

Medical Coverage Policy | Percutaneous Electrical Nerve Field Stimulator System for Functional Abdominal Pain Disorders (IB-Stim)



EFFECTIVE DATE: 01|01|2025

POLICY LAST REVIEWED: 09|18|2024

OVERVIEW

The IB-Stim is a percutaneous electrical nerve field stimulator (PENFS) system device that works by sending gentle electrical impulses into cranial nerve bundles located in the ear. This stimulation targets brain areas involved in processing pain and aids in the reduction of functional abdominal pain associated with Irritable Bowel Syndrome (IBS) in pediatric patients. This policy is intended to address the medical necessity use of a percutaneous electrical nerve field stimulator system as a treatment option for pediatric individuals with functional abdominal pain associated with Irritable Bowel Syndrome.

Note: This policy is intended for the Percutaneous Electrical Nerve Field Stimulator System/IB-Stim device only. For percutaneous electrical nerve stimulation not related to functional abdominal pain and the IB-STIM device, please refer to the Percutaneous Electrical Nerve Stimulation, Percutaneous Neuromodulation Therapy, and Restorative Neurostimulation Therapy policy.

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

Percutaneous electrical nerve field stimulator system (IB-STIM) may be considered medically necessary in children and adolescents when ALL of the following criteria has been met:

- 11-18 years of age; AND
- Individual must be diagnosed with a ROME IV defined-functional gastrointestinal disorder which includes 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 GI symptoms have been present for at least 9 months; AND
- The individual has tried and failed at least one medication in all 3 of the following categories in addition to diet modification:
 - acid suppression (H2-blockers or PPIs); AND
 - antispasmodics or motility medications (hyoscyamine, dicyclomine, erythromycin/linacotide, prucalopride); AND
 - neuromodulators (amitriptyline/nortriptyline/gabapentin/pericatin/aprepitant); AND
- Individual does not have a history of a cardiac pacemaker, hemophilia, or psoriasis vulgaris

All other uses of the percutaneous electrical nerve field stimulator system (IB-Stim) that do not meet the above criteria are considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products.

PRIOR AUTHORIZATION

Prior authorization is required for Medicare Advantage Plans and recommended for Commercial Products.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Percutaneous electrical nerve field stimulator system (IB-STIM) may be considered medically necessary when the medical criteria above has been met.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable benefits.

BACKGROUND

Abdominal pain-related functional gastrointestinal disorders are defined as a group of gastrointestinal disorders with symptoms that cannot be attributed to any other condition and that have pain as the driving complaint. These disorders include irritable bowel syndrome (IBS), functional dyspepsia, abdominal migraine, functional abdominal pain, and functional abdominal pain syndrome. Children with abdominal pain-related functional gastrointestinal disorders have higher disability scores and worse quality of life than their peers. There is little evidence to support drug therapies for pediatric functional abdominal pain disorders (FAPDs) as these do not effectively address the underlying cause. These medications are being used off-label and have the potential for serious side-effects. Due to the complex nature and unclear pathophysiology of abdominal pain-related functional gastrointestinal disorders, management is challenging.

A new approach using a percutaneous electrical nerve field stimulation (PENFS) has been developed to treat pain. The non-surgical device called the Neuro-Stim/IB-Stim (Innovative Health Solutions, Versailles, IN, USA) is an FDA-cleared auricular device that uses alternating frequencies of stimulation to target central pathways through branches of four cranial nerves (V, VII, IX, and X) that innervate the external ear. This stimulation targets brain areas that process pain and helps reduce functional abdominal pain associated with IBS. The IB-Stim device is a 5-day (120 hours) treatment typically worn for 3 consecutive weeks.

The evidence includes randomized, double-blind, sham-controlled trials supporting that auricular neurostimulation reduces abdominal pain scores. One study concluded that 59% of patients receiving active PENFS therapy showed at least a 30% reduction in their worst abdominal pain from baseline to 3 weeks of therapy. At the extended follow-up (8-12 weeks after end of therapy), 32% of the treatment group continued to have improvement of at least 30% from baseline in worst pain compared with 18% in the sham group. Additionally, 82% of the active PENFS group reported global symptom improvement compared to 26% of the patients in the sham group (Krasaelap 2020).

A study was performed to compare outcomes of PENFS treatment to standard medical treatment using amitriptyline or cyproheptadine with the aim of comparing improvements in abdominal pain, nausea and disability using validated measures between these treatment options. PENFS significantly improved both abdominal pain and disability with a trend for improvement in nausea when assessed three months after treatment. Amitriptyline also improved abdominal pain compared to baseline. PENFS was more effective than cyproheptadine in improving abdominal pain scores but did not differ from amitriptyline. PENFS showed a trend for greater improvement in disability compared to SMT. PENFS was superior in decreasing abdominal pain compared with cyproheptadine while amitriptyline was superior to cyproheptadine in improving disability. Several studies now support PENFS as an effective treatment option to pharmacotherapy with a relatively safe side-effect profile (Santucci, 2023).

The medical management of pediatric functional abdominal pain disorders (FAPDs) is challenging due to a number of factors. Little evidence exists to support drug therapies for pediatric FAPDs as these do not effectively address the underlying cause. As a result, these drug therapies are being used off-label and have potential for serious side-effects in children and adolescents. Deep brain and spinal cord stimulation can improve abdominal pain and altered bowel habits in adult IBS patients, but are invasive and costly procedures. Peripheral neurostimulation approaches have gained attention due to noninvasive modulation of central pain pathways via stimulation of peripheral cranial neurovascular bundles in the external ear. Emerging studies have shown that the percutaneous electrical nerve field stimulation (PENFS) compared with a sham device significantly reduced worst abdominal pain and composite pain scores both short and long term, while improving global wellbeing and functioning (Krasaelap, 2020). There is no other device available that attains the level of clinical efficacy of PENFS/IB-Stim with minimal side effects or contraindications. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code(s) is considered medically necessary when the above medical criteria above are met:

0720T Percutaneous electrical nerve field stimulation, cranial nerves, without implantation

RELATED POLICIES

None

PUBLISHED

Provider Update, November 2024

REFERENCES

1. Krasaelap A., Sood M., 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.
2. Dvgulik. (2024, April 2). IB-Stim - NeurAxis. NeurAxis.
3. FDA. (2018). De novo classification request for IB-STIM regulatory information. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180057.pdf
4. Kovacic, K., Hainsworth, K., Sood, M., Chelimsky, G., Unteutsch, R., Simpson, P., & Adrian Miranda. (2017). Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomised, double-blind, sham-controlled trial. The Lancet Gastroenterology & Hepatology, 2(10), 727–737.
5. Santucci NR, Sahay R, El-Chammas KI, Graham K, Wheatley M, Vandenbrink M, Hardy J and Fei L (2023) Percutaneous electrical nerve field stimulation compared to standard medical therapy in adolescents with functional abdominal pain disorders. Frontiers in Pain Research 4:1251932. doi: 10.3389/fpain.2023.1251932. <https://www.frontiersin.org/journals/pain-research/articles/10.3389/fpain.2023.1251932/full>

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