Subject: Percutaneous Electrical Nerve Field Stimulator (PENFS) [IB-Stim Device] for Functional Abdominal Pain in Adolescents		Original Effective Date: 12/9/20
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Contents

DISCLAIMER

This Molina clinical policy is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina clinical policy document and provide the directive for all Medicare members.[1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

The IB-Stim (Innovative Health Solutions Inc.) is a percutaneous electrical nerve field stimulator (PENFS) system intended to be used in patients 11-18 years of age with functional abdominal pain associated with irritable bowel

syndrome (IBS). The device is a single-use electrical nerve stimulator that is placed behind the patient's ear. Stimulating 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 continuously for 5 days, at which time it is replaced. 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. Treatment protocols are for 3 consecutive weeks, and not to exceed 4 weeks. The device is contraindicated for patients with hemophilia, patients with cardiac pacemakers or those diagnosed with psoriasis vulgaris (a condition in which skin cells build up and form scales and itchy, dry patches). [2 8]

Functional abdominal pain disorders (FAPD) can be diagnosed in children who have chronic (≥2 months) abdominal pain, negative workup, normal physical examination, and a stool sample negative for occult blood. The goal of management of FAPDs in children and adolescents is a rehabilitation approach that includes return to normal function rather than complete elimination of pain. Management is individualized according to child and family behavior, triggers, and symptoms and includes both medical and behavioral treatments. Most cases can be managed in the primary care setting and resolve over several months in the majority of children. [10]

Food and Drug Administration (FDA)

On June 7, 2019, the FDA issued a De Novo classification order (DEN180057) allowing the IB-Stim device to be marketed in the United States. According to an FDA press release, the classification order permits marketing of the device as an adjunct to therapies for irritable bowel syndrome (IBS), to help reduce functional abdominal pain in patients 11 to 18 years of age. [2]

RECOMMENDATION CLINICAL CRITERIA

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

CONTINUATION OF THERAPY

N/A

LIMITATIONS

N/A

SUMMARY OF MEDICAL EVIDENCE

There is insufficient published evidence to assess the safety and efficacy of the IB-Stim device on health outcomes or management of patients with functional abdominal pain associated with irritable bowel syndrome. A very limited number of randomized controlled sham trials have included small patient populations (n=50-115) with a limited number of sessions and short-term follow-ups (4 weeks). Outcomes are mixed. Larger trials

that compare the IB-Stim to conventional treatments need to be conducted to determine safety and efficacy, outcomes, confirm the results, determine the optimal setting and duration of treatment and patient selection criteria for those with functional abdominal pain related to IBS. At the current time, percutaneous electrical nerve field stimulator (PENFS) cannot be recommended for children with functional abdominal pain associated with irritable bowel syndrome.

Kovacic et al., (2017) reported the results of a double blind, randomized, sham-controlled 4 week trial that enrolled a mixed population of patients with functional gastrointestinal disorders. According to this study "In this randomized, sham-controlled trial, we enrolled adolescents (aged 11-18 years) who met Rome III criteria for abdominal pain-related functional gastrointestinal disorders from a single US outpatient gastroenterology clinic. Patients were randomly assigned (1:1) with a computer-generated randomization scheme to active treatment or sham (no electrical charge) for 4 weeks. Patients were stratified by sex and presence or absence of nausea. Allocation was concealed from participants, caregivers, and the research team. The primary efficacy endpoint was change in abdominal pain scores. Improvement in worst abdominal pain was measured and composite pain score using the Pain Frequency-Severity-Duration (PFSD) scale. Participants with less than 1 week of data and those with organic disease identified after enrolment were excluded from the modified intention-to-treat population. 115 children with abdominal pain-related functional gastrointestinal disorders were enrolled and assigned to either PENFS (n=60) with an active device or sham (n=55). After exclusion of patients who discontinued treatment (n=1 in the PENFS group; n=7 in the sham group) and those who were excluded after randomization because they had organic disease (n=2 in the PENFS group; n=1 in the sham group), 57 patients in the PENFS group and 47 patients in the sham group were included in the primary analysis. Patients in the PENFS group had greater reduction in worst pain compared with sham after 3 weeks of treatment Effects were sustained for an extended period (median follow-up 9·2 weeks in the PENFS group at baseline at follow-up versus sham. Median PFSD composite scores also decreased significantly in the PENFS group compared with sham with a mean decrease after 3 weeks. These effects were sustained at extended follow-up in the PENFS group at follow-up, compared with sham. Ten patients reported side-effects (three of whom discontinued the study): ear discomfort (n=6; three in the PENFS group, three in the sham group), adhesive allergy (n=3; one in the PENFS group, two in the sham group), and syncope due to needle phobia (n=1; in the sham group). There were no serious adverse events. According to the authors, the results show that PENFS with Neuro-Stim has sustained efficacy for abdominal pain-related functional gastrointestinal disorders in adolescents." This study is limited by small sample size and short-term follow-up. [3]

