BlueCross BlueShield of Vermont

An Independent Licensee of the Blue Cross and Blue Shield Association.

Remote Electrical Neuromodulation for Migraines (i.e., Nerivio®) Corporate Medical Policy

File Name: Remote Electrical Neuromodulation
File Code: 7.01.VT171
Origination: New Policy
Last Review: 07/2026
Next Review: 07/2027
Effective Date: 11/01/2026

Description/Summary

Nerivio® is a wearable, non-pharmacologic device that uses remote electrical neuromodulation (REN) to treat and prevent migraines by stimulating nerves in the upper arm. The noninvasive device is controlled by a smartphone application. REN has been suggested as an alternative option for treatment of migraine, potentially reducing reliance on abortive or preventive medications and lowering the risk of medication overuse

Policy

Coding Information

Click the links below for attachments, coding tables & instructions.
Attachment I

When a service may be considered medically necessary

Remote electrical neuromodulation for the treatment and prevention of migraines may be considered **medically necessary** when the following criteria are met:

Initial use of the FDA approved remote electrical neuromodulation device (i.e., Nerivio®) for the treatment and prevention of migraine in individuals who meet **ALL** the following four criteria:

- Are eight years of age or older; **AND**
- Have a six-month history of headaches that meet International Classification of Headache Disorders (ICHD 3-beta) diagnostic criteria for migraine with or without aura; **AND**
- One of the following conditions exists:

    - Insufficient response, contraindication, or intolerance to 2 or more guideline-recommended headache medications (e.g., anticonvulsants, antihypertensives, antidepressants, CGRP inhibitors); **OR**
    - Pregnancy, breastfeeding, or planning to conceive; **OR**
    - At risk for or have a history of medication overuse headache; **OR**
    - At risk for drug-drug interactions with medications for comorbid conditions; **OR**
    - Children that have a documented contraindication or intolerance to a medication; **AND**
- Meets one of the following indications:
    - Remote electrical neuromodulation (REN) is used to treat acute migraines; **OR**
    - Remote electrical neuromodulation is used to prevent migraine for individuals with 6 to 24 headache days (defined as a calendar day with headache regardless of severity or duration) per 28-day period in each of the 3 months preceding use of the REN device.

Continued use of the FDA approved remote electrical neuromodulation device (i.e., Nerivio®) for the prevention or treatment of acute migraine in individuals when **BOTH** of the following are demonstrated:

- Compliance with use; **AND**
- Clinical benefit (for example, fewer migraines or shorter duration of migraines).

NOTE: Each prescription, whether initial or refill, includes 18 treatments. For acute migraine management, individuals typically use 2 treatments per day, with a maximum of 6 per day. In contrast, preventative migraine treatment involves one treatment every other day. Based on these patterns, it is estimated that an individual would need approximately one prescription per year for acute migraines and two prescriptions per year for prevention.

When a service is considered investigational

- Non-FDA approved REN devices
- Individuals with contraindications to use of REN devices
- Trigeminal nerve stimulation (e.g., Cefaly) devices for migraine treatment
- All other indications for REN not meeting the above criteria

Note: Contraindications include: Individuals with uncontrolled epilepsy and those with an active implantable medical device (e.g., pacemaker, hearing aid implant, or any implanted electronic device). Nerivio® has not been evaluated in individuals with congestive heart failure, severe cardiac or cerebrovascular disease or patients under the age of 8 years.

Replacement of lost, stolen or destroyed Durable Medical Equipment

We will replace one lost, stolen or destroyed Durable Medical Equipment, prosthetic or orthotic per Plan Year if not covered by an alternative entity (including but not limited to homeowners insurance and automobile insurance) if:

- the Durable Medical Equipment, prosthetic or orthotic's absence would put the member at risk of death, disability or significant negative health consequences such as a hospital admission;
- the Durable Medical Equipment is still under warranty.

Note: In order to replace a stolen item we require you to submit documentation, such as a police report, with the request.

