Botulinum Toxin

Override(s)	Approval Duration
Prior Authorization	Chronic migraine headaches: Initial approval: 6 months Renewal approval: 1 year All other indications: 1 year

Medications	Comment	Dosing Limit
Botox (onabotulinumtoxinA)	Non-Preferred	See table below
Daxxify (daxibotulinumtoxinA-lanm		
Dysport (abobotulinumtoxinA)		
Myobloc (rimabotulinumtoxinB)		
Xeomin (incobotulinumtoxinA)	Preferred (except for CA, CO, WI where non-formulary)	

Drug	Limit Per Indication	Maximum amount allowed for indication*
Botox (onabotulinumtoxinA) 100 unit, 200 unit vial **NOTE:** follow indication-specific dosage and administration recommendations; in a 3 month interval do not exceed a total dose [cumulative for all indications treated] of: • Adults: 400 units • Pediatrics: the lesser of 10 units/kg or 340 units	**Idiopathic Overactive Bladder:** 100 units as frequently as every 12 weeks **Neurogenic Overactive Bladder (including neurogenic detrusor overactivity in children age 5 and older):** 200 units as frequently as every 12 weeks **Chronic Migraine:** 155 units as frequently as every 12 weeks **Cervical Dystonia:** 400 units as frequently as every 12 weeks **Axillary hyperhidrosis**: 50 units per axilla as frequently as every 8 weeks **Blepharospasm**: 200 units as frequently as every 12 weeks **Dystonia-associated strabismus:** 25 units per	100 units 200 units 200 units 400 units 100 units 200 units 100 units

	muscle; as frequently as every 12 weeks **Upper limb spasticity in adults:** Dose selected based on muscles affected, severity of muscle activity, prior response to treatment and adverse event history (maximum dose 400 units) as frequently as every 12 weeks **Lower limb spasticity in adults:** 300 units to 400 units divided across lower limb muscles as frequently as every 12 weeks **Upper limb spasticity in pediatric patients:** 3 Units/kg to 6 Units/kg (maximum 200 Units) as frequently as every 12 weeks **Lower limb spasticity in pediatric patients:** 4 units/kg to 8 units/kg (maximum 300 units) as frequently as every 12 weeks **Achalasia**: 100 units as frequently as every 12 weeks (DP) **Hemifacial spasm:** 25 units as frequently as every 12 weeks (DP) **Spasmodic Dysphonia**: 25 units as frequently as every 12 weeks (DP) **Other indications**: Up to 400 units as frequently as every 12 weeks	400 units 400 units 200 units 300 units 100 units 100 units 100 units 400 units
Daxxify (daxibotulinumtoxinA-lanm 50 unit, 100 unit vial	**Cervical Dystonia:** 125 units to 250 units as a divided dose among affected muscles as frequently as every 3 months	250 units
Dysport (abobotulinumtoxinA) 300 unit, 500 unit vial	**Blepharospasm:** 120 units per eye as frequently as every 12 weeks (DP) **Hemifacial spasm:** 220 units as frequently as every 12 weeks (DP)	300 units 300 units

	Upper and lower limb spasticity in adults: 1500 units (cumulative for all treated muscles) as frequently as every 12 weeks **Cervical Dystonia:** 1000 units as frequently as every 12 weeks **Upper limb spasticity in pediatric patients:** 8 units/kg to 16 units/kg per limb; maximum per treatment session 16 units/kg or 640 units, whichever is lower; as frequently as every 16 weeks **Lower limb spasticity in pediatric patients:** 10 units/kg to 15 units/kg; total dose must not exceed 15 units/kg for unilateral lower limb or 30 units/kg for bilateral injections or 1000 units, whichever is lower; as frequently as every 12 weeks **Other indications:** Up to 1500 units as frequently as every 12 weeks	1500 units 1000 units 800 units 1000 units 1500 units
Myobloc (rimabotulinumtoxinB) 2500 unit, 5000 unit, 10000 unit vial	**Cervical dystonia:** Initial dose of 2,500 – 5,000 units divided among effected muscles as frequently as every 12 weeks; subsequent doses should be based on individual response to treatment, up to 10,000 units as frequently as every 12 weeks **Chronic sialorrhea in adults:** 1,500 – 3.500 units (500 units – 1,500 units per parotid gland and 250 units per submandibular gland) as frequently as every 12 weeks **All Indications:** 10,000 units as frequently as every 12 weeks	10,000 units 5000 units 10,000 units
Xeomin (incobotulinumtoxinA)	**Cervical dystonia:** Initial dose of 120 units as frequently as every 12 weeks; subsequent	400 units

