Vagus Nerve Stimulator (VNS)

[For the list of services and procedures that need preauthorization, please refer to www.mcs.com.pr, go to “Comunicados a Proveedores”, and click “Cartas Circulares”.]

Medical Policy: MP-DME-04-10
Original Effective Date: September 16, 2010
Revised: May 10, 2018
Next Revision: May, 2019

This policy applies to products subscribed by the following corporations, MCS Life Insurance Company (Commercial), and MCS Advantage, Inc. (Classicare) and Medical Card System, Inc., provider’s contract; unless specific contract limitations, exclusions or exceptions apply. Please refer to the member’s benefit certification language for benefit availability. Managed care guidelines related to referral authorization, and precertification of inpatient hospitalization, home health, home infusion and hospice services apply subject to the aforementioned exceptions.

DESCRIPTION

Vagus Nerve Stimulation (VNS) is a medical therapy that involves the direct delivery of intermittent retrograde electrical impulses to the left vagus nerve via a pulse generator, similar to a pacemaker, that is surgically implanted under the skin of the left chest with an electrical lead (wire) connected from the generator to the left vagus nerve. Electrical signals are sent from the battery-powered generator to the vagus nerve via the lead. These signals are in turn sent to the brain. (CMS NCD (160.18))

In 1997, Vagus Nerve Stimulation (VNS) received US Food and Drug Administration (FDA) approval for the adjunctive treatment of refractory seizures in patients older than 12 years.

In 2005, the VNS was approved for the treatment of chronic or recurrent depression in patients older than 18 years.

VNS may also have a beneficial effect on mood in patients with epilepsy in addition to its antiepileptic effect. The mechanism of action of VNS is uncertain, but may be related to metabolic activation of brain stem, limbic, or thalamic structures.

At this Point, the VNS is the only FDA-approved medical device for the treatment of epilepsy. However, other approaches, such as deep-brain stimulation of the anterior nucleus of the thalamus, responsive neurostimulation, trigeminal nerve stimulation, and transcranial magnetic stimulation, are in development. (Wilner AN. MD, 2013)

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate member certificate and subscriber agreement contract for applicable diagnostic imaging, DME, laboratory, machine tests, benefits and coverage.
INDICATIONS

Medical Card System, Inc. (MCS) considers Vagus Nerve Stimulation (VNS) reasonable and medically necessary when BOTH of the following criteria are met:

1. For adults and children older than 4 years of age that have medically refractory (see notes below) partial-onset seizures.

Note1: Medically refractory means seizures that occur in spite of therapeutic levels of anti-epileptic drugs (NHS England, 2013).

Note2: Seizures that cannot be treated with therapeutic levels of anti-epileptic drugs because of intolerable adverse side effects.

2. The patient has failed or is NOT eligible for surgical treatment (CMS NCD 160.18, 2007).

Note3: Patients with refractory epilepsy present inadequate seizure control using potentially effective antiepileptic drugs and have failed two or more antiepileptic drugs (AED) treatment.

CONTRAINDICATIONS/LIMITATIONS

1. VNS is not indicated for persons with all other types of seizure disorders which are medically refractory and for whom surgery is not recommended or for whom surgery has failed (CMS NCD 160.18, 2007).

2. VNS is not reasonable and necessary for resistant depression (CMS NCD 160.18, 2007).

3. VNS cannot be used in patients after a left or bilateral cervical vagotomy, (FDA, 2005).

4. Do not use short wave diathermy, microwave diathermy or therapeutic ultrasound diathermy on patients implanted with a VNS Therapy System. Diagnostic ultrasound is not included in this contraindication (FDA, 2005).

5. Optimal VNS settings are still unknown, and the evidence is insufficient to support a recommendation for the use of standard stimulation (30 seconds “on” and 300 seconds “off”) versus rapid stimulation (usual VNS settings are 7 seconds “on” and 30 seconds “off”) to reduce seizure occurrence (AAN, 2013).

