MASSACHUSETTS

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Medical Policy

Remote Electrical Neuromodulation for Migraines

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Policy Number: 145

BCBSA Reference Number: N/A
NCD/LCD: N/A

Related Policies

Anti-Migraine Policy #021

Policy[1]

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

Treatment of acute migraines

The use of the remote electrical neuromodulation (REN) device Nerivio™, for the treatment of acute migraines may be considered **MEDICALLY NECESSARY** when **all** the following criteria have been met:

- Individual is 12 years of age or older
  AND
- Individual is experiencing one or more of the following
  - Contraindication to migraine medications (Triptans and/or gepants) **OR**
  - Adverse effects or unsatisfactory performance from guideline-directed therapy

  AND
- Individual meets one or more of the following criteria
  - Acute onset of migraine headache with or without aura **OR**
  - Onset of aura usually associated with migraine headache in the individual.

Preventive treatment of chronic or recurrent migraines

The use of the remote electrical neuromodulation (REN) device Nerivio™, for the preventative treatment of chronic or recurrent migraines may be considered **MEDICALLY NECESSARY** when all the following criteria have been met:

- Individual is 12 years of age or older, **AND**
- Experiencing 4 or more migraine headache days per month (prior to initiating a migraine preventative medication(s)); **AND**

- Previous trial with an inadequate response, adverse reaction, or contraindication to at least **TWO (2)** different classes of medications recommended for preventive treatment of migraines (e.g., beta blockers, tricyclic antidepressants, anticonvulsants, calcium channel blockers in adults OR cyproheptadine in children).

The use of Nerivio™ for any other indication than that listed above is considered **INVESTIGATIONAL**.

The use of any other remote neuromodulation device for the treatment of migraines 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)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

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 above medical necessity criteria MUST be met for the following codes to be covered 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

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

ICD-10-CM diagnosis codes:	Code Description
G43.001	Migraine without aura, not intractable, with status migrainosus
G43.009	Migraine without aura, not intractable, without status migrainosus
G43.011	Migraine without aura, intractable, with status migrainosus
G43.019	Migraine without aura, intractable, without status migrainosus

G43.101	Migraine with aura, not intractable, with status migrainosus
G43.109	Migraine with aura, not intractable, without status migrainosus
G43.111	Migraine with aura, intractable, with status migrainosus
G43.119	Migraine with aura, intractable, without status migrainosus
G43.401	Hemiplegic migraine, not intractable, with status migrainosus
G43.409	Hemiplegic migraine, not intractable, without status migrainosus
G43.411	Hemiplegic migraine, intractable, with status migrainosus
G43.419	Hemiplegic migraine, intractable, without status migrainosus
G43.501	Persistent migraine aura without cerebral infarction, not intractable, with status migrainosus
G43.509	Persistent migraine aura without cerebral infarction, not intractable, without status migrainosus
G43.511	Persistent migraine aura without cerebral infarction, intractable, with status migrainosus
G43.519	Persistent migraine aura without cerebral infarction, intractable, without status migrainosus
G43.601	Persistent migraine aura with cerebral infarction, not intractable, with status migrainosus
G43.609	Persistent migraine aura with cerebral infarction, not intractable, without status migrainosus
G43.611	Persistent migraine aura with cerebral infarction, intractable, with status migrainosus
G43.619	Persistent migraine aura with cerebral infarction, intractable, without status migrainosus
G43.701	Chronic migraine without aura, not intractable, with status migrainosus
G43.709	Chronic migraine without aura, not intractable, without status migrainosus
G43.711	Chronic migraine without aura, intractable, with status migrainosus
G43.719	Chronic migraine without aura, intractable, without status migrainosus
G43.A0	Cyclical vomiting, in migraine, not intractable
G43.A1	Cyclical vomiting, in migraine, intractable
G43.B0	Ophthalmoplegic migraine, not intractable
G43.B1	Ophthalmoplegic migraine, intractable
G43.C0	Periodic headache syndromes in child or adult, not intractable
G43.C1	Periodic headache syndromes in child or adult, intractable
G43.D0	Abdominal migraine, not intractable
G43.D1	Abdominal migraine, intractable
G43.801	Other migraine, not intractable, with status migrainosus
G43.809	Other migraine, not intractable, without status migrainosus
G43.811	Other migraine, intractable, with status migrainosus
G43.819	Other migraine, intractable, without status migrainosus
G43.821	Menstrual migraine, not intractable, with status migrainosus
G43.829	Menstrual migraine, not intractable, without status migrainosus
G43.831	Menstrual migraine, intractable, with status migrainosus
G43.839	Menstrual migraine, intractable, without status migrainosus
G43.901	Migraine, unspecified, not intractable, with status migrainosus
G43.909	Migraine, unspecified, not intractable, without status migrainosus
G43.911	Migraine, unspecified, intractable, with status migrainosus
G43.919	Migraine, unspecified, intractable, without status migrainosus
G43.E01	Chronic migraine with aura, not intractable, with status migrainosus
G43.E09	Chronic migraine with aura, not intractable, without status migrainosus
G43.E11	Chronic migraine with aura, intractable, with status migrainosus
G43.E19	Chronic migraine with aura, intractable, without status migrainosus

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.[21,] Overall migraine prevalence in the United States is about 15% but varies according to population group.[4,] 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.[15,] Specific International Classification of Headache Disorders[1,] 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.[3,] 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.[3,]

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.[13] 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 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), the evidence includes 2 randomized controlled trials (RCTs), an observational study, a systematic review and meta-analysis, and multiple reviews, data analysis, and clinical trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. In a randomized, double-blind, sham-controlled, multicenter study, use of an active REN device resulted in pain relief and pain freedom of 66.7% and 37.4% of participants respectively at 2 hours post-treatment. Pain relief and pain freedom was sustained 48 hours post-treatment.[22] The participants of this study were invited to continue in an open label extension lasting 8 weeks with incorporation of the REN device into their usual care. Of the 117 participants in this phase 89.7% treated their migraine attacks with only the REN device. The authors concluded that REN may reduce the use of acute migraine medications.[9] A randomized, double-blind, parallel-group, sham-controlled, multicenter study performed a post-hoc analysis of a subgroup of participants from the Yarnitsky et. al. RCT and found that REN is non-inferior to current acute migraine therapies. Use of REN in adolescents has also been evaluated via a clinical trial and a post hoc analysis. Outcomes suggest that use of REN may have a higher efficacy than certain pharmacological treatments for the acute treatment of migraines in adolescents.[7,8] Based on the existing evidence REN use has a very low incidence of adverse events, hence it is a safe, stable and effective treatment for acute migraines. The evidence 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 one clinical trial. 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. 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, Nerivio is safe and could provide meaningful reduction in the amount of migraine days per month. Nerivio could also 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.[10]The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
2/2025	New medical policy describing medically necessary indications for remote electrical neuromodulation using Nerivio™. Effective 2/1/2025.

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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Endnotes

[1] Based on expert opinion