Medical Policy

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

Vagus Nerve Stimulation (VNS)

Policy Number: PG0237
Last Review: 01/03/2022

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.
- Durable Medical Equipment (DME) frequency limitations are calculated based on The Center for Medicare and Medicaid Services (CMS) criteria and guidelines, National Coverage Determinations (NCD), and Local Coverage Determinations (LCD) rules and regulations.

SCOPE:

X Professional
X Facility

DESCRIPTION:

Stimulation of the vagus nerve can be performed using a pulsed electrical stimulator implanted within the carotid artery sheath. It is connected by wire to a lead that is wrapped around the left vagus nerve in the neck. There are also devices available that are implanted at different areas of the vagus nerve. Through the vagus nerve, it delivers intermittent electrical pulses 24 hours a day to the brain. This technique has been proposed as a treatment for refractory seizures, depression, and other disorders. When a patient senses the impending onset of a seizure, he/she can activate the device through a hand-held magnet to deliver an additional dose of stimulation. Treatment with the vagus nerve stimulator is not free of side effects. Patients have experienced cough, hoarseness, alterations in their voice, and shortness of breath.

Vagus nerve stimulation (VNS) may be considered medically necessary as a treatment of medically refractory seizures. VNS has been shown to shorten the duration and reduce the severity of seizures in certain patients who remain refractory despite optimal drug therapy or surgical intervention or in those with debilitating side effects of anti-epileptic medications. The premise is that the VNS stimulates the vagal visceral afferents, which then diffuse the central nervous system projection, and the activation of these pathways has a widespread effect on neuronal excitability. VNS may also stimulate vagal efferent pathways that innervate the heart, vocal cords, and other laryngeal and pharyngeal muscles, and provide parasympathetic innervation to the gastrointestinal tract.

VNS with an implantable vagus nerve stimulator is also being investigated as an adjunctive therapy for treatment resistant depression. It has been proposed that the impulses from the generator are transmitted to the mood centers in the brain to achieve the therapeutic effects against depression. Currently, the precise mechanism of how VNS might enhance mood remains unknown. Due to the lack of reliable, long-term evidence from well-designed randomized, controlled trials, the evidence is insufficient to permit conclusions about the benefit of VNS in the treatment of any other condition beyond refractory seizures. Therefore, VNS is considered investigational for all indications other than selected patients with refractory seizures.

Refractory Seizures:

- Seizures that occur in spite of therapeutic levels of antiepileptic drugs or

- Seizures that cannot be treated with therapeutic levels of antiepileptic drugs because of intolerable adverse effects of these drugs.

Transcutaneous vagus nerve stimulation (tVNS) is being investigated as a noninvasive alternative to surgery for VNS for numerous indications. Most of the evidence in the peer-reviewed literature for tVNS consists of pilot studies or case series for a variety of indications, therefore conclusions about safety and efficacy cannot be made at this time.

POLICY:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Vagus Nerve Stimulation (VNS) with an implantable vagus nerve stimulator for refractory seizures does not require prior authorization, for ALL product lines (procedure 64568 - Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator).

VNS with an implantable vagus nerve stimulator for all other indications is considered experimental/investigation and is non-covered for all product lines.

Intra-abdominal vagus nerve blocking therapy is considered investigational in all situations; procedure codes 0312T, 0313T, 0314T, 0315T, 0316T, 0317T are non-covered for all product lines.

Non implantable vagus nerve stimulation or transcutaneous noninvasive vagus nerve stimulation (nVNS) or (tVNS) are considered experimental, investigational and/or unproven for all indications.

K1020 Non-invasive vagus nerve stimulator is non-covered for all product lines.

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Implantable vagus nerve stimulators are proven and medically necessary for treating epilepsy in individuals with all the following:

- Medically refractory epileptic seizures with failure of two or more trials of single or combination antiepileptic drug therapy; and
- Seizures that cannot be treated with therapeutic levels of antiepileptic drugs because of intolerable adverse effects of these drugs; and
- The Member is not a candidate for epilepsy surgery, has failed epilepsy surgery (such as a lesionectomy or medial temporal lobectomy), or refuses epilepsy surgery after Shared Decision Making discussion; and
- No history of left or bilateral cervical vagotomy. The U.S. Food and Drug Administration (FDA) identifies a history of left or bilateral cervical vagotomy as a contraindication to vagus nerve stimulation.

VNS with an implantable vagus nerve stimulator is considered medically necessary for the treatment of Lennox-Gastaut syndrome in members who remain refractory to optimal anti-epileptic medications, and/or surgical intervention (such as a corpus callosotomy or lesional epilepsy surgery), or who have debilitating side effects from antiepileptic medications, and who have no history of a bilateral or left cervical vagotomy.

Replacement/revision of a vagus nerve therapy system/handheld magnet medically necessary if the original system/magnet met criteria as medically necessary, is no longer under warranty, and cannot be repaired.

Non-Coverage

Implantable vagus nerve stimulation is considered experimental, investigational and/or unproven as a treatment of other conditions, including but not limited to:

- Psychological disorders
- Depression
- Treatment of autism
- Heart failure
- Upper-limb impairment due to stroke
- Essential tremor

- Addictions
- Anxiety disorders
- Bulimia
- Headaches
- Migraines
- Fibromyalgia
- Back and neck pain
- Tinnitus
- Traumatic brain injury
- Obesity
- Coma
- Narcolepsy
- Sleep disorder
- Tourette's syndrome
- Cognitive impairment associated with Alzheimer's disease
- Obsessive-compulsive disorder
- Chronic ischemic stroke rehabilitation therapy – MicroTransponder Vivistim Paired VNS System (MicroTransponder Inc., Austin, TX) [Vagus nerve stimulation (VNS) has been proposed as an adjunct to standard rehabilitation therapy in individuals with stroke to improve function. The literature is limited in quantity and by small patient populations and short-term follow-ups with an inability to generalize findings across a broad range of patient populations.]

