Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP343

Section: Medical Benefit Policy

Subject: Percutaneous Electrical Nerve Field Stimulation (PENFS)

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**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.

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.

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
0720T Percutaneous electrical nerve field stimulation, cranial nerves, without implantation
0783T Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment

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.

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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.

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)

Reviewed:

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