6. The VNS Therapy System should only be prescribed and monitored by physicians who have specific training and expertise in the management of seizures and the use of this device. It should only be implanted by physicians who are trained in surgery of the carotid sheath and have received specific training in the implantation of this device (LivaNova, Inc. (2017)).
7. The safety and efficacy of the VNS Therapy System have not been established for uses outside the “Intended Use/Indications” section.

8. The safety and effectiveness of the VNS Therapy System have not been established for use during pregnancy. VNS should be used during pregnancy only if clearly needed.

WARNINGS

1. The safety and effectiveness of the VNS Therapy System in patients with predisposed dysfunction of cardiac conduction systems (re-entry pathway) have not been established. Post-implant electrocardiograms and Holter monitoring are recommended if clinically indicated.

2. Difficulty swallowing (dysphagia) may occur with active stimulation, and aspiration may result from the increased swallowing difficulties. Patients with pre-existing swallowing difficulties and those with a history of drooling or hypersalivation are at greater risk for aspiration.

3. Dyspnea (shortness of breath) may occur with active VNS Therapy. Any patient with underlying pulmonary disease or insufficiency such as chronic obstructive pulmonary disease or asthma may be at increased risk for dyspnea.

4. Patients with obstructive sleep apnea (OSA) may have an increase in apneic events during stimulation. Lowering stimulus frequency or prolonging “OFF” time may prevent exacerbation of OSA. Vagus nerve stimulation may also cause new onset sleep apnea in patients who have not previously been diagnosed with this disorder.

5. Magnetic resonance imaging (MRI) should not be performed using a transmit RF body coil for certain VNS therapy device configurations or under certain specific conditions.

6. External defibrillation may damage the generator.

7. Use of electrosurgery [electrocautery or radio frequency (RF) ablation devices] may damage the generator.

8. Extracorporeal shockwave lithotripsy may damage the generator.

9. Routine therapeutic ultrasound could damage the generator and may be inadvertently concentrated by the device, causing harm to the patient.
**CODING INFORMATION**

CPT® Codes (List may not be all inclusive):

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<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>61888</td>
<td>Revision or removal of cranial neurostimulator pulse generator or receiver</td>
</tr>
<tr>
<td>64568</td>
<td>Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator</td>
</tr>
<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>
</tr>
<tr>
<td>64585</td>
<td>Revision or removal of peripheral Neurostimulator electrode array</td>
</tr>
<tr>
<td>95970</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude pulse 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 (i.e., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming</td>
</tr>
<tr>
<td>95974</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate pulse amplitude pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurement); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour.</td>
</tr>
<tr>
<td>+95975</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude pulse 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)</td>
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ICD-10 Codes (List may not be all inclusive)

<table>
<thead>
<tr>
<th>ICD 10 CODES</th>
<th>DESCRIPTION</th>
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</thead>
<tbody>
<tr>
<td>G40.011</td>
<td>Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epilepticus</td>
</tr>
<tr>
<td>G40.019</td>
<td>Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus</td>
</tr>
<tr>
<td>G40.111</td>
<td>Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus</td>
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</tbody>
</table>
Clinical Medical Policy Department  
Clinical Affairs Division  

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>G40.119</td>
<td>Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus</td>
</tr>
<tr>
<td>G40.211</td>
<td>Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus</td>
</tr>
<tr>
<td>G40.219</td>
<td>Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus</td>
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</tbody>
</table>

**HCPCS® Codes Covered for the Commercial Line of Business (LOB) Only & Not Covered for The Classicare LOB: (List may not be all inclusive)**

