# MEDICAL POLICY

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| **SUBJECT: VAGUS NERVE STIMULATION AND VAGUS NERVE BLOCKING THERAPY** | **EFFECTIVE DATE: 11/15/01**<br>**REVISED DATE: 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** |
| **POLICY NUMBER: 7.01.05**<br>**CATEGORY: Technology Assessment** | **PAGE: 1 OF: 9** |

- ***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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.***
- ***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.***

## 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 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

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.

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 |
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*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.

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| **CPT:** | 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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| **HCPCS:** | 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 |
| **ICD10:** | 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.

**REFERENCES:**

Aaronson ST, et al. A 5-year observational study of patients with treatment-resistant depression treated with vagus nerve stimulation or treatment as usual: comparison of response, remission, and suicidality. Am J Psychiatry 2017 July 1;174(7):640-548.

Aihua L, et al. A controlled trial of transcutaneous vagus nerve stimulation for the treatment of pharmacoresistant epilepsy. Epilepsy Behav 2014 Oct;39:105-110.

Apovian CM, et al. Two-year outcomes of vagal nerve blocking (vBloc) for the treatment of obesity in the ReCharge trial. Obes Surg 2017 Jan;27(1):169-176.

Arya R, et al. Predictors of response to vagus nerve stimulation in childhood-onset medically refractory epilepsy. J Child Neurol 2014 Dec;29(12):1652-1659.

*Bajbouj M, et al. Two-year outcome of vagus nerve stimulation in treatment-resistant depression. J Clin Psychopharm 2010 Jun;30(3):273-81.

Barbanti P, et al. Non-invasive vagus nerve stimulation for acute treatment of high-frequency and chronic migraine: an open-label study. J Headache Pain 2015;16:61.

Berry SM, et al. A patient-level meta-analysis of studies evaluating vagus nerve stimulation therapy for treatment-resistant depression. Med Devices 2013;6:17-35.

BlueCross BlueShield Association. Vagal nerve blocking therapy for treatment of obesity. Medical Policy Reference Manual Policy #7.01.150. 2017 Feb 9.

BlueCross BlueShield Association. Vagus nerve stimulation. Medical Policy Reference Manual Policy #7.01.20. 2016 Feb 11.

*BlueCross BlueShield Association Technology Evaluation Center (TEC). Vagus nerve stimulation for treatment-resistant depression. 2006 Aug;21(7).

*Christancho P, et al. Effectiveness and safety of vagus nerve stimulation for severe treatment-resistant major depression in clinical practice after FDA approval: outcomes at 1 year. J Clin Psychiatry 2011 Oct;72(10):1376-82.

Cukiert A, et al. A prospective long-term study on the outcome after vagus nerve stimulation at maximally tolerated current intensity in a cohort of children with refractory secondary generalized epilepsy. Neuromodulation 2013 Nov-Dec;16(6):551-6.

Dawson J, et al. Safety, feasibility, and efficacy of vagus nerve stimulation paired with upper-limb rehabilitation after ischemic stroke. Stroke 2016 Jan;47(1):143-150.

De Ridder D, et al. safety and efficacy of vagus nerve stimulation paired with tones for the treatment of tinnitus: a case series. Neuromodulation 2014 Feb;17(2):170-9.

Englot DJ, et al. Quality-of-life metrics with vagus nerve stimulation for epilepsy from provider survey data. Epilepsy Behav 2017 Jan;66:4-9.

Entermedics ™ VBLOC Therapy. [http://ir.enteromedics.com/documentdisplay.cfm?documentid=2692] accessed 9/13/17.

Food and Drug Administration. Premarket Approval Application gammaCore. [https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171306.pdf]. accessed 9/13/17.

Gaul C, et al. Non-invasive vagus nerve stimulation for PREVention and Acute treatment of chronic cluster headache (PREVA): a randomized controlled study. Cephalalgia 2016 May;36(6):534-546.

Gaul C, et al. Effects of non-invasive vagus nerve stimulation on attack frequency over time and expanded response rates in patients with chronic cluster headache: a post hoc analysis of the randomized, controlled PREVA study. J headache pain 2017 Dec;18(1):22.

Goadsby PJ, et al. Effect of noninvasive vagus nerve stimulation on acute migraine: an open-label pilot study. Cephalalgia 2014 Oct;34(12):986-993.

Grazzi L, et al. Non-invasive vagus nerve stimulation (nVNS) as mini-prophylaxis for menstrual/menstrually related migraine: an open-label study. J Headache Pain 2016 Dec;17(1):19.

Hasan A, et al. Transcutaneous noninvasive vagus nerve stimulation (tVNS) in the treatment of schizophrenia: a bicentric randomized controlled pilot study. Eur Arch Psychiatry Clin Neurosci 2015 Oct;265(7):589-600.

Hein E, et al. Auricular transcutaneous electrical nerve stimulation in depressed patients: a randomized controlled pilot study. J Neural Transm 2013 May;120(5):821-827.

Huang F, et al. Effect of transcutaneous auricular vagus nerve stimulation in impaired glucose tolerance: a pilot randomized study. BMC Complement Altern Med 2014 June 26;14:203.

Ikramuddin S, et al. Effect of reversible intermittent intra-abdominal vagal nerve blockade on morbid obesity: the ReCharge randomized clinical trial. JAMA 2014 Sep 3;312(9):915-22.

Jacobs HI, et al. Transcutaneous vagus nerve stimulation boosts associative memory in older individuals. Neurobiol Aging 2015 May;36(5):1860-1867.

Kinfe TM, et al. Cervical non-invasive vagus nerve stimulation (nVNS) for preventative and acut treatment of episodic and chronic migraine and migraine-associated sleep disturbance: a prospective observational cohort study. J Headache Pain 2015:16:101.

