Medicare Advantage Policy Manual **Policy ID:** M-SUR74

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.

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 the Centers of Medicare and Medicaid Services (CMS) policies, when available. 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 CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

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.

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), and is considered medically necessary by the health plan.

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	For ***implantable VNS when used as treatment of medically refractory partial onset seizures*** *and* ***all other types of seizure disorders***: ✓ Vagus Nerve Stimulation (VNS) (160.18) For **surgically implanted VNS used for treatment resistant depression (TRD) effective 02/15/2019**: ✓ Decision Memo for Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD) (CAG-00313R2) *The DM states, "The scope of this review is limited to surgically implanted VNS only for the treatment of TRD." Note coverage is under coverage with evidence development (CED) only. The DM also states, "CMS will review studies to determine if they meet the 13 criteria listed... If CMS determines that they meet these criteria, the study will be posted on CMS' CED website" (LINK) (Once the NCD 160.18 is updated to reflect this coverage, the DM will be removed from the policy.)* For **Parkinson's disease and migraine headaches**: ✓ 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.")*
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	For the following uses of VNS: ✓ ***Treatment of depression not otherwise addressed by the decision memo above (implantable or non-implantable);*** ✓ ***Transcutaneous VNS (t-VNS®) system (NEMOS®)*** ✓ ***Implantable VNS when used to treat obesity, and*** ✓ ***Chest wall respiratory sensor electrode (Category III code 0466T)***:

	o Non-Covered Services (L35008) *(For the t-VNS system or NEMOS®, the LCD states, "Medical devices that are not approved for marketing by the Food and Drug Administration (FDA) are considered investigational by Medicare and are not considered reasonable and necessary.")* 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, nor does Medicare coverage include non-implantable or non-invasive devices. 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-invasive and non-implantable VNS 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.

electroCore, LLC has developed a non-invasive VNS (gammaCore®) 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." *(Noridian LCD L35008)* 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-19

Electrical Stimulation and Electromagnetic Therapy Devices, Durable Medical Equipment, Policy No. M-83

Auricular Electrostimulation, Medicine, Policy No. M-146

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

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

Vagus Nerve Blocking Therapy for Obesity, Surgery, Policy No. M-200

REFERENCES

None

CODING

Codes	Number	Description
CPT	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	Incision for implantation of cranial nerve (e.g., 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

Codes	Number	Description
	~~95974~~	~~; complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour~~ *(Code deleted 01/01/2019)*
	~~95975~~	~~; 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)~~ *(Code deleted 01/01/2019)*
	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
	0466T	Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (List separately in addition to code for primary procedure)
HCPCS	C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
	E1399	Durable medical equipment, miscellaneous
	L8679	Implantable neurostimulator, pulse generator, any type
	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.*