Clinical Coverage Guidelines: Vagus Nerve Stimulation

Current Effective Date: 09/01/12
Original Effective Date: 06/09/06*
Policy Number: OCA: 3.51
Product Applicability:
- MassHealth
- Commonwealth Care
- Commercial

Summary: Vagus nerve stimulation (VNS) requires prior authorization and is considered medically necessary for eligible members who are 12 years of age or older with medically refractory seizures, for whom epileptic surgery is not recommended or for whom epileptic surgery has failed. Other applications of vagus nerve stimulation are considered experimental and investigational including but not limited to the treatment of depression, modifying eating behavior and weight in adults with depression. VNS requires prior authorization.

Description of Item or Service:
Vagus Nerve Stimulation (VNS): VNS is a treatment for epilepsy where electrical pulses are delivered to a portion of the vagus nerve via a generator that is implanted. Vagus nerve stimulation is indicated for use as an adjunctive therapy for reducing the frequency of seizures in patients who are medically refractory to antiepileptic medication and who are not candidates for surgery or if surgery has failed.

Clinical Guideline Statement:
1. Vagus nerve stimulation (VNS) requires prior authorization and is considered medically necessary for eligible members who are 12 years of age or older with medically refractory seizures, for whom epileptic surgery is not recommended or for whom epileptic surgery has failed.
2. Other applications of vagus nerve stimulation are considered investigational including but not limited to the treatment of depression and modifying eating behavior and weight in adults with depression.

Additional Definitions:
Medically Refractory Seizures: Seizures that continue to occur after treatment with therapeutic levels of antiepileptic medications or seizures that cannot be treated with antiepileptic medications because the side effects are not tolerable. Medically refractory...
seizures occur when a patient continues to have seizures despite treatment with a maximally tolerated dose of a first-line antiepilepsy drug (AED) as monotherapy or in combination with at least one adjuvant medication.

**Vagus Nerve:** Also known as the pneumogastric or 10th cranial nerve, the vagus nerve is a mixed nerve with motor and sensory functions. The vagus nerve starts at the brainstem and ends in the colon. The vagus nerve controls the sensory and motor functions of the pharynx, larynx, trachea, lungs, heart and esophagus.

**Applicable Coding:** Codes may not be all inclusive as the American Medical Association (AMA) code updates may occur more frequently or at different intervals than policy updates. These codes are not intended to be used for coverage determinations.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>61885</td>
<td>Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array</td>
</tr>
<tr>
<td>61886</td>
<td>Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays</td>
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<tr>
<td>61888</td>
<td>Revision or removal of cranial neurostimulator pulse generator or receiver</td>
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<tr>
<td>64553</td>
<td>Percutaneous implantation of neurostimulator electrodes; cranial nerve</td>
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<tr>
<td>64568</td>
<td>Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator</td>
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<tr>
<td>64569</td>
<td>Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator</td>
</tr>
<tr>
<td>64570</td>
<td>Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator</td>
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<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
</tr>
<tr>
<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only</td>
</tr>
<tr>
<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8683</td>
<td>Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver</td>
</tr>
<tr>
<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
</tr>
</tbody>
</table>
This guideline provides information on BMC HealthNet Plan claims adjudication processing guidelines. The use of this guideline is not a guarantee of payment and will not determine how a specific claim(s) will be paid. Reimbursement is based on member benefits and eligibility, medical necessity review, where applicable, coordination of benefits, adherence to Plan policies, clinical coding criteria, and the BMC HealthNet Plan agreement with the rendering or dispensing provider. Reimbursement policies may be amended at BMC HealthNet Plan’s discretion. BMC HealthNet Plan will always use the most recent CPT and HCPCS coding guidelines. All Plan policies are developed in accordance with state, federal and accrediting organization guidelines and requirements, including NCQA.

### L8686
Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension

### L8687
Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension

### L8688
Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

### L8689
External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

**Limitations:**
Vagus nerve stimulation is considered experimental and investigational for the treatment of depression and modifying eating behavior and weight in adults with depression.

