MEDICAL POLICY

Excellus

SUBJECT: VAGUS NERVE STIMULATION	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
POLICY NUMBER: 7.01.05 CATEGORY: Technology Assessment	PAGE: 1 OF: 9

- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

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

I. Vagus nerve stimulation has been medically proven to be effective and therefore **medically appropriate** when used as a treatment for medically refractory seizures in patients for whom surgery is not recommended or in whom surgery has failed.

II. Vagus nerve stimulation 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).

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

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.

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.

Vagus nerve stimulation (VNS) is a treatment alternative for patients with medically refractory seizures for whom 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, 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.

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.

VBLOC Therapy (Maestro System by Enteromedics) is under clinical investigation and is not currently FDA approved for commercial use in the United States. VBLOC Therapy is available for clinical investigational use at participating investigational centers through an investigational device exemption (IDE) study approved by the United States Food and Drug Administration. 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.

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.

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)

HCPCS:	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

ICD9: **Medically Appropriate codes:**

345.00-345.91	Epilepsy (code range)

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. Vagus nerve stimulation therapy randomized to different amounts of electrical charge for treatment-resistant depression: acute and chronic effects. Brain Stimul 2013 Jul;6(4):631-40.

*Amar AP, et al. Vagus nerve stimulation for control of intractable seizures in childhood. Pediatr Neurosurg 2001 Apr;34(4):218-23.

Andrade P, et al. Neurostimulatory and ablative treatment options in major depressive disorder: a systematic review. Acta Neurochir 2010 Apr;152(4):565-77.

*Ardesch JJ, et al. Vagus nerve stimulation for medically refractory epilepsy: a long-term follow-up study. Seizure 2007 Oct;16(7):579-85.

Arhan E, et al. The efficacy of vagal nerve stimulation in children with pharmacoresistant epilepsy: practical experience at a Turkish tertiary referral center. Eur J Paediatr Neurol 2010 Jul;14(4):334-9.

Arya R, et al. Predictors of response to vagus nerve stimulation in childhood-onset medically refractory epilepsy. J Child Neurol 2013 Dec 5 [Epub ahead of print].

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

*Ben-Menachem E. Vagus nerve stimulation, side effects, and long-term safety. J Clin Neurophysiol 2001 Sep;18(5):415-8.

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. Vagus nerve stimulation. Medical Policy Reference Manual Policy #7.01.20. 2014 Mar 13.

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

*Bodenlos JS, et al. Vagus nerve stimulation acutely alters food craving in adults with depression. Appetite 2007 Mar;48(2):145-53.

*Bohdjalian A, et al. One-year experience with Tantalus: a new surgical approach to treat morbid obesity. Obes Surg 2006 May;16(5):627-634.

*Buoni S, et al. Vagus nerve stimulation for drug resistant epilepsy in children and young adults. Brain Dev 2004 Apr;26(3):158-63.

*California Technology Assessment Forum (CTAF). Vagal nerve stimulation for treatment resistant depression. 2006 Feb [http//ctaf.org.] accessed 6/28/13.

*Camilleri M, et al. Intra-abdominal vagal blocking (VBLOC therapy): clinical results with a new implantable medical device. Surgery 2008 Jun;143(6):723-31.

*Camilleri M, et al. Selection of electrical algorithms to treat obesity with intermittent vagal block using an implantable medical device. Surg Obes Relat Dis 2009 Mar-Apr;5(2):224-9.

*Carpenter LL, et al. Cervical vagus nerve stimulation for treatment-resistant depression. Neurosurg Clin N Am 2003 Apr;14(2):275-82.

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.

Christmas D, et al. Vagus nerve stimulation for chronic major depressive disorder: 12-month outcomes in highly treatment-refractory patients. J Affect Disord 2013 Sep 25;150(3):1221-5.

Connor DE Jr, et al. Vagal nerve stimulation for the treatment of medically refractory epilepsy: a review of the current literature. Neurosurg Focus 2012 Mar;32(3):E12.

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.

*Daban C, et al. Safety and efficacy of vagus nerve stimulation in treatment-resistant depression. A systematic review. J Affect Disord 2008 Sep;110(1-2):1-15.

*DeGiorgio CM, et al. Prospective long-term study of vagus nerve stimulation for the treatment of refractory seizures. Epilepsia 2000;41(9):1195-200.

De Ferrari GM, et al. Chronic vagus nerve stimulation: a new and promising therapeutic approach for chronic heart failure. Eur Heart J 2011 Apr;32(7):847-55.

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.

Elliott RE, et al. Refractory epilepsy in tuberous sclerosis: vagus nerve stimulation with or without subsequent resective surgery. Epilepsy Behav 2009 Nov;16(3):454-60.

Elliott RE, et al. Vagus nerve stimulation for children with treatment-resistant epilepsy: a consecutive series of 141 cases. J Neurosurg Pediatr 2011 May;7(5):491-500.

