Molina Clinical Policy
IB-Stim Device for Abdominal Pain in Adolescents (Percutaneous Electrical Nerve Field Stimulation)
Policy No. 383

Last Approval: 12/14/2022
Next Review Due By: December 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Irritable bowel syndrome (IBS), a functional gastrointestinal (GI) illness, characterized by persistent stomach pain with episodic exacerbations and abnormalities in bowel movements, which may include intermittent bouts of diarrhea or constipation that vary in severity and duration. The etiology of IBS is unknown, but current literature suggests that a multifactorial pathogenesis involving brain-gut axis dysregulation, GI autonomic nervous system abnormalities, some intestinal inflammation, increased bowel sensitivity, decreased pain thresholds, and psychological factors such as stress and anxiety (Ikechi et al., 2017; Devanarayana and Rajindrajith, 2018). There is currently no definitive diagnostic test for IBS and is currently diagnosed based on a symptom complex, medical and family history, and a thorough physical examination. Diagnostic evaluation may include stool tests, colonoscopy, CT, upper endoscopy, lactose intolerance testing, and breath tests to detect bacterial overgrowth in the GI tract (Moleski, 2020). IBS has been subtyped according to predominant stool pattern. Four IBS subtypes have been identified: IBS with constipation; IBS with diarrhea; IBS with mixed symptoms of constipation and diarrhea (mixed type); or unclassified (Ford et al. 2017; ACG 2018). Treatment for IBS is aimed at resolving symptoms such as pain, bloating, cramping, and diarrhea or constipation, and conventional treatment includes dietary changes, probiotics, antispasmodics, fiber supplementation, and mental health interventions (e.g., cognitive behavioral therapy, hypnosis) and antidepressants (WGO, 2015; NIDDK, 2017). Standard treatments for pediatric patients with IBS are comparable to those for adults, with a greater emphasis on cognitive behavioral therapy and other biopsychosocial interventions as first-line therapies (Hayes, 2022). IBS affects an estimated 1.2% and 2.9% of in the pediatric population in the United States with symptoms reported in 14% of high school students and 6% of middle school students (Hyams et al. 2016).

Percutaneous electrical nerve field stimulation (PENFS), also known as Percutaneous Electrical Nerve Stimulation (PENS), is a conservative, minimally invasive pain treatment that involves inserting acupuncture-like needles into the skin and connecting them via a cable to an external power source. The needle is placed near the site of pain and is percutaneous rather than cutaneous (e.g., TENS). PENS electrodes are not implanted permanently, as in SCS. The mechanism of action of PENS is thought to involve endogenous opioid-like substances modulating the hypersensitivity of nerves that cause persistent pain.

The IB-Stim (Innovative Health Solutions Inc.) is a PENFS system intended for use in patients 11 to 18 years of age with functional abdominal pain associated with IBS. The prescription-only device consists of a small single-use electrical nerve stimulator that is placed behind the patient’s ear. The stimulation of nerve bundles in and around the ear is thought to provide pain relief. The battery-powered chip of the device emits low-frequency electrical pulses to stimulate branches of certain cranial nerves continuously for 5 days before being replaced. The IB-Stim is intended to be used for 120 hours per week for 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. Treatment protocols are for 3 consecutive weeks, not to exceed 4 weeks. The device is contraindicated for patients with hemophilia, patients with cardiac pacemakers, or those diagnosed with psoriasis vulgaris (Hayes, 2021; Food and Drug Administration, 2019 & 2018; Innovative Health Solutions, n.d.).

Functional abdominal pain disorders (FAPD) can be diagnosed in children who have chronic (≥ two months) abdominal pain, negative workup, normal physical examination, and a stool sample negative for occult blood. The goal of FAPD management in children and adolescents is a rehabilitation approach that includes a return to normal function rather than complete elimination of pain. Management is individualized based on the behavior of the child and family, triggers, and symptoms, and includes both medical and behavioral treatments. Most cases in children can be managed in the primary care setting and resolve over several months. (Chacko & Chiou, 2021).

