PROVIDER POLICIES & PROCEDURES

BAROREFLEX STIMULATION DEVICE

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 a baroreflex stimulation device (including any interrogation and evaluation services). 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.

A baroreflex stimulation device provides electrical stimulation of the baroreceptors in the carotid arteries via an implanted device. Activation of the baroreceptors inhibit the sympathetic nervous system resulting in various physiologic changes, including a slower heart rate and a lower blood pressure.

One such device, the BaroStim Neo® System, has been approved by the U.S. FDA for use in individuals with heart failure who have not responded to maximally tolerated guideline-directed medical therapy (GDMT) and device therapy. The device has also been proposed as a treatment for other conditions, including hypertension.

CLINICAL GUIDELINE

Coverage guidelines for a baroreflex stimulation device (including any interrogation and evaluation services) 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 his or her 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:

A baroreflex stimulation device (including any interrogation and evaluation services) is considered **investigational and therefore not medically necessary**, for any indication**,** as there is insufficient evidence in peer-reviewed, published, medical literature supporting its clinical efficacy and improved health outcomes.

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

Requests for coverage of a baroreflex stimulation device (including any interrogation and evaluation services) will be reviewed in accordance with procedures in place for reviewing requests for surgical

procedures. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

EFFECTIVE DATE
This Clinical Guideline is effective for prior authorization requests for a baroreflex stimulation device (including any interrogation and evaluation services) for individuals covered under the HUSKY A, B, C, and D programs on or after August 01, 2026.

LIMITATIONS
N/A

CODES:

Code	Description
64654	Initial implantation of baroflex activation therapy (BAT) modulation system, including lead placement onto the carotid sinus, lead tunnelling, connection to a pulse generator placed in a distant subcutaneous pocket (i.e., total system), and intraoperative interrogation and programming
64655	Revision or replacement of baroflex activation (BAT) modulation therapy system with intraoperative interrogation and programming; lead only
64656	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; pulse generator only
64657	Removal of baroreflex activation therapy (BAT) modulation system; total system, including lead and pulse generator
64658	Removal of baroreflex activation therapy (BAT) modulation system; lead only
64659	Removal of baroreflex activation therapy (BAT) modulation system; pulse generator only
93145	Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (BAT) modulation system including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (e.g., battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); without programming
93146	Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (BAT) modulation system including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (e.g., battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); with programming, including optimization of tolerated therapeutic level setting

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:

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- Shi R, Sun T, Wang M, et al. Baroreflex activation therapy for heart failure with reduced ejection fraction: A comprehensive systematic review and meta-analysis. Heliyon. January 2024;10(2):
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PUBLICATION HISTORY

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