Molina Clinical Policy
Percutaneous Electrical Nerve Field Stimulation for Abdominal Pain
Policy No. 383

Last Approval: 12/10/2025
Next Review Due By: December 2026

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Irritable bowel syndrome (IBS), a functional gastrointestinal (GI) illness, is characterized by persistent stomach pain with episodic exacerbations and abnormalities in bowel movements that vary in severity and duration. The etiology of IBS is unknown, but current literature suggests that a multifactorial pathogenesis involving brain-gut axis dysregulation, GI autonomic nervous system abnormalities, some intestinal inflammation, increased bowel sensitivity, decreased pain thresholds, and psychological factors such as stress and anxiety contribute to the disorder. IBS is currently diagnosed based on symptoms, medical and family history, and physical examination. Diagnostic evaluation may include stool tests, colonoscopy, computed tomography (CT), upper endoscopy, lactose intolerance testing, and breath tests to detect bacterial overgrowth in the GI tract. Treatment for IBS is aimed at resolving symptoms such as pain, bloating, cramping, and diarrhea or constipation. Conventional treatment includes dietary changes, probiotics, antispasmodics, fiber supplementation, mental health interventions (e.g., cognitive behavioral therapy, hypnosis), and antidepressants (Hayes 2025).

Functional abdominal pain disorders (FAPD) (also called disorders of gut-brain interaction, DGBIs, or pain-predominant functional gastrointestinal disorders) are conditions that arise from complex interactions between regulatory mechanisms in both the enteric and central nervous systems. They are often linked to heightened sensitivity to visceral pain, a lowered pain threshold caused by altered processing of visceral signals in the brain, abnormal pain responses following rectal distension in irritable bowel syndrome (IBS), or impaired gastric accommodation after eating. Ongoing pain experiences can negatively impact psychological well-being (Balakrishnan & Chiou 2025). The goal of FAPD management in children and adolescents is a rehabilitation approach that includes a return to normal function rather than complete elimination of pain. Management is individualized based on the behavior of the child and family, triggers, and symptoms, and includes both medical and behavioral treatments (Balakrishnan & Chiou 2025; Fishman, Aronson, & Di Lorenzo 2025).

Percutaneous electrical nerve field stimulation (PENFS) is a conservative, minimally invasive pain treatment that involves inserting acupuncture-like needles into the skin and connecting them via a cable to an external power source. PENFS electrodes are not implanted permanently. The mechanism of action of PENFS is thought to involve endogenous opioid-like substances modulating the hypersensitivity of nerves that cause persistent pain.

Regulatory Status

IB-Stim is currently the only FDA-cleared PENFS for the treatment of abdominal pain in adolescents with IBS. IB-Stim device was granted a De Novo classification order in 2018 under the number DEN180057 and product code QHH. The original approval was intended to be used in patients 11-18 years of age with functional abdominal pain associated with irritable bowel syndrome (IBS). On October 30, 2024, the FDA issued a determination of substantial equivalence for marketing of the device for age range to 8–21 years (K241533).

On May 15, 2025, the FDA issued a determination of substantial equivalence for marketing of the device for the indication of functional dyspepsia (FD) in 8- to 21-year-olds (K250451), and on October 16, 2025, the FDA issued a determination of substantial equivalence for marketing for use in patients 8 years and older with functional abdominal pain associated IBS and FD (K252024). The IB-Stim is intended to be used for only 120 hours per week for up to 4

consecutive weeks (FDA 2018, 2019, 2024 and 2025).

