



PROVIDER POLICIES & PROCEDURES

PERCUTANEOUS ELECTRICAL NERVE FIELD STIMULATOR (IB-STIM DEVICE) FOR FUNCTIONAL ABDOMINAL PAIN IN ADOLESCENTS

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for the IB-Stim device. By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

The IB-Stim device is a percutaneous electrical nerve field stimulator (PENFS) system for individual's 11-18 years of age with functional abdominal pain and irritable bowel syndrome (IBS). The device is comprised of a small single-use electrical nerve stimulator that is placed behind the person's ear. It contains a battery-powered chip that emits low-frequency electrical pulses to stimulate branches of certain cranial nerves continuously for five days, at which time the device is replaced. Stimulating nerve bundles in and around the ear is thought to provide pain relief. The IB-Stim is intended to be used for 120 hours per week up to 3 consecutive weeks to reduce functional abdominal pain associated with IBS. The device is contraindicated for individuals with hemophilia, individuals with cardiac pacemakers or those diagnosed with psoriasis vulgaris.

CLINICAL GUIDELINE

Coverage guidelines for the IB-Stim device are made in accordance with the DSS definition of Medical Necessity. The following criteria are guidelines *only*. Coverage determinations are based on an assessment of the individual and their unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

Use of the IB-Stim device is considered **investigational and therefore not medically necessary** as there is insufficient evidence in peer-reviewed, published, medical literature to assess its safety or impact on health outcomes in children with functional abdominal pain associated with irritable bowel syndrome .

NOTE: EPSDT Special Provision

Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE

Please note that authorization is based on medical necessity at the time the authorization is issued and is not a guarantee of payment. Payment is based on the individual having active coverage, benefits and policies in effect at the time of service.

To determine if a service or procedure requires prior authorization, CMAP Providers may refer to the *Benefit and Authorization Grids* summaries on www.ct.gov/husky by clicking on "For Providers" followed by "Benefit Grids". For a definitive list of benefits and service limitations, CMAP Providers may access the CMAP provider fee schedules and regulations at www.ctdssmap.com.

Prior authorization for the IB-Stim device is required. Requests for coverage are reviewed in accordance with procedures in place for reviewing requests for durable medical equipment. Coverage determinations are based upon a review of requested and/or submitted case-specific information.

The following information is needed to review requests for the IB-Stim device:

1. Fully completed authorization request via on-line web portal; and
2. Documentation from the requesting physician supporting medical necessity.

EFFECTIVE DATE

This policy for the prior authorization for the IB-Stim device for individuals covered under the HUSKY Health Program is effective May 1, 2022.

LIMITATIONS

Not Applicable

CODE:

| Code | Description |
|------|-------------|
| None | N/A |

DEFINITIONS

1. **HUSKY A:** Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B:** Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children’s Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C:** Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D:** Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program:** The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP:** Connecticut’s implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **HUSKY Plus Physical Program (or HUSKY Plus Program):** A supplemental physical health program pursuant to Conn. Gen. Stat. § 17b-294, for medically eligible members of HUSKY B in Income Bands 1 and 2, whose intensive physical health needs cannot be accommodated within the HUSKY Plan, Part B.
8. **Medically Necessary or Medical Necessity:** (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain

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the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B) recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.

9. **Prior Authorization:** A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

REFERENCES

- Food and Drug Administration (FDA). De Novo Summary. DEN180057. October 25, 2018. IB-Stim. Available at:
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- Krasaelap A, Sood MR, Li BUK, et al. Efficacy of Auricular Neurostimulation in Adolescents With Irritable Bowel Syndrome in a Randomized, Double-Blind Trial. *Clin Gastroenterol Hepatol.* 2020;18(9):1987-1994.e2. doi:10.1016/j.cgh.2019.10.012
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PUBLICATION HISTORY

| Status | Date | Action Taken |
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