Geisinger Health Plan Policies and Procedure Manual

Policy: MP219

Section: Medical Benefit Policy

Subject: Implantable Percutaneous Electrical Nerve Stimulation (PENS) and Neuromodulation Therapy (PTN)

Applicable line of business:

Commercial	**x**	**Medicaid**	**x**
Medicare	**x**	**ACA**	**x**
CHIP	**x**		

I. Policy: Implantable Percutaneous Electrical Nerve Stimulation (PENS) and Neuromodulation Therapy (PTN)

II. Purpose/Objective:
To provide a policy of coverage regarding Implantable Percutaneous Electrical Nerve Stimulation (PENS) and Neuromodulation Therapy (PTN)

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

Percutaneous Peripheral Nerve Stimulation
PENS is performed with needle electrodes to stimulate peripheral sensory nerves in the soft tissue. Percutaneous neuromodulation therapy (PNT) is a variant form of Percutaneous Electrical Nerve Stimulation (PENS) in which up to 10 fine filament electrodes are temporarily placed at specific anatomical landmarks in the back. Treatment regimens consist of 30-minute sessions, once or twice a week for approximately eight to ten sessions. This modality is thought to offer symptomatic relief and management of chronic or intractable pain.

Implantable Peripheral Nerve Stimulation
Implantable peripheral nerve stimulation (PNS) is a type of neuromodulation therapy in which electrodes are surgically placed next to a selected peripheral nerve considered to be the source of chronic pain. The electrode delivers electrical energy to the affected nerve. This electrical current is thought to disrupt the normal transmission of pain signals resulting in reduced levels of pain.

Restorative Neurostimulation
Restorative neurostimulation is a minimally invasive method of innervating the multifidus muscle of the lower back to override the cycle of lumbar multifidus muscle degeneration. It is intended to be used as a rehabilitative therapy for individuals with impaired neuromuscular control associated with mechanical chronic low back pain.

Remote Electrical Neuromodulation – REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE

Remote Electrical Neuromodulation (e.g., Nerivio) for the treatment of pediatric medication-refractory migraine headache may be considered medically necessary when **ALL** of the following criteria are met:

- Member’s age is 8 years or greater; **and**
- The device is ordered by a neurologist or migraine specialist; **and**
- Documented failure or intolerance to a trial of one triptan (if age 12 or above); **and/or**
- Failure or intolerance to a trial of one CGRP agent (if age 18 or older)*

Initial authorization duration will be for a period no longer than 6 months to allow for evaluation of the effectiveness in treatment of the member; **and**
The device must be used in conjunction with the included app. Failure to coordinate use of the device with the app during the initial six month trial phase will result in a denial of further use of the device.

* CGRPs are off-label for the pediatric population, but they are frequently used

For Medicare Business Segment: please refer to NCD Electrical Nerve Stimulators (160.7)

EXCLUSIONS:
The Plan does **NOT** provide coverage for Implantable Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy (PTN) for any indication because it is considered **unproven** and not medically necessary, and therefore **NOT COVERED.** There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies

The Plan does **NOT** provide coverage for restorative neurostimulation (e.g., ReActiv8, StimRouter PNS System, StimQ, Nalu) for any indication including but not limited to chronic low back pain is considered **Unproven** and not medically necessary and therefore **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

Medicaid Business Segment:
Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment.**

CODING ASSOCIATED WITH: Percutaneous Neuromodulation Therapy
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

64999 Unlisted procedure, nervous system
64555 Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64575 Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64590 Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver

64596 Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array
64697 Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; each additional electrode array
A4438 Adhesive clip applied to the skin to secure external electrical nerve stimulator controller, each

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

K1023 Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:
American Academy of Pain Medicine (AAPM). Chronic pain medical treatment guidelines. Aug 2007. Accessed August 15, 2008. Available at URL address: http://www.painmed.org/pdf/medical_treatment_utilization_schedule_guidelines.pdf

ECRI TARGET Report (online). Percutaneous neuromodulation therapy (PNT) for low back pain. ECRI Institute. Current as of April 2005. Accessed on August 15, 2008.

