



# Vagus Nerve Stimulation For Treatment Resistant Depression

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## Introduction & Instructions for Use

### Introduction

Medicare Coverage Summaries are a set of objective and evidence-based behavioral health criteria used by medical necessity plans to standardize coverage determinations, promote evidence-based practices, and support members’ recovery, resiliency, and wellbeing for Medicare behavioral health benefit plans managed by Optum® .

### Instructions for Use

This guideline is used to make coverage determinations as well as to inform discussions about evidence-based practices and discharge planning for behavioral health benefit plans managed by Optum. When deciding coverage, the member’s specific benefits must be referenced.

All reviewers must first identify member eligibility, the member-specific benefit plan coverage, and any federal or state regulatory requirements that supersede the member’s benefits prior to using this guideline. In the event that the requested service or procedure is limited or excluded from the benefit, is defined differently or there is otherwise a conflict between this guideline and the member’s specific benefit, the member’s specific benefit supersedes this guideline. Other clinical criteria may apply. Optum reserves the right, in its sole discretion, to modify its clinical criteria as necessary using the process described in Clinical Criteria.

This guideline is provided for informational purposes. It does not constitute medical advice.

Optum may also use tools developed by third parties that are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Optum may develop clinical criteria or adopt externally-developed clinical criteria that supersede this guideline when required to do so by contract or regulation.

## Vagus Nerve Stimulation

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. FDA approved VNS for treatment of refractory epilepsy in 1997 and for resistant depression in 2005.

## Applicable States

This Medicare Coverage Summary is based on the following CMS National Coverage Determinations (NCDs), and is applicable to all states. (CMS 160.18) Vagus Nerve Stimulation (VNS).

## Coverage Indications

The Centers for Medicare & Medicaid Services (CMS) will cover FDA-approved VNS devices for treatment resistant depression (TRD) through [Coverage with Evidence Development \(CED\)](#), effective on or after February 15, 2019, 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. Please see the CMS Decision Memo for the research questions, patient criteria, and CED criteria that must be addressed for an approved CED study: [Decision Memo for Vagus Nerve Stimulation \(VNS\) for Treatment Resistant Depression \(TRD\)](#). Information on location sites for the CED study can be found here: [CenterWatch Clinical Trial Information](#).

## Limitations and Exclusions

Effective for services performed on or after February 15, 2019, 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.

## 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.

## References

Centers for Medicare and Medicaid Services. (2020). National Coverage Determination, Vagus Nerve Stimulation (VNS) (160.18). CMS website: [www.cms.gov](http://www.cms.gov).

Centers for Medicare and Medicaid Services. (2021). Coverage with Evidence Development (CED). CMS website: <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/VNS>.

## Revision History

Date	Summary of Changes
May 18, 2020	Annual Review
April 19, 2021	Annual review, updated with CED information
April 19, 2022	Annual Review
April 18, 2023	Annual review