# *Vagus Nerve Stimulation (VNS)*

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***IMPORTANT REMINDER***

*The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.*

*The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.*

*Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). 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. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.*

## 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).

- This policy does not address deep brain stimulation, or DBS. DBS is electrical stimulation targeting one of these three nerves: the thalamic ventralis intermedius nucleus (VIM), subthalamic nucleus (STN) and globus pallidus interna (GPi)(see Cross References).

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| **CMS Coverage Manuals*** | For the following uses of VNS:<br>✓ ***Transcutaneous VNS (t-VNS®) system (NEMOS®)***<br>✓ ***Implantable VNS when used to treat obesity***<br>According to the Medicare Benefit Policy Manual, Chapter 14, while approval by the U.S. Food and Drug Administration (FDA) does not automatically guarantee coverage under Medicare, in order to be considered for coverage under Medicare, devices must be either FDA- or Institutional Review Board (IRB)-approved. NEMOS® has not been FDA approved for use in the US, nor have any implantable VNS systems for obesity.<br>For ***removal of the VNS devices only*** (CPT code 64570) as well as ***revision/replacement*** of *not medically necessary devices*:<br>Medicare Benefit Policy Manual<br>Chapter 16 - General Exclusions From Coverage<br>*See Section 180 in the following link:*<br>§180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare<br>Note: Please read the applicable section, in its entirety, for complete criteria details. ***Removal only*** (without replacement) of a device may be allowed as medically necessary when the removal is required in order to treat a medical condition or complication. Even if initial placement of the device did not meet medical necessity coverage criteria and the complication or subsequent medical condition is the result of a prior non-covered service, coverage may be allowed in select circumstances for the removal of the device.<br>However, a procedure or device that doesn't meet medical necessity criteria is non-covered and any ***revision or replacement*** to allow for the *continued* use of the non-covered device would not meet Medicare's general requirements for coverage. |

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| | For ***revision/replacement*** requests of previously placed *medically necessary devices*:<br>Medicare Benefit Policy Manual<br>Chapter 15 – Covered Medical and Other Health Services<br>*See Section 120 in the following link:*<br>§120 - Prosthetic Devices, D. Supplies, Repairs, Adjustments, and Replacement[1]<br>Note: Replacement of previously placed medically necessary devices or their components that are non-functioning and irreparable (e.g., device malfunction, etc.) may be considered medically necessary in accordance with the above Medicare reference if the stimulator continues to be medically indicated and is no longer under manufacturer warranty or if the component is not included under the warranty.[1] For the replacement of VNS devices for TRD, see the NCD 160.18 below. |
| **National Coverage Determinations (NCDs)*** | For ***implantable VNS when used for treatment resistant depression (TRD), all other indications for the treatment of depression, as treatment of medically refractory partial onset seizures*** *and* ***all other types of seizure disorders***:<br>✓ Vagus Nerve Stimulation (VNS) (160.18) *(Note, this NCD only allows coverage of VNS for TRD through the coverage with evidence development (CED) provision when offered in a CMS-approved trial (see Section B, specifically "Patient Criteria"). All other indications of VNS for the treatment of depression are nationally non-covered (Section C), as is VNS for TRD when provided* ***outside*** *the context of a Medicare-approved CED study (Section C). For Medicare-approved VNS studies for TRD, see CMS Website.)*<br>For **Parkinson's disease and migraine headaches**:<br>✓ Transmittal 1875, Change Request (CR) CR10184 *(Specifically see page 9, which states, "160.18 is only for refractory seizures - Parkinson's disease is non-covered…" and page 10, which states, "Remove migraine ICD-9… & ICD-10... Per CMS, VNS is not appropriate for treatment of migraine at this time and is investigational only.")* |

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| **Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*** | For ***chest wall respiratory sensor electrode (Category III code 0466T)***:<br>✓ Because this code has been non-covered until hypoglossal nerve stimulation criteria were developed, coverage for this code is limited to use for hypoglossal nerve stimulation for obstructive sleep apnea (OSA) only. See also the Article for *Billing and Coding: Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea* (A57949).<br><br>For the ***treatment of peripheral neuropathy***:<br>✓ Nerve Blockade for Treatment of Chronic Pain and Neuropathy L35457*(See the section for peripheral neuropathy within the LCD)*<br><br>**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, nor does Medicare coverage include non-implantable or non-invasive devices. Therefore, the health plan's medical policy is applicable for these scenarios.*<br><br>For ***implantable VNS when used as treatment of all other indications and non-invasive and non-implantable VNS not previously specified***:<br>✓ 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:

For initial placement:

- 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.

