IB-Stim (Percutaneous Electrical Nerve Field Stimulation) for Functional Abdominal Pain Clinical Coverage Criteria

Description

This policy's coverage determination applies to percutaneous electrical nerve field stimulation (PENFS) for functional abdominal pain using the IB-Stim (NeurAxis, Inc.) device.

IB-Stim (NeurAxis, Inc.) is a disposable battery-operated stimulation device designed for a single use. IB-Stim stimulator is placed behind the patient's ear and transmits low-frequency electric pulses to branches of Cranial Nerves V, VII, IX and X, and the occipital nerve, as an aid in the reduction of functional abdominal pain associated with irritable bowel syndrome (IBS) and functional dyspepsia (FD). The IB-Stim device is intended to be worn for 120 hours per week (continuous use over 5 days) for 4 consecutive weeks and combined with other therapies for IBS and FD.

Policy

This Policy applies to the following Fallon Health products:

☒ Fallon Medicare Plus
☒ MassHealth ACO
☒ NaviCare HMO SNP
☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
☒ Community Care

IB-Stim is covered for MassHealth ACO members only in accordance with MassHealth guidance (MassHealth Transmittal Letter PHY-172 March 2025) and requires prior authorization.

Fallon Health Clinical Coverage Criteria

Fallon Health considers IB-Stim (percutaneous electrical nerve field stimulation) for the treatment of functional abdominal pain associated with irritable bowel syndrome and functional dyspepsia experimental/investigational and not medically necessary.

Medicare Variation

Medicare statutes and regulations do not have coverage criteria for IB-Stim (percutaneous electrical nerve field stimulation) for the treatment of functional abdominal pain. Medicare does not have an NCD for IB-Stim (percutaneous electrical nerve field stimulation) for the treatment of functional abdominal pain. National Government Services, Inc. the Part A/B Medicare Administrative Contractor with jurisdiction in the Plan's service area does not have an LCD for IB-Stim (percutaneous electrical nerve field stimulation) for the treatment of functional abdominal pain (Medicare Coverage Database search 06/19/2026).

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs, or LCDs, the Plan may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature.

MassHealth Variation

In accordance with MassHealth Transmittal Letter PHY-172 (March 2025), IB-Stim is covered for 4 consecutive weeks for MassHealth ACO members when all of the following medical necessity criteria are met:

1. The member is 11 to 18 years of age;
2. The member has a diagnosis of functional abdominal pain associated with irritable bowel syndrome (IBS) and functional dyspepsia (FD). See Rome IV Criteria below.
3. There is documentation that organic gastrointestinal causes have been reasonably ruled out, including:
    a. Comprehensive history and physical examination
    b. Diagnostic testing as clinically indicated (e.g., laboratory studies, imaging, stool studies, endoscopy)
4. There is documentation of inadequate response, intolerance, or contraindication to standard treatments, including:
    a. Dietary interventions
    b. Pharmacologic interventions
    c. Behavioral and supportive therapies.
5. The member does not have any of the following contraindications to the IB-Stim device: cardiac pacemakers, hemophilia, and psoriasis vulgaris.

IB-Stim percutaneous electrical nerve field stimulation (PENFS) is not covered when the medical necessity criteria listed above are not met.

Rome IV Diagnostic Criteria for Child Functional Abdominal Pain
Must be fulfilled at least 4 times per month and include:
1. Episodic or continuous abdominal pain that does not occur solely during physiologic event (e.g., eating, menses)
2. Insufficient criteria for IBS, functional dyspepsia, or abdominal migraine
3. After appropriate evaluation, the abdominal pain cannot be fully explained by another condition.

Criteria fulfilled for at least 2 months before diagnosis.

Rome IV Diagnostic Criteria for Child IBS:
Must include all of the following:
1. Abdominal pain at least 4 days per month associated with one or more of the following:
    a. Related to defecation
    b. A change in frequency of stool
    c. A change in form (appearance) of stool
2. In children with constipation, the pain does not resolve with resolution of the constipation (children in whom the pain resolves have functional constipation, not irritable bowel syndrome)
3. After appropriate evaluation, the symptoms cannot be fully explained by another medical condition

Criteria fulfilled for at least 2 months before diagnosis.

Rome IV criteria for Child Functional Dyspepsia
Must include 1 or more of the following bothersome symptoms at least 4 days per month:
1. Postprandial fullness
2. Early satiation
3. Epigastric pain or burning not associated with defecation
4. After appropriate evaluation, the symptoms cannot be fully explained by another medical condition.

Criteria fulfilled for at least 2 months before diagnosis.

Hyams J, Di Lorenzo C, Saps M, et al., Childhood Functional Gastrointestinal Disorders: Child/Adolescent. Gastroenterology. 2016; 150:1456-68.

Exclusions

- First Relief v1 (Dyansys, Inc.) FDA 510(k) K202940 is not covered under this policy. This policy's coverage determination is specific to IB-Stim, for which clinical evidence was reviewed. Published evidence for First Relief v1 has not been separately evaluated under this policy.