Regulatory

The Food and Drug Administration (FDA) issued a De Novo classification order (DEN180057) in 2019. The product code for the class II device is QHH (non-implanted nerve stimulator for pain associated with IBS). IB-Stim is currently the only FDA-cleared PENFS for the treatment of abdominal pain in adolescents with IBS. The FDA classification order permits the device to be marketed as an adjunct to IBS therapies to help reduce functional abdominal pain in patients aged 11 to 18 years.

COVERAGE POLICY

Percutaneous electrical nerve field stimulator systems (including the IB-Stim device) **are considered experimental, investigational, and unproven** due to insufficient published evidence assessing the safety and/or impact on health outcomes in children with functional abdominal pain disorders associated with IBS.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

There is insufficient published evidence to assess the safety and efficacy of the IB-Stim device on health outcomes or the management of patients with functional abdominal pain associated with IBS. A single center, blinded, sham RCT with a small study population (n=104) was the basis of FDA approval of IB-Stim (formerly NeuroStim) Kovacic et al. (2017). Larger trials comparing the IB-Stim to conventional treatments are needed to determine safety and efficacy, confirm the results, determine the optimal setting and duration of treatment, and establish patient selection criteria for those with functional abdominal pain caused by IBS. The PENFS cannot be recommended for children with functional abdominal pain associated with IBS at this time.

Kovacic et al. (2017) conducted a single center, blinded, sham RCT evaluating the efficacy of a PENFS device, NeuroStim (Innovative Health Solutions), in adolescents with abdominal pain-related functional GI disorders. The four-week trial that enrolled a mixed population of adolescent patients (ages 11-18) with functional GI disorders and who met Rome III criteria for related disorders. The primary outcome was change in abdominal pain scores (change in worst pain intensity and a composite PFSD score). Global symptom improvement was assessed as a secondary endpoint using the Symptom Response Scale (SRS). Participants were followed for a median of 9.2 weeks after the last week of treatment. The study included 104 children (n=104) with abdominal pain-related functional GI disorders who met the study criteria and were randomly assigned to PENFS (n=57) with an active device or sham (n=47).

- The worst pain score improved statistically significantly more in the PENFS group than in the sham group between baseline and week 3 (difference between groups 2.15 points, p0.0001). However, there was no significant difference between the PENFS group and the sham group in the proportion of participants who improved by 30% or more from baseline to extended follow-up in worst pain or usual pain.
- At week 3, the median PFSD composite scores decreased significantly more in the PENFS treatment group than in the sham treatment group (difference between groups: 11.48 points). At the end of the study, the PENFS group improved significantly more than the sham treatment group in terms of both the median worst pain score and the composite PFSD score.

- SRS scores improved in the PENFS group versus the sham group at 3 weeks, but no significant difference between groups was observed at the extended follow-up.
- The authors noted that the study did not evaluate changes in bowel habits, which were considered the most bothersome IBS symptom, and instead focused solely on pain relief. The reported side effects were comparable between the two groups, and there were no serious adverse effects.

Study limitations include small sample size and short follow-up period (8-12 weeks) and exclusions after randomization. The preliminary findings of this study is encouraging; however further research is required to validate the findings. Considering the chronic condition of abdominal pain-related functional GI disorders, a longer evaluation period is also required to determine efficacy durability. Furthermore, based on current findings, determining the clinical significance of the PENFS's alleged effects is difficult.

Post-hoc Analysis of IBS subgroup

Krasaelap et al. (2020) performed post-hoc secondary analyses of the pivotal trial conducted by Kovacic et al. (2017) as requested by the FDA to support whether the results for patients in the IBS sub-group, which comprised the majority of the trial participants, were consistent with the overall cohort studied. Fifty patients (n=50) were randomly assigned to groups that received PENFS (n=27) or a sham stimulation (n=23) 5 days per week for 4 weeks. The primary endpoint was the number of patients who experienced a 30% or greater reduction in the severity of their worst abdominal pain after three weeks. Secondary endpoints were improvement in overall symptoms based on a symptom response scale after 3 weeks, a decrease in the composite abdominal pain severity score, and a decrease in the severity of typical abdominal pain.

- At 3 weeks, the active treatment group had at least a 30% reduction in worst abdominal pain compared to the sham group: 59% of patients who received PENFS experienced a 30% or greater reduction in their worst abdominal pain, compared to 26% of patients who received sham stimulation (59% versus 26%, p=0.024).
- It was reported that 82% of PENFS patients had a symptom response scale score of 2 or higher, compared with 26% of sham patients. There were no significant side effects reported.

It was concluded that auricular neurostimulation reduced abdominal pain scores, resulting in an overall improvement among adolescents with IBS. The study concluded that PENFS is a noninvasive treatment option for the IBS pediatric population although the sample size was small and short-term follow-up of the trial.

The studies reported by Kovacic et al. (2017) and Krasaelap et al. (2020) suggests that the IB-Stim is associated with clinically significant benefits in pain and function at 3 to 4 weeks but was not sustained at 8 to 12 weeks. Kovacic et al. (2020) conducted a small study to determine whether pretreatment vagal efficiency (VE), respiratory sinus arrhythmia, and heart period can predict pain improvement with auricular neurostimulation in pediatric functional abdominal pain disorders. The study included 92 adolescents (n=92) with FAPD who participated a four-week randomized, double-blinded, sham-controlled auricular neurostimulation trial. Pain was predicted using mixed effects modeling from baseline electrocardiogram data. A three-way interaction demonstrated that treatment group participants with a low baseline VE had decreased pain levels at week 3. No significant changes were reported in the placebo (or high VE treatment group) subjects, which was supported by the strong correlation between baseline VE and the degree of pain reduction in the treatment group. The study concluded that impaired cardiac vagal regulation measured by VE predicts pain improvement with auricular neurostimulation; however, the study is limited by its small sample size and short-term follow-up period.

ECRI (2021) published a Clinical Evidence Assessment on the IB-Stim device in 2021, which is intended to treat adolescents (aged 11 to 18 years) with IBS-related abdominal pain. The authors identified a single published post hoc subgroup analysis of adolescents with IBS who were included in the IB-Stim pivotal trial, which compared the efficacy of the device in a sham-controlled trial with 27 adolescents who received IB-Stim treatment versus 23 adolescents who received sham stimulation (Krasaelap et al. 2020). By 3-week follow-up, IB-Stim reduced abdominal pain more than sham stimulation, but the benefits were not sustained through 12-week follow-up. The pivotal trial itself was excluded from the Assessment because it included pooled outcomes from patients with other GI disorders in addition to IBS. The authors stated that the major limitations of the post hoc analysis were that it does not allow conclusions due to the design of the pivotal study itself, that the subgroup analysis compromised the pivotal study's randomization because

the randomization was not stratified by patient condition, that the analysis had a small sample size, a single center design, and a lack of published independent studies to validate the findings. They also noted that the post hoc analysis had a high risk of bias, rendering the evidence inconclusive. To address evidence gaps, the authors suggested RCTs comparing IB-Stim to pharmacotherapy and other noninvasive pain management techniques in adolescents and reporting on patient-oriented outcomes.

An updated evidence analysis research brief concluded that the published evidence remains insufficient to evaluate the IB-Stim PENFS device (Innovative Health Solutions, Inc., Versailles, IN) for treatment of pain associated with IBS in patients aged 11 to 18 years (Hayes 2019, updated 2021).

