



**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.

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**Vagus Nerve
Stimulation for
Treatment Resistant
Depression**

Policy Number: HS-058

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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.

POSITION STATEMENT

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

CODING

CPT®* Codes - No applicable codes

ICD-9-CM Diagnosis Codes - No applicable codes

HCPCS Codes - No applicable codes

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

*Current Procedural Terminology (CPT) 2009 American Medical Association: Chicago, IL.®©

REFERENCES

Peer Reviewed

1. Hayes Directory. Vagus Nerve Stimulation for Depression. October 24, 2005.

Government Agencies, Professional and Medical Organizations

1. Centers for Medicare and Medicaid Services (CMS), National Coverage Determination (NCD) for Vagus Nerve Stimulation for Treatment of Seizures (160.18).
2. Local Coverage Determination for Vagal Nerve Stimulation (DL22754). Mutual of Omaha Insurance Company. August 10, 2008.

Other

1. BlueCross BlueShield Association Technology Assessment. Vagus Nerve Stimulation for Treatment-Resistant Depression. August, 2006.
2. Kaiser Permanente Care Management Institute. Depression clinical practice guidelines. 2006.
3. UnitedHealthcare Technology Assessment. Vagus Nerve Stimulation for Epilepsy and Depression. January 31, 2008.

HISTORY AND REVISIONS

Date	Action
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
8/12/2011	<ul style="list-style-type: none">• Approved by MPC.