

02-61000-22

Original Effective Date: 06/15/00

Reviewed: 01/27/22

Revised: 01/01/23

Subject: Vagus Nerve Stimulation

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Stimulation of the [vagus nerve](#) can be performed by means of an implantable stimulator within the carotid artery sheath. This technique has been proposed as a treatment for refractory seizures, depression, and other disorders.

Transcutaneous vagus nerve stimulation (tVNS) has been investigated as a non-invasive alternative to surgery for implantable vagus nerve stimulators. tVNS involves stimulation of superficial branches of the vagus nerve on the ear. Investigators have hypothesized that direct stimulation of the afferent nerve fibers on the ear area with afferent vagus nerve distribution may produce an effect similar to VNS with an implanted stimulator.

Vagus nerve blocking therapy for obesity consists of an implantable device that delivers electrical stimulation to branches of the vagus nerve on the anterior abdominal wall. The intent is to intermittently block signals to the intra-abdominal vagus nerve to disrupt hunger sensations and induce feelings of satiety.

POSITION STATEMENT:

Vagus nerve stimulation **meets the definition of medical necessity** as a treatment of medically refractory seizures, defined as seizures that occur despite therapeutic levels of antiepileptic drugs or seizures that cannot be treated with therapeutic levels of antiepileptic drugs, because of intolerable adverse events of these drugs.

The available scientific evidence does not support conclusions regarding the effectiveness of vagus nerve stimulation for all other indications. Vagus nerve stimulation is considered **experimental or investigational** for all other conditions, including but not limited to the following:

- Depression
- Heart failure
- Upper limb impairment due to stroke
- Essential tremor
- Headache
- Fibromyalgia
- Tinnitus
- Traumatic brain injury

Intra-abdominal vagus nerve blocking therapy is considered **experimental or investigational** for all indications, including but not limited to the treatment of obesity. Data in published medical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

The use of **transcutaneous vagus nerve stimulation (tVNS)** (nonimplantable vagus nerve stimulation device) (e.g., Stivax, GammaCore, and Gammacore Sapphire stimulators) is considered **experimental or investigational** for the treatment of any condition, as there is insufficient clinical evidence to permit conclusions on net health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

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
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
64568	Open implantation of cranial nerve (eg, 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
64570	Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator

HCPCS Coding:

K1020	Non-invasive vagus nerve stimulator (investigational)
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REIMBURSEMENT INFORMATION:

Refer to sections entitled [POSITION STATEMENT](#) and [PROGRAM EXCEPTIONS](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: VAGUS Nerve Stimulation (VNS) (160.18) located at cms.gov.

DEFINITIONS:

Epilepsy: recurrent, unprovoked paroxysmal transient disturbances of brain function that may be manifested as episodic impairment or loss of consciousness, abnormal motor phenomena, psychic or sensory disturbances, or perturbation of the autonomic nervous system.

Seizure: a transient disturbance of cerebral function due to an abnormal paroxysmal neuronal discharge in the brain.

Vagus nerve (nervus vagus): tenth cranial nerve; supplies sensory fibers to the ear, tongue, pharynx, and larynx, motor fibers to the pharynx, larynx, and esophagus, and parasympathetic and visceral afferent fibers to thoracic and abdominal viscera.

RELATED GUIDELINES:

[Gastric Electrical Stimulation, 01-91000-04](#)

OTHER:

None applicable.

REFERENCES:

1. AHRQ National Guideline Clearinghouse. Guideline Summary NGC-3925. The diagnosis and management of the epilepsies in adults and children in primary and secondary care. London (UK): Royal College of General Practitioners; 2004 Oct.
2. AHRQ National Guideline Clearinghouse. Guideline Summary NGC-7711. VA/DoD clinical practice guideline for management of major depressive disorder (MDD). Washington (DC): Department of Veteran Affairs, Department of Defense; 2009 May.
3. AHRQ National Guideline Clearinghouse. Guideline Summary NGC-8093. Practice guideline for the treatment of patients with major depressive disorder, third edition. Arlington (VA): American Psychiatric Association (APA); 2010 Oct.
4. AHRQ National Guideline Clearinghouse. Guideline Summary NGC-8696. Care of the patient with seizures. Second edition. Glenview (IL): American Association of Neuroscience Nurses; 2009 Dec.
5. AHRQ National Guideline Clearinghouse. Guideline Summary NGC-8985. The epilepsies: the diagnosis and management of the epilepsies in adults and children in primary and secondary care. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 (Clinical guideline; no. 137).
6. American Headache Society. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. ISSN 0017-8748 Headache doi: 10.1111/head.12866 VC 2016. Published by Wiley Periodicals, Inc.

