CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines:
Xeomin® (incobotulinumtoxinA)

Effective: January 1, 2024

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

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 Xeomin (incobotulinumtoxinA) is based on Local Coverage Determination (LCD) Botulinum Toxins (L33646).

Food and Drug Administration-Approved Indications:
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 Xeomin for Members when the following criteria are met:

Sialorrhea

1. Documented diagnosis of chronic sialorrhea

AND

2. The member is 2 years of age or older

AND

3. Documented inadequate response to or intolerance of a traditional therapy (e.g., anticholinergics and speech therapy), or did not tolerate anticholinergic therapy, or the Provider has determined that anticholinergic therapy is clinically inappropriate

AND

Upper limb spasticity in adults

1. Documented diagnosis of upper limb spasticity

AND

2. The member is 18 years of age or older

Upper limb spasticity in pediatric patients 2 to 17 years of age

1. Documented diagnosis of upper limb spasticity, excluding spasticity caused by cerebral palsy

AND

2. The member is between the age of 2 and 17 years of age

Cervical dystonia in adults

1. Documented diagnosis of cervical dystonia

AND

2. The member is 18 years of age or older

AND

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

Blepharospasm

1. Documented diagnosis of blepharospasm

AND

2. The member is 12 years of age or older

Hemifacial spasm

1. Documented diagnosis of hemifacial spasm

AND

2. The member is 18 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)

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)

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)

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

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. 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
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. Accessed Dec 2023.
3. Xeomin (onabotulinumtoxin A). [package insert]. Irvine, CA: Allergan, Inc.; April 2021.

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 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- September 12, 2023: Removed coverage criteria for chronic anal fissure, hyperhidrosis, urinary incontinence, and headache/migraine. Removed the Limitations The Plan may cover Xeomin for up to 12 months duration if clinical criteria are met and All other indications are considered experimental/investigational and not medically necessary. 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: Removed the requirement that blepharospasm is required to be associated with dystonia, added coverage criteria for Hemifacial spasm, esophageal achalasia in adults, chronic anal fissure, severe axillary hyperhidrosis, overactive bladder with symptoms of urge incontinence, urinary incontinence due to detrusor overactivity associated with a neurologic condition, and prophylaxis of headaches in adult patients with chronic migraine. 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.

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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.