VAGUS NERVE STIMULATION
SUR712.021
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COVERAGE:

Vagus Nerve Stimulation (VNS) is considered **medically necessary** as a treatment of medically refractory partial-onset seizures.

VNS is considered **experimental or investigational** in patients with seizures other than partial-onset seizures.

VNS is considered **experimental or investigational** as a treatment of depression.

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. Seizures have been further subclassified into those with a generalized onset, (beginning throughout the brain), and those with a partial onset, (having a discrete focal onset).

There are 3 principal subtypes of partial-onset seizures:

- **Simple partial seizures**: do not involve alteration of consciousness but may have observable motor components or may solely be a subjective sensory or emotional phenomenon;

- **Complex partial seizures**: are partial onset seizures that involve an alteration of consciousness;

- **Complex partial seizures, (secondarily generalized)**: are partial onset seizures that progress to involve both sides of the brain and result in a complete loss of consciousness.

In the past 10 years there have been significant advances in surgical and medical treatment of epilepsy with newly developed and approved medications. Despite these advances, 25% to 50% of patients with epilepsy experience breakthrough seizures or suffer from debilitating adverse effects of antiepileptic drugs.

Mechanisms for the antiepileptic effects of (VNS) are 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 vagal 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 time intervals or upon demand (by the patient or family members) by placing a magnet against the subclavicular implant site. In 1997 the U.S. Food and Drug Administration (FDA) approved a VNS device called the NeuroCybernetic...
Prosthesis (NCP) system.

Since 1997, it has been reported that recipients of a vagus nerve stimulator have experienced improvements in mood. Therefore, there has been research in VNS as a treatment of refractory depression.

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.

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

RATIONALE:

This policy is based in part on a 1998 TEC assessment that offered the following conclusions.

1. Published evidence from two large, multicenter trials demonstrated that the use of VNS as an adjunct to optimal use of antiepileptic drugs) in the treatment of medically refractory patients with at least 6 partial-onset seizures/month, reduces seizure frequency by approximately 25% after 3 months of treatment. In patients who achieve an initial reduction in seizure frequency, the beneficial treatment effect appears to be maintained and may increase with time.

2. Adverse effects are mild and consist primarily of hoarseness of voice change during “on” periods of stimulation.

There is limited information about the use of VNS in patients with other types of seizure disorders.

VNS IN CHILDREN

The original FDA approval limited the use of VNS to those over the age of 12. Since that time, there has been interest in expanding the use of VNS to younger patients. Several studies have now reported results that support the safety of the device in children with refractory seizures. The major limitations of VNS are the facts that stimulation generally does not completely eliminate seizures and it is not possible to predict which patients will optimally respond. Therefore, some authors suggest that VNS may be most appropriately used in patients with refractory seizures who are not candidates for surgery.

VNS AS A TREATMENT OF REFRACTORY DEPRESSION

Interest in this application of VNS is related to reports of improvement in depressed mood among epileptic patients undergoing VNS.
One pilot study reported at least a 50% reduction in baseline score of the Hamilton Depression Rating Scale in 40% of 30 adult patients. Currently there is a clinical study of the safety and efficacy of VNS in patients with depression. As of 7/2002 enrollment in this 235 patient clinical study has been completed.

PRICING:

None

REFERENCES:

• Consortium Health Plans Medical Policy Reference Manual, 11/20/01, Surgery, Vagus Nerve Stimulation, 7.01.20
• Cyberonics Web site: www.cyberonics.com/depression/depression-study-info.htm

DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically. HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for
information regarding HMO claims/reimbursement information and other general polices and procedures.