For replacement:

- For replacement of irreparable devices or their components, documentation must support reason for replacement (e.g., device malfunction, etc.) and whether or not the stimulator is still under manufacturer warranty or that the component excluded from the warranty.

For revisions and removal only (without replacement):

- Revisions to previously placed medically necessary devices and removals do not require additional documentation.

**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."

An implantable VNS device from SetPoint Medical received FDA breakthrough device designation for patients with moderate-to-severe rheumatoid arthritis who had an incomplete response or intolerance to one or more biologic disease-modifying antirheumatic drugs (bDMARDs) or DMARDs, such as Janus Kinase (JAK) inhibitors.

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.

electroCore, LLC has developed a non-invasive VNS (aka, nVNS; gammaCore® or gammaCore Sapphire D™) released for use by the FDA in April of 2017. The device is intended for non-invasive vagus nerve stimulation on the side of the neck to treat cluster headache and to reduce the frequency of cluster headache attacks. In 2018, the FDA

expanded clearance for this device to include treatment of pain associated with migraine in adults.

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.

Note, the fact a service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, CMS or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

## CROSS REFERENCES

Behavioral Health (Psychiatric) Services, Behavioral Health, Policy No. M-BH19

Electrical Stimulation and Electromagnetic Therapy Devices, Durable Medical Equipment, Policy No. M-DME83

Auricular Electrostimulation, Medicine, Policy No. M-MED146

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-MED149

Deep Brain Stimulation (DBS), Surgery, Policy No. M-SUR84

Gastric Electrical Stimulation, Surgery, Policy No. M-SUR111

## REFERENCES

1. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §40.4 - Items Covered Under Warranty

## CODING

| Codes | Number | Description |
|---|---|---|
| **CPT** | 0908T | Open implantation of integrated neurostimulation system, vagus nerve, including analysis and programming, when performed |
| | 0909T | Replacement of integrated neurostimulation system, vagus nerve, including analysis and programming, when performed |

| Codes | Number | Description |
|---|---|---|
| | 0910T | Removal of integrated neurostimulation system, vagus nerve |
| | 0911T | Electronic analysis of implanted integrated neurostimulation system, vagus nerve; without programming by physician or other qualified health care professional |
| | 0912T | Electronic analysis of implanted integrated neurostimulation system, vagus nerve; with simple programming by physician or other qualified health care professional |
| | 61885 | Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array |
| | 61886 | With connection to two or more electrode arrays |
| | 61888 | Revision or removal of cranial neurostimulator pulse generator or receiver |
| | 64553 | Percutaneous implantation of neurostimulator electrode array; cranial nerve |
| | 64568 | Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator |
| | 64569 | Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator |
| | 64570 | Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator |
| | 95970 | Electronic analysis of implanted neurostimulator pulse generator/transmitter(e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve,spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming |
| | 95971 | ; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional |
| | 95976 | ; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional |
| | 95977 | ; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional |
| **HCPCS** | C1822 | Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system |
| | C1827 | Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller |
| | E0735 | Non-invasive vagus nerve stimulator |
| | E1399 | Durable medical equipment, miscellaneous |
| | L8678 | Electrical stimulator supplies (external) for use with implantable neurostimulator, per month |
| | L8679 | Implantable neurostimulator, pulse generator, any type |

| Codes | Number | Description |
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| | L8680 | Implantable neurostimulator electrode, each *(Code non-covered by Medicare – see L8679)* |
| | L8681 | Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only |
| | 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 *(Code non-covered by Medicare – see L8679)* |
| | L8686 | Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension *(Code non-covered by Medicare – see L8679)* |
| | L8687 | Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension *(Code non-covered by Medicare – see L8679)* |
| | L8688 | Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension *(Code non-covered by Medicare – see L8679)* |
| | L8689 | External recharging system for battery (internal) for use with implantable neurostimulator |

***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.*