Exclusions

We do not cover the replacement of a lost, stolen or destroyed Durable Medical Equipment, prosthetic or orthotic:

- if the criteria above have not been met; **AND**
- for more than one lost, stolen or destroyed Durable Medical Equipment, prosthetic or orthotic per Plan Year.

Policy Guidelines

Summary of Evidence

For individuals with acute migraine due to episodic or chronic migraine who receive REN, the evidence includes 2 RCTs and nonrandomized, uncontrolled studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Use of an 5 active REN device resulted in more patients with improved pain and symptoms at 2-hour follow-up compared with a sham device based on 2 small (N=212) RCTs with numerous relevance limitations. However, no significant between-group difference in functional disability or quality of life was noted in a post-hoc analysis of the pivotal RCT. Although, controlled studies in pediatric populations are lacking a non-randomized clinical trial in adolescents showed pain relief at 2 hours and improved functional disability relief. That data is consistent with emerging prospective real-world studies in younger children. Additional information was assessed from clinicians currently practicing at various academic medical centers. Respondents noted that all individuals with migraine may benefit from a nonpharmacologic option for either stand-alone or adjunctive use, particularly among those who have failed other options, who have contraindications or an intolerance to alternatives, who are at risk for or have a history of medication overuse headache, or who are at risk of drug-drug interactions. It was also noted that while some clinicians trial acute treatment with REN first, failure in the abortive setting does not preclude success with preventive use. Respondents additionally emphasize that the discreet nature of the REN device is ideal for use by children and adolescents in the school setting. Our assessment of the clinical input concluded that clinicians generally support use of REN for acute or preventive treatment, particularly in adolescent and pediatric populations where there are limited alternatives with evidence of efficacy or tolerable side effect profiles. The comprehensive evidentiary review which includes the clinical input is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who may benefit from preventive migraine therapy, including those with frequent or long-lasting episodic or chronic migraines, migraine attacks that diminish quality of life or cause significant disability despite acute treatment, contraindications to or failure of acute therapies, and risk of medication overuse headache, who receive REN, the evidence includes 1 RCT and 1 prospective, observational study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Use of an active REN

device resulted in more adults with decreased migraine days per month, regardless of episodic or chronic subtype, when used every other day for 8 weeks compared with a sham device based on 1 small (N=248) RCT with numerous relevance limitations. Prospective, observational data in 2 real world evidence studies using the device for acute treatment of migraine demonstrated a significant reduction in migraine headache days from baseline to months 2 and 3 with device use in adolescent patients. Based on the existing evidence, it is unclear how Nerivio® would fit into the current migraine prevention pathway, although it could provide benefit for those who do not receive adequate benefit from pharmacologic first- or second-line therapies, or who may have a contraindication to pharmacologic therapies. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Reference Resources

1. Ailani J, Burch RC, Robbins MS. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. July 2021; 61(7): 1021-1039. PMID 34160823
2. Ailani J, Rabany L, Tamir S, et al. Real-World Analysis of Remote Electrical Neuromodulation (REN) for the Acute Treatment of Migraine. Front Pain Res (Lausanne). 2021; 2: 753736. PMID 35295483
3. Burch R, Rizzoli P, Loder E. The prevalence and impact of migraine and severe headache in the United States: Updated age, sex, and socioeconomic-specific estimates from government health surveys. Headache. Jan 2021; 61(1): 60-68. PMID 33349955
4. Burch RC, Loder S, Loder E, et al. The prevalence and burden of migraine and severe headache in the United States: updated statistics from government health surveillance studies. Headache. Jan 2015; 55(1): 21-34. PMID 25600719
5. Diener HC, Tassorelli C, Dodick DW, et al. Guidelines of the International Headache Society for controlled trials of acute treatment of migraine attacks in adults: Fourth edition. Cephalalgia. May 2019; 39(6): 687-710. PMID 30806518
6. Food and Drug Administration (FDA). 510(k) Summary. Theranica Bio-Electronics LTD.'s Nerivio Infinity and Nerivio (K241756). October 8, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf24/K241756.pdf.
7. Grosberg B, Rabany L, Lin T, et al. Safety and efficacy of remote electrical neuromodulation for the acute treatment of chronic migraine: an open-label study. Pain Rep. Nov-Dec 2021; 6(4): e966. PMID 34667919
8. Hayes, Inc. Evolving Evidence Review. Nerivio (Theranica Bio-Electronics Ltd.) for treatment of acute migraine episodes. https://evidence.hayesinc.com. Published July 23, 2021.
9. Hershey AD, Irwin S, Rabany L, et al. Comparison of Remote Electrical Neuromodulation and Standard-Care Medications for Acute Treatment of Migraine in Adolescents: A Post Hoc Analysis. Pain Med. Apr 08 2022; 23(4): 815-820. PMID 34185084
10. Hershey AD, Lin T, Gruper Y, et al. Remote electrical neuromodulation for acute treatment of migraine in adolescents. Headache. Feb 2021; 61(2): 310-317. PMID 33349920

