2.01.106	Percutaneous Electrical Nerve Field Stimulation for Disorders of Gut-Brain Interaction		
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Section:	2.0 Medicine	**Page:**	Page 1 of 13

Policy Statement

I. Percutaneous electrical nerve field stimulation for abdominal pain in individuals with disorders of gut-brain interaction, including but not limited to irritable bowel syndrome and functional dyspepsia, is considered **investigational.**

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

The Rome IV diagnostic criteria provide definitions for abdominal pain-related disorders of gut-brain interaction. See Table 1.

Coding

See the Codes table for details.

Description

Percutaneous electrical nerve field stimulation involves the transmission of electrical impulses to cranial nerve bundles in the ear targeting brain areas involved in processing pain. In the case of patients with abdominal pain-related disorders of gut-brain interaction, nerves processing pain for the abdominal region are targeted.

Summary of Evidence

For individuals with abdominal pain-related disorders of gut-brain interaction who receive percutaneous electrical nerve field stimulation (PENFS), the evidence includes a single randomized controlled trial (RCT) and observational, uncontrolled studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The RCT (N=115) included a heterogeneous population of adolescent patients aged 11 to 18 years with pain-related functional gastrointestinal disorders. Treatment was administered for 3 weeks, and reductions in pain were observed with the active device compared with a sham PENFS device at end of treatment and end of follow-up (maximum of 12 weeks). The subgroup of patients with IBS also had improved pain at the end of treatment with the active device compared with the sham device. However, the trial is limited by its small sample size, heterogeneous population of gastrointestinal disorders, lack of bowel habit measurement, and the short duration of follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Not applicable.

Related Policies

- Cranial Electrotherapy Stimulation and Auricular Electrostimulation
- Percutaneous Electrical Nerve Stimulation, Percutaneous Neuromodulation Therapy, and Restorative Neurostimulation Therapy

Benefit Application

Benefit determinations should be based in all cases on the applicable member health services contract language. To the extent there are conflicts between this Medical Policy and the member health services contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal law may prohibit health plans from denying FDA-approved Healthcare Services as investigational or experimental. In these instances, Blue Shield of California may be obligated to determine if these FDA-approved Healthcare Services are Medically Necessary.

Regulatory Status

In 2019, the IB-Stim device (previously known as Neuro-Stim; Innovative Health Solutions, Inc.) was cleared for marketing by the FDA through the de novo 513(f)(2) process (DEN180057). Both the IB-Stim and the similar NSS-2 BRIDGE device (Innovative Health Solutions, Inc.) are derivatives of the Electro Auricular Device (Navigant Consulting, Inc.). As of October 2025, the IB-Stim device (NeurAxis) is indicated for patients 8 years of age and older with functional abdominal pain associated with IBS and functional dyspepsia when combined with other therapies. It is intended to be used for 120 hours per week for 4 consecutive weeks. The expanded indication for use in adults was based on extrapolation of clinical data. The First Relief v1 (DyAnsys, Inc.) device was deemed substantially equivalent to the IB-Stim device in 2020 and the TEA Device (Transtimulation Research, Inc.) was deemed substantially equivalent to the IB-Stim device in 2023. FDA product code: QHH.

Rationale

Background

Abdominal Pain-Related Disorders of Gut-Brain Interaction

The Rome IV diagnostic criteria (published in 2016) provide definitions for the abdominal pain-related disorders of gut-brain interaction (Table 1).[1] This family of conditions has historically been called functional gastrointestinal disorders, but the Rome IV criteria proposed updated terminology based on newer understanding of pathophysiology and lack of clarity about the word "functional". The Rome V diagnostic criteria are expected to be released in 2026.[2]

Table 1. Abdominal Pain-Related Disorders of Gut-Brain Interaction According to Rome IV Criteria

