



March 30, 2020

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Via e-mail: shtap@hca.wa.gov

Subject: Washington State Health Care Authority Evidence Report for Re-review of Vagus Nerve Stimulation (VNS) for Epilepsy and Depression

Dear Mr. Morse:

On behalf of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), the American Society for Stereotactic and Functional Neurosurgery (ASSFN) and the Washington State Association of Neurological Surgeons (WSANS), we appreciate the opportunity to review the draft evidence report prepared by the Center for Evidence-based Policy of the Oregon Health & Science University for the review of vagus nerve stimulation (VNS) for epilepsy and treatment-resistant depression (TRD). As we have previously noted, we support the re-review of this topic by the Washington State Health Care Authority (HCA) Health Technology Assessment (HTA) program. We believe that new evidence, which has become available since the HTA program's non-coverage decision in 2009, warrants a change to positive coverage.

Despite decades of research, patients with treatment-resistant depression (TRD) continue to have very limited options. We were pleased to see that the Washington State HTA program has recognized that additional evidence exists for VNS for TRD, and we hope the HCA HTA Health Technology Clinical Committee will recommend positive coverage to allow patients in the state of Washington to have access to this critical treatment option for their TRD. We believe the current literature is robust and shows clear evidence of efficacy and cost-benefit for VNS for TRD. As part of the Food and Drug Administration (FDA) approval process in 2005, and since that time, a substantial 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 the HCA to make this potentially life-saving procedure available to appropriately selected patients without undue burden on the patient or the treating surgeon.

Organized neurosurgery has been active in reviewing, commenting on, and attending meetings regarding procedures under consideration by the HCA HTA program for over a decade. We share a common dedication to safe and effective treatments, and nothing is more important to our members than the well-being of their patients. We disagree with the evidence report conclusion that "there is a lack of robust evidence on the effectiveness of VNS for depression in adults." We believe the evidence generated over the last ten years that the HCA cited to open the reconsideration supports coverage for appropriately selected patients. In particular, there is extensive evidence that neuromodulatory interventions for epilepsy have increasing efficacy over a matter of years, and that this is very likely to be true for behavioral disorders such as depression. Attempting to show this with Class I evidence would be unethical and impractical as patients in a double-blind study would have to undergo sham treatment for years. We do have open-label evidence of efficacy over a five-year time-frame,¹ and we believe that this is compelling. It shows significantly improved cumulative five-year response rate, significantly improved remission rates, and significantly lower mortality in the VNS group compared with treatment as usual.

In their February 2019 decision memo, CMS provided a coverage pathway for new patient implants as part of the coverage with evidence development trial. At a minimum, the Washington State HCA should provide similar access to all appropriately selected patients with documented TRD. Requiring patients with no other options to wait for the completion of more studies leaves them with no hope for improvement of their severe, disabling, and, in some cases, life-threatening depression. While we agree that coverage for study patients is better than no coverage at all, we do not believe that requiring a prospective randomized controlled trial that will duplicate pivotal studies that have already shown VNS for TRD to be safe and effective is necessary. We would, therefore, urge the HCA to cover VNS for TRD and 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.

Thank you for considering our recommendations and for the reconsideration of the 2009 non-coverage policy for VNS for TRD. If you have any questions or need additional information, please do not hesitate to contact us.

Sincerely,



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Reference

1. Aaronson ST, Sears P, Ruvuna F, et al. A 5-year observational study of patients with treatment-resistant depression treated with vagus nerve stimulation or treatment as usual: comparison of response, remission, and suicidality. *Am J Psychiatry*. 2017;174(7):640-648. doi: 10.1176/appi.ajp.2017.16010034.