Medical Policy

Northwood

Non-Invasive Vagus Nerve Stimulator

Description

The non-invasive vagus nerve stimulator is a handheld prescription device intended to deliver transcutaneous vagus nerve stimulation for the acute treatment of pain associated with episodic/chronic cluster headaches.

This device is being investigated as a noninvasive alternative to implantable VNS for indications such as pain, epilepsy, tinnitus, and depression. An example of this type of device is the gammaCore (ElectroCore, LLC).

Policy Guidelines

The non-invasive vagus nerve stimulator (E0735) is considered **experimental** and **investigational** for any indication, therefore, noncovered.

HCPCS Level II Codes and Description

E0735	Non-invasive vagus nerve stimulator (effective change 01-01-24 from K1020)

General Indications and Limitations of Coverage and/or Medical Necessity

For a DMEPOS item to be covered, it must 1) be eligible for a defined benefit category and 2) be reasonable and necessary for the treatment of illness or injury or improve the functioning of a malformed body member or used to replace all or part of a body part or all or part of the functions of a permanently disabled or poorly functioning body organ. For the items addressed in medical policy, the criteria for "reasonable and necessary" are defined by the carrier or plan sponsor's indications and limitations of coverage and/or medical necessity.

Certain statutory and/or regulatory requirements may be applicable to the carrier or plan sponsor which may affect coverage or benefits (e.g., certain states mandate coverage of, or waiver of co-payments for, diabetic/glucose monitoring supplies, prosthetic wigs, etc.).

Important Note:

Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary. Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Non-Invasive Vagus Nerve Stimulator

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Northwood's policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Northwood follows all CMS National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), as applicable.

Documentation Requirements:

Items in this policy may be subject to the Affordable Care Act (ACA) 6407 requirements.

The Affordable Care Act (ACA) 6407 requires that the treating physician conduct a face-to-face examination during the six-month period preceding the written order. The documentation must be received by the provider prior to delivery for certain DME items. The documentation must describe a medical condition for which the DME is being prescribed.

References

1. Aetna Vagus Nerve Stimulation, Policy 0191; https://www.aetna.com/cpb/medical/data/100_199/0191.html Last accessed and reviewed December 12, 2024.

2. Hayes, Inc. Health Technology Assessment. Noninvasive Vagus Nerve Stimulation with gammaCore for Prevention or Treatment of Cluster Headache. Lansdale, PA: Hayes, Inc., May 2020.

3. UnitedHealthcare Vagus and External Trigeminal Nerve Stimulation Medical Policy Number: 2022T0101EE https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/vagus-nerve-stimulation.pdf Last accessed and reviewed December 12, 2024.

4. Molina Healthcare, Vagal Nerve Stimulation (VNS) for Epilepsy, Policy Number: MCR-006 https://www.molinahealthcare.com/-/media/Molina/PublicWebsite/PDF/Providers/il/Medicaid/Vagal-Nerve-Stimulation-for-Epilepsy_MCR_006.pdf Last accessed and reviewed December 12, 2024.

5. PubMed.gov https://pubmed.ncbi.nlm.nih.gov/32109020/ ARTICLE.

Change/Authorization History

Revision Number	Date	Description of Change	Prepared / Reviewed by	Approved by	Review Date:	Effective Date:
A	9-14-22	Initial release.	Carol Dimech	Dr. C. Lerchin	n/a	9-14-2022
1	12-13-22	Annual review. No changes.	Lisa Wojno	Dr. C. Lerchin	December 13, 2022	December 2022
2	12-04-23	Annual review. Per CMS HCPCS changed from K1020 to E0735 effective 01-01-24	Susan Glomb/Carol Dimech	Dr. C. Lerchin	Dec 04,2023	Dec.04,2023
3	12/12/24	Annual review. Updated references.	Susan Glomb/Carol Dimech	Dr. C. Lerchin	12/12/24	

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