Categorization of Disorders	Specific Disorder Names
Esophageal disorders	Functional chest pain Functional heartburn Reflux hypersensitivity Globus Functional dysphagia
Gastrointestinal disorders	Functional dyspepsia (includes postprandial distress syndrome, epigastric pain syndrome) Belching disorders (includes excessive supragastric belching, excessive gastric belching)

Categorization of Disorders	Specific Disorder Names
	Nausea and vomiting disorders (includes chronic nausea vomiting syndrome, cyclic vomiting syndrome, cannabinoid hyperemesis syndrome) Rumination syndrome
Bowel disorders	Irritable bowel syndrome Functional constipation Functional diarrhea Functional abdominal bloating/distension Unspecified functional bowel disorder Opioid-induced constipation
Centrally mediated disorders of gastrointestinal pain	Centrally mediated abdominal pain syndrome Narcotic bowel syndrome/opioid-induced gastrointestinal hyperalgesia
Gallbladder and sphincter of Oddi disorders	Biliary pain (including functional gallbladder disorder, functional biliary sphincter of Oddi disorder) Functional pancreatic sphincter of Oddi disorder
Anorectal disorders	Fecal incontinence Functional anorectal pain (including levator ani syndrome, unspecified functional anorectal pain, proctalgia fugax) Functional defecation disorders (including inadequate defecatory propulsion, dyssynergic defecation)
Childhood functional gastrointestinal disorders: neonate/toddler	Infant regurgitation Rumination syndrome Cyclic vomiting syndrome Infant colic Functional diarrhea Infant dyschezia Functional constipation
Childhood functional gastrointestinal disorders: child/adolescent	Functional nausea and vomiting disorders (including cyclic vomiting syndrome, functional nausea and functional vomiting, rumination syndrome, aerophagia) Functional abdominal pain disorders (including functional dyspepsia, postprandial distress syndrome, epigastric pain syndrome) Irritable bowel syndrome Abdominal migraine Functional abdominal pain - not otherwise specified Functional defecation disorders (including functional constipation, nonretentive fecal incontinence)

Irritable Bowel Syndrome

Irritable bowel syndrome (IBS) is estimated to affect 5% to 10% of the population globally, and accounts for between 2.4 and 3.5 million physician visits in the United States each year.[3] Up to two-thirds of patients with IBS are female, and it is most common in patients less than 50 years of age. The cause of IBS remains unknown, but is believed to be due to a dysfunction in gut-brain interaction.[4] Symptoms of IBS can include diarrhea, constipation, or both. Abdominal pain and bloating are also common IBS symptoms. These symptoms decrease patient quality of life and create a significant healthcare burden.[5] The American College of Gastroenterology (ACG) recommends that patients diagnosed with IBS are categorized by subtypes: IBS with constipation (IBS-C), IBS with diarrhea (IBS-D), IBS with mixed symptoms (IBS-M), or IBS without abnormal stools (IBS-U).

Treatment

First-line treatment of patients with IBS generally involves dietary changes. If dietary changes fail to achieve therapeutic goals, there are numerous pharmacotherapeutic options for patients with IBS. Pharmacologic treatment is based on the IBS subtype, and the predominance of either constipation

or diarrhea (Table 2).[6,5,7] Notably, many IBS treatments are not Food and Drug Administration (FDA)-approved for children or adolescents. The American College of Gastroenterology recommends that gut-directed psychotherapy such as cognitive-behavior therapy and gut-directed hypnotherapy may be beneficial for global IBS symptoms.[5]

Table 2. Pharmacologic Treatment of Irritable Bowel Syndrome

IBS-D	IBS-C	Abdominal Pain
Antidiarrheal agents (e.g., loperamide)	Laxatives (e.g., polyethylene glycol)	Antispasmodics (e.g., dicyclomine, hyoscyamine, peppermint oil)
Mu-opioid receptor agonist (eluxadoline for refractory patients only)	Chloride channel activator (lubiprostone)	TCA
5-HT3 receptor antagonist (alosetron or ondansetron)	Guanylate cyclase agonists (linaclotide or plecanatide)	SSRI
Antibiotic (rifaximin)	Sodium/hydrogen exchanger 3 (tenapanor)	

HT: hydroxytryptamine (serotonin); IBS-C: irritable bowel syndrome with constipation; IBS-D: irritable bowel syndrome with diarrhea; SSRI: selective serotonin reuptake inhibitor; TCA: tricyclic antidepressant.

