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

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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. 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, computed tomography (CT), upper endoscopy, lactose intolerance testing, and breath tests to detect bacterial overgrowth in the GI tract. Rome IV is another diagnostic tool that considers frequency and duration of symptoms and defines specific stool and pain patterns. 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. 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, mental health interventions (e.g., cognitive behavioral therapy, hypnosis) and antidepressants. 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).

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., transcutaneous electrical nerve stimulation). PENS electrodes are not implanted permanently, as in spinal cord stimulation. 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 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; FDA 2018 & 2019).

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 stimulation (including the IB-Stim device) **is 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 irritable bowel syndrome.

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 randomized controlled trial (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. 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 , in adolescents with abdominal pain-related functional GI disorders. The four-week trial 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 pain-frequency-severity-duration (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 in the PENFS group compared to the sham group between baseline and week 3 (difference of 2.15 points, p = 0.0001). 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 of 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 are 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.

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 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, 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 (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 in 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 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.

Chogle et al. (2023) performed a prospective study to analyze the effect of auricular PENFS on the quality of life of children with disorders of gut-brain interaction. The study consisted of 31 participants between 11-18 years (mean age 15.7 years) with 80.6% female participants. Thirteen patients had IBS and 9 patients had functional dyspepsia. Patients received PENFS therapy (IB-Stim NeurAxis, Versailles, IN) once a week during a four-week period. Outcomes were measured with self-reported Abdominal Pain Index (API), Nausea Severity Scale (NSS), Functional Disability Inventory (FDI), Child Somatization Inventory (CSI), Patient-Reported Outcomes Measurement Information System (PROMIS) Global Health Anxiety, PROMIS Global Health Depression, and Quality of Life (QoL) questionnaires including the Pediatric Quality of Life (PedsQL) generic core scale and PedsQL general well-being scale. Patients reported significant reductions in API, NSS, FDI, CSI, and PROMIS Anxiety ($p < 0.05$). Self-reported QoL and PROMIS Depression scores did not change ($p > 0.05$). The study concluded that PENFS enhances the QoL of children with pain related disorders of gut-brain interaction. Limitations of this study included a small sample size, absence of a control group, and lack of long-term follow-up data.

Castillo et al. (2023) conducted a RCT to assess the effects of PENFS on the microbiome in pediatric patients with IBS. The study consisted of 27 patients with IBS and 34 Health Control (HC) patients. Of the 27 patients with IBS, 17 patients (all female) completed weekly treatment with PENFS via IB-Stim for four weeks. Participants were between 8-20 years of age (average age 15.4) and 82% of IBS participants were female while 41% of patients in the HC group

were female. Inclusion criteria included meeting Rome IV criteria for diagnosis of IBS and negative testing for celiac disease and inflammatory disorders. Participants were excluded from the study if they had a diagnosis of organic gastrointestinal disorder, were on probiotics or antibiotics, or receiving formula as their sole source of nutrition. Results were measured by self-reported measures including Abdominal Pain Index (API), Pain Catastrophizing Scale for Children (PCS-C), Functional Disability Inventory-Child Version (FDI), Screen for Child Anxiety Related Disorders (SCARED), and Pediatric Insomnia Severity Index. Participants also used a daily diary to include pain rating with the Visual Analog Scale (VAS) for Pain Intensity and Pain Unpleasantness, stool frequency, and stool consistency, using the Modified Bristol Stool Form Scale for Children. Participants of the study also provided stool samples that were used to evaluate their microbiome species, metabolic pathways, and fecal calprotectin levels.

Patients that received PENFS treatment reported reductions from baseline to post-treatment and follow-up visits after treatment with PENFS for API (−3.09 versus 2.33 versus 2.22, p= 0.01) and FDI (22.79 versus 16.27 versus 15.11, p= 0.007). PCS-C scores were reduced from baseline to post-treatment and follow-up visits (23.58 versus 13.96 versus 15.56, p= 0.003) and from baseline to follow-up visits (23.58 vs 15.56). Decrease trends in anxiety, sleep disturbance, and VAS pain scores were reported. Increase trends in stool consistency and frequency were reported. Four microbiome species were depleted at post-treatment compared to baseline (R.bromii, C. bolteae, B. caccae, A. finegoldii) but no species had increased at follow-up. Eighteen metabolic pathways decreased in post-treatment. Eight were related to fatty acid biosynthesis and four were related to sugar fermentation or degradation. The study concluded PENFS led to improvements in abdominal pain, functioning, and catastrophizing. Limitations of this study include small sample size and selection bias with more females in the IBS group compared to control. Researchers were also unable to control for diet and medications that may have affected the microbiome.

Professional Society Guidelines

There are no professional guidelines recommending PENFS IB-stim electrical stimulation therapy in this population.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Code

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

HCPCS (Healthcare Common Procedure Coding System) Codes

HCPCS	Description
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

12/13/2023	Policy reviewed. No changes in coverage position; updated Summary of Medical Evidence and References.
12/14/2022	Policy reviewed. No changes in coverage position; updated Overview, Summary of Medical Evidence, and References.
12/08/2021	Policy reviewed, no changes, updated references.
12/09/2020	New policy. IRO Peer Review. October 2, 2020. Reviewed by practicing, board-certified physician in Pediatrics.

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APPENDIX

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