VAGUS NERVE STIMULATION FOR EPILEPSY
HS-064

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.

Vagus Nerve Stimulation for Epilepsy

Policy Number: HS-064

Original Effective Date: 12/4/2008
Revised Date(s): 12/14/2009; 12/28/2010; 12/1/2011; 12/1/2012

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. 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

Approximately 2.3 million people in the United States have epilepsy. It has been estimated that approximately 600,000 people experience complex partial seizures, i.e., seizures that involve loss of consciousness and which cannot be controlled by treatment with the currently available antiepileptic drugs. These are known as medically refractory seizures. It has been estimated that 33% of patients with epilepsy have inadequate seizure control. Resective brain surgery can be effective in some patients with medically refractory seizures; however, seizure surgery carries significant risk and may not be a viable option for many patients.

Observation that stimulation of the vagus nerve could alter electric brain activity in animals led to the theory that synchronous epileptic discharges could be interrupted or prevented by stimulation of the vagus nerve. After initial studies with rats, dogs, and monkeys, pilot studies were conducted to evaluate the effect of vagus nerve stimulation (VNS) on people with intractable partial seizures. These initial studies were successful in reducing seizure frequencies and resulted in further clinical trials. This research resulted in the 1997 approval by the Food and Drug Administration (FDA) of a device called a neurocybernetic prosthesis, an implantable generator that provides intermittent electrical stimulation to the cervical portion of the vagus nerve for chronic intermittent VNS. During the past 10 years, studies have attempted to elucidate the precise mechanism of action for VNS therapy.

The vagus nerve is the tenth and longest cranial nerve. Its name is derived from the Latin word vagus, meaning “wandering,” and it is so called due to the complex path it takes through the body from the brainstem through organs in the neck, thorax, and abdomen. The vagus nerve innervates vital structures in the body such as the heart, intestines, esophagus, stomach, liver, and muscles of vocalization. In the brain, the vagus nerve forms connections with the medulla. Of these, the connection with the nucleus tractus solitarius (NTS) is regarded as pivotal to understand the possible mechanism of the therapeutic effect of VNS for epilepsy. The NTS is connected to a wide range of nerve projections from and to other areas of the brain. Among these, the vagus nerve is the primary sensory organ of the NTS. It is also capable of processing extensive information and has been likened to a small brain within the larger brain. It is through the NTS that the vagus nerve gains access to centers in the brain that have been related to the generation of seizures such as the amygdala, hippocampus, entorhinal cortex—a part of the limbic system that most often generates complex partial seizures.

The only device currently available for vagus nerve stimulation (VNS), the NeuroCybernetic Prosthesis (NCP) System, consists of a programmable generator that is implanted subcutaneously into the patient’s chest and delivers pulses of current via electrodes attached to the vagus nerve in the left side of the neck. The stimulus is delivered periodically as a charge balanced, biphasic, constant current pulse. The stimulation settings are tailored to individual patient tolerance. The most commonly studied stimulation paradigm has been a 20- to 30-Hertz (Hz), 1.0- to 2.0-milliampere (mA), 500-microsecond (usec) pulse width with 30 seconds on and 5 minutes off, 24 hours a day. Safety features prevent sudden or excessive bursts of current. The intensity, width, and frequency of the electrical pulse can be adjusted, and telemetry data regarding the operating characteristics of the pulse generator can be retrieved with a programming wand using software run on a personal computer. Patients also have control of the stimulator by means of a magnet (Model 200 VNS Therapy Magnets), which can be worn on the wrist like a bracelet or watch, or clipped onto a belt or pants. When the patient senses the onset of a seizure, the stimulator can be activated by holding the magnet near the device for 1 to 2 seconds. If there is discomfort or if the device is malfunctioning, stimulation can be stopped by placing the magnet over the vagal nerve stimulator permanently. The stimulator will resume as soon as the magnet is removed (Cyberonics Inc., 2007). The device is not affected by microwaves or airport security systems; however, strong electromagnetic fields may cause the device to activate. Implantation of the NCP System takes approximately 1 hour and can be performed under general or local anesthesia (from Hayes, 2007). Vagus nerve stimulation has not been shown to be effective in treating seizures disorders other than complex partial seizures. (i.e. absence, simple complex, tonic-clonic).
POSITION STATEMENT

Vagus Nerve Stimulation for the treatment of medically refractory complex partial seizures is considered medically necessary and a covered benefit if ALL of the following criteria are met:

- Member suffers from partial onset seizures with a seizure frequency of at least six per month while on antiepileptic medication; AND,
- Member is refractory to antiepileptic medications or has debilitating side effects from antiepileptic medications; AND,
- Member is not a candidate for or has failed resective epilepsy surgery; AND,
- Member does not present with previous resection of the vagus nerve; AND,
- The physician performing the procedure has experience and expertise in the treatment of epilepsy and the use of vagus nerve stimulation.

CODING

Covered CPT® Codes

Open Procedure via subcutaneous pocket

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 from subcutaneous pocket.

Percutaneous Procedure

64553 Percutaneous Implantation of neurostimulator electrodes; cranial nerve.

64568 Incision Implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and 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

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.
VAGUS NERVE STIMULATION
FOR EPILEPSY
HS-064

Covered ICD-9-CM Procedure Codes
04.92  Implantation or replacement of peripheral neurostimulator lead(s)
04.93  Removal of peripheral neurostimulator lead(s)
86.05  Removal of neurostimulator pulse generator (single array, dual array)
86.94  Insertion or replacement of single array neurostimulator pulse generator for peripheral nerve, not specified as rechargeable.
86.95  Insertion or replacement of dual array neurostimulator pulse generator for peripheral nerve, not specified as rechargeable.
86.97  Insertion or replacement of single array rechargeable neurostimulator pulse generator for peripheral nerve
86.98  Insertion or replacement of dual arrays rechargeable neurostimulator pulse generator

Covered HCPCS Code
C1767  Generator, neurostimulator (implantable), nonrechargeable
C1778  Lead, neurostimulator (implantable)
C1816  Receiver and/or transmitter, neurostimulator (implantable)
C1883  Adapter/extension, pacing lead or neurostimulator lead (implantable)
L8680  Implantable neurostimulator electrode, each
L8681  Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
L8682  Implantable neurostimulator radiofrequency receiver
L8683  Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
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 battery (internal) for use with implanted neurostimulator
L8695  External recharging system for battery (external) for use with implantable neurostimulator

Covered ICD-9-CM Diagnosis Codes
345.40 - Localization-related (focal) (partial) refractory epilepsy and epileptic syndromes with complex partial seizures
345.41  Seizures

Covered ICD-10-CM Diagnosis Codes
G40.00 - G40.919  Epilepsy and recurrent seizures


REFERENCES

Peer Reviewed

Government Agencies, Professional and Medical Organizations
<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/6/2012</td>
<td>Approved by MPC. No changes.</td>
</tr>
<tr>
<td>12/1/2011</td>
<td>Approved by MPC. Reformatted references. No changes. No code changes.</td>
</tr>
<tr>
<td></td>
<td>New template design approved by MPC.</td>
</tr>
</tbody>
</table>