



December 17, 2018

Tamara Syrek Jensen, JD  
Director, Coverage and Analysis Group  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Mail Stop S3-02-01  
Baltimore, MD 21244-1850

Dear Ms. Jensen:

I am writing on behalf of the Association for Behavioral Health and Wellness (ABHW). ABHW is the national voice for payers that manage behavioral health insurance benefits. ABHW member companies provide coverage to approximately 200 million people in both the public and private sectors to treat mental health, substance use disorders, and other behaviors that impact health and wellness. We appreciate the opportunity to comment on the Proposed Decision Memo for Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD) (CAG-00313R2).

ABHW is supportive of research to determine whether or not VNS is an appropriate treatment for TRD. We recognize the impact that TRD has on the health and well-being of individuals, on employment, and on health care spending. However, we believe this research should be done via a grant, perhaps from the National Institutes of Health (NIH), or by the companies seeking coverage for the VNS treatment they developed. We do not believe it is the role of the Centers for Medicare and Medicaid Services (CMS) to fund a clinical trial via the Medicare program and are unaware of this approach being considered a common practice. In fact, we believe moving forward with implementation of the proposed Decision Memo would set a dangerous precedent for Medicare, and other federal programs, funding services through investigational studies.

This proposal sets up a scenario where CMS is in essence diverting federal treatment dollars to fund research of a treatment that has limited evidence to date. We also don't believe that CMS is in the best position to be evaluating clinical trials or making judgements on their results. Is there something that makes VNS so different that it can't go through the normal clinical trial process with research dollars from usual funders instead of having the program funded by the Medicare program that typically pays for evidence based treatment?

Additionally, as we read the proposed Decision Memo it is setting up a scenario where the managed care organization (MCO) has to manage the investigational randomized trials. This is outside the normal scope of a payer. MCOs are not set up to adjudicate who should be approved for a clinical trial without Institutional Review Board (IRB) protections. Furthermore, there is not a lot of valid science available to make a decision regarding who gets enrolled in a VNS trial and the criteria in the proposed Decision Memo that must be used to identify patients demonstrating TRD is vague. For example, there is no definition of "adequate" dose and duration of treatment in the criteria that the patient must have "four prior failed treatments of adequate dose and duration."

We urge CMS to encourage funding for VNS clinical trials through a source other than the Medicare program.

Thank you again for the opportunity to comment on the proposed Decision Memo. If you would like to discuss ABHW's comments please call Pamela Greenberg, MPP, President and CEO, at (202) 449-7660.

Sincerely,

Pamela Greenberg, MPP  
President and CEO