

## Corporate Medical Policy

### Vagus Nerve Stimulation

<b>File Name:</b>	vagus_nerve_stimulation
<b>Origination:</b>	6/1998
<b>Last CAP Review:</b>	5/2019
<b>Next CAP Review:</b>	5/2020
<b>Last Review:</b>	5/2019

#### Description of Procedure or Service

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Stimulation of the vagus nerve can be performed using a pulsed electrical stimulator implanted 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.

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 two 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.

Based on observations that patients treated with VNS experience improvements in mood, VNS has been evaluated for the treatment of refractory depression. VNS has been investigated for multiple other conditions which may be affected by either the afferent or efferent stimulation of

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the vagus nerve, including heart failure, headaches, tremor, fibromyalgia, tinnitus, and traumatic brain injury.

In 1997, the U.S. Food and Drug Administration (FDA) approved a vagus nerve stimulation device called the NeuroCybernetic Prosthesis (NCP®) system (Cyberonics, Houston, TX) through the Premarket Approval (PMA) process. The device was approved for use in conjunction with drugs or surgery “as an adjunctive treatment of adults and adolescents over 12 years of age with medically refractory partial onset seizures.” There have been subsequent expanded approvals. In July 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.” In 2017, Cyberonics received PMA approval from FDA expanding the indicated use as adjunctive therapy for seizures in patients 4 years of age and older with partial-onset seizures that are refractory to antiepileptic medications.

On May 30, 2017, the gammaCore-S® (electroCore LLC, Basking Ridge, NJ), a noninvasive VNS device, was cleared for marketing through the 510(k) process (K171306) for the acute treatment of adults with pain associated with episodic cluster headaches and migraine headaches. When the device is applied to the side of the neck by the patient, a mild electrical stimulation of the vagus nerve is carried to the central nervous system. Each stimulation using gammaCore-S® lasts 2 minutes. The patient controls the stimulation strength.

Cerbomed (Erlangen, Germany) 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.

***\*\*\*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

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**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

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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

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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.

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## When Vagus Nerve Stimulation is not covered

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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
5. headaches
6. obesity
7. heart failure
8. fibromyalgia
9. tinnitus
10. traumatic brain injury
11. Upper limb impairment due to stroke.

Transcutaneous (nonimplantable) vagus nerve stimulation devices are considered **investigational** for all indications.

## Policy Guidelines

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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.

For individuals who have seizures refractory to medical treatment who receive vagus nerve stimulation, the evidence 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 that the technology results in a meaningful improvement in the net health outcome.

For individuals who have treatment-resistant depression who receive VNS, the evidence includes an 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.

For individuals who have chronic heart failure who receive VNS, the evidence includes RCTs and case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCTs did not show significant improvements in the primary outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have upper-limb impairment due to stroke who receive VNS, the evidence includes a single pilot study. Relevant outcomes are symptoms, change in disease status, and functional outcomes. There was preliminary support for improvement in functional outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have essential tremor, obesity, headache, fibromyalgia, tinnitus, or autism who receive VNS, the evidence 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.

For individuals with episodic cluster headaches who receive transcutaneous VNS, the evidence includes three RCTs. One RCT for a cluster headache showed a reduction in headache frequency but did not include a sham treatment group. Two randomized, double-blind, sham-controlled studies

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showed efficacy of achieving pain-free status within 15 minutes of treatment with noninvasive VNS in patients with episodic cluster headaches but not in patients with chronic cluster headaches. The RCTs for episodic cluster headaches are promising, however, additional studies with larger relevant populations are required to establish the treatment efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with cluster headache who receive noninvasive transcutaneous VNS (nVNS) to treat acute cluster headache, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, quality of life and functional outcomes. These studies suggest that people with episodic and chronic cluster headaches may respond differently to acute treatment with nVNS. Studies designed to focus on episodic cluster headache are needed. Quality of life and functional outcomes have not been reported. Treatment periods ranged from only 2 weeks to 1 month with extended open-label follow-up of up to 3 months. There are few adverse events of nVNS and they are mild and transient. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with migraine headache who receive noninvasive transcutaneous VNS (nVNS) to treat acute migraine headache, the evidence includes one RCT. Relevant outcomes are symptoms, change in disease status, quality of life and functional outcomes. One RCT has evaluated nVNS for acute treatment of migraine with nVNS in 248 patients with episodic migraine with/without aura. There was not a statistically significant difference in the primary outcome of the proportion of participants who were pain-free without using rescue medication at 120 minutes. However, the nVNS group had a higher proportion of patients with decrease in pain from moderate or severe to mild or no pain at 120 minutes and a higher proportion of patients who were pain-free at 120 minutes for 50% or more of their attacks. There are few adverse events of nVNS and they are mild and transient. Quality of life and functional outcomes were not reported and the double-blind treatment period was 4 weeks with an additional 4 weeks of open-label treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have other neurologic, psychiatric, or metabolic disorders (e.g., epilepsy, depression, schizophrenia, noncluster headache, or impaired glucose tolerance) who receive transcutaneous VNS, the evidence includes RCTs 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**

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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.bcsnc.com](http://www.bcsnc.com). They are listed in the Category Search on the Medical Policy search page.

