MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy**
Policy Number	**7.01.05**
Category	**Technology Assessment**
Original Effective Date	**10/18/01**
Committee Approval Date	**11/15/01, 09/19/02, 07/17/03, 05/19/04, 05/18/05, 12/15/05, 12/21/06, 09/20/07, 08/21/08, 10/29/09, 09/16/10, 08/18/11, 07/19/12, 10/17/13, 09/18/14, 09/17/15, 11/17/16, 10/19/17, 08/16/18, 07/18/19, 06/18/20, 07/15/21, 07/21/22, 07/20/23, 08/22/24**
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Archive Review Date	**N/A**
Product Disclaimer	• *Services are contract dependent; If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

Based upon our criteria and assessment of the peer-reviewed literature:

I. An implantable vagus nerve stimulation device has been medically proven to be effective and, therefore, is considered **medically appropriate** when used as a treatment for medically refractory seizures.

II. An implantable vagus nerve stimulation device has not been medically proven to be effective and, therefore, is considered **investigational** as a treatment for patients with depression or any other non-epileptic conditions (e.g., heart failure, fibromyalgia, tinnitus, traumatic brain injury, essential tremor, headache, post-stroke).

III. Vagus nerve stimulation implants that allow detection and stimulation based on increased heart rate (e.g., AspireSR Model) have not been medically proven to be effective and, therefore, are considered **investigational** for **ALL** indications.

IV. Vagus nerve blocking therapy has not been medically proven to be effective and, therefore, is considered **investigational** as a treatment for patients with morbid obesity.

Refer to Corporate Medical Policy #1.01.55 Electrical Stimulation as a Treatment for Pain and Other Medical Conditions

Refer to Corporate Medical Policy #7.01.103 Responsive Neurostimulation for the Treatment of Refractory Focal Epilepsy

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

This medical policy does not address occipital nerve stimulation for chronic migraines or occipital neuralgia. In occipital nerve stimulation, the neurostimulator delivers electrical impulses via insulated lead wires tunneled under the skin near the occipital nerves at the base of the head.

This medical policy does not address trigeminal nerve stimulation for migraines. Please refer to Corporate Medical Policy #1.01.55 Electrical Stimulation as a Treatment for Pain and Other Medical Conditions

This medical policy does not address hypoglossal nerve stimulation for obstructive sleep apnea. Please refer to Corporate Medical Policy #7.01.41 Surgical Management of Sleep Disorders

This medical policy does not address percutaneous nerve field stimulators (e.g., NSS-2 BRIDGE). Please refer to Corporate Medical Policy #1.01.55 Electrical Stimulation as a Treatment for Pain and Other Medical Conditions

DESCRIPTION

Seizures have been defined as paroxysmal disorders of the central nervous system characterized by abnormal cerebral neuronal discharge, with or without loss of consciousness. Medically refractory seizures are defined as 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.

The goal of epilepsy surgery is to either remove the seizure-producing area of the brain or to limit the spread of seizure activity. Surgical results can be considered curative (stopping the seizures) or palliative (restricting the spread of the seizures). The type of surgery performed is dependent on the type of seizure and where the seizures begin in the brain. Curative procedures (e.g., temporal lobectomy, cortical excision, hemispherectomy) are performed when tests consistently point to a specific area of the brain where the seizures begin. Palliative procedures (e.g., corpus callosotomy, subpial transections) are performed when a seizure focus cannot be determined or it overlaps brain areas critical for speech, movement or vision.

Vagus nerve stimulation (VNS) is a treatment alternative for patients with medically refractory seizures for whom epilepsy surgery is not recommended or for whom surgery has failed. While the mechanism for the antiepileptic effects of vagus nerve stimulation is not fully understood, the basic premise of VNS in the treatment of epilepsy is that vagal visceral afferents have a diffuse central nervous system projection, and activation of these pathways has a widespread effect upon neuronal excitability.

Surgery for implantation of a vagus nerve stimulator involves wrapping two spiral electrodes around the left vagus nerve within the carotid sheath. The electrodes are connected to an infraclavicular generator pack. The programmable stimulator may be programmed in advance, to stimulate at regular times or upon demand by the patient or caregiver by placing a magnet against the subclavicular implant site.

