PROVIDER POLICIES & PROCEDURES

BOTULINUM TOXIN FOR THE TREATMENT OF CHRONIC MIGRAINE

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 in the treatment of chronic migraine. 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:

An initial six (6) month trial of botulinum toxin for prevention of chronic migraine headaches is generally considered medically necessary when the following criteria are met:

1. Adult individual diagnosed with chronic migraine headache; **AND**
2. Fifteen (15) or more headache-days per month with headache lasting four (4) hours or longer; **AND**
3. First episode at least six (6) months ago; **AND**
4. Symptoms persist despite trials of at least one (1) agent in any two (2) of the following classes of medications used to prevent migraines or reduce migraine frequency:
    a. Antidepressants
    b. Antihypertensives
    c. Antiepileptics.

Continuing treatment with botulinum toxin injection for ongoing prevention of chronic migraine headaches is considered medically necessary for individuals who have previously met the criteria above and completed an initial six (6) month trial when:

1. Migraine headache frequency was reduced by at least seven (7) days per month (when compared to pre-treatment average) by the end of the initial trial; **OR**
2. Migraine headache duration was reduced by at least one-hundred (100) total hours per month (when compared to the pre-treatment average) by the end of the initial trial.

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
  Exception: when the initial product was stopped due to a product specific intolerance or allergic reaction (rather than clinical failure), this investigational and not medically necessary statement does not apply.

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 chronic migraine for individuals covered under the HUSKY Health Program beginning January 1, 2017.

LIMITATIONS
N/A

CODE:

Code	Description
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (e.g., for chronic migraine)

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	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. Approved By CHNCT Clinical Quality Subcommittee on March 19, 2018. Approved by DSS on April 5, 2018.
Update	June 2018	Update to Clinical Guideline section. Added language stating that the use of Xeomin® (incobotulinumtoxinA), Dysport® (abobotulinumtoxinA) and Myobloc® (rimabotulinumtoxinB) in the treatment of chronic migraine is considered investigational and therefore not medically necessary. Removed redundant language in Clinical Guideline – Investigational and Not Medically Necessary

		section regarding assessment of the individual and their unique clinical needs. Reference to person-centered reviews already stated in first paragraph under Clinical Guidelines. Changes approved at the CHNCT Medical Policy Review Committee on June 13, 2018. Changes approved by the CHNCT Clinical Quality Subcommittee on June 18, 2018. Approved by DSS on June 20, 2018.
Reviewed	April 2019	Reviewed and approved without changes at the April 10, 2019 Medical Reviewer meeting. Approved without changes by the CHNCT Clinical Quality Subcommittee on June 17, 2019. Approved by DSS on July 25, 2019.