200 unit, 100 unit, 50 unit vial	doses should be based on past dose, response to treatment, duration of effect and adverse event history; up to 400 units as frequently as every 12 weeks	
	Chronic sialorrhea: 100 units as frequently as every 16 weeks	100 units
	Blepharospasm: Initial dose 50 units (25 units per eye) as frequently as every 12 weeks; subsequent doses based on past dose, response to treatment, duration of effect and adverse event history; dose should not exceed 100 units per treatment session (50 units per eye) as frequently as every 12 weeks	100 units
	Upper limb spasticity: 400 units as frequently as every 12 weeks	400 units
	Other indications: Up to 400 units as frequently as every 12 weeks	400 units

*Based on maximum dose for condition and vial size available
DP = DrugPoints off label use/dosing
§ Dosing in initial and sequential treatment sessions should be tailored to the individual patient based on the patient's head and neck position, localization of pain, muscle hypertrophy, patient response, and adverse event history; mean dose in clinical study was 236 units (25^{th} to 75^{th} percentile range of 198 units to 300 units)

APPROVAL CRITERIA

Requests for Botox, Daxxify, Dysport, and Myobloc may be approved if the step therapy criteria are met in addition to the prior authorization criteria.

Xeomin only needs to meet the prior authorization criteria:

STEP THERAPY CRITERIA:

I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to Xeomin (does not apply in CA, CO, WI where non-formulary); **OR**
II. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label use policy for the prescribed indication and the requested non-preferred agent does.

PRIOR AUTHORIZATION CRITERIA:

I. Individual has one of the following diagnoses:
   A. Disorders listed below if associated with spasticity or dystonia:
      1. Blepharospasm; **OR**
      2. Cerebral palsy; **OR**
      3. Facial nerve (VII) dystonia; **OR**
      4. Hemifacial Spasm; **OR**
      5. Hereditary spastic paraparesis; **OR**
      6. Idiopathic torsion dystonia; **OR**
      7. Lower limb spasticity; **OR**
      8. Multiple sclerosis; **OR**
      9. Neuromyelitis optica; **OR**
      10. Organic writer's cramp; **OR**
      11. Orofacial/oromandibulardystonias, including jaw closure dystonia and Meige's syndrome; **OR**
      12. Schilder's disease; **OR**
      13. Spasmodic dysphonia or laryngeal dystonia (a disorder of speech due to abnormal control of the laryngeal muscles present only during the specific task of speaking)
      14. Spastic hemiplegia; **OR**
      15. Spasticity related to stroke, spinal cord injury, or traumatic brain injury; **OR**
      16. Dystonia-associated strabismus; **OR**
      17. Symptomatic torsion dystonia; **OR**
      18. Other forms of upper motor neuron spasticity; **OR**
      19. Upper limb spasticity; **OR**
   B. Achalasia, including but not limited to internal anal sphincter achalasia abnormal rectoanal inhibitory reflex (RAIR) or internal anal sphincter hypertonicity shown by anorectal manometry (ARM) (Irani 2008); **OR**
   C. Anal fissures; **OR**
   D. Significant drooling in individuals who are unable to tolerate anticholinergic therapy (ex. glycopyrrolate, scopolamine); **OR**
   E. Idiopathic overactive bladder in adults who are unresponsive to or intolerant of a trial of anticholinergic therapy; **OR**
   F. Neurogenic overactive bladder (also referred to as detrusor overactivity or detrusor sphincter dyssynergia) that is inadequately controlled with anticholinergic therapy; **OR**
   G. Hirschsprung disease and associated functional obstruction caused by the inability of the internal anal sphincter to relax after prior surgical treatment;

OR

II. Individual has a diagnosis of cervical dystonia (spasmodic torticollis) of moderate or greater severity; **AND**

III. Individual is requesting initial treatment; **AND**

IV. Individual has a history of recurrent clonic or tonic involuntary contractions of one or more of the following muscles: sternocleidomastoid, splenius, trapezius and/or posterior cervical muscles; **AND**

V. Abnormal posturing, with limited range of motion in the neck, or sustained head tilt; **AND**
VI. The duration of the condition is greater than 6 months;

OR
VII. Individual has a diagnosis of cervical dystonia (spasmodic torticollis) of moderate or greater severity; **AND**
VIII. Individual is requesting subsequent injections; **AND**
IX. There is clinically significant improvement or stabilization in clinical signs and symptoms of the disease;

