



PROVIDER POLICIES & PROCEDURES

EXTERNAL LOWER EXTREMITY NERVE STIMULATOR

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP Providers) with the information needed to support a medical necessity determination for an external lower extremity nerve stimulator. 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 external lower extremity nerve stimulator is a device which delivers electrical stimulation to the peroneal nerves via a pair of bilaterally leg-worn devices and aids in reducing symptoms of restless leg syndrome.

CLINICAL GUIDELINE

Coverage guidelines for an external lower extremity nerve stimulator will be 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:

The use of an external lower extremity nerve stimulator (e.g., NTX-100 Tonic Motor Activation [TOMAC] System) is considered **investigational and therefore not medically necessary** for the treatment of any condition, including, but not limited to, restless leg syndrome as there is insufficient evidence in peer-reviewed, published medical literature supporting safety and clinical efficacy.

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

Prior authorization for an external lower extremity nerve stimulator 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.

EFFECTIVE DATE

This Clinical Guideline is effective for prior authorization requests for individuals covered under the 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.

HUSKY A, B, C, and D programs on or after February 1, 2025.

LIMITATIONS

N/A

CODES:

| Code | Description |
|------|---|
| N/A | There is no specific code for external lower extremity nerve stimulator |

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. **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 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. prescription.
8. **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.

ADDITIONAL RESOURCES AND REFERENCES:

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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.

- Bogan RK, Roy A, Kram J, Ojile J, Rosenberg R, Hudson JD, Scheuller HS, Winkelman JW, Charlesworth JD. Efficacy and safety of tonic motor activation (TOMAC) for medication-refractory restless legs syndrome: a randomized clinical trial. *Sleep*. 2023 Oct 11;46(10):zsad190. doi: 10.1093/sleep/zsad190. PMID: 37458698; PMCID: PMC10566236.
- Buchfuhrer, Mark J., et al. "Adjunctive Tonic Motor Activation Enables Opioid Reduction for Refractory Restless Legs Syndrome: A Prospective, Open-Label, Single-Arm Clinical Trial - BMC Neurology." *BioMed Central*, BioMed Central, 21 Nov. 2023, bmcneurol.biomedcentral.com/articles/10.1186/s12883-023-03462-6#Sec2.
- Charlesworth JD, Adlou B, Singh H, Buchfuhrer MJ. Bilateral high-frequency noninvasive peroneal nerve stimulation evokes tonic leg muscle activation for sleep-compatible reduction of restless legs syndrome symptoms. *J Clin Sleep Med*. 2023 Jul 1;19(7):1199-1209. doi: 10.5664/jcsm.10536. PMID: 36856064; PMCID: PMC10315589.
- ClinicalTrials.gov. NCT06076499, A Post-Market Study for Long-Term Effectiveness and Safety of the NTX100 for RLS (Thrive). Available at: <https://clinicaltrials.gov/study/NCT06076499> . Accessed on July 23, 2024.
- Roy A, Ojile J, Kram J, Olin J, Rosenberg R, Hudson JD, Bogan RK, Charlesworth JD. Long-term efficacy and safety of tonic motor activation for treatment of medication-refractory restless legs syndrome: A 24-Week Open-Label Extension Study. *Sleep*. 2023 Oct 11;46(10):zsad188. doi: 10.1093/sleep/zsad188. PMID: 37439365; PMCID: PMC10566237.
- Ryschon AM, Cao KN, Roy A, Pietzsch JB. Cost-Effectiveness of Tonic Motor Activation (TOMAC) Therapy for Patients with Restless Legs Syndrome: An Exploratory Analysis. *Neurol Ther*. 2023 Dec;12(6):2133-2146. doi: 10.1007/s40120-023-00551-z. Epub 2023 Oct 12. PMID: 37824047; PMCID: PMC10630268.

PUBLICATION HISTORY

| Status | Date | Action Taken |
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