

2.01.106	Percutaneous Electrical Nerve Field Stimulation for Irritable Bowel Syndrome		
Original Policy Date:	July 1, 2023	Effective Date:	July 1, 2023
Section:	2.0 Medicine	Page:	Page 1 of 10

Policy Statement

- I. Percutaneous electrical nerve field stimulation for abdominal pain in individuals with irritable bowel syndrome is considered **investigational**.

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

Policy Guidelines

Coding

The following code may be used to report for this treatment:

- 0720T: Percutaneous electrical nerve field stimulation, cranial nerves, without implantation

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 irritable bowel syndrome, nerves processing pain for the abdominal region are targeted.

Related Policies

- Cranial Electrotherapy Stimulation and Auricular Electrostimulation

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the 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 mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In 2019, the IB-Stim device (previously known as Neuro-Stim; Innovative Health Solutions, Inc.) was cleared for marketing by the U.S. Food and Drug Administration (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.). The IB-Stim device is indicated for patients 11 to 18 years of age with functional abdominal pain associated with IBS when combined with other IBS therapies. It is intended to be used for 120 hours per week up to 3 consecutive weeks. The First Relief v1 (DyAnsys, Inc.) device was deemed substantially equivalent to the IB-Stim device in 2020. FDA product code: QHH.

Rationale

Background

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.¹ 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.² 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.³ 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 1).^{4,3,5} 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.³

Table 1. 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-HT ₃ 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.

Percutaneous Electrical Nerve Field Stimulation

Because there are few pharmacologic treatments for children and adolescents with IBS, 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.⁶ 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 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Irritable Bowel Syndrome

Clinical Context and Therapy Purpose

The purpose of percutaneous electrical nerve field stimulation (PENFS) in patients who have irritable bowel syndrome (IBS) 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 to IBS.

Interventions

The therapy being considered is PENFS with the IB-Stim device.

Comparators

The following therapies are currently being used to treat IBS: 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

Randomized Controlled Trials

Kovacac 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 2).⁷ 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. 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), 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 Kovacac et al (2017) RCT (Table 2).⁸ At 3 weeks there were more responders with the active treatment (response defined as $\geq 30\%$ reduction in worst abdominal pain) than with the sham device (Table 3). At the extended follow-up (8-12 weeks), the percentage of responders was similar between groups (32% vs. 18%; $p=.33$).

Table 2. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions
Kovacac (2017) ⁷	US	1	2015-2016	Adolescents (11-18 years of age) with abdominal pain related to a functional GI disorder	Active: Neuro-Stim (n=60) Comparator: Sham (n=55)
Krasaelap (2020) ^{8,a}	US	1	2015-2016	Adolescents (11-18 years of age) with abdominal pain related to IBS	Active: Neuro-Stim (n=27) Comparator: Sham (n=23)

GI: gastrointestinal; IBS, irritable bowel syndrome; RCT: randomized controlled trial.

^aA subgroup analysis of Kovacac et al (2017).

Table 3. Summary of Key RCT Results

Study	Worst Pain (Week 3)	PFSD Composite Score (Week 3)	Worst Pain Decrease of $\geq 30\%$ from Baseline to Week 3	Average Pain decrease of $\geq 30\%$ from Baseline to Week 3	SRS (Week 3)
Kovacac (2017) ⁷	N=104	N=104	N=93	N=93	N=104

Study	Worst Pain (Week 3)	PFSD Composite Score (Week 3)	Worst Pain Decrease of $\geq 30\%$ from Baseline to Week 3	Average Pain decrease of $\geq 30\%$ from Baseline to Week 3	SRS (Week 3)
PENFS	Median 5.0 (IQR, 4.0-7.0)	Median 8.4 (IQR, 3.2-16.2)	29 (60%)	28 (58%)	Median 3.0 (IQR, 1.0-4.8)
Sham	Median 7.0 (IQR, 5.0-9.0)	Median 15.2 (IQR, 4.4-36.8)	10 (22%)	13 (29%)	Median 1.0 (IQR, 0.0-2.3)
LSM (95% CI); p-value	2.15 (1.37-2.93); <.0001	11.48 (6.63-16.32); <.0001	NR;.00031	NR; p=.007	NR;.0003
Krasaelap (2020)⁸	N=50	N=50	N=50		N=50
PENFS	Median 5.0 (IQR, 4.0-7.0)	Median 7.5 (IQR, 3.6-14.4)	16 (59%)		Median 3.0 (IQR, 2-4)
Sham	Median 7.0 (IQR, 5.0-9.0)	Median 14.4 (IQR, 4.5-39.2)	6 (26%)		Median 0 (IQR, 0-2)
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; PFSD: Pain Frequency-Severity-Duration; RCT: randomized controlled trial; SRS, symptom response scale.

The purpose of the study limitations tables (see Tables 4 and 5) 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 4. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Kovacic (2017)⁷	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 5. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Kovacic (2017) ⁷				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.

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 2021.³ The ACG recommendations do not include percutaneous electrical nerve field stimulation.

The American Gastroenterological Association

The American Gastroenterological Association (AGA) updated guidelines for both IBS with constipation and IBS with diarrhea in 2022.^{5,4} Neither of these guidelines include recommendations for percutaneous electrical nerve field stimulation.

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 6.

Table 6. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT04428619	Neuromodulation With Percutaneous Electrical Nerve Field Stimulation for Adults With Irritable Bowel Syndrome: A Randomized, Double-Blind, Sham-Controlled Pilot Study	54	Nov 2024

NCT: national clinical trial.

References

1. IBS Facts and Statistics. International Foundation for Gastrointestinal Disorders. <https://aboutibs.org/what-is-ibs/facts-about-ibs/>. Accessed March 7, 2023.
2. Definition & Facts for Irritable Bowel Syndrome. National Institute of Diabetes and Digestive and Kidney Diseases. <https://www.niddk.nih.gov/health-information/digestive-diseases/irritable-bowel-syndrome/definition-facts>. Updated November 2017. Accessed March 7, 2023.
3. Lacy BE, Pimentel M, Brenner DM, et al. ACG Clinical Guideline: Management of Irritable Bowel Syndrome. *Am J Gastroenterol*. Jan 01 2021; 116(1): 17-44. PMID 33315591
4. Lembo A, Sultan S, Chang L, et al. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome With Diarrhea. *Gastroenterology*. Jul 2022; 163(1): 137-151. PMID 35738725
5. Chang L, Sultan S, Lembo A, et al. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome With Constipation. *Gastroenterology*. Jul 2022; 163(1): 118-136. PMID 35738724
6. IB-Stim. <https://ibstim.com/research/#FDA-Classification>. Accessed March 14, 2023.
7. 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*. Oct 2017; 2(10): 727-737. PMID 28826627
8. 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*. Aug 2020; 18(9): 1987-1994.e2. PMID 31622740

Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation
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.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

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.

We are 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.

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

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. 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 contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	AFTER <u>Blue font: Verbiage Changes/Additions</u>
<p>New Policy</p> <p>Policy Statement: N/A</p>	<p>Percutaneous Electrical Nerve Field Stimulation for Irritable Bowel Syndrome 2.01.106</p> <p>Policy Statement:</p> <ul style="list-style-type: none"> I. Percutaneous electrical nerve field stimulation for abdominal pain in individuals with irritable bowel syndrome is considered investigational.