7. American Psychiatric Association practice guideline for the treatment of patients with major depressive disorder. *Am J Psychiatry* 2000 Apr; 157(4 Suppl): 1-45.
8. American Psychiatric Association. Practice guideline for the treatment of patients with bipolar disorder (revision). *Am J Psychiatry*. 2002 Apr; 159(4 Suppl): 1-50.
9. Apovian CM, Shah SN, Wolfe BM, et al. Two-Year Outcomes of Vagal Nerve Blocking (vBloc) for the Treatment of Obesity in the ReCharge Trial. *Obes Surg*. 2017;27(1):169–176. Doi:10.1007/s11695-016-2325-7.
10. Bajbouj M. Two-year outcome of vagus nerve stimulation in treatment-resistant depression. *J Clin Psychopharmacol*. 2010 Jun;30(3):273-81.
11. 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 Sep;22(9):1260-8.
12. Berry SM, Broglio K, Bunker M, Jayewardene A, Olin B, Rush AJ. A patient-level meta-analysis of studies evaluating vagus nerve stimulation therapy for treatment-resistant depression. *Med Devices (Auckl)*. 2013;6:17-35.
13. Blue Cross and Blue Shield Association. Technology Evaluation Center (TEC). Chronic Vagus Nerve Stimulation for Treatment of Seizures. TEC Assessments 1998, Tab 9.
14. Blue Cross and Blue Shield Association. Technology Evaluation Center (TEC). Vagus Nerve Stimulation for Treatment-Resistant Depression. TEC Assessments 2005, Volume 20, No.8.
15. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.20 - Vagus Nerve Stimulation, 05/21.
16. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.150 - Vagus Nerve Blocking Therapy for Treatment of Obesity (Archived 03/21).
17. Blue Cross Blue Shield of Florida TEC Assessment Summary. Vagus Nerve Stimulation for Treatment of Epilepsy, 03/09/00.
18. California Technology Assessment Forum (CTAF). Vagal Nerve Stimulation for Treatment Resistant Depression. Technology Assessment. San Francisco, CA: February 15, 2006.
19. Carpenter LL. Neurostimulation in resistant depression. *J Psychopharmacol*. 2006 May; 20 (3 Suppl): 35-40.
20. Center for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) L33777. Noncovered Services (10/01/15) (Retired 07/01/20).
21. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) Vagus Nerve Stimulation (VNS) 160.18 (02/15/19) (Revised 07/22/20).
22. ClinicalTrials.gov. Vagus Nerve Stimulation for Treating Adults With Severe Fibromyalgia. NCT00294281. University of Medicine and Dentistry New Jersey. 2011.
23. ClinicalTrials.gov. Vagus Nerve Stimulation in Rheumatoid Arthritis. NCT00859859. North Shore Long Island Jewish Health System. 2011.
24. ClinicalTrials.gov. Vagal Nerve Stimulation and Glucose Metabolism. NCT01117311. Mayo Clinic. 2011.
25. ClinicalTrials.gov. Transcutaneous Non-invasive Vagus Nerve Stimulation (t-VNS) in the Treatment of Schizophrenia (02VNS2009). NCT01176721. Cerbomed GmbH. 2011.
26. ClinicalTrials.gov. Vagus Nerve Stimulation a New Approach in the Treatment of Crohn's Disease (VNS). NCT01569503. University Hospital, Grenoble. 2012.
27. Conway CR, Sheline YI, Chibnall JT, George MS, Fletcher JW, Mintun MA. Cerebral blood flow changes during vagus nerve stimulation for depression. *Psychiatry Res*. 2006 Mar 31; 146(2): 179-84.

