# PROVIDER POLICIES & PROCEDURES

## BOTULINUM TOXIN FOR THE TREATMENT OF HYPERHIDROSIS

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 use of botulinum toxin for the treatment of hyperhidrosis. 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.

Botulinum is a family of toxins produced by the anaerobic organism Clostridia botulinum. When administered intramuscularly, all botulinum toxins reduce muscle tone by interfering with the release of acetylcholine from nerve endings.

### CLINICAL GUIDELINE

Coverage guidelines for botulinum toxin are made in accordance with the Department of Social Services (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 clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

**Initial Authorization**

Onabotulinumtoxina is typically considered medically necessary as second line treatment of *primary* hyperhidrosis for those individuals who have failed a six (6) month trial of lifestyle changes and first line therapy (e.g., topical antiperspirants or glycopyrronium cloth) and meet any ONE of the following criteria:

1. Presence of medical complications or skin maceration with secondary infection; **OR**
2. Significant functional impairment (a disruption of professional and/or social life has occurred due to excessive sweating), as documented in the medical record.

**Reauthorization**

Onabotulinumtoxina is typically considered medically necessary for continued treatment of primary hyperhidrosis when the following criteria are met:

1. The criteria for initial authorization have been met; and
2. There is documentation of a positive clinical response.

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 of treatment with botulinum toxin is required. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

**The following information is needed to review requests for botulinum toxin:**
1. Fully completed Outpatient Prior Authorization Request Form or fully completed authorization request via on-line web portal;
2. Clinical information supporting the medical necessity of the treatment; and
3. Other information as requested.

**EFFECTIVE DATE**
This Policy is effective for prior authorization requests for botulinum toxin as treatment for hyperhidrosis for individuals covered under the HUSKY Health Program beginning January 1, 2017.

**LIMITATIONS**
N/A

**CODES:**

| Code | Description |
|---|---|
| 64650 | Chemodenervation of eccrine glands; both axillae |
| 64653 | Chemodenervation of eccrine glands; other area(s) (e.g., scalp, face, neck), per day |

**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:


1. BOTOX (onabotulinumtoxin A) [Full Prescribing Information]. Irvine, CA. Allergan Pharmaceuticals Ireland. Revised 2011. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103000s5236lbl.pdf. Accessed on February 20, 2020.
2. Ibrahim O, Kakar R, Bolotin D, et al. The comparative effectiveness of suction-curettage and onabotulinumtoxin-A injections for the treatment of primary focal axillary hyperhidrosis: a randomized control trial. J Am Acad Dermatol. 2013; 69(1):88-95.
3. Lowe NJ, Glaser DA, Eadie N, et al.; North American Botox in Primary Axillary Hyperhidrosis Clinical Study Group. Botulinum toxin type A in the treatment of primary axillary hyperhidrosis: a 52-week multicenter double-blind, randomized, placebo-controlled study of efficacy and safety. J Am Acad Dermatol. 2007; 56(4):604-611.
4. Lowe NJ, Yamauchi PS, Lask GP, et al. Efficacy and safety of botulinum toxin type A in the treatment of palmar hyperhidrosis: a double-blind, randomized, placebo-controlled study. Dermatol Surg. 2002; 28(9):822-827.
5. Naumann M, Lowe NJ. Botulinum toxin type A in treatment of bilateral primary axillary hyperhidrosis: randomized, parallel group, double blind, placebo controlled trial. BMJ. 2001; 323(7317):596-599.
6. Naumann M, Lowe NJ, Kumar CR, Hamm H.; Hyperhidrosis Clinical Investigators Group. Botulinum toxin type A is a safe and effective treatment for axillary hyperhidrosis over 16 months: a prospective study. Arch Dermatol. 2003; 139(6):731-736.
7. Naumann MK, Hamm H, Lowe NJ.; Botox Hyperhidrosis Clinical Study Group. Effect of botulinum toxin type A on quality of life measures in patients with excessive axillary sweating: a randomized controlled trial. Br J Dermatol. 2002; 147(6):1218-1226.
8. Naver H, Swartling C, Aquilonius SM. Palmar and axillary hyperhidrosis treated with botulinum toxin: one year clinical follow-up. Eur J Neurol. 2000; 7(1):55-62.
9. Odderson IR. Hyperhidrosis treated by botulinum A exotoxin. Dermatol Surg. 1998; 24(11):1237-1241.
10. Shelley WB, Talanin NY, Shelley ED. Botulinum toxin therapy for palmar hyperhidrosis. J Am Acad Dermatol. 1998; 38(2 Pt 1):227-229.
11. Smith, C.C., Pariser, D. Primary focal hyperhidrosis. (2020). A.O. Ofori (Ed.). UpToDate. Available at: https://www.uptodate.com. Accessed on February 20, 2020

**PUBLICATION HISTORY**

| Status | Date | Action Taken |
|---|---|---|
| Original Publication | January 2017 | Approved by CHNCT Medical Policy Review Committee on December, 14, 2016. Approved by CHNCT Clinical Quality Subcommittee on December 20, 2016. Approved by DSS on January 3, 2017. |
| Update | April 2018 | Reviewed and approved without changes by the CHNCT Medical Policy Review Committee on January 24, 2018. Approve by CHNCT Clinical Quality Subcommittee on March 19, 2018. Approved by DSS on April 5, 2018. |
| Reviewed | February 2019 | Reviewed and approved at the February 27, 2019 Medical Reviewer Meeting without changes.<br><br>Reviewed and approved by the CHNCT Clinical Quality Subcommittee on March 18, 2019.<br><br>Approved by DSS on March 27, 2019. |
| Update | April 2020 | Updates to Clinical Guideline section.<br><br>• Clarified that only onabotulinumtoxina is medically necessary as treatment for hyperhidrosis<br>• Clarified that onabotulinumtoxina is a second line treatmer<br>• Updated list of treatments that would be considered first line treatment<br>• Qualified term *significant functional impairment*<br>• Removed criteria for secondary hyperhidrosis as treatmen not indicated for this condition<br>• Added criteria for continued treatment<br><br>Updates to Additional Resources and References section.<br><br>Changes approved at the March 11, 2020 Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on March 16, 2020. Approved by DSS on April 16, 2020. |
| Review | March 2021 | Policy reviewed and approved without changes at the February 10, 2021 CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on March 15, 2021. Approved by DSS on March 22, 2021. |
| Review | March 2022 | Policy reviewed at approved without changes at the January 12, 2022 CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on March 21, 2022. Approved by DSS on March 24, 2022. |