Englot DJ, et al. Vagus nerve stimulation for epilepsy: a meta-analysis of efficacy and predictors of response. J Neurosurg 2011 Dec;115(6):1248-55.

Englot DJ, et al. Efficacy of vagus nerve stimulation in posttraumatic versus nontraumatic epilepsy. J Neurosurg 2012 Nov;117(5):970-7.

Entermedics ™ VBLOC Therapy. [http://ir.enteromedics.com/documentdisplay.cfm?documentid=2692] accessed 8/4/14.

Garcia-Navarrete E, et al. Long-term results of vagal nerve stimulation for adults with medication-resistant epilepsy who have been on unchanged antiepileptic medication. Seizure 2013 Jan;22(1):9-13.

*George MS, et al. Vagus nerve stimulation therapy: a research update. Neurol 2002 Sept;59(6 Suppl 4):S56-61.

*George MS, et al. A one-year comparison of vagus nerve stimulation with treatment as usual for treatment-resistant depression. Biol Psychiatry 2005 Sep 1;58(5):364-73.

*George MS, et al. Brain stimulation for the treatment of psychiatric disorders. Curr Opin Psych 2007 May;20(3):250-4.

Ghaemi K, et al. Vagus nerve stimulation: outcome and predictors of seizure freedom in long-term follow-up. Seizure 2010 Jun;19(5):264-8.

*Handforth A, et al. Vagus nerve stimulation for essential tremor: a pilot efficacy and safety trial. Neurol 2003 Nov 5;61(10):1401-5.

He W, et al. Transcutaneous auricular vagus nerve stimulation as a complementary therapy for pediatric epilepsy: a pilot trial. Epilepsy Behav 2013 Sep;28(3):343-6.

Healy S, et al. Vagal nerve stimulation in children under 12 years old with medically intractable epilepsy. Childs Nerv Syst 2013 Nov;29(11):2095-9.

Helmers SL, et al. Clinical outcomes, quality of life, and costs associated with implantation of vagus nerve stimulation therapy in pediatric patients with drug-resistant epilepsy. Eur J Paediatr Neurol 2012 Sep;16(5):4490458.

*Holmes MD, et al. Effect of vagus nerve stimulation on adults with pharmaco-resistant generalized epilepsy syndromes. Seizure 2004 Jul;13(5):340-5.

Jenkins B, et al. Neurostimulation of primary headache disorders: part 2, review of central neurostimulator for primary headache, overall therapeutic efficacy, safety, cost, patient selection, and future research in headache modulation. Headache 2011 Oct;51(9):1408-18.

Kabir SM, et al. Vagus nerve stimulation in children with intractable epilepsy: indications, complications and outcome. Childs Nerv Syst 2009 Sep;25(9):1097-100.

Kahlow H, et al. Complications of vagal nerve stimulation for drug-resistant epilepsy: a single center longitudinal study of 143 patients. Seizure 2013 Dec;22(10):827-33.

Kenneday SH, et al. Canadian Network for Mood and Anxiety Treatments (CANMAT) Clinical guidelines for the management of major depressive disorder in adults. IV. Neurostimulation therapies. J Affect Disord 2009 Oct;117 Suppl 1:S44-53.

Klinkenberg S, et al. Vagus nerve stimulation in children with intractable epilepsy: a randomized controlled trial. Dev Med Child Neurol 2012 Sep;54(9):855-61.

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.

*Kossoff EH, et al. Combined ketogenic diet and vagus nerve stimulation: rational polytherapy? Epilepsia 2007 Jan;48(1):77-81.

*Kostov H, et al. Is vagus nerve stimulation a treatment option for patients with drug-resistant idiopathic generalized epilepsy? Acta Neurol Scand Suppl 2007;187:55-8.

Kostov K, et al. Long-term vagus nerve stimulation in the treatment of Lennox-Gastaut syndrome. Epilepsy Behav 2009 Oct;16(2):321-4.

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].

Lancman G, et al. Vagus nerve stimulation vs corpus callosotomy in the treatment of Lennox-Gastaut syndrome: a meta-analysis. Seizure 2013;22(10):3-8.

Lange G, et al. Safety and efficacy of vagus nerve stimulation in fibromyalgia: a phase I/II proof of concept trial. Pain Med 2011 Sep;12(9):1406-13.

Lulic D, et al. Vagus nerve stimulation. Neurosurg Focus 2009 Sep;27(3):E5.

Lund C, et al. Efficacy and tolerability of long-term treatment with vagus nerve stimulation in adolescents and adults with refractory epilepsy and learning disabilities. Seizure 2011 Jan;20(1):34-7.

*Marangell LB, et al. Vagus nerve stimulation (VNS) for major depressive episodes: one year outcomes. Bio Psych 2002;51:280-7.

