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MEDICAL POLICY – 2.01.106

Percutaneous Electrical Nerve Field Stimulation for Disorders of Gut-Brain Interaction

BCBSA Ref. Policy:	2.01.106
Effective Date:	Nov. 6, 2026
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Replaces:	N/A

RELATED MEDICAL POLICIES:

7.01.588	Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy
8.01.540	Cranial Electrotherapy Stimulation and Auricular Electrostimulation

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Introduction

Percutaneous electrical nerve field stimulation is a treatment that uses small electrical signals delivered through the skin (percutaneous electrical nerve field stimulation). It is designed to affect nerves that connect the brain and the digestive system. Disorders of gut-brain interaction are conditions where the stomach and intestines do not work as expected, even though no clear structural problem is found. Common examples include irritable bowel syndrome and functional dyspepsia, which can cause ongoing pain, bloating, or discomfort. These symptoms can affect daily life and may not improve with standard treatments. New approaches like nerve stimulation are being studied to see if they can help manage symptoms in these conditions. This type of treatment has not yet been proven to be effective and more studies are needed. It is considered investigational for treatment of disorders of gut-brain interaction.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Percutaneous electrical nerve field stimulation	**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. (e.g., IB Stim, First Relief v1, TEA Device).**

Coding

Code	Description
CPT	
64567	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation (new code effective 01/01/26)
0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation (code termed effective 01/01/26)

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Related Information

N/A

Evidence Review

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 individuals with abdominal pain-related disorders of gut-brain interaction, nerves processing pain for the abdominal region are targeted.

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) 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 (See **Table 2**).[5,6,7]

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.

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.[12] 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 three 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in **Table 3**.

Table 3. 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.

Practice Guidelines and Position Statements

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

Guidelines or position statements will be considered for inclusion 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 ten 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.

Medicare National Coverage

There is no national coverage determination.

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 four 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.

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History

Date	Comments
08/01/23	New policy, approved July 11, 2023. Policy created with literature review through March 8, 2023. Percutaneous electrical nerve stimulation for abdominal pain in individuals with irritable bowel syndrome is considered investigational. Added CPT code 0720T for percutaneous nerve stimulation.
10/04/23	Updated related policy. Policy 7.01.29 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy was renumbered to 7.01.588 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy.
05/01/24	Minor update to related policies. 8.01.58 was replaced with 8.01.540 Cranial Electrotherapy Stimulation and Auricular Electrostimulation.
11/01/24	Annual Review, approved October 7, 2024. Policy updated with literature review through June 12, 2024. No references added; policy statement unchanged.

Date	Comments
01/01/26	Annual Review, approved December 8, 2025. Policy updated with literature review through August 28, 2025. Reference added; policy statement unchanged. Added new CPT code 64567 added; replaces 0720T, effective January 1, 2026.
08/01/26	Annual Review, approved July 14, 2026. Effective for dates of service on or after November 6, 2026, following 90-day provider notification. Title updated from 2.01.106 Percutaneous Electrical Nerve Field Stimulation for Irritable Bowel Syndrome to 2.01.106 Percutaneous Electrical Nerve Field Stimulation for Disorders of Gut-Brain Interaction. Policy updated with literature review through March 10, 2026. References added. Investigational policy statement updated to reflect abdominal pain-related disorders of gut-brain interaction, including irritable bowel syndrome and functional dyspepsia. Removed CPT code 0720T from table.

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