Klinkenberg S, et al. Behavioural and cognitive effects during vagus nerve stimulation in children with intractable epilepsy- a randomized controlled trial. Eur J Paediatr Neurol 2013 Jan;17(1):82-90.

Kreuzer PM, et al. Feasibility, safety, and efficacy of transcutaneous vagus nerve stimulation in chronic tinnitus: an open pilot study. Brain Stimul 2014 Jun 4 [Epub ahead of print].

Liu AY, et al. Brain stimulation in the treatment of late-life severe mental illness other than unipolar nonpsychotic depression. Am J Geriatr Psychiatry 2014 Mar;22(3):216-40.

Maestro Rechargeable System. Summary of Safety and Effectiveness Data (SSED): [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p130019] accessed 9/13/17.

Marras CE, et al. Vagus nerve stimulation in refractory epilepsy: new indications and outcome assessment. Epilepsy Behav 2013 Sep;28(3):374-8.

Meng FG, et al. Vagus nerve stimulation for pediatric and adult patients with pharmaco-resistant epilepsy. Chin Med J 2015 Oct 5;128(19):2599-2604.

Morton JM, et al. Effect of vagal nerve blockade on moderate obesity with an obesity-related comorbid condition: the ReCharge study. Obes Surg 2016 May;26(5):983-989.

National Institute for Health and Clinical Excellence (NICE). Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine. IPG 552 March 2016. [https://www.nice.org.uk]. accessed 9/13/17.

Orosz I, et al. Vagus nerve stimulation for drug-resistant epilepsy: a European long-term study up to 24 months in 347 children. Epilepsia 2014 Oct;55(10):1576-84.

Papasavas P, et al. American Society for Metabolic and Bariatric Surgery position statement on vagal blocking therapy for obesity. Surg Obes Dis 2016;12(3):460-461.

Panebianco M, et al. Vagus nerve stimulation for partial seizures. Cochrane Database Syst Rev 2015 April 3;(4):CD002896.

Patel KS, et al. Efficacy of vagus nerve stimulation as a treatment for medically intractable epilepsy in brain tumor patients. A case-controlled study using the VNS therapy Patient Outcome Registry. Seizure 2013 oct;22(8):627-33.

Premchand RK, et al. Autonomic regulation therapy via left or right cervical vagus nerve stimulation in patients with chronic heart failure: results of the ANTHEM-HF trial. J Card Fail 2014 Nov;20(11):808-16.

Revesz D, et al. Complications and safety of vagus nerve stimulation: 25 years of experience at a single center. J Neurosurg Pediatr 2016 July;18(1):97-104.

Rolston JD, et al. Corpus callosotomy versus vagus nerve stimulation for atonic seizures and drop attacks: a systematic review. Epilepsy Behav 2015 Oct;51:13-17.

Rong P, et al. Effect of transcutaneous auricular vagus nerve stimulation on major depressive disorder: a randomized controlled pilot study. J Affect Disord 2016 May;195:172-179.

Ryvlin P, et al. The long-term effect of vagus nerve stimulation on quality of life in patients with pharmacoresistant focal epilepsy: the PuLsE (Open Prospective Randomized Long-term Effectiveness) trial. Epilepsia 2014 Jun;55(6):893-900.

Sarr MG, et al. The EMPOWER study: randomized, prospective, double-blind, multicenter trial of vagal blockade to induce weight loss in morbid obesity. Obes Surg 2012 Nov;22(11):1771-82.

Shi C, et al. Vagus nerve stimulation to augment recovery from severe traumatic brain injury impeding consciousness: a prospective pilot clinical trial. Neurol Res 2013 Apr;35(3):263-76.

Shikora SA, et al. Sustained weight loss with vagal nerve blockage but NOT with sham: 18-month results of the ReCHarge trial. J Obes 2015;2015:365604.

Shikora SA, et al. Intermittent vagal nerve block for improvements in obesity, cardiovascular risk factors, and glycemic control in patients with Type 2 diabetes mellitus: 2-year results of the VBLOC DM2 Study. Obes Surg 2016 May;26(5):1021-1028.

Silberstein SD, et al. Chronic migraine headache prevention with noninvasive vagus nerve stimulation: The EVENT study. Neurology 2016 Aug 2;87(5):529-538.

Silberstein SD, et al. Non-invasive vagus nerve stimulation for the acute treatment of cluster headache: findings from the randomized, double-blind, sham-controlled ACT1 Study. Headache 2016 Sept;56(8):1317-1332.

Tisi G, et al. Vagus nerve stimulation therapy in treatment-resistant depression: a series report. Psychiatry Clin Neurosci 2014 Aug;68(8):606-11.

Ulate-Campos A, et al. Vagus nerve stimulator implantation for epilepsy in a paediatric hospital: outcomes and effect on quality of life. Neurologia 2015 Oct;30(8):465-471.

Wasade VS, et al. Long-term seizure and psychosocial outcomes of vagus nerve stimulation for intractable epilepsy. Epilepsy Behav 2015 Dec;53;:31-36.

Yu C, et al. Outcomes of vagal nerve stimulation in a pediatric population: a single center experience. Seizure 2014 Feb;23(2):105-11.

Zannad F, et al. Chronic vagal stimulation for the treatment of low ejection fraction heart failure: results of the NEural Cardiac TherApy FoR Heart Failure (NECTAR-HF) randomized controlled trial. Eur Heart J 2015 Feb 14;36(7):425-33.

*key articles

**KEY WORDS:**

Treatment- resistant depression, Epilepsy, Seizures

# 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=gAAAABAAAAAA&.