



Medicare Part C Medical Coverage Policy

Vagus Nerve Stimulators (VNS)

Origination: June 30, 1988

Review Date: August 16, 2023

Next Review: August 2024

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

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:

Coverage with Evidence Development (CED): At times, The Centers for Medicare & Medicaid (CMS) issues a national coverage determination with data collection as a condition of coverage. The CED concept considers the item or service to be reasonable and necessary only while evidence is being developed regarding member's health outcomes in a clinical trial. CMS lists these clinical trials with CED at <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>.

Medically Refractory Seizures: these are defined as seizures that occur despite 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 Determinations (NCDs);

- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and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 members with medically refractory partial onset seizures for whom surgery is not recommended or for whom surgery has failed.
- 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.

3. Treatment Resistant Depression (TRD): VNS is covered for the following indication:

- a. Through Coverage with Evidence Development (CED) when offered in a CMS approved study.
- b. The member must be in a major depressive disorder (MDD) episode for greater than or equal to two (2) years or have had at least four (4) episodes of MDD, including the current episode. In order to confirm the member has MDD, accepted diagnostic criteria from the most current edition of the Diagnostic and Statistical Manual for Mental Disorder (DSM) and a structured clinical assessment are to be used.
- c. The member's depressive illness meets a minimum criterion of four (4) prior failed treatments of adequate dose and duration as measured by a tool designed for this purpose.
- d. The member is experiencing a major depressive episode (MDE) as measured by a guideline recommended depression scale assessment tool on two (2) visits, within a 45-day span prior to implantation of the VNS device.
- e. The member must maintain a stable medication regimen for at least four (4) weeks before device implantation.

Note: Members implanted with a VNS device for TRD may receive a VNS device replacement if it is required due to the end of battery life, or any other device-related malfunction.

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 non-covered for the treatment of TRD when furnished outside of a CMS-approved CED study. All other indications of VNS for the treatment of depression are nationally non-covered.

LIMITATIONS

Treatment Resistant Depression: If members with bipolar disorder are included, the condition must be carefully characterized. The member must not have the following:

- a. Current or lifetime history of psychotic features in any MDE;
- b. Current or lifetime history of schizophrenia or schizoaffective disorder;
- c. Current or lifetime history of any other psychotic disorder;
- d. Current or lifetime history of cycling bipolar disorder;
- e. Current secondary diagnosis of delirium, dementia, amnesia, or other cognitive disorder;
- f. Current suicidal intent; or
- g. Treatment with another investigational device or investigational drugs.

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, K1020.

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:

1. Medicare National Coverage Determination for Vagus Nerve Stimulation (VNS) (ID #160.18); Effective date: 7/23/07; Accessed via www.cms.gov; on 07/27/2023.
2. Medicare National Coverage Analysis (NCA) for Vagus Nerve Stimulation for Treatment of Resistant Depression (TRD); (CAG-00313R) Decision Memo 05/04/2007; viewed at www.cms.gov on 07/27/2023.
3. Medicare National Coverage Analysis (NCA) for Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD) (CAG-00313R2) Decision Memo 2/15/2019. Viewed at www.cms.gov on 07/27/2023.

Policy Implementation/Update Information:

Revision Date: February 25, 2002; November 3, 2003 (Policy renamed: Vagus Nerve Stimulator (VNS) for Epilepsy, 11/3/2003.

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.

Revision Date: April 20, 2016: Annual Review; Description section – updated to be consistent with NCD, removed Corporate Medical Policy language. Indications For Coverage – updated item 2-a, to be consistent with NCD, removed Corporate Medical Policy criteria. When Coverage Not Approved – updated with NCD non-coverage language for consistency. Code section – removed L8680 (not covered by Medicare). Reference section – updated and removed Corporate Medical Policy reference.

Revision Date: February 21, 2018-No CMS Updates. Minor Revisions Only.

Revision Date: March 16, 2020-Annual Review, CMS updates of coverage of VNS for TRD through CED, Addition of Definition of CED under Definition section; Indications for Coverage: Addition of Criteria 3.a,b,c,d, and e. Limitations Section: Addition of TRD a, b, c, d, e, f, and g and removal of Mental Retardation information.

Revision Date: April 21, 2021; Coding Update; K1020 added to coding section.

Revision Date: February 8, 2022; No CMS Updates. Minor Revisions Only.

Revision Date: August 16, 2023; Annual Review; No CMS Updates. Minor Revisions Only-Verbiage added to reflect NCD.

Approval Dates:

Medical Coverage Policy Committee: August 16, 2023

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