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 recipient meets the published criteria, and the recipient has a diagnosis of medically intractable epilepsy.

Criteria for Recipient Selection

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

- Partial epilepsy confirmed and classified according to the International League Against Epilepsy (ILAE) classification. The recipient may also have associated generalized seizures, such as tonic, tonic-clonic, or atonic. The VNS may have efficacy in primary generalized epilepsy as well.

- Age 12 years or older, 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.

- Seizures refractory to medical anti-epilepsy treatment, with adequately documented trials of appropriate standard and newer anti-epilepsy drugs or documentation of recipient's inability to tolerate these medications.

- Recipient has undergone surgical evaluation and is considered not to be an optimal candidate for epilepsy surgery.

- Recipient is experiencing at least four to six identifiable partial onset seizures each month. Recipient 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 recipient.

- Recipient 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.

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

- Psychogenic seizures or other non-epileptic seizures,
- Insufficient body mass to support the implanted system,
- Systemic or localized infections that could infect the implanted system, or
- 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 recipient 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

PA for implantation of the VNS shall be requested after the recipient evaluation has been completed but prior to stimulator implantation.

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

- A surgeon who has been trained and is familiar with the carotid sheath,
- A psychiatrist or neurologist,
- The recipient's attending physician,
- A nurse,
- A social worker, and
- 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:

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

Billing for the Cost of the Vagus Nerve Stimulator

The VNS is reimbursable by Louisiana Medicaid; 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 words "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).

Billing for Implantation of the VNS

Implantation of the VNS must be prior authorized. The surgeon who implants the VNS shall submit a Prior Authorization Request (PA-01 Form) to the PA Unit as part of the multi-disciplinary team's packet. The surgeon must use his/her individual, rather than group, provider number on the PA-01 Form. The provider shall bill for the implantation of the generator by

submitting the appropriate *Current Procedural Terminology* (CPT) procedure codes on a CMS-1500 form, and the PA number given to the surgeon must be written in Item 23 when submitting a hard copy claims. However, providers are encouraged to bill electronically.

Programming

Programming of the VNS stimulator must be performed by the surgeon who performed the implant procedure or by a licensed neurologist.

Programming subsequent to the first three times may be subject to post-authorization review for medical necessity prior to payment of the claim.

Authorization for payment will only be considered when there is documented clinical evidence indicating the recipient has experienced seizures since the previous programming attempts.

Payment for the programming procedure will be authorized when it is performed as an attempt to reduce or prevent future episodes of seizures.

After the third programming service, providers must submit hardcopy claims to the Provider Relations Unit with documentation attached supporting the medical necessity of the procedure. Payment will not be made on claims billed electronically or claims lacking the required documentation. The required documentation includes:

- Recipient response – the status of seizure control, i.e. frequency and severity of seizures,
- Current VNS program settings, i.e., current output, pulse width, duty cycle, and signal frequency,
- Frequency of medications and dose schedule,
- Documentation of adverse effects such as swallowing problems, hoarseness, coughing and neck tightness,
- Magnet setting, and
- Reasons for reprogramming.

Subsequent Implants/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.