

Medical Policy

Policy:	201004	Effective Date:	09/01/2024
SUBJECT:	Peripheral Nerve Stimulation (Percutaneous or Implanted) and Electrical Stimulation for Chronic Intractable Pain and Other Conditions	Annual Review Date:	07/25/2024
		Last Revised Date:	07/25/2024

Prior approval is required for some or all of the procedure codes listed in this Corporate Medical Policy.

Definition: Peripheral nerve stimulation (PNS) involves surgical or percutaneous insertion of an electrode along a specific peripheral nerve determined to be responsible for regional pain. The electrode is connected to a lead that is tunneled to a receiver unit located within a subcutaneous pocket. Electrical impulses generated by a stimulator attached to the skin overlying the receiver are transmitted along the electrode to the peripheral nerve, thereby blocking or masking pain sensation. A therapeutic trial may be attempted by placement of a temporary electrode to determine if nerve stimulation leads to significant therapeutic analgesia - by at least 50 %. Individuals that experience significant pain relief may then be eligible for permanent implantation.

Percutaneous electrical nerve stimulation (PENS) involves the use of thin filiform needle electrodes that are placed percutaneously near a peripheral nerve. They may also involve the use of a needle-like introducer that inserts an electrode near a peripheral nerve. An electrical current drawn from an external pulse generator is delivered to the area, aiming to interfere with pain sensation. PENS devices are temporary and do not require invasive procedures to administer.

In addition to PNS and PENS, there are a number of electrical stimulation devices that are purported to treat various pain and other conditions. However, many of these devices have minimal support for their use and further clinical studies are needed to confirm their safety and efficacy.

Medical Necessity:

I. Temporary (trial) peripheral nerve stimulation and PENS: The Company considers peripheral nerve stimulation (PNS) as well as percutaneous electrical nerve stimulation (PENS) **medically necessary** and eligible for reimbursement providing that **all** of the following medical criteria are met:

- Chronic intractable pain refractory to conventional medical therapy, including (when appropriate) pharmacological, physical therapy, local/regional injections, and sympathetic blocks; and
- There is documented evidence of underlying objective pathology; and
- Individual has undergone screening and clearance by a multidisciplinary team that includes a licensed psychologist or psychiatrist and is considered an appropriate candidate for peripheral nerve stimulation[†]; and
- Individual is willing and able to comply with pre- and postoperative treatment plans; and
- Electrical stimulation is the last resort for treatment of chronic intractable pain.

Medical Policy

AND

At least one of the following clinical conditions is present:

- Diabetes with neurological manifestations
- Reflex sympathetic dystrophy or Complex Regional Pain Syndrome (CRPS) type I
- Mononeuritis of upper limb and mononeuritis multiplex
- Mononeuritis of lower limb and unspecified site
- Neuralgia (including postherpetic), neuritis, and radiculitis, unspecified
- Late effect of spinal cord injury
- Late effect of injury to nerve root(s), spinal plexus(es), and other nerves of trunk
- Late effect of injury to peripheral nerve of shoulder girdle and upper limb
- Late effect of injury to peripheral nerve of pelvic girdle and lower limb
- Injury to nerve roots and spinal plexus
- Injury to other nerve(s) of trunk, excluding shoulder and pelvic girdles
- Injury to peripheral nerve(s) of shoulder girdle and upper limb
- Injury to peripheral nerve(s) of pelvic girdle and lower limb

†PENS coverage does not require a multidisciplinary screening and clearance. PENS coverage is limited to 30 days with indwelling stimulators (e.g., Sprint PNS System) or up to 12 treatment sessions with devices intended for clinical use only (e.g., BiowavePENS).

NOTE: PENS coverage is limited to devices that are classified by U.S. Food and Drug Administration (FDA) as PENS devices and does **NOT** include electro-acupuncture devices. The use of electro-acupuncture or acupuncture with electrical stimulation is not addressed in this corporate medical policy. The Sprint PNS system is classified by the FDA as a PENS device.

II. Permanent implantation of peripheral nerve stimulator: The Company considers permanent implantation of a peripheral nerve stimulator **medically necessary** and eligible for reimbursement providing that **all** of the following medical criteria are met:

- Criteria for temporary implantation of peripheral nerve stimulator are met; and
- Temporary peripheral nerve stimulation resulted in at least 50% improvement in pain relief; and
- Individual is willing and able to comply with pre- and postoperative treatment plans.

Medical Policy

III. Investigational Procedures and/or Devices: The Company considers the following electrical stimulation procedures and/or devices **investigational** and **not** eligible for reimbursement:

- Peripheral nerve stimulation using the ReActiv8 Implantable Neurostimulation System and the StimQ Peripheral Nerve Stimulator System
- Peripheral nerve field stimulation (PNFS) and percutaneous electrical nerve field stimulation (PENFS) (e.g., IB-Stim)
- Percutaneous neuromodulation therapy (e.g. Vertis Percutaneous Neuromodulation Therapy)
- Interferential therapy (e.g. RS-4i Sequential Stimulator)
- Transcutaneous electrical modulation pain reprocessing (e.g., Scrambler therapy)
- Electrical stimulation for treatment of headaches or migraines.
- Peripheral nerve stimulation to treat restless leg syndrome (e.g. NTX100 Tonic Motor Activation System).