Vagus nerve stimulation is also being investigated for a variety of other non-epileptic conditions, including depression that has not responded to conventional treatment, bipolar disorder, obesity, autism, essential tremor, refractory anxiety, cluster headaches/migraines, bulimia, stroke, and Alzheimer's disease.

The vagus nerves play a significant role in food processing, in signaling the feeling of fullness, and in prolonging the absence of hunger through nervous control of multiple functions. A new therapy (VBLOC, vagal blocking therapy) is being developed to induce intermittent intra-abdominal vagal blocking to treat obesity, using high-frequency electrical currents. The electrodes are positioned laparoscopically on the anterior and posterior vagal trunks near the esophagogastric junction (EGJ), without anatomic modification or tissue compression of the alimentary tract. Blocking vagus nerve signals may reduce appetite and create weight loss by limiting the expansion of the stomach*;* and by reducing the frequency and intensity of stomach contractions. Vagal blocking therapy may also reduce the absorption of calories by decreasing the secretion of digestive enzymes. When the blocking is paused, two-way neural signals resume, and the stomach and pancreas return to normal function. Vagal blocking therapy's intermittent active therapeutic episodes are programmed for twelve hours per day, to prevent the body's natural tendency to circumvent the blocked neural signals and prolong the therapeutic effect during the patient's waking hours.

RATIONALE

The U.S. Food and Drug Administration (FDA) approved a vagus nerve stimulation device called the NeuroCybernetic Prosthesis system for treatment of seizures in July 1997. The data published in the medical literature are sufficient to conclude that vagal nerve stimulation improves health outcomes for patients with partial onset seizures who are not

candidates for surgery and whose seizures are refractory to other treatment. Studies have demonstrated that vagal nerve stimulation, as an adjunct to the optimal use of antiepileptic medications, in the treatment of medically refractory patients with partial onset seizures reduces seizure frequency by approximately 25% after three months and, in most cases, the benefit treatment effect increases over time (up to a 50% reduction). Although FDA approval of this device is for patients twelve years of age or older, studies on younger patients have reported results similar to the adult trials, supporting the safety and efficacy of VNS in children with refractory seizures. Vagus nerve stimulation is carried out in centers experienced in the treatment of epilepsy.

The FDA approved Cyberonic's VNS Therapy System in July 2005 as an 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 at least four adequate antidepressant treatment regimens (medications and/or ECT). It is not intended as a first-line treatment, even for patients with severe depression. In the D-01 depression case series, after 10-weeks of active VNS therapy, 30.5% of patients had a 50% reduction in the depressive symptoms, based on the 28-item Hamilton Rating Scale for Depression (HRSD-28). In reports of longer-term outcomes, improvements in depressive symptoms continue out to one year, with 45% of patients having a 50% improvement in HRSD-28. These outcomes seem to stabilize out to two years, but there were substantial losses to follow-up (only 42 patients out of 60 available at two-year follow-up). The D-02 depression study was a double blind, randomized, placebo-controlled study (Rush et al., 2005). Fifteen percent of patients in the active VNS group showed a 50% improvement on depressive symptoms, whereas 10% of patients in the sham group showed a 50% improvement. A secondary outcome measurement, Inventory of Depressive Symptomology, self-rated (IDS-SR), showed a significant difference between the two groups, with 17.4% of patients in the VNS active group versus 7.5% of patients in the sham group demonstrating improvement. This randomized trial failed to achieve statistical significance with its primary endpoint. The available evidence does not permit conclusions about the usefulness of vagus nerve stimulation in the treatment of depression. Long-term data regarding the tolerability, as well as symptomatic and functional outcomes, of depressed patients receiving VNS are needed, to ascertain the effectiveness of this procedure for treating refractory depression.

In August 2021, the FDA approved a first-of-its-kind drug-free rehabilitation system intended to treat moderate to severe upper extremity motor deficits associated with chronic ischemic stroke using vagus nerve stimulation (VNS). The MicroTransponder Vivistim Paired VNS System (Vivistim System) is intended to be used to stimulate the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment.