COVERAGE POLICY

Percutaneous electrical nerve field stimulation (i.e., IB-Stim Device) may be **considered medically necessary** when ALL the following criteria are met:

1. Member is 8-21 years of age
2. Member has a confirmed diagnosis of at least ONE of the following:
   a. Functional abdominal pain associated with irritable bowel syndrome (IBS)
   b. Functional dyspepsia (FD) with abdominal pain
3. Organic underlying gastrointestinal (GI) diseases have been ruled out
4. The GI symptoms have been present for a minimum of 9 months
5. Member has tried and failed at least one medication from each of the following categories:
   a. Acid Suppressants (e.g., H2-blockers or proton pump inhibitors)
   b. Antispasmodics or motility medications (e.g., hyoscyamine, dicyclomine, erythromycin/linaclotide, prucalopride)
   c. Neuromodulators (e.g., amitriptyline, nortriptyline, gabapentin, cyproheptadine [periactin], aprepitant)
6. Member has tried and failed diet modification

All other uses of percutaneous electrical nerve field stimulation are considered **experimental, investigational, and unproven** due to insufficient published evidence assessing the safety and/or impact on health outcomes.

Limitations and Exclusions

Percutaneous electrical nerve field stimulation (i.e., IB-Stim Device) is intended to be used only for 120 hours per week for up to 4 consecutive weeks.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Randomized Controlled Trials

Castillo et al. (2023) conducted a RCT to assess the effects of percutaneous electrical nerve field stimulation (PENFS) on the microbiome in pediatric patients with IBS. The study consisted of 27 patients with IBS and 34 Health Control (HC) patients. Of the 27 patients with IBS, 17 patients (all female) completed weekly treatment with PENFS via IB-Stim for four weeks. Participants were between 8-20 years of age (average age 15.4) and 82% of IBS participants were female while 41% of patients in the HC group were female. Inclusion criteria included meeting Rome IV criteria for diagnosis of IBS and negative testing for celiac disease and inflammatory disorders. Participants were excluded from the study if they had a diagnosis of organic gastrointestinal disorder, were on probiotics or antibiotics, or receiving formula as their sole source of nutrition. Results were measured by self-reported measures including Abdominal Pain Index (API), Pain Catastrophizing Scale for Children (PCS-C), Functional Disability Inventory-Child Version (FDI), Screen for Child Anxiety Related Disorders (SCARED), and Pediatric Insomnia Severity Index. Participants also used a daily diary to include pain rating with the Visual Analog Scale (VAS) for Pain Intensity and Pain Unpleasantness, stool frequency, and stool consistency, using the Modified Bristol Stool Form Scale for Children. Participants of the

study also provided stool samples that were used to evaluate their microbiome species, metabolic pathways, and fecal calprotectin levels. Patients that received PENFS treatment reported reductions from baseline to post-treatment and follow-up visits after treatment with PENFS for API (−3.09 versus 2.33 versus 2.22, p= 0.01) and FDI (22.79 versus 16.27 versus 15.11, p= 0.007). PCS-C scores were reduced from baseline to post-treatment and follow-up visits (23.58 versus 13.96 versus 15.56, p= 0.003) and from baseline to follow-up visits (23.58 vs 15.56). Decrease trends in anxiety, sleep disturbance, and VAS pain scores were reported. Increase trends in stool consistency and frequency were reported. Four microbiome species were depleted at post-treatment compared to baseline (R. bromii, C. bolteae, B. caccae, A. finegoldii) but no species had increased at follow-up. Eighteen metabolic pathways decreased in post-treatment. Eight were related to fatty acid biosynthesis and four were related to sugar fermentation or degradation. The study concluded PENFS led to improvements in abdominal pain, functioning, and catastrophizing. Limitations of this study include small sample size and selection bias with more females in the IBS group compared to control. Researchers were also unable to control for diet and medications that may have affected the microbiome.

Kovacic et al. (2020) conducted a small study to determine whether pretreatment vagal efficiency (VE), respiratory sinus arrhythmia, and heart period can predict pain improvement with auricular neurostimulation in pediatric functional abdominal pain disorders. The study included 92 adolescents (n=92) with FAPD who participated in a four-week randomized, double-blinded, sham-controlled auricular neurostimulation trial. Pain was predicted using mixed effects modeling from baseline electrocardiogram data. A three-way interaction demonstrated that treatment group participants with a low baseline VE had decreased pain levels at week 3. No significant changes were reported in placebo (or high VE treatment group) subjects, which was supported by the strong correlation between baseline VE and the degree of pain reduction in the treatment group. The study concluded that impaired cardiac vagal regulation measured by VE predicts pain improvement with auricular neurostimulation; however, the study is limited by its small sample size and short-term follow-up period.

