

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 10, 2020 October 7, 2020, January 15, 2021, September 8, 2021, May 2, 2023, January 24, 2024

BOTULINUM TOXINS

Clinical PA required (Preferred Agent): Botox® and Dysport®

Clinical PA required (Non-preferred agents): Myobloc® and Xeomin®

LENGTH OF AUTHORIZATION: SIX MONTHS

REVIEW CRITERIA:

Dysport® (abobotulinumtoxinA):

Cervical Dystonia

- Patient is 18 years or older.
- Patient has a diagnosis of cervical dystonia.

Spasticity

- Patient is 2 years of age or older.
- Patient has a diagnosis of spasticity.

Botox® (onabotulinumtoxinA):

Blepharospasm and Strabismus

- Patient is 12 years of age or older.
- Diagnosis of blepharospasm or strabismus associated with dystonia.

Cervical Dystonia:

- Patient is 18 years of age or older.
- Patient has diagnosis of cervical dystonia, to reduce the severity of abnormal head position and neck pain.

Upper limb spasticity:

- Patient is 2 years of age or older.
- Patient has diagnosis of upper limb spasticity.

Lower limb spasticity:

- Patient is 2 years of age or older.
- Patient has a diagnosis of lower limb spasticity.

Neurogenic Detrusor Overactivity (NDO)

- Patient is 5 years of age or older.
- Patient has a diagnosis of NDO.
- Trial and failure of an anticholinergic medication is required.

Primary Axillary Hyperhidrosis:

- Patient is 18 years of age or older.
- Patient has a diagnosis of severe axillary hyperhidrosis.
- Documentation submitted of at least a six month trial and failure of topical agents **OR**

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- Trial and failure of an anticholinergic agent.

Prophylaxis of Headaches with chronic migraines

- Patient is 18 years of age or older.
- Patient has been seen by a neurologist or in consultation with a neurologist.
- Documentation submitted of 15 or more days a month of headaches lasting 4 or more hours.
- Trial and failure of at least two different migraine prophylaxis medications (e.g. calcium channel blockers, beta blockers, anticonvulsants, or tricyclic antidepressants).

Overactive Bladder

- Patient is 18 years of age or older.
- Symptoms include urge urinary incontinence, urgency, and frequency.
- Trial and failure of an anticholinergic medication is required.

Detrusor Overactivity associated with a Neurologic Condition

- Patient is 18 years of age or older.
- Patient has the diagnosis of urinary incontinence due to detrusor over activity associated with a neurologic condition (e.g. spinal cord injury, multiple sclerosis).
- Trial and failure of an anticholinergic medication is required.

Myobloc® (rimabotulinumtoxinB):

Cervical Dystonia

- Patient is 18 years of age or older.
- Patient has the diagnosis of cervical dystonia.
- Trial and failure of preferred agent required.

Chronic Sialorrhea

- Patient is 18 years of age or older
- Patient has a diagnosis of chronic sialorrhea
- Trial and failure to anticholinergic medication is required.

Xeomin® (incobotulinumtoxinA)

Blepharospasm

- Patient is 18 years of age or older
- Diagnosis of blepharospasm

Cervical Dystonia

- Patient is 18 years of age or older
- Patient has the diagnosis of cervical dystonia
- Trial and failure of preferred agent required.

Chronic Sialorrhea

- Patient is 2 years of age or older

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- Patient has a diagnosis of chronic sialorrhea
- Trial and failure of an anticholinergic medication is required.

Upper limb spasticity

- Patient is 2 years of age or older
- Patient has the diagnosis of upper limb spasticity
 - Excluding spasticity caused by cerebral palsy for patients 2 to 17 years of age
- Trial and failure of preferred agent is required.

CONTINUATION OF THERAPY:

- Patient has met initial review criteria.
- A clinical response is documented with therapy.
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>