

POLICY TITLE: Vagus Nerve Stimulation

POLICY STATEMENT: Vagus Nerve Stimulation (VNS) is a unique non-drug treatment for seizures, major depression and bipolar disorders. MAHP has established this policy to ensure that MAHP members meet established criteria for VNS Therapy for coverage.

PROCEDURE: The vagus nerves are a pair of large nerves carrying much information from the body up through the neck, to the appropriate areas of the brain. VNS therapy is a device similar to a pacemaker that is placed in the chest wall. It sends small electrical pulses via a wire up to the vagus nerve in the left side of the chest wall. It sends small electrical pulses via a wire up to the vagus nerve in the left side of the neck. Then the vagus nerve delivers these pulses directly to the neck and brain area felt to be responsible for the seizure activity, depression or bipolar disorder.

1. Seizures – criteria for coverage

- Requested by a Neurologist or ENT physician
- Pt must be 12 years or older
- 6 or more seizures per month while on seizure meds
- Medical refractory-partial seizures that the patient is not a candidate for surgery or in whom surgery has failed.
 - A. Simple-partial seizures – patient remains conscious, experiences unusual feelings or sensations. Unexplained emotions such as anger, sadness or perceives smells, sounds or tastes things not present.
 - B. Complex partial seizures – change or loss in consciousness, signs of altered state, dreamlike experiences, repetitive behaviors such as blink or twitch.

NOTE: This does **NOT** include generalized epilepsy or Lennox-Gastaut Syndrome.

CMS has issued an NCD for coverage in patients with medical refractory partial-onset seizures whom surgery is not recommended or has failed surgical treatment. **MAHP will cover if meets the above criteria.**

2. Major Depression & Bipolar Disorders

NOTE: MAHP does **NOT** cover VNS for these diagnoses due to Apollo Medical Review Criteria on last page of policy. CMS has issued a national **non-coverage** decision for VNS therapy for the treatment of depression and bipolar disorders.

MEDICAL ASSOCIATES HEALTH PLANS
HEALTH CARE SERVICES POLICY & PROCEDURE MANUAL
POLICY NUMBER: PP 18

3. Battery Replacement: This involves changing the pulse generator that contains the battery. It is considered an outpatient surgical procedure, some stay overnight. The battery life is 3-8 years depending on settings.

References: www.VNSTherapy.com
CMS website
Medical Review Criteria-Apollo

Judy Riniker, RN
Manager of Health Care Services/
Quality Improvement

Date

Mary Leary, RN
Director of Health Care Services/
Quality Improvement

Date

Original: 11/09
Reviewed: 03/10
Revised: 02/11
Revised: 01/12

MEDICAL ASSOCIATES HEALTH PLANS
HEALTH CARE SERVICES POLICY & PROCEDURE MANUAL
POLICY NUMBER: PP 18

Vagus/Vagal Nerve Stimulation (VNS) for the Treatment of Depression

The FDA approved the Vagus Nerve Stimulation (VNS) Therapy System in July 2005 “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.”

The VNS Therapy System is the first FDA-approved implantable device-based treatment for depression and the first treatment developed, studied, approved and labeled specifically for patients with treatment-resistant depression (TRD). The VNS Therapy System was approved as a treatment for medically refractory epilepsy in Europe in 1994 and in the United States and Canada in 1997 and as a treatment for TRD in Europe and Canada in 2001. The VNS Therapy System is now commercially available for the treatment-resistant depression and refractory epilepsy approved uses in the United States, European Union and Canada. For more information on VNS Therapy for treatment-resistant depression, including the contraindications, warnings and precautions, refer to the Physician’s and Patient’s Manuals and other information at www.cyberonics.com or www.vnstherapy.com or call 1-877-NOW 4 VNS.

“There is no good quality evidence that vagal nerve stimulation is an effective treatment for this (treatment-resistant depression) condition.” (Little, 2009)

Coverage limitations/exclusions

Vagus nerve stimulation for the treatment of depression is considered investigational by health plans and by Medicare; therefore, not a covered benefit.

Resources – VNS for depression: refer to additional resources in text.