

Applicable Drugs: Botox (onabotulinumtoxinA), Daxxify (daxibotulinumtoxinA), Dysport (abobotulinumtoxinA), Myobloc (rimabotulinumtoxinB), Xeomin (incobotulinumtoxinA)

Preferred: Xeomin (incobotulinumtoxinA), Dysport (abobotulinumtoxinA) for approved indications.

Non-preferred:

Date of Origin: 3/30/2019

Date Last Reviewed / Revised: 6/25/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III 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 (e.g., oxybutynin, trospium, tolterodine, or solifenacin) for a minimum of 12 weeks.
 - 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 (e.g., oxybutynin, trospium, tolterodine, or solifenacin) for a minimum of 12 weeks.
 - C. Blepharospasm and strabismus associated with dystonia, benign essential blepharospasm or VII nerve disorders
 - D. Cervical dystonia/spasmodic torticollis
 1. Diagnosis is documented and is neurologically based.
 2. Documentation of involuntary contractions of head and neck.
 - E. Severe axillary hyperhidrosis
 1. Documentation of severe, persistent axillary hyperhidrosis resulting in medical complication.
 2. Secondary causes such as hyperthyroidism have been ruled out.
 3. Inadequate response or treatment failure of aluminum chloride (hexahydrate) 20% (Drysol®).
 - 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 the patient does not suffer from rebound headaches due to medication overuse headache.
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 a 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.

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. 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.
- III. 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 different botulinum toxin products for the same indication.

OTHER CRITERIA

Table 1. Botulinum Toxin Recommended Dosing, Quantity, and Days Supply Limits By Indication and Preferred Products

Drug (Dosage Forms and Strengths)	Recommended Dosing by Indication and Age	Quantity Limit/Days Supply Per Indication
Botox (100 unit, 200 unit SDV)	OAB (≥18 years old): • 100 units up to every 12 weeks	100 units/84 days
	NDO (≥ 5 years old): • < 34kg: 6 units/kg up to every 12 weeks • ≥ 34kg: 200 units up to every 12 weeks	200 units/84 days
	Chronic Migraine (≥18 years old): • 155 units up to every 12 weeks	200 units/84 days
	Upper Limb Spasticity • ≥18 years old: 75-400 units up to every 12 weeks • 2 to 17 years old: ○ Upper limb: 3-6 units/kg (200 units max) up to every 12 weeks ○ Upper and lower limbs in combination: 10 units/kg (340 units max) in a single treatment up to every 12 weeks	≥18 years old: 400 units/84 days 2 to 17 years: • 200 units/84 days (upper limb) • 400 units/84 days (upper and lower limbs in combination)
	Lower Limb Spasticity ○ ≥18 years old: 300-400 units up to every 12 weeks ○ 2 to 17 years: ▪ Lower limb: 4-8 units/kg (300 units max) up to every 12 weeks ▪ Both lower limbs or the upper and lower limbs in combination: 10 units/kg (340 units max) in a single treatment up to every 12 weeks	≥18 years old: 400 units/84 days 2 to 17 years: • 300 units/84 days (lower limb) • 400 units/84 days (both lower limbs or upper and lower limbs in combination)
	Cervical Dystonia (≥18 years old): • 100 - 400 units up to every 12 weeks	400 units/84 days
	Severe axillary hyperhidrosis (≥18 years old): • 50 units per axilla up to every 12 weeks	100 units/84 days
	Blepharospasm (≥12 years old): • initial dose 1.25-2.5 units into each of 3 sites per affected eye	200 units/84 days

