

02-61000-22

Original Effective Date: 06/15/00

Reviewed: 10/31/17

Revised: 01/01/19

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.

Significant advances have occurred in surgical treatment for epilepsy and in medical treatment of epilepsy with newly developed and approved medications. Despite these advances, however, 25–50% of patients with epilepsy experience breakthrough seizures or suffer from debilitating adverse effects of antiepileptic drugs. Vagus nerve stimulation (VNS) has been investigated as a treatment alternative in patients with [medically refractory partial-onset seizures](#) for whom surgery is not recommended or for whom surgery has failed.

While the mechanisms for the therapeutic effects of vagal nerve stimulation are not fully understood, the basic premise of VNS in the treatment of various conditions is that vagal visceral afferents have a diffuse central nervous system projection, and activation of these pathways has a widespread effect on neuronal excitability. Surgery for implantation of a vagal nerve stimulator involves wrapping 2 spiral electrodes around the left vagus nerve within the carotid sheath. The electrodes are connected to an infraclavicular generator pack. The programmable stimulator may be programmed in advance to stimulate at regular times or on demand by patients or family by placing a magnet against the subclavicular implant site. Vagal nerve stimulation requires not only the surgical implantation of the device, but also subsequent neurostimulator programming, which occurs intraoperatively and typically during additional outpatient visits.

Since 1997, it has been reported that recipients of vagus nerve stimulator have experienced improvements in mood. There has been research interest in VNS as a treatment of refractory depression. Although VNS is associated with mood improvements in patients with epilepsy, further large, randomized, controlled studies with long-term follow-up are needed to confirm its effect on refractory depression. VNS

therapy has also been investigated for use in other conditions such as headaches, obesity, chronic heart failure, fibromyalgia and essential tremors.

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.

POSITION STATEMENT:

Vagus nerve stimulation **meets the definition of medical necessity** when **ALL** of the following criteria are met:

- An FDA-approved device is used; **AND**
- The member has a history of medically refractory [seizures](#); **AND**
- Resective epilepsy surgery is not recommended or has failed.

The available scientific evidence does not support conclusions regarding the effectiveness of vagus nerve stimulation for all other indications. Therefore, vagus nerve stimulation is considered experimental or investigational as a treatment for ALL other indications including, but not limited to:

- Depression
- Essential tremor
- Headaches
- Obesity
- Fibromyalgia
- Chronic pain
- Alzheimer's disease
- Anxiety
- Tourette's syndrome
- Heart failure
- Autism
- Paralysis agitans

The use of **transcutaneous vagus nerve stimulation (tVNS)** (nonimplantable vagus nerve stimulation device) 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:

The following codes are frequently used for reporting this procedure.

CPT Coding:

0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ),
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	with implantation of pulse generator, includes programming (investigational)
0313T	Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator (investigational)
0314T	Vagus nerve blocking therapy (morbid obesity); laparoscopic removal of vagal trunk neurostimulator electrode array and pulse generator (investigational)
0315T	Vagus nerve blocking therapy (morbid obesity); removal of pulse generator (investigational)
0316T	Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator (investigational)
0317T	Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed (investigational)
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	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
64570	Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator

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.

The following Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date:
Noncovered Services (L33777) located at fcso.com.

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.

Medically refractory seizures: seizures that occur in spite of therapeutic levels of antiepileptic drugs or seizures that cannot be treated with therapeutic levels of antiepileptic drugs because of intolerable adverse effects of these drugs.

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 Psychiatric Association practice guideline for the treatment of patients with major depressive disorder. *Am J Psychiatry* 2000 Apr; 157(4 Suppl): 1-45.
7. American Psychiatric Association. Practice guideline for the treatment of patients with bipolar disorder (revision). *Am J Psychiatry*. 2002 Apr; 159(4 Suppl): 1-50.

