EFFECTIVE DATE: 10/01/2005
POLICY LAST UPDATED: 05/20/2014

OVERVIEW
This medical policy documents the coverage determination for vagal nerve stimulation (VNS). 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.

PRIOR AUTHORIZATION
Prior authorization is not required.

POLICY STATEMENT
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.

Vagal 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.

Vagus nerve stimulation is considered not medically necessary as a treatment of other conditions, including but not limited to heart failure, fibromyalgia, depression, essential tremor, obesity, headaches, tinnitus, and traumatic brain injury. There is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

Blue CHIP for Medicare and Commercial:
Non implantable vagus nerve stimulation devices are considered investigational for all indications. The device is not FDA approved and therefore is a contract exclusion.

MEDICAL CRITERIA
Not Applicable

BACKGROUND
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. 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.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for applicable diagnostic tests or surgery benefits.

CODING

Blue CHiP for Medicare and Commercial

The following CPT codes are covered for medically necessary VNS:

61885	**61886**	**61888**	**63650**	**64553**
64568	**64569**	**64570**	**95974**	**95975**

The following HCPC codes are covered for medically necessary VNS:

L8680*	**L8681**	**L8682**	**L8683**	**L8685**
L8686	**L8687**	**L8688**	**L8689**	

* Effective April 1, 2014 code L8680 is no longer separately billable: Use alternate code 63650

RELATED POLICIES

None

PUBLISHED

Provider Update	Aug 2014
Provider Update	Mar 2013
Provider Update	Dec 2011
Provider Update	Jan 2011
Provider Update	Sep 2009
Provider Update	Oct 2008
Policy Update	Oct 2007

REFERENCES

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