Medical Coverage Policy

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Percutaneous Electrical Nerve Field Stimulation (PENFS)

Table of Contents

Related Coverage Resources

Electric Stimulation for Pain, Swelling and Function in a Clinic Setting
Electrical Stimulation Therapy and Devices in a Home Setting
Gastric Pacing/Gastric Electrical Stimulation (GES)
Headache, Occipital, and/or Trigeminal Neuralgia Treatment
Peripheral Nerve Stimulation and Peripheral Nerve Field Stimulation
Vagus Nerve Stimulation (VNS)

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Overview

This Coverage Policy addresses non-implantable percutaneous electrical nerve field stimulation (PENFS) for the treatment of abdominal pain associated with specific disorders of gut-brain interaction (i.e., irritable bowel syndrome, functional dyspepsia).

Coverage Policy

1. An initial course of percutaneous electrical nerve field stimulation (PENFS) is considered **medically necessary** when **ALL** of the following criteria are met (a through e):
    a. persistent abdominal pain associated with **EITHER** of the following:
        i. irritable bowel syndrome (IBS)
        ii. functional dyspepsia (FD)
    b. documented failure of conservative management (e.g., dietary modification; cognitive behavioral therapy [CBT]; medications [e.g., acid suppression therapy, antispasmodics])
    c. age 8 to 21 years
    d. PENFS is delivered as part of a comprehensive treatment plan by or under the direction of a gastroenterologist
    e. absence of **ANY** of the following contraindications (i through iii):
        i. hemophilia
        ii. cardiac pacemaker
        iii. psoriasis vulgaris affecting the treatment area

2. Percutaneous electrical nerve field stimulation (PENFS) is considered **not medically necessary** for **ANY** other indication due to insufficient evidence of safety and efficacy.

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
64567	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation
0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation (Code deleted 12/31/2025)

Background and Supporting Information

Percutaneous Electrical Nerve Field Stimulation (PENFS)

Percutaneous electrical nerve field stimulation (PENFS) refers to a non-implanted electrical device that provides nerve stimulation, primarily for the purpose of pain relief, and provides the stimulation remotely from the source of pain. Sometimes referred to as percutaneous auricular neurostimulation, PENFS has been proposed for the treatment of various conditions, including in children and adolescents with reported symptoms of abdominal pain associated with specific disorders of gut-brain interaction (e.g., irritable bowel syndrome, functional dyspepsia); postoperative pain; and opioid withdrawal symptoms. PENFS devices are placed behind the ear, with electrodes placed in and around the ear to stimulate specific nerves around the ear.

PENFS for Disorders of Gut-Brain Interaction (DGBI)

Disorders of gut-brain interaction (DGBI), previously called functional gastrointestinal disorders, refer to a group of disorders characterized by chronic or recurrent gastrointestinal symptoms, in the absence of structural disease. Symptoms of DGBI are thought to originate from a combination of gastrointestinal motility disturbance, visceral hypersensitivity, altered mucosal and immune function, altered gut microbiota, and/or altered central nervous system processing. Abdominal pain-related DGBI (AP-DGBI), also termed functional abdominal pain disorders, have historically included functional dyspepsia (FD), irritable bowel syndrome (IBS), abdominal migraine, and functional abdominal pain not otherwise specified (FAP-NOS) (Maqbool, et al., 2025). It is estimated that DGBI may affect around more than 40% of adults worldwide, while nearly 12% of children may be affected by a functional abdominal pain disorder, with a higher prevalence noted in women and girls (Vermeijden, et al., 2025; Sperber, et al., 2020). These disorders can have a significant negative impact on an individual's quality of life and lead to abdominal pain-associated disability (e.g., missing school or extracurricular activities, anxiety, depression) (Balakrishnan and Chiou, 2026).

