Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs

Botulinum Toxins: Botox® (onabotulinumtoxin A), Dysport® (abobotulinumtoxin A), Myobloc® (rimabotulinumtoxin B), Xeomin® (incobotulinumtoxin A)

Effective: July 1, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☒ Tufts Health Plan Commercial products; Fax 617-673-0988
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☐ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

BOTOX FDA-APPROVED INDICATIONS (NON-COSMETIC):

Botox (onabotulinumtoxin A) is indicated for the treatment of:

Adult Bladder Dysfunction

- The treatment of overactive bladder with symptoms of urgent 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 in an adult that is inadequately managed with topical agents.

Spasticity

- The treatment of spasticity in patients 2 years of age and older.

BOTOX (onabotulinumtoxin A) **COMPENDIAL USES:**

- Chronic anal fissures
- Hemifacial spasm
- Spasmodic dysphonia (laryngeal dystonia)
- Oromandibular dystonia
- Focal hand dystonia
- Palmar and plantar hyperhidrosis

DYSPORT (abobotulinumtoxin A) **FDA-APPROVED INDICATIONS:**

Dysport (abobotulinumtoxin A) is indicated for the treatment of:

Cervical Dystonia

- The treatment of cervical dystonia in adults.

Spasticity

- The treatment of spasticity in patients 2 years of age and older.

MYOBLOC (rimabotulinumtoxin B) **FDA-APPROVED INDICATIONS:**

Myobloc (rimabotulinumtoxin B) is indicated for the treatment of:

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) FDA-APPROVED INDICATIONS:

Xeomin (incobotulinumtoxinA) is indicated for the treatment of:

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.

Clinical Guideline Coverage Criteria

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.

Botox (onabotulinumtoxin A):

1. **Blepharospasm** (eyelid spasms / blinking) or **Strabismus** (cross-eyes, esotropia, exotropia)
   a. The Member is over the age of 12 years
   b. Documented diagnosis of blepharospasm or strabismus

2. **Spasmodic Torticollis / Cervical Dystonia**
   c. Documented diagnosis of spasmodic torticollis / cervical dystonia

3. **Anal fissures**
   a. Documented diagnosis of anal fissures
   b. Inadequate response to or failure of prescription topical therapy (e.g., nitroglycerin ointment)

4. **Jaw-closing oromandibular dystonia, and masseter spasticity**
   a. Documented diagnosis of jaw closing oromandibular dystonia or masseter spasticity
   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

6. **Focal limb dystonia (Organic writer's cramp, foot dystonia)**
   a. Documented diagnosis of focal limb dystonia

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 anti-spasticity medication)

8. **Hemifacial Spasms**
   a. Documented diagnosis of hemifacial spasms

9. **Hyperhidrosis**
   a. Documented diagnosis of primary axillary, palmar, or plantar hyperhidrosis
   b. Treatment failure of the following prescription topical antiperspirant, e.g., Aluminum Chloride (hexahydrate) 20% (Drysol®)

10. **Chronic Migraine Headaches**
    a. Documented diagnosis of chronic migraine defined as
       i. History of migraine headaches lasting 4 hours a day or longer

       WITH

       ii. Migraine headaches occurring on ≥ 15 days per month

       AND

    b. Documentation of prior treatment, for a trial of at least 2 months, with at least **one** agent each from **two** of the four therapeutic classes listed below, or contraindication to **all:**
       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)

       OR

       v. All four therapeutic classes are contraindicated or considered clinically inappropriate

       AND

    c. The requested drug has been prescribed by or in consult with a neurologist

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

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 or a Urogynecologist

Dysport (abobotulinumtoxin A):

1. **Spasmodic Torticollis / Cervical Dystonia**
   a. Member has failed treatment with Botox (onabotulinumtoxin A)
   b. Documented diagnosis of spasmodic torticollis or cervical dystonia

2. **Spasticity**
   a. Member has failed treatment with Botox (onabotulinumtoxin A)
   b. Documented diagnosis of upper or lower limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity

Myobloc (rimabotulinumtoxin B)

1. **Spasmodic Torticollis / Cervical Dystonia**
   a. Member has failed treatment with Botox (onabotulinumtoxin A)
   b. Documented diagnosis of spasmodic torticollis or cervical dystonia

2. **Chronic Sialorrhea**
   a. Documented diagnosis of chronic sialorrhea
   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

Xeomin (incobotulinumtoxin A)

1. **Blepharospasm (eyelid spasms/blinking)**
   a. Member has failed treatment with Botox (onabotulinumtoxin A)
   b. Documented diagnosis of blepharospasm

2. **Spasmodic Torticollis / Cervical Dystonia**
   a. Member has failed treatment with Botox (onabotulinumtoxin A)
   b. Documented diagnosis of spasmodic torticollis or cervical dystonia

3. **Chronic Sialorrhea**
   a. Documented diagnosis of chronic sialorrhea
   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

4. **Upper Limb Spasticity**
   a. Member has failed treatment with Botox (onabotulinumtoxin A)
   b. Documented diagnosis of upper limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity

Limitations

- The Plan does not provide coverage for cosmetic procedures that involve the use of botulinum toxin injection.
- The Plan does not cover botulinum toxin therapy for the treatment of:
  - Any conditions or diagnoses not listed above
  - Any patients with other types of muscle spasms not listed in the Medical Necessity 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 Medical Necessity Guidelines.

Codes

The following code(s) require prior authorization:
Table 1: HCPCS Codes

HCPCS Codes	Description
J0585	Injection, onabotulinumtoxin A, 1 unit
J0586	Injection, abobotulinumtoxin A, 5 units
J0587	Injection, rimabotulinumtoxin B,100 units
J0588	Injection, incobotulinumtoxin A, 1 unit

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

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Approval And Revision History

April 19, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)

May 9, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- Originally approved September 13,2022 by P&T and September 21,2022 by MPAC committees effective January 1, 2023
- Administrative update: April 2023 added Medical Benefit Drugs to title and updated MATogether and RITogether fax numbers to 617-673-0939
- May 17, 2023: Added Urogynecologist to Overactive Bladder 12d. criteria effective July 1, 2023

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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