



Geisinger Health Plan Policies and Procedure Manual

Policy: MP343

Section: Medical Benefit Policy

Subject: Percutaneous Electrical Nerve Field Stimulation (PENFS)

Applicable line of business:

Commercial	x	Medicaid	x
Medicare	x	ACA	x
CHIP	x		

I. Policy: Percutaneous Electrical Nerve Field Stimulation (PENFS)

II. Purpose/Objective:

To provide a policy of coverage regarding Percutaneous Electrical Nerve Field Stimulation (PENFS)

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 Electrical Nerve Field Stimulation (PENFS) has been proposed as a treatment of functional abdominal pain secondary to inflammatory bowel disease in children and adolescents. The IB-Stim is intended to be used for 120 hours per week up to 3 consecutive weeks, through application to auricular branches of cranial nerves V, VII, IX and X, and the occipital nerves identified by transillumination. Once the desired neurovascular bundles are visualized by transillumination, the electrode needle is secured and implanted percutaneously with gentle pressure. The four-needle electrode array, attached to the white wire, is placed on the ventral side of the ear lobe.

Commercial Business Segment: Requires Prior Authorization by a Plan Medical Director or designee

Percutaneous electrical nerve field stimulation (PENFS) with an FDA approved device (e.g., IB-STIM®) is considered to be medically necessary in children and adolescents when **ALL** of the following are met:

- Member is age 11-18; and
- Diagnosed with a ROME IV criteria* defined-functional gastrointestinal disorder (functional abdominal pain, functional abdominal pain syndrome, irritable bowel syndrome, functional dyspepsia, or abdominal migraine) with symptoms present for at least 9 months; and
- No evidence of organic gastrointestinal disease (e.g., neoplasm, infection, etc.); and
- Failure or intolerance to treatment with diet modification and probiotics; and
- Failure or intolerance to at least 3 months of treatment with acid suppressors, antispasmodics, and neuromodulators
- The device is prescribed by a pediatric gastroenterologist; and
- The device will be used up to 120 hours per week, up to 3 consecutive weeks, not to exceed 4 weeks

* Rome Foundation. Rome IV Diagnostic Criteria for FGIDs (2019). <https://theromefoundation.org/wp-content/uploads/Rome-Foundation-Diagnostic-Criteria-Booklet-2019.pdf>.

EXCLUSIONS:

Unless otherwise noted, the Plan does **NOT** provide coverage for Percutaneous Electrical Nerve Field Stimulation (PENFS) for treatment of functional abdominal pain because it is considered **unproven**. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established treatments or technologies.

The Plan does NOT provide coverage for tonic motor activation (TOMAC) external lower extremity nerve stimulation device for restless leg syndrome (RLS) because it is considered **unproven**. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established treatments or technologies.

The Plan does NOT provide coverage for Percutaneous Electrical Nerve Field Stimulation (PENFS) or auricular neurostimulation (e.g., Sparrow Ascent) for treatment of opioid withdrawal symptoms because it is considered **unproven**. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established treatments or technologies Sparrow Ascent **(E0721)**

Medicare Business Segment:

Auricular Peripheral Nerve Stimulation (Electro-Acupuncture Device)

The following devices are listed under the Food and Drug Administration (FDA) approval documents as electro-acupuncture devices used for stimulation of auricular acupuncture points and as such are non-covered. Acupuncture for stimulation of auricular points is not a covered Medicare benefit.

- **NeuroStim system/NSS**
- **P-Stim**
- **ANSiStim**
- **E-Pulse**

The following device is FDA classified as a percutaneous nerve stimulator for substance use disorders; Class II device:

- **NSS-2 Bridge**

This device is an electrical nerve stimulator (percutaneous nerve field stimulator [PNFS] system) that is placed behind the patient's ear (auricular). The NSS-2 Bridge is described as nearly identical to the Electronic Auricular Device (EAD) for a different intended use (to aid in the reduction of opioid withdrawal symptoms). This device is non-covered by Medicare when used for acupuncture (stimulation of auricular acupuncture points) for any indication.

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.

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

CODING ASSOCIATED WITH: Percutaneous Electrical Nerve Field Stimulation (PENFS) for Treatment of Functional Abdominal Pain

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
E1399 Miscellaneous durable medical equipment
E0721 Transcutaneous electrical nerve stimulator, stimulates nerves in the auricular region
E0743 External lower extremity nerve stimulator for restless legs syndrome, each
0720T Percutaneous electrical nerve field stimulation, cranial nerves, without implantation
0783T Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment
A4543 Supplies for transcutaneous electrical nerve stimulator, for nerves in the auricular region, per month

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

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 supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Kovacik K, Hainsworth K, Sood M et al. Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomised, double-blind, sham-controlled trial. *Lancet Gastroenterol Hepatol* 2017
[http://dx.doi.org/10.1016/S2468-1253\(17\)30253-4](http://dx.doi.org/10.1016/S2468-1253(17)30253-4).