The evidence on VNS for treatment of upper-limb impairment due to stroke consists of 3 small RCTs and a systematic review that pooled their data. Two RCTs compared VNS plus rehabilitation to rehabilitation alone. Dawson et al. (2016) conducted a randomized pilot trial of VNS in patients (n=21) with upper-limb dysfunction after ischemic stroke, which failed to show significant improvements for the VNS group on response and function outcomes. Dawson et al. (2021) conducted a similar RCT with a larger patient population (n=106), which found a significant difference in response and function outcomes. The third RCT compared VNS to sham (n=17) found that although VNS significantly improved response rate, there were 3 serious adverse events related to surgery (Kimberley et al., 2019).

Ramos-Castaneda et al. (2022) published a systematic review evaluating VNS on upper limb motor recovery after stroke, reporting that implanted VNS improved upper limb motor function based on Fugl-Meyer Assessment-Upper Extremity (FMA-UE) score when compared to control. This systematic review and meta-analysis concluded that VNS together with physical rehabilitation improves upper limb motor function in stroke patients; however, with several knowledge gaps and limitations, the authors acknowledge that more studies are needed to evaluate the efficacy.

Results from other pilot studies suggest that VNS might induce weight loss in obese patients and improve cognitive function in patients with Alzheimer's disease. However, these findings need to be validated in large, randomized, placebo-controlled trials with long-term outcomes reported.

<u>AspireSR Model 106 (Cyberonics) for Vagus Nerve Stimulation</u>

The AspireSR Model 106 (Cyberonics, Inc.) received FDA premarket approval in February 2014. The newest modification to the vagus nerve stimulation (VNS) implant detects tachycardia heart rates, which may be associated with an impending seizure, and automatically delivers stimulation to the vagus nerve. Like its predecessors, the AspireSR can

also deliver stimulation in the normal and magnet modes. However, when programmed for AutoStim mode, the AspireSR requires no patient interaction to trigger the delivery of electrical stimulation, as it is programmed to detect tachycardia and respond by delivering an extra automatic stimulation. The AutoStim mode should not be used in patients with significant arrhythmias being treated with pacemakers and/or an implantable defibrillator, beta-blockers, or any other treatment that may impact the intrinsic heart rate. A few small, preliminary studies and case reports have evaluated the AspireSR Model 106 and have shown positive results. However, there is insufficient evidence to establish the safety and efficacy of the AspireSR Model 106 in reducing seizures until further prospective RCTs establish its clinical value.
In November 2015, the FDA published a class 2 devices recall on all AspireSR Model 106 devices, due to a delay in the "Verify Heartbeat Detection" feature, which could decrease its battery life. In June 2017, Cyberonics recalled the M106 generators because of a manufacturing defect that could lower the longevity of the device. Instructions were sent to affected hospitals and physicians to monitor patients. In November 2017, Cyberonics recalled Model 3000 VNS Therapy Programmer, including models equipped with the Model 106 generator, due to a variety of problems that could lead to device failure or other complications, including delivery of more stimulation than intended or no stimulation. In January 2018, VNS Therapy Systems with the Model 106 generator were recalled because of a display warning issue.

Vagus Nerve Blocking Therapy

The FDA approved the Maestro Rechargeable System (Enteromedics) through the PMA process in January 2015. The device is indicated for use in adults aged 18 years and older who have a BMI of 40 to 45 kg/m2 or a BMI of 35 to 39.9 kg/m2 with one or more obesity-related comorbidities and have failed at least one supervised weight management program within the past five years. The current literature is insufficient to determine the overall safety and efficacy of treating obesity using vagal nerve blocking therapy. A randomized controlled clinical trial, EMPOWER, (~~MG~~ Sarr, et al. 2012) found that VBLOC therapy to treat morbid obesity was safe overall; however, the weight loss was not any greater in the treatment group compared to the control group.