28. de Coo IF, Marin JC, Silberstein SD, et al. Differential efficacy of non-invasive vagus nerve stimulation for the acute treatment of episodic and chronic cluster headache: A meta-analysis. *Cephalalgia*. 2019 Jul;39(8):967-977. doi: 10.1177/0333102419856607. Epub 2019 Jun 10.
29. Deuchars SA, Lall VK, Clancy J, et al. Mechanisms underpinning sympathetic nervous activity and its modulation using transcutaneous vagus nerve stimulation. *Exp Physiol*. 2018;103(3):326–331. Doi:10.1113/EP086433.
30. Dunner DL, Rush AJ, Russell JM, Burke M, Woodard S, Wingard P, Allen J. Prospective, long-term, multicenter study of the naturalistic outcomes of patients with treatment-resistant depression. *J Clin Psychiatry*. 2006 May; 67(5): 688-95.
31. ECRI. Custom Hotline Response. Implantable Vagus Nerve Stimulator for Epilepsy. Plymouth Meeting, PA: ECRI. 03/07/08.
32. ECRI. Custom Hotline Response. Implantable Vagus Nerve Stimulator for Treatment-resistant Depression. Plymouth Meeting, PA: ECRI. 05/01/07.
33. ECRI. Target Database. Target Report 80. Implantable Vagus nerve stimulator for treatment resistant depression. Plymouth Meeting, PA: ECRI. May 2007.
34. ECRI Institute Health Technology Forecast: Vagus Nerve Stimulation for Treating Chronic Heart Failure. 29 January 2013.
35. ECRI Institute Health Technology Forecast: Vagus Nerve Blocking for Treating Obesity. 02 May 2011.
36. Fisher RS, Handforth A. Reassessment: Vagus nerve stimulation for epilepsy: A Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Copyright © 1999 by the American Academy of Neurology.
37. Fochtmann, LJ & Gelenberg, AJ. Guideline Watch: practice guideline for the treatment of patients with major depressive disorder, 2nd Edition. Arlington (VA): American Psychiatric Association; 2005 Winter. 9 p.
38. Frangos E, Komisaruk BR. Access to Vagal Projections via Cutaneous Electrical Stimulation of the Neck: fMRI Evidence in Healthy Humans. *Brain Stimul*. 2017 Jan-Feb;10(1):19-27. doi: 10.1016/j.brs.2016.10.008. Epub 2016 Oct 20.
39. Gaul C, Diener HC, Silver N, Magis D, Reuter U, Andersson A, Liebler EJ, Straube A; PREVA Study Group. Non-invasive vagus nerve stimulation for PREvention and Acute treatment of chronic cluster headache (PREVA): A randomised controlled study. *Cephalalgia*. 2016 May;36(6):534-46. doi: 10.1177/0333102415607070. Epub 2015 Sep 21.
40. Gaul C, Magis D, Liebler E, Straube A. Effects of non-invasive vagus nerve stimulation on attack frequency over time and expanded response rates in patients with chronic cluster headache: a post hoc analysis of the randomised, controlled PREVA study. *J Headache Pain*. 2017 Dec;18(1):22. doi: 10.1186/s10194-017-0731-4. Epub 2017 Feb 14.
41. George MS, Rush AJ, Marangell LB, Sackeim HA, Brannan SK, Davis SM, Howland R, Kling MA, Moreno F, Rittberg B, Dunner D, Schwartz T, Carpenter L, Burke M, Ninan P, Goodnick P. A one-year comparison of vagus nerve stimulation with treatment as usual for treatment-resistant depression. *Biol Psychiatry*. 2005 Sep 1; 58(5): 364-73.
42. Gil K, Bugajski A, Thor P. Electrical Vagus Nerve Stimulation Decreases Food Consumption and Weight Gain in Rats Fed a High-fat Diet. *Journal of Physiology and Pharmacology* 2011, 62, 6, 637-646.
43. Goadsby PJ, de Coo IF, Silver N, Tyagi A, Ahmed F, Gaul C, Jensen RH, Diener HC, Solbach K, Straube A, Liebler E, Marin JC, Ferrari MD; ACT2 Study Group. 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 Apr;38(5):959-969. doi: 10.1177/0333102417744362. Epub 2017 Dec 12.