Functional Dyspepsia

According to the Rome IV criteria, functional disorders are diagnosed based on symptoms reported by the patient, rather than based on objective structural or motility findings.[1] Dyspepsia affects about 12% of the US population.[8] The most common symptoms are postprandial gastrointestinal distress (feeling full during or after a meal) as well as epigastric pain.[9] The American College of Gastroenterology published guidelines for management of dyspepsia in 2017.[10] Treatment of dyspepsia includes empiric proton pump inhibitor therapy or treatment for *Helicobacter pylori* infection in patients with *H. pylori* infection. If first-line treatment is not effective, prokinetic or tricyclic antidepressant therapy are second-line options.

Percutaneous Electrical Nerve Field Stimulation

Because there are few pharmacologic treatments for children and adolescents with abdominal pain-related disorders of gut-brain interaction, nonpharmacologic options are commonly explored. Percutaneous electrical nerve field stimulation (PENFS) is a potential treatment option for these patients. PENFS involves a non-implantable device which stimulates nerves remotely from the site of pain and has been studied for a variety of musculoskeletal or neuropathic pain conditions or for patients with opioid withdrawal.[11] The IB-Stim device is a type of PENFS that is intended for use only in patients with IBS. The device is disposable and battery-operated. Key components of the device include a percutaneous electrical nerve field stimulator placed behind the ear which connects to a multi-wire electrode array consisting of 4 leads. The electrodes have thin needles and attach to the ear at points (preauricular, lobule, and superior crus) where cranial nerve peripheral branches are located just beneath the skin. A pen light included with the device is used to visualize the neurovasculature features and aid in proper electrode placement.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.
To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the

evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials (RCTs) are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Abdominal Pain-Related Disorders of Gut-Brain Interaction

Clinical Context and Therapy Purpose

The purpose of percutaneous electrical nerve field stimulation (PENFS) in individuals who have abdominal pain-related disorders of gut-brain interaction is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with abdominal pain-related disorders of gut-brain interaction.

Interventions

The therapy being considered is PENFS.

Comparators

The following therapies are currently being used to treat abdominal pain-related disorders of gut-brain interaction: dietary modification, behavior modification, and pharmacotherapy.

Outcomes

The general outcomes of interest are pain, bowel function, and quality of life. Follow-up at 3 months is of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Irritable Bowel Syndrome

Randomized Controlled Trials

Kovacic et al (2017) conducted an RCT comparing the Neuro-Stim PENFS device with a sham device in adolescent patients with abdominal pain-related functional gastrointestinal disorders including IBS (Table 3).[12] Patients 11 to 18 years of age with abdominal pain (pain score ≥3 on an 11-point scale) occurring at least twice weekly for at least 2 months were included. Various diagnoses were represented in the study population, including IBS (49%), abdominal migraine (31%), functional dyspepsia (25%), and functional abdominal pain syndrome (16%); 26 patients met criteria for multiple disorders. The devices were worn for 5 days each week for 4 weeks. Baseline medications were continued with the exception of antispasmodics which were not allowed during the study period. Enrolled patients were primarily female (91%) and White (90%). Pain, as measured on the Pain

