Medical Necessity Guidelines

Medical Benefit Drugs

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

Effective: February 1, 2025

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 One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care 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

Botulinum toxins are potent neuromuscular blocking agents that are useful in treating various focal muscle spastic disorders and excessive muscle contractions, such as dystonia's, spasms, and twitches. Although Botulinum toxins have only been Food and Drug Administration (FDA)-approved for limited uses, they are frequently used off-label as well. A patient who is not responsive or who ceases to respond to one botulinum toxin product may respond to another. Coverage criteria for Botox is based on Local Coverage Determination (LCD) Botulinum Toxins (L33646).

Food and Drug Administration--Approved Indications:

Botox (onabotulinumtoxin A) is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for:

- Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication

- 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
- Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer)
- Treatment of spasticity in patients 2 years of age and older
- Treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain
- Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients
- Treatment of blepharospasm associated with dystonia in patients 12 years of age and older
- Treatment of strabismus in patients 12 years of age and older

Daxxify (daxibotulinumtoxinA-lanm) is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the treatment of cervical dystonia in adult patients.

Dysport (abobotulinumtoxin A) is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for:
- The treatment of cervical dystonia in adults
- The treatment of spasticity in patients 2 years of age and older

Myobloc (rimabotulinumtoxin B) is an acetylcholine release inhibitor indicated for:
- Treatment of cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia in adults
- Treatment of chronic sialorrhea in adults

Xeomin (incobotulinumtoxinA) is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the treatment or improvement of:
- Chronic sialorrhea in patients 2 years of age and older
- Upper limb spasticity in adults
- Upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy
- Cervical dystonia in adults
- Blepharospasm in adults

Botox (onabotulinumtoxinA) and Xeomin (incobotulinumtoxinA) are the preferred botulinum toxin products.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Botox, Daxxify, Dysport, Myobloc, or Xeomin for Members when the following criteria are met:

Overactive Bladder with Symptoms of Urge Urinary Incontinence
1. Documented diagnosis of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency

AND

2. Documented inadequate response to or intolerance to **one (1)** anticholinergic medication or the provider has determined that an anticholinergic medication is clinically inappropriate (e.g., oxybutynin, tolterodine, darifenacin)

Urinary incontinence due to detrusor overactivity associated with a neurologic condition
1. Documented diagnosis of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis)

AND

2. Documented inadequate response to or intolerance to **one (1)** anticholinergic medication, or the provider has determined that an anticholinergic medication is clinically inappropriate (e.g., oxybutynin, tolterodine, darifenacin)

Neurogenic detrusor overactivity in pediatric patients
1. Documented diagnosis of neurogenic detrusor overactivity

AND

2. The member is 5 years of age and older

AND

3. Documented inadequate response to or intolerance of an anticholinergic medication (e.g., oxybutynin, tolterodine, darifenacin), or the provider has determined that an anticholinergic medication is clinically inappropriate

Headaches/migraine

1. Documented diagnosis of chronic migraine headaches, defined as headache disorders occurring greater than 15 days a month in many cases daily with a duration of four or more hours for a period of at least three months

AND

2. Documentation of significant disability due to the headaches

AND

3. Documentation the patient is refractory to standard and usual conventional therapy

Spasticity

1. Documented diagnosis of spasticity

AND

2. The member is 2 years of age or older

Cervical dystonia

1. Documented diagnosis of cervical dystonia

AND

2. The member is 18 years of age and older

Severe axillary hyperhidrosis

1. Documented diagnosis of severe axillary hyperhidrosis (primary focal hyperhidrosis) defined by **one (1)** of the following:
   a. Severe sweating, beyond physiological needs
   b. Focal, visible, severe sweating of at least six months duration without apparent cause with at least two of the following characteristics: bilateral and relatively symmetric, significant impairment in daily activities, age of onset less than 25 years, positive family history, and cessation of focal sweating during sleep

AND

2. Documented inadequate response to or intolerance of **one (1)** topical agent or the Provider has determined that topical agents would be clinically inappropriate (e.g., Drysol (20% aluminum chloride hexahydrate)

Blepharospasm

1. Documented diagnosis of blepharospasm and/or hemifacial spasm

Strabismus

1. Documented diagnosis of strabismus

AND

2. The member is 12 years of age or older

Achalasia

1. Documented diagnosis of esophageal achalasia

AND

2. The member is 18 years of age or older

AND

3. Documentation of **one (1)** of the following:
   a. Patient has not responded satisfactorily to conventional therapy
   b. Patient is at high risk of complication from pneumatic dilation or surgical myotomy
   c. Treatment failure with pneumatic dilation or surgical myotomy
   d. Perforation from pneumatic dilation
   e. An epiphrenic diverticulum or hiatal hernia
   f. Esophageal varices

