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

Policy¹
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ 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/linactotide, prucalopride) and neuromodulators (amitriptyline/nortriptyline/gabapentin/periaxptin/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.

<table>
<thead>
<tr>
<th>Service Type</th>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>Prior authorization is not required.</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
<td>Prior authorization is not required.</td>
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<tr>
<td>Medicare HMO BlueSM</td>
<td>Prior authorization is not required.</td>
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<tr>
<td>Medicare PPO BlueSM</td>
<td>Prior authorization is not required.</td>
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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.

The following codes are included below for informational purposes only; this is not an all-inclusive list

CPT Codes
The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tr>
<td>0720T</td>
<td>Percutaneous electrical nerve field stimulation, cranial nerves, without implantation</td>
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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 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.

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 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. 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

<table>
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<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>7/2022</td>
<td>Clarified coding information</td>
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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


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](https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180057.pdf)