Vagus Nerve Stimulation (VNS)

DESCRIPTION

Vagus nerve stimulation (VNS) is a pulse generator, with an electrical lead (wire) connected to the vagus nerve. It may be implantable or non-implantable. Electrical signals are sent from the battery-powered generator to the vagus nerve via the lead, and these signals are in turn sent to the brain. VNS is proposed as a treatment of various conditions, including but not limited to, seizures, depression, and obesity. *(National Coverage Determination 160.18)*

MEDICARE ADVANTAGE POLICY CRITERIA

Note: This policy only addresses vagus nerve stimulation therapy. It does not address vagal nerve blocking therapy (i.e., the Maestro® Rechargeable System, or VBLOC), which is addressed in a separate Medicare Advantage medical policy (see Cross References).

| CMS Coverage Manuals* | None |

* Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.
For **implantable VNS when used as treatment of medically refractory partial onset seizures, all other types of seizure disorders, and resistant depression** (for VNS for depression, see also the LCD L35008 below):

- Vagus Nerve Stimulation (VNS) ([160.18](#))

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*

For **treatment of depression (implantable or non-implantable), implantable VNS when used to treat obesity, and chest wall respiratory sensor electrode (0466T):**

- Non-Covered Services ([L35008](#))

For the **treatment of peripheral neuropathy:**

- Nerve Blockade for Treatment of Chronic Pain and Neuropathy ([L35457](#)) (See the section for peripheral neuropathy within the LCD)

**Scroll to the “Public Version(s)” section at the bottom of the LCD for links to prior versions if necessary.**

### Medical Policy Manual

*Medicare coverage guidance is not available for vagus nerve stimulation for certain indications. Therefore, the health plan’s medical policy is applicable for these scenarios.*

For **implantable VNS when used as treatment of all other indications, and non-implantable VNS where not previously specified:**

- Vagus Nerve Stimulation, Surgery, [Policy No. 74](#) (see “NOTE” below)

**NOTE:** If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. ([Medicare IOM Pub. No. 100-04, Ch. 23, §30 A](#)). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an **objective, evidence-based process, based on authoritative evidence.** ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan’s evidence-assessment process (see Cross References).

### POLICY GUIDELINES

### REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:
• Medical records and supporting pertinent clinical records documenting the indication being treated;
• The specific VNS device to be used, and whether it is implantable or non-implantable.

REGULATORY STATUS

Implantable VNS Devices
Several VNS therapy systems by Cyberonics Inc. have pre-market approval (PMA) from the U.S. Food and Drug Administration (FDA) for treatment of refractory partial-onset seizures and chronic or recurrent depression, when certain criteria are met. For example, in 1997, the NeuroCybernetic Prosthesis (NCP®) system was approved for use in conjunction with drugs or surgery “as an adjunctive treatment of adults and adolescents over 12 years of age with medically refractory partial onset seizures.” The VNS Therapy™ System was approved in 2005 “for the adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments.”

Non-implantable VNS Devices
Cerbomed has developed a transcutaneous VNS (t-VNS®) system, NEMOS®, that uses a combined stimulation unit and ear electrode to stimulate the auricular branch of the vagus nerve, which supplies the skin over the concha of the ear. Patients self-administer electric stimulation for several hours a day; no surgical procedure is required. The device has not been FDA approved for use in the US. In addition, Electrocore has developed a non-invasive VNS (gammaCore®) that is currently being investigated for headache; the device does not have FDA approval.

Other Types of VNS Devices
Other types of vagus nerve stimulators are also available. The VBLOC Maestro® Rechargeable System (EnteroMedics, Inc) consists of a subcutaneously-implanted pulse generator and electrodes that are placed in contact with the trunks of the vagus nerve at the gastroesophageal junction. This type of stimulator differs in the location of the pulse generator and electrodes, as well as the stimulation programming settings. The Maestro device is not addressed in this policy.

CROSS REFERENCES

Investigational (Experimental) Services and New and Emerging Medical Technologies and Procedures, Medicine, Policy No. M-149

Bariatric Surgery, Surgery, Policy No. M-58

Gastric Electrical Stimulation, Surgery, Policy No. M-111
REFERENCES

None

CODING

<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<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></td>
<td>61886</td>
<td>With connection to two or more electrode arrays</td>
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<td></td>
<td>61888</td>
<td>Revision or removal of cranial neurostimulator pulse generator or receiver</td>
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<td></td>
<td>64553</td>
<td>Percutaneous implantation of neurostimulator electrode array; cranial nerve</td>
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<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></td>
<td>64569</td>
<td>Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator</td>
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<td>64570</td>
<td>Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator</td>
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<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 (ie, cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming</td>
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<td>95971</td>
<td>; simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming</td>
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<td>95974</td>
<td>; complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour</td>
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<td>95975</td>
<td>; 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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<td>0466T</td>
<td>Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (List separately in addition to code for primary procedure)</td>
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<td>C1822</td>
<td>Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system</td>
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<td>L8679</td>
<td>Implantable neurostimulator, pulse generator, any type</td>
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<td>L8680</td>
<td>Implantable neurostimulator electrode, each (Code non-covered by Medicare – see L8679)</td>
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<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only</td>
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<td>Implantable neurostimulator radiofrequency receiver</td>
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<td>Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver</td>
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<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension <em>(Code non-covered by Medicare – see L8679)</em></td>
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<td>L8689</td>
<td>External recharging system for battery (internal) for use with implantable neurostimulator</td>
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*IMPORTANT NOTE: Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan’s web control as these sites are not maintained by the health plan.*