

**18.2.25.2 Vagus Nerve Stimulators**

Consideration shall be given for Medicaid reimbursement for implantation of the vagus nerve stimulator (VNS) if the treatment is considered medically necessary, the beneficiary meets the published criteria, and the beneficiary has a diagnosis of medically intractable epilepsy.

**Criteria for Beneficiary Selection**

The following criteria are used to determine beneficiary eligibility and approval of the VNS:

1. Partial epilepsy confirmed and classified according to the International League Against Epilepsy (ILAE) classification. The beneficiary may also have associated generalized seizures, such as tonic, tonic-clonic, or atonic. The VNS may have efficacy in primary generalized epilepsy as well;
2. Age of 12 years or greater, although case by case consideration may be given to younger children who meet all other criteria and have sufficient body mass to support the implanted system;
3. Seizures refractory to medical anti-epilepsy treatment, with adequately documented trials of appropriate standard and newer anti-epilepsy drugs or documentation of beneficiary's inability to tolerate these medications;
4. Beneficiary has undergone surgical evaluation and is considered not to be an optimal candidate for epilepsy surgery;
5. Beneficiary is experiencing at least four to six identifiable partial onset seizures each month. Beneficiary must have had a diagnosis of intractable epilepsy for at least two years. The two-year period may be waived if waiting would be seriously harmful to the beneficiary;
6. Beneficiary must have undergone quality of life (QOL) measurements. The choice of instruments used for the QOL measurements must assess quantifiable measures of daily life in addition to the occurrence of seizures; and
7. In the expert opinion of the treating physician, there must be reason to believe that QOL will improve as a result of implantation of the VNS. This improvement should occur in addition to the benefit of seizure frequency reduction. The treating

physician must document this opinion clearly in the request for prior authorization (PA).

### Exclusion Criteria

Regardless of the criteria for beneficiary selection, **authorization for VNS implantation shall not be given if the beneficiary has one or more of the following criteria:**

1. Psychogenic seizures or other non-epileptic seizures;
2. Insufficient body mass to support the implanted system;
3. Systemic or localized infections that could infect the implanted system; or
4. A progressive disorder contraindicated to VNS implantation, e.g., malignant brain neoplasm, Rasmussen's encephalitis, Landau-Kleffner syndrome and progressive metabolic and degenerative disorders.

### Place of Service Restriction

Surgery to implant the VNS is restricted to an outpatient hospital, unless medically contraindicated. If it is medically necessary for the beneficiary to be hospitalized, the hospital must obtain pre-certification for the stay as well as obtain PA to perform the surgery and purchase the device.

### Prior Authorization

Prior authorization (PA) for implantation of the VNS shall be requested after the beneficiary evaluation has been completed but prior to stimulator implantation.

This request to initiate implantation shall come from the multi-disciplinary team that evaluates the beneficiary. The multi-disciplinary team should be comprised of the following:

1. A surgeon who has been trained and is familiar with the carotid sheath;
2. A psychiatrist or neurologist;
3. The beneficiary's attending physician;

4. A nurse;
5. A social worker; and
6. Allied health professionals (physical therapist, occupational therapist, etc.).

These professionals shall have expertise in the evaluation, management, and treatment of epilepsy and have undergone VNS implantation training by a nationally recognized product supplier with expertise in VNS.

The following documentation shall be labeled and submitted in one package by the multi-disciplinary team:

1. A recent history with documentation of assessments in the following areas:
  - a. Medical and physical including a history of prior drug experience;
  - b. Neurological information about seizure type and epilepsy syndrome diagnosis, and the results of EEG and/or video EEG monitoring;
  - c. Functional and psychosocial assessment; and
  - d. Result of evaluation of epilepsy surgery.
2. Documentation of any other findings about the beneficiary's condition which would be of interest to or would assist the Medical Review team in making a decision regarding the medical necessity for beneficiary implantation.

### **Billing for the Cost of the Vagus Nerve Stimulator**

The VNS is reimbursable by the Medicaid program; however, reimbursement of the device is dependent upon approval of the surgeon to perform the procedure. Hospitals should confirm the surgeon has received an authorization for the procedure prior to submitting the claim. Hospitals shall submit the appropriate Healthcare Common Procedure Coding System (HCPCS) code for the VNS generator and VNS leads, to the fiscal intermediary on a CMS-1500 claim form with the acronym "DME" written in red on the top of the form. The claim will pend to the fiscal intermediary's medical review department for review of the surgeon's approved PA request. If

the surgeon's request is approved, the hospital claim will be allowed to process for payment. If there is no valid authorization, the hospital claim will deny with edit 191 (PA required).

### **Subsequent Implants and Battery Replacement**

Battery replacement and subsequent implants require PA. In order to be considered, the request must contain documentation demonstrating the benefits of the original VNS transplant.