

MEDICAL POLICY



SUBJECT: VAGUS NERVE STIMULATION AND VAGUS NERVE BLOCKING THERAPY	EFFECTIVE DATE: 10/08/99 REVISED 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
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare 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.</i>	

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 **medically appropriate** when used as a treatment for medically refractory seizures.
- II. An implantable vagus nerve stimulation device has not been medically proven effective and, therefore, is considered **investigational** as a treatment for patients with depression and any other non-epileptic conditions (e.g., heart failure, fibromyalgia, tinnitus, traumatic brain injury, essential tremor, headache, post stroke).
- III. Vagus nerve blocking therapy has not been medically proven effective and therefore is considered **investigational** as a treatment for patients with morbid obesity.
- IV. The following types of vagus nerve stimulation therapy have not been medically proven effective, and therefore are considered **investigational** for all indications:
 - a. Transcutaneous/nonimplantable vagus nerve stimulation devices (tVNS);
 - b. Aspire SR Model 106 (Cybertronics) for vagus nerve stimulation.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and 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 hypoglossal nerve stimulation for obstructive sleep apnea. Please refer to Corporate Medical policy #7.01.41 regarding Surgical Management of Sleep Disorders.

POLICY GUIDELINES:

- I. When available, all requests for approval must be coordinated through a comprehensive epilepsy center.
- II. The Federal Employees Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

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 seizure). The type of surgery performed is dependent on the type of seizure and where they begin in the brain. Curative

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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, VNS) 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 2 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 that include depression that has not responded to conventional treatment, bi-polar 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 intraabdominal 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.

Various types of devices that stimulate the vagus nerve transcutaneously have been developed as well. Transcutaneous Vagus nerve stimulation (tVNS) is a medical treatment that involves delivering electrical impulses to the auricular branch of the vagus nerve or cervical vagus nerve. It has been proposed as an adjunctive treatment for certain types of ,treatment-resistant depression, tinnitus, diabetes, endotoxemia, memory, myocardial Infarction, headache, pain intractable epilepsy and stroke.

RATIONALE:

The FDA approved a vagus nerve stimulation device called the NeuroCybernetic Prosthesis system for treatment of seizures in July 1997. There is sufficient data published in the medical literature 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 3 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 12 years of age or older, studies on younger patients have reported results similar to the adult trials that support 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.

While the FDA approved indication states that VNS is for use in medically refractory partial onset seizures, an increasing number of studies investigating patients with generalized seizures have been published that report seizure reduction rates similar or greater than those reported in the studies on partial epilepsy (De Herdt, et al. 2007, H Kostove, et al. 2007, SJ

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You, et al. 2008, E Rossingol, et al. 2008). This body of evidence suggests that VNS has a broad antiepileptic efficacy and is an effective treatment for refractory seizures other than partial 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 4 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 HRSD-28. In reports of longer-term outcomes, improvements in depressive symptoms continue out to 1 year, with 45% of patients having a 50% improvement in HRSD-28. These outcomes seem to stabilize out to 2 years, but there were substantial losses to follow-up (only 42 patients out of 60 available at 2-year follow-up). The D-02 depression study is a double blind, randomized, placebo-controlled study. There are minimal outcome data on this study (not published in a peer-reviewed journal as yet, but outcome data can be found in the FDA summary of the safety and effectiveness of the device). There were 15% of patients in the active VNS group that showed a 50% improvement on depressive symptoms, whereas 10% of patients in the sham group showed a 50% improvement. A secondary outcome measurement, IDS-SR, (Inventory of Depressive Symptomology, self rated) showed a significant difference between the 2 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.

Results from 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 being reported.

Nonimplanted/transcutaneous VNS

Cerbomed has developed a transcutaneous VNS (t-VNS®) system 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 electrical stimulation for several hours a day; no surgical procedure is required. The device received the CE mark in Europe in 2011, but has not been FDA approved for use in the United States. In May 2017, the gammaCore-S (electroCore® LLC), a noninvasive vagus nerve stimulation device, was cleared for marketing through the 510(K) process (K171306) for the acute treatment of adults with episodic cluster headaches. When the device is applied to the side of the neck by the patient, a mild electrical stimulation of the vagus nerve is carried to the central nervous system. Each stimulation using gammaCore-S lasts 2 minutes. The patient controls the stimulation strength.

The evidence for transcutaneous VNS stimulation in individuals who have epilepsy, depression, schizophrenia, headache, or impaired glucose tolerance includes at least 1 RCT and case series for some of the conditions. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCTs are all small and have various methodologic problems. None shows definitive efficacy of transcutaneous VNS in improving outcomes among patients. The evidence is insufficient to determine the effects of the technology on health outcomes.

AspireSR Model 106 (Cyberonics) for Vagus Nerve Stimulation

The AspireSR Model 106 (Cyberonics Inc.) received FDA Premarket Approval (PMA) 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.

There is insufficient evidence to establish the safety and efficacy of the AspireSR Model 106 in reducing seizures until further, high quality trials establish its clinical value. In November 2015, the FDA published a class 2 devices recall on all AspireSR Model 106 devices.

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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 age 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 1 or more obesity-related comorbidities and have failed at least 1 supervised weight management program within the past 5 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 body mass index of 40 to 45 or 35 to 40 and 1 or more obesity-related condition and was conducted at 10 sites in the United States and Australia. 166 patients received an active vagal nerve block device and 77 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.

CODES: Number Description

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.

<u>CPT:</u>	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 or neurostimulator electrodes; 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 neurostimulator (e.g., vagus nerve) electrode array and pulse generator
	95974	Complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour
	95975	Complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour
	0312T-0317T (E/I)	Vagus nerve blocking therapy (morbid obesity) (code range)

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<u>HCPCS:</u>	C1767	Generator, neurostimulator (implantable), nonrechargeable
	C1820	Generator, neurostimulator (implantable), non-high frequency with rechargeable battery and charging system
	C1822	Generator, neurostimulator (implantable), high frequency with rechargeable battery and charging system
	C1787	Patient programmer; neurostimulator
	L8679	Implantable neurostimulator pulse generator, any type
	L8680	Implantable neurostimulator electrode, each
	L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
	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 battery (internal) for use with implantable neurostimulator
<u>ICD10:</u>	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)
	G40.401-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)
	G40.A01-G40.A19	Absence epileptic syndrome (code range)
	G40.B01-G40.B19	Juvenile myoclonic epilepsy, not intractable (code range)

Investigational Codes:

All other ICD9 and ICD10 diagnosis codes are considered investigational.

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*key articles

KEY WORDS:

Treatment- resistant depression, Epilepsy, Seizures

SUBJECT: VAGUS NERVE STIMULATION AND VAGUS NERVE BLOCKING THERAPY	EFFECTIVE DATE: 10/08/99
POLICY NUMBER: 7.01.05	REVISED 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
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CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Vagus Nerve Stimulation. Please refer to the following NCD website for Medicare Members: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=230&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAA&>.