# Botulinum Toxins

**Generic Name:** onabotulinumtoxinA, abobotulinumtoxinA, incobotulinumtoxinA

**Therapeutic Class or Brand Name:** Botox®, Dysport®, Xeomin®

**Applicable Drugs (if Therapeutic Class):** N/A

**Preferred:** Xeomin® for approved indications.

**Non-preferred:** Botox®, Dysport®

**Date of Origin:** 3/30/2019

**Date Last Reviewed / Revised:** 2/13/2023

## PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documentation of one of the following diagnoses A through I AND must meet all criteria listed under applicable diagnosis:

A. Neurogenic detrusor overactivity (NDO)

1. History of treatment failure, intolerance, or contraindication to 2 or more anticholinergic therapies (such as oxybutynin, trospium, tolterodine, or solifenacin).
2. Minimum age requirement: 5 years old.

B. Overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency

1. History of treatment failure, intolerance, or contraindication to 2 or more anticholinergic therapies (such as oxybutynin, trospium, tolterodine, or solifenacin).
2. Minimum age requirement: 18 years old.

C. Blepharospasm and strabismus associated with dystonia, benign essential blepharospasm or VII nerve disorders

1. Minimum age requirement: 12 years old.

D. Cervical dystonia/spasmodic torticollis

1. Diagnosis is documented and is neurologically based.
2. Documentation of involuntary contractions of head and neck.
3. Minimum age requirement: 18 years old.

E. Severe axillary hyperhidrosis

1. Documentation of severe, persistent axillary hyperhidrosis resulting in medical complication.
2. Secondary causes such as hyperthyroidism has been ruled out.
3. Inadequate response or treatment failure of aluminum chloride (hexahydrate) 20% (Drysol®)
4. Minimum age requirement: 18 years old.

F. Chronic Migraine

1. Documentation of ≥15 headache days per month with headache lasting 4 hours a day or longer.
2. Documentation that evaluation has been performed demonstrating patient does not suffer from rebound headaches due to medication overuse (medication overuse headache, or MOH).
3. Documented treatment failure with two or more guideline recommended migraine prophylaxis medications, at optimized dosing, for a duration of at least 8 weeks. The medications tried must be from at least two of the following drug categories, or the member must have contraindication to all drug categories:
    a) Anticonvulsant: topiramate, divalproex sodium
    b) Beta-blocker: propranolol, metoprolol, atenolol
    c) Antidepressant: amitriptyline, nortriptyline, duloxetine, venlafaxine
    d) ACE Inhibitor or angiotensin receptor blocker: lisinopril, candesartan
4. Treatment is prescribed by or in consultation with a neurologist or headache specialist.
5. Injections are limited to every 12 weeks.
6. Minimum age requirement: 18 years old.

G. Lower limb spasticity

1. Documented diagnosis of lower limb spasticity with increased muscle tone in ankle and toes.
2. Documented failure to control spasticity by conventional therapies (e.g. physical therapy, splinting, bracing, systemic anti-spasticity medication)
3. Injections are limited to every 12 weeks.

H. Upper limb spasticity

1. Documented failure to control spasticity by conventional therapies (e.g. physical therapy, splinting, bracing, systemic antispasticity medication).
2. Injections are limited to every 12 weeks.
3. For patients 2 to 17 years of age, documentation that spasticity is not caused by cerebral palsy (Xeomin only)

I. Chronic sialorrhea

1. Documented treatment failure with one or contraindication to all the following: glycopyrrolate, scopolamine, or benztropine.
2. Injections are limited to every 16 weeks.

II. Documentation that the dystonia/movement disorder contributes to significant functional impairment and/or pain and other more conservative/less intensive levels/alternative treatments have been tried and failed.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines. Refer to Table 1 for FDA approved indications.

IV. Refer to Table 1 for the list of preferred products by indication. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to preferred product(s).

## EXCLUSION CRITERIA

- Co-administration of products Botox®, Dysport®, Xeomin®

## OTHER CRITERIA

Table 1. Xeomin® is the preferred product for certain indications.

| Indication | Botox | Xeomin | Dysport |
|---|---|---|---|
| Overactive Bladder | ≥18 years old | | |
| Neurogenic detrusor Overactivity | ≥5 years old | | |
| Chronic Migraine | ≥18 years old | | |
| Spasticity | ≥2 years old | | ≥2 years old |
| Cervical Dystonia | ≥16 years old | ≥18 years old (Preferred) | ≥18 years old |
| Severe Axillary Hyperhidrosis | ≥18 years old | | |
| Blepharospasm | ≥12 years old | ≥18 years old (Preferred) | |
| Strabismus | ≥12 years old | | |
| Chronic Sialorrhea | | ≥2 years old (Preferred) | |
| Upper Limb Spasticity | ≥2 years old | ≥2 years old (Preferred) | |
| Lower Limb Spasticity | ≥2 years old | | |

## QUANTITY / DAYS SUPPLY RESTRICTIONS

- Botulinum toxin products are all produced using different methods. Dosing and potencies are not interchangeable.

## APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** up to 12 months

- Chronic migraine: an updated letter of medical necessity or progress notes showing sustained clinical benefits from the drug treatment, including at least a 50% improvement in functional impairment and headache severity (as measured by a reduction in the need for abortive therapies, acute care, monthly headache days, missed days at work or school, or an increased ability to perform activities of daily living).
- All other diagnoses: An updated letter of medical necessity or progress notes showing that current medical necessity criteria are met and that the medication is effective.

## APPENDIX

N/A

## REFERENCES

1. Botox. Prescribing information. Allergan; 2022. Accessed February 13, 2023. http://www.allergan.com/assets/pdf/botox_pi.pdf
2. Dysport. Prescribing information. Ipsen Biopharmaceuticals Inc; 2020. Accessed February 13, 2023. https://www.galderma.com/us/sites/g/files/jcdfhc341/files/2020-11/1066038%20Dysport%20PI.pdf
3. Xeomin. Prescribing information. Merz Pharmaceuticals LLC; 2022. Accessed February 13, 2023 https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3f35d6e0-3450-4abc-a0da-cc7b277e7c6e
4. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1-211. doi:10.1177/0333102417738202
5. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016;86(19):1818-1826. doi:10.1212/WNL.0000000000002560