Vagus Nerve Stimulator (VNS) for Epilepsy

Origination: June 30, 1988
Review Date: April 20, 2016
Next Review: April, 2018

DESCRIPTION OF PROCEDURE OR SERVICE
VNS is a pulse generator, similar to a pacemaker, that is surgically implanted under the skin of the left chest and an electrical lead (wire) is connected from the generator to the left vagus nerve. Electrical signals are sent from the battery-powered generator to the vagus nerve via the lead. These signals are in turn sent to the brain. FDA approved VNS for treatment of refractory epilepsy in 1997 and for resistant depression in 2005.

DEFINITIONS:
Medically Refractory Seizures: these 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.

POLICY STATEMENT
Coverage will be provided for vagus nerve stimulator when it is determined to be medically necessary, as outlined in the below guidelines and medical criteria.

BENEFIT APPLICATION
Please refer to the member’s individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations if the criteria are met.

Coverage decisions will be made in accordance with:
- The Centers for Medicare & Medicaid Services (CMS) national coverage decisions;
- General coverage guidelines included in original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member’s particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

INDICATIONS FOR COVERAGE
1. Preauthorization by the Plan Services is required;

2. Refractory epilepsy: VNS is covered for the following indication:
   a. Effective for services performed on or after July 1, 1999, VNS is reasonable and necessary for patients with medically refractory partial onset seizures for whom surgery is not recommended or for whom surgery has failed.
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b. Approval is based on medical necessity and applies only to medically refractory partial (focal) onset seizures that are clinically recognizable. A partial onset seizure has a focal onset in one area of the brain and may or may not involve a loss of motor control or alteration of consciousness. Partial onset seizures may be simple, complex, or complex partial seizures, secondarily generalized.
   i. The seizures must have been refractory to multiple drugs. This includes both conventional, and newer anticonvulsant drugs (Ex: Felbamate, Lamotrigine, Gabapentine, Vigabatrine, Topiramate, Tiagabine) given as add-on treatment; OR
   ii. The member may have history of failed surgery; OR
   iii. The member is not a candidate for epilepsy surgery.

WHEN COVERAGE WILL NOT BE APPROVED

VNS is not reasonable and necessary for all other types of seizure disorders which are medically refractory and for whom surgery is not recommended or for whom surgery has failed.

VNS is not reasonable and necessary for resistant depression.

LIMITATIONS

Mental retardation (MR), by itself, is not a contraindication. Behavioral and somatic manifestation of MR, however, may obscure recognition of seizure phenomena. Disabilities due to MR may confound assessment of benefits resulting from VNS. Therefore, when a diagnosis of MR exists, the treating physician must document how VNS will benefit the recipient in spite of the MR. This type of expectation applies to members with psychosis as well.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable codes: 61885, 61886, 61888, 64553, 64568, 64585, 64590, 64595, 95970, L8681, L8682, L8683, L8679 L8689.

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

References:

Policy Implementation/Update Information:
Revision Date: Policy name: Electrical Stimulators – Vagus Nerve); June 22, 2005
Revision Date: February 21, 2007; Updated codes; no criteria changes made.
Revision Date: May 16, 2007- Increased age limit to 12.
Revision Date: September 2009: No changes proposed to the review criteria. Formatting and minor wording changes only.
Revision Date: March 2012: No changes to the criteria.
Revision Date: April 16, 2014; Criteria mirrored NCD; Added VNS is not covered for resistant depression per CMS. Codes were updated. References were updated. 

Approval Dates:
Medical Coverage Policy Committee: April 20, 2016

Policy Owner: Jennifer Davis, RN, MHA
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