44. Handforth A, Ondo WG, Tatter S, Mathern GW, Simpson RK Jr, Walker F, Sutton JP, Hubble JP, Jankovic J. Vagus nerve stimulation for essential tremor: a pilot efficacy and safety trial. *Neurology*. 2003 Nov 25; 61(10): 1401-5.
45. Hayes, Inc. Hayes Medical Technology Directory. Vagus Nerve Stimulation for Epilepsy. Lansdale, PA: Hayes, Inc.; Dec 2007.
46. Hayes, Inc. Hayes Medical Technology Directory. Vagus Nerve Stimulation for Depression. Lansdale, PA: Hayes, Inc.; Oct 2005. Updated May 2007.
47. Henssen DJHA, Derks B, van Doorn M, et al. Vagus nerve stimulation for primary headache disorders: An anatomical review to explain a clinical phenomenon. *Cephalalgia*. 2019 Aug;39(9):1180-1194. doi: 10.1177/0333102419833076. Epub 2019 Feb 20.
48. Holle-Lee D, Gaul C. Noninvasive vagus nerve stimulation in the management of cluster headache: clinical evidence and practical experience. *Ther Adv Neurol Disord*. 2016 May;9(3):230-4.
49. Kong J, Fang J, Park J, Li S, Rong P. Treating Depression with Transcutaneous Auricular Vagus Nerve Stimulation: State of the Art and Future Perspectives. *Front Psychiatry*. 2018;9:20. Published 2018 Feb 5. Doi:10.3389/fpsyt.2018.00020.
50. Lange G, Janal MN, Maniker A, Fitzgibbons J, Fobler M, Cook D, Natelson BH. Safety and efficacy of vagus nerve stimulation in fibromyalgia: a phase I/II proof of concept trial. *Pain Med*. 2011 Sep;12(9):1406-13.
51. Liu A, Rong P, Gong L, et al. Efficacy and Safety of Treatment with Transcutaneous Vagus Nerve Stimulation in 17 Patients with Refractory Epilepsy Evaluated by Electroencephalogram, Seizure Frequency, and Quality of Life. *Med Sci Monit*. 2018;24:8439–8448. Published 2018 Nov 23. Doi:10.12659/MSM.910689.
52. Marin J, Giffin N, Consiglio E, McClure C, Liebler E, Davies B. Non-invasive vagus nerve stimulation for treatment of cluster headache: early UK clinical experience. *J Headache Pain*. 2018 Nov 23;19(1):114. doi: 10.1186/s10194-018-0936-1.
53. Martelletti P, Jensen RH, et al. Neuromodulation of chronic headaches: position statement from the European Headache Federation. *J Headache Pain*. 2013 Oct 21;14:86.
54. McGlone J, Valdivia I, Penner M, Williams J, Sadler RM, Clarke DB. Quality of life and memory after vagus nerve stimulator implantation for epilepsy. *Can J Neurol Sci*. 2008 Jul; 35(3):287-96.
55. Meneses MS, Rocha SF, Simão C, Santos HN, Pereira C, Kowacs PA. Vagus nerve stimulation may be a sound therapeutic option in the treatment of refractory epilepsy. *Arq Neuropsiquiatr*. 2013 Jan;71(1):25-30.
56. Min B, Jian Z, Guo-ming L. Treatment of drug-resistant epilepsy with vagus nerve stimulation: review of 45 cases. *Chin Med J* 2011;124(24):4184-4188.
57. Nahas Z, Marangell LB, Husain MM, Rush AJ, Sackeim HA, Lisanby SH, Martinez JM, George MS. Two-year outcome of vagus nerve stimulation (VNS) for treatment of major depressive episodes. *J Clin Psychiatry*. 2005 Sep; 66(9): 1097-104.
58. National Institute for Health and Clinical Excellence (NICE). Interventional Procedure Guidance (IPG) 050: Vagus nerve stimulation for refractory epilepsy in children. 24 March 2004. Accessed at <http://www.nice.org.uk/> on 04/22/13.
59. National Institute for Health and Clinical Excellence (NICE). Interventional Procedure Guidance (IPG) 330: Vagus nerve stimulation for treatment-resistant depression. 16 December 2009.. Accessed at <http://www.nice.org.uk/>.
60. National Institute for Health and Clinical Excellence (NICE). Clinical Guideline (CG) 137: The Epilepsies: The diagnosis and management of the epilepsies in adults and children in primary and secondary care. 11 January 2012. Accessed at <http://www.nice.org.uk/>.

