



## Medical Policy Manual

**Draft New Policy: Do Not Implement** 

### Implantable Peripheral Nerve Stimulation Devices as a Treatment for Pain

#### **DESCRIPTION**

Peripheral nerve stimulation, also referred to as PNS or PNFS, is being proposed to treat acute and chronic pain. It involves surgery that places a small electrical device (wire like electrode) next to one of the peripheral nerves or group of peripheral nerves that is located beyond the brain or spinal cord. The electrode delivers rapid electrical pulses that are felt like mild tingles. During the testing period, the electrode is connected to an external device. If the trial is successful, a generator is then placed in the individual's body. The individual is then able to control stimulation by turning the device on and off and adjusting stimulation parameters as needed. Examples of FDA approved PNS devices include: Reactiv8 Implantable Restorative Neurostimulation, Sprint® Peripheral Nerve Stimulation System, StimRouter® PNS System and the StimQ PNS System and Nalu Neurostimulation Systems.

#### **POLICY**

Implantable peripheral nerve stimulation devices for the treatment of acute and chronic pain are 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, the express terms of the health plan will govern.

#### ADDITIONAL INFORMATION

Overall, there is a lack of literature evaluating long-term efficacy and adverse events associated with implantable PNS devices. Long-term data are especially important for these technologies due to being implanted in the body and in some cases permanent. Potential long-term complications include those seen with spinal cord stimulators, lead migration, lead fracture, seroma, infection and hematoma.

### **SOURCES**

Centers for Medicare & Medicaid Services. CMS.gov. NCD for Electrical nerve stimulators (160.7). Retrieved February 22, 2023 from <a href="http://www.cms.gov">http://www.cms.gov</a>.

Char, S., Jin, M.Y., Francio, V.T., Hussain, N., Wang, E.J., Morsi, Mahmoud., et al. (2022). Implantable peripheral nerve stimulation for peripheral neuropathic pain: A systematic review of perspective studies. *Biomedicines*, 10 (10), 2606. (Level 2 evidence)

Gilligan, C., Volschenk, W., Russo, M., Green, M., Gilmore, C., Mehta, V., et al. (2021). An implantable restorative-neurostimulator for refractory mechanical chronic lowback pain: a randomized sham-controlled clinical trial. *Pain*, 162 (10), 2486 – 2498. (Level 1 evidence)

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Sarica, C., Lorio-Morin, C., Aguirre-Padilla, D.H., Paff, M., Villeneuve, S., Vetkas, A., et al. (2022). Clinical outcomes and complications of peripheral nerve field stimulation in the management of refractory trigeminal pain: a systematic review and meta-analysis. *Journal of Neurosurgery*, 1-9 doi:10.3171/2021.12.JNS212869. (Level 1 evidence)

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**EFFECTIVE DATE** 

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