Vagus Nerve Stimulation

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. There are also devices available that are implanted at different areas of the vagus nerve. This policy addresses only devices implanted within the carotid sheath, and not to other types of devices.

Vagus nerve stimulation (VNS) was initially 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. Over time, the use of VNS has expanded to generalized seizures, and it has been investigated for a range of other conditions.

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. Electrical stimulus is applied to axons of the vagus nerve, which have their cell bodies in the nodose and junctional ganglia and synapse on the nucleus of the solitary tract in the brainstem. From the solitary tract nucleus, vagal afferent pathways project to multiple areas of the brain. There are also vagal efferent pathways that innervate the heart, vocal cords, and other laryngeal and pharyngeal muscles, and provide parasympathetic innervation to the gastrointestinal tract that may also be stimulated by VNS.

The type of VNS device addressed in this policy consists of an implantable, programmable electronic pulse generator that delivers stimulation to the left vagus nerve at the carotid sheath. The pulse generator is connected to the vagus nerve via a bipolar electrical lead. Surgery for implantation of a vagal nerve stimulator involves implantation of the pulse generator in the infraclavicular region and wrapping 2 spiral electrodes around the left vagus nerve within the carotid sheath. 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.

VNS was originally approved for the treatment of medically refractory epilepsy. 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% to 50% of patients with epilepsy experience breakthrough seizures or suffer from debilitating adverse effects of antiepileptic drugs. VNS has been used as an alternative to or adjunct to epilepsy surgery or medications as a therapy for refractory seizures.

In 1997, the U.S. Food and Drug Administration (FDA) approved a vagus nerve stimulation device called the NeuroCybernetic Prosthesis (NCP®) system through the Premarket Approval (PMA) process. The device was approved for use in conjunction with drugs or surgery “as an adjunctive
Vagus Nerve Stimulation

treatment of adults and adolescents over 12 years of age with medically refractory partial onset seizures.”

Since 1997, it has been reported that recipients of a vagus nerve stimulator have experienced improvements in mood. Therefore, there has been research interest in VNS as a treatment of refractory depression. On July 15, 2005, Cyberonics received PMA approval by the FDA for the VNS Therapy™ System “for the adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments.”

VNS therapy has also been investigated for use in other conditions such as headaches, obesity, and essential tremors.

Cerbomed has developed a transcutaneous VNS (t-VNS®) system that uses a combined stimulation unit and ear electrode to stimulate the auricular branch of the vagus nerve, which supplies the skin over the concha of the ear. Patients self-administer electric stimulation for several hours a day; no surgical procedure is required. The device received the CE mark in Europe in 2011, but has not been FDA approved for use in the US. Electrocore has developed a non-invasive VNS (gammaCore®) that is currently being investigated for headache; the device does not have FDA approval.

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

BCBSNC will provide coverage for Vagus Nerve Stimulation for Treatment of Seizures when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Vagus Nerve Stimulation for the treatment of essential tremor and other conditions is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Vagus Nerve Stimulation is covered

Vagus Nerve Stimulation may be considered medically necessary when both of the following criteria are met:
1. The patient has medically refractory seizures, and
2. The patient has failed or is not eligible for surgical treatment.

When Vagus Nerve Stimulation is not covered

Vagus nerve stimulation is considered investigational as treatment for the following conditions, including but not limited to:
1. indications that do not meet the criteria listed above
2. patients who can be treated successfully with anti-epileptic drugs
3. depression
4. essential tremor
Vagus Nerve Stimulation

5. headaches  
6. obesity  
7. heart failure  
8. fibromyalgia  
9. tinnitus  
10. traumatic brain injury.

Non-implantable vagus nerve stimulation devices are considered **investigational** for all indications.

Policy Guidelines

Medically refractory seizures are defined as 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.

The evidence for vagus nerve stimulation (VNS) in individuals who have seizures refractory to medical treatment includes randomized controlled trials (RCTs) and multiple observational studies. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCTs reported a significant reduction in seizure frequency for patients with partial-onset seizures. The uncontrolled studies have consistently reported large reductions for a broader range of seizure types in both adults and children. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for VNS in individuals who have treatment-resistant depression includes 1 RCT and other nonrandomized comparative studies and case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCT reported only short-term results and found no significant improvement for the primary outcome. Other available studies are limited by small sample sizes, potential selection bias, and lack of a control group in the case series. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for VNS in individuals who have chronic heart failure or upper-limb impairment due to stroke includes RCTs and case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCTs for both conditions did not show significant improvements in the primary outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for VNS in individuals who have essential tremor, obesity, headache, fibromyalgia, or tinnitus includes case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Case series are insufficient to make conclusions regarding efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for transcutaneous VNS stimulation in individuals who have epilepsy, depression, schizophrenia, headache, or impaired glucose tolerance includes at least 1 RCT and case series for some of the conditions. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCTs are all small and have various methodologic problems. None shows definitive efficacy of transcutaneous VNS in improving outcomes among patients. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

**Applicable service codes:** 61885, 61886, 61888, 64553, 64568, 64569, 64570, 64585, 95970, 95974, 95975, L8679, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689
Vagus Nerve Stimulation

Diagnoses that are subject to medical necessity review: 278 – 278.03, 296, 296.2, 296.2x, 296.3, 296.3x, 296.5, 296.5x, 296.8, 296.82, 307.81, 311, 333.1, 346 - 346.9x, 428-428.9, 625.4, 627.2, 729.1, 784.0

