Molina Clinical Policy
Remote Electrical Neuromodulation (REN) for Migraines: MEDICARE
Policy No. 491b

Initial Approval: 10/21/2026
Next Review Due By: October 2027

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment. Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of the Federal government or CMS for Medicare. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Migraine is a primary headache disorder. Under the International Classification of Headaches Disorders, 3rd edition, (ICHD-3), migraine without aura is diagnosed when a patient has had at least five attacks lasting 4-72 hours untreated, the pain has at least two of four features (unilateral location, pulsating quality, moderate or severe intensity, or aggravation by routine physical activity), and the attack is accompanied by nausea and/or vomiting or photophobia and phonophobia , and is not better accounted for by another diagnosis. Migraine with aura is classified separately when reversible focal neurologic symptoms precede or accompany the headache (Headache Classification Committee of the International Headache Society [IHS] 2018).

Compared with people who do not have migraines, U.S. adults with migraines have higher direct medical spending and lower quality of life (Masurkar and Goswami 2024). In Medical Expenditure Panel Survey data from 2019 through 2021, migraine was associated with approximately $6,079 in additional annual health care expenditures after adjustment, with prescription drugs accounting for a substantial proportion of overall spending, especially as newer preventive therapies, including calcitonin gene-related peptide (CGRP) monoclonal antibodies, contributed to increased pharmacy expenditures (Nguyen et al. 2022).

Treatment for migraines is divided into acute treatment or preventative treatment, dependent on the frequency and severity of migraine attacks. Acute treatment is given at the onset of headache or aura to abort or reduce the severity. Acute treatment is typically pharmacotherapy (e.g., nonsteroidal anti-inflammatory drugs, triptans, ditans, gepants, etc.), with a few newer FDA approved over-the-counter noninvasive electrical devices that show promise in treating acute migraines. Some examples include Cefaly Dual, HeadaTerm 2, and the Enso for Migraine. Preventive treatment's goal is to reduce attack frequency, severity, and associated disability in people with frequent or disabling migraine. Options include selected antihypertensives, anticonvulsants, antidepressants, onabotulinumtoxinA, and CGRP-targeted therapies (Ailani 2021; [1]Puledda 2024; [2]Puledda 2024; Schwedt and Garza 2026).

Remote electrical neuromodulation (REN) is a novel approach to acute and preventive migraine treatment. REN devices are a prescribed, wearable, smartphone-controlled device applied to the upper arm. The unit delivers patient adjusted, non-painful electrical pulses for approximately 45 minutes. The proposed mechanism is conditioned pain modulation by stimulating peripheral C and Aδ nociceptive fibers in the arm with the intention to activate an endogenous descending pain-inhibitory pathway that can reduce pain remote from the stimulation site, including the head. The device can be used as both preventative and acute treatment, as it is approved for use at the onset of headache or aura, and/or every other day as prevention (Yarnitsky 2019).

Regulatory Status

Nerivio and Nerivio Infinity (Theranica Bio-Electronics Ltd.) are the commercially available REN systems in the United States. Nerivio originally received FDA authorization through the De Novo pathway (DEN 180059), on May 20, 2019, as a Class II trunk and limb electrical stimulator to treat headache, product code QGT. That first order was limited to acute treatment of migraine with or without aura in adults 18 years of age or older who did not have chronic migraine. The devices have had multiple subsequent approvals via the 510(k) pathway with the latest clearance (K241756) for acute and/or preventive treatment of migraines with or without aura in patients 8 years of age or older (FDA 2024).

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COVERAGE POLICY

Remote electrical neuromodulation (REN), including but not limited to Nerivio and Nerivio Infinity devices, for the treatment of migraines is considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

DOCUMENTATION REQUIREMENTS: Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the Member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

The published evidence from 2019 to 2025 includes a small number of randomized trials, several open label studies used to support label expansion, manufacturer associated real world analysis drawn from device application diary, and recent reviews that combine these mixed designs. A 2025 systematic review counted four randomized trials among 12 included studies. Two of those randomized trials are the sham-controlled studies that inform the current acute and preventive labels in adults (Tepper 2023; Yarnitsky 2019). The remaining trials are limited in size, design, or were conducted as part of the manufacture's own developmental program rather than an independent research group. Overall, the available studies do not adequately define durability, comparative effectiveness versus established abortive and preventive therapies, or a reproducible place in the current treatment pathway.