Summary of Evidence

The evidence supporting IB-Stim percutaneous electrical nerve field stimulation (PENFS) is derived primarily from a randomized, sham-controlled trial conducted by Kovacic et al. (2017) involving 115 adolescents with abdominal pain-related functional gastrointestinal disorders. After exclusions, 57 patients receiving PENFS and 47 receiving sham treatment were included in the primary analysis. Following 3 weeks of treatment, patients treated with PENFS experienced significantly greater reductions in abdominal pain than patients treated with a sham device. Median worst pain scores were 5.0 (interquartile range [IQR], 4.0-7.0) in the PENFS group compared with 7.0 (IQR, 5.0-9.0) in the sham group ($p<0.0001$). Similarly, Pain Frequency-Severity-Duration (PFSD) composite scores improved significantly with PENFS, decreasing from a median of 24.5 at baseline to 8.4 at 3 weeks, compared with a decrease from 22.8 to 15.2 in the sham group. Overall symptom scores measured using the Symptom Response Scale also favored PENFS treatment.

The investigators reported that treatment effects persisted beyond the active treatment period. At a median follow-up of 9.2 weeks after treatment completion, worst pain and PFSD composite scores remained significantly improved from baseline in the PENFS group compared with the sham group. Median PFSD scores at follow-up were 12.0 in the PENFS group compared with 16.8 in the sham group ($p=0.018$). However, the magnitude of improvement was smaller than that observed immediately following treatment, and the clinical significance of these longer-term differences is uncertain. In addition, the study was limited by a relatively small sample size, short follow-up duration, a predominantly White (90%) and female (91%) study population, and inclusion of multiple functional gastrointestinal disorders rather than patients with IBS alone, which may limit generalizability.

A subsequent subgroup analysis by Krasaelap et al. (2020) evaluated 50 patients with IBS from the original trial and found that significantly more patients receiving PENFS achieved a clinically meaningful response, defined as at least a 30% reduction in worst abdominal pain, at the end of the 3-week treatment period. However, at extended follow-up (8 to 12 weeks), responder rates were no longer significantly different between groups (32% versus 18%; $p=.33$).A subsequent subgroup analysis by Krasaelap et al. 2020 evaluated patients with IBS from the original randomized trial and found that a greater proportion of patients receiving PENFS achieved a clinically meaningful response, defined as at least a 30% reduction in worst abdominal pain, at the end of the 3-week treatment period compared with sham stimulation. However, during extended follow-up at 8 to 12 weeks after treatment, responder rates were no longer significantly different between groups. Although some improvements from baseline persisted in the active-treatment group, the attenuation of treatment effects over time raises uncertainty regarding the durability of benefit after device removal.

Additional evidence includes a prospective pilot study by Bora et al., 2023, that evaluated the effects of IB-Stim PENFS on the gut microbiome in 20 female adolescents with IBS. Following 4 weeks of treatment, statistically significant improvements were observed in IBS symptom severity (IBS-SSS), visceral hypersensitivity (Visceral Sensitivity Index), and functional disability (Functional Disability Inventory). However, the study did not include a control group, was limited to a small sample of female participants, and was not designed to evaluate comparative treatment efficacy. The primary objective was to assess potential changes in the gut microbiome. No significant overall changes in microbial diversity or microbiome composition were observed following PENFS therapy. Although responders demonstrated higher microbial diversity and greater abundance of specific bacterial taxa, including *Blautia*, these findings were exploratory and do not establish a causal relationship between microbiome characteristics and clinical response.

Castillo et al.2023 conducted a prospective cohort study evaluating the gut microbiome in 27 adolescents with IBS and compared findings with 34 healthy controls. A subset of 17 female patients subsequently received 4 weeks of percutaneous electrical nerve field stimulation (PENFS) and underwent repeat clinical and microbiome assessments immediately after treatment and at 3 months. Following PENFS treatment, statistically significant improvements were reported in abdominal pain ($p=0.012$), functional disability ($p=0.007$), and pain catastrophizing ($p=0.003$). Metagenomic analyses demonstrated reductions in microbial pathways associated with carbohydrate degradation and long-chain fatty acid synthesis following treatment, suggesting possible modulation of gut-brain-microbiome interactions. However, the study was not designed to evaluate treatment efficacy and lacked a sham or active comparator group.

The small sample size, inclusion of only female participants in the treatment cohort, and potential for placebo effects limit interpretation of the clinical outcomes. While the findings provide preliminary evidence supporting biologic plausibility and suggest improvements in patient-reported symptoms following PENFS therapy, they do not establish comparative effectiveness or long-term clinical benefit.