Kovacic et al. (2017) conducted a single center, blinded, sham RCT evaluating the efficacy of a PENFS device, NeuroStim, in adolescents with abdominal pain-related functional GI disorders. The four-week trial enrolled a mixed population of adolescent patients (ages 11-18) with functional GI disorders and who met Rome III criteria for related disorders. The primary outcome was change in abdominal pain scores (change in worst pain intensity and a composite pain-frequency-severity-duration (PFSD) score). Global symptom improvement was assessed as a secondary endpoint using the Symptom Response Scale (SRS). Participants were followed for a median of 9.2 weeks after the last week of treatment. The study included 104 children (n=104) with abdominal pain-related functional GI disorders who met the study criteria and were randomly assigned to PENFS (n=57) with an active device or sham (n=47). The worst pain score improved statistically significantly in the PENFS group compared to the sham group between baseline and week 3 (difference of 2.15 points, p = 0.0001). However, there was no significant difference between the PENFS group and the sham group in the proportion of participants who improved by 30% or more from baseline to extended follow-up in worst pain or usual pain. At week 3, the median PFSD composite scores decreased significantly more in the PENFS treatment group than in the sham treatment group (difference of 11.48 points). At the end of the study, the PENFS group improved significantly more than the sham treatment group in terms of both the median worst pain score and the composite PFSD score. SRS scores improved in the PENFS group versus the sham group at 3 weeks, but no significant difference between groups was observed at the extended follow-up. The authors noted that the study did not evaluate changes in bowel habits, which were considered the most bothersome IBS symptom, and instead focused solely on pain relief. The reported side effects were comparable between the two groups, and there were no serious adverse effects. Study limitations include small sample size and short follow-up period (8-12 weeks) and exclusions after randomization. The preliminary findings of this study are encouraging; however further research is required to validate the findings. Considering the chronic condition of abdominal pain-related functional GI disorders, a longer evaluation period is also required to determine efficacy durability. Furthermore, based on current findings, determining the clinical significance of the PENFS's alleged effects is difficult.

Krasaelap et al. (2020) performed post-hoc secondary analyses of the pivotal trial conducted by Kovacic et al. (2017) as requested by the FDA to support whether the results for patients in the IBS sub-group, which comprised the majority of the trial participants, were consistent with the overall cohort studied. Fifty patients were randomly assigned to groups that received PENFS (n=27) or a sham stimulation (n=23) 5 days per week for 4 weeks. The primary endpoint was the number of patients who experienced a 30% or greater reduction in the severity of their worst abdominal pain after three weeks. Secondary endpoints were improvement in overall symptoms based on a symptom response scale after 3 weeks, a decrease in the composite abdominal pain severity score, and a decrease in the severity of typical abdominal pain. At 3 weeks, 59% of patients who received PENFS experienced a 30% or greater reduction in their worst