Benefits for investigational services are subject to each specific benefit plan.

IV. Not Medically Necessary Procedures and/or Devices: The Company considers the following electrical stimulation procedures and/or devices **not medically necessary** and **not** eligible for reimbursement:

- Microcurrent electrical nerve stimulation (MENS) (e.g. Alpha-Stim 100)
- Pulsed electrical stimulation (PES) (e.g. J-Stim 1000)
- Cranial electrical stimulation

NOTE: Spinal cord stimulation for treatment of chronic pain is addressed in Corporate Medical Policy 200602 (Spinal Cord (Dorsal Column) Stimulation).

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member, and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results, and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply, and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

NOTE: After reviewing the relevant documentation, the Company reserves the right to apply this policy to the procedure performed regardless of how the procedure was coded by the Provider.

NOTE: HCPCS Codes C1778, C1787, C1816, and C1820 are temporary codes established by the Centers for Medicare and Medicaid Services and should be submitted on a facility/institutional claim.

Medical Policy

Coverage may differ for Medicare Advantage plan members; please see any applicable national and/or local coverage determinations for details. This information may be available at the Centers for Medicare & Medicaid Services (CMS) website.

Medical Policy

Sources of Information:

- Birk DM, Yin D, Slavin KV. (2015). Regulation of peripheral nerve stimulation technology. *Prog Neurol Surg*, 29:225–237.
- Bogan RK, Roy A, Kram J, et al. Efficacy and safety of tonic motor activation (TOMAC) for medication-refractory restless legs syndrome: a randomized clinical trial. *Sleep*. 2023;46(10).
- Buchfuhrer MJ, Roy A, Rodriguez S, Charlesworth JD. Adjunctive tonic motor activation enables opioid reduction for refractory restless legs syndrome: a prospective, open-label, single-arm clinical trial. *BMC Neurol*. 2023;23(1):415.
- Centers for Medicare & Medicaid Services.
 - Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1). National coverage determination. Effective June 19, 2006.
 - Electrical Nerve Stimulators (160.7). National coverage determination. Effective August 7, 1995.
- Chakravarthy KV, Xing F, Bruno K, Kent AR, Raza A, Hurlemann R, Kinfe TM. (2019). A review of spinal and peripheral neuromodulation and neuroinflammation: Lessons learned thus far and future prospects of biotype development. *Neuromodulation*, 22(3):235–243.
- Cohen S, Gilmore C, Kapural L, Hanling S, Plunkett A, McGee M, Boggs J. (2019). Percutaneous peripheral nerve stimulation for pain reduction and improvements in functional outcomes in chronic low back pain. *Mil Med*, 184(Suppl 1):537–541.
- Corriveau M, Lake W, Hanna A. (2019). Nerve Stimulation for Pain. *Neurosurg Clin N Am*, 30(2):257–264.
- Deer TR, Gilmore CA, Desai MJ, Li SC, DePalma MJ, Hopkins TJ, Burgher AH, Spinner DA, Cohen SP, McGee MJ, Boggs JW. Percutaneous Peripheral Nerve Stimulation of the Medial Branch Nerves for the Treatment of Chronic Axial Back Pain in Patients After Radiofrequency Ablation. *Pain Med*. 2021 Mar 18;22(3):548-560.
- Deer TR, Lamer TJ, Pope JE, Falowski SM, Provenzano DA, Slavin K, ... Mekhail N. (2017). The Neurostimulation Appropriateness Consensus Committee (NACC) safety guidelines for the reduction of severe neurological injury. *Neuromodulation*, 20(1):15–30.
- Deer TR, Naidu R, Strand N, Sparks D, Abd-Elseyed A, Kalia H, ... Gulati A. (2020). A review of the bioelectronic implications of stimulation of the peripheral nervous system for chronic pain conditions. *Bioelectron Med*, 6:9.
- Deer TR, Provenzano DA, Hanes M, Pope JE, Thomson SJ, Russo MA, ... Mekhail N. (2017). The Neurostimulation Appropriateness Consensus Committee (NACC) recommendations for infection prevention and management. *Neuromodulation*, 20(1):31–50.
- Gilligan C, Volschenk W, Russo M, et al. (2021). ReActiv8-B Investigators. Long-Term Outcomes of Restorative Neurostimulation in Patients With Refractory Chronic Low Back Pain Secondary to Multifidus Dysfunction: Two-Year Results of the ReActiv8-B Pivotal Trial. *Neuromodulation*. S1094-7159.
- Gilligan C, Volschenk W, Russo M, et al. (2023). Three-Year Durability of Restorative Neurostimulation Effectiveness in Patients With Chronic Low Back Pain and Multifidus Muscle Dysfunction. *Neuromodulation*. 26(1):98-108.
- Gilmore C, Ilfeld B, Rosenow J, Li S, Desai M, Hunter C, ... Boggs J. (2019). Percutaneous peripheral nerve stimulation for the treatment of chronic neuropathic postamputation pain: a multicenter, randomized, placebo-controlled trial. *Reg Anesth Pain Med*, 44(6):637–645.

