Subject: Vagus Nerve Stimulation for Epilepsy and Depression

Medical Policy #: 22.4 **Original Effective Date:** 06/01/2006

Status: Reviewed **Last Review Date:** 12-13-2023

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

Vagus nerve stimulation (VNS) is used for the treatment of refractory epilepsy. A battery-powered generator is implanted under the skin of the left chest and an electrical lead (wire) is connected from the generator to the vagus nerve. Electrical signals are sent from the battery-powered generator to the vagus nerve via the lead. These signals are in turn sent to the brain.

Clinical evidence has shown that VNS is a safe and effective treatment for patients with medically refractory partial-onset seizures, for whom surgery has failed or is not an option. The aim of the adjunctive therapy is to reduce the frequency of seizures in adults and adolescents who have medically refractory, partial-onset seizures.

Coverage Determination

Prior Authorization is not required.

1. **For Treatment of Refractory Epilepsy:**

   VNS devices used for refractory of partial onset seizures for whom surgery is not recommended or for whom surgery has failed is a covered service:

   A. Covered for **Commercial.** PHP follows MCG guideline # **A-0424**. Due to contractual restrictions, providers may not access the MCG website but may obtain a copy of the criteria from the Prior Authorization staff.

   B. Covered for **Medicare and Medicaid.** PHP follows NCD for Vagus Nerve Stimulation (VNS), **(160.18)** for patients with medically refractory partial onset seizures for whom surgery is not recommended **or** for whom surgery has failed.

2. **For Treatment of Resistant Depression (TRD):**

   A. Non-covered for **Commercial and Medicaid**. PHP follows MCG, Vagus Nerve Stimulation, Implantable: Behavioral Health Care, ORG: B-821-T (BHG). Due to contractual restrictions, providers may not access the MCG website but may obtain a copy of the criteria from the Prior Authorization staff.

   B. Covered for **Medicare.** PHP follows NCD 160.18 for VNS devices for treatment resistant depression (TRD) through Medicare approved Coverage with Evidence Development (CED).

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT & HCPCS	CPT listing for Medicaid and Commercial
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array.
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve. (Not payable by NCD 160.18)
64568	Incision for implantation of cranial nerve neurostimulator electrode array and pulse generator.
64569	Revision or replacement of cranial nerve neurostimulator electrode array, including connection to existing pulse generator

CPT & HCPCS	CPT listing for Medicaid and Commercial
64570	Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), non-high frequency with rechargeable battery and charging system
C1827	Generator, neurostimulator (implantable), nonrechargeable, with implantable stimulation lead and external paired stimulation controller
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
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
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes

CPT	CPT listing for Medicare
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 2 or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
64568	Incision for implantation of cranial nerve neurostimulator electrode array and pulse generator.
64569	Revision or replacement of cranial nerve neurostimulator electrode array, including connection to existing pulse generator
64570	Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator.
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse

CPT	CPT listing for Medicare
	generator/transmitter programming by physician or other qualified health care professional.
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional.
C1827	Generator, neurostimulator (implantable), nonrechargeable, with implantable stimulation lead and external paired stimulation controller

ICD-10 CM codes
Please follow the link below for the NCD spreadsheets for ICD-10 CM for Seizures and TRD: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/CR13391.zip

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee: Gray Clarke MD
Medical Director: Ana Maria Rael MD
Date Approved: 12-13-2023

References

1. MCG Health, Ambulatory Care 27th Edition, Vagus Nerve Stimulation, Implantable, ACG: A-0424 (AC), Last update: 9/21/2023. [Cited 11/08/2023]
2. Hayes, VNS Therapy (LivaNova Inc.) for Seizure Control, Publication Date: March 16, 2018. Report Archived on: April 16, 2019. [Cited 10-24-2022].
3. Hayes, Vagus Nerve Stimulation for Epilepsy, ARCHIVED July 08, 2019. Annual review: May 25, 2018. [Cited 11/08/2023]
4. Hayes, Vagus Nerve Stimulation for Treatment Resistant Depression, Health Technology Assessment, Publication date:Feb 21, 2019, Annual review: Jan 26/2022. [Cited 11/08/2023]
5. CMS, National Coverage Determination (NCD- 160.18) for Vagus Nerve Stimulation (VNS), Effective Date of this Version: 02/15/2019 , Version 3. [Cited 11/08/2023]
6. CMS Manual System, Pub 100-20 One-Time Notification, https://www.cms.gov/files/document/r11025otn.pdf, Date September 28, 2021. [Cited 10/24/2022]
7. MCG -Vagus Nerve Stimulation, Implantable: Behavioral Health Care, ORG: B-821-T (BHG). Last updated 9/21/2023 [Cited 11/08/2023]
8. Hayes, Vagus Nerve Stimulation for Epilepsy in Pediatric Patients, Health Technology Assessment, Jan25, 2021, Annual review: March 24, 2023. [Cited 11/08/2023]
9. CMS 100-04, TN 11737- CR 13031, Date: January 20, 2023 [Cited 11/09/2023]