11. Hershey AD, Shmuely S, Stark-Inbar A, et al. Patterns, Barriers, and Preferences of Treating Migraine Within the School Setting: A Survey Study of Students. Children (Basel). Oct 25 2024; 11(11). PMID39594861
12. Management of Headache Work Group. VA/DoD Clinical Practice Guideline. Washington, DC. September 2023. https://www.healthquality.va.gov/HEALTHQUALITY/guidelines/pain/headache/VA-DOD-CPG-Headache-Full-CPG.pdf.
13. Marmura MJ, Lin T, Harris D, et al. Incorporating Remote Electrical Neuromodulation (REN) Into Usual Care Reduces Acute Migraine Medication Use: An Open-Label Extension Study. Front Neurol. 2020; 11: 226. PMID 32318014
14. Monteith TS, Stark-Inbar A, Shmuely S, et al. Remote electrical neuromodulation (REN) wearable device for adolescents with migraine: a real-world study of high-frequency abortive treatment suggests preventive effects. Front Pain Res (Lausanne). 2023; 4: 1247313. PMID 38028429.
15. Nierenburg H, Rabany L, Lin T, et al. Remote Electrical Neuromodulation (REN) for the Acute Treatment of Menstrual Migraine: A Retrospective Survey Study of Effectiveness and Tolerability. Pain Ther. Dec 2021; 10(2): 1245-1253. PMID 34138449
16. Nierenburg, H., & Stark-Inbar, A. (2022). Nerivio® remote electrical neuromodulation for acute treatment of chronic migraine. *Pain management*, *12*(3), 267–281. https://doi.org/10.2217/pmt-2021-0038
17. Nierenburg H, Vieira JR, Lev N, et al. Remote Electrical Neuromodulation for the Acute Treatment of Migraine in Patients with Chronic Migraine: An Open-Label Pilot Study. Pain Ther. Dec 2020; 9(2): 531-543. PMID 32648205
18. Oskoui M, Pringsheim T, Billinghurst L, et al. Practice guideline update summary: Pharmacologic treatment for pediatric migraine prevention: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology. Sep 10 2019; 93(11): 500-509. PMID 31413170
19. Oskoui M, Pringsheim T, Holler-Managan Y, et al. Practice guideline update summary: Acute treatment of migraine in children and adolescents: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Headache Society. Headache. Sep 2019; 59(8): 1158-1173. PMID 31529481
20. Rapoport AM, Bonner JH, Lin T, et al. Remote electrical neuromodulation (REN) in the acute treatment of migraine: a comparison with usual care and acute migraine medications. J Headache Pain. Jul 22 2019; 20(1): 83. PMID 31331265
21. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Neurology. Apr 24 2012; 78(17): 1337-45. PMID 22529202
22. Silberstein SD. Practice parameter: evidence-based guidelines for migraine headache (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. Sep 26 2000; 55(6): 754-62. PMID 10993991
23. Singh RBH, VanderPluym JH, Morrow AS, et al. Acute Treatments for Episodic Migraine. Rockville (MD): Agency for Healthcare Research and Quality (US); December 2020.
24. Synowiec A, Stark-Inbar A, Santamaria DD, et al. Coverage with evidence development study shows benefits in patients with migraine treated with remote electrical neuromodulation. Am J Manag Care. Apr 08 2025. PMID 40834199