61. National Institute for Health and Care Excellence (NICE). Interventional procedures guidance (IPG) 552: Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine (March 2016). Accessed at <http://www.nice.org.uk/>.
62. National Institute for Health and Care Excellence (NICE). Medical technologies guidance [MTG46]: gammaCore for cluster headache (December 2019). Accessed at <http://www.nice.org.uk/>.
63. Nemeroff CB, Mayberg HS, Krahl SE, McNamara J, Frazer A, Henry TR, George MS, Charney DS, Brannan SK. VNS therapy in treatment-resistant depression: clinical evidence and putative neurobiological mechanisms. *Neuropsychopharmacology*. 2006 Jul; 31(7): 1345-55.
64. NeurosurgeryToday.org. Treatment-Resistant Depression (TRD). Vagus Nerve Stimulation. (May 2007).
65. Nonis R, D'Ostilio K, Schoenen J, Magis D. Evidence of activation of vagal afferents by non-invasive vagus nerve stimulation: An electrophysiological study in healthy volunteers. *Cephalalgia*. 2017 Nov;37(13):1285-1293. doi: 10.1177/0333102417717470. Epub 2017 Jun 26.
66. Papasavas P, El Chaar M, Kothari SN; American Society for Metabolic and Bariatric Surgery Clinical Issues Committee. American Society for Metabolic and Bariatric Surgery position statement on vagal blocking therapy for obesity. *Surg Obes Relat Dis*. 2016;12(3):460–461. Doi:10.1016/j.soard.2015.12.004.
67. Parhizgar F, Nugent, K, Raj R. Obstructive Sleep Apnea and Respiratory Complications Associated with Vagus Nerve Stimulators. *Clin Sleep Med* 2011;7(4):401-407.
68. Pelot NA, Grill WM. Effects of vagal neuromodulation on feeding behavior. *Brain Res*. 2018;1693(Pt B):180–187. Doi:10.1016/j.brainres.2018.02.003.
69. Privitera MD, Welty TE, Ficker DM, Welge J. Vagus nerve stimulation for partial seizures. *The Cochrane Database of Systematic Reviews* 2002, Issue 1. Art. No.: CD002896. DOI: 10.1002/14651858.CD002896.
70. Prudic J, Olfson M, Marcus SC, Fuller RB, Sackeim HA. Effectiveness of electroconvulsive therapy in community settings. *Biol Psychiatry*. 2004 Feb 1; 55(3): 301-12.
71. Reuter U, McClure C, Liebler E, Pozo-Rosich P. Non-invasive neuromodulation for migraine and cluster headache: a systematic review of clinical trials. *J Neurol Neurosurg Psychiatry*. 2019 Jul;90(7):796-804. doi: 10.1136/jnnp-2018-320113. Epub 2019 Mar 1.
72. Robbins MS, et al. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. *Headache*. 2016; 56(7):1093-1106.
73. Rong PJ, Fang JL, Wang LP, Meng H, Liu J, Ma YG, Ben H, Li L, Liu RP, Huang ZX, Zhao YF, Li X, Zhu B, Kong J. Transcutaneous vagus nerve stimulation for the treatment of depression: a study protocol for a double blinded randomized clinical trial. *BMC Complement Altern Med*. 2012 Dec 14;12:255.
74. Rush AJ, Marangell LB, Sackeim HA, George MS, Brannan SK, Davis SM, Howland R, Kling MA, Rittberg BR, Burke WJ, Rapaport MH, Zajecka J, Nierenberg AA, Husain MM, Ginsberg D, Cooke RG. Vagus nerve stimulation for treatment-resistant depression: a randomized, controlled acute phase trial. *Biol Psychiatry*. 2005 Sep 1; 58(5): 347-54.
75. Rush AJ, Sackeim HA, Marangell LB, George MS, Brannan SK, Davis SM, Lavori P, Howland R, Kling MA, Rittberg B, Carpenter L, Ninan P, Moreno F, Schwartz T, Conway C, Burke M, Barry JJ. Effects of 12 months of vagus nerve stimulation in treatment-resistant depression: a naturalistic study. *Biol Psychiatry*. 2005 Sep 1; 58(5): 355-63.
76. Shafique S, Dalsing MC. Vagus nerve stimulation therapy for treatment of drug-resistant epilepsy and depression. *Perspect Vasc Surg Endovasc Ther*. 2006 Dec; 18(4): 323-7; discussion 328.
77. Silberstein SD, Calhoun AH, Treppendahl C, Dodick DW, Rapoport AM, Mamidi A, Vargas P, Ebert TH, Tepper SJ. The emerging role of gammaCore® in the management of cluster headache: expert panel recommendations. *Am J Manag Care*. 2017 Nov;23(17 Suppl):S326-S333.

