| | |
|---|---|
| **AbobotulinumtoxinA (Dysport®)**<br>**IncobotulinumtoxinA (Xeomin®)**<br>**OnabotulinumtoxinA (Botox®)**<br>**RimabotulinumtoxinB (Myobloc®)** | **Place of Service**<br>**Office Administration**<br><br>**HCPCS**<br>**Botox: J0585** per 1 unit<br>**Dysport: J0586** per 5 units<br>**Myobloc: J0587** per 100 units<br>**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)**

**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.**

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

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

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

**Cervical dystonia/Spasmodic torticolis**

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

**Cranial nerve disorder VII or hemifacial spasm**

**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)

**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

**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)

**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**
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

**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

**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

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

**Covered Doses**
- Botox® up to 30 units per treatment

**ICD-10:**
J38.5

**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

**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)*
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 treatmentMyobloc®: 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)*

**Strabismus**

**Covered Doses**

- 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

**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 must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

**(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):

- 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 2012[1] 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** |
| • divalproex sodium | • metoprolol | (None listed) | (None listed) |
| • sodium valproate | • propranolol | | |
| • topiramate | • timolol | | |
| **Level B** | **Level B** | **Level B** | **Level B** |
| (None listed) | • atenolol | • amitriptyline | • naratriptan^ |
| | • nadolol | • venlafaxine | • 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

## (6) References


- AHFS®. Available by subscription at http://www.lexi.com
- Botox® (onabotulinumtoxinA) [Prescribing information]. Madison, NJ: Allergan; 7/2021.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Dysport® (abobotulinumtoxinA) [Prescribing information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; 7/2020.
- Dysport prescribing information [United Kingdom]. Ispen Pharmaceuticals. Available at: http://emc.medicines.org.uk/document.aspx?documentId=870
- Karsai S, Raulin C. Current evidence on the unit equivalence of different botulinum neurotoxin A formulations and recommendations for clinical practice in dermatology. Dermatol Surg. 2009;35(1):1-8.
- Myobloc® (rimabotulinumtoxinB) [Prescribing information]. Rockville, MD: Solstice Neurosciences, Inc.; 3/2021.
- Yoon SJ, Ho J, Kang HY, et al. Low-dose botulinum toxin type A for the treatment of refractory piriformis syndrome. Pharmacotherapy. 2007 May; 27(5):657-65.
- Xeomin® (incobotulinumtoxinA) [Prescribing information]. Raleigh, NC: Merz Pharmaceuticals, LLC.; 8/2021.

1. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults: Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. (reaffirmed 2015). Neurology. 2012 Apr 24;78(17):1337-45 available online at: http://n.neurology.org/content/neurology/78/17/1337.full.pdf


## (7) Policy Update

Date of last review: 4Q2023

Date of next review: 4Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

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