Evidence-Based Clinical Practice Guidelines

The European Society for Paediatric Gastroenterology Hepatology and Nutrition ESPGHAN) and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHN) (Groen et al., 2025) developed guidelines for the treatment of IBS and functional abdominal pain in children age 4 to 18 years. The guidelines include 10 best practice statements for these patients, with one statement relevant to use of percutaneous electrical nerve field stimulation (PENFS). The guideline development group concluded that the overall certainty of evidence supporting efficacy was moderate, although certainty was downgraded for imprecision due to the limited number of participants and uncertainty regarding the magnitude of treatment effect. While reductions in pain intensity were among the largest reported across evaluated treatment modalities, the evidence was based on a single-center study in a relatively small pediatric population. The guideline suggests auricular PENFS as a treatment option for patients who have shown considerable difficulty in achieving pain relief (moderate certainty of evidence, moderate effect size). The recommendation is based on only one single-center study and its post hoc analysis. This study shows that a favorable effect likely exists, but that its size has yet to be determined, which, in the context of limited availability and experience, does not create sufficient grounds for a strong recommendation for all children with abdominal pain related disorders of gut–brain interaction. The guideline notes that this treatment comes at a relatively high initial cost and requires weekly new device placement for the duration of the treatment course. Moreover, PENFS has only recently been implemented as a treatment option for abdominal pain related disorders of gut–brain interaction and will likely undergo further development in the coming years.

Analysis of Evidence (Rationale for Determination)

The evidence for IB-Stim percutaneous electrical nerve field stimulation (PENFS) for functional abdominal pain associated with irritable bowel syndrome (IBS) includes a subgroup analysis of a randomized controlled trial (Krasaelap et al., 2020) and two prospective cohort studies (Bora et al., 2023; Castillo et al., 2023). Across these studies, 64 unique patients with IBS were evaluated. Participants were 11 to 18 years of age, and most were female. Follow-up ranged from 3 to 4 weeks during active treatment, with limited post-treatment follow-up available. One study reported outcomes at 3 weeks, one study reported outcomes at 4 weeks, and one study reported outcomes at 4 weeks and 3 months after treatment; however, only a small subset of participants completed the 3-month follow-up assessment.

Patients receiving IB-Stim PENFS generally experienced improvements in abdominal pain severity, IBS symptom burden, functional disability, and other patient-reported outcomes during the active treatment period. In the randomized subgroup analysis, a greater proportion of patients treated with PENFS achieved a clinically meaningful reduction in abdominal pain compared with sham treatment at the conclusion of therapy. However, differences between treatment groups were not maintained during extended follow-up. The prospective cohort studies also reported improvements in symptom severity and functional outcomes, but the absence of control groups limits interpretation of these findings and raises the possibility that observed improvements were attributable, in part, to placebo effects, regression to the mean, or the natural course of disease.

Overall, the available evidence suggests that IB-Stim PENFS may provide short-term reductions in abdominal pain and symptom burden during active treatment. However, confidence in the long-term effectiveness and durability of benefit is limited by the small number of studies, modest sample sizes, predominance of female participants, short follow-up periods, and limited evidence demonstrating sustained improvements beyond the treatment phase. Additional well-designed randomized controlled trials with larger patient populations and longer-term follow-up are needed to establish the long-term clinical effectiveness of IB-Stim PENFS for IBS-associated functional abdominal pain.

Coding

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

IB-Stim is a single-use, disposable percutaneous electrical nerve field stimulation (PENFS) device. The cost of the device is included in the reimbursement for CPT code 64567 and should not be billed separately. The device is applied by a physician once weekly for 4 consecutive weeks. Following each application, the patient wears the device continuously for up to 120 hours (5 days) and removes the device at home before returning for the next weekly treatment.

CPT code 64567 should be reported for each placement of the IB-Stim device.

It is generally not appropriate to report a separate evaluation and management (E/M) service on the same date as device placement because routine assessment of treatment tolerance, device-related complications, and symptom improvement is considered part of the work included in CPT code 64567. A separate E/M service may be reported when the requirements for a significant, separately identifiable E/M service are met and appropriately documented.

Code	Description
64567	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation

References

1. Kovacic K, Hainsworth K, Sood M, et al. 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.
2. 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.
3. Bora G, Atkinson SN, Pan A, et al. Impact of auricular percutaneous electrical nerve field stimulation on gut microbiome in adolescents with irritable bowel syndrome: a pilot study. J Dig Dis. 2023;24(5):348-358.
4. Castillo DF, Denson LA, Haslam DB, et al. The microbiome in adolescents with irritable bowel syndrome and changes with percutaneous electrical nerve field stimulation. Neurogastroenterol Motil. 2023;35(7):e14573.
5. Groen J, Gordon M, Chogle A, et al. ESPGHAN/NASPGHAN guidelines for treatment of irritable bowel syndrome and functional abdominal pain-not otherwise specified in children aged 4-18 years. J Pediatr Gastroenterol Nutr. Aug 2025; 81(2): 442-471.
6. Symplr Software LLC. Health Technology Assessment. IB-Stim (NeurAxis Inc.) for Treatment of Pain Associated With Irritable Bowel Syndrome in Adolescents. symplr Software LLC.; April 13, 2026.

Policy history

Origination date: 08/01/2026
Review/Approval(s): Technology Assessment Committee: 06/23/2026 (policy origination).
Utilization Management Committee: 07/21/2026: (policy origination; approved).

Instructions for Use

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health generally follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follows CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making

medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.