

AbobotulinumtoxinA (Dysport®)
IncobotulinumtoxinA (Xeomin®)
OnabotulinumtoxinA (Botox®)
RimabotulinumtoxinB (Myobloc®)

Place of Service
Office Administration

HCPCS

Botox: J0585 per 1 unit
Dysport: J0586 per 5 units
Myobloc: J0587 per 100 units
Xeomin: J0588 per 1 unit

Conditions listed in policy (see criteria for details)

- [Achalasia](#)
- [Anal fissures](#)
- [Anismus/Puborectalis syndrome](#)
- [Blepharospasm associated with dystonia](#)
- [Cervical dystonia/Spasmodic torticollis](#)
- [Cranial nerve disorder VII \(e.g., hemifacial spasm\)](#)
- [Focal limb dystonia of the upper extremity](#)
- [Hand tremor](#)
- [Hyperhidrosis](#)
- [Migraine](#)
- [Overactive bladder \(OAB\)](#)
- [Pediatric \(infantile\) cerebral palsy](#)
- [Piriformis syndrome](#)
- [Sialorrhea](#)
- [Spasmodic dysphonia/Laryngeal spasm](#)
- [Spasticity](#)
- [Strabismus associated with dystonia](#)
- [Urinary incontinence due to detrusor overactivity associated with a neurological condition](#)

AHFS therapeutic class: Miscellaneous Therapeutic Agent

Mechanism of action: Botulinum toxin disrupts neurotransmission by inhibiting release of acetylcholine at cholinergic nerve terminals of the peripheral nervous system and at ganglionic nerve terminals of the autonomic nervous system, inducing a chemical denervation and flaccid paralysis and inhibiting glandular secretion. Botulinum toxin has been used for a wide variety of conditions in which the principal therapeutic aim is to reduce undesired or excessive contraction of striated or smooth (involuntary) muscle.

(1) Special Instructions and Pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

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All requests for Botox®, Dysport®, Myobloc®, or Xeomin® (botulinum toxins) for conditions NOT listed in section 3 must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Anal Fissures

1. Inadequate response to at least two of the following conservative treatment measures: laxative, anal dilator, local anesthetic, oral medication to reduce anal sphincter contraction, topical nitroglycerin, or topical calcium channel blocker.

Covered Doses

Botox®: Up to 100 units

Dysport®: Up to 150 units

Coverage Period

Total number of covered units divided over a 12-month period

Re-authorization: 1 year (if patient had clinical benefit)

ICD-10:

K60.1

Cervical dystonia/Spasmodic torticollis

1. Clonic or tonic involuntary contractions of multiple neck muscles exists, **AND**
2. Sustained head torsion and/or tilt with limited range of motion in the neck is present

Covered Doses

Botox®: Up to 400 units per injection in patients with an extended history of prior botulinum Toxin Type A use

Dysport®: Up to 500 units initially given intramuscularly as a divided dose among the affected muscles

Myobloc®: Up to 5,000 units initially divided among affected muscles

Xeomin®: Up to 240 units total dose

Coverage Period

One treatment every 12 weeks for 4 treatments.

Re-authorization: Indefinite (if patient had clinical benefit)

Requests for treatment sooner than indicated will be reviewed on a case-by-case basis.

ICD-10:

G24.3

Focal limb dystonia of the upper extremity (Organic writer's cramp)

1. Documented diagnosis of focal limb dystonia of the upper extremity (e.g. Organic writer's cramp), **AND**
2. Evidence of functional impairment and/or pain

Covered Doses

Botox[®]: Average 210 units per treatment

Dysport[®]: Mean dose injected per session was 133 units

Coverage Period

Authorization provided on an episodic basis, per treatment basis

ICD-10:

G25.89

Hyperhidrosis

1. Diagnosis of hyperhidrosis [(axillary, plantar, palmar, gustatory (Frey syndrome)], **AND**
2. Failure to respond to one of the following:
 - a. Topical therapy for hyperhidrosis (i.e. aluminum chloride [Drysol[®], Xerac[®]], anticholinergics [Qbrexza], OR
 - b. Failure to respond to or intolerant to pharmacotherapy for excessive sweating (e.g. anticholinergics [glycopyrrolate, oxybutynin, propantheline, benztropine], benzodiazepines [lorazepam, diazepam, clonazepam], or beta blockers [propranolol], clonidine)

Covered Doses

Primary Axillary Hyperhidrosis:

Botox[®] and Xeomin[®]: Up to 100 units per treatment (50 units per axilla)

Dysport[®]: 100 units per axilla initially. Can titrate up to 200 units per axilla for subsequent injection if desired effect not seen

Myobloc[®]: Up to 2,000 units per axilla distributed among 25 sites

Non-axillary Hyperhidrosis:

Botox[®] and Xeomin[®]: Up to 200 units per treatment (i.e. 100 units per palm)

Dysport[®]: Up to 150 units per treatment

Myobloc[®]: Up to 9,000 units per palm, distributed among 30-35 sites

Coverage Period

Botox[®] and Xeomin[®]: One treatment per six-month period for 1 year

Dysport[®]: One treatment per four-month period for 1 year

Myobloc[®]: One treatment per four-month period for 1 year

Re-Authorization

- Indefinite (if patient had clinical benefit)
- Requests for treatment sooner than indicated will require documented loss of response

ICD-10:

L74.510-L74.513, L74.519, L74.52

Migraine

1. Being used as prophylaxis of headaches in patients with chronic migraine, **AND**
2. Patient experiences a migraine greater than or equal to 15 days per month with headache lasting 4 hours a day or longer as evidenced by headache diary or chart documentation of frequency of headache days and length of headache, **AND**
3. Prescribed by or in consultation with a neurologist, **AND**

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4. Either of the following:
 - a. Patient has had an inadequate response or intolerance to at least two prophylactic therapies from any of the following drug classes: beta-blockers, antidepressants, anticonvulsants, OR
 - b. Patient has a contraindication to all AAN-supported Level A or B migraine prophylactic agents (See Section (5))

Covered Doses

Botox®: Up to 200 units per treatment

Coverage Period

Initial: Cover 1 treatment every 12 weeks for 2 treatments

First Reauthorization: 1 treatment every 12 weeks for 4 treatments *after documentation of reduction in number of headache days* following initial authorization.

Subsequent re-authorization: 1 treatment every 12 weeks for 4 treatments *with continued benefit from therapy*

ICD-10:

G43.001-G43.819

Sialorrhea (Drooling)

1. Documented diagnosis of sialorrhea (drooling) due to neurodegenerative disease (eg, Parkinson's disease), **AND**
2. Conservative measures have been tried and/ or considered and ruled out (eg; behavioral therapy, oral motor training, anticholinergic therapy)

Covered Doses

Botox® and Xeomin®: Initial 100 units per treatment

Dysport®: Initial 450 units per treatment

Myobloc®: Initial 3500 units per treatment

Coverage Period

One treatment every 12 weeks for 4 treatments

Re-authorization: Indefinite (if patient had clinical benefit)

Requests for treatment sooner than indicated will be reviewed on a case-by-case basis

ICD-10:

K11.7

Spasticity

1. Meets for either of the following:
 - a. Documented diagnosis of spasticity with underlying cause [eg; stroke-related spastic hemiplegia, trauma, multiple sclerosis, neoplasm involving the CNS, hereditary spastic paraparesis] with evidence of functional impairment and/ or pain, **OR**
 - b. Documented upper or lower limb spasticity with evidence of functional impairment and/ or pain

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Covered Doses

Botox[®]: Up to 400 units per treatment

Dysport[®]:

- Adults: Upper limb: Up to 1,000 units per treatment
 - Lower limb: Up to 1500 units per treatment
Maximum recommended total dose per treatment session is 1500 units (upper and lower limb combined)
- Pediatrics: Up to 1000 units per treatment

Myobloc[®]: 10,000-15,000 units per treatment

Xeomin[®]: Upper limb spasticity up to 400 units

Coverage Period

Spasticity: Up to 4 treatments per year (12 weeks apart)

Spasticity with underlying cause: One treatment every 12 weeks for 4 treatments

Reauthorization: Indefinite (if patient had clinical benefit).

Requests for treatment sooner than indicated will be reviewed on a case by case basis.

ICD-10:

Spasticity with Underlying cause: (not all inclusive)

G11.4 (hereditary spastic paraparesis)

G35 (multiple sclerosis)

G81.10-G81.14 (stroke related hemiplegia)

I69.03- I69.069, I69.131-I69.169, I69.231-I69.269, I69.331-I69.369, I69.831-I69.-869, I69.931-I69.969 (late effects of cerebrovascular disease: hemiplegia/hemiparesis, monoplegia of upper limb, monoplegia of lower limb, or other paralytic syndrome)

Overactive bladder (OAB)/Urinary Incontinence due to detrusor overactivity associated with a neurologic condition

1. Inadequate response or intolerance with at least two antispasmodic therapies, **AND**
2. One of the following:
 - a. Diagnosis of overactive bladder (OAB), OR
 - b. Diagnosis of incontinence due to detrusor overreactivity (urge incontinence), either idiopathic or neurogenic (e.g., spinal cord injury, multiple sclerosis)

Covered Doses

Botox[®]: Up to 300 units per treatment

Dysport[®]: Up to 500 units per treatment

Myobloc[®]: 2,500-15,000 units per treatment

Coverage Period

Authorization on an episodic basis, per treatment basis

ICD-10:

N31.0, N31.1, N31.8, N31.9, N32.81, N36.44, N39.41, N39.46, N39.498

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for botulinum toxin for conditions NOT LISTED in section 3 must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Achalasia: Failure of dilatation therapy and poor candidates for surgical intervention.

