Auricular Stimulation for Abdominal Pain From Irritable Bowel Syndrome

Clinical Policy ID: CCP.1482

Recent review date: 3/2026

Next review date: 7/2027

Policy contains: Auricular stimulation; functional abdominal pain; IB-Stim; irritable bowel syndrome; Neuro-Stim; percutaneous electrical nerve field stimulation.

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Coverage policy

Auricular stimulation (percutaneous electrical nerve field stimulation) is clinically proven and, therefore, may be medically necessary for treating functional abdominal pain related to irritable bowel syndrome in members age four to 18 years who have not achieved adequate pain relief with gut-brain psychotherapies and other conservative measures (European and North American Societies for Pediatric Gastroenterology, Hepatology and Nutrition [Groen, 2025]).

For any determinations of medical necessity for medications, refer to the applicable state-approved pharmacy policy.

Limitations

Auricular stimulation is contraindicated in members with (NeurAxis, Inc., 2026):

- A cardiac pacemaker, because no clinical data are available.
- Hemophilia.
- Psoriasis vulgaris.

Alternative covered services

Standard-of-care treatment customized to member's specific symptoms and underlying triggers. Care options include, but are not limited to, lifestyle and dietary modification, gut-brain psychotherapies (e.g., hypnotherapy and cognitive behavioral therapy), and pharmaceuticals.

Background

Treatment options are limited for children with functional abdominal pain from irritable bowel syndrome (Gupta, 2018). Pharmacologic therapies and complementary treatments are widely used, often off-label, and have limited supportive data. There is emerging interest in non-pharmacologic options such as psychosocial approaches, mind-body interventions, and percutaneous electrical nerve field stimulation (e.g., auricular stimulation) for treatment of these pain disorders in children (Thapar, 2020). One theory behind treating irritable bowel syndrome with auricular nerve stimulation is that gastrointestinal disorders can result from a chronic maladaptive state of autonomic neural control mechanisms after traumatic stress (Leontiadis, 2020).

The U.S. Food and Drug Administration cleared the NeurAxis IB-Stim® (formerly Neuro-Stim™; NeurAxis, Inc., Carmel, Indiana) as a Class II, non-implanted percutaneous nerve stimulator for use in patients age eight years and older to reduce functional abdominal pain and functional dyspepsia associated with irritable bowel syndrome when combined with other therapies. It applies low voltage electrical current to branches of cranial nerves V, VII, IX and X, and the occipital nerve field around the ear identified by transillumination. It is intended to be used for 120 hours per week for up to four consecutive weeks. It is not intended to relieve pelvic pain (U.S. Food and Drug Administration, 2025).

While the exact mechanism of action for IB-Stim has not been demonstrated in humans, in preclinical studies, the device appears to work by controlling activity of pain areas in the central nervous system, particularly the amygdala and spinal cord. The IB-Stim is contraindicated in patients with a cardiac pacemaker due to an absence of clinical data, hemophilia, and psoriasis vulgaris (NeurAxis, Inc., 2026).

Findings

The evidence from professional guidelines and a randomized controlled trial support the safety and efficacy of auricular percutaneous electrical nerve field stimulation for treating functional abdominal pain caused by irritable bowel syndrome in children and adolescents. In adult populations, safety and efficacy have been studied inadequately and lack guideline support.

Guidelines

A joint guideline from the European and North American Societies for Pediatric Gastroenterology, Hepatology and Nutrition issued a conditional recommendation for auricular percutaneous electrical nerve field stimulation for treating irritable bowel syndrome and functional abdominal pain in children age four to 18 years who have shown considerable difficulty in achieving pain relief with gut-brain psychotherapies and other conservative measures. The recommendation was based on the results of one randomized controlled trial of moderate certainty (Kovacic, 2017) and one post-hoc analysis (Krasaelap, 2020) showing that a positive effect on pain is likely, although the size of the effect cannot be determined as yet (Groen, 2025).

A possible placebo effect of the IB-Stim suggests a potential role for psychological interventions for symptom improvement in irritable bowel syndrome. Both the American College of Gastroenterology (Ford, 2018) and the National Institute for Health and Care Excellence (2017) offered weak recommendations based on low-quality evidence for some psychological therapies (provider-directed cognitive behavioral therapy, relaxation therapy,

hypnotherapy, and multicomponent psychological therapy) in adult populations who do not respond to pharmacological treatments and who develop a continuing symptom profile.

Evidence review

The U.S. Food and Drug Administration based its approval on the results of one randomized, double-blind, sham-controlled trial and a post-hoc analysis (Kovacic, 2017; Krasaelap, 2020). One additional retrospective cohort study provides supplementary safety information on the device (Roberts, 2016).

Kovacic (2017) enrolled 115 children with various abdominal pain-related functional gastrointestinal disorders and assigned them to either the active IB-Stim device (n = 60) or sham (n = 55); 104 children finished the trial. Twenty-eight patients in the active group and 23 patients in the sham control group, 90% of whom were females, met Rome III criteria for irritable bowel syndrome, and all but one patient in the active group completed the study. The majority of participants (78%) had not responded to one or more pharmacological treatments, and 22% were treatment-naïve.