Frequency-Severity-Duration (PFSD) scale, was the primary outcome. The PFSD scale incorporates several aspects of the pain experience and is generally calculated over a 14-day period, but was modified as a weekly score in this trial with a high composite score of 70. Both "worst pain" and median PFSD composite scores were better with PENFS than placebo (Table 3). The Symptom Response Scale (-7 to +7 [with negative scores as worse and positive scores as better]) was used to assess the overall symptoms. Although the authors reported statistically significantly improved scores with the Neuro-Stim device at 3 weeks (Table 3), numerical differences between groups were small. Longer-term pain scores obtained at a median of 9.2 weeks after treatment remained improved from baseline in the active treatment group with a decrease of composite PFSD scores of -8.4 compared with 0.0 in the sham group. Adverse events including ear discomfort and adhesive allergy were similar between groups. The study is limited by the small sample size, the heterogeneous population of gastrointestinal disorders, lack of bowel habit measurement, and short duration of follow-up. Krasaelap et al (2020) evaluated a subgroup of 50 patients with IBS from the Kovacic et al (2017) RCT (Table 2).[13] At 3 weeks there were more responders with the active treatment (response defined as ≥30% reduction in worst abdominal pain) than with the sham device (Table 4). At the extended follow-up (8 to 12 weeks), the percentage of responders was similar between groups (32% vs. 18%; p=.33).

Table 3. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Kovacic et al (2017)[12]	US	1	2015-2016	Adolescents (11 to 18 years of age) with abdominal pain related to a functional GI disorder	Neuro-Stim (n=60)	Sham (n=55)
Krasaelap et al (2020)[13][a]	US	1	2015-2016	Adolescents (11 to 18 years of age) with abdominal pain related to IBS	Neuro-Stim (n=27)	Sham (n=23)

GI: gastrointestinal; IBS, irritable bowel syndrome.
[a]A subgroup analysis of Kovacic et al (2017).

Table 4. Summary of Key Randomized Controlled Trial Results

Study	Worst Pain (Week 3)	PFSD Composite Score (Week 3)	Worst Pain Decrease of ≥30% from Baseline to Week 3	Average Pain decrease of ≥30% from Baseline to Week 3	SRS (Week 3)
Kovacic et al (2017)[12]	N=104	N=104	N=93	N=93	N=104
PENFS	Median, 5.0 (IQR, 4.0 to 7.0)	Median, 8.4 (IQR, 3.2 to 16.2)	29 (60%)	28 (58%)	Median, 3.0 (IQR, 1.0 to 4.8)
Sham	Median, 7.0 (IQR, 5.0 to 9.0)	Median, 15.2 (IQR, 4.4 to 36.8)	10 (22%)	13 (29%)	Median, 1.0 (IQR, 0.0 to 2.3)
LSM (95% CI); p-value	2.15 (1.37 to 2.93); <.0001	11.48 (6.63 to 16.32); <.0001	NR;.00031	NR;.007	NR;.0003
Krasaelap et al (2020)[13]	N=50	N=50	N=50		N=50
PENFS	Median, 5.0 (IQR, 4.0 to 7.0)	Median, 7.5 (IQR, 3.6 to 14.4)	16 (59%)		Median, 3.0 (IQR, 2 to 4)
Sham	Median, 7.0 (IQR, 5.0 to 9.0)	Median, 14.4 (IQR, 4.5 to 39.2)	6 (26%)		Median, 0 (IQR, 0 to 2)

Study	Worst Pain (Week 3)	PFSD Composite Score (Week 3)	Worst Pain Decrease of ≥30% from Baseline to Week 3	Average Pain decrease of ≥30% from Baseline to Week 3	SRS (Week 3)
LSM (95% CI); p-value	NR;.0074	NR;.026	NR;.024		NR;.003
NNT			3		

CI: confidence interval; IQR: interquartile range; LSM: least squares mean; NNT: number needed to treat; NR: not reported; PENFS: percutaneous electrical nerve field stimulation; PFSD: Pain Frequency-Severity-Duration; SRS: symptom response scale.

The purpose of the study limitations tables (see Tables 5 and 6) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement. Limitations are only reported from the Kovacic et al (2017) study as those in the subgroup analysis by Krasaelap et al (2020) mirror the parent study.