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>C1767</td>
<td>Generator, neurostimulator (implantable), nonrechargeable</td>
</tr>
<tr>
<td>C1778</td>
<td>Lead, neurostimulator (implantable)</td>
</tr>
<tr>
<td>C1816</td>
<td>Receiver and/or transmitter, neurostimulator (Implantable)</td>
</tr>
<tr>
<td>C1883</td>
<td>Adapter/Extension, pacing lead or neurostimulator lead (Implantable)</td>
</tr>
<tr>
<td>L8679</td>
<td>Implantable neurostimulator, pulse generator, any type</td>
</tr>
<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>
<tr>
<td>L8686</td>
<td>Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension</td>
</tr>
<tr>
<td>L8687</td>
<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension</td>
</tr>
<tr>
<td>L8689</td>
<td>External recharging system for battery (internal) for use with implanted neurostimulator, replacement only</td>
</tr>
<tr>
<td>L8695</td>
<td>External recharging system for battery (external) for use with implantable neurostimulator, replacement only</td>
</tr>
</tbody>
</table>


**REFERENCES**


POLICY HISTORY

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 16, 2010</td>
<td>Origination of Policy</td>
<td></td>
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This document is designated for informational purposes only and is not an authorization, or an explanation of benefits (EOB), or a contract. Medical technology is constantly changing and we reserves the right to review and update our policies periodically.
<table>
<thead>
<tr>
<th>September 29, 2011</th>
<th>Yearly review</th>
<th>Revised</th>
<th>References updated.</th>
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<tbody>
<tr>
<td>November 7, 2012</td>
<td>Revised</td>
<td></td>
<td>To Coding Information: Deleted CPT® Code 64573. Added new CPT® Codes 64568, 64569, 64570.</td>
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</table>

<table>
<thead>
<tr>
<th>October 18, 2013</th>
<th>Revised</th>
<th>References updated.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>New references were added: numbers 1-7, 9, 11-12, 16-27.</td>
</tr>
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</table>

**To the Description Section:**

- **Deleted:** Vagus Nerve Stimulation (VNS) is delivered via a pacemaker like a device called a pulse generator that is surgically implanted in the left upper chest underneath the skin. The pulse generator is connected to an implanted lead that is attached to the left vagus nerve in the neck and delivers electrical impulses to the nerve at preprogrammed durations, frequencies, and currents. The impulses are further transmitted to centers in the brain to achieve the therapeutic effects. Common side effects and adverse health problems associated with VNS include voice changes, hoarseness, cough, neck pain, breathing problems, difficulty swallowing, tingling or prickling of the skin, and sore throat. There is a high quality scientific evidence from randomized controlled trials comparing high stimulation with low stimulation placebo vagus nerve stimulation (VNS) and long-term studies regarding the benefit and safety of VNS to conclude that VNS reduces seizure rates in some patients older than 12 years of age with medically refractory partial seizures who are not suitable candidates for surgery treatment has failed. VNS is being used to treat many children and adults with intractable epilepsy. The current available evidence is insufficient to permit conclusions regarding the efficacy and safety of vagus nerve stimulation (VNS) as an adjunct therapy in adult patients with treatment resistant major depression disorder and bipolar disorder. Seizures have been defined as paroxysmal disorders of the central nervous system characterized by abnormal cerebral neuronal discharge, with or without a loss of consciousness. Seizures have been further sub-classified into those with a generalized onset, beginning throughout the brain, and those with a partial onset, having a discrete focal onset. There are 3 principal subtypes of partial-onset seizures: Simple partial seizures: These do not involve alteration of consciousness but may have observable motor components or may solely be a subjective sensory or emotional phenomenon. Complex partial seizures: These are partial-onset seizures that involve an alteration of consciousness. Complex partial seizures secondarily generalized tonic-clonic convulsions: These are partial-onset seizures that progress to involve both sides of the brain and result in a complete loss of consciousness.

- **Added:** Vagus Nerve Stimulation (VNS) therapy involves the direct delivery of intermittent retrograde electrical impulses to the left vagus nerve via a pulse generator, similar to a pacemaker, that is surgically implanted under the skin of the left chest with an electrical lead (wire) connected from the generator to the left vagus nerve. Electrical signals are sent from the battery-powered generator to the vagus nerve via the lead. These signals are in turn sent to the brain. This device was initially approved in 1997 for epilepsy and there is a Medicare National Coverage Decision (NCD) for that indication (i.e. NCD for Vagus Nerve Stimulation (VNS) (160.18)) (CMS LCD L29406, 2012). In 1997, the US Food and Drug Administration (FDA) approved Vagus Nerve Stimulation (VNS) as adjunctive therapy for reducing the frequency of seizures in patients > 12 years of age with partial onset seizures refractory to antiepileptic medications. A 1999 American Academy of Neurology (AAN) technology assessment concluded that VNS is indicated for...
patients > 12 years with medically intractable partial seizures who are not candidates for potentially curative surgical resections such as lesionectomies or mesial temporal lobectomies. The authors also recommended that patients undergo a thorough epilepsy evaluation to rule out non-epileptic conditions or treatable symptomatic epilepsies before implantation of a vagus nerve stimulator. At that time, evidence was insufficient to recommend VNS for epilepsy in young children or for seizures associated with Lennox-Gastaut syndrome (LGS). Since the 1999 AAN assessment, the FDA has approved VNS for the adjunctive long-term treatment of chronic or recurrent depression in patients > 18 years who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments. Moreover, there are new reports of long-term efficacy and VNS use in pediatric epilepsy and other seizure types and syndromes. In 2013 the American Academy of Neurology (AAN) indicates that: VNS may be considered for seizures in children, for LGS-associated seizures, and for improving mood in adults with epilepsy (Level C of evidence). VNS may also be considered to have improved efficacy over time (Level C of evidence). Children should be carefully monitored for site infection after VNS implantation (AAN, 2013). However, at present, the available evidence based on publications in peer-reviewed literature and other pertinent sources, is not sufficient to support VNS therapy for depression. Therefore, this medical policy finds VNS therapy as not reasonable and necessary and not eligible for reimbursement at this time (CMS LCD L29406, 2012). Adverse effects (e.g., hoarseness/voice changes, throat discomfort, cough, and dyspnea) are mild, appear during stimulation, and tend to diminish over time. Thus, VNS can be described as a long-lasting, hassle-free, on-demand therapy, with no interactions or black box warnings regarding potential life-threatening adverse effects (Rielo & Benbadis, 2013).

To the Indications Section:

- Added the direct citations from which the information came from. To Indication 1 added: (FDA, 1997) & (CMS NCD 160.18, 2007). To Note 1 added: (NHS England, 2013). To Note 2 added: (ECRI, 9/25/12). To Indication 2 added: (CMS NCD 160.18, 2007).

- To Note 3, embedded the hyperlink for the medical policy entitled: (MP-ME-08-09 Epilepsy Monitoring Unit/Video EEG).

To the Contraindications/Limitations Section:

- Revised and rewrote #1: VNS is not indicated for persons with all other types of seizures disorders which are medically refractory and for whom surgery is not recommended or for whom surgery has failed (CMS LCA, A48621).
- To #2 added direct citation: (CMS LCD L29406, 2012).
- Deleted #3: Patients with previous vagus nerve resection are not considered appropriate candidates for VNS, due to lack of scientific evidence.
- To new #3 previously on medical policy: VNS cannot be used in persons with left or bilateral cervical vagotomy, added the direct citation: (FDA. 2005).
- Added new Contraindications/Limitations #4-7.

