CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines:
Medical Benefit Drugs
# Botox® (onabotulinumtoxin A)

*Effective: January 1, 2024*

| **Prior Authorization Required**<br>If REQUIRED, submit supporting clinical documentation pertinent to service request. | Yes ☒ No ☐ |
|---|---|

**Applies to:**

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, 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 dystonias, 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

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

## Clinical Guideline Coverage Criteria

The plan may authorize coverage of Botox 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. The member is 5 years of age or older

**AND**

3. 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. The member is 18 years of age or older

**AND**

3. 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

**Prophylaxis of headaches in adult patients with chronic migraine**

1. 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. Documentation the requested medication is being prescribed as preventive therapy

**AND**

3. The member is 18 years of age or older

**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

**AND**

3. Documentation the requested medication is being prescribed to reduce the severity of abnormal head position and neck pain

**Severe axillary hyperhidrosis**

1. Documented diagnosis of severe axillary hyperhidrosis

**AND**

2. The member is 18 years of age and older

**AND**

3. 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**

2. The member is 12 years of age or older

**Strabismus in patients 12 years of age and older**

1. Documented diagnosis of strabismus

**AND**

2. The member is 12 years of age or older

**Esophageal achalasia in adults**

1. Documented diagnosis of esophageal achalasia

**AND**

2. The member is 18 years of age or older

**AND**

3. Documentation the member is considered a poor candidate for surgical intervention

**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**

2. 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

**Hemifacial spasm in adults**
1. Documented diagnosis of hemifacial spasm

**AND**

2. The member is 18 years of age or older

**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:
    1. The requested medications is being prescribed for the treatment of severely disabling or aggressive vocal tics
    2. 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**

Documented inadequate response to traditional therapies (e.g., anticholinergic, speech therapy

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## Limitations

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

## 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 (L33646). Cms.Gov, 2021, https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33646. Accessed Dec 2023
3. 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 Dec 2023.


## 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. (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).

## 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.