MASSACHUSETTS

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Medical Policy

Remote Electrical Neuromodulation for Migraines

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Policy Number: 145

BCBSA Reference Number: 7.01.171 (For Plan internal use only)
NCD/LCD: N/A

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

Remote electrical neuromodulation for acute migraine or prevention of migraine is considered **INVESTIGATIONAL**.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is **not** a covered service.
Commercial PPO and Indemnity	This is **not** a covered service.
Medicare HMO Blue[SM]	This is **not** a covered service.
Medicare PPO Blue[SM]	This is **not** a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following HCPCS code is considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
A4540	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm

Description

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:

1. Untreated or unsuccessfully treated headache lasting 4 to 72 hours
2. Headache has at least 2 of the following characteristics:
    a. Unilateral location
    b. Pulsating quality
    c. Moderate or severe pain intensity
    d. Aggravation by or causing avoidance of routine physical activity
2. At least 1 of the following during headache:
    a. Nausea and/or vomiting
    b. Photophobia or phonophobia.

Chronic migraine:

1. Migraine-like or tension-type headache on 15 or more days per month for more than 3 months
2. 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
3. On more than 8 days per month for more than 3 months, fulfilling any of the following criteria:
    1. For migraine without aura, episodic migraine criteria 2 and 3
    2. For migraine with aura, episodic migraine criteria 1 and 2
    3. 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

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 patient's smartphone or tablet. For acute treatment, at~~At~~ onset of migraine or aura and no later than within 1 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

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.

Summary of Evidence

For individuals with acute migraine due to episodic or chronic migraine who receive remote electrical neuromodulation (REN)~~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.

Policy History

Date	Action
5/2024	Added coverage information above code table.
3/2024	Annual policy review. 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 investigational. Effective 3/1/2024.
1/2024	Coding information clarified.
7/2022	New medical policy describing ongoing investigational indications. Code K1023 was transferred from MP 400 Medical Technology Assessment Noncovered Services.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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