There is not yet enough information in published medical studies to show how well it works for other conditions.

Similarly, non-implanted devices to stimulate the vagus nerve for treatment of any condition are also investigational due to lack of evidence that they improve one's health.

- Transcutaneous (nonimplantable) vagus nerve stimulation devices are considered experimental, investigational and/or unproven for ALL indications (e.g., gammaCore (ElectroCore), i.e., not all-inclusive; post-laminectomy syndrome, prevention of chronic migraine attacks, the prevention/attenuation of myocardial ischemia-reperfusion injury, and seizures not indicated above.

FDA approved or cleared Vagus Nerve Stimulators include, NeuroCybernetic Prosthesis (NCP)/VNS Therapy, gammaCore, grammaCore-2, gammaCore-Sapphire,

Elite (Medicare Advantage) Plans

National Coverage Determination (NCD) for Vagus Nerve Stimulation (VNS) (160.18)

Effective for services performed on or after February 15, 2019, the Centers for Medicare & Medicaid Services (CMS) will cover FDA-approved VNS devices for treatment resistant depression (TRD) through Coverage with Evidence Development (CED) when offered in a CMS-approved, double-blind, randomized, placebo-controlled trial with a follow-up duration of at least one year with the possibility of extending the study to a prospective longitudinal study when the CMS-approved, double-blind, randomized placebo-controlled trial has completed enrollment, and there are positive interim findings.

Each study must be approved by CMS and as a fully described, written part of its protocol, must address whether VNS improves health outcomes for TRD patients compared to a control group, by answering all the following research questions below. The details of the prospective longitudinal study must be described in the original protocol for the double-blind, randomized, placebo-controlled trial. Response is defined as a ≥ 50% improvement in depressive symptoms from baseline, as measured by a guideline recommended depression scale assessment tool. Remission is defined as being below the threshold on a guideline recommended depression scale assessment tool. The following research questions must be addressed in a separate analysis for patients with bipolar and unipolar disease

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES

61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; 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 (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 system (e.g., rate, pulse amplitude and 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, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
95976	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 simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95977	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 complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming
0313T	Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator
0314T	Vagus nerve blocking therapy (morbid obesity); laparoscopic removal of vagal trunk neurostimulator electrode array and pulse generator
0315T	Vagus nerve blocking therapy (morbid obesity); removal of pulse generator
0316T	Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator
0317T	Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed
Note	Transcutaneous vagal nerve stimulation – no specific code
HCPCS CODES	
HCPCS codes related to covered medical policy coverage; covered if selection criteria are met:	
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1883	Adaptor/ extension, pacing lead or neurostimulator lead (implantable)
K1020	Non-invasive vagus nerve stimulator Effective 04/01/2021
L8679	Implantable neurostimulator, pulse generator, any type

L8680	Implantable neurostimulator electrode (with any number of contact points), each
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
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689	External recharging system for implanted neurostimulator (replacement only)
L8695	External recharging system for battery (external) for use with implantable neurostimulator (replacement only)
ICD-10 codes covered if medical policy coverage criteria are met:	
G40.001-G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable/not intractable, with/without status epilepticus
G40.101-G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable/not intractable, with/without status epilepticus
G40.311-G40.319	Generalized idiopathic epilepsy and epileptic syndromes, intractable, with/without status epilepticus
G40.811-G40.814	Lennox-Gastaut syndrome
G40.909	Epilepsy, unspecified, not intractable, without status epilepticus
G40.919	Epilepsy, unspecified, intractable, without status epilepticus

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 06/15/2009

Date	Explanation & Changes
07/18/14	• CPT code 64573 removed because deleted 12/31/10 • Removed CPT codes 61888 & 64585 • Added new HCPCS code L8679 effective 1/1/14 • Added CPT codes 64550, 64568, 64569, & 64570 • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
05/21/15	• Added codes 0312T, 0313T, 0314T, 0315T, 0316T, 0317T as non-covered • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
05/27/16	• Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
08/25/17	• Codes C1767, C1778, C1816, C1883 removed from policy per administrative direction • Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
08/23/18	• Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
12/16/2020	• Medical policy placed on the new Paramount Medical Policy Format
05/13/2021	• Policy reviewed and updated to reflect most current clinical evidence • Removed Deleted CPT codes 64550, 95974, 95975 • Added CPT codes 95976, 95977, C1767, C1778, C1787, C1816, C1820, C1822, C1883, K1020 • Added ICD-10 codes supporting medical policy coverage criteria.
01/03/2022	• Added Chronic ischemic stroke rehabilitation therapy – MicroTransponder Vivistim Paired VNS System (MicroTransponder Inc., Austin, TX) to the noncovered listing
02/16/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023

03/29/2023	• Medical Policy updated to reflect DME limits calculated by CMS criteria/guidelines.
03/06/2024	• Medical Policy placed on the new Paramount Medical Policy format

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/
Industry Standard Review

Hayes, Inc., https://www.hayesinc.com/

Industry Standard Review