Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

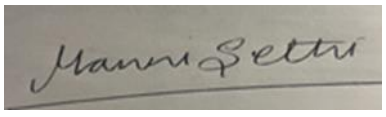
Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date: 4/1/2025
Policy Number: ccp.1482.07	Effective Date: 3/2021 Revision Date: 3/2025
Policy Name: Auricular stimulation for abdominal pain from irritable bowel syndrome	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Keystone First
Family of Health Plans

Auricular stimulation for abdominal pain from irritable bowel syndrome

Clinical Policy ID: CCP.1482-07

Recent review date: 3/2025

Next review date: 7/2026

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

Coverage policy

Auricular stimulation (percutaneous electrical nerve field stimulation) for treating functional abdominal pain related to irritable bowel syndrome is investigational/not clinically proven and, therefore, not medically necessary.

Note: Coverage decisions will be made on a case-by-case basis, and the Medical Director will have the discretion to approve coverage for this service when appropriate.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Standard-of-care treatment customized to member's specific symptoms and underlying triggers.

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 approved the IB-Stim® (formerly Neuro-Stim™; Innovative Health Solutions Inc., Versailles, Indiana) as a Class II, non-implanted percutaneous nerve stimulator for use in patients eight to 21years of age to reduce functional abdominal pain 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 three consecutive weeks. It is not intended to relieve pelvic pain (U.S. Food and Drug Administration, 2024). 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 (Innovative Health Solutions, 2025).

Findings

Guidelines

As of this writing, no guidelines specifically recommend percutaneous electrical nerve field stimulation for treating abdominal pain from irritable bowel syndrome.

A possible placebo effect of the IB-Stim suggest 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. There were no specific recommendations for children.

Evidence review

The U.S. Food and Drug Administration based its approval on the results of one randomized, double-blind, sham-controlled trial (Kovacic, 2017). One additional retrospective cohort study provides supplementary safety information on the device (Roberts, 2016). We identified no other studies or guidelines that addressed percutaneous electrical nerve field stimulation as a treatment for pain associated with irritable bowel syndrome.

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. The results are as follows (Krasaelap, 2020; U.S. Food and Drug Administration, 2018):

- Fifty-nine percent (59%, 16/27) of IB-Stim participants versus 26% (6/23) of sham participants showed a greater than 30% reduction in worst abdominal pain from baseline to three weeks of therapy (*P* = .024).
- At the end of three weeks of therapy:
    - Fifty-two percent (52%, 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 Neuro-Stim System family of devices and minimal risk to the patient (Roberts, 2016).

The IB-Stim is contraindicated in patients with (Innovative Health Solutions, 2025):

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

A follow-up randomized, double-blinded, sham-controlled trial of 92 adolescents underwent four weeks of auricular neurostimulation trial to predict pain. Patients in the treatment group with low baseline vagal efficiency had lower pain scores after three weeks. No substantial changes were observed in the placebo or high vagal efficiency groups (Kovacic, 2020).

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 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.

References

On February 3, 2025, 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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3/2021: initial review date and clinical policy effective date: 3/2021

3/2022: Policy references updated.

3/2023: Policy references updated.

3/2024: Policy references updated.

3/2025: Policy references updated.