Mass General Brigham
Health Plan

Medical Policy
IB-Stim

Policy Number: 096

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization Required		X (64999)	
No Prior Authorization			
Not Covered/ Payable	X	X (0720T)	X

Overview
This document describes the guidelines Mass General Brigham Health Plan uses to determine medical appropriateness for the IB-Stim percutaneous electrical nerve field stimulator system. The IB-Stim stimulates branches of cranial and occipital nerves by transmitting low-frequency electrical pulses. The exact mechanism of action has not been demonstrated in humans; however, the stimulation may control pain processing in the brain and central nervous system.

Criteria
IB-Stim is covered for Mass General Brigham Health Plan ACO patients only when all of the following medical necessity criteria are met:

A. The member is between the ages of 11 and 18; AND

B. The member has functional abdominal pain associated with irritable bowel syndrome or functional dyspepsia as defined below:
   1. **Irritable bowel syndrome.** Recurrent abdominal pain on average at least one day/week in the last three months, with symptom onset at least six months ago, associated with two or more of the following criteria:
      - related to defecation; and/or
      - associated with a change in frequency of stool; and/or
      - associated with a change in form (appearance) of stool; or
   2. **Functional dyspepsia.** Evaluation including upper endoscopy shows no evidence of structural disease likely to explain symptoms, and at least one of the following criteria:
      - Bothersome postprandial fullness; and/or
      - Bothersome early satiation; and/or
      - Bothersome epigastric pain; and/or
      - Bothersome epigastric fullness; AND

C. The member has decreased functioning (e.g., school absence, avoidance of extracurricular activities, social avoidance) due to abdominal symptoms that persist despite at least three of the following:
    1. Behavioral modification; and
    2. Educational interventions or psychotherapy to teach coping mechanisms such as relaxation, distraction, or guided imagery; and
    3. Dietary changes or trigger avoidance; and
    4. Pharmacologic interventions; AND

D. The member's skin is healthy, clean, and intact at the implantation site.

Dosage

- 120 hours per week for up to three consecutive weeks and no more than four consecutive weeks.

Exclusions

- Use of cardiac pacemakers; or
- Hemophilia; or
- Psoriasis vulgaris; or
- Infected areas of skin at implantation site; or
- History of sensitivity to compound benzoin tincture.

MassHealth Variation

Mass General Brigham Health Plan uses guidance from MassHealth for medical necessity determinators for its MassHealth ACO members. **At the time of Mass General Brigham Health Plan's most recent policy review, MassHealth did not have medical necessity guidelines for IB-Stim.** However, MassHealth does have documentation requirements for IB-Stim.

Medicare Variation

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and documentation included in the Medicare manuals are the basis for coverage determinations. **At the time of Mass General Brigham Health Plan's most recent policy review, there was no NCD or LCD on percutaneous electrical nerve field stimulators.** When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for coverage and medical necessity determinations.

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Authorized Code	Code Description
0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation.
64999	Unlisted procedure, nervous system

Summary of Evidence

Recent literature on percutaneous electrical nerve field stimulation (PENFS) as an approach for managing functional abdominal pain and irritable bowel syndrome (IBS) in children and adolescents emphasizes both clinical efficacy and cost considerations. Balakrishnan and Chiou (2024) notes emerging evidence supporting the use of auricular PENFS as a promising non-pharmacologic intervention that reduced abdominal pain severity, frequency, and duration, and improved overall well-being, though they highlight a need for more studies to confirm the results of PENFS and determine its optimal setting, dosage, and target population before it should be routinely recommended as a treatment option for adolescents with disorders of gut-brain interaction (DGBIs).

Studies by Chogle et al. (2023) and Santucci et al. (2023) demonstrate significant improvements in quality of life and symptom control among pediatric patients with DGBIs following PENFS treatment. After four weeks, patients reported significant improvement in quality of life, abdominal pain, functional ability, somatization, and anxiety. Krasaelap et al. (2020) conducted a randomized, double-blind trial confirming that auricular neurostimulation was more effective than sham stimulation in adolescents who fulfilled criteria for IBS based on the Rome III version of the Questionnaire on Pediatric Gastrointestinal Symptoms. However, they also note that even after treatment, patients with DGBIs have significantly lower quality of life than healthy controls.

Additionally, an economic analysis by Shah et al. (2024) suggests that PENFS is a cost-beneficial alternative which added 18 healthy days over one year of follow-up, increased annual parental wages due to fewer missed workdays to care for the child, and cost savings to insurance compared to standard medical therapies.

In an Evolving Evidence Review, Hayes Inc. (2022) considered evidence for the IB-Stim device by NeurAxis and found that clinical studies offered “no/limited” support for IB-Stim based on one modestly sized study without any active comparison treatment group. A practice guideline from ESPGHAN/NASPGHAN gave a conditional recommendation for auricular PENFS based on moderate certainty evidence, noting the small size of the population studied to date from a single institution and the high cost of the intervention. These references indicate that PENFS may offer a viable option for managing functional abdominal pain and IBS in selected adolescents who have had difficulty managing symptoms with other interventions.

With such limited evidence of effectiveness, unclear durability, and only a conditional recommendation in one major practice guideline, Mass General Brigham Health Plan currently considers PENFS to be an experimental/investigational therapy for members of commercial and Medicare Advantage plans.

Effective Dates
August 2025: Effective date.

References
Balakrishnan K, Chiou EH. (2024). Functional abdominal pain in children and adolescents: management in primary care. UpToDate. Retrieved May 8, 2025, from https://www.uptodate.com/contents/functional-abdominal-pain-in-children-and-adolescents-management-in-primary-care

Chogle A, Visnagra K, Janchoi J, et al. Prospective study of the effect of auricular percutaneous electrical nerve field stimulation on quality of life in children with pain related disorders of gut-brain interaction. Front Pain Res (Lausanne). 2023 Sep 8;4:1223932. doi: 10.3389/fpain.2023.1223932. PMID: 37745801; PMCID: PMC10515210.

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Krasaelap A, Sood MR, Li BUK, 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. doi: 10.1016/j.cgh.2019.10.012. Epub 2019 Oct 14. PMID: 31622740.

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