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MEDICAL POLICY – 7.01.171

Remote Electrical Neuromodulation for Migraines

BCBSA Ref. Policy:	7.01.171	
Effective Date:	Jan. 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	Dec. 11, 2023	None
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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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. The use of remote electrical neuromodulation to treat migraine headaches is unproven (investigational). More studies are needed to see if this type of treatment improves health outcomes.

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	Investigational
Remote electrical neuromodulation (REN)	**Remote electrical neuromodulation (REN) for acute migraine or prevention of migraine is considered investigational. (e.g., Nerivio)**

Coding

Code	Description
HCPCS	
A4540	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm (Nerivio) (new code effective 1/1/2024)
K1023	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm (Nerivio) (code termed effective 1/1/2024)

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

N/A

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 United States 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 be 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 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. 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 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 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 two and thre 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.

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
Ongoing			

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT05102591	A Pilot Clinical Trial of a New Neuromodulation Device for Acute Attacks of Migraine in Children and Adolescents Visiting the Emergency Department	40	Feb 2025
NCT05940870[a]	A Prospective, Open-label, Post-marketing Observational Study Assessing the Safety and Efficacy of Nerivio for Migraine Prevention in Real-world Environment	300	May 2024

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

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 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 2019 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[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.

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 and age or older and was cleared for marketing through the 510(k) process (K223169).[13]

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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 prevention of migraine is considered investigational. Added new HCPCS code A4540 and termed HCPCS code K1023.

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ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-722-1471 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-722-1471 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-722-1471 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-722-1471 (TTY: 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-722-1471 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-722-1471 (TTY: 711).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-722-1471 (ATS : 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-722-1471 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-722-1471 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-722-1471 (TTY: 711) تماس بگیرید.