abdominal pain, compared to 26% of patients who received sham stimulation (p=0.024). It was reported that 82% of PENFS patients had a symptom response scale score of 2 or higher compared with 26% of sham patients. There were no significant side effects reported. It was concluded that auricular neurostimulation reduced abdominal pain scores, resulting in an overall improvement among adolescents with IBS. The study concluded that PENFS is a noninvasive treatment option for the IBS pediatric population although the sample size was small and short-term follow-up of the trial.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Santucci et al. (2024) completed a prospective study evaluating the efficacy of PENFS in children and adolescents diagnosed with functional dyspepsia, including post-prandial distress and epigastric pain syndrome, and compared outcomes between patients treated with PENFS alone and those receiving PENFS combined with a behavioral intervention. Charts of 84 patients completing four weeks of PENFS were analyzed, with 61% receiving concurrent behavioral therapy and 39% receiving PENFS alone. Outcomes were assessed using validated instruments including the Abdominal Pain Index, Nausea Severity Scale, Functional Disability Inventory, Pittsburgh Sleep Quality Index, Children's Somatic Symptoms Inventory, and PROMIS Pediatric Anxiety and Depression Scales. Across the entire cohort, significant improvements were observed from baseline to three weeks and sustained at three months in abdominal pain, nausea severity, functional disability, somatization, sleep quality, anxiety, and depression scores, with p-values ranging from <0.0001 to 0.02. Subjective reports indicated nausea improvement at week three ($p = 0.01$) and a trend toward abdominal pain improvement ($p = 0.07$). In the PENFS plus behavioral intervention group, abdominal pain showed significant subjective improvement at both week three and three months ($p = 0.003$ and 0.02), nausea improved at both time points ($p = 0.01$ and 0.04), and sleep disturbances demonstrated a trend toward improvement ($p = 0.08$ and 0.07). The authors concluded that PENFS leads to improvements in pain, nausea, functioning, somatization, sleep, anxiety, and depression in pediatric functional dyspepsia, and that combining PENFS with behavioral therapy provides suggested additive benefit, particularly for subjective pain and nausea outcomes. The authors recommend larger, multicenter trials to confirm efficacy, assess long term outcomes, and define the role of integrated neuromodulation and behavioral therapy in this population.

Chogle et al. (2024) completed a multicenter, prospective registry study evaluating PENFS in pediatric patients with abdominal pain-related disorders of gut brain interaction (i.e., IBS, functional dyspepsia). A total of 292 children aged 8 - 18 years were enrolled across ten U.S. pediatric gastroenterology referral centers. Treatment with percutaneous electrical nerve field stimulation (IB-Stim) for four consecutive weeks demonstrated significant improvements in pain and symptom-related scores within three weeks, with sustained benefits for some measures over time. In a cohort of 288 participants, median child-reported Abdominal Pain Index (API) scores decreased from 2.68 (IQR 1.84–3.58) at baseline to 1.99 (1.13–3.27) after three weeks ($p < 0.001$), and further to 1.81 (0.85–3.20) at three months ($n = 75$; $p < 0.001$). Nausea Severity Scale (NSS) scores showed similar improvements, persisting at three months ($n = 74$; $p < 0.001$) and six months ($n = 55$; $p < 0.001$). Functional Disability Inventory (FDI) scores also declined at three months ($n = 76$; $p = 0.01$), though these gains were not maintained beyond that point. PENFS therapy administered over four weeks resulted in statistically significant reductions in abdominal pain severity ($p < 0.001$), nausea ($p< 0.001$), and functional disability scores ($p < 0.001$). The authors noted that PENFS was associated with significant improvements in patient reported outcomes, but emphasized limitations including the open label design, short term follow up, and recruitment from tertiary centers, which may affect generalizability. They recommend further randomized controlled trials and long-term studies to confirm efficacy and durability of response.

Chogle et al. (2023) performed a prospective study to analyze the effect of auricular PENFS on the quality of life of children with disorders of gut-brain interaction. The study consisted of 31 participants between 11-18 years (mean age 15.7 years) with 80.6% female participants. Thirteen patients had IBS, and 9 patients had functional dyspepsia. Patients received PENFS therapy (IB-Stim NeurAxis, Versailles, IN) once a week during a four-week period. Outcomes were measured with self-reported Abdominal Pain Index (API), Nausea Severity Scale (NSS), Functional Disability Inventory (FDI), Child Somatization Inventory (CSI), Patient-Reported Outcomes Measurement Information System (PROMIS) Global Health Anxiety, PROMIS Global Health Depression, and Quality of Life (QoL) questionnaires including the Pediatric Quality of Life (PedsQL) generic core scale and PedsQL general well-being scale. Patients reported significant reductions in API, NSS, FDI, CSI, and PROMIS Anxiety ($p < 0.05$). Self-reported QoL and PROMIS Depression scores did not change ($p > 0.05$). The study concluded that PENFS enhances the QoL of children with pain related disorders of gut-brain interaction. Limitations of this study included a small sample size, absence of a control group, and lack of long-term follow-up data.

