VAGUS NERVE STIMULATION FOR TREATMENT RESISTANT DEPRESSION
HS-058

Harmony Behavioral Health, Inc.
Harmony Behavioral Health of Florida, Inc.
Harmony Health Plan of Illinois, Inc.
HealthEase of Florida, Inc.
‘Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona, Inc.
WellCare Health Insurance of Illinois, Inc.
WellCare Health Insurance of New York, Inc.
WellCare Health Plans of New Jersey, Inc.
WellCare of Florida, Inc.
WellCare of Connecticut, Inc.
WellCare of Georgia, Inc.
WellCare of Kentucky, Inc.
WellCare of Louisiana, Inc.
WellCare of New York, Inc.
WellCare of Ohio, Inc.
WellCare of Texas, Inc.
WellCare Prescription Insurance, Inc.

Vagus Nerve Stimulation for Treatment Resistant Depression

Policy Number: HS-058

Original Effective Date: 11/6/2008

Revised Date(s): 11/11/2009; 8/12/2011; 6/7/2012

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member’s Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.
BACKGROUND

Major depression is characterized by a combination of symptoms occurring during a major depressive episode (MDE) that interfere with the person’s daily activities such as their ability to work, sleep, and eat. An MDE may occur several times in a lifetime and may last for several weeks or years. Dysthymia is a less severe type of depression, which involves long-term chronic symptoms that do not disable, but prevent the patient from feeling good. Bipolar disorder, also referred to as manic-depressive disorder, is characterized by drastic mood changes; a severe high (mania, manic cycle) is followed by a low (depression, depressed cycle). This health technology assessment focuses on treatment of major depression and bipolar disorder.

Treatment depends on the type and severity of depression. Milder forms of depression are initially treated with psychotherapy. Moderate to severe depression is often treated with a combined approach of antidepressants and psychotherapy. Electroconvulsive therapy (ECT) is a choice for severe and life threatening depression (major depression, bipolar disorder) or patients who cannot take or do not respond to antidepressant medication. It is also used in combination with antidepressants. Chronic intermittent electrical stimulation of the left vagus nerve, originally designed as a treatment for medically refractory epilepsy, has recently been introduced as a possible adjunctive therapy for treatment-resistant major depression and bipolar disorder (from Hayes, 2005).

VNS Therapy System

The Neuro Cybernetic Prosthesis (NCP)® System, also called the VNS Therapy™ System, manufactured by Cyberonics Inc., is the only device currently available for this type of neuromodulation therapy; in July 2005, the NCP System was approved by the Food and Drug Administration (FDA) for adjunctive long-term treatment of chronic or recurrent depression in patients 18 years of age or older who are experiencing a major antidepressant episode and have not had an adequate response to four or more adequate antidepressant treatments. The NCP system includes a pulse generator and lead designed to deliver physician-programmed stimulation to the vagus nerve. The device, implanted subcutaneously in the upper chest, delivers pulses of current via electrodes attached to the left vagus nerve in the neck. A telemetry system and programming wand can be used to tailor the stimulation parameters to the patient’s needs. In addition, a handheld magnet may be used to stop stimulation if there is discomfort or if the device malfunctions.

Hayes, Inc. Conclusion

The currently available evidence is insufficient to permit conclusions regarding the efficacy and safety of VNS as an adjunct therapy in treatment-resistant major depression and bipolar disorder. While a moderate treatment effect was observed in one small, uncontrolled study and in a larger open-label extension study, the one published randomized controlled study failed to demonstrate a significant difference in primary outcomes after 10 weeks of active or sham VNS. There is a substantial placebo effect associated with depression treatments and the lack of data from prospective randomized controlled clinical studies considerably limits the conclusions that can be drawn from the available evidence.

Hayes Ratings

A rating of C was given for vagus nerve stimulation (VNS) as an adjunctive treatment in adults with severe major depression and bipolar disorder I and II when symptoms associated with a major depressive episode are refractory to multiple regimens of standard medication and other therapies, including electroconvulsive therapy and psychotherapy.

A rating of D was given for VNS as an adjunctive treatment in adults with severe, treatment-resistant rapid-cycling bipolar disorder (insufficient evidence). In addition, a rating of D was given for VNS in patients with other types of depression and in patients with major depression or bipolar disorder who respond to medical treatment.
psychotherapy, and/or electroconvulsive therapy (insufficient evidence).

**POSITION STATEMENT**

Vagus nerve stimulation (VNS) for the treatment of depression is **considered experimental and investigational and NOT a covered benefit.**

**CODING**

**CPT® Codes**

**Implant**
- **64573** Incision for implantation of neurostimulator electrodes; cranial nerve
- **61885** Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array

**Revision or Removal**
- **64585** Revision or removal of peripheral neurostimulator electrodes
- **61888** Revision or removal of cranial neurostimulator pulse generator or receiver

**ANALYSIS-PROGRAMMING**

- **95970** Electronic analysis of implanted neurostimulator pulse generator system (eg, 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 (ie, cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming

- **95974** Electronic analysis of implanted neurostimulator pulse generator system (eg, 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 (eg, 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)

**ICD-9-CM Procedure Codes**

- **04.92** Implantation or replacement of peripheral neurostimulator lead(s)
- **86.94** Insertion or replacement of single array neurostimulator pulse generator
- **04.93** Removal of peripheral neurostimulator lead(s)
- **86.05** Incision with removal of foreign body or device from skin and subcutaneous tissue; Removal of neurostimulator pulse generator (single array, dual array)
VAGUS NERVE STIMULATION FOR TREATMENT RESISTANT DEPRESSION HS-058

HCPCS Codes

C1767 Generator, Neurostimulator
C1778 Lead, Neurostimulator

Non-Covered ICD-9-CM Diagnosis Codes - This list may not be all inclusive.

296.31 Major depressive disorder, recurrent episode; mild
296.32 Major depressive disorder, recurrent episode; moderate
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
296.35 Major depressive disorder, recurrent episode; in partial or unspecified remission
301.12 Chronic depressive personality disorder


REFERENCES

Peer Reviewed


Government Agencies, Professional and Medical Organizations


Other


HISTORY AND REVISIONS

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>6/7/2012</td>
<td>Approved by MPC. Inserted Hayes rating. No other changes.</td>
</tr>
<tr>
<td>12/1/2011</td>
<td>New template design approved by MPC.</td>
</tr>
<tr>
<td>8/12/2011</td>
<td>Approved by MPC.</td>
</tr>
</tbody>
</table>