Vagus Nerve Stimulation (VNS)

Date of Origin: 12/2008 **Last Review Date: 05/27/2020** **Effective Date: 06/01/2020**

Dates Reviewed: 07/2010, 07/2011, 07/2012, 05/2013, 07/2014, 01/2016, 01/2017, 06/2018, 05/2019, 05/2020

Developed By: Medical Necessity Criteria Committee

I. Description

A vagus nerve stimulator (VNS) is an implantable device that is used as an adjunctive treatment for medical refractory partial onset seizures. Similar to a pacemaker, the VNS pulse generator is surgically implanted under the skin near the collar bone. A lead wire connects the pulse generator to the left vagus nerve in the neck. The VNS is then programmed to produce weak electrical signals that travel along the vagus nerve to the brain at regular intervals. These signals help prevent the electrical bursts in the brain that cause seizures.

II. Criteria (CWQI: HCS-0068A)

A. Moda Health considers vagus nerve stimulators medically necessary durable medical equipment (DME) and will allow coverage to plan limitations when **ALL** of the following criteria are met
   a. The member is 4 years of age or older (FDA approved for 4 years old and older);
   b. The member has not had a bilateral or Left cervical vagotomy
   c. The member has medically refractory partial onset seizures and **1 or more** of the following:
      i. Medically refractory seizures that occur in spite of therapeutic levels of anti-epileptic medications; **or**
      ii. Seizures that cannot be treated with therapeutic levels of anti-epileptic drugs because of intolerable side effects
   d. Unsuccessful surgical intervention *(lesionectomy or medial temporal lobectomy)* with **1 or more** of the following conditions:
      i. Seizures refractory to surgical intervention
      ii. Patient was not a surgical candidate
      iii. Patient refused surgical intervention

B. Note – Electronic analysis of an implanted neurostimulator pulse generator system for VNS is considered medically necessary when criteria are met

C. Moda Health considers replacement/revision of a vagus nerve therapy system/handheld magnet medically necessary if the original system/magnet met criteria as medically necessary and is no longer under warranty and cannot be repaired.

D. Moda Health considers vagus nerve stimulation experimental and investigational for use in treatment-resistant depression due to the lack of well-designed controlled clinical trials. Only one randomized control trial evaluating the effectiveness of VNS for treatment-resistant depression has

been identified. This study did not find statistically significant improvement on most measures of depression. Therefore, the available evidence is not sufficient to permit conclusions on the effect of VNS therapy on health outcomes or its effects compared with alternative therapies for depression treatment.

E. Moda Health considers vagus nerve stimulation experimental and investigational for the treatment of all other indications, including but not limited to, addictions, Alzheimer's disease, anxiety disorders, autism, cognitive impairment associated with Alzheimer's disease, depression, headaches, obesity, obsessive compulsive disorder and Tourette's syndrome. The effectiveness of vagus nerve stimulation for the treatment of these, or other conditions, has not been established.

III. Information Submitted with the Prior Authorization Request:

1. Medical records from the treating neurologist documenting a diagnosis of partial onset seizures as well as medical and surgical treatment tried and failed.

IV. Applicable CPT or HCPC codes

Codes	Description
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode array
64553	Percutaneous implantation of neurostimulator electrodes; cranial nerve
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64569	Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
64570	Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
L8682	Implantable neurostimulator radiofrequency receive
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receive
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes Extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

V. References

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22. Physician Advisors

VI. Annual Review History

Review Date	Revisions	Effective Date
05/2013	Annual Review: Added table with review date, revisions, and effective date.	05/2013
07/2014	Annual Review: No change	07/2014
01/2016	Annual Review: No change	01/27/2016
01/2017	Annual Review: Updated to new template, removed word refractory from the depression indication in III.C	01/25/2017
06/2018	Annual Review: No change	06/27/2018
05/2019	Annual Review: Updating and rewording the criteria. Removed deleted codes	06/01/2019
05/2020	Annual Review: No content changes	06/01/2020

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
G40.A01	Absence epileptic syndrome, not intractable, with status epilepticus
G40.A09	Absence epileptic syndrome, not intractable, without status epilepticus
G40.A11	Absence epileptic syndrome, intractable, with status epilepticus
G40.A19	Absence epileptic syndrome, intractable, without status epilepticus
G40.101	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, with status epilepticus
G40.109	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, not intractable, without 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
G40.201	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, with status epilepticus
G40.209	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable, without status epilepticus

ICD-10	ICD-10 Description
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
G40.301	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, with status epilepticus
G40.309	Generalized idiopathic epilepsy and epileptic syndromes, not intractable, without status epilepticus
G40.311	Generalized idiopathic epilepsy and epileptic syndromes, intractable, with status epilepticus
G40.401	Other generalized epilepsy and epileptic syndromes, not intractable, with status epilepticus
G40.409	Other generalized epilepsy and epileptic syndromes, not intractable, without status epilepticus
G40.411	Other generalized epilepsy and epileptic syndromes, intractable, with status epilepticus
G40.419	Other generalized epilepsy and epileptic syndromes, intractable, without status epilepticus
G40.501	Epileptic seizures related to external causes, not intractable, with status epilepticus
G40.509	Epileptic seizures related to external causes, not intractable, without status epilepticus
G40.802	Other epilepsy, not intractable, without status epilepticus
G40.804	Other epilepsy, intractable, without status epilepticus
G40.821	Epileptic spasms, not intractable, with status epilepticus
G40.822	Epileptic spasms, not intractable, without status epilepticus
G40.823	Epileptic spasms, intractable, with status epilepticus
G40.824	Epileptic spasms, intractable, without status epilepticus
G40.901	Epilepsy, unspecified, not intractable, with status epilepticus
G40.909	Epilepsy, unspecified, not intractable, without status epilepticus
G40.911	Epilepsy, unspecified, intractable, with status epilepticus
G40.919	Epilepsy, unspecified, intractable, without status epilepticus
O99.351	Diseases of the nervous system complicating pregnancy, first trimester
O99.352	Diseases of the nervous system complicating pregnancy, second trimester
O99.353	Diseases of the nervous system complicating pregnancy, third trimester
O99.355	Diseases of the nervous system complicating the puerperium
R56.01	Complex febrile convulsions
R56.1	Post traumatic seizures
R56.9	Unspecified convulsions

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

NCD/LCD Document (s): NCD 160.18
https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=230&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Oregon&KeyWord=Vagus+Nerve+Stimulation&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAAAA%3d%3d&

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC