



American
Association of
Neurological
Surgeons



Congress of
Neurological
Surgeons



March 27, 2019

Josiah Morse, MPH, Program Director
Washington State Health Care Authority
Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

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

Subject: Washington State Health Care Authority Proposal 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 wish to express our support for the inclusion of vagus nerve stimulation (VNS) for epilepsy and treatment-resistant depression (TRD) on the list of procedures for re-review by the Washington State Health Care Authority (HCA) Health Technology Assessment (HTA) program in 2019. We agree with the HCA that new evidence has become available since the HTA program decision in 2009 not to cover VNS for depression.

Despite decades of research, patients with treatment-resistant depression (TRD) continue to have very limited options. We are pleased to see that the Washington State HTA program has recognized that additional evidence exists for VNS for TRD and we hope the review will result in a policy that will permit more patients in the state of Washington to have access to this important 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 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 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 are pleased the HCA has recognized the existence of new data and will review and consider reversing its 2009 decision not to cover VNS for depression. We note that the Centers for Medicare & Medicaid Services (CMS) has recently changed its non-coverage policy to permit coverage for patients enrolled in a clinical trial. 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 including a reconsideration of the 2009 non-coverage policy for VNS for TRD on the list of policies for review in 2019. If you have any questions or need additional information, please do not hesitate to contact us.

Sincerely,



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



Ganesh Rao, MD, FAANS, President
Congress of Neurological Surgeons



Robert E. Gross, MD, PhD, FAANS, President
American Society for Functional and
Stereotactic Neurosurgery



Jean-Christophe Leveque, MD, President
Washington State Association of Neurological
Surgeons

Staff Contact:

Catherine Jeakle Hill
Senior Manager, Regulatory Affairs
AANS/CNS Washington Office
25 Massachusetts Avenue, NW, Suite 610
Washington, DC 20001
Phone: 202-446-2026
E-mail: chill@neurosurgery.org