MEDICAL POLICY

Medical Policy Title	**Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy**
Policy Number	**7.01.05**
Current Effective Date	August 21, 2025
Next Review Date	August 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

***This policy does not address transcutaneous vagus nerve stimulation. Refer to CMP 1.01.55 Electrical Stimulation as a Treatment for Pain and Other Medical Conditions.

I. An implantable vagus nerve stimulation (VNS) device is **medically appropriate** when used as a treatment for medically refractory seizures.

II. An implantable VNS device is **investigational** as a treatment for individuals 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) are **investigational** for **ALL** indications.

IV. Vagus nerve blocking therapy is **investigational** as a treatment for individuals with morbid obesity.

RELATED POLICIES

Corporate Medical Policy

1.01.55 Electrical Stimulation as a Treatment for Pain and Other Medical Conditions

7.01.103 Responsive Neurostimulation for the Treatment of Refractory Focal Epilepsy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

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.

The vagus nerve extends from the brain down the side of the neck to the large intestines, helping regulate key body systems such as the heart and digestion. A vagus nerve stimulator device (VNS) is a device used as an add-on therapy for individuals with epilepsy that is not well controlled by medication. It delivers mild electrical impulses to the vagus nerve targeting areas of the brain involved in seizure activity. VNS is especially important for individuals whose seizures do not respond to drug therapy, who are not candidates for epilepsy surgery, or for whom surgery has failed to significantly reduce sized frequency.

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 individual or caregiver by placing a magnet against the subclavicular implant site.

VNS 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. Vagal blocking (VBLOC), 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 individual's waking hours.

SUPPORTIVE LITERATURE

Vagus Nerve Stimulation for Focal Epilepsy

Panebianco et al (2022) updated the original 2015 review on the effectiveness of VNS as an add-on treatment for individuals with drug resistance focal epilepsy. The analysis included data from 439 participants and assessed treatment withdrawals, adverse effect, quality of life (QOL), cognition, mood, overall risk ratio for those who experience greater reduction in seizure frequency. The authors did not identify any new studies for this update thereby concluding the result are unchanged. VNS appears to be an effective treatment for individuals with intractable focal epilepsy. High level simulation was associated with greater reduction in seizure frequency compared to low level stimulation. Common side effects include voice alteration, hoarseness, pain, shortness of breath, cough, nausea, tingling sensations, headache, and infection at the surgical site. Shortness of breath, voice changes, and hoarseness occurred more frequently with high level stimulation. However, the evidence on both the effectiveness and side effects of the VNS therapy is limited and imprecise due to the small number of studies and participants, as well as gaps in trial designs and reporting. The certainty of evidence was rated as moderate to low meaning that future research is likely or very likely to impact confidence in these findings and may change the estimates.

Hamilton et al (2018) evaluated the efficacy of the AspireSR VNS, (including cardiac based seizure detection [CBSD]) by comparing outcomes in individuals receiving new AspireSR implants, and those individuals who underwent a battery replacement of AspireSR from an older VNS model. The results showed that the new implant group (AspireSR as first VNS) had a reduction in median seizures per year reduced from 192 to 64 and 59% experienced ≥50% reduction in seizures. A total of 41% saw greater than 80% reduction, 6% became seizure free during follow up, and 10% reported no anti-epileptic benefit. The battery replacement group (previously VNS to ApsireSR) showed a seizure reduction from 336 pre-VNS to 90 (post initial VNS) to 72 (post AspireSR). After the AspireSR upgrade, 71% achieved ≥50% additional reduction, and 74% required no change in stimulation duty cycle. Improvement was significantly greater from original VNS. Minimal surgical complications were reported, four cases of transient vocal cord paresis (2.6%), one lead migration (0.7%), and no infections or hemorrhage reported. Overall authors reported that AspireSR AutoStim feature (ictal tachycardia detection) provided significant value over traditional VNS.

<u>VNS for Limb Dysfunction after Stroke</u>

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.

VNS for Depression

Conway et al (2025) evaluated the safety and efficacy of the Food and Drug Administration (FDA) approved adjunctive VNS in adults with marked treatment resistant depression (TRD). The study consisted of a 12-month, double-blind multi center randomized sham-controlled trial that included 493 adults with TRD. Participants were randomized to either active VNS plus treatment as usual (Tau) or no-stimulation sham VNS therapy prior to device implantation and activation. The primary outcome was percentage of time in response from months 3 to 12, with response defined as a ≥50 % reduction from baseline on the Montgomery-Åsberg Depression Rating Scale (MADRS). Overall, 88.4% of participants completed the trial. The percentage of time in MADRS define response, did not significantly differ between the active and sham VNS groups. However, ratings from on-site clinicians (Clinical Global Inventory–Impression [CGI-I]), patients (Quick Inventory of Depressive Symptomology–Self Report [QIDS-SR]), and offsite masked raters (Quick Inventory of Depressive Symptomology–Clinician [QIDS-C]) revealed antidepressant benefits significantly favoring active VNS. Researchers concluded that although the primary outcome (percentage time in MADRS response) did not significantly differentiate VNS from sham, multiple secondary measures showed statistically and clinically significant improvements in patients receiving active VNS. Overall, the study supports VNS as a safe and moderately effective adjunctive treatment for patients with marked TRD especially when partial improvements are clinically meaningful.

Vagus Nerve Blocking Therapy

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.

PROFESSIONAL GUIDELINE(S)

The American Academy of Neurology reaffirm their 2013 guidelines addressing vagus nerve stimulation for the treatment of epilepsy. The recommendations include the following guidance:

- VNS may be considered as adjunctive treatment for children with partial or generalized epilepsy (Level C, 14 Class III studies).
- VNS may be considered in patients with Lennox-Gastaut syndrome (LGS) (Level C, 4 Class III studies). The responder rate for patients with LGS does not appear to differ from that of the general population of patients with medication-resistant epilepsy.
- In adult patients receiving VNS for epilepsy, improvement in mood may be an additional benefit (Level C, 2 Class III studies).
- VNS may be considered progressively effective in patients over multiple years of exposure (Level C, 2 Class III studies).

The National Institute for Health and Clinical Excellence (NICE) 2020 guidelines for implanted vagus nerve stimulation for treatment-resistant depression recommends the following guidance:

- Evidence suggests that in implanted VNS for treatment-resistant depression does not raise significant safety concerns though it is associated with common well known side effects. However, the evidence supporting its effectiveness is of limited quality. As a result, the use of this procedure should be restricted to a setting with appropriate clinical governance, informed consent processes, and provisions for audit or research.

The American Psychological Association (APA) clinical practice guideline addressing the treatment of depressive disorders in children, adolescents, adults, and older adults (2022) examined the efficacy of psychological treatments, pharmacotherapy, and complementary and alternative medicine treatments.

- VNS may be an additional option for individuals who have not responded to at least four adequate trials of antidepressant treatment, including electroconvulsive therapy (ECT).
- VNS is approved for use in patients with treatment-resistant depression on the basis of its potential benefit with long-term treatment. There is no indication for the use of VNS in acute phase treatment of depression, as data showed no evidence for acute efficacy.

REGULATORY STATUS

The FDA regulates vagus stimulators as medical devices. All vagus stimulators including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 July 3]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2025 July 3]

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 individuals 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 individuals 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 individuals twelve years of age or older, studies on younger individuals 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 individuals 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 individuals with severe depression. In the D-01 depression case series, after 10-weeks of active VNS therapy, 30.5% of individuals 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.

AspireSR Model 106 (Cyberonics) for Vagus Nerve Stimulation

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.

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 Food and Drug Administration.[Internet]. Maestro Rechargeable System. Summary of Safety and

Effectiveness Data (SSED). Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130019b.pdf [accessed 2025 July 8]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

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 (effective 01/01/25)
0910T (E/I)	Removal of integrated neurostimulation system, vagus nerve (effective 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))

Code	Description
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
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

Code	Description
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
Investigational Codes:	
All other ICD10 diagnosis codes are considered investigational.	

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Vagus Nerve Stimulation (NCD 160.18) [accessed 2025 Jul 8]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, 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 HISTORY/REVISION

Committee Approval Dates

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, 08/21/25

Date	Summary of Changes
08/21/25	• Annual review. Policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.

10/18/01	• Original effective date