

## botulinum toxin

### Commercial Medical Benefit Drug Policy

#### Place of Service

Office Administration

abobotulinumtoxinA (Dysport)

incobotulinumtoxinA (Xeomin)

onabotulinumtoxinA (Botox)

rimabotulinumtoxinB (Myobloc)

#### Drug Details

**USP Category:** SKELETAL MUSCLE RELAXANTS

**Mechanism of Action:** blocks neuromuscular conduction by binding to receptor sites on motor nerve terminals, entering the nerve terminals, and inhibiting the release of acetylcholine

#### HCPCS:

J0585:Injection, onabotulinumtoxina, 1 unit

J0586:Injection, abobotulinumtoxina, 5 units

J0587:Injection, rimabotulinumtoxinb, 100 units

J0588:Injection, incobotulinumtoxin a, 1 unit

#### 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)

#### Condition(s) listed in policy *(see coverage criteria for details)*

- Achalasia: Failure of Dilatation Therapy and Poor Candidates for Surgical Intervention
- Anal Fissures
- Anismus/Puborectalis Syndrome
- Blepharospasm Associated with Dystonia, including Benign Essential Blepharospasm
- Cervical Dystonia/Spasmodic Torticollis
- Cranial Nerve Disorder VII or Hemifacial Spasm
- Focal Limb Dystonia of the Upper Extremity (Organic Writer's Cramp)
- Hand Tremor
- Hyperhidrosis
- Migraine
- Overactive Bladder (OAB)/Urinary Incontinence due to Detrusor Overactivity Associated with a Neurologic Condition
- Pediatric (Infantile) Cerebral Palsy
- Piriformis Syndrome
- Sialorrhea (Drooling)
- Spasmodic Dysphonia/ Difficulty Speaking - Disturbance in Speech/ Laryngeal Spasm
- Spasticity
- Strabismus associated with dystonia

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

### **Special Instructions and Pertinent Information**

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

### **Coverage Criteria**

**The following condition(s) require Prior Authorization/Preservice.**

#### **Anal Fissures**

**Meets medical necessity if all the following are met:**

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:**

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

Reauthorization: Yearly (if patient had clinical benefit)

#### **ICD-10:**

K60.1

#### **Cervical Dystonia/Spasmodic Torticollis**

**Meets medical necessity if all the following are met:**

1. Clonic or tonic involuntary contractions of multiple neck muscles exists
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:**

Initial: One treatment every 12 weeks for 4 treatments.

Reauthorization: Yearly (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)**

**Meets medical necessity if all the following are met:**

1. Documented diagnosis of focal limb dystonia of the upper extremity (e.g. Organic writer's cramp)
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**

**Meets medical necessity if all the following are met:**

1. Diagnosis of hyperhidrosis [(axillary, plantar, palmar, gustatory (Frey syndrome))]
2. Failure to respond to ONE of the following:
  - a. Topical therapy for hyperhidrosis (i.e. aluminum chloride [Drysol®, Xerac®], anticholinergics [Qbrexza])
  - 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:**

Initial:

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

Reauthorization:

- Yearly (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**

**Meets medical necessity if all the following are met:**

1. Being used as prophylaxis of headaches in patients with chronic migraine
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
3. Prescribed by or in consultation with a neurologist
4. Meets ONE 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, CGRPs
  - b. Patient has a contraindication to all guideline-supported (e.g., AAN-supported Level A or B) migraine prophylactic agents

**Covered Doses:**

Botox: Up to 200 units per treatment

**Coverage Period:**

Initial: 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 reauthorization: 1 treatment every 12 weeks for 4 treatments with continued benefit from therapy

**ICD-10:**

G43.001-G43.819

**Overactive Bladder (OAB)/Urinary Incontinence due to Detrusor Overactivity Associated with a Neurologic Condition**

**Meets medical necessity if all the following are met:**

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

**Covered Doses:**

botulinum toxin

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

**Sialorrhea (Drooling)**

**Meets medical necessity if all the following are met:**

1. Documented diagnosis of sialorrhea (drooling) due to neurodegenerative disease (eg, Parkinson's disease)
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:**

Initial: One treatment every 12 weeks for 4 treatments

Reauthorization: Yearly (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**

**Meets medical necessity if all the following are met:**

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
  - 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)*
- 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:**

Initial: One treatment every 12 weeks for 4 treatments

Reauthorization: Yearly (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)*

*169.03- 169.069, 169.131-169.169, 169.231-169.269, 169.331-169.369, 169.831-169.-869, 169.931-169.969  
(late effects of cerebrovascular disease: hemiplegia/hemiparesis, monoplegia of upper limb,  
monoplegia of lower limb, or other paralytic syndrome)*

**The following condition(s) DO NOT require Prior Authorization/Preservice if ALL its parameters are met, otherwise Prior Authorization/Preservice is required.**

**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**

#### **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:**

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 associated with dystonia**

#### **Covered Doses:**

Botox: Initial dose up to 5 units per muscle injected given no sooner than every 12 weeks

Dose increase following inadequate response: For patients who experience incomplete paralysis of

botulinum toxin

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:

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

#### Additional Information

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 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"> <li>divalproex sodium</li> <li>sodium valproate</li> <li>topiramate</li> </ul>	<ul style="list-style-type: none"> <li>metoprolol</li> <li>propranolol</li> <li>timolol</li> </ul>	(None listed)	(None listed)
Level B	Level B	Level B	Level B
(None listed)	<ul style="list-style-type: none"> <li>atenolol</li> <li>nadolol</li> </ul>	<ul style="list-style-type: none"> <li>amitriptyline</li> <li>venlafaxine</li> </ul>	<ul style="list-style-type: none"> <li>naratriptan<sup>^</sup></li> <li>zolmitriptan<sup>^</sup></li> </ul>

**Level A** = Established efficacy ( $\geq 2$  Class I trials)

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

<sup>^</sup>= for short term prophylaxis of menstrual migraine only

- Per the American Headache Society position statement update (published February 2024): "The CGRP-targeting therapies should be considered as a first-line approach for migraine prevention along with previous first-line treatments without a requirement for prior failure of other classes of migraine preventive treatment."

#### References

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- Dysport (abobotulinumtoxinA) Prescribing Information. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; 9/2023.
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### Review History

Date of Last Annual Review: 4Q2025

Changes from previous policy version:

- Migraine: Clarified prerequisite therapies for prevention of migraines to include calcitonin gene-related peptide (CGRP) antagonists. (Rationale: Guideline-supported therapy, 2024 AHS guidelines)

*Blue Shield of California Medication Policy to Determine Medical Necessity*  
*Reviewed by P&T Committee*