

# Vagus Nerve Stimulation (VNS) (NCD 160.18)

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[↪ Terms and Conditions](#)

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**Related Medicare Advantage Policy Guidelines**

- [Deep Brain Stimulation for Essential Tremor and Parkinson’s Disease \(NCD 160.24\)](#)
- [Hypoglossal Nerve Stimulation for the Treatment Of Obstructive Sleep Apnea](#)

**Related Medicare Advantage Coverage Summaries**

- [Mental Health Services and Procedures](#)
- [Neurologic Services and Procedures](#)

## Policy Summary

[↪ See Purpose](#)

### Overview

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.

VNS provides indirect modulation of brain activity through the stimulation of the vagus nerve. The vagus nerve, the tenth cranial nerve, has parasympathetic outflow that regulates the autonomic (involuntary) functions of heart rate and gastric acid secretion, and also includes the primary functions of sensation from the pharynx, muscles of the vocal cords, and swallowing. It is a nerve that carries both sensory and motor information to/from the brain.

### Guidelines

#### *Nationally Covered Indications*

VNS treatment 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 vagus nerve stimulation (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. To access the approval of CMS Coverage with Evidence Development for Vagus Nerve Stimulation (VNS), go to [Clinical Study Approvals for VNS for TRD](#).

#### *Nationally Non-Covered Indications*

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 treatment resistant depression (TRD) when

furnished outside of a CMS-approved Coverage with Evidence Development (CED) study. All other indications of VNS for the treatment of depression are nationally non-covered.

### 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.

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Coding Clarification: It is mandatory to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under coverage with evidence development (CED).

CPT Code	Description
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array [See the Medicare Advantage Policy Guideline titled <a href="#">Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (NCD 160.24)</a> ]
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays [See the Medicare Advantage Policy Guideline titled <a href="#">Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (NCD 160.24)</a> ]
64568	Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator [See the Medicare Advantage Policy Guideline titled <a href="#">Hypoglossal Nerve Stimulation for the Treatment Of Obstructive Sleep Apnea</a> ]
64569	Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
64570	Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

*CPT® is a registered trademark of the American Medical Association*

Modifier	Description
CED Only	
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study

Condition Code	Description
CED Only	
30	Qualifying clinical trial (Institutional claims)

Diagnosis Code	Description
CED Only	
Z00.6	Encounter for examination for normal comparison and control in clinical research program

## Questions and Answers

1	Q:	Have you verified the CPT/HCPCS code(s) on your claim may have limited coverage under CED (Coverage with Evidence Development) for vagus nerve stimulation for treatment resistant depression?
	A:	<ul style="list-style-type: none"> <li>If no, clinical trial number, modifier Q0 and diagnosis code Z00.6 should not be submitted.</li> <li>If yes, the three requirements listed in the preceding bullet are required. Claims without the required information will be denied.</li> </ul>

## References

### CMS National Coverage Determinations (NCDs)

[NCD 160.18 Vagus Nerve Stimulation](#)

Reference NCDs: [NCD 160.24 Deep Brain Stimulation for Essential Tremor and Parkinson's Disease](#); [NCD 160.7 Electrical Nerve Stimulators](#)

### CMS Benefit Policy Manual

[Chapter 14: § 10 Coverage of Medical Devices](#)

[Chapter 15: § 260 Ambulatory Surgical Center Services](#)

### CMS Claims Processing Manual

[Chapter 12: § 90.3 Physicians' Services Performed in Ambulatory Surgical Centers \(ASC\)](#)

[Chapter 14: § 10 General ASC Information](#)

[Chapter 20: § 110 General Billing Requirements - for DME, Prosthetics, Orthotic Devices, and Supplies](#)

[Chapter 32: § 50 Deep Brain Stimulation for Essential Tremor and Parkinson's Disease, §69 Qualifying Clinical Trials, § 200 Billing Requirements for Vagus Nerve Stimulation \(VNS\)](#)

### CMS Transmittal(s)

[Transmittal 2243, Change Request 11134, Dated February 1, 2019 \(International Classification of Diseases, 10th Revision \(ICD - 10\) and Other Coding Revisions to National Coverage Determination \(NCDs\)\)](#)

[Transmittal 2955, Change Request 8401, Dated May 14, 2014 \(Mandatory Reporting of an 8 - Digit Clinical Trial Number on Claims\)](#)

[Transmittal 10199, Change Request 11461, Dated June 23, 2020 \(National Coverage Determination \(NCD\) 160.18 Vagus Nerve Stimulation \(VNS\)\)](#)

[Transmittal 10515, Change Request 12027, Dated December 10, 2020 \(International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determination \(NCDs\)–April 2021\)](#)

### MLN Matters

[Article MM8401, Mandatory Reporting of an 8 - Digit Clinical Trial Number on Claims](#)

[Article MM11134, International Classification of Diseases, 10<sup>th</sup> Revision \(ICD - 10\) and Other Coding Revisions to National Coverage Determinations \(NCDs\)](#)

[Article SE1344, Related Change Request 8401, Further Information on Mandatory Reporting of an 8 - Digit Clinical Trial Number on Claims](#)

## UnitedHealthcare Commercial Policy

### [Vagus Nerve Stimulation](#)

#### Other(s)

[ClinicalTrials.gov: A Prospective, Multi - center, Randomized Controlled Blinded Trial Demonstrating the Safety and Effectiveness of VNS Therapy® System as Adjunctive Therapy Versus a No Stimulation Control in Subjects With Treatment - Resistant Depression \(RECOVER\)](#)

[CMS Approved Clinical Trials for Vagus Nerve Stimulation \(VNS\) for Treatment Resistant Depression \(TRD\), CMS Website](#)  
[CMS Coverage with Evidence Development](#)

[Decision Memo for Vagus Nerve Stimulation \(VNS\) for Treatment Resistant Depression \(TRD\) \(CAG - 00313R2\)](#)

[Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development](#)

[Mandatory Reporting of National Clinical Trial \(NCT\) Identifier Numbers on Medicare Claims - Qs & As](#)

[Medicare Managed Care Manual, Chapter 4; § 10.7.3 Payment for Clinical Studies Approved Under Coverage with Evidence Development \(CED\)](#)

[National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development](#)

## Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	<b>Template Update</b> <ul style="list-style-type: none"><li>Reformatted policy; transferred content to new template</li></ul>
01/13/2021	<b>Policy Summary</b> <p><i>Nationally Non-Covered Indications</i></p> <ul style="list-style-type: none"><li>Replaced language indicating “VNS is <i>not reasonable and necessary</i> for resistant depression, <i>unless performed under a CMS-approved study through Coverage with Evidence Development (CED), as referenced [in the policy]</i>” with “VNS is <i>non-covered</i> for treatment resistant depression (TRD) when furnished outside of a CMS-approved Coverage with Evidence Development (CED) study”</li><li>Added language to indicate all other indications of VNS for the treatment of depression [not listed as a nationally covered indication] are nationally non-covered</li></ul> <p><i>Other</i></p> <ul style="list-style-type: none"><li>Added language to indicate 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</li></ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"><li>Revised coding clarification language to indicate it is mandatory to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under coverage with evidence development (CED)</li></ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"><li>Updated <i>References</i> section to reflect the most current information</li><li>Archived previous policy version MPG342.09</li></ul>

## Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

## Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document\* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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\*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).