

Medical Affairs Policy & Procedure

Title/Service: Vagus Nerve Stimulation

Revised	
Reviewed	01/28/01, 04/26/02, 07/02/04, 06/02/06, 11/16/07, 11/21/08, 12/28/09, 10/22/10, 11/18/11
Developed	
Policy Committee Approval	11/18/11

Description:

Vagus nerve stimulation (VNS) is a treatment for intractable epilepsy where intermittent electrical pulses are delivered to the cervical portion of the vagus nerve by a generator that is usually implanted in the chest. The goal of VNS is a reduction on the frequency and/or severity of seizures in patients whose seizures are refractory to medications.

Indications of Coverage:

Vagus nerve stimulation is considered medically necessary when all of the following are documented:

The individual is over twelve years of age

The individual has been diagnosed with intractable epilepsy for a minimum of two years and is experiencing a minimum of four identifiable partial onset seizures each month

The individual continues to experience seizures despite a trial of two or more anti-seizure medications

The seizures significantly interfere with activities of daily living (ADLs)

Surgery to remove a seizure focus is contraindicated or has previously failed

Limitations of Coverage:

Review contract and endorsements for exclusions and prior authorization or benefit requirements.

If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative. **Intractable epilepsy is the only approved condition/diagnosis covered for this device/procedure.**

If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

Vagus nerve stimulation is considered not medically necessary when any of the following are documented:

- Malignancy of the brain
- Rasmussen's encephalitis
- Landau-Kleffner syndrome
- Progressive metabolic and degenerative disorders

Vagus nerve stimulation is considered investigational for the treatment of depression as there is insufficient peer-reviewed scientific literature supporting the effectiveness of the treatment.

Documentation Required:

- Office notes and relevant prior procedure reports

Rationale:

Clear guidelines regarding patient selection criteria and stimulation levels have not been established for VNS, but an assessment by the American Academy of Neurology supports the use of the device in selected individuals diagnosed with untreatable epilepsy when other treatment has failed or is contraindicated. Recently there has been increased interest in the effectiveness of VNS for the treatment of depression. Several recent analyses, including a comprehensive review by CMS, found that the use of VNS for depression could not be supported.

References:

1. BlueCross BlueShield Association (BCBSA), Technology Evaluation Center (TEC). Vagus Nerve Stimulation for Treatment-Resistant Depression. TEC Assessment Program. Chicago, IL. August 2006; 21(7). Available at: www.bcbs.com/blueresources/tec/tec-assessments.html. Accessed: 7 Oct 10.
2. Center for Medicare and Medicaid Services (CMS). National Coverage Analysis: Vagus Nerve Stimulation for Treatment of Resistant Depression. Baltimore, MD. May 4, 2007. Available at: www.cms.gov/mcd/viewnca.asp?where=index&nca_id=195&basket=nca:00313R:195:Vagus+Nerve+Stimulation+for+Treatment+of+Resistant+Depression+%28TRD%29:Close:d:1st+Recon:19. Accessed: 7 Oct 10.
3. Center for Medicare and Medicaid Services (CMS). National Coverage Decision: Vagus Nerve Stimulation. NCD 160.18. Effective date: 05/04/07. Available at: www.cms.gov/mcd/index_list.asp?list_type=ncd. Accessed: 7 Oct 10



4. Fisher R, Handforth A. Reassessment: VNS for epilepsy: a report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology (AAN). Available at: www.neurology.org/cgi/reprint/53/4/666.pdf. Accessed: 7 Oct 10.

Approved by the Medical Director