



**VAGAL NERVE STIMULATION FOR DEPRESSION**

**Effective Date: February 23, 2010**  
**Date Of Origin: April 11, 2007**

**Review Dates: 4/07, 2/08, 2/09, 2/10**  
**Status: Current**

**Summary of Changes**

Clarifications:

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Deletions:

- Pg. 1, Section I, language stating VNS for depression has been a proposed as a treatment for TRD.

Additions:

- Pg. 1, Section I, language added to reflect VNS for depression is an FDA approved treatment for TRD.
- Pg. 2, Section II, 3. Two hospitalizations or partial hospitalizations replaced with: “Two previous intensive levels of care”.

**I. DESCRIPTION**

Vagal Nerve Stimulation (VNS) for depression is an FDA approved treatment for Treatment Resistant Depression (TRD). The term VNS generally relates to electrical stimulation of the left vagal nerve at the cervical level. Left VNS is preferred to right VNS because the heart rate is mostly influenced by the right vagal nerve and stimulation could induce cardiovascular complications. VNS was first introduced for the treatment of medically refractory seizures. The rationale for its use as an antiseizure treatment was based on the observation that stimulation of the vagus nerve could alter electric brain activity in animals. This led to the theory that synchronous epileptic discharges could be interrupted or prevented by stimulation of the vagus nerve. Clinical studies of vagus nerve stimulation were successful in reducing seizure frequencies and resulted in the 1997 approval by the Food and Drug Administration (FDA) of a device called the neurocybernetic prosthesis, an implantable generator that provides intermittent electrical stimulation to the cervical portion of the vagus nerve. During these clinical trials, investigators observed that VNS improved mood and cognition in epilepsy patients receiving VNS. In addition, other observations indicate that VNS may be effective for the treatment of depression, including:

- Antiepileptic drugs are effective in the treatment of mood disorders.
- Positron emission tomography (PET) studies demonstrate that VNS affects metabolism and thus function of limbic structures that suggest an antidepressant effect.
- VNS modulates concentrations of monoamines within the central nervous system.
- An anatomic connection exists between the vagus nerve and brain structures related to mood disorders.



The exact mechanism of action by which VNS is thought to reduce the symptoms of depression is yet unknown, but it has been shown that VNS has an effect on brain metabolism and brain function.

The FDA approved indications for VNS for depression are:

- Adjunctive, long-term treatment of chronic or recurrent depression
- $\geq$  18 years of age
- Experiencing a major depressive episode
- Inadequate response to 4 or more adequate antidepressant treatments

## II. POLICY/CRITERIA

Vagal nerve stimulator therapy for treatment resistant depression may be covered on an exception basis following Medical Director Review when the following criteria are met.

The patient must have treatment resistant depression as defined by **ALL** of the following:

1. Failure of at least four adequate antidepressant medication trials, either single or in combination.
2. Failure of at least one acute course of electroconvulsive therapy, unless ECT is medically contraindicated. Failure is defined by a lack of improvement or intolerable side effects. A typical course of ECT is 3 treatments per week up to 12 treatments.
3. Two previous intensive levels of care for depression-related illnesses.

In addition the patient must:

1. Have an independent second opinion from an approved tertiary care center regarding the appropriateness of current treatment, alternatives to current treatment, and recommendations on use of vagal nerve stimulation, AND
2. Be under current management of treatment resistant depression by a board certified psychiatrist, AND
3. Have no contraindications to VNS therapy as outlined in the FDA approval criteria, AND
4. Provide informed consent which outlines the likelihood of benefit from the device and the potential complications.

This policy is based on review and recommendations of Priority Health's Technology Assessment Committee in February 2007. Participating psychiatrists have reviewed and provided input to the policy. Priority Health's Behavioral Health Committee reviewed this policy in May 2007.

## III. MEDICAL NECESSITY REVIEW

Required

Not Required

Not Applicable



#### IV. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS).*
- ❖ **MEDICAID:** *Coverage is determined by the Michigan Medicaid Provider Manual and the Michigan Medicaid Fee Schedule at: [http://www.michigan.gov/mdch/0,1607,7-132-2945\\_42542\\_42543\\_42546\\_42551-159815--,00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html).*
- ❖ **MICHILD:** *For MICHILD members, this policy will apply unless MICHILD certificate of coverage limits or extends coverage.*

#### V. CODING INFORMATION

##### ICD-9 Codes that may support Medical Necessity

- 296.3 Major depressive disorder, recurrent episode
- 296.30 Major depressive disorder, recurrent episode, unspecified
- 296.33 Major depressive disorder, recurrent episode, severe, without mention of psychotic behavior
- 296.34 Major depressive disorder, recurrent episode, severe, specified as with psychotic behavior
- 298.0 Depressive type psychosis
- 301.1 Affective personality disorder
- 301.12 Chronic depressive personality disorder
- 309.1 Prolonged depressive reaction as adjustment reaction
- 311 Depressive disorder, not elsewhere classified

##### CPT/HCPCS Codes:

- 61885 Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
- 61886 Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays
- 61888 Revision or removal of cranial neurostimulator pulse generator or receiver (no auth)
  
- 64553 Percutaneous implantation of neurostimulator electrodes; cranial nerve
- 64573 Incision for implantation of neurostimulator electrodes; cranial nerve
- 64585 Revision or removal of peripheral neurostimulator electrodes (no auth)
- 64590 Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling



- 64595 Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver (no auth)
  
- C1767 Generator, neurostimulator (implantable), nonrechargeable
- C1778 Lead, neurostimulator (implantable)
- C1816 Receiver and/or transmitter, neurostimulator (implantable)
- C1820 Generator, neurostimulator (implantable), with rechargeable battery and charging system
- C1883 Adapter/ extension, pacing lead or neurostimulator lead
- C1897 Lead, neurostimulator test kit (implantable)
  
- L8680 Implantable neurostimulator electrode, each
- L8681 Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
- 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
  
- (No auth required for these services)
- 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
- 95974 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); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour
- 95975 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); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)



## VI. REFERENCES

Vagus Nerve Stimulation for Treatment-Resistant Depression, BlueCross BlueShield Association, TEC Assessments, August 2006. Available on the World Wide Web @ [http://www.bcbs.com/betterknowledge/tec/vols/21/21\\_07.html](http://www.bcbs.com/betterknowledge/tec/vols/21/21_07.html)

Vagus Nerve Stimulation for Depression, October 2005, Hayes, Inc. Updated searches January & July 2006.

Vagus Nerve Stimulation, Aetna Clinical Policy Bulletin, August 2006. Available on the World Wide Web @ [http://www.aetna.com/cpb/medical/data/100\\_199/0191.html](http://www.aetna.com/cpb/medical/data/100_199/0191.html)

Vagus Nerve Stimulation, Cigna Healthcare Coverage Position, October 2006. Available on the World Wide Web @ [http://www.cigna.com/health/provider/medical/procedural/coverage\\_positions/medical/index.html](http://www.cigna.com/health/provider/medical/procedural/coverage_positions/medical/index.html)

Vagal Nerve Stimulation for Depression, BlueCross BlueShield of Massachusetts, January 2007. Available on the World Wide Web @ [http://www.bluecrossma.com/common/en\\_US/medical\\_policies/medcat.htm](http://www.bluecrossma.com/common/en_US/medical_policies/medcat.htm)

Proposed Decision Memo for Vagus Nerve Stimulation for Treatment of Resistant Depression (TRD), CMS, February 5, 2007. Available on the World Wide Web @ <http://cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=195>

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