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.

If there is an absence of any applicable Medicare statutes, regulations, National or Local Coverage Determinations offering guidance, Optum utilizes adopted external criteria as follows:

- Level of Care Utilization System (LOCUS):
  - Standardized level of care assessment tool developed by the American Association of Community Psychiatrists used to make determinations and placement decisions for adults ages eighteen and older.
- Child and Adolescent Level of Care/Service Intensity Utilization System (CALOCUS-CASII):

- Standardized assessment tool developed by the American Academy of Child and Adolescent Psychiatry and the American Association of Community Psychiatrists used to make determinations and to provide level of service intensity recommendations for children and adolescents ages 6-18.
- Access the CALOCUS-CASII Criteria here

- Early Childhood Service Intensity Instrument (ECSII):
  - Standardized assessment tool developed by the American Academy of Child and Adolescent Psychiatry used to make determinations and to provide level of service intensity recommendations for children ages 0-5.
  - Access the ECSII Criteria here
- Optum Supplemental Clinical Criteria: developed criteria based on "acceptable clinical literature"
  - Electroconvulsive Therapy (ECT)
  - National criteria used to make clinical determinations for ECT.
- National criteria that stem from evaluation of new services or treatments or new applications of existing services or treatments and are used to make coverage determinations regarding experimental and investigation services and treatments. Optum Behavioral Clinical Policies:
  - Complementary and Alternative Medicine (CAM) Treatments
  - Computer Based Treatment for Cognitive Behavioral Therapy (CBTCBT)
  - Neurofeedback
  - Transcranial Magnetic Stimulation
  - Wilderness Therapy
- *Optum utilizes The ASAM Criteria to supplement the Medicare National Coverage Determinations (NCDs 130.1-130.7) for Alcohol and Substance Abuse Treatment to ensure consistency in making medical necessity determinations.*
  - Access the ASAM Criteria *here*

Use of The ASAM Criteria to supplement the general provisions outlined under 42 CFR 422.101(b)(6)(i) provides clinical benefits that are highly likely to outweigh any clinical harms from delayed or decreased access to items or services.

Specifically, The ASAM Criteria are consulted when the NCDs do not fully address the type of treatment or appropriate treatment setting that will likely lead to improvement of the member's condition. The ASAM Criteria are also consulted due to the comprehensive six-dimension analysis to determine if comorbid medical, mental health and substance related factors add to the evidence for services not offered in the NCDs.

These criteria represent current, widely used treatment guidelines developed by organizations representing clinical specialties, or Optum developed criteria based on "acceptable clinical literature" according to 422.101(b)(6)(i). Optum selects and uses clinical criteria that are consistent with generally accepted standards of care, including objective criteria that are based on sound clinical evidence. Optum uses the criteria to make standardized coverage determinations and to inform discussions about evidence-based practices and discharge planning. The use of such criteria is highly likely to outweigh any clinical harms from delayed or decreased access to care.

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 ≥ 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: NCT03887715: Contacts and Locations.

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.

Centers for Medicare and Medicaid Services. (2023). Coverage with Evidence Development (CED). CMS website: https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/VNS.

Revision History

Date	Summary of Changes
April 19, 2021	Annual review, updated with CED information
April 19, 2022	Annual Review
April 18, 2023	Annual review
April 16, 2024	Annual Review