Randomized Controlled Trials

Tepper et al. (2023) assessed REN every other day for migraine prevention in a multicenter, double-blind, sham-controlled trial. Two hundred forty-eight adults with episodic or chronic migraine were randomized (128 active, 120 sham). One hundred seventy-nine met criteria for the modified intention-to treat analysis (95 active, 84 sham). The intervention period was 8 weeks. The primary endpoint was change from baseline in mean monthly migraine days. In the modified intention-to-treat population, active treatment reduced migraine days by 4.0 days per month compared with 1.3 days with sham (net difference 2.7 days). The difference remained statistically significant when episodic and chronic subgroups were analyzed separately. Secondary results favored active treatment for moderate to severe headaches, headache days of all severities, the proportion of participants with at least a 50% reduction in moderate-to-severe headache days (51.6% versus 35.7%), and days of acute medication use. No serious device related adverse effects were reported. This trial provided the primary clinical evidence supporting FDA clearance of preventive use in patients 12 years of age or older (K223169), with labeled every-other-day dosing. The study is the only sham-controlled prevention trial of the device. Limitations include short follow up time, small sample size, the trial was industry sponsored, and it did not compare with standard treatment options. The results support a short-term reduction in migraine days versus sham. They do not establish durability beyond eight weeks, comparative effectiveness versus covered preventative drugs, or net health benefit in routine covered care.

Yarnitsky et al. (2019) conducted a multicenter, double-blind, sham-controlled trial of acute REN in 252 adults aged 18 to 75 years with two to eight migraine days per month. Participants treated a qualifying attack within one hour of onset. Among those with evaluable 2-hour data, pain relief occurred in 66.7% of the active group and 38.8% of the sham group. Pain freedom at two hours was 37.4% versus 18.4%. Relief of the most bothersome symptom also favored active stimulation. At 48 hours, sustained pain relief (without rescue medication) was achieved in 39.1% of the active group and 16.9% of the sham group. Sustained pain freedom was seen in 20.7% of the active group versus 7.9% of the sham group. The proportion of participants who were completely free of their most bothersome symptoms at 2 hours did not differ significantly between groups (40.7% active vs 36.4% sham). Device-related adverse events were infrequent and similar between arms. The trial showed superiority over sham treatment for short-term migraine endpoint in adults with episodic migraine. It does not compare the device with a specified pharmacologic abortive, evaluated on a single treated migraine attack, does not measure longer-term disability or health-service use, and does not establish comparative effectiveness relative to standard acute pharmacologic therapies.

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Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Werner et al. (2024) reported a prospective real-world analysis of acute REN in children aged 6 to 11 years. Data came from the device application diary for U.S. users who treated at least one attack between May 2020 and December 2023. Two hundred ninety-three children were included. A total of 5,493 treatments were logged. Safety was assessed from the overall group that consisted of anyone that simply used the device. There were no serious adverse events reported. However, effectiveness was calculated only for the small number of children who filled out optional pain and function questions at the start of treatment and again at 2 hours. Benefit results therefore apply to far fewer children than the safety results and should not be read as if they represent the fully treated group. In that subset, consistent pain relief was 72.2% (13/18), pain freedom 36% (9/25), functional disability relief 83.3% (8/15), and functional disability freedom 38.9% (7/18). Freedom from associated symptoms in at least half of treated attacks was reported in 7 out of 10 children for nausea and vomiting, 4 out of 8 for phonophobia, and 2 out of 9 for photophobia. Seven of 11 children were free from at least one associated symptom in at least half of treated attacks. These counts are smaller than the pain and function samples and much smaller than the 293-child safety group. The investigators also evaluated repeat device use within 24 hours and interpreted the relatively low frequency of additional treatment sessions as suggestive of limited short-term recurrence. The FDA used this analysis, with prior adolescent data, to extend labeled acute and preventive use to age 8 years (K241756). As this study did not have a control group, results cannot isolate a device effect from placebo response, concurrent medication use, selective or incomplete reporting, natural variation in attack severity, or other sources of bias. Accordingly, the study provides supportive evidence regarding short-term tolerability and feasibility in younger pediatric patients but does not establish comparative effectiveness, long-term clinical benefit, or net health benefit relative to established migraine therapies.

Hershey et al. (2021) assessed acute REN in adolescents 12 to 17 years of age in a prospective, open-label, single arm, multicenter U.S. study. Forty-five adolescents completed at least one treatment. Thirty-nine completed a designated test treatment used for the primary efficacy analysis. Pain relief at 2 hours was reported in 71% (28/39) and pain freedom in 35% (14/39). Among those with functional data, 69% reported improved function at 2 hours. One device related adverse effect (2%) was recorded - temporary pain in the arm. No serious device related events were reported. This study provided key clinical evidence supporting FDA clearance for acute use in patients 12 years of age and older (K203181). The design has no sham or active drug control, and the evaluable efficacy set is small. Results cannot isolate a device effect from placebo response, natural attack resolution, or concurrent abortive medication. Follow-up was limited to short-term treatment outcomes. The study supports short-term tolerability in adolescents. It cannot establish comparative effectiveness or net health benefit for covered care.