To the Experimental, Investigational or Unproven Coverage Section:

- Added: 16. Acute suicidal thinking or behavior; 17. History of schizophrenia, schizoaffective disorder or delusional disorders; 18.
History of rapid cycling bipolar disorder; 19. History of previous therapeutic brain surgery or CNS injury; 20. Progressive neurological diseases other than epilepsy; 21. Cardiac arrhythmias or other abnormalities; 22. History of dysautonomias; 23. History of respiratory diseases or disorders, including dyspnea and asthma; 24. History of ulcers (gastric, duodenal, or other); 25. History of vasovagal syncope; 26. Only one vagus nerve; 27. Other concurrent forms of brain stimulation; 28. Pre-existing hoarseness; 29. VNS for children under 12 years of age; & 30. Primary generalized seizures.

To the Coding Information:

- Added new NON-COVERED (do not support medical necessity) for BOTH the Commercial & Classicare LOB: ICD-9-CM Codes: 296.00-99, 298.0, 300.4, 309.0, 309.1, 309.28, & 311.
- To the HCPCS® Codes, made distinctive heading: HCPCS® CODES COVERED FOR THE COMMERCIAL LINE OF BUSINESS (LOB) ONLY & NOT COVERED FOR THE CLASSICARE LOB.

February 21, 2014
Revised

To the Coding section: A new ICD-10 Codes (Preview Draft) section was added to the policy.

September 26, 2014
Revised

References updated.

To the Description Section:
Some words where added to different paragraphs to give more consistence to the description (Third and Fourth paragraphs).

To the Contraindications/Limitations:
The Word “Persons” was substituted with the word “patients” for be more consistent in this section.

To the Coding Section:
- New HCPCS codes were added to the Policy (C1767, C1778, and L8679).

To the References Section:
- New References were added to the Policy (#5, 13, 20, 21, 22, 23, 24, 25, 27, 28, 29, 30, 34, 36, and 37).

October 24, 2014
Revised

EXPERIMENTAL, INVESTIGATIONAL OR UNPROVEN COVERAGE Section was eliminated from this medical policy for a consultation with Dr. Melissa Wheeler.

To the References Section:
- Reference # 13 was eliminated because was considered belonging to the experimental uses into this medical policy.
- New References were added to the Policy (#27, 43).

November 23, 2015
Revised

To the coding section:
- Eliminate ICD-9 codes since they are no longer valid for diagnosis classification.
- Add new section of ICD-10 codes which are the valid diagnosis classification system since October 1, 2015.

September 23, 2016
Revised

To the Description Section:
New Phrase “Is a Medical” and the word “that” were added to the First paragraph of the description Section.

To the Indications Section:
Note3 was revised and adapted to the information contained in the Update 2015 for this Policy:
<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 10, 2018</td>
<td>- <strong>Revised</strong>&lt;br&gt;Limit of “12 years of age” was deleted and substitute by “4 years” at the Indication #1.</td>
</tr>
<tr>
<td></td>
<td>- <strong>To the Indications Section:</strong>&lt;br&gt;Limit of “12 years of age” was deleted and substitute by “4 years” at the Indication #1.</td>
</tr>
<tr>
<td></td>
<td>- New Warnings Section was added to the Policy.</td>
</tr>
<tr>
<td></td>
<td>- <strong>To the Coding Information Section:</strong>&lt;br&gt;To the CPT Code Section:&lt;br&gt;CPT code 61886 was deleted from this Policy.</td>
</tr>
<tr>
<td></td>
<td>- <strong>To the References Section:</strong>&lt;br&gt;The Following References were added to the Policy:&lt;br&gt;#11, 14, and 15.</td>
</tr>
</tbody>
</table>

**To the Contraindications/Limitations Section:**<br>Contraindication #6 was Deleted from this Policy. It was Repetitive with the information described in the Contraindication #3.

**To the Coding Information Section:**<br>- ICD-10 Codes Section that Do not Support Medical Necessity were deleted from this Policy.
- To the HCPCS Codes Section:<br>New HCPCS Codes C1816 and C1883 were added to this Section.

**To the References Section:**<br>- New References #5, 6 and 24 were added to the Policy.
- References #14, 15, 16, 17, 18, 19 and 35 were deleted from this Policy.