MEDICAL POLICY

Medical Policy Title	**Specialized Neuromodulation for Specific Conditions**
Policy Number	**1.01.62**
Current Effective Date	**May 21, 2026**
Next Review Date	**May 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

I. The following neuromodulation modalities are **investigational** for all indications:

A. Transcutaneous Afferent Patterned Stimulation (TAPS) [e.g., Cala One, Cala Trio, Felix NeuroAI];

B. Remote Electrical Neuromodulation (REN) [e.g., Nerivio].

RELATED POLICIES

Corporate Medical Policy

1.01.01 Durable Medical Equipment (DME) and Devices, Standard and Non-Standard

1.01.07 Medical Management of Obstructive Sleep Apnea

1.01.19 Pelvic Floor Electrical Stimulation as a Treatment for Urinary or Fecal Incontinence

1.01.58 Cranial and Auricular Neurostimulation

1.01.59 Electromagnetic and Pulsed Field Stimulation

1.01.60 Implantable and Invasive Neuromodulation Systems

1.01.61 Non-Invasive Surface Electrical Stimulation for Pain and Rehabilitation

7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy

7.01.10 Sacral Nerve Stimulation

7.01.41 Surgical Management of Sleep Disorders

8.01.22 Tibial Nerve Stimulation (TNS) for Voiding Dysfunction

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Remote Electrical Neuromodulation (REN)

REN is a nonpharmacologic abortive treatment for migraine. The Nerivio device (Theranica) was cleared by the FDA through de novo classification in 2019 for the treatment of acute migraine in adults who do not have chronic migraine. It is a wireless stimulation device applied to the lateral upper arm in 45-minute sessions and triggers weak electrical impulses to start conditioned pain modulation, a proprietary electrical signal to stimulate noxious sensory fibers and relieve acute migraine. It is controlled by a mobile app that includes a migraine diary to track migraine headaches and treatment sessions. Each device had a shelf life of 8 treatments, after which, it was disposed of and a new device was required. In October of 2020, Nerivio was cleared for marketing through the 510(k) process, removing the exclusion of chronic migraine and extending its shelf life to 12 treatments. In January 2021, the FDA expanded the age clearance in 12-year-olds. In February of 2023, the indications were further expanded to include the preventative treatment of migraine with or without aura in individuals 12 years of age and older. In May of 2025, both the Nerivio and the rechargeable Nerivio infinity devices were cleared for marketing with an expanded indication for acute and/or preventative treatment of migraines with or without aura in patients eight years of age or older. The Nerivio infinity refill units are used for 18 treatments. Nerivio is considered 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.

Afferent Patterned Stimulation Therapy for Essential Tremor

The Cala Trio (Cala Health) is an external upper limb stimulator. It is a hand-specific device indicated to relieve tremors in adults with essential tremor. The device is worn like a wristwatch. Electrodes embedded into a disposable cloth band deliver stimulation to the median and radial nerves of the wrist after being calibrated to the specific motion of the user. The digital display provides prompts, time, offers the ability to adjust intensity and notifies the user when the band requires changing. The contained accelerometer measures the tremor and adjusts simulation. Sessions are for 40-minutes, and the device is recommended to be used twice daily prior to activities requiring use of that hand.

SUPPORTIVE LITERATURE

Remote Electrical Neuromodulation

Yarnitsky et al (2019) conducted a vendor- funded double blind RCT from involving 252 patients at 12 different sites who met the international classification of headache disorders criteria for migraine, had two to eight migraines per month and less than 12 headache days per year. The authors aimed to evaluate the efficacy and safety of REN for the acute treatment of migraine. Treatment sessions with the device were 45 minutes. Pain relief was defined as improvement from severe or moderate pain to mild or none, or improvement from mild pain to none, of which 66.7% of the active treatment group achieved pain relief at 2 hours post-treatment compared to 38% in sham group. Sustained relief (48 hours post treatment) was achieved by 39% of the treatment group, and 16% of the sham group. Adverse events were mild and rare. The authors report that the findings are equivalent to migraine relief found with triptan use. The approval of Nerivio for adolescents was based on a study

