Vagus Nerve Stimulation
Clinical Coverage Criteria

Overview

A vagus nerve stimulator consists of an implantable pulse generator and electrical lead, and an external programming system used to change the device settings. The pulse generator is surgically implanted in the left chest. The lead (wire) is then connected to the pulse generator and the left vagus nerve. Electrical signals are transmitted from the pulse generator to the vagus nerve via the lead. The external programming system is

The Food and Drug Administration (FDA) approved the VNS Therapy System (LivaNova USA., Inc., formerly Cyberonics), in July 1997 for use as an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years of age with partial onset seizures, which are refractory to antiepileptic medications (PMA 970003). In June 2017, the indication for refractory partial onset seizures was expanded to include children 4 years of age and older (PMA P97003 S207). This device is indicated for use as an adjunctive therapy in reducing the frequency of seizures in patients 4 years of age and older with partial onset seizures that are refractory to antiepileptic medications

The FDA approved the VNS Therapy System (LivaNova USA., Inc., formerly Cyberonics) for the adjunctive long-term treatment of chronic or recurrent depression in patients 18 years of age or older who are experiencing a major depressive episode and have not had adequate response to four or more adequate antidepressant treatments (PMA P97003 S50).

Policy

This Policy applies to the following Fallon Health products:

☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
☒ MassHealth ACO
☒ NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
☒ NaviCare SCO (MassHealth-only)
☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
☒ Community Care (Commercial/Exchange)

Prior authorization is required for vagus nerve stimulation.

Medicare Advantage
Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for vagus nerve stimulation. Medicare has an NCD for Vagus Nerve Stimulation (160.18), Version Number 3, Effective Date of this Version 02/15/2019. National Government Services, Inc. is the Part A and B Medicare Administrative Contractor

(MAC) with jurisdiction in the Plan's service area. National Government Services, Inc. does not have an LCD for vagus nerve stimulation (Medicare Coverage Database search 07/22/2024).

Coverage criteria for vagus nerve stimulation is fully established by Medicare, therefore, the Plan's coverage criteria are not applicable.

Link: **NCD Vagus Nerve Stimulation (160.18)**, Version Number 3, Effective Date of this Version 02/15/2019

Indications and Limitations of Coverage
B. Nationally Covered Indications
Effective for services performed on or after July 1, 1999, VNS 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 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.

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. The following research questions must be addressed in a separate analysis for patients with bipolar and unipolar disease.

C. Nationally Non-Covered Indications
Effective for services performed on or after July 1, 1999, 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 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.

D. 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.

* Regarding Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression, Fallon Health covers *routine costs* incurred by members participating in **CMS-approved Coverage with Evidence Development (CED) studies for Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression** in accordance with § 422.101(b)(1), §422.109 and MMCM, Chapter 4, Section 10.7.3 – Payment for Clinical Studies Approved under Coverage with Evidence Development (CED).

Routine costs include all items and services that are otherwise available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national noncoverage decision) and that would be otherwise furnished even if the member were not enrolled in a clinical trial.

For Billing/coding guidelines for clinical trial-related services, please refer to Fallon Health **Clinical Trials Payment Policy**.

MassHealth ACO
Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth does not have Guidelines for Medical Necessity Determination for vagus nerve stimulation (MassHealth website search 07/22/2024), therefore, the Plan's coverage criteria are applicable.

NaviCare HMO SNP, NaviCare SCO
For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria for vagus nerve stimulation apply to Community Care and MassHealth ACO members. For Medicare Advantage, NaviCare and PACE members, follow coverage criteria described in the Policy section above.

These coverage criteria apply only to vagus nerve stimulation using an FDA-approved implantable vagus nerve stimulator.

Effective for dates of service on or after August 1, 2024, Fallon Health will use InterQual® Criteria when making medical necessity determinations for implantable vagus nerve stimulation.

For coverage criteria, refer to the InterQual criteria in effect on the date of service:
- InterQual® CP:Procedures, Vagus Nerve Stimulation
- InterQual® CP:Procedures, Vagus Nerve Stimulation (Pediatric)

Fallon Health makes InterQual criteria available to the public through the transparency tool on our website, effective January 1, 2024.

Exclusions

- Vagus nerve stimulation is considered experimental/investigational for all other indications.
- Non-implantable/non-invasive vagus nerve stimulator (E0735), including transcutaneous vagus nerve stimulation systems for all indications.

- Rechargeable vagal blocking systems for all indications, including but not limited to weight reduction. (Category III CPT codes 0312T, 0313T, 0314T, 0315T, 0316T, 0317T were sunset effective January 1, 2023).

Evidence Summary

N/A

Analysis of Evidence (Rationale for Determination)

N/A

Coding

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

Code	Description
Full system placement or replacement	
64568	Open Implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
Generator/battery replacement	
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
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
Removal of generator	
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
Analysis and programming	
95970	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 brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
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

Device C-codes

Code	Description
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)

Device L-codes

Code	Description
L8680	Implantable neurostimulator electrode, each
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension

References

1. Medicare National Coverage Determination (NCD) for Vagus Nerve Stimulation (VNS) (160.18). Version Number 3. Effective Date of this Version: 02/15/2019. Available at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx.
2. U.S. Food and Drug Administration. Summary of safety and effectiveness data (SSED). VNS therapy system. Epilepsy. 2017; https://www.accessdata.fda.gov/cdrh_docs/pdf/p970003s207b.pdf.
3. U.S. Food and Drug Administration. Summary of safety and effectiveness data (SSED). VNS therapy system. Depression. 2005; https://www.accessdata.fda.gov/cdrh_docs/pdf/P970003S050b.pdf.
4. LivaNova, USA., Inc. (formerly Cyberonics, Inc.). 2024 VNS Therapy™ Codes. Available at: https://www.livanova.com/epilepsy-vnstherapy/getmedia/bf89232d-144a-49a2-b612-4c9040dcf268/2024-code-sheets_in-use_1.pdf.

Policy history

Origination date: 01/01/2014

Review/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), 02/08/2022 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section), 07/23/2024 (annual review, adopted InterQual 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.