Systematic Reviews / Professional Society Guidelines

No systematic reviews addressing the use of IB-stim or PENFS for the management of IBS-associated pain in adolescents were identified. There are no professional guidelines recommending PENFS IB-stim electrical stimulation therapy in this population were identified.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation
S8930	Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with patient (when used to describe the IB-Stim device)
E1399	Durable medical equipment, miscellaneous (when used to describe the IB-Stim device)

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/14/2022	Policy reviewed. No changes in coverage position; updated Overview, Summary of Medical Evidence, and References.
12/8/2021	Policy reviewed, no changes, updated references.
12/9/2020	New policy. IRO Peer Review. October 2, 2020. Reviewed by practicing, board-certified physician in the area of Pediatrics.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: IB-Stim, PENFS, neuromodulation for IBS, functional abdominal pain). Available from CMS. Accessed November 2022.
2. Food and Drug Administration (FDA). De novo summary (DEN180057). Published October 25, 2018. Available at:
   - Device Classification Under Section 513(f)(2)(De Novo). Accessed November 2022.
   - De Novo Classification Request LASSIFICATION REQUEST. Accessed November 2022.
3. Food and Drug Administration (FDA).
   - FDA News Release. FDA permits marketing of first medical device for relief of pain associated with irritable bowel syndrome in patients 11-18 years of age. Available from FDA. Published June 7, 2019. Accessed November 2022.
   - Center for Devices and Radiological Health (CDRH). IB-Stim [de novo classification request for IB-Stim] (DEN180057). Published October 25, 2018. Available from FDA. Accessed November 2022.

Manufacturer

1. Innovative Health Solutions (IHS). IHS on the NeuroStim website links to the NeuroAxis IB-Stim home page. Accessed November 2022.

Other Evidence Based Reviews and Publications

1. Hayes. Evidence analysis research brief: IB-Stim (Innovative Health Solutions) for treatment of pain associated with irritable bowel syndrome. Published March 5, 2021. Archived April 5, 2022. Accessed November 2022.Registration and login required.
2. Hayes. Evolving evidence review: IB-Stim (NeurAxis) for treatment of pain associated with irritable bowel syndrome in adolescents. Published July 14, 2022. Accessed November 2022. Registration and login required.
3. Functional Abdominal Pain Associated with IBS. Available from IBStim. Accessed November 2022.
4. Chacko M, Chiou E. Functional abdominal pain in children and adolescents: Management in primary care. Available from UpToDate. Updated October 18, 2022. Accessed November 2022. Registration and login required.

Peer Reviewed Publications

1. Devanarayana NM, Rajindrajith S. Irritable bowel syndrome in children: Current knowledge, challenges and opportunities. World J Gastroenterol. 2018;24(21):2211-2235. doi:10.3748/wjg.v24.i21.2211
2. Ford AC, Lacy BE, Talley NJ. Irritable bowel syndrome. N Engl J Med. 2017 Jun 29;376(26):2566-2578.
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9. Roberts A, Sithole A, Sedghi M, Walker CA, Quinn TM. Minimal adverse effects profile following implantation of periauricular percutaneous electrical nerve field stimulators: A retrospective cohort study. Med Devices (Auckl). 2016; 9: 389–393. doi: 10.2147/MDER.S107426.

National and Specialty Organizations

1. Ford AC, Moayyedi P, Chey WD, et al. American College of Gastroenterology monograph on management of irritable bowel syndrome. Am J Gastroenterol. 2018 Jun;113(Suppl 2):1-18. doi: 10.1038/s41395-018-0084-x.
2. ECRI Institute. IB-Stim (Innovative Health Solutions) for treating abdominal pain in patients with irritable bowel syndrome. Plymouth Meeting (PA): ECRI; 2021 February 10. (Clinical Evidence Assessment).
3. World Gastroenterology Organisation (WGO). Irritable bowel syndrome: A global perspective [World Gastroenterology Organisation Global Guidelines]. Updated September 2015. Available from WGO . Accessed November 2022.

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*