

Policy Number: MP.025.MPC Last Review Date: 05/27/2021 Effective Date: 08/01/2021

MP.025.MPC - Vagus Nerve Stimulators

Maryland Physicians Care considers **Vagus Nerve Stimulators (VNS)** medically necessary for the following indications:

- 1. Members over 4 years of age with intractable partial onset seizures who remain refractory to optimal anti-epileptic medications and/or surgical intervention.
- 2. Members over 4 years of age with intractable generalized seizures who remain refractory to optimal anti-epileptic medications and/or surgical intervention may be benefited.

Limitations

- 1. VNS is considered experimental and investigational; and therefore, it is not covered for all other indications including, but not limited to: depression, addictions, anxiety disorders, bulimia, migraines, mood disorders, and heart failure.
- 2. All other types of seizure disorders not indicated in this policy.
- 3. Members 4 years old and younger.
- 4. Benefits may improve over several months trial
- 5. Members who have undergone LEFT vagotomy.
- 6. Members with untreated bradycardia and AV conduction abnormalities.
- 7. Members with suspected OSA should be evaluated and treated prior to VNS implantation.

Background

The Centers for Medicare and Medicaid (CMS) defines VNS as a pulse generator implanted in the left chest with an electrical lead wire connected to the left vagus nerve. The pulse generator sends electrical signals to the vagus nerve and eventually to the brain. Electrical stimulation of the vagus nerve has been shown to interrupt epileptic discharges and prevent seizures. VNS is an FDA approved effective therapy for management of medically refractory partial onset seizures due to epilepsy. VNS has shown to reduce both frequency and severity of seizures in patients that are unresponsive to antiepileptic medications.

The Cyberonics VNS Therapy System was approved by the FDA in 1997 as an adjunctive therapy for reducing frequency of seizures in adults and adolescents and children aged 4 years and over who remain refractory to antiepileptic medications and surgical interventions. VNS Therapy is continuing to be investigated as a potential



Policy Number: MP.025.MPC Last Review Date: 05/27/2021 Effective Date: 08/01/2021

treatment for anxiety disorders, Alzheimer's disease, chronic headache/migraine and bulimia.

Codes:

CPT Codes	/ HCPCS Codes / ICD-10 Codes
Code	Description
64553	Percutaneous implantation of neurostimulator electrodes, cranial nerve
64568	Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
64569	Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling, with connections to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling, with connections to two or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
ICD-10 code	es covered for 64568 and 64569
G40.A11	Absence epileptic syndrome, intractable, w/status epilepticus
G40.A19	Absence epileptic syndrome, intractable, w/o status epilepticus
G40.111	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus
G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus
G40.211	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus
G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus
G40.311	Generalized idiopathic epilepsy and epileptic syndromes, intractable, with status epilepticus



Policy Number: MP.025.MPC Last Review Date: 05/27/2021 Effective Date: 08/01/2021

G40.319	Generalized idiopathic epilepsy and epileptic syndromes, intractable, without status epilepticus
G40.911	Epilepsy, unspecified, intractable, with status epilepticus
G40.919	Epilepsy, unspecified, intractable, without status epilepticus

References

- Beekwilder JP, Beems T. Overview of the Clinical Applications of Vagus Nerve Stimulation. J Clin Neurophysiol. 2010 Apr;27(2):130-8. doi: 10.1097/WNP.0b013e3181d64d8a. <u>http://www.ncbi.nlm.nih.gov/pubmed/20505378</u>
- 2. Center for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) No. 160.7 Electrical Nerve Stimulators Effective: 08/07/1995. <u>http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=240&ncdver=1&bc=AAAAgAAAAAAAA3d%3d&</u>
- 3. Center for Medicare and Medicaid Services (CMS): National Coverage Determination (NCD) No. 160.18 - Vagus Nerve Stimulation (VNS). Effective Date: 07/23/2007. <u>http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=230&ncdver=2&bc=AAAAgAAAAAAAAA3d%3d&</u>
- 4. Cyberonics: Important safety information-brief summary of safety information for the VNS therapy system (epilepsy and depression indications). January 2012. https://vnstherapy.co.uk/safety-information
- Department of Health and Human Services (HHS). Agency for Healthcare Research and Quality (AHRQ). National Guideline Clearinghouse (NGC). Evidence-based guideline update: vagus nerve stimulation for the treatment of epilepsy. Report of the Guideline Development Subcommittee of the American Academy of Neurology. NGC: 010046. Dated: Nov. 18, 2013. <u>http://www.guideline.gov/content.aspx?id=47336&search=vagus+nerve+stimulat</u> ors
- Englot DJ, Chang EF, Auguste KI. Vagus nerve stimulation for epilepsy: a metaanalysis of efficacy and predictors of response. A review. J Neurosurg. 2011 Dec; 115(6): 1248-1255. <u>http://thejns.org/doi/abs/10.3171/2011.7.JNS11977?url_ver=Z39.88-</u> 2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed&
- Karceski S, Schacter SC. Vagus nerve stimulation therapy for the treatment of epilepsy. UpToDate®. Last updated: April 27, 2018. Topic 2229. Version: 12.0. <u>http://www.uptodate.com/contents/vagus-nerve-stimulation-therapy-for-thetreatment-ofepilepsy?topicKey=NEURO%2F2229&elapsedTimeMs=4&view=print&displayed View=full
 </u>



Policy Number: MP.025.MPC Last Review Date: 05/27/2021 Effective Date: 08/01/2021

- National Institute for Health and Clinical Excellence (NICE). Interventional Practice Guidelines (IPG) No. 330. Vagus nerve stimulation for treatmentresistant depression. Issued: December 2009. <u>https://www.nice.org.uk/guidance/ipg330</u>
- 9. National Institute of Neurological Disorders and Stroke. NINDS Epilepsy Information Page. Last updated: June 18, 2018. Available at: <u>http://www.ninds.nih.gov/disorders/epilepsy/epilepsy.htm</u>
- 10. Rush AJ, Sackeim HA, Marangell LB. Effects of 12 Months of Vagus Nerve Stimulation in Treatment-Resistant Depression: A Naturalistic Study. Biol Psychiatry. 2005 Sep 1;58(5):355-363. https://pubmed.ncbi.nlm.nih.gov/16139581/
- 11. U.S. Food and Drug Administration (FDA). VNS Therapy System-P970003/S050 - Summary of Safety and Effectiveness Data. Panel Recommendation: June 15, 2004. http://www.accessdata.fda.gov/cdrh_docs/pdf/P970003S050b.pdf
- 12. U.S. Food and Drug Administration (FDA). VNS Therapy System- P970003s050. Approval Date 07/15/2005 <u>https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970003</u> <u>S050</u>

Archived References

 Hayes Medical Technology Director. Vagus Nerve Stimulation for Epilepsy. Publication date: 06/09/2014. Annual review date: 05/28/2018. Archived: 07/09/2019.

Disclaimer:

Maryland Physicians Care medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of Maryland Physicians Care and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

Maryland Physicians Care reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.



Policy Number: MP.025.MPC Last Review Date: 05/27/2021 Effective Date: 08/01/2021

These policies are the proprietary information of Maryland Physicians Care. Any sale, copying, or dissemination of said policies is prohibited.

