MASSACHUSETTS

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Medical Policy

Percutaneous Electrical Nerve Field Stimulation for Functional Abdominal Pain Disorders

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Policy Number: 922

BCBSA Reference Number: N/A
NCD/LCD: N/A

Related Policies

Cranial Electrotherapy Stimulation and Auricular Electrostimulation #362

Policy[1]

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

IB-STIM® may be considered **MEDICALLY NECESSARY** in children and adolescents when **ALL** of the following criteria is 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.

All other uses of IB-STIM® device is considered **INVESTIGATIONAL**.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There are not any CPT codes for this service.

Description

IB-STIM is a percutaneous electrical nerve field stimulator (PENFS) system is 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 4[1] 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.

This nonsurgical device works by sending electrical impulses into the cranial nerve bundles located in the ear. The stimulation targets the brain areas that are involved with processing pain, and aids in the reduction of functional abdominal pain, that is associated with inflammatory bowel syndrome (IBS).

Summary

Percutaneous Electrical Nerve Field Stimulation (PENFS) 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.

The current standard for children with functional abdominal pain is to use off-label medications, most of which have serious side-effects and black-box warnings. These medications include tricyclic antidepressants (amitriptyline), selective serotonin reuptake inhibitor (SSRIs), prokinetics, gabapentin and cyproheptadine.

The evidence includes 2 randomized, double-blind, sham-controlled trial. 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. *Kovacic (2017); Krasaelap (2020)*

Clinical input obtained in 2021 was in agreement that PENFS is medically necessary for the management of functional gastrointestinal disorders. There are no other IBS approaches that attain the level of clinical

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

Policy History

Date	Action
3/2022	New medical policy describing medically necessary indications. Effective 3/1/2022.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

1. Gupta, S., Schaffer, G., & Saps, M. Pediatric irritable bowel syndrome and other functional abdominal pain disorders; an update of non-pharmacological treatments. Expert Review of Gastroenterology & Hepatology. 2018; 12(5): 447-456.
2. Kovacic, K, Hainsworth, M., et al. Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomised, double-blind, sham-controlled trial. The Lancet: Gastroenterology & Hepatology. 2017; 2(10): 727-737.
3. Madani, S., Parikh, S., et al. Long-term study of children with ROME III functional gastrointestinal disorders managed symptomically in a biophysical model. Gastroenterol Res. 2017;10(2): 84-91.
4. Walker, L.S., Dengler-Crish, C.M., et al. Functional abdominal pain in childhood and adolescence inreases risk for chronic pain in adulthood. Pain. 2010; 150(3); 568-572
5. Non-implanted nerve stimulator for functional abdominal pain relief. Regulatory Class: Class II Device. https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180057.pdf
6. Amornluck Krasaelap, Manu R Sood, B U K Li et al. 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.
7. Katja Kovacic, Jacek Kolacz, Gregory F. Lewis et al. Impaired Vagal Efficiency Predicts Auricular Neurostimulation Response in Adolescent Functional Abdominal Pain Disorders. Am J Gastroenterol 2020 Sep;115(9):1534-1538.
8. de Bruijn CMA, et al. Antidepressants for functional abdominal pain disorders in children and adolescents. Cochrane Database Syst Rev. 2021.
9. Gottfried-Blackmore A et al. Noninvasive vagal nerve stimulation for gastroenterology pain disorders. Pain Manag. 2021 Jan;11(1):89-96.

Endnotes

[1] Based on expert opinion.

Regulatory Status: The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has approved IB-Stim, a prescription device for the following indications:

The 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 3 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.

Regulatory Class: FDA classified the IB-Stim as Class II device. This device does not meet the Centers for Medicare and Medicaid Services definition of Durable Medical Equipment.
https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180057.pdf