

## VAGUS NERVE STIMULATION

**Policy Number: 200601-0001**

**Effective Date: 11/1/2000**

**Revision Date: 01/24/2006**

### Overview

Epilepsy is one of the most common disorders of the nervous system. Epilepsy affects more than 2.7 million Americans of all ages and can develop at any time. Epilepsy makes people susceptible to seizures. A seizure is a change in sensation, awareness or behavior brought about by a brief electrical disturbance in the brain. Seizures may vary from a momentary disruption of the senses, to short periods of unconsciousness or staring spells, to convulsions. Some people have just one type of seizure. Others have more than one type. When the diagnosis of epilepsy has been made, the physician will usually prescribe seizure-preventing drugs. If drugs are not successful other methods of controlling seizures may be tried, such as surgery or vagus nerve stimulation.

Surgery for epilepsy either removes the portion of the brain where the seizures originate or cuts nerve fibers to prevent the nerve impulses that occur during a seizure from spreading to other parts of the brain.

Vagus nerve stimulation provides intermittent electrical stimulation to a nerve outside of the brain, the vagus, or tenth cranial nerve, which influences certain patterns of brain activity. The vagus nerve is a major connection between the brain and the rest of the body. It carries sensory information from the body to the brain and motor commands from the brain to the body. It is not known exactly how vagus nerve stimulation works to reduce seizure activity.

At the present time, there is only one device that has been approved by the FDA for vagus nerve stimulation. The device was originally approved by the FDA in 1997 under the trade name Neurocybernetic Prosthesis System™ as adjunctive therapy in reducing the frequency of seizures in adults and children over the age of 12 years of age with partial onset seizures, which are refractory to anti-epileptic medications. In 2002, the name of the device was changed to VNS Therapy System™.

### Covered Services

**Preauthorization by an FCHP Medical Director is required.**

**FCHP covers vagus nerve stimulation for adults and children over 12 years of age with partial onset seizures<sup>1</sup> when all of the following criteria are met:**

1. Diagnosis of partial onset seizures which are refractory to anti-epileptic medications or who have debilitating side effects from anti-epileptic medications, AND
2. Failed surgery for epilepsy or is not a suitable surgical candidate.

### Exclusions

1. VNS Therapy System™ cannot be used in patients with left or bilateral cervical vagotomy.
2. Vagus nerve stimulation is not covered for individuals with seizure types other than partial onset.

- Vagus nerve stimulation is not covered for refractory depression, or for any other indication, including but not limited to autism, obesity, Alzheimer's disease and obsessive compulsive disorder, because it is considered experimental or investigational for these proposed indications.

## Codes

Surgically implanted devices are not subject to the durable medical equipment benefit limit.

Codes	Number	Description
CPT	61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
	61888	Revision or removal of cranial neurostimulator pulse generator or receiver
	64573	Incision for implantation of neurostimulator electrodes; cranial nerve
	95970	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
HCPCS	L8680	Implantable neurostimulator electrode, each
	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
	L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
	L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
	L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
	L8689	External recharging system for implanted neurostimulator, replacement only

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## Products to Which This Policy Applies

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ MassHealth
- ⊕ Non-Group: FCHP Independent Care, Direct Enrollment, & Bill-at-Home
- ⊕ Fallon Senior Plan™

## References

- Centers for Medicare & Medicaid Services (CMS)** National Coverage Determination for Vagus Nerve Stimulation for Treatment of Seizures (160.18)
- Centers for Medicare & Medicaid Services (CMS)** Draft Local Coverage Determination for Vagal Nerve Stimulation for Depression (DL21863)  
[http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd\\_id=21682&lcd\\_version=8&basket=lcd%3A21682%3A8%3AVAGAL+NERVE+STIMULATION+%28VNS%29++FOR+DEPRESSION%3ACarrier%3ANational+Heritage+Insurance+Company+%2831143%29%3A21683](http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=21682&lcd_version=8&basket=lcd%3A21682%3A8%3AVAGAL+NERVE+STIMULATION+%28VNS%29++FOR+DEPRESSION%3ACarrier%3ANational+Heritage+Insurance+Company+%2831143%29%3A21683)
- U. S. Food and Drug Administration (FDA)** Cyberonics, Inc. VNS Therapy System – P970003/S050. <http://www.fda.gov/cdrh/pdf/p970003s050.html>.

4. **U. S. Food and Drug Administration (FDA)** Cyberonics, Inc. Neurocybernetic Prosthesis System – P970003, <http://www.fda.gov/cdrh/pdf/p970003.pdf>.
5. Encyclopedia of Surgery, Vagal Nerve Stimulation <http://www.surgeryencyclopedia.com/St-Wr/Vagal-Nerve-Stimulation.html>
6. Blue Cross Blue Shield Association Technology Evaluation Center, *Vagus Nerve Stimulation for Treatment Resistant Depression*, Volume 20, No. 8, August 2005. [http://www.bcbs.com/tec/vol20/20\\_08.html](http://www.bcbs.com/tec/vol20/20_08.html).
7. Nahas, et al. Two-Year Outcome of Vagus Nerve Stimulation (VNS) for Treatment of Major Depressive Episodes. *Journal of Clinical Psychology* 2005 September; 66(9):1097-104.

**Committee Review Dates**

Technology Assessment Committee: 11/1/2000, 01/31/2006

Benefits Committee: 01/2001, 10/2001

Technology Assessment Subcommittee: 01/24/2006

Approved by:

*Signature on file*

Dennis A. Batey, MD – Chief Medical Officer

01/31/2006

Date

**IMPORTANT NOTE**

**Not all services are covered for all products or employer groups.** This medical policy expresses FCHP’s determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy. Medicare and Medicaid policies will only apply to benefits paid for under Medicare or Medicaid rules, and not to any other health benefit plan benefits. CMS’s Coverage Issues Manual can be found on the following website: <http://cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp>

<sup>1</sup> Partial onset seizures are seizures characterized by onset in a limited area in the brain. Partial onset seizures may be simple or complex. The International Classification of Epileptic Seizures classifies simple partial seizures as those that are not associated with any impairment of consciousness. Complex partial seizures cause impaired consciousness.