78. Silberstein SD, Mechtler LL, Kudrow DB, Calhoun AH, McClure C, Saper JR, Liebler EJ, Rubenstein Engel E, Tepper SJ; ACT1 Study Group. Non-Invasive Vagus Nerve Stimulation for the ACute Treatment of Cluster Headache: Findings From the Randomized, Double-Blind, Sham-Controlled ACT1 Study. *Headache*. 2016 Sep;56(8):1317-32. doi: 10.1111/head.12896.
79. Silberstein SD, Yuan H, Najib U, Ailani J, Morais AL, Mathew PG, Liebler E, Tassorelli C, Diener HC. Non-invasive vagus nerve stimulation for primary headache: A clinical update. *Cephalalgia*. 2020 Oct;40(12):1370-1384. doi: 10.1177/0333102420941864. Epub 2020 Jul 27.
80. Simon B, Blake J. Mechanism of action of non-invasive cervical vagus nerve stimulation for the treatment of primary headaches. *Am J Manag Care*. 2017 Nov;23(17 Suppl):S312-S316.
81. Terra VC, Nisyiama MA, Abrão J, Sakamoto AC, Machado HR, Arida RM, Cavalheiro EA, Scorza FA. Epileptologists probe vagus nerve stimulation in children with refractory epilepsy: a promise against sudden unexpected death in epilepsy. *Arq Neuropsiquiatr*. 2012 Dec;70(12):953-5.
82. United States Food and Drug Administration (FDA). DeNovo Summary DEN150048: gammaCore Non-invasive Vagus Nerve Stimulator. September 1, 2017. Accessed at <https://www.accessdata.fda.gov/>.
83. United States Food and Drug Administration (FDA). 510(k) Summary K203546: gammaCore Sapphire. Regulation Number: 21 CFR 882.5892. Accessed at <https://www.accessdata.fda.gov/>.
84. UpToDate. Cluster headache: Treatment and prognosis. 2021. Accessed at [uptodate.com](https://www.uptodate.com).
85. UpToDate. Vagus nerve stimulation therapy for the treatment of epilepsy. 2021. Accessed at [uptodate.com](https://www.uptodate.com).
86. Urits I, Schwartz R, Smoots D, et al. Peripheral Neuromodulation for the Management of Headache. *Anesth Pain Med*. 2020 Nov 30;10(6):e110515. doi: 10.5812/aapm.110515.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 01/27/22.

GUIDELINE UPDATE INFORMATION:

06/15/00	New Medical Coverage Guideline.
08/23/01	Review of guideline with no revisions.
06/15/02	Revised to delete age limitation.
06/15/03	Review of guideline with no changes in coverage.
06/15/04	Review and revision of guideline; consisting of updated references.
01/01/05	Annual HCPCS update; consisting of the revision of 61885, 61886 and 64590.
04/15/05	Review and revision of guideline; consisting of updated references.
04/15/06	Review and revision of guideline consisting of updated references.
01/01/07	HCPCS coding update consisting of the revision of 64590 and 64595.
06/15/07	Review and revision of guideline consisting of updated references and reformatted guideline.
04/15/08	Review and revision of guideline consisting of updated references.
06/15/09	Scheduled review; no change to position statement. Update references.
01/01/10	Annual HCPCS coding review: revise descriptor for CPT code 61886.
06/15/10	Biennial review; no change in position statement. References updated.

01/01/11	Annual HCPCS coding update. Added codes 64568, 64569 and 64570; deleted code 64573.
01/01/12	Annual HCPCS coding update. Revised 64553, 95974 and 95975 descriptors.
06/15/12	Scheduled review. Revised description section and position statement (added additional indications which are considered experimental/investigational); revised Medicare Advantage program exception and updated references.
01/01/13	Annual CPT coding update. Added codes 0312T, 0313T, 0314T, 0315T, 0316T and 0317T.
06/15/13	Scheduled review. Revised description, position statement and program exceptions section. Updated references and reformatted guideline.
11/15/17	Unscheduled review. Maintained position statement. Revised CPT coding and program exceptions section. Updated references and reformatted guideline.
01/01/18	Annual CPT/HCPCS coding update: revised 64550.
01/01/19	Annual CPT/HCPCS coding update. Deleted 64550, 95974, 95975.
03/15/20	Scheduled review. Revised description and position statement. Updated references.
04/01/21	Quarterly CPT/HCPCS coding update. Added code K1020.
01/01/21	Annual CPT/HCPCS coding update. Revised descriptor 64568.
02/15/22	Scheduled review. Maintained position statement and updated references.
01/01/23	Annual CPT/HCPCS coding update. Deleted 0312T, 0313T, 0314T, 0315T, 0316T, 0317T.