In the 2014 ReCharge trial, S Ikramuddin and colleagues conducted a randomized, double-blind, sham-controlled clinical trial to evaluate the effectiveness and safety of intermittent, reversible vagal nerve blockade therapy for obesity treatment. This study involved 239 participants who had a BMI of 40 to 45 or 35 to 40 and one or more obesity-related condition. It was conducted at ten sites in the United States and Australia. Of the initial 239 participants, 157 patients received an active vagal nerve block device, and 75 received a sham device. All participants received weight management education. The coprimary efficacy objectives were to determine whether the vagal nerve block was superior in mean percentage excess weight loss to sham by a 10-point margin with at least 55% of patients in the vagal block group achieving a 20% loss and 45% achieving a 25% loss. The authors concluded that, among patients with morbid obesity, the use of vagal nerve block therapy compared with a sham control device did not meet either of the prespecified coprimary efficacy objectives, although weight loss in the vagal block group was statistically greater than in the sham device group. The treatment was well-tolerated, having met the primary safety objective.

The ReCharge trial 24-month outcomes were reported by Apovian et al. (2017). At 24-months, participants (n=123) remaining in the trial had a mean excess weight loss (EWL) of 21%; mean total weight loss (TWL) of 8%; 58% had ≥ 5% TWL; and 34% had ≥ 10% TWL. Significant improvements ($p<0.05$) were seen in mean LDL, HDL, triglycerides, and systolic and diastolic blood pressures. Adverse events were reported as mild or moderate, with the most frequently reported related adverse events were heartburn and dyspepsia, neuroregulator site pain, nausea, belching, and dysphagia. Study limitations include short-term follow-up, missing data, lack of a blinded control group, and small study size.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
0908T **(E/I)**	Open implantation of integrated neurostimulation system, vagus nerve, including analysis and programming, when performed *(effective 01/01/25)*
0909T **(E/I)**	Replacement of integrated neurostimulation system, vagus nerve, including analysis and programming, when performed (e*ffective 01/01/25)*
0910T **(E/I)**	Removal of integrated neurostimulation system, vagus nerve (e*ffective 01/01/25)*
0911T **(E/I)**	Electronic analysis of implanted integrated neurostimulation system, vagus nerve; without programming by physician or other qualified health care professional *(effective 01/01/25)*
0912T **(E/I)**	Electronic analysis of implanted integrated neurostimulation system, vagus nerve; without programming by physician or other qualified health care professional *(effective 01/01/25)*
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to single electrode array
61886	with connection to 2 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 neurostimulator (e.g., vagus nerve) electrode array and pulse generator
64999 **(*E/I)**	Unlisted procedure, nervous system **(*E/I when billed as vagus nerve blocking (e.g., Maestro))**
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
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 Codes

Code	Description
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer; neurostimulator

Code	Description
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
E0735 **(E/I)**	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

ICD10 Codes

Code	Description
G40.001-G40.219	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset (code range)
G40.301-G40.319	Generalized idiopathic epilepsy and epileptic syndromes (code range)
G40.A01-G40.A19	Absence epileptic syndrome (code range)
G40.B01-G40.B19	Juvenile myoclonic epilepsy, not intractable (code range)
G40.401-G40.419	Other generalized epilepsy and epileptic syndromes (code range)
G40.501-G40.509	Epileptic seizures related to external causes (code range)
G40.801-G40.919	Other epilepsy and recurrent seizures (code range)
G93.45	Developmental and epileptic encephalopathy *(effective 10/01/24)*
Investigational Codes:	
All other ICD10 diagnosis codes are considered investigational.	

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*Key Article

KEY WORDS

Treatment- resistant depression, Epilepsy, Seizures, Stroke, Weight loss, Obesity

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Vagus Nerve Stimulation 160.18. Please refer to the following NCD website for Medicare Members:

[NCD - Vagus Nerve Stimulation (VNS) (160.18) (cms.gov)] accessed 07/12/24.

There is currently a Decision Memo for Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD) CAG-00313R2. Please refer to the following website for Medicare Members:

[https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=292&type=Closed&bc=ACAAAAAAQAAA&] accessed 07/12/24.

CMS approved studies for Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD) under Coverage with Evidence Development (CED) are located here:

[https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/VNS] accessed 07/12/24.