Kang RW, Lewis PB, Kramer A et al. Prospective randomized single-blinded controlled clinical trial of percutaneous neuromodulation pain therapy device versus sham for the osteoarthritic knee: a pilot study. Orthopedics 2007; 30(6):439-45.

Weiner DK, Rudy TE, Glick RM, Boston JR, Lieber SJ, Morrow LA, et al. Efficacy of percutaneous electrical nerve stimulation for the treatment of chronic low back pain in older adults. J Am Geriatr Soc. 2003 May;51(5):599-608.

Washington State Department of Labor and Industries. Office of the Medical Director Technology Assessment. Percutaneous Neuromodulation Therapy. January 13, 2004. Accessed August 15, 2008. Available at URL address: http://www.lni.wa.gov/ClaimsIns/Providers/Treatment/CovMedDev/SpecCovDec/PercutNeur.asp

Weiner DK, Perera S, Rudy TE et al. Efficacy of percutaneous electrical nerve stimulation and therapeutic exercise for older adults with chronic low back pain: a randomized controlled trial. Pain 2008; 140(2):344-57

Wanich T, Gelber J, Rodeo S et al. Percutaneous neuromodulation pain therapy following knee replacement. J Knee Surg 2011; 24(3):197-202.

Nayak R and Banik R. Current innovations in peripheral nerve stimulation. Pain Res Treat 2018; 2018:9091216.

Gofeld M, Agur A. Peripheral nerve stimulation for chronic shoulder pain: a proof of concept anatomy study. Neuromodulation 2018 Apr;21(3):284-289.

Kurlinsky S, Palmer SC, Arroliga MJ, et. al. Neuromodulation in postherpetic neuralgia: case reports and review of the literature. Pain Med 2018 Jun 1;19(6):1237-1244.

Beltran-Alacreu H, Serrano-Munoz D, Martin-Caro D, et al. Percutaneous versus transcutaneous electrical nerve stimulation for the treatment of musculoskeletal pain. A systematic review and meta-analysis. Pain Med. Feb 15 2022.

Price R, Smith D, Franklin G, et al. Oral and Topical Treatment of Painful Diabetic Polyneuropathy: Practice Guideline UpdateSummary: Report of the AAN Guideline Subcommittee. Neurology. Jan 04 2022; 98(1): 31-43.

Yarnitsky D, Dodick DW, Grosberg BM, et al.(2019) Remote Electrical Neuromodulation (REN) Relieves Acute Migraine: A Randomized, Double-Blind, Placebo-Controlled, Multicenter Trial. Headache. Sep 2019; 59(8): 1240-1252.

Yarnitsky D, Volokh L, Ironi A, et al.(2017) Nonpainful remote electrical stimulation alleviates episodic migraine pain. Neurology. Mar 28 2017; 88(13): 1250-1255.

Rapoport AM, Bonner JH, Lin T, et al.(2019) Remote electrical neuromodulation (REN) in the acute treatment of migraine: a comparison with usual care and acute migraine medications. J Headache Pain. Jul 22 2019; 20(1): 83.

Nierenburg H, Rabany L, Lin T, et al.(2021) Remote Electrical Neuromodulation (REN) for the Acute Treatment of Menstrual Migraine: a Retrospective Survey Study of Effectiveness and Tolerability. Pain Ther. Dec 2021; 10(2): 1245-1253.

Nierenburg H, Stark-Inbar A.(2022) Nerivio ® remote electrical neuromodulation for acute treatment of chronic migraine. Pain Manag. Apr 2022; 12(3): 267-281.

Nierenburg H, Vieira JR, Lev N, et al.(2020) Remote Electrical Neuromodulation for the Acute Treatment of Migraine in Patients with Chronic Migraine: An Open-Label Pilot Study. Pain Ther. Dec 2020; 9(2): 531-543.

Grosberg B, Rabany L, Lin T, et al.(2021) Safety and efficacy of remote electrical neuromodulation for the acute treatment of chronic migraine: an open-label study. Pain Rep. Nov-Dec 2021; 6(4): e966.