Medical Policy

- Günter C, Delbeke J, Ortiz-Catalan M. (2019). Safety of long-term electrical peripheral nerve stimulation: review of the state of the art. *J Neuroeng Rehabil*, 16(1):13.
- Harsh V, Mishra P, Gond PK, Kumar A. (2019). Peripheral nerve stimulation: black, white and shades of grey. *Br J Neurosurg*, 33(3):332–336.
- Hayes, Inc., Lansdale, PA.
 - IB-Stim (NeurAxis) for Treatment of Pain Associated with Irritable Bowel Syndrome in Adolescents (2023, July 31).
 - Nidra (Noctrix Health Inc.) for Treatment of Restless Legs Syndrome (2024, May 31).
 - Percutaneous Peripheral Nerve Stimulation for Treatment of Chronic Pain (2023, April 31)
 - Peripheral Nerve Field Stimulation for Treatment Of Chronic Low Back Pain (2023, March 16).
 - ReActiv8 Implantable Neurostimulation System (Mainstay Medical Ltd.) for Chronic Low Back Pain (2023, April 31).
 - SPRINT PNS System (SPR Therapeutics) for Chronic Pain (2023, March 16).
 - Scrambler/Calmare Pain Therapy (Calmare Therapeutics Inc.) for the Management of Chronic Pain Related to Cancer or D2Cancer Treatment (2023, April 25).
- Nayak R, Banik RK. (2018). Current Innovations in Peripheral Nerve Stimulation. *Pain Res Treat*, 2018:9091216.
- Hofmeister M, Memedovich A, Brown S, Saini M, Dowsett LE, Lorenzetti DL, ... Clement F. (2020). Effectiveness of neurostimulation technologies for the management of chronic pain: A systematic review. *Neuromodulation*, 23(2):150–157.
- Krasaelap A, Sood MR, Li BUK, Unteutsch R, Yan K, Nugent M, Simpson P, Kovacic K. Efficacy of Auricular Neurostimulation in Adolescents With Irritable Bowel Syndrome in a Randomized, Double-Blind Trial. *Clin Gastroenterol Hepatol*. 2020 Aug;18(9):1987-1994.
- Roy A, Ojile J, Kram J, et al. Long-term efficacy and safety of tonic motor activation for treatment of medication-refractory restless legs syndrome: a 24-week open-label extension study. *Sleep*. 2023;46(10).
- Sivanesan E, Gulati A. (2019). Resurgence of peripheral nerve stimulation with innovation in device technologies. *Reg Anesth Pain Med*, 44(6):615–616.
- Slavin KV. Peripheral nerve stimulation for neuropathic pain. *US Neurology*, 2011;7(2):144-148.
- van Gorp E-J, Eldabe S, Slavin KV, Rigoard P, Goossens S, Mielke D, ... Luyet P-P. (2020). peripheral nerve field stimulation for chronic back pain: Therapy outcome predictive factors. *Pain Pract*, 20(5):522–533.

Applicable Code(s):	
CPT:	0278T, 0720T, 64555, 64575, 64580, 64585, 64590, 64595, 64596, 64597, 64598, 64999
HCPCS:	A4540, A4596, C1778, C1787, C1816, E0732, E0762, E1399, L8678, L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689, S8130, S8131
ICD10 Procedure Codes:	00HE0MZ, 00HE3MZ, 00HE4MZ, 01HY0MZ, 01HY3MZ, 01HY4MZ, 01PY0MZ, 01PY3MZ, 01PY4MZ, 01PYXMZ, 0DH60MZ, 0DH63MZ, 0DH64MZ, 0DP60MZ, 0DP63MZ, 0DP64MZ, 0JH60BZ, 0JH60CZ, 0JH60DZ, 0JH60EZ, 0JH63BZ, 0JH63CZ, 0JH63DZ, 0JH63EZ, 0JH70BZ, 0JH70CZ, 0JH70DZ, 0JH70EZ, 0JH73BZ, 0JH73CZ, 0JH73DZ, 0JH73EZ, 0JH80BZ, 0JH80CZ, 0JH80DZ, 0JH80EZ, 0JH83BZ, 0JH83CZ, 0JH83DZ, 0JH83EZ, 0JPT0MZ, 0JPT3MZ