

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10199	Date: June 23, 2020
	Change Request 11461

Transmittal 10145, dated May 22, 2020, is being rescinded and replaced by Transmittal 10199, dated, June 23, 2020 to update business requirement 11461.1 with clarifying language to the MACs and to extend the implementation date from June 23, 2020 to July 22, 2020. All other information remains the same.

SUBJECT: National Coverage Determination (NCD) 160.18 Vagus Nerve Stimulation (VNS)

I. SUMMARY OF CHANGES: Effective for claims with dates of service on or after February 15, 2019, the Centers for Medicare & Medicaid Services covers Food and Drug Administration-approved vagus nerve stimulator devices for treatment-resistant depression through Coverage with Evidence Development when all reasonable and necessary criteria are met. This is National Coverage Determination 160.18, Vagus Nerve Stimulation.

The Federal government creates NCDs that are binding on the MACs who review and/or adjudicate claims, make coverage determinations, and/or payment decisions, and also binds quality improvement organizations, qualified independent contractors, the Medicare appeals council, and Administrative Law Judges (ALJs) (see 42 Code of Federal Regulations (CFR) section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: February 15, 2019

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: July 22, 2020

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/160.18/Vagus Nerve Stimulation

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to

be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

Attachment - Business Requirements

Pub. 100-03	Transmittal: 10199	Date: June 23, 2020	Change Request: 11461
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SUBJECT: National Coverage Determination (NCD) 160.18 Vagus Nerve Stimulation (VNS)

EFFECTIVE DATE: February 15, 2019

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I. GENERAL INFORMATION

A. Background: Vagus nerve stimulation (VNS) is an example of neurostimulation therapy, which targets specific regions of the brain. VNS provides indirect modulation of brain activity through the stimulation of the vagus nerve. The implanted VNS system includes a pulse generator, which is surgically inserted underneath the skin of the chest. For treatment of treatment resistant depression (TRD), it is subcutaneously connected to an electrode attached to the left vagus nerve in the neck.

Section 160.18 of the Medicare National Coverage Determinations (NCD) Manual establishes conditions of coverage for VNS. In 1999, the Centers for Medicare & Medicaid Services (CMS) issued an NCD to provide coverage for VNS for patients with medically refractory partial onset seizures, for whom surgery is not recommended or for whom surgery has failed. On May 4, 2007, CMS determined that there was sufficient evidence to conclude that VNS was not reasonable and necessary for TRD and it has remained non-covered since then.

B. Policy: The scope of this reconsideration is limited to VNS for TRD. Effective for claims with dates of service on or after February 15, 2019, CMS will cover Food and Drug Administration-approved VNS devices for TRD through Coverage with Evidence Development (CED) when offered in a CMS-approved, double-blind, randomized, placebo-controlled trial with a follow-up duration of at least one year with the possibility of extending the study to a prospective longitudinal study when the CMS-approved, double-blind, randomized placebo-controlled trial has completed enrollment, and there are positive interim findings.

Each study must be approved by CMS and as a fully-described, written part of its protocol, must address whether VNS improves health outcomes for TRD patients compared to a control group, by answering all of the research questions included in the coverage criteria.

There is also criteria that must be used to identify patients demonstrating TRD.

Individuals who receive placebo VNS will be offered active VNS at the end of the trial.

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.

Patients previously 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. These patients do not require either ICD-10 diagnosis codes or CED-related coding. These claims WILL require the –KX modifier attesting to the reasonable and necessary need for the replacement device based off NCD160.18 criteria.

NOTE: VNS for medically refractory seizures and hypoglossal nerves continue to be processed as they are currently.

NOTE: A subsequent Change Request will be issued shortly that will provide updates to the Pub. 100-04 Claims Processing Manual and instructions for processing claims through the CMS shared systems in regard to VNS for TRD.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility										
		A/B MAC			D M E	Shared-System Maintainers				Other		
		A	B	H H H		F M V C	M C M S	V M S S	C W F			
11461.1	<p>Effective February 15, 2019, contractors shall cover VNS for TRD for patients that meet the specific coverage indications and criteria described at Pub. 100-03, NCD Manual, section 160.18.</p> <p>That is, until a subsequent Change Request is implemented with specific claims processing/coding details, ensure your local systems do not contain any current edits that would prevent the appropriate coverage of these VNS claims.</p>	X	X									
11461.2	A/B MACs shall work together collaboratively to ensure consistent national editing across jurisdictions.	X	X									
11461.2.1	<p>Contractors shall attend up to 3 1-hour calls to discuss feedback regarding implementation of coding for this policy in a subsequent Change Request, and how to ensure consistent national editing across MACS locally. Contractors shall provide appropriate points-of-contact for staffing the meetings and send the contact information within 7 business days of the date of issuance of this CR to:David.Dolan@cms.hhs.gov.</p> <p>NOTE: CMS shall schedule the calls at a later date.</p>	X	X									
11461.3	A/B MACs shall implement local edits in each respective jurisdiction until such time as CMS may determine shared edits to be appropriate. A subsequent CR transferring some of this editing to the shared systems is forthcoming shortly.	X	X									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E D I	C M E D I
		A	B	H H H		
11461.4	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	X	X			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): David Dolan, 410-786-3365 or David.Dolan@cms.hhs.gov (Coverage and Analysis)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