by Hershey et al (2020), a vendor-funded single-arm multicenter study of 39 patients with migraine between the ages of from the ages of 12 and 17. Pain relief at 2 hours was achieved by 71% (28/39) of the patients, and 35% (14/39) were pain free within 2 hours. Study enrollment was shortened to 60% of the planned target due to the coronavirus pandemic however since pain relief at 2 hours was achieved by more than 60% it was determined to be complete. Of those that had pain relief and pain freedom, 90% had sustained relief or freedom for 24 hours. Additional symptoms of nausea, photophobia and phonophobia disappeared at 2 hours in 54%, 41% and 40% of treated individuals. There were mild and low device related adverse events for both of the studies. The writers concluded that Nerivio is both safe and effective for the treatment of acute migraine in adolescents. Longer and larger RCTs with relevant comparators are needed to determine if results can be replicated in other populations, and if the treatment is superior to the current standard of care.

Alnajjar and colleagues (2025) aimed to evaluate the safety and efficacy of remote electrical neuromodulation (REN) in order to address current gaps in the literature. Of a total of 182 articles, 12 studies met eligibility criteria (published in peer-reviewed journals, single-arm studies, observational studies, RCTs, non-randomized controlled trials, and crossover studies including children or adults having migraine attacks and using REN alone for acute or preventive migraine treatment. The authors noted a concern for bias related to the analysis as well as missing outcome data (Yarnitsky 2017). The results of the review demonstrated that REN significantly reduced pain two hours after migraine attacks in 64% of the population (based on a single-arm meta-analysis), and that pain free status at 2 hours post treatment was achieved in 22 % of the patients. There were no serious systemic adverse events, device related events were experienced by 0.4% of the patients and included symptoms such as bilateral tingling of the temples, double vision, redness, skin rash, and pain in the arm. The authors concluded that REN has been confirmed as safe and effective, but that further research is needed to assess long term benefits. Further, that future research should focus on longer and larger RCTs and included parallel comparisons with other neuromodulation techniques (e.g., transcranial magnetic stimulation or vagus nerve stimulation), as well as the inclusion of subgroup analyses on the type of migraine to guide more personalized treatment strategies.

Afferent Pattern Stimulation

Pahwa et al (2019) studied the use of a novel peripheral (radial and median nerves) stimulation device for the treatment of essential tremor via a RCT of 77 patients and compared to sham stimulation. Although the primary endpoint (an improvement in the Tremor Research Group Essential Tremor Rating Assessment Scale (TETRAS) Archimedes spiral scores) was not met, the authors noted significant improvements in some subject-rated tasks in activities of daily living and clinical global impression-improvement (CGI-I) rating after stimulation. The outcomes were similar to the ranges of improvement offered by standard medications utilized for the treatment of tremor. The authors concluded that peripheral nerve stimulation may provide a safe, well-tolerated, and effective treatment for transient relief of hand tremor symptoms, however future studies over time and multiple sessions are needed.

Isaacson et al (2020) evaluated the repeated home use of an FDA-cleared wrist-worn neuromodulation device in the Prospective Study for Symptomatic Relief of Essential Tremor with

Cala Therapy (PROSPECT) trial. For each active treatment session, the device electrically stimulated the median and radial nerves for 40 minutes with an alternating burst pattern tuned to the frequency of each patient's tremor. The pre-specified co-primary endpoints were improvements on the clinician-rated Tremor Research Group Essential Tremor Rating Assessment Scale (TETRAS) and patient-rated Bain & Findley Activities of Daily Living (BF-ADL) dominant hand scores. Of the 263 enrolled patients, 205 completed the visit three follow-up and were included in the primary analysis. Results revealed a significant improvement in TETRAS and BF-ADL from pre- to post-stimulation at each clinic visit ($p<.0001$ for all comparisons). Pre-stimulation tremor levels were improved from Visit 1 to 3 on both TETRAS and BF-ADL ($p<.0001$ for both). Patients rated as "severe" or moderate" improved with both TETRAS (49.3% at baseline to 21% at study exit) and BF-ADL (64.8% at baseline to 23% at study exit) scoring. Tremor power is a calculation of amplitude and frequency. Tremor power decreases with lower amplitude motions and lower frequency motions. Tremor power was also noted to significantly improve with therapy from pre- to post-stimulation ($p<.0001$). No device-related serious adverse events were reported. Non-serious device related adverse events occurred in 18% of patients (e.g., persistent skin irritation, sore/lesion, discomfort, electrical burns, and minor skin irritation). Conclusions were that the repeated in-home use of this neuromodulation device over three months was effective and safe for patients with essential tremor. Limitations identified were the open-label, single-arm design, the lack of consensus for the definition of clinically meaningful improvement in TETRAS or BF-ADL, as well as the exclusion of 58 patients who exited the study early from the pre-specified primary and secondary endpoint analyses.