	Repeat dosing: Initial dose may be increased up to two-fold if initial response does not last longer than 2 months up to every 12 weeks (cumulative dose not to exceed 200 units in 30 days)	
	Strabismus (≥12 years old): - Initial dose: - Vertical muscles and horizontal strabismus < 20 prism diopters: 1.25-2.5 units in any one muscle - Horizontal strabismus of 20-50 prism diopters: 2.5-5 units in any one muscle - Persistent VI nerve palsy (duration ≥ 1 month): 1.25-2.5 units in the medius rectus muscle - Subsequent doses for residual or recurrent strabismus - Adequate paralysis of target muscle with initial dosing: Repeat initial dose up to every 12 weeks - Incomplete paralysis of target muscle with initial dosing: Increase up to twice previously administered dose (max 25 units in any one muscle) up to every 12 weeks	100 units/84 days
Daxxify (50 unit, 100 unit SDV)	Cervical Dystonia (≥18 years old): 125 – 250 units up to every 12 weeks	250 units/84 days
Dysport (preferred) (300 unit, 500 unit SDV)	Cervical dystonia (≥18 years old) - Initial dose: 500 units - Subsequent dose: 250 units to 1000 units (max) up to every 12 weeks	1000 units/84 days
	Upper Limb Spasticity ≥18 years old: - Upper limb: 500 -1000 units up to every 12 weeks - Upper and lower limb in combination: 1500 units (total dose max) up to every 12 weeks 2 -17 years old (minimum weight of 10kg: - Upper limb: 8 – 16 units/kg (640 units max) up to every 16 weeks - Upper and lower limbs in combination: 30 units/kg (1000 units max in a single treatment) up to every 12 weeks	≥18 years old: - Upper limb: 1000 units/84 days - Upper and lower limbs in combination: 1500 units/84 days 2 to 17 years: - Upper limb: 800 units/112 days - Upper and lower limbs in combination: 1000 units/ 84 days
	Lower Limb Spasticity ≥18 years old:	≥18 years old:

	- Lower limb: 1000 - 1500 units up to every 12 weeks - Upper and lower limb in combination: 1500 units (total dose max) up to every 12 weeks 2 -17 years old (minimum weight of 10kg): - Lower limb: - Unilateral limb: 10-15 units/kg (1000 units max) up to every 12 weeks - Bilateral limbs: 20 -30 unit/kg (1000 units max) up to every 12 weeks - Upper and lower limbs in combination: 30 units/kg (1000 units max in a single treatment) up to every 12 weeks	- Lower limb: 1500 units/84 days - Upper and lower limbs in combination: 1500 units/84 days 2 to 17 years: - Unilateral or bilateral lower limbs: 1000 units/84 days - Upper and lower limbs in combination: 1000 units/ 84 days
Myobloc (2500 units/0.5 mL, 5000 units/mL, 10,000 units/2 mL SDV)	Cervical Dystonia (≥18 years old): 2500 – 5000 units (10,000 units max) up to every 12 weeks	10,000 units/84 days
	Chronic Sialorrhea (≥18 years old): 1500 – 3500 units (500 units – 1,500 units per parotid gland and 250 units per submandibular gland) up to every 12 weeks	5000 units/84 days
Xeomin (preferred) (50 unit, 100 unit, 200 unit SDV)	Cervical dystonia (≥18 years old): Initial recommended dose: 120 units. Clinical trial dosing 120 – 240 units up to every 12 weeks	250 units/84 days
	Blepharospasm (≥18 years old): - Treatment-naïve: 50 units (25 units per eye) - Subsequent dose: 100 units max per treatment session (50 units per eye) up to every 12 weeks	100 units/84 days
	Chronic Sialorrhea ≥18 years old: 100 units up to every 16 weeks 2 -17 years old: up to every 16 weeks 12 to < 15 kg: 20 units 15 to < 19 kg: 30 units 19 to < 23 kg: 40 units 23 to < 27 kg: 50 units 27 to < 30 kg: 60 units ≥ 30 kg: 75 units	100 units/112 days
	Upper Limb Spasticity ≥18 years old: 400 units (max) up to every 12 weeks 2 -17 years old:	≥18 years old: 400 units/84 days 2 -17 years old: Single upper limb: 200 units/84 days

	○ Single upper limb: 8 units/kg (200 units max) up to every 12 weeks ○ Bilateral upper limbs: 16 units/kg (400 units max) up to every 12 weeks	● Bilateral upper limbs: 400 units/84 days
Abbreviations: max, maximum; NDO, neurogenic detrusor overactivity; OAB, overactive bladder; SDV, single dose vial,		

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Dosed as appropriate for the indication and the individual product's prescribing information.
- Botulinum toxin products are all produced using different methods. Dosing and potencies are not interchangeable.

APPROVAL LENGTH

- **Authorization:** 12 months
- **Re-Authorization:** 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

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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.