Preauthorization is required.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Description

Stimulation of the vagus nerve can be performed by means of an implantable stimulator within the carotid artery sheath. This technique has been proposed as a treatment for refractory seizures, depression, and other disorders. There are also devices available that are implanted at different areas of the vagus nerve. This Protocol addresses only devices implanted within the carotid sheath, and not to other types of devices.

Summary of Evidence

For patients with refractory seizures, evidence from randomized controlled trials (RCTs) and multiple observational studies supports a reduction in seizure frequency following vagus nerve stimulation (VNS). A TEC Assessment concluded that the evidence is sufficient to permit conclusions on the efficacy of this technique for treatment of refractory seizures. Therefore, VNS may be considered medically necessary for patients with refractory seizures.

For patients with depression, there is some evidence supporting improvements in depressive symptoms after VNS. However, there are a number of limitations of these data, including uncertain clinical significance, lack of evidence on durability, and lack of comparison with alternative treatments. As a result, it is not clear if VNS is as effective as alternatives for specific populations of patients with depression, and VNS is considered investigational for this indication.

For other conditions, including but not limited to headaches, obesity, essential tremor, heart failure, fibromyalgia, tinnitus, and traumatic brain injury, the evidence is limited and not sufficient to permit conclusions on efficacy. VNS is considered investigational for these indications.

The body of evidence for the use of transcutaneous VNS (t-VNS) consists of small RCTs with methodologic limitations and case series. The evidence is insufficient to allow conclusions on the efficacy of t-VNS, and there are no transcutaneous stimulation devices that have U.S. Food and Drug Administration approval; therefore, transcutaneous VNS is considered investigational.

Policy

Vagus nerve stimulation may be considered medically necessary as a treatment of medically refractory seizures.
Vagus nerve stimulation is considered **investigational** as a treatment of other conditions, including but not limited to heart failure, fibromyalgia, depression, essential tremor, obesity, headaches, tinnitus, and traumatic brain injury.

Nonimplantable vagus nerve stimulation devices are considered **investigational** for all indications.

**Policy Guidelines**

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.

Vagal nerve stimulation requires not only the surgical implantation of the device, but also subsequent neurostimulator programming, which occurs intraoperatively and typically during additional outpatient visits.

**Medicare Advantage**

For Medicare Advantage, the seizures must be medically refractive partial-onset seizures for which surgery is not recommended or for which surgery has failed for vagus nerve stimulator to be considered **medically necessary**.

**Background**

*Vagus Nerve Stimulation*

VNS was initially investigated as a treatment alternative in patients with medically refractory partial-onset seizures for whom surgery is not recommended or for whom surgery has failed. Over time, the use of VNS has expanded to generalized seizures, and it has been investigated for a range of other conditions.

While the mechanisms for the therapeutic effects of VNS are not fully understood, the basic premise of VNS in the treatment of various conditions is that vagal visceral afferents have a diffuse central nervous system projection, and activation of these pathways has a widespread effect on neuronal excitability. Electrical stimulus is applied to axons of the vagus nerve, which have their cell bodies in the nodose and junctional ganglia and synapse on the nucleus of the solitary tract in the brainstem. From the solitary tract nucleus, vagal afferent pathways project to multiple areas of the brain. There are also vagal efferent pathways that innervate the heart, vocal cords, and other laryngeal and pharyngeal muscles, and provide parasympathetic innervation to the gastrointestinal tract that may also be stimulated by VNS.

The type of VNS device addressed in this Protocol consists of an implantable, programmable electronic pulse generator that delivers stimulation to the left vagus nerve at the carotid sheath. The pulse generator is connected to the vagus nerve via a bipolar electrical lead. Surgery for implantation of a vagal nerve stimulator involves implantation of the pulse generator in the infraclavicular region and wrapping two spiral electrodes around the left vagus nerve within the carotid sheath. The programmable stimulator may be programmed in advance to stimulate at regular times or on demand by patients or family by placing a magnet against the subclavicular implant site.

Other types of vagus nerve stimulators are also available. The Maestro® System (Enteromedics, St. Paul, MN) consists of a subcutaneously-implanted pulse generator and electrodes that are placed in contact with the trunks of the vagus nerve at the gastroesophageal junction. These types of stimulators differ in the location of the pulse generator and electrodes and the stimulation programming settings, and are not addressed in this Protocol.
Potential Indications for VNS

VNS was originally approved for the treatment of medically refractory epilepsy. Significant advances have occurred in surgical treatment for epilepsy and in medical treatment of epilepsy with newly developed and approved medications. Despite these advances, however, 25% to 50% of patients with epilepsy experience breakthrough seizures or suffer from debilitating adverse effects of antiepileptic drugs. VNS has been used as an alternative to or adjunct to epilepsy surgery or medications as a therapy for refractory seizures.

Based on observations that patients treated with VNS experienced improvements in mood, VNS has been evaluated for the treatment of refractory depression. VNS has been investigated for multiple other conditions which may be affected by either the afferent or efferent stimulation of the vagus nerve, including headaches, tremor, obesity, heart failure, fibromyalgia, tinnitus, and traumatic brain injury.

Regulatory Status

In 1997, FDA approved a VNS device called the NeuroCybernetic Prosthesis (NCP®) system through the premarket approval (PMA) process. The device was approved for use in conjunction with drugs or surgery “as an adjunctive treatment of adults and adolescents over 12 years of age with medically refractory partial onset seizures.”

Since 1997, it has been reported that recipients of a vagus nerve stimulator have experienced improvements in mood. Therefore, there has been research interest in VNS as a treatment for refractory depression. On July 15, 2005, Cyberonics received PMA supplement approval by FDA for the VNS Therapy™ System “for the 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 four or more adequate antidepressant treatments.”

VNS therapy has also been investigated for use in other conditions such as headaches, obesity, and essential tremors. FDA product code: LYJ.

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 electric 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. Electrocore has developed a noninvasive VNS (gammaCore®) that is currently being investigated for headache; the device does not have FDA approval.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.
References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