25. Tassorelli C, Diener HC, Silberstein SD, et al. Guidelines of the International Headache Society for clinical trials with neuromodulation devices for the treatment of migraine. Cephalalgia. Oct 2021; 41(11-12): 1135-1151. PMID 33990161
26. Tepper SJ, Lin T, Montal T, et al. Real-world Experience with Remote Electrical Neuromodulation in the Acute Treatment of Migraine. Pain Med. Dec 25 2020; 21(12): 3522-3529. PMID 32935848
27. Tepper SJ, Rabany L, Cowan RP, et al. Remote electrical neuromodulation for migraine prevention: A double-blind, randomized, placebo-controlled clinical trial. Headache. Mar 2023; 63(3): 377-389. PMID 36704988
28. U.S. Food and Drug Administration. 501(k) Summary: Theranica Bio-Electronics LTDs Nerivio. https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180059.pdf.
29. U.S. Food and Drug Administration. 510(k) Summary (K223169): Nerivio Approval for Preventative Treatment. https://www.accessdata.fda.gov/cdrh_docs/pdf22/K223169.pdf.
30. U.S. Food and Drug Administration. 510(k) Summary: Nerivio Approval in Adolescents. https://www.accessdata.fda.gov/cdrh_docs/pdf20/K203181.pdf.
31. U.S. Food and Drug Administration. De Novo Classification Request for Nerivio Migra. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180059.pdf.
32. VanderPluym JH, Halker Singh RB, Urtecho M, et al. Acute Treatments for Episodic Migraine in Adults: A Systematic Review and Meta-analysis. JAMA. Jun 15 2021; 325(23): 2357-2369. PMID 34128998
33. Werner K, Gerson T, Stark-Inbar, A, et al. Acute treatment of migraine in children aged 6- 11: Real-world analysis of remote electrical neuromodulation (REN). Annals of the Child Neurology Society. May 21,2024; 2(2): 135-145.
34. Yarnitsky D, Dodick DW, Grosberg BM, et al. Remote Electrical Neuromodulation (REN) Relieves Acute Migraine: A Randomized, Double-Blind, Placebo-Controlled, Multicenter Trial. Headache. Sep 2019; 59(8): 1240-1252. PMID 31074005
35. Yarnitsky D, Volokh L, Ironi A, et al. Nonpainful remote electrical stimulation alleviates episodic migraine pain. Neurology. Mar 28 2017; 88(13): 1250-1255. PMID 28251920

Related Policies

Transcutaneous Electrical Nerve Stimulation (TENS) and Transcutaneous Afferent Patterned Stimulation (TAPS)

Document Precedence

Blue Cross and Blue Shield of Vermont (Blue Cross VT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, Blue Cross VT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

Audit Information

Blue Cross VT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, Blue Cross VT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

Incomplete authorization requests may result in a delay of decision pending submission of missing information. To be considered compete, see policy guidelines above.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

7/2026	New Policy created with medical necessity criteria for use of Remote Electrical Neuromodulation (i.e., Nerivio®) for treatment and prevention of migraine headache. Added code A4540 as requiring prior approval to coding table.

Eligible Providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by Blue Cross VT Medical Directors

Tom Weigel, MD, MBA
Vice President and Chief Medical Officer

Attachment I

Code Type	Number	Description	Policy Instructions
The following codes will be considered as medically necessary when applicable criteria have been met.			
HCPCS	A4540	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm	Prior Approval Required