Covered Doses

- Botox[®]: 100 units per treatment
- Dysport[®]: 250 units per treatment
- Xeomin[®]: Up to 100 units per treatment

ICD-10:

K22.0

Anismus/Puborectalis syndrome

Covered Doses

- Botox[®] 30 units per treatment

ICD-10:

K62.89

Blepharospasm associated with dystonia, including benign essential blepharospasm

Covered Doses

- Botox[®] up to 200 units per treatment every 12 weeks
- Dysport[®]: up to 120 units per eye every 12 weeks
- Xeomin[®]: up to 75 units total dose every 12 weeks

ICD-10:

G24.5

Cranial nerve disorder VII or hemifacial spasm

- Member is being treated by a neurologist or ophthalmologist

Covered Doses

Botox[®]: Up to 100 units per treatment every 12 weeks

ICD-10:

G51.2X-G51.9X (X = any number, After the decimal, there can be up to 3 numbers)

Hand tremor

Covered Doses

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- Botox[®] up to 100 units per treatment

ICD-10:
R25.1

Pediatric (infantile) cerebral palsy

Covered Doses

- Botox[®] up to 200 units per treatment
- Dysport[®]: up to 1000 units per treatment

ICD-10:
G80.0-G80.2, G80.8, G80.9

Piriformis syndrome

Covered Doses

- Botox[®] up to 150 units per treatment

ICD-10:
G57.00-G57.02

Spasmodic dysphonia/ Difficulty speaking- disturbance in speech/ Laryngeal spasm

Covered Doses

- Botox[®] up to 30 units per treatment

ICD-10:
J38.5

Strabismus

Covered Doses

Initial Dose:

- Botox[®] Initial dose up to 5 units per muscle injected

Dose increase following inadequate response: For patients who experience incomplete paralysis of the target muscle, dose may be increased up to two times the size of the previously administered dose. Subsequent injections should not be administered until the effects of the previous dose have dissipated.

ICD-10:
H50.00, H50.2-H50.22, H50.60, H50.69, H50.8, H50.89, H50.9
H49.8, H49.88x, H49.9

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

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- Club Foot
- Benign Prostatic Hyperplasia
- Delayed gastric emptying
- Epiphora
- Eye Lift
- Headaches:
 - Cervicogenic Headaches
 - Tension Headaches

- Head Tremor
- Myofascial Pain Syndrome
- Nasal hypersecretion or allergic rhinitis
- Pain – post hemorrhoidectomy
- Pancreas divisum-pancreatitis
- Tardive dyskinesia
- Tourette’s syndrome

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

Botox: 100, 200 units (single-use)

Dysport: 300, 500 units (single-use)

Xeomin: 50, 100, or 200 units (single-use)

Myobloc: 2,500, 5,000, and 10,000 units (single-use)

Medical literature and medical consensus support general similarity among botulinum toxin products. It will be the responsibility of the provider to choose the appropriate option for the patient, as the products are similar but not identical.

AAN 2012¹ Level A and B Recommended Preventive Anti-Migraine Agents by Drug Class:

Antiepileptic Drugs	Beta Blockers	Antidepressants	Other
Level A	Level A	Level A	Level A
<ul style="list-style-type: none"> divalproex sodium sodium valproate topiramate 	<ul style="list-style-type: none"> metoprolol propranolol timolol 	(None listed)	(None listed)
Level B	Level B	Level B	Level B
(None listed)	<ul style="list-style-type: none"> atenolol nadolol 	<ul style="list-style-type: none"> amitriptyline venlafaxine 	<ul style="list-style-type: none"> naratriptan[^] zolmitriptan[^]

Level A = Established efficacy (≥ 2 Class I trials)

Level B = Probably effective (1 Class I or 2 Class II studies)

[^]= for short term prophylaxis of menstrual migraine only

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(7) Policy Update

Date of last revision: 1Q2023

Date of next review: 4Q2023

Changes from previous policy version:

- No clinical change to policy following revision.

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*