Vagus 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.

*Applicable service codes: 61885, 61886, 61888, 64553, 64568, 64569, 64570, 64585, 95970, 95974, 95975, 95976, 95977, 95983, 95984, L8679, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689*

*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, F32.89, 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, G43.011, 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,*

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*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

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

Medical Policy Advisory Group 12/2/1999

Specialty Matched Consultant Advisory Panel - 8/2001

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

BCBSA Medical Policy Reference Manual, 7.01.20; 4/29/03

ECRI, TARGET Report #73, 1/2002

ECRI Windows on Medical Technology, Issue No. 14, December 1998

Specialty Matched Consultant Advisory Panel - 7/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.20, 11/9/2004.

Specialty Matched Consultant Advisory Panel - 6/2005

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.20, 6/27/05

BCBSA TEC Assessment. (June 2005) Vagus nerve stimulation for treatment-resistant depression. Retrieved 9/26/05 from [http://www.bcbsa.com/tec/vol20/20\\_08.html](http://www.bcbsa.com/tec/vol20/20_08.html)

ECRI Target Database. (2005, October). Implantable vagus nerve stimulator for treatment resistant depression. Retrieved 11/8/05 from [http://www.target.ecri.org/summary/detail.aspx?e=5&doc\\_id+74&q=vagus&anm=WynneB](http://www.target.ecri.org/summary/detail.aspx?e=5&doc_id+74&q=vagus&anm=WynneB).

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.20, 10/10/2006

Specialty Matched Consultant Advisory Panel - 5/2007

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.20, 11/13/08

Specialty Matched Consultant Advisory Panel - 5/2009

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.20, 11/12/2009

Medical Director – 10/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.20, 1/13/11

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Specialty Matched Consultant Advisory Panel – 5/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.20, 3/8/12

Specialty Matched Consultant Advisory Panel – 5/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.20, 3/13/2013

Specialty Matched Consultant Advisory Panel – 5/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.20, 3/13/2014

Specialty Matched Consultant Advisory Panel – 5/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.20, 3/12/2015

Specialty Matched Consultant Advisory Panel – 5/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.20, 2/11/2016

Specialty Matched Consultant Advisory Panel – 5/2016

Specialty Matched Consultant Advisory Panel – 5/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.20, 10/12/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.20, 3/8/2018

Specialty Matched Consultant Advisory Panel – 5/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.20, 2/14/2019

Specialty Matched Consultant Advisory Panel – 5/2019

## **Policy Implementation/Update Information**

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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.
8/01	Specialty Matched Consultant Advisory Panel - Approved. No changes. Typo corrected.
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.

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- 4/03 Codes E0751 and E0753 removed from Billing/Coding section. System coding changes.
- 9/03 Specialty Matched Consultant Advisory Panel review 7/15/03. Benefits Application section revised. Sources added. Removes codes E0756, E0757, E0758, and E0765 from the policy.
- 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, L8688, and L8689 to "Billing/Coding" section.
- 6/18/07 Specialty Matched Consultant Advisory Panel review 5/23/2007. No change to policy statement. Added CPT code 64553 to "Billing/Coding" section. References added.
- 3/16/09 Added 61886 to "Billing/Coding" section.
- 7/6/09 Specialty Matched Consultant Advisory Panel review 5/28/09. No change to policy statement. Added additional indications to the "When Not Covered" section; "7. For the treatment of obesity." Updated rationale in the "Policy Guidelines" section. References added. Notice given 7/6/09. Policy effective 10/12/09. (btw)
- 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 deleted code, 64573. (btw)
- 3/29/11 References updated. (btw)

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- 7/1/11 Specialty Matched Consultant Advisory Panel review 5/25/2011. “Description” section revised. No change to policy statement. (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 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)
- 7/1/15 Specialty Matched Consultant Advisory Panel review 5/27/2015. (sk)
- 4/1/16 Reference added. (sk)
- 7/1/16 Specialty Matched Consultant Advisory Panel review 5/25/2016. (sk)
- 9/30/16 Code F32.89 added to Billing/Coding section. (sk)
- 6/30/17 Specialty Matched Consultant Advisory Panel review 5/31/2017. (sk)
- 11/10/17 Reference added. Regulatory Status and Policy Guidelines updated. ICD-9 codes removed from Billing/Coding section. No change to coverage criteria. (sk)
- 6/29/18 Reference added. Regulatory Status and Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/23/2018. (sk)
- 1/1/19 Added codes 95976, 95977, 95983, and 95984 to Billing/Coding section. (sk)
- 6/11/19 Reference added. Policy Guidelines updated to include additional information on transcutaneous vagus nerve stimulation to treat acute cluster headache and acute migraine headache. Policy statement unchanged. Specialty Matched Consultant Advisory Panel review. (sk)



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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.