Kovacac K, Kolacz J, Lin GF, Porges SW. Impaired Vagal Efficiency Predicts Auricular Neurostimulation Response in Adolescent Functional Abdominal Pain Disorders *Am J Gastroenterol* 2020;00:1–5

Krasaelap A, Sood MR, et al. Efficacy of Auricular Neurostimulation in Adolescents With Irritable Bowel Syndrome in a Randomized, Double-Blind Trial. *Clinical Gastroenterology and Hepatology* 2020 Aug;18(9):1987-1994.e2.

Hayes. Evidence Analysis Research Brief. IB-Stim (Innovative Health Solutions) for Treatment of Pain Associated with Irritable Bowel Syndrome. Mar 5, 2021.

Geisinger Technology Assessment Committee Triage Group. April 2021

Centers for Medicare & Medicaid Services. A55240 Billing and Coding: Auricular Peripheral Nerve Stimulation (Electro-Acupuncture Device) <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=55240>

Gottfried-Blackmore A et al. Noninvasive vagal nerve stimulation for gastroenterology pain disorders. *Pain Manag.* 2021 Jan;11(1):89-96.

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.

Babygirija R, Sood M, et al. Percutaneous Electrical Nerve Field Stimulation Modulated Central Pain Pathways and Attenuates Post-inflammatory Visceral and Somatic Hyperalgesia in Rats. *Neuroscience* 356 (2017) 11–21

Krasaelap A, Sood MR, et al. Efficacy of Auricular Neurostimulation in Adolescents With Irritable Bowel Syndrome in a Randomized, Double-Blind Trial. *Clinical Gastroenterology and Hepatology* 2020

Santucci NR, King C, et al. Effect of percutaneous electrical nerve field stimulation on mechanosensitivity, sleep, and psychological comorbidities in adolescents with functional abdominal pain disorders. *Neurogastroenterology & Motility.* 2022;34:e14358.

Santucci NR, Beigarten AJ, et al. Percutaneous Electrical Nerve Field Stimulation in Children and Adolescents With Functional Dyspepsia—Integrating a Behavioral Intervention. *Neuromodulation* 2023;1-10.

Bora G, Atkinson SN, et al. Impact of auricular percutaneous electrical nerve field stimulation on gut microbiome in adolescents with irritable bowel syndrome: A pilot study. *Pediatric Gastroenterol Nutr.* 2022;75(Suppl 1):S106–S108.

Castillo DF, Denson LA, et al. The microbiome in adolescents with irritable bowel syndrome and changes with percutaneous electrical nerve field stimulation. *Neurogastroenterology & Motility.* 2023;00:e14573.

Chogle A, Visnagra K, et al. Prospective study of the effect of auricular percutaneous electrical nerve field stimulation on quality of life in children with pain related disorders of gut-brain interaction. *Front. Pain Res.* 2023; 4:1223932

Santucci NR, Sahay R, et al. Percutaneous electrical nerve field stimulation compared to standard medical therapy in adolescents with functional abdominal pain disorders. *Front. Pain Res.* 2023;4:1251932.

Miranda A. Opinion: Percutaneous electrical nerve field stimulation compared to standard medical therapy in adolescents with functional abdominal pain disorders. *Front. Pain Res.* 2024; 5:1279946.

Chogle A, El-Chammas, K, Santucci N, et al. A multicenter registry study on percutaneous electrical nerve field stimulation for pediatric disorders of gut–brain interaction. *J Pediatr Gastroenterol Nutr.* 2024;1-10.

Shah E, Eswaran S, Harer K, et al. Percutaneous electrical nerve field stimulation for adolescents with irritable bowel syndrome: cost-benefit and cost-minimization analysis. *J Pediatr Gastro Nutr.* 2024;1-6.

Rodriguez Lagos L, Arribas-Romano A, Fernández-Carnero J, et al. Effects of Percutaneous and Transcutaneous Electrical Nerve Stimulation on Endogenous Pain Mechanisms in Patients with Musculoskeletal Pain: A Systematic Review and Meta-Analysis. *Pain Med.* 2023;24(4):397-414.

Miranda A, Taca A. Neuromodulation with percutaneous electrical nerve field stimulation is associated with reduction in signs and symptoms of opioid withdrawal: a multisite, retrospective assessment. *Am J Drug Alcohol Abuse.* 2018; 44(1):56-63.

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):zsad190.

Buchfuhrer MJ, Baker FC, Singh H et al. Noninvasive neuromodulation reduces symptoms of restless legs syndrome. *J Clin Sleep Med*. 2021; 17(8):1685-1694.

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.

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):zsad188.

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

Devised: 4/21

Revised: 6/22 (Add Exclusions/Title Change), 6/23, 6/24 (add PA coverage for Commercial lob); 3/25 (add exclusion for TOMAC, PENFS)

Reviewed:

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

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.

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>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.