely to benefit is unethical. Patients with TRD by definition have tried and failed other treatment options and are at high risk for suicide. Furthermore, although the draft decision memo proposes coverage for patients in a clinical trial, the patient would be subject to a co-payment, even if they were placed in the implanted but untreated control group. In addition to the ethical considerations of sham surgery, there is the practical

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issue of difficulty in replicating the experience of having the device turned on for the patients in the control group. For all of the reasons stated, we urge the agency to finalize a national coverage policy with fewer restrictions and a greater consideration of the clear efficacy and safety of VNS for TRD.

Thank you for considering our recommendations. Please contact us if you have any questions or need additional information.

Sincerely,

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