



Vagus Nerve Stimulation Clinical Coverage Criteria

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

Policy

This Policy applies to the following Fallon Health products:

- Commercial
- Medicare Advantage
- MassHealth ACO
- NaviCare
- PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare has an NCD for Vagus Nerve Stimulation(160.18). National Government Services is the Medicare Administrative Contractor (MAC) with jurisdiction in our service area. National Government Services does not have an LCD or LCA for vagus nerve stimulation (MCD search 07-20-2021).

For plan members enrolled in NaviCare and PACE plans, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health will follow guidance published by MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Each PACE plan member is assigned to an Interdisciplinary Team. When there is no Medicare or MassHealth guidance, the member's Interdisciplinary Team is responsible for coverage determinations.

Prior authorization is required for vagus nerve stimulation.

Commercial and MassHealth ACO

Fallon Health considers vagus nerve stimulation medically necessary for plan members with medically refractory partial onset seizures for whom surgery is not recommended or for whom surgery has failed.

All other indications for vagus nerve stimulation are considered experimental and not covered, including but not limited to:

- All other types of seizure disorders which are medically refractory and for whom surgery is not recommended or for whom surgery has failed.
- Treatment resistant depression, Alzheimer's disease, obesity, tachycardia, and headaches.

Medicare

Fallon Health follows coverage criteria in Medicare NCD for Vagus Nerve Stimulation (160.18) for Medicare members, including Medicare Advantage, NaviCare and PACE plan members.

Policy References:

NCD link: [Vagus Nerve Stimulation \(160.18\)](#)

Nationally Covered Indications:

1. VNS is considered medically necessary for plan members with medically refractory partial onset seizures for whom surgery is not recommended or for whom surgery has failed.
2. Effective for dates of service on or after February 15, 2019, the Centers for Medicare & Medicaid Services (CMS) will cover FDA-approved VNS devices for treatment resistant depression 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. CMS-approved CED clinical studies for vagus nerve stimulation are listed on the CMS website at: <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/VNS>.

For additional information:

CMS Manual System: [Transmittal 10145, Date: June 23, 2020](#)

MLN Matters: [MM11461](#)

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.

Claims for services related to CMS-approved CED clinical trials must be submitted to Fallon Health with the NCT Identifier, ICD-10-CM diagnosis code Z00.6 in either the primary/secondary position and modifier Q0/Q1 as appropriate. See **Fallon Health Clinical Trials Payment Policy** for additional information.

Nationally Non-Covered Indications

- VNS is not medically 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 treatment resistant depression when furnished outside of a CMS-approved CED study.

Exclusions

- Transcutaneous (non-implantable) vagus nerve stimulation devices for all indications.
- Vagus nerve blocking therapy for morbid obesity (Codes 0312T, 0313T, 0314T, 0315T, 0316T, 0317T).

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

Code	Description
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays
64553	Percutaneous implantation of neurostimulator electrodes; cranial nerve
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64569	Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
64570	Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, 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 (eg, 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

References

1. Medicare National Coverage Determination (NCD) for Vagus Nerve Stimulation (VNS) (160.18). Effective Date of this Version: 02/15/2019. Available at: <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>.

Policy history

Origination date: 01/01/2014
Approval(s): Technology Assessment Committee 10/23/2013 (Adopted Interqual Criteria) 01/28/2015 (annual review) 01/27/2016 (annual review), 01/25/2017 (annual review), 01/24/2018 (annual review), 01/23/2019 (annual review); 05/27/2020 (adopted Fallon Health criteria)

07/20/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section)

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-

funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.