

## Clinical Policy: Vagus Nerve Stimulation

Reference Number: WA.CP.MP.12

Date of Last Review: 09/22

Effective Date: 11/01/24

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Vagus nerve stimulation (VNS) has been used in the treatment of epilepsy and has been studied for the treatment of refractory depression and other indications. Electrical pulses are delivered to the cervical portion of the vagus nerve by an implantable device called a neurocybernetic prosthesis. Chronic intermittent electrical stimulation of the left vagus nerve is designed to treat medically refractory epilepsy.<sup>1</sup> VNS has recently been introduced and approved by the Food and Drug Administration (FDA) as an adjunctive therapy for treatment-resistant major depression.<sup>2</sup>

### Policy/Criteria

- I. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's Health Technology Assessment and Health Care Authority Billing Guidelines, that vagal nerve stimulation for epilepsy is considered **medically necessary** when all the following are met:
  - A. Member/Enrollee is 4 years of age or over, and
  - B. Both of the following:
    - i. Seizure disorder is refractory to medical treatment, defined as adequate trials of at least 3 appropriate but different anti-epileptic medications.
    - ii. Surgical treatment is not recommended or has failed.
- II. It is the policy of Coordinated Care of Washington, Inc., in accordance with the Health Care Authority's Health Technology Assessment and Health Care Authority Billing Guidelines, that VNS therapy is **not medically necessary** for the treatment of depression.
- III. It is the policy of Coordinated Care of Washington, Inc., that the safety and efficacy of VNS therapy has not been proven for any other conditions, including but not limited to the following:
  - A. Headaches
  - B. Cognitive impairment associated with Alzheimer's disease
  - C. Addiction
  - D. Anxiety Disorders
  - E. Autism
  - F. Eating Disorders
  - G. Cancer
  - H. Crohn's Disease
  - I. Essential trauma
  - J. Fibromyalgia
  - K. Heart failure
  - L. Impaired glucose tolerance/pre-diabetes

- M. Inflammation
- N. Overweight and obesity
- O. Obsessive-compulsive disorder
- P. Panic disorder
- Q. Post-traumatic stress disorder
- R. Prader-Willi Syndrome
- S. Sjogren’s Syndrome
- T. Rheumatoid arthritis
- U. Schizophrenia
- V. Sleep disorders
- W. Stroke
- X. Tinnitus
- Y. Tourette’s syndrome
- Z. Traumatic brain injury

**IV.** It is the policy of Coordinated Care of Washington, Inc., that the current research does not support the use of the following types of VNS therapy over other currently available alternatives, due to the lack of large, high-quality studies supporting their use:

- A. Aspire SR Model 106 (Cyberonics) for VNS;
- B. Transcutaneous VNS or active auricular transcutaneous electrical nerve stimulation.

**Background**

This policy is based primarily on Washington State Health Care Authority (HCA) Health Technology Assessment (HTA) and Health Care Authority Billing Guidelines.

**Coding Implications**

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® 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 arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
64568	Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator

<b>CPT® Codes</b>	<b>Description</b>
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

**HCPCS Codes that Support Coverage Criteria**

<b>HCPCS Codes</b>	<b>Description</b>
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

**HCPCS Codes that Do Not Support Coverage Criteria**

<b>HCPCS Codes</b>	<b>Description</b>
K1020	Noninvasive vagus nerve stimulator

<b>Reviews, Revisions, and Approvals</b>	<b>Revision Date</b>	<b>Approval Date</b>
Policy adopted.	09/19	12/19