The Rome criteria are a widely accepted symptom-based diagnostic framework for DGBI, developed through an international expert consensus process. The 2016 Rome IV criteria established the following diagnostic criteria specific to functional dyspepsia and irritable bowel syndrome in children and adolescents (Rome Foundation, 2026; Hyams, et al., 2016):

- Functional dyspepsia (FD) diagnostic criteria*
  Must include one or more of the following bothersome symptoms at least four (4) times a month for at least two (2) months prior to diagnosis:
  1. Postprandial fullness
  2. Early satiation
  3. Epigastric pain or burning not associated with defecation

4. After appropriate evaluation, the symptoms cannot be fully explained by another medical condition

**Criteria fulfilled for at least two (2) months prior to diagnosis*

This includes the following FD subtypes:

- Postprandial distress syndrome includes bothersome postprandial fullness or early satiation which prevents finishing a regular meal. Supportive features include upper abdominal bloating, postprandial nausea, or excessive belching.
- Epigastric pain syndrome which includes all of the following: bothersome (severe enough to interfere with normal activities) pain or burning localized to the epigastrium. The pain is not generalized or localized to other abdominal or chest regions and is not relieved by defecation or passage of flatus. Supportive criteria can include (a) burning quality of the pain but without a retrosternal component, (b) commonly induced or relieved by ingestion of a meal but may occur while fasting.

- Irritable bowel syndrome (IBS) diagnostic criteria*

  Must include all of the following:

  1. Abdominal pain at least four (4) days per month over at least two (2) months associated with one or more of the following:
     a. Related to defecation
     b. A change in frequency of stool
     c. A change in form (appearance) of stool
  2. In children with abdominal pain and constipation, the pain does not resolve with resolution of the constipation (children in whom the pain resolves have functional constipation, not IBS)
  3. After appropriate evaluation, the symptoms cannot be fully explained by another medical condition

  **Criteria fulfilled for at least two (2) months prior to diagnosis*

Updated Rome V criteria for DGBI were published in 2026, with some differences in diagnostic criteria and the inclusion of new diagnoses (Di Lorenzo, et al., 2026; Rosen, et al., 2026).

Interventions for DGBI vary by subtype and adult versus pediatric populations. Treatment of children and adolescents with abdominal pain-related DGBI may include avoidance of triggers, cognitive behavioral therapy (CBT), dietary modification, fiber supplements, probiotics, peppermint capsules, and acid suppression therapies (e.g., proton pump inhibitors [PPIs], histamine-2 [H2] blockers) (Balakrishnan and Chiou, 2026; Groen, et al., 2025). Other pharmacologic therapies may include tricyclic antidepressants, cyproheptadine, and antispasmodics or motility-directed therapies, though many are used off-label and with varying degrees of effectiveness and limited evidentiary support (Di Lorenzo, et al., 2026; Rosen, et al., 2026; Groen, et al., 2025).

PENFS has been evaluated as a treatment for children and adolescents with AP-DGBI. The PENFS device is applied to the external ear with percutaneously placed electrodes applied to auricular areas innervated by branches of four cranial nerves (V [trigeminal], VII [facial], IX [glossopharyngeal], and X [vagus]). The device is placed in-office by a provider, worn for several (typically five) consecutive days, and is then removed at home. This is repeated for up to four consecutive weeks. PENFS is thought to provide pain relief through noninvasive auricular electrical stimulation by modulating central pain pathways and reducing visceral hyperalgesia (Krasaelap, et al., 2019; Kovacic, et al., 2017). Allodynia (i.e., pain caused by a stimulus that does not normally provoke pain) has been reported with auricular PENFS, including pulsation, soreness, and localized ear pain at the site of device placement (Santucci, et al., 2025).

U.S. Food and Drug Administration: In 2019, the FDA approved the IB-Stim percutaneous electrical nerve field stimulator (Neuraxis, Inc.) for functional abdominal pain relief, via the De Novo pathway as a Class II device. The initial indications for use for IB-Stim (formerly Neuro-Stim) stated the device is "intended to be used in patients 11-18 years of age with functional abdominal pain associated with irritable bowel syndrome (IBS). The IB-Stim is intended to be used for 120 hours per week up to 3 consecutive weeks, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination, as an aid in the reduction of pain when combined with other therapies for IBS." The device is contraindicated in individuals with cardiac pacemakers, hemophilia, and psoriasis vulgaris.

Subsequent updates to the indications for use extended the treatment population to ages 8-21; the treatment duration from three to four weeks using one device per week; and added functional dyspepsia as a treatment indication. In October 2025, the age range was again modified to "8 years and older" based on an extrapolation of clinical data from children and adolescents to the adult population. Other DGBI (i.e., other than irritable bowel syndrome and functional dyspepsia) are not currently cleared indications/conditions for use of IB-Stim.

Device or Product	Identifier	Manufacturer
IB-Stim	DEN180057 K241533	NeurAxis
First Relief v1	K202940	DyAnsys

*FDA product codes: QHH

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review: Evidence in the published peer-reviewed literature generally demonstrates the effectiveness of an initial course of PENFS as a supplemental therapy for children and adolescents (i.e., ages 8-21) with refractory functional dyspepsia and irritable bowel syndrome. This population has demonstrated significant improvements with the use of PENFS in outcomes including abdominal pain, nausea, functional disability, anxiety, and oral intake. Evidence consists of a randomized sham-controlled trial, prospective observational studies, a multicenter registry study, and retrospective comparative and noncomparative studies. Published evidence is presently insufficient to support the effectiveness of PENFS in the adult population, or for repeated courses of PENFS (Waheed, et al., 2026; Chogle, et al., 2024; Castillo, et al., 2023; Chogle, et al., 2023; Santucci, et al., 2023a; Santucci, et al., 2023b; Santucci, et al., 2022).

Kovacic et al. (2017) conducted a randomized controlled trial to evaluate the efficacy of PENFS using the Neuro-Stim device in adolescents with abdominal pain related to functional gastrointestinal disorders (e.g., irritable bowel syndrome, functional dyspepsia). There were 104 patients aged 11-18 years old who underwent either PENFS with an active device (n=60) or sham (n=55); however, 11 patients were lost to follow up, leaving a total of 93 patients analyzed at long term follow up. Adolescents who met Rome III criteria for abdominal pain-related functional gastrointestinal disorders and had an average abdominal pain rating of three or higher and a minimum of two pain days per week were included. Patients who had less than one week of data and those with organic disease were excluded. Patients were also excluded if they had a history of seizures or developmental delay, or had an implanted electrical device. The intervention, Neuro-Stim device, delivered electrical stimulation two hours on and two hours off for five days per week for four weeks. The comparator was sham (no electrical charge). The primary outcome measure was change or improvement in abdominal pain scores using the Pain Frequency-Severity-Duration (PFSD) scale. Secondary outcomes were global symptoms improvement (global wellbeing scale),

functioning (Functional Disability Inventory), and anxiety (State-Trait Anxiety Inventory for Children). Follow-up occurred every seven days for three weeks and again at 8-12 weeks following therapy. Results showed that patients in the active PENFS group had a statistically significant greater reduction in worst pain compared to the sham group after three weeks of treatment ($p<0.0001$) and was sustained for an average of 9.2 weeks. Additionally, median pain scores were reduced by 11.48 points after three weeks of treatment. Ten patients reported side effects including: ear discomfort (n=3 in the active group; n=3 in the sham group), adhesive allergy (n=1 in the active group; 2 in the sham group), and syncope due to needle phobia (n=1 in the sham group). The study was limited by the small patient population, patient attrition, and short-term follow-up.

In a subanalysis of the above study, Krasaelap et al. (2019) evaluated the effects of the Neuro-Stim device on the subset of individuals with irritable bowel syndrome (IBS). Twenty seven subjects received PENFS, and 23 received the sham intervention. A 30% decrease of worst abdominal pain was observed in a statistically significant number of patients who received PENFS versus sham stimulation ($p=0.024$). A statistically significant reduction in composite pain median score in the PENFS treatment group versus the sham group ($p=0.026$), statistically significant reduction in usual pain median score in the PENFS group versus sham ($p=0.029$), and a statistically significant improvement in global symptoms in the PENFS group versus sham ($p\leq0.001$) were all observed.

Professional Societies/Organizations: Professional society support for PENFS is currently limited to pediatric gastroenterology-related guidelines. Society support for PENFS for other indications and/or in the adult population is lacking.

European and North American Societies for Pediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN/NASPGHAN): On behalf of ESPGHAN/NASPGHAN, Groen at al. (2025) published guidelines for the treatment of irritable bowel syndrome (IBS) and functional abdominal pain (FAP) in children 4–18 years of age. The guidelines state "Percutaneous Electrical Nerve Field Stimulation (PENFS) is suggested as a treatment option (Conditional recommendation, Moderate certainty evidence)". The recommendation was based upon the outcomes from the randomized trial cited above (Kovacic, et al., 2017). The authors provided additional rationale for the recommendation:

> "Despite moderate certainty of evidence, the pain intensity reduction was among the highest across all studied treatment options. This is a very new field in the treatment of [abdominal pain related disorders of gut–brain interaction] (AP-DGBIs) and has only been studied in a small population. The study included in these guidelines comes from a single institution. This study shows that a favorable effect likely exists, but that its size has yet to be determined, which, in the context of limited availability and experience, does not create sufficient grounds for a strong recommendation for all children AP-DGBIs. The [Guideline Development Group] (GDG) notes that this treatment comes at a relatively high initial cost and requires weekly new device placement for the duration of the treatment course. Moreover, PENFS has only recently been implemented as a treatment option for AP-DGBIs and will likely undergo further development in the coming years. The GDG suggests that this treatment option may be utilized for patients who have shown considerable difficulty in achieving pain relief."

PENFS for Other Conditions

PENFS has also been proposed for use in other conditions, including for the alleviation of opioid withdrawal symptoms and postoperative pain management.

Opioid withdrawal syndrome refers to the range of symptoms that occur after stopping or greatly reducing the dose of opioid drugs after heavy and prolonged use. Symptoms may include cravings, anxiety, tachycardia, sweating, insomnia, muscle aches, and gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Opioid withdrawal management typically refers to the process of withdrawing an individual from a substance safely and effectively, under medical supervision. First-line treatments for opioid withdrawal include buprenorphine and methadone, with alpha-2 adrenergic agonists as possible alternatives (American Society of Addiction Medicine [ASAM], 2020). PENFS has been proposed as a noninvasive, drug-free alternative or supplement to standard pharmacologic treatment for opioid withdrawal symptoms.

For acute postoperative pain, a multimodal approach is generally recommended. Multimodal analgesia uses two or more agents that employ different mechanisms for pain management, while avoiding excessive use of opioids. Interventions vary by the type of surgery performed, and the individual's needs. Pharmacologic therapies may include acetaminophen, nonsteroidal anti-inflammatory medications (NSAIDs), and local or regional analgesia techniques, along with opioids as needed. Nonpharmacologic treatments may include compression, elevation, and ice therapy (Mariano, 2026). The off-label use of PENFS has been explored in the postoperative setting as a means of controlling pain and reducing opioid use.

U.S. Food and Drug Administration: In 2017, the FDA approved the NSS-2 (Bridge) percutaneous nerve field stimulator (Innovative Health Solutions, Inc.) via the De Novo pathway, as a Class II device. The NSS-2 Bridge is a battery-powered device proposed as an aid to reduce the symptoms of opioid withdrawal, through application to branches of cranial nerves V, VII, IX and X, and occipital nerves identified by transillumination. Subsequent iterations have been cleared via the FDA 510(k) premarket notification process.

Device or Product	Identifier	Manufacturer
NSS-2 (Bridge) System	DEN170018	Innovative Health Solutions, Inc.
Drug Relief	K173861	DyAnsys

*FDA product codes: PZR

Note: Coverage decisions are not based solely on FDA approval. Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. This list is not intended to reflect all available products or technologies.

