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Subject: CMS National Coverage Analysis (NCA) 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 the 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).

Despite decades of research, patients with TRD continue to have very limited options. In fact, in four decades, there has not been a single new and unique class of medication to address this significantly at-risk population that has reached the market. The only new available therapy that has received Medicare coverage is repetitive transcranial magnetic stimulation (rTMS), the results of which are described below. While VNS for TRD had been FDA approved since 2005, CMS' 2007 National Coverage Determination (NCD) has left Medicare patients without this significant treatment option for their TRD — despite the continuing body of evidence of its efficacy and cost-benefit for society.

Following FDA approval in 2005, the body of evidence for VNS's effectiveness for TRD has continued to grow. Two significant post-market studies have clearly demonstrated the substantial benefit of VNS for patients with TRD.[1,2] In essence, these studies demonstrate the overwhelming advantage of VNS compared to the standard combination of cognitive and pharmacotherapies. In particular, the second study, published in 2017, showed a significantly higher 5-year cumulative response rate (67.6% compared with 40.9%) and a significantly higher remission rate (cumulative first-time remitters, 43.3% compared with 25.7%). These studies represent the largest and longest cohort of patients ever published with TRD and represent a major addition to the medical literature. The outcomes of VNS for TRD far exceed those reported in rTMS trials for TRD, in which response rates are 15-27%, and remission rates are 14-30%.[3] These short-term rTMS outcomes (not accounting for post-rTMS relapse) are significantly inferior to the long-term outcomes reported for VNS, highlighting the important role that VNS therapy can play in the management of TRD.

While cost-analysis is not a part of the metric CMS uses to make coverage decisions, it is useful to bring to your attention the following data. An analysis of the Medicare population with TRD have shown that VNS can reduce annual costs of treatment by 36 percent.[4] Given the growing efficacy data and the cost/

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benefit to our payment systems, there are very few data-driven arguments against offering VNS as an option for TRD. Moreover, there is accumulating evidence of the long-term safety of VNS.[5]

The AANS, CNS, and ASSFN concur with comments submitted by the American Psychiatric Association (APA) on September 6, 2006, which support Medicare coverage of VNS for TRD in patients who are deemed appropriate candidates for this device. As neurosurgeons, we look forward to the ongoing collaboration with our colleagues in psychiatry in bringing this method of treatment to these patients.

In 2005, the FDA assessed that this device met the legal standard of reasonable assurance of safety and effectiveness and recommended further studies. The continually growing body of evidence over the last decade suggests that this standard has now been surpassed. TRD is a potentially fatal illness, as suicide continues to be among the top ten causes of death in the United States.[6] Medicare patients who meet the established criteria for this treatment should, therefore, have unfettered access to this life-changing and life-saving therapy.

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

Sincerely,

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