OR
X. Individual has a diagnosis of chronic migraine headaches; **AND**
XI. Individual is requesting initial treatment; **AND**
XII. Individual has 15 (fifteen) or more headache-days per month for more than 3 months, which, on at least 8 days per month, has features of a migraine headache (ICHD-3);

AND
XIII. If individual is also currently using a calcitonin gene-related peptide (CGRP) agent for chronic migraine prophylaxis and is going to be using CGRP and botulinum toxin together (i.e., not switching from one agent to another), the following must apply:
A. Individual has had a reduction in the overall number of migraine days or reduction in number of severe migraine days per month with CGRP use; **AND**
B. Individual continues to experience a significant number of migraine headache days or severe migraine days per month requiring additional therapy for migraine prevention;

OR
XIV. Individual has a diagnosis of chronic migraine headaches; **AND**
XV. Individual is requesting continued treatment; **AND**
XVI. Individual has completed an initial 6-month trial and the following criteria are met:
A. Individual has a reduction in the overall number of migraine days or reduction in number of severe migraine days per month; **AND**
B. Individual has obtained clinical benefit deemed significant by individual or prescriber including any of the following (AHS 2021):
1. 50% reduction in frequency of days with headache or migraine; **OR**
2. Significant decrease in attack duration; **OR**
3. Significant decrease in attack severity; **OR**
4. Improved response to acute treatment; **OR**
5. Reduction in migraine-related disability and improvements in functioning in important areas of life; **OR**
6. Improvements in health related quality of life and reduction in psychological stress due to migraine;

AND
C. If individual is using concurrently with a CGRP agent for migraine prophylaxis, the following must apply:

1. Individual has had further reduction in the overall number of migraine days or reduction in number of severe migraine days per month compared to monotherapy with the initial agent (either botulinum toxin or the CGRP agent);

OR

XIX. Individual has a diagnosis of primary hyperhidrosis; **AND**

XX. Individuals has failed a 6-month trial of any one or more types of nonsurgical treatment (for example: topical dermatologics such as aluminum chloride, tannic acid, glutaraldehyde or anticholinergics, systemic anticholinergics, tranquilizers or non-steroid anti-inflammatory drugs); **AND**

XXI. Individual has one of the following:

A. Presence of medical complications or skin maceration with secondary infection; **OR**

B. Significant functional impairment (including but not limited to social, occupational, physical or emotional impairment), defined by frequent interference with daily activities;

OR

XXII. Individual has a diagnosis of secondary hyperhidrosis; **AND**

XXIII. Condition is related to surgical complications; **AND**

XXIV. Individual has one of the following:

A. Presence of medical complications or skin maceration with secondary infection; **OR**

B. Significant functional impairment (including but not limited to social, occupational, physical or emotional impairment), defined by frequent interference with daily activities.

Requests for botulinum toxin may not be approved for the following:

I. Individual is using for skin wrinkles or other cosmetic indications; **OR**

II. Individual has headache diagnosis other than chronic migraine (example, tension, episodic migraine [14 migraine days per month or less], or chronic daily headaches); **OR**

III. Individual has any diagnosis not listed as an approvable diagnosis, including, but not limited to, the following:

a. Anismus (pelvic floor dyssynergia)
b. Bechet's syndrome
c. Benign Prostatic Hypertrophy
d. Brachial Plexus Palsy
e. Carpal tunnel syndrome
f. Chronic motor tic disorder
g. Disorders of the esophagus (except as listed above)
h. Epicondylitis
i. Fibromyalgia/fibromyositis

j. Gastroparesis
k. Low back pain
l. Myofascial pain syndrome
m. Neck pain not related to conditions mentioned above
n. Nystagmus
o. Parkinson’s disease
p. Post-mastectomy reconstruction syndrome
q. Reynaud's syndrome
r. Sphincter of Oddi dysfunction
s. Stuttering
t. Tics associated with Tourette’s Syndrome
u. Tinnitus
v. Tourette’s Syndrome
w. Tremors
x. Urinary and anal sphincter dysfunction (except as listed above)
y. Vaginismus
z. Whiplash related disorders
aa. Zygomatic Fractures

Key References:

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4. Bellet JS; Diagnosis and treatment of primary focal hyperhidrosis in children and adolescents. Semin Cutan Med Surg. 2010; 29:121-126. Available from: https://pdfs.semanticscholar.org/b8fd/2a8019355ede6543d90ea4bf61d36fbbf831.pdf.
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12. Dessie S, Bargen E, Hacker M, et al. A randomized, double-blind, placebo-controlled trial of onabotulinumtoxinA trigger point injections for myofascial pelvic pain. Am J Obstet Gynecol 2019.
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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.