Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Botox® (onabotulinumtoxin A)

Effective: January 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 617-673-0988
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0988
☒ 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

Botulinum toxin injections are used to treat various focal muscle spastic disorders and excessive muscle contractions such as dystonia, spasms, twitches, etc. These drugs produce a presynaptic neuromuscular blockade by preventing the release of acetylcholine from the nerve endings. The resulting chemical denervation of muscle produces local paresis or paralysis and allows individual muscles to be weakened selectively. Botulinum toxins have the advantage of being potent neuromuscular blocking agents with good selectivity and duration of action.

Food and Drug Administration (FDA) Approved Indications (Non-Cosmetic):

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

Off-Label Covered Uses

Botox® (onabotulinumtoxin A) may be considered medically reasonable and necessary in patients for the following conditions:

- Esophageal achalasia in adults
- Chronic anal fissure
- Essential hand tremor
- Focal limb dystonia
- Hemifacial spasm in adults
- Isolated oromandibular dystonia
- Laryngeal dystonia (spastic dysphonia) for adductor type (ADSD)
- Bothersome simple motor tics in adolescents and adults
- Severely disabling or aggressive vocal tics in older adolescents and adults

LOCAL COVERAGE POLICY (LCD)

Covered Indication(s):

- Spasticity
- Blepharospasm
- Achalasia
- Anal Fissure
- Hyperhidrosis
- Sialorrhea
- Urinary Incontinence
- Headache/Migraine

Limitations:

- Medicare will allow payment for one injection per site regardless of the number of injections made into the site. A site is defined as one eye (including all muscles surrounding the eye including both upper and lower lids); one side of the face; or all muscles of one limb and their associated girdle muscles.
- Treatment of wrinkles using Botulinum toxins is considered to be cosmetic and is not covered under Medicare.
- Payment will not be made for any spastic condition of smooth muscle, such as spastic colon and biliary dyskinesia.

Clinical Guideline Coverage Criteria

The Plan may authorize coverage of Botox® (onabotulinumtoxin A) when the following criteria are met:

Overactive Bladder with Symptoms of Urge Urinary Incontinence

1. The Member has a documented diagnosis of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency

AND

2. The Member is 18 years of age or older

AND

3. The Member has experienced an 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

Urinary incontinence due to detrusor overactivity associated with a neurologic condition

1. The Member has a documented diagnosis of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)]

AND

2. The Member is 18 years of age or older

AND

3. The Member has experienced an 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

Neurogenic detrusor overactivity (NDO) in pediatric patients

1. The Member has a documented diagnosis of neurogenic detrusor overactivity (NDO)

AND

2. The Member is 5 years of age and older

AND

3. The Member has experienced an 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

Prophylaxis of headaches in adult patients with chronic migraine

1. The Member has a documented diagnosis of chronic migraine headaches, defined as headaches occurring on at least 15 or more days per month and lasting at least 4 hours a day or longer

AND

2. Botox® (onabotulinumtoxin A) is being prescribed as preventive therapy

AND

3. The Member is 18 years of age or older

Spasticity in patients 2 years of age and older

1. The Member requires treatment for spasticity and is 2 years of age or older

Cervical dystonia in adults

1. The Member has a documented diagnosis of cervical dystonia

AND

2. The Member is 18 years of age and older

AND

3. Botox® (onabotulinumtoxin A) is being prescribed to reduce the severity of abnormal head position and neck pain

Severe axillary hyperhidrosis

1. The Member has a documented diagnosis of severe axillary hyperhidrosis

AND

2. The Member is 18 years of age and older

AND

3. The Member has experienced an inadequate response to or intolerance of topical agents (e.g. Drysol (20% aluminum chloride hexahydrate) or the Provider has determined that topical agents would be clinically inappropriate.

Blepharospasm associated with dystonia

1. The Member has a documented diagnosis of blepharospasm associated with dystonia and is at least 12 years of age or older.

Strabismus in patients 12 years of age and older

1. The Member has a documented diagnosis of strabismus and is at least 12 years of age or older.

Esophageal achalasia in adults

1. The Member has a documented diagnosis of Esophageal achalasia

AND

2. The Member is 18 years of age or older

AND

3. The Member is considered a poor candidate for surgical intervention

Chronic anal fissure

1. The Member has a documented diagnosis of Chronic anal fissure(s)

AND

2. The Member has had an inadequate response to or intolerance of conservative or pharmacologic treatments, including, but not limited to topical calcium channel blockers or nitrates, or the Provider has determined that other conservative or pharmacologic treatments are clinically inappropriate.

Essential hand tremor

1. The Member has high amplitude essential hand tremor that disrupts activities of daily living (ADL)

AND

2. The Member has had an inadequate response to or intolerance of at least one oral agent including, but not limited to propranolol or primidone, or the Provider has determined that oral therapy is clinically inappropriate

Focal limb dystonia

1. The Member has a 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.

Hemifacial spasm in adults

1. The Member has a documented diagnosis of hemifacial spasm

AND

2. The Member is 18 years of age or older

AND

3. The Member has had an inadequate response to or intolerance of at least one oral agent which may include one of the following: carbamazepine, baclofen, or a benzodiazepine (e.g., clonazepam), or the Provider has determined that these oral treatments are clinically inappropriate.

Isolated oromandibular dystonia

1. The Member has a documented diagnosis of oromandibular dystonia (OMD)

AND

2. The Member is 18 years of age or older

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

1. The Member has a documented diagnosis of Laryngeal dystonia (spasmodic dysphonia) for adductor type (ADSD)

Bothersome simple motor tics in adolescents and adults

1. The Member has a 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 in older adolescents and adults

1. Botox® (onabotulinumtoxin A) is being prescribed for the treatment of older adolescents and adults with severely disabling or aggressive vocal tics

OR

2. Botox® (onabotulinumtoxin A) is being prescribed for the treatment of Gilles de la Tourette's syndrome

AND

3. The Member is 18 years of age or older

Note: Refer to Center for Medicare and Medicaid National Coverage Determination (NCD) for Botulinum Toxins (L38809) at https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38809&ver=6.

Limitations

- The health plan may authorize coverage of Botox up to 12 months if coverage criteria are met
- The health plan does not cover Botox for localization procedures
- The health plan does not cover Botox for cosmetic procedures, such as treatment of wrinkles (e.g., glabellar lines, smoker's lines, crow's feet, laugh lines and aging neck).
- The health plan does not cover Botox for prophylaxis of episodic migraine, defined as less than or equal to 14 headache days per month
- The health plan does not cover Botox for hyperhidrosis in body areas other than axillary
- All other indications are considered experimental/investigational and not medically necessary.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0585	Injection, onabotulinumtoxinA, 1 unit

References:

1. Botox [package insert]. Irvine, CA: Allergan, Inc.; February 2021.
2. 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.
3. United States Food and Drug Administration. Package Insert-BOTOX. https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103000s5232lbl.pdf

Approval And Revision History

- September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)
- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

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.