PROFESSIONAL GUIDELINE(S)

The International Headache Society (IHS) established a working group to evaluate and grade the available studies on the efficacy of The United States Food and Drug Administration (FDA)-cleared or CE-marked non-invasive neuromodulation devices, while also developing evidence-based guidelines on the use of the devices in the treatment of migraine in all age populations. The guidelines reviewed eight total devices, including Nerivio and asked whether the devices are superior to sham treatments for both the acute and preventive treatment of migraines. 15 studies out of 957 identified studies were included in the review with two randomized controlled trials available for the review of Nerivio (Yarnitsky 2019 and Theranica 2017). The panel issued conditional recommendations for the use of Nerivio for treatment of acute and preventative migraine in adult subjects, stating that the strength of recommendation was 1) weak in favor, and 2) the quality of evidence cited as very low (Yuan et al 2025).

REGULATORY STATUS

The FDA regulates electrical stimulation devices as medical devices. All electrical stimulation devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 July 27]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 July 27]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

HCPCS Codes

Code	Description
A4540 (E/I)	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm (e.g., Nerivio)
A4542 (E/I)	Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist
E0734 (E/I)	External upper limb tremor stimulator of the peripheral nerves of the wrist (e.g., Cala Trio, Felix NeuroAI)
E1399 (*E/I)	Durable medical equipment, miscellaneous (*E/I when used for any of the modalities included within this policy.)

ICD10 Codes

Code	Description
G25.0	Essential Tremor
G43.001-G43.919	Migraine (code range)
R51.0-R51.9	Headache (code range)

REFERENCES

Hershey AD, et al. Remote electrical neuromodulation for acute treatment of migraine in adolescents. Headache. 2020 Nov 16;61:310-317.

Isaacson SH, et al. Prospective home-use study on non-invasive neuromodulation therapy for essential tremor. Tremor Other Hyperkinet Mov. 2020 Aug 14;10:29.

Pahwa R, et al. An acute randomized controlled trial of noninvasive peripheral nerve stimulation in essential tremor. Neuromodulation. 2019;22:537-545.

Theranica [Internet]. A prospective, randomized, double-blind, sham controlled multi-center clinical trial- migraine headache treatment with Nerivio migra neurostimulation device. 2017 March 03 [updated 2025 July 07, accessed 07/29/26). Available from: Study Results | NCT03076515 | Migraine Treatment With Nerivio Migra Neurostimulation Device | ClinicalTrials.gov

VanderPluym, JH, et al. A narrative review of treatments on the horizon for migraine in children and adolescents. Neurology. 2023;101:788-797.

Yarnitsky D, et al. Nonpainful remote electrical stimulation alleviates episodic migraine pain (Abstract). Neurology. 2017 Mar 28;88(13):1250-1255.

Yarnitsky D, et al. Remote electrical neuromodulation (REN) relieves acute migraine: a randomized, double-blind, placebo-controlled, multicenter trial. Headache J Head Face Pain. 2019;59:1240–52.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

External Upper Limb Tremor Stimulator Therapy (LCD L39591) [accessed 2026 July 27]

External Upper Limb Tremor Stimulator Therapy (LCA A59680) [accessed 2026 July 27]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

05/21/26	
Date	**Summary of Changes**
08/24/26	Policy edit, updates to policy description, and professional society guidelines. No change to policy intent.
05/21/26	New Policy with effective date of 05/21/26; policy content derived from 1.01.55 Electrical Stimulation as a Treatment for Pain and Other Medical Conditions.