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MEDICAL POLICY – 7.01.171

Remote Electrical Neuromodulation for Migraines

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Introduction

Migraines are moderate to severe headaches that have other symptoms. These symptoms may include aura, sensitivity to light, nausea, and vomiting. Migraines can last for hours to days. Episodic migraines occur 14 or fewer days each month. Chronic migraines occur 15 or more days each month. The most common way to treat migraine headaches is with over-the-counter or prescription drugs. Treatment can help prevent migraines and/or relieve pain when they occur. Another possible way to treat migraines is remote neuromodulation (REN). REN uses a device that is worn on the upper arm. This device stimulates nerves in a process called conditioned pain modulation (CPM). The idea is that pain in one area of the body reduces the perception of pain in another part of the body. Pain occurs in the arm, and this pain is thought to reduce the perceived intensity of the migraine headache. This policy describes when the use of remote electrical neuromodulation to treat migraine headaches may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Procedure	Medical Necessity

Preventive treatment: Initiation of use	**Remote electrical neuromodulation (REN [e.g., Nerivio]) for the prevention of migraine may be considered medically necessary in individuals when the following criteria are met:**
	• The individual is 18 years of age or older
	AND
	• Headaches meet the International Classification of Headache Disorders (ICHD-3) diagnostic criteria for migraine with or without aura (see **Related Information**)
	AND
	• The REN device will be used in the following clinical scenario:
	  ○ For the prevention of migraine in 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)
	AND
	• One of the following additional criteria must also be met:
	  ○ Insufficient response, contraindication, or intolerance to 2 or more guideline-recommended preventive headache medications (e.g., anticonvulsants, antihypertensives, antidepressants, calcitonin gene-related peptide (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

Preventive treatment: Continuation of use	**Continued use of the REN device and/or accessories for the prevention of migraine is considered medically necessary in individuals when the following criteria are met:** • Compliance with ongoing use **AND** • Documentation of clinical benefit is provided (see **Related Information**).

Procedure	Investigational
Remote electrical neuromodulation (REN) for acute migraine	**Remote electrical neuromodulation (REN) for acute migraine is considered investigational. (e.g., Nerivio)** **Remote electrical neuromodulation for prevention of migraine outside of the above criteria is considered investigational (**see Related Information**).**

Coding

Code	Description
HCPCS	
A4540	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm (Nerivio)

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Remote Electrical Neuromodulation Contraindications

Nerivio is contraindicated in patients with uncontrolled epilepsy and patients with an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device. Nerivio has not been evaluated in patients with congestive heart failure, severe cardiac or cerebrovascular disease, pregnancy, or patients under the age of 8 years.

Criteria for Migraine

The International Classification of Headache Disorders ICDH-3 criteria for migraine with and without aura can be accessed at **https://ichd-3.org/1-migraine/**. (Accessed November 11, 2025)

Clinical Benefit for Continuation of Use

Documentation of clinical benefit for continuation of use may include a clinician attestation regarding any of the following outcomes:

- Improvements in pain relief or freedom, particularly for acute use
- Reduction in headache frequency, duration, or severity
- Reduction in functional disability
- Reduction in absenteeism
- Reduction in concomitant headache medications.

Based on observed outcomes of pivotal studies of Nerivio and study duration recommendations from the International Headache Society concerning migraine neuromodulation trial designs, assessment for clinical benefit is reasonable after a minimum of 8-12 weeks for preventive treatment.

Evidence Review

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.

Background

Migraine

Migraine is a neurologic disease characterized by recurrent moderate to severe headaches with associated symptoms that can include aura, photophobia, nausea, and/or vomiting.[1] Overall

migraine prevalence in the US is about 15% but varies according to population group.[2] Prevalence is higher in women (21%), among American Indian/Alaska Natives (22%), and among 18- to 44-year-olds (19%). Social determinants including low education level (18%), use of Medicaid (27%), high poverty level (23%), and being unemployed (22%) are also associated with higher rates of migraine.

Migraine is categorized as episodic or chronic depending on the frequency of attacks. Generally, episodic migraine is characterized by 14 or fewer headache days per month and chronic migraine is characterized by 15 or more headache days per month.[3] Specific International Classification of Headache Disorders[4] diagnostic criteria are as follows:

- Episodic migraine:
    - Untreated or unsuccessfully treated headache lasting 4 to 72 hours
    - Headache has at least 2 of the following characteristics:
        - Unilateral location
        - Pulsating quality
        - Moderate or severe pain intensity
        - Aggravation by or causing avoidance of routine physical activity
    - At least 1 of the following during headache:
        - Nausea and/or vomiting
        - Photophobia or phonophobia.
- Chronic migraine:
    - Migraine-like or tension-type headache on 15 or more days per month for more than 3 months
    - At least 5 headache attacks without aura meet episodic migraine criteria 1 to 3, and/or at least 5 headache attacks with aura meet episodic migraine criteria 2 to 3
    - On more than 8 days per month for more than 3 months, fulfilling any of the following criteria:
        - For migraine without aura, episodic migraine criteria 2 and 3
        - For migraine with aura, episodic migraine criteria 1 and 2

- Believed by the patient to have migraine at onset and relieved by a triptan or ergot derivative.

