Medical Coverage Policy

Vagal Nerve Stimulation

☐ Device/Equipment ☐ Drug ☒ Medical ☐ Surgery ☐ Test ☐ Other

Effective Date:	10/1/2005	Policy Last Updated:	1/8/2013

☐ **Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

☒ **Prospective review is not required.**

Description:

VNS is a pulse generator, similar to a pacemaker, that is surgically implanted under the skin of the left chest and an electrical lead (wire) is connected from the generator to the left vagus nerve. Electrical signals are sent from the battery-powered generator to the vagus nerve via the lead. These signals are in turn sent to the brain.
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. In 1997, the U.S. Food and Drug Administration (FDA) approved a VNS 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.”

All partial seizures are characterized by onset in a limited area, or focus, of one cerebral hemisphere. The International Classification of Epileptic Seizures (ICES) classifies simple partial seizures (SPS) as those that are not associated with any impairment of consciousness.[1] Although the ability to respond may be preserved, motor manifestations or anxiety relating to the seizure symptoms may prevent a patient from responding appropriately.

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.

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 for refractory depression. On July 15, 2005, Cyberonics received PMA supplement 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."

Given the limitations of prior literature as described in the 2006 TEC Assessment, combined with the lack of substantial new clinical trials, the scientific evidence is considered to be insufficient to permit conclusions concerning the effect of this technology on major depression.

VNS therapy has also been investigated for use in other conditions such as headaches, obesity, and essential tremors. The evidence is limited and not sufficient to permit conclusion on efficacy

Medical Criteria:

None

Policy:

BlueChip for Medicare:

Vagal nerve stimulation is reasonable and **medically necessary** for patients with medically refractory partial onset seizures when surgery is not recommended or has failed.

Vagel Nerve Stimulation for all other conditions, including treatment for depression, is **not medically necessary**, as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

Commercial:
VNS may be considered medically necessary as a treatment of medically refractory seizures

Vagel Nerve Stimulation for all other conditions, including treatment for depression, is **not medically necessary**, as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

Preauthorization is not required or recommended.

Coverage:

Benefits may vary between groups/contracts. Please refer to the appropriate evidence of coverage or subscriber agreement for applicable diagnostic imaging, lab, and machine tests or surgery benefits.

Coding:

61885
61886
61888
64553
64573
64568
64569
64570
95974
95975

L8680 Implantable neurostimulator electrode, each
L8681 Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
L8682 Implantable neurostimulator radiofrequency receiver
L8683 Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
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 battery (internal) for use with implantable neurostimulator

Also known as:
NCP
NeuroCybernetic prosthesis
Vagal nerve stimulation
Vagal nerve stimulation for epilepsy, NeuroCybernetic prosthesis

Related Topics:
Not applicable

Published:
Policy Update, Nov 2002
Policy Update, Sep 2005
Policy Update, Aug2006
Policy Update, Oct 2007
Provider Update, Oct 2008
Provider Update, Sep2009
Provider Update, Jan 2011
Provider Update, Dec 2011
Provider Update, March 2013

References:

2005 TEC Assessment; Tab 8.

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Vagal nerve stimulation for epilepsy:

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.* Neurology 1999;53:666-669.

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Kwan P, Brodie MJ. *Early Identification of Refractory Epilepsy.* New England Journal of Medicine; February 3, 2000;342;5:314-319.

Murphy JV, Torkelson R, Dowler I, Simon S, Hudson S. *Vagal Nerve Stimulation in Refractory Epilepsy The First 100 Patients Receiving Vagal Nerve Stimulation at a Pediatric Epilepsy Center.* Archives of Pediatrics & Adolescent Medicine; 2003;157:560-564.

Vagal nerve stimulation for depression:

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