Easy Choice Health Plan, Inc.
Harmony Health Plan of Illinois, Inc.
Missouri Care, Inc.
‘Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona, Inc.
WellCare Health Insurance of Illinois, Inc.
WellCare Health Plans of New Jersey, Inc.
WellCare Health Insurance of Arizona, 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 South Carolina, Inc.
WellCare of Texas, Inc.
WellCare Prescription Insurance, Inc.
Windsor Health Plan for Medicare Advantage Part D
Windsor Rx Medicare Prescription Drug Plan

Vagus Nerve Stimulation for Treatment Resistant Depression

Policy Number: HS-058
Original Effective Date: 11/6/2008

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. Note: The lines of business (LOB) are subject to change without notice; consult www.wellcare.com/Providers/CCGs for list of current LOBs.

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.

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, 2009).

POSITION STATEMENT

Applicable To:
☑ Medicaid – All Markets
☑ Medicare – All Markets

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

Non-covered CPT® Codes

Implant, Revision, Replacement or Removal

61885  Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array

64568  Incision for implantation of cranial nerve (vagus nerve) neurostimulator electrode array & pulse generator

64569  Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator

64570  Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator

Analysis Programming

95971  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 spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming

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

Non-covered HCPCS® Codes

C1767  Generator, Neurostimulator

C1778  Lead, Neurostimulator

Non-covered 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)

DRAFT Non-Covered 2013 ICD-10-PCS Codes

Refer to the following ICD-10-PCS table(s) for specific PCS code assignment based on physician documentation.

NOTE:     Per ICD-10-PCS Coding Guidelines, “ICD-10-PCS codes are composed of seven characters. Each character is an axis of classification that specifies information about the procedure performed. Within a defined code range, a character specifies the same type of information in that axis of classification. One of 34 possible values can be assigned to each axis of classification in the seven-character code”.

00H  Med/Surg, Central Nervous System, Insertion

00P  Med/Surg, Central Nervous System, Removal

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

300.4  Dysthymic disorder

301.12  Chronic depressive personality disorder
Non-Covered Draft 2013 ICD-10-CM Diagnosis Codes
F33.0  -  F33.3  Major depressive disorder, recurrent
F33.41 Major depressive disorder, recurrent, in partial remission
F34.1 Dysthymic disorder


REFERENCES

Peer Reviewed

Government Agencies, Professional and Medical Organizations

Other

HISTORY AND REVISIONS

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