Literature Review: Evidence in the published peer-reviewed literature is limited and insufficient to support the efficacy of PENFS for the treatment of postoperative pain or withdrawal symptoms related to substance use disorders. Published studies investigating the use of PENFS for substance use disorders are primarily in the form of small case series, prospective nonrandomized trials, and retrospective reviews with small patient populations (Miranda and Taca, 2017). Several small pilot randomized trials and case series have reported on the off-label use of NSS-2 Bridge to treat pain after abdominal, breast, and musculoskeletal surgeries, with mixed results (Chelly, et al., 2021). Evidence to support the use of PENFS for these indications is lacking, and additional well-designed controlled trials with adequate sample sizes and long-term follow-up are needed.

Chelly et al. (2021) conducted a nonrandomized comparative study (n=20) to investigate whether auricular field nerve stimulation using the NSS-2 BRIDGE device may reduce opioid consumption and pain following kidney donor surgery. There were 10 subjects in the NSS-2 BRIDGE device group and 10 in the control group. The intervention was placement of the device in the post-anesthesia care unit, while the control group did not receive the device. The primary outcome was opioid consumption expressed in oral morphine equivalent (OME) at 24 hours following surgery.

Secondary outcomes included pain at 24 and 48 hours, incidence of postoperative nausea and vomiting at 24 hours, time to oral intake, time to ambulation, time to discharge from the recovery room, time to discharge from the hospital, and device tolerability during follow-up. Individuals who received the device were asked to wear it for five days. Compared with the control group, the NSS-2 BRIDGE device group had a 75.4% reduction in opioid consumption at 24 hours (8.3 ± 9.6 versus 33.5 ± 37.3 mg OME, respectively; p=0.03), a significant 58.3% reduction in pain scores at 24 hours (2.5 ± 2.0 versus 6 ± 1.4; p<0.001), and 73.3% lower pain at 48 hours (1.6 ± 1.6 versus 6.0 ± 2.8; p=0.0004). At 48 hours, opioid consumption was similar between groups (p=0.33). Time to oral intake was similar between groups (p=0.19), while ambulation was earlier in the NSS-2 BRIDGE device group (11.6 ± 7.4 hours versus 18.9 ± 6.9 hours, respectively; p=0.02). The time to hospital discharge was similar between groups, and patient satisfaction related to pain management was recorded as 9.9 versus 9.4 in the NSS-2 BRIDGE device group versus control group, respectively. Study limitations included the nonrandomized, non-placebo-controlled design; small sample size; and incomplete post-discharge follow-up in the control group.

Miranda and Taca (2017) conducted an open-label, uncontrolled, retrospective study (n=73) to evaluate the effects of the BRIDGE percutaneous electrical nerve field stimulation device on withdrawal scores during the induction phase of opioid withdrawal therapy in an outpatient setting. The study included individuals who met DSM-IV criteria for opioid dependence and voluntarily presented to outpatient drug treatment clinics. The intervention was treatment with the BRIDGE device. No control or comparator group was utilized. Inclusion criteria included age ≥ 18, with a history of dependence on heroin or other opioids. Individuals with a history of dependence on alcohol, or who were pregnant, were excluded. The primary outcomes were changes in Clinical Opioid Withdrawal Scale (COWS) scores and successful transition to medication-assisted therapy (MAT), with follow-up limited to the 5-day device-use period. Mean COWS scores decreased from 20.1 (±6.1) before treatment to 7.5 (±5.9) at 20 minutes, 4.0 (±4.4) at 30 minutes, and 3.1 (±3.4) at 60 minutes (all p<0.001). All subjects experienced a reduction in COWS scores by 60 minutes, 78.0% had scores ≤3 at 60 minutes, and the mean day-5 COWS score was 0.6 among the subset with available data (n=33). Additionally, 88.8% of participants successfully transitioned to MAT. Limitations included the uncontrolled retrospective study design, small sample size, missing outcome data, inability to assess some psychiatric and drug-use factors, lack of interim withdrawal assessments between days 1 and 5, and absence of long-term follow-up. The authors concluded that BRIDGE use was associated with reduced opioid withdrawal scores and successful transition to secondary therapy, while noting that additional studies are needed.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

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Revision Details

Type of Revision	Summary of Changes	Date
New Policy	• N/A	9/15/2026