

MEDICAL POLICY – 2.01.106**Percutaneous Electrical Nerve Field Stimulation for Irritable Bowel Syndrome**

BCBSA Ref. Policy: 2.01.106

Effective Date: Aug. 1, 2023

Last Revised: May 1, 2024

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

Select a hyperlink below to be directed to that section.

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Introduction

Percutaneous electrical nerve field stimulation is a treatment for irritable bowel syndrome (IBS) that uses gentle electrical currents on specific nerves near the skin to help reduce IBS symptoms. The procedure is noninvasive and involves placement of small electrodes on the skin to send electrical signals to the nerves that affect the stomach and intestines, which can make IBS symptoms like stomach pain and bloating feel better. This type of treatment has not yet been proven to be effective and more studies are needed. It is considered investigational for treatment of IBS.

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 irritable bowel syndrome is considered investigational (e.g., IB Stim).

Coding

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

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



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 (See [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



IBS-D	IBS-C	Abdominal Pain
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.

Summary of Evidence

For individuals with irritable bowel syndrome (IBS) who receive percutaneous electrical nerve field stimulation (PENFS), the evidence includes a subgroup analysis of a single randomized controlled trial (RCT). 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.



Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in [Table 2](#).

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
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.

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 2021.³ 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.

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 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.

References

1. IBS Facts and Statistics. International Foundation for Gastrointestinal Disorders. <https://aboutibs.org/what-is-ibs/facts-about-ibs/>. Accessed June 5, 2023.
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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



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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

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.

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