BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.171 Remote Electrical Neuromodulation for Migraines

Annual Effective Policy Date: January 1, 2024

Original Policy Date: September 2022

Related Policies:

None

Remote Electrical Neuromodulation for Migraines

Description

Description

Migraine attacks due to episodic or chronic migraine require acute management. Some individuals may also require preventive migraine therapy. Current first-line therapy for treatment and prevention of acute migraine involves use of various pharmacologic interventions. Regular use of pharmacologic interventions can result in medication overuse and increased risk of progression from episodic to chronic migraine. Nonpharmacologic remote electrical neuromodulation (REN) may offer an alternative to pharmacologic interventions for patients with migraine.

OBJECTIVE

The objective of this evidence review is to determine whether acute treatment or preventive treatment with remote electrical neuromodulation improves the net health outcome in patients with acute migraine due to episodic or chronic migraine.

POLICY STATEMENT

Remote electrical neuromodulation for acute migraine or prevention of migraine is considered **not medically necessary**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

In May 2019, Nerivio Migra™ (Theranica Bio-Electronics Ltd.) was granted a de novo classification by the FDA (class II, special controls, product code: QGT).[10,] This new classification applied to this device and substantially equivalent devices of this generic type. Nerivio Migra was initially cleared for treatment of acute migraine in adults who do not have chronic migraine.

In October 2020, Nerivio was cleared for marketing by the FDA through the 510(k) process (K201824). FDA determined that this device was substantially equivalent to Nerivio Migra for use in adults.[11,] The device name changed to just "Nerivio" and the exclusion of chronic migraine patients was removed. The Nerivio device can provide more treatments than the predicate Nerivio Migra (12 treatments vs. 8 treatments) and has a longer shelf life (24 months vs. 9 months). In January 2021, the Nerivio device was cleared for use in patients aged 12 to 17 years.[12,]In February 2023, Nerivio's indication was expanded to include preventive treatment of migraine with or without aura in individuals 12 years and age or older and was cleared for marketing through the 510(k) process (K223169).[13,]

RATIONALE

Summary of Evidence

For individuals with acute migraine due to episodic or chronic migraine who receive remote electrical neuromodulation (REN) , the evidence includes 2 randomized controlled trials (RCTs) and nonrandomized, uncontrolled studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Use of an 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. Based on the existing evidence, it is unclear how Nerivio would fit into the current acute migraine management pathway. The specific intended use and associated empirically-documented recommended regimen(s) must be specified in order to adequately evaluate the net health benefit. Additionally, functional outcomes and quality of life must be evaluated in well-designed and conducted studies in defined populations using documented Nerivio regimens. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with 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 adolescents (N=61) 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. This data was extrapolated to support the indication for preventative use in adolescents. 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 specific intended use and associated empirically-documented recommended regimen(s) must be specified in order to adequately evaluate the net health benefit. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Neurology/American Headache Society

A 2012 joint guideline by the American Academy of Neurology (AAN) and the American Headache Society (AHS) on pharmacologic treatment for episodic migraine prevention in adults was published prior to the approval of Nerivio in the US and did not address the use of remote electrical neuromodulation (REN) or other nonpharmacologic treatments.[7,] Similarly, 2019 joint guidelines issued by AAN and AHS on the treatment of acute migraine[28,] and prevention of migraine[8,] in children and adolescents did not address the use of REN or other nonpharmacologic treatments.

American Headache Society

In 2021, AHS issued guidance on the integration of new migraine treatments, including REN, into clinical practice.[4,] The AHS addressed the use of neuromodulatory devices as a group that included electrical trigeminal nerve stimulation, noninvasive vagus nerve stimulation, single-pulse transcranial magnetic stimulation, and REN; no guidance specific to REN use was issued.

The AHS determined that initiation of a neuromodulatory device is appropriate when all of the following criteria are met:

- Prescribed/recommended by a licensed clinician
- Patient is at least 18 years of age (*the guidance noted that 3 devices, including REN, are approved for use in patients age 12 to 17 years*)
- Diagnosis of International Classification of Headache Disorders (ICHD)-3 migraine with aura, migraine without aura, or chronic migraine
- Either of the following:
    - Contraindications to or inability to tolerate triptans
    - Inadequate response to 2 or more oral triptans, as determined by EITHER of the following:
        - Validated acute treatment patient-reported outcome questionnaire (Migraine Treatment Optimization Questionnaire, Patient Perception of Migraine Questionnaire-Revised, Functional Impairment Scale, Patient Global Impression of Change)
        - Clinician attestation.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

1. 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
2. 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
3. Singh RBH, VanderPluym JH, Morrow AS, et al. Acute Treatments for Episodic Migraine. Rockville (MD): Agency for Healthcare Research and Quality (US); December 2020. Accessed August 29, 2023.
4. Ailani J, Burch RC, Robbins MS. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. Jul 2021; 61(7): 1021-1039. PMID 34160823
5. 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
6. 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
7. 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
8. 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
9. Nierenburg H, Stark-Inbar A. Nerivio remote electrical neuromodulation for acute treatment of chronic migraine. Pain Manag. Apr 2022; 12(3): 267-281. PMID 34538078
10. U.S. Food and Drug Administration. De Novo Classification Request for Nerivio Migra. Accessed August 27, 2023.
11. U.S. Food and Drug Administration. 501(k) Summary: Theranica Bio-Electronics LTDs Nerivio. Accessed August 29, 2023.
12. U.S. Food and Drug Administration. 510(k) Summary: Nerivio Approval in Adolescents. Accessed August 28, 2023.
13. U.S. Food and Drug Administration. 510(k) Summary (K223169): Nerivio Approval for Preventative Treatment. Accessed August 25, 2023.
14. 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
15. 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
16. 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
17. 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
18. 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
19. 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
20. 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
21. 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
22. 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
23. 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
24. 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
25. 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. 2021; 6(4): e966. PMID 34667919
26. 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
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. 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

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2022	New policy	Policy created with literature review through March 22, 2022. Remote electrical neuromodulation for acute migraine is considered investigational.
December 2023	Replace policy	Policy updated with literature review through August 29, 2023; references added. Evidence review added for prevention of migraine based on recent expansion of FDA-approved indications. Remote electrical neuromodulation for acute migraine or prevention of migraine is considered not medically necessary for FEP due to market approval via the 510K Process.