Publication History

06-01-06: Original effective date for Benefit Alert
11-18-09: Benefit Alert transitioned to Medical Policy
01-18-12: Review and Revised
01-30-13: Review and Revised
01-29-14: Presbyterian Policy Retired
01-29-14: Presbyterian now uses MCG Criteria A-0424
05-25-16: Annual Review. MCG A-0424 accessed. Last Update 1/28/16. No changes.
05-22-19: Annual Review. Noted future, upcoming changes to CMS NCD 160.18 for TRD coverage. No change in content of coverage for MCG.
11-18-20 Annual Review. Reviewed by PHP Medical Policy Committee on 10-14-2020. Coverage status changed: For Medicare members will now follow MCG N160.18v3 or NCD (160.18); changed Commercial and Medicaid to follow MCG A-0424 for treatment of Refractory Epilepsy. VNS is non- covered for Commercial and Medicaid for treatment of resistant depression (TRD) based on Hayes for treatment of resistant rapid cycling BPD and other payers consider this experimental. However, VNS will be covered for the treatment of TRD for Medicare only when furnished in a CMS approved CED study. Separate Tables were created to separate Medicare & Commercial from Medicare, since MCG and NCD (160.18) do not list CPT/HCPCS the same, also to avoid confusion. Removed erroneous HCPCS codes L8682 and L8683 from policy and added C1767 & C1778 to Medicaid and Commercial Table. Add CPT codes 61885, 64568, 64569, 64570, 95976, & 95977

to the Medicare Table. All listed codes will continue without PA. The following codes will be set to not pay: L8682, L8685, L8686, L8687, L8688, C1767, C1778 and 0466T for all LOB. Extended the name of title to include "for Epilepsy and Depression."

11-17-21 Annual review. Reviewed by PHP Medical Policy Committee on 11/03/2021.

1. Refractory Epilepsy:
   A. No change, non-Medicare will continue to follow MCG A-0424. Rationale: Hayes and other competitors (Aetna, Cigna, Humana and UHC) all support coverage for refractory epilepsy.
   B. No change, Medicare will continue to follow the coverage statement in NCD 160.18 for refractory seizure.
2. Treatment of Resistant Depression:
   A. No change, continue no coverage for Medicaid and commercial. PHP will now follow MCG -Vagus Nerve Stimulation, Implantable: Behavioral Health Care, ORG: B-821-T (BHG). Rationale: Magellan, Hayes and competitors (Aetna, Cigna, Humana and UHC) considers treatment for resistant depression as experimental and investigational.
   B. No change, Medicare will continue to follow NCD 160.18. VNS devices for treatment resistant depression (TRD) will be covered through Coverage with Evidence Development (CED).

OPPS HCPCS codes C1820 (Status-N- (see also MPM 7.2 & MPM 51.0 (previously configured)), L8679 (status Indicator-N), L8680 (status indicator- E1). Codes L8679 and L8680 will be set to not pay for all product line, (L8679 also applies to MPM 7.2 and L8680 also applies MPM 51.0). New codes added to policy from (NCD 160.18): 61886, 61888 and 64553. Prior Authorization will continue to not be required for all codes listed in policy.

11-16-22 Annual review. Reviewed by PHP Medical Policy Committee on 10-28-2022. No change.

1. Refractory Epilepsy: No change. Covered benefit for non-Medicare will continue to follow MCG A-0424. Medicare will continue to follow NCD 160.18 for refractory seizure.
2. Treatment of Resistant Depression: Continue non-coverage for Medicaid and commercial. Continue to follow MCG -Vagus Nerve Stimulation, Implantable: Behavioral Health Care, ORG: B-821-T (BHG). Medicare will continue to follow NCD 160.18. VNS devices for treatment resistant depression (TRD) will be covered through Coverage with Evidence Development (CED).

Continue no PA requirement.

12-13-23 Annual review. Reviewed by PHP Medical Policy Committee on 11/09/2023.

Refractory Epilepsy: Change. Medicaid will now follow Medicare. Both Medicare and Medicaid will follow NCD 160.18 for medically refractory partial seizure when surgery is not recommended or that surgery has failed. No change. Commercial will continue to follow MCG A-0424.

Treatment Resistant Depression (TRD): No change. Commercial and Medicaid will continue follow MCG B-821-as non-covered for VNS for treatment resistant depression. Medicare will continue to follow NCD 160.18 for VNS devices for TRD through Medicare approved Coverage with Evidence Development. Added code C1827 by directive of CMS TN/CR, that this code should be billed with 64568 under CED. Removed ICD-10 listings and replaced to see link for NCD spreadsheets for ICD-10 CM for both seizures and TRD. Continue CY 2021 config of OPPS HCPCS codes C1820-Status-N- (see also MPM 7.2 & MPM 51.0); L8679 (Status Indicator-N); L8680 (status indicator- E1).

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: ***Click here for Medical Policies***

Web links:

At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.