IMPLANTABLE HYPOGLOSSAL NERVE STIMULATION

The 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 implantable hypoglossal nerve stimulation. 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.

Implantable hypoglossal nerve stimulation is used in the treatment of moderate to severe obstructive sleep apnea (OSA) in adults who have failed or are unable to tolerate CPAP. The stimulator is an implanted medical device intended to reduce the occurrence of OSA by electrically stimulating the hypoglossal nerve, resulting in tongue movement. The device stimulates the nerve in time with breathing to relieve any upper airway obstruction.

CLINICAL GUIDELINE

Coverage guidelines for implantable hypoglossal nerve stimulation are made in accordance with the DSS definition of Medical Necessity. The following criteria are guidelines *only*. Coverage determinations are based on an individual assessment of the member 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:

FDA-approved hypoglossal nerve stimulation is considered medically necessary for adults with OSA when **ALL** of the following criteria are met:

A. 18 years of age or older;
B. A body mass index (BMI) < 40 kg/m^2;
C. A polysomnography (PSG) is performed within 24 months of first consultation for the hypoglossal nerve stimulation implant;
D. Documented moderate to severe OSA (apnea hypopnea index (AHI) greater than or equal to 15 and less than or equal to 100;
E. Predominantly obstructive events (defined as less than 25% central or mixed apnea of the total AHI);
F. Documented positive airway pressure (PAP) failure (defined as AHI of greater than 15 despite PAP usage) or intolerance to PAP therapy (defined as less than 4 hours per night, 5 nights per week or the PAP system has been returned) despite consultation with a sleep expert with attempts to resolve reasons for failure/intolerance;
G. Absence of complete concentric collapse at the soft palate level (as seen on drug-induced sleep endoscopy); and
H. Absence of any anatomical findings that would compromise performance of the device (e.g., a tonsil size of 3 or 4 per standardized tonsillar hypertrophy grading scale).

Hypoglossal nerve stimulation may be considered medically necessary for children with Down syndrome when the following criteria are met:

A. Age ≥13 years;
B. Severe OSA (AHI 10 to 50);
C. Nonconcentric collapse of the airway shown by endoscopy;
D. Not a candidate for adenotonsillectomy or is status post adenotonsillectomy;
E. Not able to use or tolerate PAP; and
F. Have been considered for or tried other appropriate alternative treatments.

Removal/Revision/Replacement:

I. Procedures for removal, replacement, or revision of a previously implanted hypoglossal nerve stimulator may be considered medically necessary to address complications including, but not limited to:
   - Implant-related infection
   - Generator or lead migration
   - Failure to address the symptoms of OSA

II. The replacement of an FDA-approved implantable upper airway hypoglossal nerve stimulation device, generator battery and/or leads may also be considered medically necessary when a previously implanted device, generator battery and/or leads is no longer functioning appropriately, and the device is no longer under warranty.

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 is required for hypoglossal nerve stimulation. Requests for coverage of hypoglossal nerve stimulation are reviewed in accordance with procedures in place for reviewing requests for surgical procedures. Coverage determinations are based upon a review of requested and/or submitted case-specific information.

The following information is needed to review requests for hypoglossal nerve stimulation:

- Fully completed Outpatient Prior Authorization Request Form or fully completed authorization submission via web-based authorization portal
- Results of recent polysomnography testing
- Current BMI
- Documentation supporting failure of or intolerance to PAP
- Results of drug-induced sleep endoscopy
- Description of implant-related complications or malfunction (for revision/replacement procedures only)
- Other information as requested by CHNCT

EFFECTIVE DATE

This Policy is effective for prior authorization requests for hypoglossal nerve stimulation for individuals covered under the HUSKY Health Program on or after February 1, 2022.

LIMITATIONS
Not Applicable

CODES:

Code	Description
64582	Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array
64583	Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator
64584	Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array

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.

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:

- Bellamkonda N, Shiba T, Mendelsohn AH. Adverse Events in Hypoglossal Nerve Stimulator Implantation: 5-Year Analysis of the FDA MAUDE Database. Otolaryngol Head Neck Surg. 2021;164(2):443-447. doi:10.1177/0194599820960069
- Centers for Medicare and Medicaid Services. LCD for Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea. (L38310). Medicare Coverage Database. Retrieved on November 29, 2021 at https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=38310&ver=7&articleId=57948&bc=AAAAAAAAQAAA&
- Strollo PJ Jr, Soose RJ, Maurer JT, et al. Upper-airway stimulation for obstructive sleep apnea. N Engl J Med. 2014;370(2):139-149. doi:10.1056/NEJMoa1308659
- UptoDate. Hypoglossal Nerve Stimulation for Adult Patients with Obstructive Sleep Apnea. Topic last updated August 22, 2023.
- UptoDate. Management of Obstructive Sleep Apnea in Children. Topic last updated April 25, 2024.
- UptoDate. Surgical Treatment of Obstructive Sleep Apnea in Adults. Edward M. Weaver, MD, Vishesh K. Kapur, MD, MPH. Topic last updated May 28, 2024. Retrieved on November 29, 2021.

PUBLICATION HISTORY

Status	Date	Action Taken
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		meeting. Changes approved by the CHNCT Clinical Quality Subcommittee on September 16, 2024. Approved by DSS on September 27, 2024.