Hershey AD, Irwin S, Rabany L, et al.(2022) Comparison of Remote Electrical Neuromodulation and Standard-Care Medications for Acute Treatment of Migraine in Adolescents: A Post Hoc Analysis. Pain Med. Apr 08 2022; 23(4): 815-820.

Hershey AD, Lin T, Gruper Y, et al.(2021) Remote electrical neuromodulation for acute treatment of migraine in adolescents. Headache. Feb 2021; 61(2): 310-317.

Ailani J, Burch RC, Robbins MS.(2021) The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. Jul 2021; 61(7): 1021-1039.

Ailani J, Rabany L, Tamir S, et al.(2021) Real-World Analysis of Remote Electrical Neuromodulation (REN) for the Acute Treatment of Migraine. Front Pain Res 2021;2:753736.

Geisinger Health Plan Technology Assessment Committee. Remote Electrical Neuromodulation (REN) for Migraines. February 2024, January 2025

Gilligan C, Volschenk W, Russo M, et al. An implantable restorative-neurostimulator for refractory mechanical chronic low back pain: a randomized sham-controlled clinical trial. Pain. Oct 01 2021; 162(10): 2486-2498.

Gilligan C, Volschenk W, Russo M, et al. Three-Year Durability of Restorative Neurostimulation Effectiveness in Patients with Chronic Low Back Pain and Multifidus Muscle Dysfunction. Neuromodulation. Jan 2023; 26(1): 98-108.

Deckers K, De Smedt K, Mitchell B, et al. New Therapy for Refractory Chronic Mechanical Low Back Pain-Restorative Neurostimulation to Activate the Lumbar Multifidus: One Year Results of a Prospective Multicenter Clinical Trial. Neuromodulation. Jan 2018; 21(1): 48-55.

Thomson S, Chawla R, Love-Jones S, et al. Restorative Neurostimulation for Chronic Mechanical Low Back Pain: Results from a Prospective Multi-centre Longitudinal Cohort. Pain Ther. Dec 2021; 10(2): 1451-1465.

Mitchell B, Deckers K, De Smedt K, et al. Durability of the Therapeutic Effect of Restorative Neurostimulation for Refractory Chronic Low Back Pain. Neuromodulation. Aug 2021; 24(6): 1024-1032.

Ardeshiri A, Shaffrey C, Stein KP, et al. Real-World Evidence for Restorative Neurostimulation in Chronic Low Back Pain-a Consecutive Cohort Study. World Neurosurg. Dec 2022; 168: e253-e259.

ECRI Clinical Evidence Assessment. ReActiv8 Implantable Neurostimulation System (Mainstay Medical Ltd.) for Treating Chronic Low-back Pain. Published 6/17/2021. Updated 1/16/2023. Updated 7/24/24

Centers for Medicare & Medicaid Services. National Coverage Determination. Electrical Nerve Stimulators (160.7)

Cowan R, Stark-Inbar A, et al. Clinical benefits and economic cost-savings of remote electrical neuromodulation (REN) for migraine prevention. J Med Econ. 2023;26(1):656-664.

Werner K, Gerson T, et al. Acute treatment of migraine in children aged 6−11:Real-world analysis of remote electrical neuromodulation (REN). Annals of the Child neurology Society. 2024;00(00):1-11

Synowiec A, Stark-Inbar A, et al. One-Year Consistent Safety, Utilization, and Efficacy Assessment of Remote Electrical Neuromodulation (REN) for Migraine Treatment. Adv Ther. 2023

Esparham A, Stark-Inbar A, et al. Acute Treatment of Migraine in Adolescents: Real-World Analysis ofRemote Electrical Neuromodulation (REN). Pediatric Neurology 2023;142:51-55

This policy will be revised as necessary and reviewed no less than annually.

Devised: 08/22/08

Revised: 10/23 (expand title and exclusions); 4/24 (add exclusion for PNS, Remote electrical neuromodulation); 2/25 Revise REN coverage for pediatrics)

Reviewed: 11/09; 11/10, 11/11, 11/12, 11/13, 11/14, 11/15; 10/16, 10/17, 10/18, 10/19, 10/20, 10/21, 10/22

CMS UM Oversight Committee Approval: 12/23, 7/24, 4/25

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies