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## **1.0 Description of the Procedure, Product, or Service**

Seizures have been defined as paroxysmal disorders of the central nervous system characterized by abnormal cerebral neuronal discharge, with or without a 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 three (3) principal subtypes of partial-onset seizures:

- a. Simple partial seizures: These do not involve alteration of consciousness but may have observable motor components or may solely be a subjective sensory or emotional phenomenon.
- b. Complex partial seizures: These are partial-onset seizures that involve an alteration of consciousness.
- c. Complex partial seizures, secondarily generalized tonic-clonic convulsions: These 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, 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%–50% of patients with epilepsy experience breakthrough seizures or suffer from debilitating adverse effects of antiepileptic drugs. VNS has been 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.

While the mechanisms for the antiepileptic effects of vagal nerve stimulation 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 on 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 times or on demand by patients or family by placing a magnet against the subclavicular implant site. In 1997, the U.S. Food and Drug Administration (FDA) approved a vagus nerve stimulation 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 of refractory depression. On July 15, 2005, Cyberonics received PMA approval by the 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.

### **1.1 Medical Term Definitions**

- a. Central nervous system: pertains to the brain, cranial nerves, and spinal cord.
- b. Refractory: not responding to treatment.

## **2.0 Eligible Recipients**

### **2.1 General Provisions**

To be eligible, NCHC recipients must be enrolled on the date of service.

## **3.0 When the Procedure, Product, or Service Is Covered**

### **3.1 General Criteria**

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

### **3.2 Specific Criteria**

Vagus nerve stimulation for treatment of seizures may be covered under the NC Health Choice Program when it is determined to be medically necessary because BOTH of the following criteria are met:

- a. The recipient has medically refractory\* partial-onset seizures\*; **AND**  
\*Medically refractory means
  - 1. seizures that occur in spite of therapeutic levels of anti-epileptic drugs; **OR**
  - 2. seizures that cannot be treated with therapeutic levels of anti-epileptic drugs because of intolerable adverse side effects.
- b. The recipient has failed or is not eligible for surgical treatment.

## 4.0 When the Procedure, Product, or Service Is Not Covered

### 4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

### 4.2 Specific Criteria

Vagus Nerve Stimulation is not covered in the following situations:

- a. For indications that do not meet the criteria in **Subsection 3.2**.
- b. For treatment of recipients with seizures other than partial-onset seizures.
- c. For recipients who can be treated successfully with anti-epileptic drugs.
- d. For treatment of recipients with depression.
- e. For the treatment of essential tremor.
- f. For the treatment of headaches.
- g. For the treatment of obesity.

### 4.3 Policy Guidelines

The available evidence is not sufficient to permit conclusions of the effect of VNS therapy on health outcomes in treatment resistant depression. The only randomized study did not show statistically significant results comparing activated VNS with sham (non-activated VNS). FDA approved the use of VNS for treatment resistant depression with the condition that they conduct 2 post approval studies. One study is to determine the optimal dosing and patient selection criteria. The second study required is a prospective, observational registry study of 1000 subjects extending up to five years to evaluate the long-term outcomes and response to therapy. Additional well-designed, large randomized controlled trials are needed to determine the safety and efficacy of VNS for treatment resistant depression.

Unintended weight loss has been observed in participants in studies of VNS prompting interest in use of the technology to prevent or treat obesity. Bodenlos et al investigated whether VNS might affect food cravings in patients with chronic, treatment-resistant depression. A number of limitations in the study prevent drawing conclusions about the impact of VNS on eating behavior including small study size, selection and lack of randomization, heterogeneity of groups with respect to depression, BMI, and age. Comorbidities including anxiety and medical conditions and drugs that might influence food intake and cravings were not considered. Large, well designed and executed controlled studies are needed to evaluate the impact of VNS on eating behavior and obesity.

## 5.0 Requirements for and Limitations on Coverage

### 5.1 Prior Approval

Prior approval is not required for vagus nerve stimulation.

## 6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

## 7.0 Additional Requirements

### 7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

## 8.0 Policy Implementation/Revision Information

**Original Effective Date:** July 1, 2010

**Revision Information:**

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, <b>Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”</b>

## Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

### A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

### B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

### C. Procedure Code(s)

CPTS Code(s)				
61885	61886	61888	64553	64573
64585	95970	95974	95975	
HCPCS Code(s)				
L8680	L8681	L8682	L8683	L8685
L8686	L8687	L8688	L8689	

### D. Modifiers

Providers are required to follow applicable modifier guidelines.

### E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

### F. Place of Service

Inpatient Hospital and Outpatient Hospital

### G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

### H. Reimbursement

Providers must bill their usual and customary charges.