Medical Necessity Guidelines
Medical Benefit Drugs

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

Effective: January 1, 2024

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

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

Food and Drug Administration (FDA) – Approved Indications (non-cosmetic):

Botox (onabotulinumtoxin A) is indicated for:

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.

Daxxify (daxibotulinumtoxinA-lanm) is indicated for the treatment of:

Cervical Dystonia

- The treatment of cervical dystonia in adults.

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) 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) is indicated for the treatment of:

Blepharospasm and Strabismus

- Blepharospasm in adults

Cervical Dystonia

- Cervical dystonia in adults

Chronic Sialorrhea

- Chronic sialorrhea in patients 2 years of age and older

Upper Limb Spasticity

- Upper limb spasticity in adult patients
- Upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy

Botox and Xeomin are the preferred Botulinum Toxins.

Clinical Guideline Coverage Criteria

Botox

The plan may authorize coverage of Botox when all the following criteria are met:

Blepharospasm (eyelid spasms / blinking) or Strabismus (cross-eyes, esotropia, exotropia)

1. Member is at least 12 years of age

AND

2. Documented diagnosis of blepharospasm or strabismus

Spasmodic Torticollis / Cervical Dystonia

1. Documented diagnosis of spasmodic torticollis or cervical dystonia

Anal fissures

1. Documented diagnosis of anal fissures

AND

2. Inadequate response to or failure of prescription topical therapy (e.g., nitroglycerin ointment)

Jaw-closing oromandibular dystonia, and masseter spasticity

1. Documented diagnosis of jaw closing oromandibular dystonia or masseter spasticity

AND

2. Inadequate response to or failure of conventional therapy such as physical therapy or local anesthetic injections

Laryngeal or spasmodic dysphonia

1. Documented diagnosis of laryngeal or spasmodic dysponia using videostroboscopy

Focal limb dystonia (Organic writer's cramp, foot dystonia)

1. Documented diagnosis of focal limb dystonia

Spasticity

1. Documented diagnosis of upper or lower limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity

AND

2. For Members 18 years of age or older, documented failure to control spasticity by conventional therapies (e.g., Physical therapy, splinting, bracing, systemic anti-spasticity medication)

Hemifacial Spasms

1. Documented diagnosis of hemifacial spasms

Hyperhidrosis

1. Documented diagnosis of primary axillary, palmar, or plantar hyperhidrosis

AND

2. Treatment failure of the following prescription topical antiperspirant, e.g., Aluminum Chloride (hexahydrate) 20% (Drysol®)

Chronic Migraine Headaches

1. Documented diagnosis of chronic migraine defined as
    a. History of migraine headaches lasting 4 hours a day or longer
    b. Migraine headaches occurring on at least 15 days per month

AND

2. Documentation of **one (1)** of the following:
    a. prior treatment, for a trial of at least 2 months, with at least **one (1)** agent each from **two (2)** 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)
    b. Beta-adrenergic blockers, antiepileptic drugs, antidepressants, and long-acting CGRP receptor inhibitors are contraindicated or considered clinically inappropriate

AND

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

Detrusor Overactivity Associated with a Neurologic Condition

1. Documented diagnosis of urinary incontinence due to detrusor overactivity associated with a neurologic condition

AND

2. Member is at least 5 years of age

AND

3. Inadequate response to or failure of one or more anticholinergic medication(s) (e.g., flavoxate, oxybutynin, tolterodine, trospium)

AND

4. Prescribed by or in consultation with a urologist

Overactive Bladder

1. Documented diagnosis of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency

AND

2. Member is at least 18 years of age

AND

3. Inadequate response to or failure of one or more anticholinergic medication(s) (e.g., flavoxate, oxybutynin, tolterodine, tolterodine ER, trospium)

AND

4. Prescribed by or in consultation with a urologist or urogynecologist

Xeomin

The plan may authorize coverage of Xeomin when all the following criteria are met:

Blepharospasm (eyelid spasms/blinking)

1. Documented diagnosis of blepharospasm

AND

2. Member is at least 18 years of age

Spasmodic Torticollis / Cervical Dystonia

1. Documented diagnosis of spasmodic torticollis or cervical dystonia

Chronic Sialorrhea

1. Documented diagnosis of chronic sialorrhea

AND

2. Inadequate response to or treatment failure of glycopyrrolate OR scopolamine, or documentation of clinical inappropriateness of treatment with anticholinergic medications

AND

3. Member is at least 2 years of age

Upper Limb Spasticity

1. Documented diagnosis of upper limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity

AND

2. For Members 18 years of age or older, documented failure to control spasticity by conventional therapies (e.g., Physical therapy, splinting, bracing, systemic anti-spasticity medication)

Daxxify

The plan may authorize coverage of Daxxify when all the following criteria are met:

Spasmodic Torticollis / Cervical Dystonia

1. Documented diagnosis of spasmodic torticollis or cervical dystonia

AND

2. Documentation the Member has failed treatment with Botox or Xeomin

Dysport

The plan may authorize coverage of Dysport when all the following criteria are met:

Spasmodic Torticollis / Cervical Dystonia

1. Documented diagnosis of spasmodic torticollis or cervical dystonia

AND

2. Documentation the Member has failed treatment with Botox or Xeomin

Spasticity

1. Documented diagnosis of upper or lower limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity

AND

2. For Members 18 years of age or older, documented failure to control spasticity by conventional therapies (e.g., Physical therapy, splinting, bracing, systemic anti-spasticity medication)

AND

3. Documentation the Member has failed treatment with Botox or Xeomin

Myobloc

The plan may authorize coverage of Dysport when all the following criteria are met:

Spasmodic Torticollis / Cervical Dystonia

1. Documented diagnosis of spasmodic torticollis or cervical dystonia

AND

2. Documentation the Member has failed treatment with Botox or Xeomin

Chronic Sialorrhea

1. Documented diagnosis of chronic sialorrhea

AND

2. Inadequate response to or treatment failure of glycopyrrolate OR scopolamine, or documentation of clinical inappropriateness of treatment with anticholinergic medications

AND

3. Member is at least 18 years of age

AND

4. Documentation the Member has failed treatment with Xeomin

Limitations

- The Plan does not provide coverage for cosmetic procedures that involve the use of botulinum toxin injection.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
C9160	Injection, daxibotulinumtoxinA-lanm, 1 unit
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit
J0585	Injection, onabotulinumtoxin A, 1 unit
J0586	Injection, abobotulinumtoxin A, 5 units
J0587	Injection, rimabotulinumtoxin B,100 units
J0588	Injection, incobotulinumtoxin A, 1 unit

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Approval And Revision History

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
- April 19, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)
- 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
- October 10, 2023: Removed the statement 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. Xeomin and Botox are preferred Botulinum Toxin Products. Minor wording updates to make coverage more concise and clearer. Added the following criteria across all Botulinum Toxins products indicated for spasticity “For Members 18 years of age, documented failure to control spasticity by conventional therapies (e.g., Physical therapy, splinting, bracing, systemic anti-spasticity medication).” Removed the Limitation 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 (effective 1/1/2024).
- December 12, 2023: Added Daxxify to the Medical Necessity Guideline (effective 1/1/2024).

- April 1, 2024: Administrative Update: Added J Code J0589 to Medical Necessity Guideline.

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.