MEDICAL MUTUAL®

Medical Policy

Policy:	**201004**	**Initial Effective Date:**	**09/22/2010**
SUBJECT:	**Peripheral Nerve Stimulation (Percutaneous or Implanted) and Electrical Stimulation for Chronic Intractable Pain and Other Conditions**	**Annual Review Date:**	**09/29/2022**
		Last Revised Date:	**04/24/2023**

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.

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.

NOTE: Based upon our findings, the Company considers peripheral nerve stimulation using the ReActiv8 Implantable Neurostimulation System and the StimQ Peripheral Neurostimulation System **investigational** and **not** eligible for reimbursement.

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)

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)

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.

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.

Sources of Information:

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- 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 (2022, July 14).
  - Percutaneous Peripheral Nerve Stimulation for Treatment of Chronic Pain (2022, April 05)
  - Peripheral Nerve Field Stimulation for Treatment Of Chronic Low Back Pain (2022, April 15).
  - ReActiv8 Implantable Neurostimulation System (Mainstay Medical Ltd.) for Chronic Low Back Pain (2022, April 20).
  - SPRINT PNS System (SPR Therapeutics) for Chronic Pain (2021, August 03).
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Applicable Code(s):	
CPT:	**0278T, 0720T, 64555, 64575, 64580, 64585, 64590, 64595, 64999**
HCPCS:	**A4596, C1778, C1787, C1816, E0762, E1399, K1002, 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**