PROVIDER POLICIES & PROCEDURES

BOTULINUM TOXINS FOR THE TREATMENT OF SELECT INDICATIONS

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 toxins in the treatment of select indications. 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, botulinum toxins interfere with the release of acetylcholine from nerve endings.

Botulinum toxins are indicated for numerous medical conditions. As these may include cosmetic treatments, the HUSKY Health program reviews select chemodenervation codes to assist in the determination of use. Please refer to the Connecticut Department of Social Services (DSS) Physician Surgical Fee Schedule for a list of the specific CPT® codes requiring prior authorization.

CLINICAL GUIDELINE

Coverage guidelines for botulinum toxin are made in accordance with the Department of Social Services 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:

Specific botulinum toxins will be considered medically necessary for individuals in the treatment of:

A. Blepharospasm [Botox® (onabotulinumtoxinA), Dysport® (abobotulinumtoxinA), or Xeomin® (incobotulinumtoxinA)]
    a. **Initial Authorization:** An initial six (6) month trial of botulinum toxin for blepharospasm will require clinical documentation to support the diagnosis to be considered medically necessary.
    b. **Reauthorization:** A continued twelve (12) month approval of botulinum toxin requires documentation of a positive clinical response.
B. Chronic Migraine [Botox]:
    a. **Initial Authorization**: An initial six (6) month trial of Botox for the prevention of chronic migraine headaches is generally considered medically necessary when the following criteria are met:
        1. The individual is ≥ 18 years of age with a diagnosis of chronic migraine headache; **AND**
        2. The individual experiences headaches 15 days or more per month; **AND**
        3. The individual experiences headaches lasting 4 hours or longer on at least 8 days per

month; **AND**

4. Symptoms persist despite trials of at least 1 agent in any 2 of the following classes of medications used to prevent migraines or reduce migraine frequency:
    a) Antidepressants
    b) Antihypertensives
    c) Antiepileptics; **AND**

    [Note: Individuals who have contraindications to preventive medications are not required to undergo a trial of these agents.]
5. FDA recommendations are followed for dosage, administration, and retreatment.

b. **Reauthorization:** Continued twelve (12) month approval of botulinum toxin for chronic migraine headaches requires documentation that the individual has achieved or maintained a reduction in monthly headache frequency since starting therapy.

C. Facial Myokymia [Botox]
   a. **Initial Authorization**: An initial six (6) month trial of botulinum toxin for facial myokymia will require clinical documentation to support the diagnosis to be considered medically necessary.
   b. **Reauthorization:** Continued twelve (12) month approval of botulinum toxin requires documentation of a positive clinical response.

D. Hyperhidrosis—Primary Hyperhidrosis (e.g., axillary, palmar, plantar) [Botox, Dysport, Xeomin, Myobloc® (rimabotulinumtoxinB)]
   a. **Initial Authorization**: botulinum toxin 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.
   b. **Reauthorization**: Continued twelve (12) month approval of botulinum toxin requires documentation of a positive clinical response.

E. Hyperhidrosis – Gustatory (Frey's Syndrome) [Botox, Dysport, Xeomin, Myobloc]
   a. **Initial Authorization:** An initial six (6) month trial of botulinum toxin for gustatory hyperhidrosis will require clinical documentation to support the diagnosis to be considered medically necessary.
   b. **Reauthorization:** Continued twelve (12) month approval of botulinum toxin requires documentation of a positive clinical response.

F. Hemifacial Spasm [Botox or Dysport]
   a. **Initial Authorization:** An initial six (6) month trial of botulinum toxin for hemifacial spasm will require clinical documentation to support the diagnosis to be considered medically necessary.
   b. **Reauthorization:** A continued twelve (12) month approval of botulinum toxin requires documentation of a positive clinical response.

G. Myofascial Pain Syndrome [Botox]
   a. **Initial Authorization:** An initial six (6) month trial of botulinum toxin for myofascial pain syndrome is generally considered medically necessary when the following criteria are met:
      1. The member has tried and failed physical therapy; **AND**
      2. The member has tried and failed other local trigger point injections.
   b. **Reauthorization**: A continued twelve (12) month approval of botulinum toxin requires documentation of a positive clinical response.

H. Oromandibular Dystonia [Botox or Dysport]
   a. **Initial Authorization:** An initial six (6) month trial of botulinum toxin for oromandibular dystonia will require clinical documentation to support the diagnosis to be considered

medically necessary.
    b. **Reauthorization:** A continued twelve (12) month approval of botulinum toxin requires documentation of positive clinical response to support.

I. Orofacial Tardive Dyskinesia [Botox]
    a. **Initial Authorization:** An initial six (6) month trial of botulinum toxin for orofacial tardive dyskinesia will require clinical documentation to support the diagnosis to be considered medically necessary.
    b. **Reauthorization:** A continued twelve (12) month approval of botulinum toxin requires documentation of positive clinical response.

J. Focal Motor and/or Phonic Tics [Botox]
    a. **Initial Authorization:** An initial six (6) month trial of botulinum toxin for focal motor or phonic tics will require clinical documentation to support the diagnosis to be considered medically necessary.
    b. **Reauthorization:** A continued twelve (12) month approval of botulinum toxin requires documentation of positive clinical response.

Investigational and Not Medically Necessary

- The use of Xeomin (incobotulinumtoxinA), Dysport (abobotulinumtoxinA) and Myobloc (rimabotulinumtoxinB) in the treatment of chronic migraine is typically considered investigational and NOT medically necessary as there are currently no FDA approved indications or well supported off-label recommendations for their use in treating this condition.
- The use of botulinum toxin is typically considered investigational and NOT medically necessary for the treatment of headache other than chronic migraine meeting the criteria above, including but not limited to tension, episodic migraine (fourteen migraine days per month or less), or chronic daily headaches.
- The use of botulinum toxin, whether the same or a different product, following failure of an initial trial for the treatment of chronic migraine is typically considered investigational and not medically necessary.
- The use of botulinum toxin for temporomandibular joint disorders is typically considered investigational and not medically necessary.
- The use of botulinum toxin for tinnitus is typically considered investigational and not medically necessary.
- The use of botulinum toxin for trigeminal neuralgia is typically considered investigational and not medically necessary.

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 for selected indications 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 select indications for individuals covered under the HUSKY Health Program beginning November 1, 2023.

LIMITATIONS

N/A

CODES

64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (e.g., for Blepharospasm, Hemifacial Spasm)
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (e.g., for Chronic Migraine)
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:

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PUBLICATION HISTORY

Status	Date	Action Taken
Original Publication	September 2023	Retired the Botulinum Toxin Chronic Migraine policy with the Botulinum Toxin Hyperidrosis policy. New policy drafted. Updated and resorted applicable references. Listed additional approvable conditions based on indication including: blepharospasm, facial myokymia, hemifacial spasms, myofascial pain syndrome, oromandibular dystonia, orofacial tardive dyskinesia, and motor and/or phonic tics. Added several indications considered investigational. Added additional HCPCS and CPT codes for informational purposes. New policy approved at the September 13, 2023, CHNCT Medical Reviewer meeting. Policy approved by the CHNCT Clinical Quality Subcommittee on September 18, 2023. Approved by DSS on October 2, 2023.