ICD-10 Diagnosis Codes: E66.01, E66.2, E66.3, E66.9, F31.30, F31.31, F31.32, F31.4, F31.5, F31.75, F31.76, F32.0, F32.1, F32.2, F32.3, F32.4, F32.5, F32.8, F32.9, F33.0, F33.1, F33.2, F33.3, F33.40, F33.41, F33.42, F33.9, G24.211, G24.219, G24.221, G25.0, G25.1, G25.2, G43.B0, G43.001, G43.009, G43.011, G43.019, G43.101, G43.109, G43.111, G43.119, G43.401, G43.409, G43.411, G43.419, G43.501, G43.509, G43.511, G43.519, G43.601, G43.609, G43.611, G43.619, G43.701, G43.709, G43.711, G43.719, G43.801, G43.809, G43.811, G43.819, G43.821, G43.829, G43.831, G43.839, G43.901, G43.909, G43.911, G43.919, G43.A0, G43.A1, G43.B1, G43.C0, G43.C1, G43.D0, G43.D1,G44.1, G44.201, G44.209, G44.229, I50.1, I50.20, I50.21, I50.22, I50.23, I50.30, I50.31, I50.32, I50.33, I50.40, I50.41, I50.42, I50.43, I50.9, M60.80, M60.811, M60.812, M60.819, M60.821, M60.822, M60.829, M60.831, M60.832, M60.839, M60.841, M60.842, M60.849, M60.851, M60.852, M60.859, M60.861, M60.862, M60.869, M60.871, M60.872, M60.879, M60.9, M79.1, M79.7, N94.3, N95.1, R51

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Blue Cross Blue Shield Association Policy, 7.01.20, issued 4/1/98

Medical Policy Advisory Group 12/2/1999


BCBSA Medical Policy Reference Manual, 7.01.20; 11/20/01


ECRI, TARGET Report #73, 1/2002


Vagus Nerve Stimulation


Medical Director – 10/2010


Policy Implementation/Update Information

6/98 Original policy adopted from the National Association

7/99 Reformatted, Description of Procedure or Service changed, Medical Term Definitions added.

12/99 Reaffirmed, Medical Policy Advisory Group

7/00 System coding changes

12/00 2001 HCPCS codes added; E0756, E0757, E0758, E0765. System coding changes.


2/02 Policy statement revised. Removed age specific indications under what is and is not covered and added treatment of patients with depression under what is not covered.

4/03 Codes E0751 and E0753 removed from Billing/Coding section. System coding changes.

Vagus Nerve Stimulation

3/04 Billing/Coding section updated for consistency.

7/7/05 Specialty Matched Consultant Advisory Panel review 6/24/2005. "Description of Procedure or Service" revised. "When Covered" section reformatted. Added to "When Not Covered" section; "1. For indications that do not meet the criteria listed above," and "5. For the treatment of essential tremor." Removed CPT codes 64553 as the code does not apply to this policy. Added CPT codes 61885, 64585, 95970, 95974, and 95975. Policy number added to "Key Words" section. References added.

10/8/05 Added additional information in "Description of Procedure or Service" related to research for the use in treating depression, headaches, and essential tremors. Statement added to "Policy" section indicating, "BCBSNC will not provide coverage for vagus nerve stimulation for the treatment of depression, headache, or essential tremors. These uses are considered investigational. BCBSNC does not cover investigational services. Added "For the treatment of headaches" under the "When not covered" section. No change to the intent of policy. References added.

12/1/05 Policy name changed from "Chronic Vagus Nerve Stimulation for the Treatment of Seizures" to "Vagus Nerve Stimulation". Rationale regarding the investigational status of Vagus Nerve Stimulation for treatment resistant depression added to the "Policy Guidelines" section. References added. Added CPT code 61888.

1/17/07 Added HCPCS codes L8680, L8681, L8682, L8683, L8685, L8686, L8687, and L8689 to "Billing/Coding" section.


3/16/09 Added 61886 to "Billing/Coding" section.


6/22/10 Policy Number(s) removed (amw)

10/26/10 Revised “Description’ section. Revised policy to indicate that VNS may be medically necessary in refractive seizures (not just in partial onset seizures). Added diagnoses codes to the “Billing/Coding” section. Reviewed by Medical Director 9/30/10. References added. (btw)

1/4/11 Added new 2011 CPT codes; 64568, 64569, and 64570 to “Billing/Coding” section. Removed code, 64573. (btw)

3/29/11 References updated. (btw)


6/12/12 Specialty Matched Consultant Advisory Panel review 5/16/2012. Description section revised. The When Not Covered section reformatted. Added treatment of heart failure and fibromyalgia to the list of investigational indications. No change to policy intent. Policy Added the following diagnoses to the Billing/Coding section: 428 – 428.9 and
Vagus Nerve Stimulation

729.1. Guidelines updated. Reference added. (btw)

7/24/12  Added CPT code, 64585, to the Billing/Coding section. Added diagnosis codes, 346 and 278.03 to Billing/Coding section. (btw)

7/1/13   Specialty Matched Consultant Advisory Panel review 5/15/2013. No change to policy statement. ICD-10 diagnosis codes added to Billing/Coding section. References added. (btw)

11/12/13 Added M60.872 and M60.879 to the ICD10 list in the Billing/Coding section. (btw)

12/31/13 Added new 2014 HCPCS code, L8679 to Billing/Coding section. (btw)

6/10/14   Specialty Matched Consultant Advisory Panel review 5/27/2014. Description section updated to include information regarding the VNS (t-VNS®) system developed by Cerbomed. The following investigational indications were added to the When Not Covered section; “headaches, tinnitus, and traumatic brain injury” and “Non-implantable vagus nerve stimulation devices are considered investigational for all indications.” No change to policy intent. Policy Guidelines updated. Reference added. (btw)

4/28/15 Reference added. Description section reviewed and updated for clarity. No change to policy statement. (sk)


4/1/16 Reference added. (sk)

7/1/16 Specialty Matched Consultant Advisory Panel review 5/25/2016. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.