Migraine attacks, whether due to episodic or chronic migraine, require acute management. The goal of acute treatment is to provide pain and symptom relief as quickly as possible while minimizing adverse effects, with the intent of timely return to normal function. Pharmacologic interventions for treatment of acute migraine vary according to migraine severity. First-line therapy for an acute episode of mild or moderate migraine includes oral non-steroidal anti-inflammatory drugs (NSAIDs) or acetaminophen. Moderate to severe migraine can be treated through the use of triptans or an NSAID-triptan combination. Antiemetics can be added for migraine accompanied by nausea or vomiting, though certain antiemetic medications used as monotherapy can also provide migraine relief. Other pharmacologic interventions used to treat acute migraine include calcitonin-gene related peptide antagonists, which can be used in patients with an insufficient response or contraindications to triptans, lasmiditan, and dihydroergotamine. Migraine can be managed at home, although acute migraine is a frequently cited reason for primary care and emergency department visits.[5] Regular use of pharmacologic interventions can result in medication overuse, which in turn could lead to rebound headache and increased risk of progression from episodic to chronic migraine.[4]

Many individuals who suffer from migraine may also benefit from preventive migraine therapy, including those with frequent or long-lasting 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.[6,7,8] The main goals of preventive therapy are to reduce future attack frequency, severity, and duration, improve responsiveness to acute treatments, improve function and reduce disability, and prevent progression of episodic migraine to chronic migraine. For most adults with episodic migraines who may benefit from preventive therapy, initial therapy with an antiepileptic drug (divalproex sodium, sodium valproate, topiramate) or beta-blockers (metoprolol, propranolol, timolol) is recommended. Frovatriptan may be beneficial as initial therapy for prevention of menstrually associated migraine. Antidepressants (amitriptyline, venlafaxine), alternative beta-blockers (atenolol, nadolol), and additional triptans (naratriptan, zolmitriptan for menstrually associated migraine prevention) may be considered if initial therapy is unsuccessful. For preventive treatment of pediatric migraine, many children and adolescents who received placebo in clinical trials improved and most preventive medications were not superior to placebo. Possibly effective preventive treatment options for children and adolescents may include amitriptyline, topiramate, or propranolol.

Remote Electrical Neuromodulation

REN may offer an alternative to pharmacologic interventions for patients with acute migraine or it may decrease the use of abortive or preventive medications and the risk of medication overuse to treat or prevent acute migraines. The only currently available REN device (Nerivio) cleared for use by the Food and Drug Administration (FDA) is worn on the upper arm and stimulates the peripheral nerves to induce conditioned pain modulation (CPM). The conditioned pain in the arm induced by the Nerivio REN device is believed to reduce the perceived migraine pain intensity.[9] Control of the REN device is accomplished through Bluetooth communication between the device and the individual's smartphone or tablet. For acute treatment, at onset of migraine or aura and no later than within one hour of onset, the user initiates use of the device through their mobile application. When used for preventive treatment, the device should be used every other day, controlled by the individual through their smartphone or tablet application. Patient-controlled stimulation intensity ranges from 0 to 100%, corresponding to 0 to 40 milliamperes (mA) of electrical current. Patients are instructed to set the device to the strongest stimulation intensity that is just below their perceived pain level. The device provides stimulation for up to 45 minutes before turning off automatically. The Nerivio manufacturer indicates that the device can be used instead of or in addition to medication.

Summary of Evidence

For individuals with acute migraine due to episodic or chronic migraine who receive remote electrical neuromodulation (REN), the evidence includes two 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 two-hour follow-up compared with a sham device based on two 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. No significant between-group difference in functional disability or quality of life was noted in a post-hoc analysis of the pivotal RCT. Additionally, controlled studies in adolescent and pediatric populations are lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For adult 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 one

RCT and one 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 one (N=248) RCT. Prospective, observational data in two real world evidence studies using the device for acute treatment of migraine, demonstrated a significant reduction in migraine headache days from baseline to months two and three 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.

For adolescent individuals who may benefit from preventive migraine therapy who receive REN, the evidence includes data from the summary submitted in the FDA approval packet and one real-world evidence (RWE) analysis. The data in the FDA summary were collected from adolescents who used the device for acute migraine treatment, but use was equivalent to the suggested preventive use (10 times per month or higher). There was substantial reduction from baseline during months two and three of device use. This data is limited by a lack of comparator and no description of medications or alternative interventions patients were additionally using. A prospective, real-world evidence analysis investigated the use of Nerivio in adolescents over a three-month period. There was a statistically significant monthly reduction in mean monthly migraine treatment days. Well-defined, controlled studies are required to confirm benefit in this population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For children who may benefit from preventive migraine therapy who receive REN, the evidence includes the FDA summary for the expanded approval of preventive use of Nerivio in pediatric patients (ages 8-11) based on a retrospective real-world analysis. Preventive use of the device was assumed by analyzing patients whose frequency of use in month one was suggestive of preventive treatments. No specific data on proportion of patients in whom preventive use was assumed or efficacy outcomes in the assumed preventive use population were reported. Well-defined, controlled studies are required to confirm benefit in this population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT05940870[a]	A Prospective, Open-label, Post-marketing Observational Study Assessing the Safety and Efficacy of Nerivio for Migraine Prevention in Real-world Environment	250	Aug 2024 (completed)

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2025 Input

Clinical input was sought to help determine whether the use of remote electrical neuromodulation (i.e., Nerivio) for the listed populations would provide a clinically meaningful improvement in net health outcome and represents generally accepted medical practice:

- Individuals who are 12 years and older with episodic or chronic migraine, with or without aura, who are treated for acute migraine or migraine prophylaxis
- Individuals who are 8-11 years old with episodic or chronic migraine, with or without aura, who are treated for acute migraine or migraine prophylaxis

In response to structured requests, clinical input was received from four respondents, including one physician-level respondent identified by the American Academy of Neurology (AAN), and three physician-level responses identified by various academic medical centers. In addition, an informal response was provided by the American Academy of Pediatrics Section on Neurology (AAP).

Clinical input supports this use provides a clinically meaningful benefit, with the majority of respondents supportive that its use is consistent with generally accepted medical practice. Respondents noted that all patients 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. While some clinicians trial acute treatment with REN first, failure in the abortive setting does not preclude success with preventive use. Additionally, clinicians support first-line use of REN for acute or preventive treatment, particularly in adolescent and pediatric populations where there are limited alternatives with evidence of efficacy or suitable side effect profiles. Respondents emphasize that the discreet nature of the REN device is ideal for use by chldren and adolescents in the school setting.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the 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 issued 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[33], 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
- The patient is at least 18 years of age (the guidance noted that 3 devices, including REN, are approved for use in patients aged 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.

Department of Veterans Affairs/ Department of Defense

The US Department of Veterans Affairs/Department of Defense (VA/DoD) 2023 guidelines for the management of headache state that "there is insufficient evidence to recommend for or

against any form of neuromodulation for the treatment and/or prevention of migraine"; examples of neuromodulation treatments mentioned include remote electrical neurostimulation.[35]

Medicare National Coverage

There is no national coverage determination.

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 of age or older and was cleared for marketing through the 510(k) process (K223169).[13] In May 2025, the Nerivio and rechargeable Nerivio Infinity devices were cleared for marketing (K241756) with an expanded indication for acute and/or preventive treatment of migraine with or without aura in patients 8 years and older.[14]

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History

Date	Comments
08/01/22	New policy, approved July 12, 2022. Policy created with literature review through March 22, 2022. Remote electrical neuromodulation for acute migraine (e.g., Nerivio) is considered investigational. Formerly on policy 1.01.507 Electrical Stimulation Devices.
01/01/24	Annual Review, approved December 11, 2023. Policy updated with literature review through August 29, 2023; references added. Policy statement modified to include prevention of migraine based on recent expansion of FDA-approved indications. Policy statement now reads: remote electrical neuromodulation for acute migraine or

Date	Comments
	prevention of migraine is considered investigational. Added new HCPCS code A4540 and termed HCPCS code K1023.
01/01/25	Annual Review, approved December 9, 2024. Policy updated with literature review through August 9, 2024; references added. Policy statements unchanged. Removed HCPCS Code K1023.
01/01/26	Annual Review, approved December 9, 2025. Policy updated with literature review through August 18, 2025; references added. Policy statement on REN changed from investigational to medically necessary in adults for prevention of migraine when criteria are met. Treatment of acute migraine remains investigational.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.