CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines
Medical Benefit Drugs

Daxxify® (daxibotulinumtoxinA-lanm)

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 Daxxify is based on Local Coverage Determination (LCD) Botulinum Toxins (L33646), and also includes Part B Step Therapy Policy requirements.

Food and Drug Administration-Approved Indications

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

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

Clinical Guideline Coverage Criteria

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

Cervical dystonia

1. Documented diagnosis of cervical dystonia

AND

2. The member is 18 years of age and older

Spasticity

1. Documented diagnosis of spasticity

AND

2. The member is 2 years of age or older

Sialorrhea

1. Documented diagnosis of sialorrhea

AND

2. The member is 18 years of age and 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

Blepharospasm

1. Documented diagnosis of blepharospasm

AND

2. The member is 12 years of age and older

Hemifacial spasm

1. Documented diagnosis of hemifacial spasm

AND

2. 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.
- 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
C9160	Injection, daxibotulinumtoxinA-lanm, 1 unit
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit

References

1. Daxxify [package insert]. Newark, CA: Revance Therapeutics Inc.; August 2023.
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..

Approval And Revision History

December 12, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

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

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.