160.18- Vagus Nerve Stimulation (VNS)

(Rev.10199, Issued: 06-23-2020, Effective:-02-15- 2019, Implementation: 07-22-2020)

A. General

Vagus Nerve Stimulation (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. The Food and Drug Administration (FDA) approved VNS for treatment of refractory epilepsy in 1997 and for resistant depression in 2005.

B. Nationally Covered Indications

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.

Effective for services performed on or after February 15, 2019, the Centers for Medicare & Medicaid Services (CMS) will cover FDA-approved VNS devices for treatment resistant depression (TRD) through Coverage with Evidence Development (CED) when offered in a CMS-approved, double-blind, randomized, placebo-controlled trial with a follow-up duration of at least one year with the possibility of extending the study to a prospective longitudinal study when the CMS-approved, double-blind, randomized placebo-controlled trial has completed enrollment, and there are positive interim findings.

Each study must be approved by CMS and as a fully-described, written part of its protocol, must address whether VNS improves health outcomes for TRD patients compared to a control group, by answering all of the following research questions below. The details of the prospective longitudinal study must be described in the original protocol for the double-blind, randomized, placebo-controlled trial. Response is defined as a $\geq 50\%$ improvement in depressive symptoms from baseline, as measured by a guideline recommended depression scale assessment tool. Remission is defined as being below the threshold on a guideline recommended depression scale assessment tool. The following research questions must be addressed in a separate analysis for patients with bipolar and unipolar disease.

Research Questions:

- What is the rate of response (defined as person months of response/total months of study participation)?*
- What is the rate of remission (defined as person months of response/total months of study participation)?*
- What is the time from treatment until response scores are first achieved?*
- What is the time from treatment until remission scores are first achieved?*
- What are the population distributions of the maximum months of response, both consecutive and overall, separately?*
- What are the population distributions of the maximum months of remission, both consecutive and overall, separately?*
- What are the patient variables associated with successful treatment of TRD with VNS?*
- What are the observed harms?*
- What are the changes in disability, quality of life, general psychiatric status, and suicidality?*

Patient Criteria:

The following criteria must be used to identify patients demonstrating TRD:

- *The patient must be in a major depressive disorder (MDD) episode for \geq two years or have had at least four episodes of MDD, including the current episode. In order to confirm the patient 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.*
- *The patient's depressive illness meets a minimum criterion of four prior failed treatments of adequate dose and duration as measured by a tool designed for this purpose.*
- *The patient is experiencing a major depressive episode (MDE) as measured by a guideline recommended depression scale assessment tool on two visits, within a 45-day span prior to implantation of the VNS device.*

Patients must maintain a stable medication regimen for at least four weeks before device implantation.

If patients with bipolar disorder are included, the condition must be carefully characterized.

Patients must not have:

- *Current or lifetime history of psychotic features in any MDE;*
- *Current or lifetime history of schizophrenia or schizoaffective disorder;*
- *Current or lifetime history of any other psychotic disorder;*
- *Current or lifetime history of rapid cycling bipolar disorder;*
- *Current secondary diagnosis of delirium, dementia, amnesia, or other cognitive disorder;*
- *Current suicidal intent; or,*
- *Treatment with another investigational device or investigational drugs.*

Individuals who receive placebo VNS will be offered active VNS at the end of the trial.

In addition, CMS will review studies to determine if they meet the 13 criteria listed below. If CMS determines that they meet these criteria, the study will be posted on CMS' CED website

(<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>).

- The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.*
- The rationale for the study is well supported by available scientific and medical evidence.*
- The study results are not anticipated to unjustifiably duplicate existing knowledge.*
- The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.*
- The study is sponsored by an organization or individual capable of completing it successfully.*
- The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and/or services, and the use and eventual disposition of the collected data.*
- All aspects of the study are conducted according to appropriate standards of scientific integrity.*
- The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.*
- The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.*
- The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the Agency for Healthcare Quality (AHRQ) Registry of Patient Registries (RoPR).*

- k) *The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessible manner; either in a peer-reviewed scientific journal (in print or online), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).*
- l) *The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.*
- m) *The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.*

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

The principal investigator must submit the complete study protocol, identify the relevant CMS research questions that will be addressed and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact information, to the address below. The information will be reviewed, and approved studies will be identified on the CMS website.

*Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd., Mail Stop S3-02-01
Baltimore, MD 21244-1850*

C. Nationally Non-Covered Indications

Effective for services performed on or after July 1, 1999, 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.

D. Other

Patients 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.

(This NCD last reviewed February 2019.)