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Lowered minimum age to 4 years. Called out non-covered services. Added additional investigational indications for VNS to section II. Removed ICD-10 Codes: G40.001, G40.009, G40.201, G40.209, G40.309, G40.A09, G40.409, G40.509, G40.802, G40.909, G40.911 and G40.919. Added ICD-10: G40.813, G40.814. References reviewed and updated.	09/20	01/21
Added new HCPCS code K1020 to a new table of codes that do not support coverage criteria. “Experimental/investigational” verbiage replaced with descriptive language. Removed duplicative reference to experimental and non-covered services. Replaced “member” with “member/enrollee”	05/21	06/21
Annual review. Changed “review date” in the header to “date of last revision” and “date” in the revision log header to “revision date.” Background updated with additional study on nVNS for migraine headaches. References reviewed and updated. Reviewed by specialist	09/21	10/21
Policy archived	09/22	10/22
Police reinstated.	08/24	09/24

**References**

- Schachter SC. Vagus nerve stimulation therapy for the treatment of epilepsy. UpToDate. [www.uptodate.com](http://www.uptodate.com). Updated January 30, 2024. Accessed June 21, 2024.
- Health Technology Assessment. Vagus nerve stimulation for treatment-resistant depression. Hayes. [www.hayesinc.com](http://www.hayesinc.com). Published February 21, 2019 (annual review January 26, 2022). Accessed June 21, 2024.
- National coverage determination: Vagus nerve stimulation (160.18). Centers for Medicare and Medicaid Services Web site. <https://www.cms.gov/>. Published February 15, 2019. Accessed June 27, 2024.
- Schachter SC. Overview of the management of epilepsy in adults. UpToDate. [www.uptodate.com](http://www.uptodate.com). Updated December 13, 2022. Accessed June 21, 2024.
- National Institute for Health and Care Excellence. Epilepsies in children, young people and adults — NICE guideline [NG217]. <https://www.nice.org.uk/guidance/ng217/chapter/8-Non-pharmacological-treatments>. Published April 27, 2022. Accessed June 17, 2024.
- National Institute for Health and Care Excellence. Vagus nerve stimulation for refractory epilepsy in children — Interventional procedures guidance [IPG50]. <https://www.nice.org.uk/guidance/ipg50/chapter/2-The-procedure>. Published March 24, 2004. Accessed June 17, 2024.
- Scottish Intercollegiate Guidelines Network. Diagnosis and management of epilepsy in adults (SIGN publication no. 143). [https://www.sign.ac.uk/media/1079/sign143\\_2018.pdf](https://www.sign.ac.uk/media/1079/sign143_2018.pdf). Published May 2015. Updated September 2018. Accessed June 17, 2024.
- Boon P, Vonck K, van Rijckevorsel K, et al. A prospective, multicenter study of cardiac-based seizure detection to activate vagus nerve stimulation. *Seizure*. 2015;32:52 to 61. Doi: 10.1016/j.seizure.2015.08.011

