



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

Policy

This Policy applies to the following Fallon Health products:

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

Prior authorization is required.

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.

For Medicare Advantage plan members:

Effective for dates of service on or after February 15, 2019, vagus nerve stimulation is covered for treatment resistant depression for Medicare Advantage plan members enrolled in a CMS-approved Coverage with Evidence Development (CED) clinical trial in accordance with National Coverage Determination for Vagus Nerve Stimulation (160.18). Vagus nerve stimulation for treatment resistant depression is not covered when furnished outside of a CMS-approved CED clinical trial.

CMS-approved CED clinical trials are listed on the CMS website at:

<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/VNS>.

Claims for services related to clinical trials must be submitted with the NCT Identifier, ICD-10-CM diagnosis code Z00.6 in either the primary/secondary position and modifier Q0/Q1 as appropriate.

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: 05/04/2007. 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)

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. For Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this policy.