

## Medical Policy Manual **Draft New Policy: Do Not Implement**

### Remote Electrical Neuromodulation (REN)

#### DESCRIPTION

Remote electrical neuromodulation (REN) is a nonpharmacologic option that is being proposed as an alternative to pharmacological interventions in individuals with migraines. The current first-line therapy is pharmacological interventions that can lead to medication overuse with regular use. An individual also has the risk of increased progression of migraines with continued use of medication.

Nerivio™ is the only current available REN device approved by the FDA in 2019. This device is worn on the upper arm and stimulates the peripheral nerves to induce conditional pain control and is presumed to reduce the sensed migraine intensity. The device is controlled via Bluetooth communication with an individual's smartphone or tablet.

#### POLICY

- Remote electrical neuromodulation (REN) for the treatment of acute migraines or prevention of migraines is considered **investigational**.

#### IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g., statement.
- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

#### ADDITIONAL INFORMATION

The evidence is insufficient to determine that technology shows improvement in the net health outcome.

#### SOURCES

Ailani, J., Burch, R.C., & Robinson, M.S. (2021). The american headache society consensus statement: update on integrating new migraine treatments into clinical practice. *Headache, The Journal of Head and Face Pain*, 61 (7), 1021-1039. (Level 1 evidence)

Ailani, J., Rabany, L., Tamir, S., Ironi, A., & Starling, A. (2022). Real-world analysis of remote electrical neuromodulation (REN) for the acute treatment of migraine. *Frontiers in Pain Research*, 2:753736. doi: 10.3389/fpain.2021.753736. (Level 2 evidence)

BlueCross BlueShield Association. Evidence Positioning System. (11:2024). *Remote electrical neuromodulation for Migraines*. (7.01.171). Retrieved October 9, 2025, from [www.bcbsaoca.com/eps/](http://www.bcbsaoca.com/eps/).

Hayes, a Sympir Company. (2025, May) Evolving Evidence Review. *Nerivio (theranica bio-electronics Ltd.) for treatment of acute migraine episodes in adults*. Retrieved October 9, 2025, from [www.Hayesinc.com/subscribers](http://www.Hayesinc.com/subscribers). (30 articles and/or guidelines reviewed)

## Medical Policy Manual **Draft New Policy: Do Not Implement**

Hershey, AD., Irwin, S., Rabany, L., Gruper, L., Ironi, A., Harris, D., et al. (2022). Comparison of remote electrical neuromodulation and standard-care medications for acute treatment of migraine in adolescents: a post hoc analysis. *Pain Medicine*, 23(4), 815-820. Abstract retrieved October 10, 2025, from PubMed database.

Hershey, AD., Lin, T., Gruper, Y., Harris, D., Ironi, A., Bank, T., et al. (2021). Remote electrical neuromodulation for acute treatment of migraine in adolescents. *Headaches*, 61(2), 310-317. Abstract retrieved October 10, 2025, from PubMed database.

Nierenburg, H., & Stark-Inbar, A. (2022). Nerivio® remote electrical neuromodulation for acute treatment of chronic migraine. *Pain Management*, 12 (3), 267-281. Abstract retrieved October 10, 2025, from PubMed database.

Tassorelli, C., Diener, HC., Silberstein, SD., Dodick, DW., Goadsby, PJ., Jensen, R.H., et al. (2021). Guidelines of the international headache society for clinical trials with neuromodulation devices for the treatment of migraine. *Cephalalgia: An International Journal of Headaches*, 41 (11-12), 1135-1151. Abstract retrieved October 10, 2025, from PubMed database.

Tepper, SJ., Rabany, L., Cowan, RP., Smith, TR., Grosberg, BM., Torphy, BD., et al. (2023). Remote electrical neuromodulation for migraine prevention: A double-blind, randomized, placebo-controlled clinical trial. *Headache*, 63(3), 377-389. (Level 1 evidence)

U.S. Food and Drug Administration. (2024, October). Center for Devices and Radiological Health. 510(k) *Premarket Notification Database*. K241756. Retrieved October 9, 2025 from [https://www.accessdata.fda.gov/cdrh\\_docs/pdf24/K241756.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf24/K241756.pdf).

VanderPluym, J.H., Singh, R.B.H., Urtecho, M., Morrow, A.S., Nayfeh, T., Roldan, V.D.T., et al. (2021). Acute treatments for episodic migraine in adults: a systematic review and meta-analysis. *JAMA*, 325 (23), 2357-2369. (Level 1 evidence)

### **EFFECTIVE DATE**

ID\_BA