Vagus Nerve Stimulation

INDEPENDENT CARE HEALTH PLAN

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Policy Number: WI.PA-1232
Line of Business: Medicare

Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

Bariatric Surgery

Related Documents

Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/ Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
NCD		160.18		

	Vagus Nerve Stimulation (VNS)			

Description

Vagus nerve stimulation (VNS) was initially developed as a treatment option for medically refractory epilepsy or the inability to control seizure activity with antiepileptic drug therapy. However, VNS has also been proposed as adjunct therapy for bipolar disorder, treatment resistant major depression and upper extremity stroke rehabilitation. VNS is being researched for a broad range of indications including Alzheimer's disease, anxiety disorders, bulimia, chronic headache/migraine, cluster headache, heart failure and obesity.

A VNS therapy system consists of an implantable pulse generator, a lead and an external programming system used to change stimulation settings. The pacemaker- like pulse generator is implanted just below the collarbone under the skin of the left upper chest and is connected by a stimulating lead to the left vagus nerve in the neck where intermittent impulses are delivered.

The vagus nerve in turn sends signals to the brain which stimulate the area believed to be involved in mood regulation and seizure activity; however, the exact mechanism of action is unknown. The pulse generator can be programmed to deliver stimulation within parameters that suit the individual's needs. The lead electrode stimulation is performed only on the left vagal nerve, as the right vagal nerve helps control the heartbeat. A handheld magnet may be used to activate or deactivate the device.

The **Vivistim Paired Vagus Nerve Stimulation System** is a US Food & Drug Administration (FDA) approved implantable neurostimulator system intended for use in combination with rehabilitative exercise in ischemic stroke rehabilitation to improve upper extremity function. The Vivistim system consists of a pulse generator, lead set, programming software and a wireless transmitter. VNS is known to cause the release of acetylcholine and norepinephrine, neurotransmitters that facilitate reorganization of cortical networks. Reportedly, when VNS is paired with rehabilitative exercises, it can help an individual's brain relearn how to perform specific tasks.

Devices classified as **nonimplantable vagus nerve stimulation or transcutaneous noninvasive vagus nerve stimulation (nVNS)** are designed to prevent and treat cluster/ migraine headaches and treat medically refractory epilepsy and depression. There are two methods by which the nVNS technology can function. The first method consists of a hand-held battery-powered stimulation unit and ear electrode combination that purportedly stimulates the auricular branch of the vagus nerve through the skin over the concha of the outer ear to deliver treatment. Stimulation treatment for medically refractory epilepsy and depression occurs several hours daily and is administered by the individual. Currently, these devices are not approved by the FDA.

The second method consists of a battery-powered portable stimulator comparable in size to a mobile phone, signal generating electronics and a digital controller. Two stainless steel round discs with conductive gel combine to function as skin contact surfaces to facilitate transmission of a mild electrical signal to the cervical branch of the vagus nerve. This stimulation for acute pain and preventive treatment for cluster

migraine headaches purportedly releases inhibitory neurotransmitters and reduces the overexpression of an excitatory neurotransmitter (glutamate). This device (eg, **GammaCore, Gammacore Sapphire)** has been approved by the FDA.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Please refer to the above CMS guidance for **Vagus Nerve Stimulation.**

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

Vagus Nerve Stimulation

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array	
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve	
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator	

64569	Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator	
64570	Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator	
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, 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	
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, 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 (eg, 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	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
C1767	Generator, neurostimulator (implantable), nonrechargeable	
C1778	Lead, neurostimulator (implantable)	
C1816	Receiver and/or transmitter, neurostimulator (implantable)	

C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller	
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)	
E1399	Durable medical equipment, miscellaneous	
K1020	Noninvasive vagus nerve stimulator	
L8679	Implantable neurostimulator, pulse generator, any type	
L8680	Implantable neurostimulator electrode, 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, nonrechargeable, includes extension	
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension	
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension	
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only	
L8695	External recharging system for battery (external) for use with implantable neurostimulator, replacement only	

References

1. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). https://www.cms.gov. Vagus nerve stimulation (VNS) (160.18). Published July 22, 2020. Updated February 15, 2019. Accessed November 1, 2023.

Change Summary

- 01/01/2024 New Policy.