8. Bajbouj M. Two-year outcome of vagus nerve stimulation in treatment-resistant depression. *J Clin Psychopharmacol*. 2010 Jun;30(3):273-81.
9. 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.
10. 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.
11. Blue Cross and Blue Shield Association. Technology Evaluation Center (TEC). Chronic Vagus Nerve Stimulation for Treatment of Seizures. TEC Assessments 1998, Tab 9.
12. Blue Cross and Blue Shield Association. Technology Evaluation Center (TEC). Vagus Nerve Stimulation for Treatment-Resistant Depression. TEC Assessments 2005, Volume 20, No.8.
13. Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.20 Vagus Nerve Stimulation (February 2016).
14. Blue Cross Blue Shield of Florida TEC Assessment Summary. Vagus Nerve Stimulation for Treatment of Epilepsy, 03/09/00.
15. California Technology Assessment Forum (CTAF). Vagal Nerve Stimulation for Treatment Resistant Depression. Technology Assessment. San Francisco, CA: February 15, 2006.
16. Carpenter LL. Neurostimulation in resistant depression. *J Psychopharmacol*. 2006 May; 20 (3 Suppl): 35-40.
17. Centers for Medicare and Medicaid Services (CMS) Manual System, Pub. 100-3, Medicare National Coverage, Chapter 1, Part 2, Section 160.18 Vagus Nerve Stimulation for Treatment of Seizures, 05/04/07.
18. Centers for Medicare and Medicaid Services (CMS). Coverage Decision Memorandum for Vagus Nerve Stimulation for Treatment of Resistant Depression (TRD). CAG-00313R. 07/23/07. (Accessed 04/22/13).
19. ClinicalTrials.gov. Vagus Nerve Stimulation for Treating Adults With Severe Fibromyalgia. NCT00294281. University of Medicine and Dentistry New Jersey. Last Updated on September 19, 2011.
20. ClinicalTrials.gov. Vagus Nerve Stimulation in Rheumatoid Arthritis. NCT00859859. North Shore Long Island Jewish Health System. Last Updated on July 19, 2011.
21. ClinicalTrials.gov. Vagal Nerve Stimulation and Glucose Metabolism. NCT01117311. Mayo Clinic. Last Updated on December 14, 2011.
22. ClinicalTrials.gov. Transcutaneous Non-invasive Vagus Nerve Stimulation (t-VNS) in the Treatment of Schizophrenia (02VNS2009). NCT01176721. cerbomed GmbH. Last Updated on September 5, 2011.
23. ClinicalTrials.gov. Vagus Nerve Stimulation a New Approach in the Treatment of Crohn's Disease (VNS). NCT01569503. University Hospital, Grenoble. Last Updated on April 2, 2012.
24. 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.
25. 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.
26. ECRI. Custom Hotline Response. Implantable Vagus Nerve Stimulator for Epilepsy. Plymouth Meeting, PA: ECRI. 03/07/08.
27. ECRI. Custom Hotline Response. Implantable Vagus Nerve Stimulator for Treatment-resistant Depression. Plymouth Meeting, PA: ECRI. 05/01/07.

28. ECRI. Target Database. Target Report 80. Implantable Vagus nerve stimulator for treatment resistant depression. Plymouth Meeting, PA: ECRI. May 2007.
29. ECRI Institute Health Technology Forecast: Vagus Nerve Stimulation for Treating Chronic Heart Failure. 29 January 2013.
30. ECRI Institute Health Technology Forecast: Vagus Nerve Blocking for Treating Obesity. 02 May 2011.
31. 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.
32. Florida Medicare Part B Local Coverage Determination. L23157 61885 Vagal Nerve Stimulation (VNS) for Intractable Depression, 10/30/06. (Retired 02/01/09).
33. Florida Medicare Part B Local Coverage Determination. L23157 61885 Vagal Nerve Stimulation (VNS) for Intractable Depression, 10/30/06. (Retired 02/01/09). (Accessed 04/22/13).
34. First Coast Service Options (FCSO) Local Coverage Determination (LCD) L29288. Noncovered Services (04/09/13). (Accessed 04/22/13).
35. First Coast Service Options (FCSO) Local Coverage Determination (LCD) L33777. Noncovered Services (05/04/07).
36. Florida Medicare Part B Local Coverage Determination. L29304 Vagal Nerve Stimulation (VNS) for Intractable Depression, 02/02/09.
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. 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.
39. 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.
40. 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.
41. Hayes, Inc. Hayes Medical Technology Directory. Vagus Nerve Stimulation for Epilepsy. Lansdale, PA: Hayes, Inc.; Dec 2007.
42. Hayes, Inc. Hayes Medical Technology Directory. Vagus Nerve Stimulation for Depression. Lansdale, PA: Hayes, Inc.; Oct 2005. Updated May 2007.
43. 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.
44. InterQual 2011®. Procedures, Adult: Vagus Nerve Stimulators.
45. InterQual® 2012.2. Procedures, Adult: Vagal Nerve Stimulator.
46. 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.
47. 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.
48. 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.

49. 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.
50. 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.
51. 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.
52. 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.
53. 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/> on 04/22/13.
54. 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/> on 04/22/13.
55. 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/>.
56. National Institute of Mental Health (NIMH). Brain Stimulation Therapies. Reviewed November 17, 2009.
57. 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.
58. NeurosurgeryToday.org. Treatment-Resistant Depression (TRD). Vagus Nerve Stimulation. (May 2007).
59. 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.
60. 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.
61. 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.
62. Robbins MS, et al. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. *Headache*. 2016; 56(7):1093-1106.
63. 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.
64. 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.
65. 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.

66. 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.
67. Terra VC, Nisyama 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.
68. 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/>.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 10/31/17.

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.