

Corporate Medical Policy

Vagus Nerve Stimulation

File Name:	vagus_nerve_stimulation
Origination:	6/1998
Last CAP Review:	5/2011
Next CAP Review:	5/2012
Last Review:	5/2011

Description of Procedure or Service

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. 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 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.

*****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.

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Vagus Nerve Stimulation for the treatment of depression, obesity, headache, or essential tremors 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

Chronic Vagus Nerve Stimulation is covered 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

1. For indications that do not meet the criteria listed above.
2. For patients who can be treated successfully with anti-epileptic drugs.
3. For treatment of patients with depression.
4. For the treatment of essential tremor.
5. For the treatment of headaches.
6. For the treatment of obesity.

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 available evidence is not sufficient to permit conclusions of the effect of VNS therapy on health outcomes in treatment resistant depression. The only randomized study did not show statistically significant results comparing activated VNS with sham (non-activated VNS). FDA approved the use of VNS for treatment resistant depression with the condition that they conduct 2 post approval studies. One study is to determine the optimal dosing and patient selection criteria. The second study required is a prospective, observational registry study of 1000 subjects extending up to five years to evaluate the long-term outcomes and response to therapy. Additional well-designed, large randomized controlled trials are needed to determine the safety and efficacy of VNS for treatment resistant depression.

Unintended weight loss has been observed in participants in studies of VNS prompting interest in use of the technology to prevent or treat obesity. Bodenlos et al investigated whether VNS might affect food cravings in patients with chronic, treatment-resistant depression. A number of limitations in the study prevent drawing conclusions about the impact of VNS on eating behavior including small study size, selection and lack of randomization, heterogeneity of groups with respect to depression, BMI, and age. Comorbidities including anxiety and medical conditions and drugs that might influence food intake and cravings were not considered. Large, well designed and executed controlled studies are needed to evaluate the impact of VNS on eating behavior and obesity.

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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, 95970, 95974, 95975, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689

Diagnoses that are subject to medical necessity review: 278 – 278.02, 296, 296.2, 296.2x, 296.3, 296.3x, 296.5, 296.5x, 296.8, 296.82, 307.81, 311, 333.1, 346.0 - 346.9x, 625.4, 627.2, 784.0

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

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

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.

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

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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

Specialty Matched Consultant Advisory Panel – 5/2011

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.
- 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.
- 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

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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)
- 7/1/11 Specialty Matched Consultant Advisory Panel review 5/25/2011. "Description" section revised. No change to policy statement. (btw)

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.