**Clinical Background Information:**
Epilepsy is a recurrent paroxysmal disorder of cerebral function that is associated with a sudden and brief attack of altered consciousness, motor activity, or sensory phenomena. Convulsive seizures are the most common form of epilepsy and result from simultaneous electrical discharge of groups of nerve cells within the brain. Epilepsy can be the result of injury, infections, structural abnormalities in the brain, abnormal fetal brain development, or exposure to toxins but in many cases the cause is unknown. The two (2) major risks that are associated with epilepsy include status epilepticus and sudden death.

Status epilepticus is a severe, life threatening condition where prolonged seizures occur lasting 10 minutes or longer or when the person does not regain consciousness between the seizures. Seizures have been defined as paroxysmal disorder of the central nervous system that is associated with abnormal cerebral neuronal discharge, with or without loss of consciousness. Seizures have been further subclassified into those with a generalized onset, beginning throughout the brain, and those with a partial onset, having a discrete focal onset. There are two principal subtypes of partial-onset seizures:

- **Simple partial seizures:** Partial onset seizures that do not involve alteration of consciousness but may have observable motor components or may be a subjective sensory or emotion phenomenon. The individual remains conscious but may experience unusual feelings or sensations.
- **Complex partial seizure:** Partial onset seizures that involve loss of consciousness. The individual has a change in or loss of consciousness.

Generalized seizures are the result of abnormal neuronal activity that is widespread throughout the brain. The types of generalized seizures include:

- **Absence seizures:** The individual may appear to be staring into space and/or have jerking, twitching muscle movements
- **Tonic seizures:** The individual has stiffening of the back, leg and arm muscles
- **Clonic seizures:** The individual has repeated jerking movements of muscles on both sides of the body
- Myoclonic seizures: The individual has jerks or twitches of muscles in the upper body, arms or legs
- Atonic seizures: The individual has a sudden loss of muscle tone leading to falls or involuntary nodding of the head
- Tonic-clonic seizures: The individual has a mixture of symptoms including stiffening of the body and repeated jerking of the arms/legs as well as a loss of consciousness

Significant advances have occurred regarding medical and surgical treatment for epilepsy but despite treatment some patients with epilepsy continue to experience seizures or suffer from serious side effects from epilepsy medications. Vagus nerve stimulation is indicated for use as an adjunctive therapy for reducing the frequency of seizures in patients who are medically refractory to antiepileptic medication and who are not candidates for surgery or if surgery has failed. Vagus nerve stimulator implantation surgery involves wrapping two (2) spiral electrodes around the left vagus nerve within the carotid sheath. The electrodes are connected to a generator pack that is implanted under the skin in the upper left chest area. The procedure lasts about 50-90 minutes with the patient under general or local anesthesia. Typically, patients may stay in the hospital one (1) day or be discharged the same day. The stimulator may be programmed in advance by the neurologist to stimulate at regular intervals or upon demand when the individual senses the onset of a seizure by using a magnet that can be worn on the wrist like a bracelet or clipped to a belt or pants. Side effects of VNS include hoarseness and a tingling sensation that is associated with stimulation. Complications of VNS include coughing and throat pain during stimulation and post-operative infections relating to the procedure. The U.S. Food and Drug Administration (FDA) approved one (1) vagus nerve stimulation device called the NeuroCybernetic Prosthesis system for the treatment of seizures in 1997.

A major depressive episode or major depression is a serious medical illness that disrupts the individual’s mood, behavior, thought processes and physical health. There are currently three major treatment modalities that have clinical evidence of effectiveness in the treatment of major depression: antidepressant drug therapy, psychotherapy and electroconvulsive therapy (ECT). There has been research reported for VNS as a treatment for refractory depression as recipients have reported an improvement in mood; however, long-term data is unknown to evaluate the safety and effectiveness of this procedure for treating depression.

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