*Marjoie HJ, et al. Vagus nerve stimulation in children with therapy-resistant epilepsy diagnosed as Lennox-Gastaut syndrome: clinical results, neuropsychological effects, and cost–effectiveness. J Clin Neurophysiol 2001 Sep;18(5):419-28.

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

Martin JL, et al. Systematic review and meta-analysis of vagus nerve stimulation in the treatment of depression: variable results based on study designs. Eur Psychiatry 2012 Apr;27(3):147-55.

*Matthews K, et al. Vagus nerve stimulation and refractory depression. Can you switch me on doctor? Br J Psych 2003;183:181-3.

*Maukop A. Vagus nerve stimulation relieves chronic refractory migraine and cluster headaches. Cephalalgia 2005 Feb; 25(2):82-6.

Morris GL, et al. Evidence-based guideline update: vagus nerve stimulation for the treatment of epilepsy: report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology 2013 Oct 15;81(16):1453-9.

Muller HH, et al. the effects of stimulation parameters on clinical outcomes in patients with vagus nerve stimulation implants with major depression. J ECT 2013 Sep;29(3):e40-42.

*Murphy JV, et al. Stimulation of the nervous system for the management of seizures: current and future developments. CNS Drugs 2003;17(2):101-15.

*Murphy JV, et al. Vagal nerve stimulation in refractory epilepsy: the first 100 patients receiving vagal stimulation at a pediatric epilepsy center. Arch Pediatr Adolesc Med 2003 Jun;157(6):560-4.

*Nahas Z, et al. Two-year outcome of vagus nerve stimulation (VNS) for treatment of major depressive episodes. J Clin Psychiatry 2005 Sep;66(9):1097-104.

*Nahas Z, et al. Serial vagus nerve stimulation functional MRI in treatment resistant depression. Neuropsychopharmacol 2007 Aug;32(8):1649-60.

National Institute for Health and Clinical Excellence (NICE). Vagus nerve stimulation for treatment resistant depression. IPG 330. Dec 2009 [www.nice.org.uk] accessed 6/28/13.

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.

*Patwardhan RV, et al. Efficacy of vagal nerve stimulation in children with medically refractory epilepsy. Neurosurg 2000 Dec;47(6):1353-8.

*Privitera MD, et al. Vagus nerve stimulation for partial seizures (Cochrane Review). In: The Cochrane Library, Issue 1, 2004. updated 2010.

Rossignol E, et al. Vagus nerve stimulation in pediatric epileptic syndromes. Seizure 2009 Jan;18(1):34-7.

*Rush AJ, et al. Vagus nerve stimulation (VNS) for treatment-resistant depressions: a multicenter study. Bio Psych 2000;46:276-86.

*Rush AJ, et al. Effects of 12 months of vagus nerve stimulation in treatment-resistant depression: a naturalistic study. Biol Psychiatry 2005 Sep 1;58(5):355-63.

*Rush AJ, et al. Vagus nerve stimulation for treatment-resistant depression: a randomized, controlled acute phase trial. Biol Psychiatry 2005 Sep 1;58(5):347-54.

Rush AJ, et al. Clinical issues in considering vagus nerve stimulation for treatment-resistant depression. Exp Neurol 2009 Sep;219(1):36-43.

*Sackeim HA, et al. Vagus nerve stimulation (VNS) for treatment-resistant depression: efficacy, side effects and predictors of outcome. Neuropsychopharmacol 2001 Nov;25(5):713-28.

*Sanmiguel CP, et al. The TANTALUS system for obesity: effect on gastric emptying of solids and ghrelin plasma levels. Obes Surg 2007 Nov;17(11):1503-9.

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.

Shahwan A, et al. Vagus nerve stimulation for refractory epilepsy in children: More to VNS than seizure frequency reduction. Epilepsia 2009 May;50(5):1220-8.

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.

Siddiqi F, et al. Cumulative effect of vagus nerve stimulators on intractable seizures observed over a period of 3 years. Epilepsy Behav 2010 Jul;18(3):299-302.

*Sjogren MJ, et al. Cognition-enhancing effect of vagus nerve stimulation in patients with Alzheimer's disease: a pilot study. J Clin Psychiatr 2002 Nov;63(11):972-80.

Stefan H, et al. Transcutaneous vagus nerve stimulation (t-VNS) in pharmacoresistant epilepsies: a proof of concept trial. Epilepsia 2012 Jul;53(7):e115-18.

*Vonck K, et al. Vagus nerve stimulation for refractory epilepsy: a transatlantic experience. J Clin Neurophysiol 2004 Jul-Aug;21(4):283-9.

Wheeler M, et al. Efficacy of vagus nerve stimulation for refractory epilepsy among patients subgroups: a re-analysis using the Engel classification. Seizure 2011 May;20(4):331-5.

*Zamponi N, et al. Intermittent vagal nerve stimulation in paediatric patients: 1-year follow-up. Childs Nerv Syst 2002 Feb; 18(1-2):61-6.

*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&