Krasaelap et al., (2020) reported the results of another small double blind, randomized, sham-controlled trial to evaluate the efficacy of PENFS in adolescents with irritable bowel syndrome (IBS). According to this study "Patients were randomly assigned to groups that received PENFS (n = 27; median age, 15.3 y; 24 female) or a sham stimulation (n = 23; median age, 15.6 y; 21 female), 5 days/week for 4 weeks. The primary endpoint was number of patients with a reduction of 30% or more in worst abdominal pain severity after 3 weeks. Secondary endpoints were reduction in composite abdominal pain severity score, reduction in usual abdominal pain severity, and improvement in global symptom based on a symptom response scale (–7 to +7; 0 = no change) after 3 weeks. Results reported reductions of 30% or more in worst abdominal pain were observed in 59% of patients who received PENFS vs 26% of patients who received the sham stimulation. The patients who received PENFS had a composite pain median score of 7.5 and a usual pain median score of 3.0 vs 5.0 in the sham group. A symptom response scale score of 2 or more was observed in 82% of patients who received PENFS vs

26% of patients in the sham group. No significant side effects were reported." The authors concluded that "auricular neurostimulation reduces abdominal pain scores and improves overall wellbeing in adolescents with IBS. PENFS is a noninvasive treatment option for pediatric patients with functional bowel disorders." This study is limited by small sample size and short-term follow-up. [5]

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. According to this study "A total of 92 adolescents with functional abdominal pain disorders underwent a 4-week randomized, double-blinded, sham-controlled auricular neurostimulation trial. Electrocardiogram-derived variables at baseline were used to predict pain using mixed effects modeling. A 3-way interaction (95% confidence intervals: 0.004-0.494) showed that the treatment group subjects with low baseline VE had lower pain scores at week 3. There was no substantial change in the placebo or high VE treatment group subjects. This effect was supported by a significant correlation between baseline VE and degree of pain reduction only in the treatment group. The authors indicated that impaired cardiac vagal regulation measured by VE predicts pain improvement with auricular neurostimulation." This study is limited by small sample size and short-term follow-up. [4]

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	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]

HCPCS	Description
	N/A

ICD-10	Description: [For dates of service on or after 10/01/2015]
	Any/All

REFERENCES

Government Agency

1. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National coverage determination (NCD) Search. Accessed at: http://www.cms.gov/medicare-coverage-database/
2. U. S. Food and Drug Administration (FDA) website:
    - De Novo Classification Request for IB-Stim. October 25, 2018. Accessed at: https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180057.pdf
    - 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. June 7, 2019. Accessed at:

https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-medical-device-relief-pain-associated-irritable-bowel-syndrome-patients

Peer Reviewed Publications

3. Kovacic K, Hainsworth K, Sood M, Chelimsky G et al. Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomised, double-blind, sham-controlled trial. Lancet Gastroenterol Hepatol. 2017 Oct;2(10):727-737.
4. Kovacic K. Kolacz J, Lewis G et al. Impaired Vagal Efficiency Predicts Auricular Neurostimulation Response in Adolescent Functional Abdominal Pain Disorders. Am J Gastroenterol. 2020 Sep;115(9):1534-1538.
5. Krasaelap A, Sood M et al. Efficacy of Auricular Neurostimulation in Adolescents with Irritable Bowel Syndrome in a Randomized Double Blind Trial. Clin Gastroenterol Hepatol. 2020 Aug;18(9):1987-1994.e2. doi: 10.1016/j.cgh.2019.10.012. Epub 2019 Oct 14.
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7. Ford et al. American College of Gastroenterology monograph on management of irritable bowel syndrome. Am J Gastroenterol. 2018. Accessed at: https://gi.org/wp-content/uploads/2018/07/IBS-Monograph-2018.pdf

Other Resources

8. Innovative Health Solutions Manufacturer [website]. IB-Stim – A Non-Drug Alternative to Reduce Functional Abdominal Pain Associated with IBS. Accessed at: https://ibstim.com/
9. Hayes a Tract Manager Company:
    - Evidence Analysis Research Brief. IB-Stim (Innovative Health Solutions) for Treatment of Pain Associated with Irritable Bowel Syndrome. Jul 24, 2019.
10. UpToDate: [website]. Waltham, MA: Walters Kluwer Health; 2020.
    - Chacko M, Chiou E. Functional abdominal pain in children and adolescents: Management in primary care.

REVISION/REVIEW HISTORY:

12/9/2020: New Policy. Peer Review: [AMR]: Policy reviewed by a practicing physician Board certified in Pediatric Gastroenterology, Pediatrics. 10/2/20