9. Fisher RS, Afra P, Macken M, et al. Automatic Vagus Nerve Stimulation Triggered by Ictal Tachycardia: Clinical Outcomes and Device Performance—The U.S. E-37 Trial. *Neuromodulation*. 2016;19(2):188 to 195. Doi:10.1111/ner.12376
10. Hampel KG, Vatter H, Elger CE, Surges R. Cardiac-based vagus nerve stimulation reduced seizure duration in a patient with refractory epilepsy. *Seizure*. 2015;26:81 to 85. Doi:10.1016/j.seizure.2015.02.004
11. Fang J, Rong P, Hong Y, et al. Transcutaneous Vagus Nerve Stimulation Modulates Default Mode Network in Major Depressive Disorder. *Biol Psychiatry*. 2016;79(4):266 to 273. Doi:10.1016/j.biopsych.2015.03.025
12. Hein E, Nowak M, Kiess O, et al. Auricular transcutaneous electrical nerve stimulation in depressed patients: a randomized controlled pilot study. *J Neural Transm (Vienna)*. 2013;120(5):821 to 827. Doi:10.1007/s00702-012-0908-6
13. Health Technology Assessment. Noninvasive vagus nerve stimulation with gammacore for prevention or treatment of cluster headache. Hayes. [www.hayesinc.com](http://www.hayesinc.com). Published May 12, 2020 (annual review June 7, 2023). Accessed June 21, 2024.
14. May A. Cluster headache: Treatment and prognosis. UpToDate. [www.uptodate.com](http://www.uptodate.com). Updated April 10, 2024. Accessed June 21, 2024.
15. Blech B, Starling AJ, Marks LA, Wingerchuk DM, O'Carroll CB. Is Noninvasive Vagus Nerve Stimulation a Safe and Effective Alternative to Medication for Acute Migraine Control?. *Neurologist*. 2020;25(4):97 to 100. Doi:10.1097/NRL.0000000000000274
16. Evers S. Non-Invasive Neurostimulation Methods for Acute and Preventive Migraine Treatment-A Narrative Review. *J Clin Med*. 2021;10(15):3302. Published 2021 Jul 27. Doi:10.3390/jcm10153302
17. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice [published correction appears in *Headache*. 2019 Apr;59(4):650 to 651] Doi:10.1111/head.13506. *Headache*. 2019;59(1):1 to 18. Doi:10.1111/head.13456
18. Schwedt TJ, Garza I. Acute treatment of migraine in adults. UpToDate. [www.uptodate.com](http://www.uptodate.com). Updated June 6, 2023. Accessed July 17, 2023.
19. Morris GL 3<sup>rd</sup>, Gloss D, Buchhalter J, Mack KJ, Nickels K, Harden C. Evidence-based guideline update: vagus nerve stimulation for the treatment of epilepsy: report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. Reaffirmed July 16, 2022. 2013;81(16):1453 to 1459. Doi:10.1212/WNL.0b013e3182a393d1
20. Sirven, JI. Evaluation and management of drug-resistant epilepsy. UpToDate. [www.uptodate.com](http://www.uptodate.com). Updated December 195, 2023. Accessed June 21, 2024.
21. Wilfong A. Seizures and epilepsy in children: Refractory seizures. UpToDate. [www.uptodate.com](http://www.uptodate.com). Updated April 4, 2024. Accessed June 21, 2024.
22. Tassorelli C, Grazi L, de Tommaso M, et al. Noninvasive vagus nerve stimulation as acute therapy for migraine: The randomized PRESTO study. *Neurology*. 2018;91(4):e364 to e373. Doi:10.1212/WNL.0000000000005857
23. Silberstein SD, Calhoun AH, Lipton RB, et al. Chronic migraine headache prevention with noninvasive vagus nerve stimulation: The EVENT study. *Neurology*. 2016;87(5):529 to 538. Doi:10.1212/WNL.0000000000002918
24. Silberstein SD, Mechtler LL, Kudrow DB, et al. Non-Invasive Vagus Nerve Stimulation for the Acute Treatment of Cluster Headache: Findings From the Randomized, Double-Blind,