Open-label studies in patients with chronic migraine (Nierenburg et al., 2020; Grosberg et al., 2021) reported 2-hour pain-relief rates ranging from 59.3% to 73.7% and low rates of device-related adverse events. However, the absence of a sham or active comparator limits interpretation of treatment effect because improvements may reflect placebo response, regression to the mean, differences in attack characteristics, concomitant medication use, or other sources of bias. These studies provide supportive evidence regarding the feasibility and tolerability of REN in chronic migraine but do not establish comparative effectiveness or net health benefit. The findings contributed to the evidence base supporting expansion of the acute treatment indication to include patients with chronic migraine.

Marmura et al. (2020) reported an open-label extension of the Yarnitsky 2019 adult acute trial. One hundred and seventeen participants with episodic migraine were analyzed. In the earlier run-in attacks were treated with usual medication. In the extension, the device was available. During the extension, 89.7% of participants treated all recorded attacks with the device only and used no abortive medication, compared with 15.4% who avoided medication on all attacks in the run-in (p ($p < 0.0001$). Rates of 2-hour pain relief and pain freedom were similar between the run-in and extension phases. The extension had no concurrent control, and participants knew the device was active. Lower medication use in that setting can reflect choice or expectations, not only a proven drug-sparing effect. The study did not measure medication over-use headaches as a diagnostic outcome. The paper may be noted as context that some trial participants used fewer abortives when the device was available. It does not independently establish net health benefit for coverage.

Rapoport at al. (2019) reported a post-hoc analysis of adults from the Yarnitsky 2019 sham-control trial. During a 2 to 4 week run in, participants treated attacks with their usual medication and recorded 2-hour outcomes. In the subsequent double-blind phase, they used active or sham stimulation. The published comparison was limited to participants who treated at least one attack with active stimulation and had 2-hour pain scores (n=99). Pain relief at 2 hours was 66.7% with active stimulation and 52.5% with that person's earlier care. Pain free rates at 2 hours were

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similar between treatment periods. An additional analysis reported relief in at least one of two attacks more often with the device than with usual care. Usual care was not assigned at random and was not restricted to a single drug class. Regiments included triptans, non-steroidal agents, and other abortives chosen by the participant. The analysis cannot isolate a device effect from sequence, expectation, or differences in which attacks were treated in each phase. It does not establish superiority or non-inferiority of a defined pharmacologic abortive and provides limited evidence regarding comparative effectiveness versus established acute therapies.

National and Specialty Organizations

The **International Headache Society** published the *International Headache society evidence-based guidelines on the use of non-invasive neuromodulation devices for the acute and preventive treatment of migraine* (Yuan 2025) which reviewed cleared neuromodulation products using GRADE. For Nerivio, the panel issued a conditional (weak) recommendation for acute treatment of episodic migraine in adults and a conditional recommendation for prevention of episodic or chronic migraine in adults. Evidence quality for those statements was low or very low. For pediatric populations, evidence was considered insufficient for formal GRADE recommendations. Accordingly, statements regarding pediatric use were based on expert consensus rather than evidence-based recommendations derived from randomized controlled trials.

The **American Headache Society** published *The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice* (Ailani 2021) which provides practical guidance on incorporating newly introduced migraine therapies into clinical practice. It states that a noninvasive neuromodulation device may be used when oral triptans are ineffective, contraindicated, or not tolerated, or when frequent abortive use raises concern for medication over use headache. REN is included among the cleared devices, however Nerivio is not addressed on its own nor compared it with other devices.

The **U.S. Department of Veterans Affairs (VA)** and **U.S. Department of Defense (DoD)** published *Clinical Practice Guideline for the Management of Headache: Recommendation 48* (Sico 2023) which reviewed noninvasive neuromodulation devices, including REN. The work group found insufficient evidence to recommend for or against these devices for the acute treatment or prevention of migraine.

CODING & BILLING INFORMATION

HCPCS (Healthcare Common Procedure Coding System)

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

CODING DISCLAIMER: Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/21/2026 New policy. IRO peer reviewed on September 28, 2026, by a practicing physician board certified in Neurology and Clinical Neurophysiology.

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