

Generic Name: onabotulinumtoxinA, abobotulinumtoxinA, incobotulinumtoxinA

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

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 7440002005, 7440002003, 7440002020

Preferred: Xeomin® for approved indications.

Non-preferred: Botox®, Dysport®

Date of Origin: 3/30/2019

Date Last Reviewed / Revised: 2/8/2021

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I and II are met)

- I. Documented diagnosis of one of the following conditions A through H AND must meet criteria listed under applicable diagnosis:
 - A. Urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) or overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency and criteria 1 and 2 are met:
 1. History of treatment failure, intolerance, or contraindication to anticholinergic therapies.
 2. Minimum age requirement: 18 years old.
 - B. Blepharospasm and strabismus associated with dystonia, benign essential blepharospasm or nerve disorders of VII nerve and following criterion is met:
 1. Minimum age requirement: 12 years old.
 - C. Cervical dystonia/spasmodic torticollis and the following criteria are met:
 1. Diagnosis is documented and is neurologically based.
 2. Documentation of involuntary contractions of head and neck.
 3. Minimum age requirement: 18 years old.
 - D. Severe axillary hyperhidrosis
 1. Documentation of severe, persistent axillary hyperhidrosis resulting in medical complication.
 2. Secondary cause 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.
 - E. Chronic Migraine and the following criteria are met:
 1. Documentation of ≥15 headache days per month with headache lasting 4 hours a day or longer.

2. An evaluation has been performed to assess for rebound headaches caused by medication use [medication overuse headache (MOH)].
 3. Documentation of treatment failure, intolerance, or contraindication to medications from all 3 of the following drug categories A through C for prevention of chronic migraine headaches for at least three months:
 - a) Beta blockers (such as, propranolol)
 - b) Anticonvulsants (such as Divalproex Sodium or Topiramate)
 - c) Antidepressants (such as Venlafaxine or Amitriptyline)
 4. Diagnosis made by headache specialist or neurologist and treatment is ordered by or in consultation with a neurologist.
 5. Not used concurrently with a calcitonin gene-related peptide (CGRP) receptor antagonist.
 6. Injections are limited to every 12 weeks.
 7. Minimum age requirement: 18 years old.
- F. Lower limb spasticity and the following criteria are met:
1. Documented diagnosis of lower limb spasticity 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.
- G. Upper limb spasticity and the following criterion is met:
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)
- H. Chronic sialorrhea and the following criteria are met:
1. Injections are limited to every 16 weeks.
- II. Documentation that presence of a dystonia/movement disorder contributes to a significant functional impairment and/or pain and other more conservative/less intensive levels/alternative treatments have been tried and failed.

EXCLUSION CRITERIA

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

OTHER CRITERIA

Xeomin® is preferred product for certain indications:

Indication	Botox	Xeomin	Dysport
Overactive Bladder/Detrusor Overactivity	x		
Chronic Migraine	x		
Spasticity	x		
Cervical Dystonia	≥16 years old	x (Preferred)	x
Severe Axillary Hyperhidrosis	x		
Blepharospasm	≥12 years old	x (Preferred)	
Strabismus	≥12 years old		
Chronic Sialorrhea		≥2 years old (Preferred)	
Upper Limb Spasticity	≥2 years old	≥2 years old (Preferred)	≥2 years old
Lower Limb Spasticity	≥2 years old		≥2 years old

QUANTITY / DAYS SUPPLY RESTRICTIONS

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

APPROVAL LENGTH

- **Authorization:** 3 months
- **Re-Authorization:** up to 12 months

APPENDIX

N/A

REFERENCES

1. Medispan.
2. Botox (onabotulinumtoxinA) [prescribing information]. Madison, NJ: Allergan USA, Inc; September 2020. https://www.allergan.com/assets/pdf/botox_pi.pdf. Accessed January 27, 2021.
3. Dysport (abobotulinumtoxinA) [prescribing information]. Basking Ridge, NJ: Ipsen Biopharmaceuticals Inc; July 2020. https://www.ipsen.com/websites/Ipsen_Online/wp-content/uploads/2020/07/10002305/DYS-US-004998_Dysport-PI-July-2020.pdf. Accessed January 27, 2021.

4. Xeomin (incobotulinumtoxinA) [prescribing information] Raleigh, NC: Merz Pharmaceuticals LLC; December 2020.
<https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=ccdc3aae-6e2d-4cd0-a51c-8375bfee9458&type=display>. Accessed January 27, 2021.
5. Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd edition. Cephalalgia. 2018;38:1-211. Available at <https://ichd-3.org/>. Accessed January 27, 2021.
6. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Neurology 2016; 86 (19): 1818-26. Available at <https://www.aan.com/Guidelines/home/GuidelineDetail/735>. Accessed January 27, 2021.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.