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Percutaneous Electrical Nerve Field Stimulation for Functional Abdominal Pain Disorders Corporate Medical Policy

File Name: Percutaneous Electrical Nerve Field Stimulation for Functional Abdominal Pain Disorders

File Code: 10.99.VT85

Origination: 07/01/2024

Last Review: 07/2024

Next Review: 07/2025

Effective Date: 10/01/2024

Description

Percutaneous electrical nerve field stimulation involves the transmission of electrical impulses to cranial nerve bundles in the ear targeting brain areas involved in processing pain. In the case of patients with functional abdominal pain disorders, nerves processing pain for the abdominal region are targeted.

IB-STIM[®] is a percutaneous electrical nerve field stimulator (PENFS) system intended to be used in patients 11-18 years of age with functional abdominal pain associated with irritable bowel syndrome (IBS). The IB-STIM[®] is intended to be used for 120 hours per week up to 41 consecutive weeks, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination, as an aid in the reduction of pain when combined with other therapies for IBS. The IB-STIM[®] procedure is typically performed in an office setting.

Summary

Percutaneous Electrical Nerve Field Stimulation is a noninvasive treatment option for pediatric patients with functional bowel disorders including irritable bowel syndrome. This noninvasive device delivers percutaneous electrical nerve field stimulation to the external ear and is a safe and effective therapy for pediatric abdominal pain-related functional gastrointestinal disorders in pediatric patients with functional abdominal pain disorders. Studies showed that PENFS modulates central pain pathways and attenuates visceral hyperalgesia.

Current evidence includes two randomized, double-blind, sham-controlled trials. Auricular neurostimulation reduces abdominal pain scores. PENFS has proven to be an effective and safe treatment for pediatric patients with abdominal pain disorders. Studies concluded that

PENFS improves overall wellbeing in adolescents with abdominal pain. PENFS with Neuro-stim (IB-STIM) showed an 81% improvement in overall symptoms, and approximately 59% of test subjects showed at least a 30% reduction in their worst pain.

The current standard of care for children with functional abdominal pain includes using off-label medications which sometimes carry side-effects.

The evidence is sufficient to determine that the IB-STIM® results in a meaningful improvement in the net health outcome.

Policy

Coding Information

Click the links below for attachments, coding tables & instructions.

[Attachment I](#)

When a service may be considered medically necessary

The IB-STIM® device may be considered **medically necessary** in children and adolescents when **ALL** of the following criteria are met:

- 11-21 years of age; **AND**
- Patient must be diagnosed with a ROME IV defined-functional gastrointestinal disorder (These include functional abdominal pain, functional abdominal pain syndrome, irritable bowel syndrome, functional dyspepsia, and abdominal migraine); **AND**
- Organic GI disease must have been ruled out; **AND**
- The problem has been present for at least 9 months; **AND**
- The patient has tried and failed medications in all 3 categories: acid suppression (H2-blockers or PPIs), antispasmodics or motility medications (hyoscyamine, dicyclomine, erythromycin/linaclotide, prucalopride) and neuromodulators (amitriptyline/nortriptyline/gabapentin/periactin/aprepitant), in addition to diet modification.

When a service is considered investigational

All other uses of IB-STIM® device not meeting the above criteria are considered **investigational**.

Replacement of lost, stolen or destroyed Durable Medical Equipment

We will replace one lost, stolen or destroyed Durable Medical Equipment, prosthetic or orthotic per Plan Year if not covered by an alternative entity (including but not limited to homeowners insurance and automobile insurance) if:

- the Durable Medical Equipment, prosthetic or orthotic's absence would put the member at risk of death, disability or significant negative health consequences such as a hospital admission;
- the Durable Medical Equipment is still under warranty.

Note: In order to replace a stolen item we require you to submit documentation, such as a police report, with the request.

Exclusions

We do not cover the replacement of a lost, stolen or destroyed Durable Medical Equipment, prosthetic or orthotic:

- if the criteria above have not been met; **AND**
- for more than one lost, stolen or destroyed Durable Medical Equipment, prosthetic or orthotic per Plan Year.

Reference Resources

1. Blue Cross Blue Shield Association Medical Policy Reference Manual. Percutaneous Electrical Nerve Field Stimulation for Irritable Bowel Syndrome. 2.01.106. Last Reviewed June, 2023. Accessed June, 2024.
2. de Bruijn CMA, Rexwinkel R, Gordon M, Benninga M, Tabbers MM. Antidepressants for functional abdominal pain disorders in children and adolescents. *Cochrane Database Syst Rev.* 2021 Feb 9;2(2):CD008013. doi: 10.1002/14651858.CD008013.pub3. PMID: 33560523; PMCID: PMC8094232.
3. Gottfried-Blackmore A, Habtezion A, Nguyen L. Noninvasive vagal nerve stimulation for gastroenterology pain disorders. *Pain Manag.* 2021 Jan;11(1):89-96. doi: 10.2217/pmt-2020-0067. Epub 2020 Oct 28. PMID: 33111642; PMCID: PMC7787175.
4. Kovacic K, Kolacz J, Lewis GF, Porges SW. Impaired Vagal Efficiency Predicts Auricular Neurostimulation Response in Adolescent Functional Abdominal Pain Disorders. *Am J Gastroenterol.* 2020 Sep;115(9):1534-1538. doi: 10.14309/ajg.0000000000000753. PMID: 32732620.
5. Kovacic K, Hainsworth K, Sood M, Chelimsky G, Unteutsch R, Nugent M, Simpson P, Miranda A. Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomised, double-blind, sham-controlled trial. *Lancet Gastroenterol Hepatol.* 2017 Oct;2(10):727-737. doi: 10.1016/S2468-1253(17)30253-4. Epub 2017 Aug 18. PMID: 28826627.
6. 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.e2. doi: 10.1016/j.cgh.2019.10.012. Epub 2019 Oct 14. PMID: 31622740.
7. Non-implanted nerve stimulator for functional abdominal pain relief. Regulatory Class: Class II Device. https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180057.pdf

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

Incomplete authorization requests may result in a delay of decision pending submission of missing information. To be considered complete, see policy guidelines above.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

07/2024	New Policy. Input received from network provider and vendor. Medical necessity criteria established for use of IB-STIM. Added code 0720T as requiring prior approval to coding table.
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Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by BCBSVT Medical Directors

Tom Weigel, MD, MBA
Vice President and Chief Medical Officer

Tammaji P. Kulkarni, MD
Senior Medical Director

Attachment I

Code Type	Number	Description	Policy Instructions
The following codes will be considered as medically necessary when applicable criteria have been met.			
CPT®	0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation	Prior Approval Required