- Sham-Controlled ACT1 Study. *Headache*. 2016;56(8):1317 to 1332.  
Doi:10.1111/head.12896
25. Goadsby PJ, de Coo IF, Silver N, et al. Non-invasive vagus nerve stimulation for the acute treatment of episodic and chronic cluster headache: A randomized, double-blind, sham-controlled ACT2 study. *Cephalalgia*. 2018;38(5):959 to 969.  
Doi:10.1177/0333102417744362
  26. Klinkenberg S, Aalbers MW, Vles JS, et al. Vagus nerve stimulation in children with intractable epilepsy: a randomized controlled trial. *Dev Med Child Neurol*. 2012;54(9):855 to 861. Doi:10.1111/j.1469-8749.2012.04305.x
  27. Holtzheimer PE. Unipolar depression in adults: Treatment with surgical approaches. UpToDate. [www.uptodate.com](http://www.uptodate.com). Updated January 20, 2022. Accessed July 17, 2023.
  28. Guan J, Karsy M, Ducis K, Bollo RJ. Surgical strategies for pediatric epilepsy. *Transl Pediatr*. 2016;5(2):55 to 66. Doi:10.21037/tp.2016.03.02
  29. Panebianco M, Rigby A, Marson AG. Vagus nerve stimulation for focal seizures. *Cochrane Database Syst Rev*. 2022;7(7):CD002896. Published 2022 Jul 14.  
Doi:10.1002/14651858.CD002896.pub3
  30. Ben-Menachem E, Revesz D, Simon BJ, Silberstein S. Surgically implanted and non-invasive vagus nerve stimulation: a review of efficacy, safety and tolerability. *Eur J Neurol*. 2015;22(9):1260 to 1268. Doi:10.1111/ene.12629
  31. Fisher RS, Shafer, PO, D'Souza, C. 2017 Revised Classification of Seizures. Epilepsy Foundation. <https://www.epilepsy.com/article/2016/12/2017-revised-classification-seizures>. Published December 2016. Accessed June 18, 2024.
  32. Bauer S, Baier H, Baumgartner C, et al. Transcutaneous Vagus Nerve Stimulation (tVNS) for Treatment of Drug-Resistant Epilepsy: A Randomized, Double-Blind Clinical Trial (cMPsE02). *Brain Stimul*. 2016;9(3):356 to 363. Doi:10.1016/j.brs.2015.11.003
  33. Center for Devices and Radiological Health (CDRH). P970003/S50. VNS Therapy System [premarket approval letter]. July 15, 2005. Food and Drug Administration. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf/p970003s050a.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf/p970003s050a.pdf) Accessed June 18, 2024.
  34. Ortler M, Unterhofer C, Dobesberger J, Haberlandt E, Trinkka E. Complete removal of vagus nerve stimulator generator and electrodes. *J Neurosurg Pediatr*. 2010;5(2):191 to 194.  
Doi:10.3171/2009.9.PEDS0810
  35. American Association of Neurological Surgeons (AANS). Vagus nerve stimulation. <https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Vagus-Nerve-Stimulation>. Updated April 9, 2024. Accessed June 20, 2024.
  36. Vargas-Caballero M, Warming H, Walker R, Holmes C, Cruickshank G, Patel B. Vagus Nerve Stimulation as a Potential Therapy in Early Alzheimer's Disease: A Review. *Front Hum Neurosci*. 2022;16:866434. Published 2022 Apr 29. Doi:10.3389/fnhum.2022.866434
  37. Pavlov VA. The evolving obesity challenge: targeting the vagus nerve and the inflammatory reflex in the response. *Pharmacol Ther*. 2021;222:107794.  
Doi:10.1016/j.pharmthera.2020.107794
  38. Emerging Technology Report. Phoenix transcutaneous auricular vagus stimulation system (Ehren Technologies Inc.) for posttraumatic stress. Hayes. [www.hayesinc.com](http://www.hayesinc.com). Published July 17, 2023. Accessed June 21, 2024.
  39. Boluk C, Ozkara C, Isler C, Uzan M. Vagus Nerve Stimulation in Intractable Epilepsy. *Turk Neurosurg*. 2022;32(1):97 to 102. Doi:10.5137/1019-5149.JTN.33775-21.2



40. Hajtovic S, LoPresti MA, Zhang L, Katlowitz KA, Kizek DJ, Lam S. The role of vagus nerve stimulation in genetic etiologies of drug-resistant epilepsy: a meta-analysis. *J Neurosurg Pediatr.* 2022;29(6):667 to 680. Published 2022 Mar 18. Doi:10.3171/2022.1.PEDS222
41. Farmer AD, Strzelczyk A, Finisguerra A, et al. International Consensus Based Review and Recommendations for Minimum Reporting Standards in Research on Transcutaneous Vagus Nerve Stimulation (Version 2020). *Front Hum Neurosci.* 2021;14:568051. Published 2021 Mar 23. doi:10.3389/fnhum.2020.568051
42. Washington State Health Care Authority. Physician-Related Services/ Health Care Professional Services Billing Guideline. [Physician-Related Services/Health Care Professional Services billing guide \(wa.gov\)](#) Revisions effective 7/1/24. Accessed 8/29/24.

### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/Enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note: For Medicaid members/enrollees**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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