Santucci et al. (2023) conducted a retrospective review to evaluate the effectiveness of PENFS versus standard medical therapy (SMT) using amitriptyline or cyproheptadine in managing symptoms of functional abdominal pain disorders (FAPD) in patients aged 11 to 21. Eligible patients met ROME IV criteria for FAPD and had no organic gastrointestinal disorders causing pain. Symptom changes in abdominal pain, nausea, and disability were assessed using the Abdominal Pain Index (API), Nausea Severity Scale (NSS), and Functional Disability Inventory (FDI) at baseline and follow-ups within three months. Results showed that the PENFS group experienced significant improvements in API ($p = 0.001$), FDI ($p = 0.048$), and a trend toward improvement in NSS ($p = 0.059$). The amitriptyline group showed a significant reduction in API scores ($p = 0.034$), but NSS and FDI scores remained unchanged. In the cyproheptadine group, scores decreased across all measures but were not statistically significant. The study was limited by its retrospective design, which did not account for baseline psychological comorbidities or other biopsychosocial factors, and the short three-month follow-up period, precluding evaluation of long-term outcomes. Despite these limitations, the study concluded that PENFS significantly improved abdominal pain and disability, with a potential benefit for nausea.

National and Specialty Organizations

The **European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN)/North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN)** published the *ESPGHAN/NASPGHAN guidelines for treatment of irritable bowel syndrome and functional abdominal pain-not otherwise specified in children aged 4-18 years* (Groen et al. 2025) that recognizes PENFS as a therapeutic option. The guideline panel notes that PENFS may be considered in children with abdominal pain related disorders of gut brain interaction who have not responded adequately to conventional therapies. Within the guideline PENFS is given a conditional recommendation supported by moderate certainty of evidence. Although the evidence was rated as moderate in certainty, the reduction in pain intensity ranked among the most substantial compared to all other treatment options evaluated. The guideline development group highlights that this therapy involves a relatively high upfront cost and requires weekly replacement of the device throughout the treatment period. Additionally, PENFS is a relatively new intervention for abdominal pain–related disorders of gut–brain interaction and is expected to evolve further as clinical experience and research progress.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation [Effective until 12/31/2025]
64567	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation [Effective 01/01/2026]

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
S8930	Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with patient [when used to describe the IB-Stim device]
E1399	Durable medical equipment, miscellaneous [when used to describe the IB-Stim device]

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/10/2025 Policy revised. Title changed to Percutaneous Electrical Nerve Field Stimulation. Coverage criteria updated to include functional

	dyspepsia with abdominal pain. Overview, Summary of Medical Evidence and References updated. IRO Peer Review on November 19, 2025, by a practicing physician board certified in Pediatric Gastroenterology.
12/11/2024	Policy reviewed. Coverage position updated from 'experimental, investigational, and unproven' to medically necessary if all criteria are met. Criteria for coverage added. Updated Summary of Medical Evidence and References. Peer Review on December 3, 2024, by practicing physician board-certified in Pediatric Gastroenterology.
12/13/2023	Policy reviewed. No changes in coverage position; updated Summary of Medical Evidence and References.
12/14/2022	Policy reviewed. No changes in coverage position; updated Overview, Summary of Medical Evidence, and References.
12/08/2021	Policy reviewed, no changes, updated references.
12/09/2020	New policy. IRO Peer Review on October 2, 2020, by practicing, board-certified physician in Pediatrics.

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