Table 5. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Kovacic et al (2017)[12]	4. Largely White, female population			1. No bowel habit outcomes included; 4. Use of modified PFSD for pain outcomes	1,2. Median follow-up duration of 9.2 weeks

PFSD: Pain Frequency-Severity-Duration.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not established and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 6. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Kovacic et al (2017)[12]				6. Modified intention-to-treat analysis excluding patients with <1 week of data or diagnosis of organic disease after enrollment		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Section Summary: Irritable Bowel Syndrome

One RCT was identified evaluating the use of PENFS for patients with abdominal pain-related functional gastrointestinal disorders including IBS. Despite finding improved pain and symptoms at the end of the treatment period (3 weeks) with the active device compared with sham, the differences between groups by 12 weeks were minimal. A subgroup analysis limited to patients with IBS (N=50) had similar results. The study is limited by its small sample size, heterogeneous population of gastrointestinal disorders, lack of bowel habit measurement, and the short duration of follow-up.

Functional Dyspepsia

Nonrandomized Studies

Waheed et al (2026) conducted a retrospective review of 90 patients (aged 9 to 28 years) with functional dyspepsia who restricted oral intake.[14] Many patients had other disorders of gut-brain interaction, including IBS (49%), rumination (7.8%), functional abdominal pain not otherwise specified (6.7%), and functional nausea/vomiting (4.4%). All patients received PENFS for at least 4 weeks. After 3 months of follow-up, scores for abdominal pain, nausea severity, functional disability, insomnia, pain coping, and somatic symptoms were significantly improved compared to baseline (all p<.0001). These results are limited by lack of a control group.

Santucci et al (2024) conducted a retrospective review of 84 children and adolescents who received PENFS therapy, with or without a behavioral intervention, for at least 4 weeks for functional dyspepsia.[15] A mixed effects proportional odds model for the entire cohort showed that mean scores for scales of abdominal pain, nausea severity, functional disability, somatic symptoms, sleep quality, anxiety, and depression decreased numerically from baseline, but statistical comparison to baseline was not performed. Subjective patient-reported symptoms for abdominal pain, nausea, anxiety, and sleep were statistically similar at 3 months compared to week 1. These results are limited by lack of a control group.

Chogle et al (2024) conducted a multicenter, prospective, open-label registry study of children (n=292) aged 8 to 18 years who received treatment with a PENFS device for an abdominal pain-related disorder of gut-brain interaction.[16] Functional dyspepsia was the most common diagnosis (68% of patients) followed by functional constipation (64.0%) and irritable bowel syndrome (IBS, 19.2%). However, a majority of patients had overlapping Rome criteria (74.3%). At 3 months, scores for abdominal pain, nausea severity, and functional disability were significantly improved compared to baseline (p<.001, p<.001, and p=.01, respectively). At 6 months, abdominal pain and nausea severity scores were still significantly better than baseline (both p<.001). At 12 months, only abdominal pain scores were significantly decreased compared to baseline (p<.001). These results are limited by lack of a control group.

Santucci et al (2023) conducted a retrospective review of 101 adolescents (aged 11 to 21 years) with functional abdominal pain disorders who received 4 weeks of PENFS, cyproheptadine, or amitriptyline.[17] After 3 months of follow-up, patients in the PENFS group reported significant differences in abdominal pain and functional disability scores from baseline (p=.001 and p=.048, respectively), but there was no difference in nausea severity scores (p=.059). Linear mixed models with subject as a random effect were used for between-treatment comparisons at 3 months. Least

squares mean abdominal pain scores were significantly different (p=.04) between cyproheptadine and PENFS at 3 months; all other comparisons between PENFS, cyproheptadine, and amitriptyline were not significant.

Section Summary: Functional Dyspepsia

Evidence for PENFS in patients with functional dyspepsia is limited to 1 prospective, open-label registry and several retrospective, cohort studies. These studies have reported symptom improvements compared to baseline, but are limited by lack of a control group.