The results suggest IB-Stim is a safe and efficacious, short-term treatment compared to sham controls. However, a placebo effect cannot be ruled out, nor can the durability of these treatment effects beyond the study period be determined. At the end of three weeks of therapy, the results are as follows (Krasaelap, 2020):

- Fifty-nine percent (16/27) of IB-Stim participants versus 26% (6/23) of sham participants showed a greater than 30% reduction in worst abdominal pain (P = .024).
- Fifty-two percent (14/27) of the IB-Stim group versus 30% (7/23) of the sham group had a greater than 30% reduction in usual abdominal pain.
- On the pain frequency-severity-duration composite pain score (reported as median, interquartile range), the IB-Stim group had a lower pain score (7.5, 3.6 to 14.4) versus the sham group (14.4, 4.5 to 39.2), significant at P = .026. The IB-Stim group had a lower worst pain score (5.0, 4.0 to 7.0) versus the sham group (7.0, 5.0 to 9.0).
- Overall symptom improvement, as measured with a symptom response scale score of greater than or equal to two, was greater with IB-Stim than sham (81% versus 26%, P < .001).

No serious adverse events were recorded in any subject. The following adverse events were reported: ear discomfort (n = 6), adhesive allergy (n = 3), and syncope (n = 1).

Although not specifically reported in the study described above, percutaneous therapies generally have risks of bleeding or infection at the puncture site, and skin irritation or pain at the site of application. Another retrospective cohort study of 1,207 devices at six clinical facilities over a one-year period confirmed the safe nature of periauricular percutaneous implantation of the devices offered by the manufacturer and minimal risk to the patient (Roberts, 2016).

In 2024, we found a small retrospective study comparing the efficacy of percutaneous electrical nerve field stimulation and pharmacological treatment (amitriptyline and cyproheptadine) for adolescents with functional abdominal pain disorders (n = 101). Those receiving percutaneous electrical nerve field stimulation (48% of participants) had a lower abdominal Pain Index (P = .001), nausea severity scale (P = .059), and functional disability inventory (P = .048) scores at the three-month follow-up. The amitriptyline group (21% of patients) had a decrease in abdominal Pain Index (P = .034) and lower functional disability inventory scores than the cyproheptadine group (P = .03). However, the cyproheptadine group (31% of patients) did not exhibit significant changes in these measures at follow-up. The study concluded that auricular stimulation is effective in improving abdominal pain, nausea, and disability in adolescents with functional abdominal pain disorders; amitriptyline also led to significant improvements, although it was less effective than auricular stimulation in reducing abdominal pain compared to cyproheptadine (Santucci, 2023).

No policy changes would be warranted, given the study's retrospective design and small sample size which limits generalizability of the results. In short, while non-pharmacological options are attractive for children who fail or refuse prescription medication for pain relief, the empirical support for these approaches is very weak, especially for children. Neuromodulatory treatments require further study before widespread use.

In 2025, we added one new economic study. For adolescents with irritable bowel syndrome, results of a cost-benefit and cost-minimalization study with a one-year time horizon suggest potential improved quality of life and reduced healthcare needs from the patient, parent, and health insurance perspectives. Percutaneous electrical nerve field stimulation was associated with 18 added healthy days over one year of follow-up, increased annual parental wages of $5,802 due to fewer missed work days to care for the child, and $4,744 in cost-savings to insurance. Estimates were based on limited outcome data from a sham-controlled double-blind trial and cost and work productivity data from observational cohort studies (Shah, 2024). No policy changes are warranted.

In 2026, we updated the references and changed the policy from investigational to medically necessary based on a new guideline recommending percutaneous electrical nerve field stimulation as a treatment option in children with refractory pain from irritable bowel syndrome.

The evidence of efficacy of IB-Stim in adults is very limited. A small, randomized, double-blind pilot study compared the efficacy of IB-Stim (n = 7) to sham (n = 8) in adults age 18 to 60 years. Participants wore the devices five days per week for four weeks. Both IB-Stim and sham produced some improvement in bowel symptoms, symptom severity scores, and quality of life scores compared to baseline, but the duration of the improvement often waned at the eight-week follow-up. No adverse events were reported in either group (ClinicalTrials.gov identifier: NCT04428619, 2023).

References

On February 5, 2026, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "IB-Stim," "Neuro-Stim," "neuromodulation," "electric stimulation therapy" (MeSH), "irritable bowel syndrome" (MeSH), and "auricular stimulation." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

3/2021: initial review date and clinical policy effective date: 4/2021

3/2022: Policy references updated.

3/2023: Policy references updated.

3/2024: Policy references updated.

3/2025: Policy references updated.

3/2026: Policy references updated. Coverage modified.

Related codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1482. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code description
64567	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation