Pharmacy Medical Necessity Guidelines: Botulinum Toxins

Effective: March 1, 2022

Effective: Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED	Department to Review	PRECERT /MM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

Commercial Products:
PRECERT:617.972.9409

Tufts Health Public Plans Products:
MM: 888.415.9055

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS (NON-COSMETIC)

Botox (onabotulinumtoxinA) is indicated for:

- **Adult Bladder Dysfunction**
  - The treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
  - The treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition in adults who have an inadequate response to or are intolerant of an anticholinergic medication.
- **Blepharospasm and Strabismus**
  The treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above.
- **Cervical Dystonia**
  The treatment of adults with cervical dystonia, to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.
- **Chronic Migraine**
  The prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer).
- **Pediatric Detrusor Overactivity associated with a Neurologic Condition**
  The treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medication.
- **Primary Axillary Hyperhidrosis**
  The treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents.
- **Spasticity**
  The treatment of spasticity in patients 2 years of age and older.

Dysport (abobotulinumtoxinA) is indicated for:

- **Cervical Dystonia**
  The treatment of cervical dystonia in adults.
- **Spasticity**
  The treatment of spasticity in patients 2 years of age and older.

Myobloc (rimabotulinumtoxinB) is indicated for:

- **Cervical Dystonia**
  The treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.
- **Chronic Sialorrhea**

The treatment of chronic sialorrhea in adults.

Xeomin (incobotulinumtoxinA) is indicated for:

- **Blepharospasm and Strabismus**
  The treatment of blepharospasm in adults.
- **Cervical Dystonia**
  The treatment of cervical dystonia in adults.
- **Chronic Sialorrhea**
  The treatment of chronic sialorrhea in patients 2 years of age and older.
- **Upper Limb Spasticity**
  The treatment of upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy, and in adults.

COVERAGE GUIDELINES

In addition to the coverage criteria listed for each diagnosis, the plan may authorize coverage of **Botox, Dysport, Xeomin**, or **Myobloc** when the presence of a dystonia/movement disorder contributes to a significant functional impairment and/or pain and other more conservative/less intensive levels/alternative treatments have been tried and failed.

OnabotulinumtoxinA (Botox)

1. **Blepharospasm** (eyelid spasms / blinking) **or Strabimus** (cross-eyes, esotropia, exotropia)
   a) The Member is over the age of 12 years
   b) Documented diagnosis
   c) Dose of 200 units or less
2. **Spasmodic Torticollis / Cervical Dystonia**
   a) Documented diagnosis
   b) Dose of 300 units or less
3. **Anal fissures**
   a) Documented diagnosis
   b) Inadequate response to or failure of prescription topical therapy (e.g., nitroglycerin ointment)
   c) Dose is 100 units or less
4. **Jaw-closing oromandibular dystonia, and masseter spasticity**
   a) Documented diagnosis
   b) Inadequate response to or failure of conventional therapy such as physical therapy or local anesthetic injections
5. **Laryngeal or spasmodic dysphonia**
   a) Documented diagnosis using videostroboscopy
   b) Dose of 100 units or less
6. **Focal limb dystonia (Organic writer's cramp, foot dystonia)**
   a) Documented diagnosis
   b) Dose of 100 units or less
7. **Spasticity**
   a) Documented diagnosis of upper or lower limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity
   b) For Members 18 years of age, documented failure to control spasticity by conventional therapies (e.g., Physical therapy, splinting, bracing, systemic antispasticity medication)
   c) Dose of 400 units or less
   d) Injections should occur no sooner than 3 months apart
8. **Hemifacial Spasms**
   a) Documented diagnosis
9. **Hyperhidrosis**
   a) Documented diagnosis of primary axillary, palmar, or plantar hyperhidrosis
   b) Treatment failure of the following prescription topical antiperspirant:
      - Aluminum Chloride (hexahydrate) 20% (Drysol®)
   c) Dose of 100 units or less per palm
   d) Injections should occur no sooner than 3 months apart
10. **Chronic Migraine Headaches**
    a) Documented diagnosis of chronic migraine defined as
       - History of migraine headaches lasting 4 hours a day or longer
       - Migraine headaches occur on ≥ 15 days per month
    b) Documentation of treatment with one of the following preventive medication classes:

- Previous treatment for at least two months with one agent from two out of four therapeutic classes listed below or contraindication to all of the following therapeutic classes:
    i. Beta-adrenergic blockers (e.g., metoprolol, propranolol, timolol)
    ii. Antiepileptic drugs (e.g., divalproex sodium, valproic acid, topiramate)
    iii. Antidepressants (e.g., amitriptyline, venlafaxine)
    iv. Long-acting CGRP receptor inhibitors (e.g., Aimovig, Emgality, Ajovy, Vyepti)

c) Must be ordered by or in consultation with a neurologist
d) Dose of 155 units or less per treatment
e) Injections should occur no sooner than 3 months apart

11. Detrusor Overactivity Associated with a Neurologic Condition

a) Documented diagnosis of urinary incontinence due to detrusor overactivity associated with a neurologic condition
b) Member is at least 5 years of age
c) Inadequate response to or failure of one or more anticholinergic medication(s) (e.g., flavoxate, oxybutynin, tolterodine, trospium, Detrol® LA, Enablex®, Toviaz®, Vesicare®)
d) Must be ordered by a urologist
e) Dose of 200 units or less per treatment
f) Injections should occur no sooner than 3 months apart

12. Overactive Bladder

a) Documented diagnosis of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency
b) Member is at least 18 years of age
c) Inadequate response to or failure of one or more anticholinergic medication(s) (e.g., flavoxate, oxybutynin, tolterodine, tolterodine ER, trospium, Enablex®, Toviaz®, Vesicare®)
d) Must be ordered by a urologist
e) Dose of 100 units or less per treatment
f) Injections should occur no sooner than 3 months apart

AbobotulinumtoxinA (Dysport)

1. Spasmodic Torticollis / Cervical Dystonia

a) Member has failed treatment with OnabotulinumtoxinA (Botox)
b) Documented diagnosis
c) The dose is 1,000 units or less

2. Spasticity

a) Member has failed treatment with Onabotulinumtoxin A (Botox)
b) Documented diagnosis of upper or lower limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity
c) The dose is 1,500 units or less
d) Injections should occur no sooner than 3 months apart

RimabotulinumtoxinB (Myobloc)

1. **Spasmodic Torticollis / Cervical Dystonia**
    a) Member has failed treatment with OnabotulinumtoxinA (Botox)
    b) Documented diagnosis
    c) Dose of 5,000 units or less
2. **Chronic Sialorrhea**
    a) Documented diagnosis
    b) Inadequate response to or treatment failure of glycopyrrolate OR scopolamine, or documentation of clinical inappropriateness of treatment with anticholinergic medications
    c) Member is over the age of 18 years of age
    d) Dose of 3,000 units or less
    e) Injections should occur no sooner than 3 months apart

IncobotulinumtoxinA (Xeomin)

1. **Blepharospasm** (eyelid spasms/blinking)
    a) Member has failed treatment with OnabotulinumtoxinA (Botox)
    b) Documented diagnosis
    c) Dose of 100 units or less
2. **Spasmodic Torticollis / Cervical Dystonia**
    a) Member has failed treatment with OnabotulinumtoxinA (Botox)
    b) Documented diagnosis

c) Dose of 120 units or less

3. **Chronic Sialorrhea**
   a) Documented diagnosis
   b) Inadequate response to or treatment failure of glycopyrrolate OR scopolamine, or documentation of clinical inappropriateness of treatment with anticholinergic medications
   c) Member is over the age of 18 years of age
   d) Dose of 100 units or less
   e) Injections should occur no sooner than 4 months apart
4. **Upper Limb Spasticity**
   a) Member has failed treatment with OnabotulinumtoxinA (Botox)
   b) Documented diagnosis of upper limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity
   c) Dose of 400 units or less
   d) Injections should occur no sooner than 3 months apart

LIMITATIONS

- The plan does not provide coverage for cosmetic procedures that involve the use of botulinum toxin injection.
- Authorizations will be granted for life of plan.
- The plan does not cover botulinum toxin therapy for the treatment of:
  - Any condition not listed above in the "Pharmacy Coverage Guidelines "or
  - Any patients with other types of muscle spasms not listed in the "Pharmacy Coverage Guidelines" including, but not limited to, smooth muscle spasms, myofascial pain, trigger points, and pyriformis syndrome.
  - Migraine headaches that occur 14 days or less per month (i.e., episodic migraine), or for other forms of headache.
  - Other types of urinary incontinence not listed in the "Pharmacy Coverage Guidelines."

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J0585	Injection, onabotulinumtoxinA, 1 unit
J0586	Injection, abobotulinumtoxinA, 5 units
J0587	Injection, rimabotulinumtoxinB,100 units
J0588	Injection, incobotulinumtoxinA, 1 unit
46505	Chemodenervation of internal anal sphincter
52287	Cystourethroscopy, with injection(s) for chemodenervation of the bladder
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (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)
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (e.g., for cervical dystonia, spasmodic torticollis)
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (e.g., for spasmodic dysphonia), includes guidance by needle electromyography, when performed
64642	Chemodenervation of one extremity; 1-4 muscle(s)
64643	Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (list separately in addition to code for primary procedure)
64644	Chemodenervation of one extremity; 5 or more muscle(s)
64645	Chemodenervation of one extremity; each additional extremity, 5 or more muscle(s) (list separately in addition to code for primary procedure)
64646	Chemodenervation of trunk muscle(s); 1-5 muscle(s)
64647	Chemodenervation of trunk muscle(s); 6 or more muscle(s)
64650	Chemodenervation of eccrine glands; both axillae
64653	Chemodenervation of eccrine glands; other area(s) (e.g., scalp, face, neck), per day

Code	Description
67345	Chemodenervation of extraocular muscle

Note: This list of codes may not be all-inclusive.

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5. Botulinum Toxin Treatment for Spasticity and Gastrointestinal Disorders, Winifred S. Hayes, Inc. January 28, 1999.
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APPROVAL HISTORY

October 2001: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. December 14, 2004: Add "when the presence of a dystonia/movement disorder contribute to a significant functional impairment and/or pain and other more conservative/less intensive levels/alternative treatments have been tried and failed" as an general qualifier to Clinical Coverage Criteria. Add treatment of Hemificial Spasms to the Clinical Coverage Criteria. Add treatment of Primary Axillary Hyperhidrosis to the Clinical Coverage Criteria. Add "ACE Inhibitors" to Exhibit B in the Coverage Limitations.
2. December 13, 2005: For Botulinum Toxin A, delete the dose limit for Blepharospasm or Strabimus, Anal fissures, and Laryngeal or spasmodic dysphonia. For Botulinum Toxin A, add the dose limit of "100 units or less" for Blepharospasm or Strabimus, Anal fissures, Laryngeal or spasmodic dysphonia, and Primary Axillary Hyperhidrosis.
3. November 14, 2006: Add clinical coverage criteria for Palmar Hyperhidrosis. Remove age limitation "Over the age of 18 years" from criteria for Primary Axillary Hyperhidrosis. Add "Aluminum Chloride (Hexahydrate) 20%" to criteria for Primary Axillary Hyperhidrosis.
4. November 13, 2007: No changes
5. September 9, 2008: Removed criteria for treatment of Migraine Headaches Removed corresponding Exhibits A and B in reference to remittive and prophylactic migraine therapies
6. January 13, 2009: Added limitation that Plantar Hyperhidrosis is not a covered indication.
7. September 8, 2009: Changed established drug names from Botulinum Toxin A to OnabotulinumtoxinA (Botox) and Botulinum Toxin B to RimabotulinumtoxinB (Myobloc).
8. January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
9. January 12, 2010: Added Dysport (abobotulinumtoxinA) to Medical Necessity Guidelines.
10. May 11, 2010: Updated HCPCS code descriptions for Botox and Myobloc. Updated diagnosis of neurologically-based limb spasticity to differentiate dosing limitations for upper and lower limb spasticity. Removed age limitation from diagnosis of spasmodic torticollis (neurologically based) and anal fissures. Removed age limitation from AbobotulinumtoxinA and RimabotulinumtoxinB. Updated initial authorization (2 months for Members 18 years of age and older, 12 months for Members below the age of 18 years old) and subsequent authorization intervals (12 months). Removed limitation language requiring a response following two sequential treatments/sets of injections in a 4-6 month period, using maximum dose for the size of the muscle for authorization of coverage of additional botulinum toxin injections.
11. July 13, 2010: Removed requirement of starch iodine test and iontophoresis from coverage criteria for palmar hyperhidrosis.
12. November 9, 2010: Changed policy title from "OnabotulinumtoxinA (Botox), abobotulinumtoxinA (Dysport) and rimabotulinumtoxinB (Myobloc)" to "Botulinum Toxins". Added requirement of documented diagnosis of cervical dystonia to Dysport (abobotulinumtoxinA) criteria. Added Xeomin (incobotulinumtoxinA) to pharmacy medical necessity guidelines. Added coverage criteria for the diagnosis of chronic migraine headaches for OnabotulinumtoxinA (Botox). Added limitation that the plan does not cover botulinum toxin therapy for the treatment of migraine headaches that occur 14 days or less per month (i.e., episodic migraine), or for other forms of headache.
13. January 1, 2011: Administrative Update: Added reimbursement code C9278
14. May 10, 2011: Clarified note regarding length of authorization. For subsequent authorizations beyond 2 months, provider needs to submit documentation of an objective measurable effect indicating clinical improvement of condition. For authorizations beyond one year, provider needs to submit documentation of sustained clinical effectiveness.
15. September 13, 2011: Added coverage criteria for treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition in adults who have an inadequate response to or are intolerant of an anticholinergic medication for OnabotulinumtoxinA (Botox). Added limitation that the plan does not cover botulinum toxin for other types of urinary incontinence not listed in the "Pharmacy Coverage Guidelines".
16. January 1, 2012: Administrative Update: Replaced reimbursement code C9278 with J0588

17. April 10, 2012: Changed maximum dose of Botox for chronic migraine headaches from 150 units to 155 units or less per treatment
18. January 1, 2013: Administrative Update: Added CPT codes 52287 and 64615
19. February 12, 2013: Added coverage criteria for treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.
20. January 1, 2014: Administrative Update. Removed CPT codes 64613 and 64614. Added CPT codes 64616, 64617, 64642 – 64647.
21. February 11, 2014: For the diagnosis of chronic migraine headaches, added neurologist or ophthalmologist prescriber requirement and prior treatment or contraindication with conventional pharmaceutical treatment measures.
22. February 10, 2015: Removed NSAIDS and Serotonin 5-HT1 receptor from previous treatment requirement for the diagnosis of chronic migraine headaches. Moved initial approval time frames and reauthorization requirements to Limitations section. Clarified "documentation" with "clinical notes from the medical record".
23. May 12, 2015: Changed dosing limitation to 400 units for upper limb spasticity.
24. September 16, 2015: Added pharmacy coverage guidelines for Dysport for the diagnosis of upper limb spasticity.
25. January 1, 2016: Administrative change to rebranded template.
26. February 9, 2016: Added pharmacy coverage guidelines for Botox for the diagnosis of lower limb spasticity and for Xeomin for the diagnosis of upper limb spasticity.
27. June 14, 2016: Clarified that neurologically-based limb spasticity refers to other than lower limb.
28. July 12, 2016: Removed ophthalmologist prescribers from chronic migraine headache indication (Botox). For chronic migraine headache, removed concurrent treatment with at least 2 traditional migraine prophylaxis medications requirement.
29. September 13, 2016: Added pharmacy coverage guidelines for Dysport for the diagnosis of Pediatric Lower Limb Spasticity.
30. November 15, 2016: Added pharmacy coverage guidelines for Botox for the diagnosis of Plantar Hyperhidrosis.
31. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
32. September 12, 2017: Effective 1/1/18, for the diagnosis of Primary Axillary Hyperhidrosis added that injections should occur no sooner than 6 months apart to the clinical criteria.
33. December 12, 2017: Effective 1/1/18, added coverage criteria for adult lower limb spasticity for Dysport based on updated package labeling.
34. August 7, 2018: Added pharmacy coverage guidelines for Xeomin for the new indication of chronic sialorrhea.
35. September 18, 2018: Updated the coverage criteria for chronic migraine headache to allow for the order to be made by or in consultation with a neurologist.
36. December 11, 2018: Updated the coverage criteria for Xeomin for upper limb spasticity to require the dose be 400 units or less based on package labeling.
37. March 12, 2019: Clarified coverage criteria language requirements for subsequent authorizations. Additional authorizations require documentation from the provider that treatment is clinically effective.
38. April 9, 2019: Updated coverage for chronic migraine to require previous treatment for at least three months with one agent from three of the following therapeutic classes or contraindication to all of the following therapeutic classes: beta-adrenergic blockers, antiepileptic drugs, antidepressants, and CGRP receptor inhibitors. Added the following limitation: "The plan does not cover combination therapy with Botox and a CGRP receptor antagonist for chronic migraine headaches."
39. May 7, 2019: Increased the max units for Botox to 200 units for blepharospasm based on FDA-approved dosing.
40. June 11, 2019: Updated the criteria for chronic migraine headaches to require previous treatment for at least two months, instead of three months, with one agent from three out of four of the therapeutic classes listed.
41. April 28, 2020: Effective May 1, 2020, removed reauthorization criteria for all indications and ages.
42. October 13, 2020: Updated the age requirements of Xeomin for upper limb spasticity based on expanded indication for use in patients at least 2 years of age. Updated coverage criteria for chronic migraine headaches for Botox throughout the Medical Necessity Guideline to clarify that only long-acting CGRP receptor inhibitors are considered.

43. January 12, 2021: Added the following Limitation to clarify the duration of approval: "Authorizations will be granted for life of plan."
44. March 9, 2021: Effective April 1, 2021, for Botox for chronic migraine headaches, updated prerequisite requirements to previous treatment for at least two months with one agent from two out of four preventive medication classes. For Commercial, Direct, and RITogether business lines, removed the following Limitation "The plan does not cover combination therapy with Botox and a long-acting CGRP receptor antagonist for prevention of chronic migraine headaches." For Botox for overactive bladder, removed "to qualify for re-treatment, Member must have reported at least 2 urinary incontinence episodes in a 30-day period." to be in line with previous removal of reauthorization criteria for all indications and ages. For Botox for plantar, palmar, and primary axillary hyperhidrosis, updated criteria to require injections should occur no sooner than 3 months apart from 6 months apart.
45. November 9, 2021: For Botox for anal fissures, updated prerequisite language to "Inadequate response to or failure of prescription topical therapy (e.g., nitroglycerin ointment)." For Botox for Jaw-closing oromandibular dystonia, and masseter spasticity, updated prerequisite language to "Inadequate response to or failure of conventional therapy such as physical therapy or local anesthetic injections." For Botox, combined criteria for all types of hyperhidrosis with no coverage changes. For Botox, combined criteria for all types of spasticity and changed criteria to: a) Documented diagnosis of upper or lower limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity, b) For Members 18 years of age, documented failure to control spasticity by conventional therapies, c) Appropriate dosing, and d) Injection should occur no sooner than 3 months apart. Other botulinum toxins indicated for spasticity require a step through Botox instead of conventional therapies. For Botox for Overactive Bladder, added the age requirements and removed the following: Member has had at least 3 urinary urgency incontinence episodes AND at least 24 micturitions in a 3-day period. For Botox, re-labeled Urinary Incontinence as Detrusor Overactivity Associated with a Neurologic Condition and added age requirements. Added coverage criteria for Chronic Sialorrhea for Myobloc based on the supplemental indication. For Xeomin for Blepharospasm and Spasmodic Torticollis/Cervical Dystonia, removed age requirements.
46. February 8, 2022: Effective March 1, 2022, removed the following Limitation to be in line with MassHealth ACPP/MCO Unified Pharmacy Product List: "Tufts Health Together does not cover combination therapy with Botox and a long-acting CGRP receptor antagonist for prevention of chronic migraine headaches." Administrative update to remove Tufts Health Freedom Plan products from the template.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services