Other Disorders

One small prospective, uncontrolled study has reported symptom improvement in children with cyclic vomiting syndrome who received 6 weeks of PENFS therapy.[18,]

Summary of Evidence

For individuals with abdominal pain-related disorders of gut-brain interaction who receive percutaneous electrical nerve field stimulation (PENFS), the evidence includes a single randomized controlled trial (RCT) and observational, uncontrolled studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The RCT (N=115) included a heterogeneous population of adolescent patients aged 11 to 18 years with pain-related functional gastrointestinal disorders. Treatment was administered for 3 weeks, and reductions in pain were observed with the active device compared with a sham PENFS device at end of treatment and end of follow-up (maximum of 12 weeks). The subgroup of patients with IBS also had improved pain at the end of treatment with the active device compared with the sham device. However, the trial is limited by its small sample size, heterogeneous population of gastrointestinal disorders, lack of bowel habit measurement, and the short duration of follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Gastroenterology

The American College of Gastroenterology (ACG) updated their recommendations for irritable bowel syndrome (IBS) management in 2021.[5,] The ACG recommendations do not include percutaneous electrical nerve field stimulation. Similarly, the ACG guideline on management of dyspepsia from 2017 does not mention percutaneous electrical nerve field stimulation.[10,]

The American Gastroenterological Association

The American Gastroenterological Association (AGA) updated guidelines for both IBS with constipation and IBS with diarrhea in 2022.[7,6,] Neither of these guidelines include recommendations for percutaneous electrical nerve field stimulation.

European Society for Paediatric Gastroenterology Hepatology and Nutrition and North American Society for Pediatric Gastroenterology, Hepatology and Nutrition

The European Society for Paediatric Gastroenterology Hepatology and Nutrition ESPGHAN) and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHN) developed guidelines for the treatment of IBS and functional abdominal pain in children age 4 to 18

years.[19] The guidelines include 10 best practice statements for these patients, with one statement relevant to use of percutaneous electrical nerve field stimulation. The guidelines suggest auricular percutaneous electrical nerve field stimulation for patients with abdominal pain-related disorders of gut-brain interaction as a conditional recommendation (moderate certainty of evidence, moderate effect size). The recommendation is based on only one single-center study and its post hoc analysis (see Review of Evidence).

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 7.

Table 7. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT04428619	Neuromodulation With Percutaneous Electrical Nerve Field Stimulation for Adults With Irritable Bowel Syndrome: A Randomized, Double-Blind, Sham-Controlled Pilot Study	15 (actual)	Feb 2023

NCT: national clinical trial.

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Documentation for Clinical Review

- No records required

Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

Type	Code	Description
CPT®	0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation ***(Deleted code effective 1/1/2026)***
	64567	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation ***(Code effective 1/1/2026)***
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
07/01/2023	New policy.
09/01/2024	Annual review. No change to policy statement. Literature review updated.
10/01/2024	No change to policy statement. Literature review updated.
11/01/2025	Annual review. No change to policy statement.
01/01/2026	Annual review. No change to policy statement. Literature review updated.
04/01/2026	Coding update.
09/01/2026	Annual review. Policy statement, guidelines and literature updated. Policy title changed from Percutaneous Electrical Nerve Field Stimulation for Irritable Bowel Syndrome to current one.

Feedback

Blue Shield of California is interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration. Our medical policies are available to view or download at www.blueshieldca.com/provider.

For medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE Red font: Verbiage removed	AFTER Blue font: Verbiage Changes/Additions
Percutaneous Electrical Nerve Field Stimulation for Irritable Bowel Syndrome 2.01.106 **Policy Statement:** I. Percutaneous electrical nerve field stimulation for abdominal pain in individuals with irritable bowel syndrome is considered **investigational.**	**Percutaneous Electrical Nerve Field Stimulation for Disorders of Gut-Brain Interaction 2.01.106** **Policy Statement:** Percutaneous electrical nerve field stimulation for abdominal pain in individuals with disorders of gut-brain interaction, including but not limited to irritable bowel syndrome and functional dyspepsia, is considered **investigational.**