Chronic anal fissure

1. Documented diagnosis of chronic anal fissure(s)

AND

2. Documented inadequate response to or intolerance of conservative or pharmacologic treatments, or the Provider has determined that conservative or pharmacologic treatments are clinically inappropriate (e.g., topical calcium channel blockers, nitrates)

Essential hand tremor

1. Documented diagnosis of a high amplitude essential hand tremor

AND

2. Documentation the tremor disrupts activities of daily living

AND

3. Documented inadequate response or intolerance to **one (1)** oral agent, or the provider has determined that oral agents are clinically inappropriate (e.g., propranolol, primidone)

Focal limb dystonia

1. Documented diagnosis of **one (1)** of the following:
    a. Focal hand dystonia (also known as "writer's cramp")
    b. Other occupational hand dystonia
    c. Non-task-specific hand dystonia

Isolated oromandibular dystonia

1. Documented diagnosis of oromandibular dystonia

AND

2. The member is 18 years of age or older

Laryngeal dystonia (spastic dysphonia) for adductor type (ADSD)

1. Documented diagnosis of Laryngeal dystonia (spasmodic dysphonia) for adductor type (ADSD)

Bothersome simple motor tics

1. Documented diagnosis of localized and bothersome simple motor tics

AND

2. The member is 12 years of age or older

Severely disabling or aggressive vocal tics

1. Documentation of **one (1)** of the following:
    a. The requested medications is being prescribed for the treatment of severely disabling or aggressive vocal tics
    b. The requested medication is being prescribed for the treatment of Gilles de la Tourette's syndrome

AND

2. The member is 18 years of age or older

Sialorrhea

1. Documented diagnosis of sialorrhea due to conditions such as motor neuron disease or Parkinson's disease

AND

2. Documented inadequate response to traditional therapies (e.g., anticholinergic, speech therapy) or contraindication to or intolerance to anticholinergic therapy

Limitations

- The plan does not provide coverage for cosmetic procedures or localization procedures that involve the use of botulinum toxin injection.
- Refer to the Medicare Part B Step Therapy Medical Necessity Guideline for additional requirements.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0589	Injection, daxibotulinumtoxinA-lanm, 1 unit
J0585	Injection, onabotulinumtoxinA, 1 unit
J0586	Injection, abobotulinumtoxinA, 5 units
J0587	Injection, rimabotulinumtoxinB, 100 units
J0588	Injection, incobotulinumtoxinA, 1 unit

References

1. Botox [package insert]. Irvine, CA: Allergan, Inc.; February 2021.
2. Daxxify [package insert]. Newark, CA: Revance Therapeutics Inc.; August 2023.
3. Dysport [package insert]. Wrexham, UK: Ipsen Biopharm, Ltd.; July 2020.

4. Myobloc [package insert]. Rockville, MD: Supernus Pharmaceuticals, Inc.; March 2021.
5. Xeomin [package insert]. Irvine, CA: Allergan, Inc.; April 2021.
6. Centers of Medicare and Medicaid Services (CMS). LCD - Botulinum Toxins (L33646). Cms.Gov, 2021, https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33646. Accessed October 2024.
7. Centers of Medicare and Medicaid Services (CMS). LCD - Botulinum Toxins (L38809). Cms.Gov, 2021, https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38809&ver=6. Accessed October 2024.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- September 12, 2023: Removed the following Limitations The health plan may authorize coverage of Botox up to 12 months if coverage criteria are met, All other indications are considered experimental/investigational and not medically necessary, The health plan does not cover Botox for hyperhidrosis, and The health plan does not cover Botox for prophylaxis of episodic migraine. Updated the Limitations regarding cosmetic and localization procedures to “The plan does not provide coverage for cosmetic procedures and localization procedures that involve the use of botulinum toxin injection.” Minor wording updates to clarify coverage. Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024 (effective 1/1/2024).
- December 12, 2023: To be in line with L38809: Added coverage criteria for Sialorrhea, expanded age requirements to at least 5 years of age for Overactive Bladder with Symptoms of Urge, removed prerequisites for hemifacial spasm, removed the requirement that blepharospasm is required to be associated with dystonia. Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule (eff 1/1/24).
- November 12, 2024: Created a therapeutic class Botulinum Toxin Medical Necessity Guideline by using the Botox Medical Necessity Guideline. Coverage has been updated to be in line with the CMS LCDs L33646 and L38809, in addition to FDA-approved indications which is now applied consistently across all botulinum toxin products (eff 2/1/25).
- December 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 2/1/25).

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

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.