Vagus nerve stimulation for epilepsy

Background

Vagus nerve stimulation (VNS) is a type of surgery for epileptic seizures that does not involve surgery on the brain. Instead, VNS involves the implantation of a pacemaker-like electrical pulse generator in the chest, which is linked to a stimulating lead coil implanted around the left vagus nerve in the neck. Intermittent electrical stimulation of the left vagus nerve has been shown to cause widespread and bilateral effects in the areas of the brain where seizure activity takes place. These effects reduce the frequency and severity of the seizures.

The battery-powered pulse generator can be programmed so that it may turn on or off at specified times, and the amplitude and frequency of stimulation can be geared to the patient and the seizures involved. Or it can also be triggered manually, with a small hand-held magnet, by those patients who experience a familiar, sensory aura forewarning them of an impending seizure.

Practitioners treating epilepsy with VNS use the NeuroCybernetic Prosthesis (NCP) System, which is produced by the Houston, TX–based company Cyberonics, Inc. VNS with the Cyberonics NCP System is the first new approach to the treatment of epilepsy in over 100 years. The NCP System was the first and continues to be the only FDA-approved medical device for the treatment of epilepsy.

VNS is appropriate for epilepsy patients who are unable to tolerate or benefit from the use of epilepsy drugs. Because the therapy is not a cure for epilepsy and does not work for everyone, patients should be evaluated to determine whether they are candidates for surgery that can potentially cure their epilepsy before they consider VNS.

Involved specialists

Epileptologists, neurologists, and neurosurgeons

Positions of societies and academies

AES

The American Epilepsy Society (AES) seeks to promote interdisciplinary communication, scientific investigation, and exchange of clinical information about epilepsy. The membership consists of clinicians, scientists investigating basic and clinical aspects of epilepsy, and other professionals interested in seizure disorders. Members represent both pediatric and adult aspects of epilepsy.

Key benefits of AES membership include the following:
• Information on the latest pharmaceuticals
• Information on the latest technology for treating patients and other practice management service
• Special interest groups to allow for networking and sharing of specialized interests
• Publications on specific topics with scientific focus and conclusions
• Programs recognizing scientific study and accomplishment
• Access to clinical and research database on the AES Website

According to the AES, the society’s mission is to promote research and education for professionals dedicated to the prevention, treatment, and cure of epilepsy.

The society’s goals are

• to be its members’ primary resource for scientific and clinical education and knowledge exchange about epilepsy
• to be a recognized advocate and resource for scientific research in the prevention, treatment, and cure of epilepsy
• to be the leader in developing resources and collaborative relationships worldwide to advance patient care, as well as to support efforts leading to the prevention and cure of epilepsy

The AES does not publish credentialing or privileging criteria for VNS.

According to the American Academy of Neurology (AAN), a neurologist’s educational background and medical training includes an undergraduate degree, four years of medical school, a one-year internship, and three years of specialized training. Many neurologists also have additional training in one area of neurology such as stroke, epilepsy, or movement disorders.

The AAN has published several articles about VNS in its journal Neurology. The following articles appeared in 1999 and 2000:

• “Vagus nerve stimulation therapy for epilepsy in older adults”

• “Long-term treatment with vagus nerve stimulation in patients with refractory epilepsy”

• “Vagus nerve stimulation for medication-resistant generalized epilepsy”
The first two articles are concerned with assessing the efficacy, safety, and tolerability of VNS. The third article compares seizure rates. These articles report favorable results for VNS but do not discuss credentialing or privileging for the therapy.

The American Board of Psychiatry and Neurology (ABPN) offers certification in neurology. An applicant seeking admission to the examination for certification in neurology must have satisfactorily completed one of the two following patterns of training:

1. A three-year neurology residency program that includes a full year of Accreditation Council for Graduate Medical Education (ACGME)-accredited training in internal medicine. Or as an acceptable alternative, a full year in an ACGME-accredited program in which a minimum of six months of training must be in internal medicine. The training director must document the details of this alternative program. The composition of these six months cannot include rotations in neurology or emergency medicine. At least two of the additional six months must be spent in internal medicine, pediatrics, and/or emergency medicine. No more than two of the remaining four months may be spent in neurology. And three full years of postgraduate specialized residency training must be in a neurology program accredited by the ACGME.

2. A four-year neurology residency program accredited by the ACGME.

Different requirements apply for applicants who began training in neurology prior to 1991.

The ABPN also offers certification in the subspecialty of clinical neurophysiology, which is an area of medicine where selected neurological disorders involving central, peripheral, and autonomic nervous systems and muscles are assessed, monitored, and treated using a combination of clinical evaluation and electrophysiological testing. A derangement of the normal physiology of the nervous system underlies these selected disorders, and an assessment of the electrophysiological abnormalities is an integral part of the evaluation process.

Clinical neurophysiology requires a detailed knowledge of the normal physiology of the nervous system, the altered abnormal electrophysiology, and the disease states involved. Clinical
neurophysiology is not confined to diagnostic techniques, but includes the application of electrical, magnetic, and mechanical methods to the evaluation and treatment of a wide range of diseases, including the epilepsies, demyelinating disorders of the nervous system, strokes, Parkinson’s disease and other movement disorders, sleep disorders, traumatic disorders, congenital and genetic disorders, intracranial mass lesions, and degenerative diseases. Another application of increasing importance is the use of intraoperative monitoring to guide surgical interventions.

Training requirements for clinical neurophysiology

Training must be for one year, and must be preceded by the completion of a residency program in neurology, child neurology, general psychiatry, or physical medicine and rehabilitation accredited in the United States. The training must be separate and distinct from all training required for certification in neurology, child neurology, general psychiatry, or physical medicine and rehabilitation.

