MEDICAL POLICY

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:**

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<th>Number</th>
<th>Description</th>
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<tr>
<td>61885</td>
<td>Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to single electrode array</td>
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<tr>
<td>61886</td>
<td>with connection to 2 or more electrode arrays</td>
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<tr>
<td>61888</td>
<td>Revision or removal of cranial neurostimulator pulse generator or receiver</td>
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<td>64553</td>
<td>Percutaneous implantation or neurostimulator electrodes; cranial nerve</td>
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<td>64568</td>
<td>Incision for implantation of cranial nerve (e.g. vagus nerve) neurostimulator electrode array and pulse generator</td>
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<td>64569</td>
<td>Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator</td>
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<td>64570</td>
<td>Removal of cranial nerve neurostimulator (e.g., vagus nerve) electrode array and pulse generator</td>
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<td>95974</td>
<td>Complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour</td>
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<td>95975</td>
<td>Complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour</td>
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<td>0312T-0317T (E/I)</td>
<td>Vagus nerve blocking therapy (morbid obesity) (code range)</td>
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**HCPCS:**

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<td>L8679</td>
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<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
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<td>L8681</td>
<td>Patient programmer (external) for use with implantable programmable neurostimulator pulse generator</td>
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<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</td>
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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:**


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<td>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, 09/15/15</td>
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<td>Page: 7 of 9</td>
</tr>
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*key articles

**KEY WORDS:**

Treatment-resistant depression, Epilepsy, Seizures
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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**


Proprietary Information of YourCare Health Plan