DRAFT Medical Coverage Policy | Remote Electrical Neuromodulation for Migraines

EFFECTIVE DATE: 12|01|2022
POLICY LAST UPDATED: 08|17|2022

OVERVIEW
Migraine attacks due to episodic or chronic migraine require acute management. Current first-line therapy for treatment 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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Remote electrical neuromodulation for acute migraine is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
Remote electrical neuromodulation for acute migraine is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not covered/not medically necessary benefits/coverage.

BACKGROUND
Migraine is a neurologic disease characterized by recurrent moderate to severe headaches with associated symptoms that can include aura, photophobia, nausea, and/or vomiting. Overall migraine prevalence in the United States is about 15% but varies according to population group. Prevalence is higher in women (21%), among American Indian/AlaskaNatives (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.

Remote electrical neuromodulation (REN) may offer an alternative to pharmacologic interventions for patients with acute migraine or it may decrease the use of abortive medications and the risk of medication overuse to treat 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. Control of the REN device is accomplished through Bluetooth communication between the device and the patient's smartphone or tablet. 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. Patient-controlled stimulation intensity ranges from 0 to 100%, corresponding to 0 to 40milliamperes (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.

For individuals with acute migraine due to episodic or chronic migraine who receive 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.

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). 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. 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.

CODING
The following code(s) is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products when filed with the following ICD-10-CM codes:

HCPCS Code:
K1023 Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm

ICD-10-CM Codes
G43.001 to G43.719
G43.801 to G43.919

RELATED POLICIES
Not applicable

PUBLISHED
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