The one-year program should provide training in the broad area of clinical neurophysiology. The training should include extensive experience in one or more of the following:

- Evoked potential studies
- Motor and sensory nerve conduction studies
- Diagnostic electromyography
- Single fiber electromyography
- Electrodiagnostic movement disorder assessment
- Electroencephalography
- Testing of motor and sensory reflexes
- Polysomnography
- Testing of autonomic function

According to George L. Morris, MD, an associate professor of neurology at the Milwaukee-based Medical College of Wisconsin, the most complicated part of VNS for epilepsy is patient selection. Before prescribing VNS, physicians have to determine whether a patient is a candidate for brain surgery that can be much more effective. Any assessment has to take into account

- the clinical appearance of the seizures
- patient EEGs
- potential recordings made of the seizures
- patient MRIs
- auxiliary testing such as neurophysiological testing

“A neurologist who has completed residency training as well as clini-
cal neurophysiology training,” says Morris, “should be qualified to make the assessment whether surgery or VNS therapy is more appropriate.”

In regard to the Cyberonics (NCP) System device for VNS, Morris takes into consideration that the process can intimidate physicians at first. So he recommends that they attend a training symposium that the company sponsors or request a company representative to come to their location and proctor their initial cases.

“Physicians should become familiar with the common adverse effects of the device,” says Morris, “and this should be a part of the training program.” For example, if a patient starts to cough, which is a common side effect, the physician would reduce the stimulation and let the patient acclimate to that level of stimulation and try again. “After five or so cases,” he says, “physicians can learn 80% or 90% of the decision-making process they need to optimize VNS therapy.”

Morris recommends that the surgeon who implants the device should also have training. “They should view an implant being done on at least one occasion,” he says. “I believe most surgeons would agree that this approach would be appropriate.”

**CRC draft criteria**

Minimal threshold criteria for requesting clinical privileges for VNS for epilepsy

**Basic education:** MD or DO
**Minimum formal training:** The applicant must be able to demonstrate successful completion of an ACGME/American Osteopathic Association (AOA)-accredited neurology residency training program followed by a one-year subspecialty program in clinical neurophysiology. The applicant must also demonstrate that he or she has completed an instruction program in the Cyberonics NCP System given by an experienced NCP System physician, by a Cyberonics company representative, or at a company symposium.

**Required previous experience:** The applicant must be able to demonstrate that he or she has successfully managed at least 10 VNS for epilepsy cases in the past 12 months.

Note: A letter that evaluates competency must come from the applicant’s NCP System instructor or from the chief of neurology or epilepsy at the institution where the applicant most recently practiced.
Reappointment

Reappointment should be based on unbiased, objective results of care according to the organization’s existing quality assurance mechanisms.

Applicants must demonstrate that they have maintained competence by showing evidence that they have successfully managed at least 10 VNS for epilepsy cases in the past 12 months.

In addition, continuing education related to VNS and epilepsy should be required.

For more information

For more information regarding this procedure, contact:
American Academy of Neurology
1080 Montreal Avenue
St. Paul, MN 55116-2325
Telephone: 651/695-2791
Fax: 651/695-2791
Web site: www.aan.com

American Board of Psychiatry and Neurology
500 Lake Cook Road, Suite 335
Deerfield, IL 60015
Telephone: 847/945-7900
Fax: 847/945-1146
Web site: www.abpn.com

American Epilepsy Society
342 North Main Street
West Hartford, CT 06117-2507
Telephone: 860/586-7505
Fax: 860/586-7550
Web site: www.aesnet.org

Medical College of Wisconsin
9200 West Wisconsin Avenue
Milwaukee, WI 53226
Telephone: 414/259-3641
Fax: 414/476-4701
Web site: www.froedtert.com
Privilege Request Form
Vagus nerve stimulation for epilepsy

In order to be eligible to request clinical privileges for VNS for epilepsy, an applicant must meet the following minimum threshold criteria:

• Education: MD or DO

• Minimum formal training: The applicant must be able to demonstrate successful completion of an ACGME/AOA-accredited neurology residency training program followed by a one-year subspecialty program in clinical neurophysiology. The applicant must also demonstrate that he or she has completed an instruction program in the Cyberonics NCP System given by an experienced NCP System physician, by a Cyberonics company representative, or at a company symposium.

• Required previous experience: The applicant must be able to demonstrate that he or she has successfully managed at least 10 VNS for epilepsy cases in the past 12 months.

• References: A letter that evaluates competency must come from the applicant’s NCP System instructor or from the chief of neurology or epilepsy at the institution where the applicant most recently practiced.

• Reappointment: Reappointment should be based on unbiased, objective results of care according to the organization’s existing quality assurance mechanisms.

Applicants must demonstrate that they have maintained competence by showing evidence that they have successfully managed at least 10 VNS for epilepsy cases in the past 12 months. In addition, continuing education related to VNS and epilepsy should be required.

I understand that by making this request I am bound by the applicable bylaws or policies of the hospital, and hereby stipulate that I meet the minimum threshold criteria for this request.

Physician’s signature: ________________________________________________

Typed or printed name: ________________________________________________

Date: ____________________________________________________________________
Vagus nerve stimulation for epilepsy

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The information contained in this document is general. It has been designed and is intended for use by hospitals and their credentials committees in developing their own local approaches and policies for various credentialing issues. This information, including the materials, opinions, and draft criteria set forth herein, should not be adopted for use without careful consideration, discussion, additional research by physicians and counsel in local settings, and adaptation to local needs. The Credentialing Resource Center does not provide legal or clinical advice; for such advice, the counsel of competent individuals in these fields must be obtained.

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