

## onabotulinumtoxinA (Botox)

### Commercial Medical Benefit Drug Policy

#### Place of Service

Office Administration

#### 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

#### How Supplied:

Botox: 100, 200 units (single-use)

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

- Achalasia
- Anal Fissures
- Blepharospasm
- Cervical Dystonia
- Focal Limb Dystonia (Writer's Cramp)
- Hand Tremor
- Hemifacial Spasm or Cranial Nerve Disorder VII
- Hyperhidrosis
- Migraine
- Overactive Bladder / Urinary Incontinence due to Detrusor Overactivity associated with a Neurologic Condition
- Pediatric Cerebral Palsy
- Sialorrhea
- Spasmodic Dysphonia / Laryngeal Spasm
- Spasticity
- Strabismus

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, and topical calcium channel blocker

#### **Covered Doses:**

Up to 100 units per treatment session given intramuscularly for two treatment sessions

#### **Coverage Period:**

1 year

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

K60.0, K60.1, K60.2

#### **Cervical Dystonia**

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

1. Involuntary contractions of the neck muscles, causing abnormal placement of the head with limited range of motion in the neck

#### **Covered Doses:**

Up to 400 units per treatment session given intramuscularly no sooner than every 12 weeks

#### **Coverage Period:**

Indefinite

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

G24.3

#### **Focal Limb Dystonia (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 or pain

#### **Covered Doses:**

Up to 60 units per affected muscle per treatment session given intramuscularly

#### **Coverage Period:**

One treatment session

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

G25.89

## **Hyperhidrosis**

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

1. Patient has axillary or palmer hyperhidrosis
2. Inadequate response or intolerable side effect to one of the following treatments: aluminum chloride (Drysol, Xerac), anticholinergics (Qbrexza, glycopyrrolate, oxybutynin, propantheline, benztropine), benzodiazepines (lorazepam, diazepam, clonazepam), beta blockers (propranolol), or clonidine

### **Covered Doses:**

Axillary: Up to 50 units per axilla per treatment session given by intradermal injection no sooner than every six months

Palmer: Up to 100 units per palm per treatment session given by intradermal injection no sooner than every six months

### **Coverage Period:**

Indefinite

### **ICD-10:**

L74.5, L74.51, L74.510, L74.512, L74.519, L74.52

## **Migraine**

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

#### Initial

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, and CGRPs
  - b. Patient has a contraindication to all guideline-supported (e.g., AAN-supported Level A or B) migraine prophylactic agents

#### First Reauthorization

1. Documentation of reduction in number of headache days following initial authorization.

#### Subsequent Reauthorization

1. Patient continues to respond to therapy

### **Covered Doses:**

Up to 200 units per treatment session given intramuscularly no sooner than every 12 weeks

### **Coverage Period:**

Initial: 2 treatment sessions

Reauthorization: Yearly

### **ICD-10:**

onabotulinumtoxinA (Botox)

G43.001-G43.819, G43.A-G43.D1

**Overactive Bladder / Urinary Incontinence due to Detrusor Overactivity associated with a Neurologic Condition**

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

Initial

1. Inadequate response or intolerance with at least two antispasmodic therapies

Reauthorization

1. Patient responded to therapy

**Covered Doses:**

Up to 200 units per treatment session given by intradetrusor injection no sooner than every 12 weeks

**Coverage Period:**

Yearly

**ICD-10:**

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

**Sialorrhea**

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

1. Patient has sialorrhea (drooling) due to a neurodegenerative disease (e.g., Parkinson's disease, amyotrophic lateral sclerosis)
2. Meets one of the following:
  - a. Patient has tried conservative treatments (e.g.; behavioral therapy, oral motor training, anticholinergic therapy)
  - b. Conservative treatments are not appropriate options for the patient

**Covered Doses:**

Up to 100 units per gland per treatment session given intramuscularly no sooner than every 12 weeks

**Coverage Period:**

Indefinite

**ICD-10:**

K11.7

**Spasticity**

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

1. Patient has upper or lower limb spasticity with evidence of functional impairment or pain

**Covered Doses:**

Adult upper limb: Up to 400 units per treatment session given intramuscularly no sooner than every 12 weeks

Adult lower limb: Up to 400 units per treatment session given intramuscularly no sooner than every 12 weeks

Pediatric upper limb: Up to 200 units per treatment session given intramuscularly no sooner than every 12 weeks

Pediatric lower limb: Up to 300 units treatment session given intramuscularly no sooner than every 12 weeks

*The max dose per treatment session is 400 units regardless of the number of limbs treated*

**Coverage Period:**

Indefinite

**ICD-10:**

G04.1, G11.4, G24.02, G24.09, G24.1, G24.2, G25.0, G25.1, G25.2, G25.61, G25.69, G25.89, G35.A, G35.B0, G35.B1, G35.B2, G35.C0, G35.C1, G35.C2, G35.D, G80.0, G80.1, G80.2, G80.3, G80.4, G80.8, G81.11, G81.12, G81.13, G81.14, G82.21, G82.22, G82.51, G82.52, G82.53, G82.54, G83.0, G83.11, G83.12, G83.13, G83.14, G83.21, G83.22, G83.23, G83.24, I69.031, I69.032, I69.033, I69.034, I69.041, I69.042, I69.043, I69.044, I69.051, I69.052, I69.053, I69.054, I69.131, I69.132, I69.133, I69.134, I69.141, I69.142, I69.143, I69.144, I69.151, I69.152, I69.153, I69.154, I69.231, I69.232, I69.233, I69.234, I69.241, I69.242, I69.243, I69.244, I69.251, I69.252, I69.253, I69.254, I69.331, I69.332, I69.333, I69.334, I69.341, I69.342, I69.343, I69.344, I69.351, I69.352, I69.353, I69.354, I69.831, I69.832, I69.833, I69.834, I69.841, I69.842, I69.843, I69.844, I69.851, I69.852, I69.853, I69.854, I69.931, I69.932, I69.933, I69.934, I69.941, I69.942, I69.943, I69.944, I69.951, I69.952, I69.953, I69.954

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

**Achalasia**

**Covered Doses:**

Up to 100 units per treatment session given intramuscularly no sooner than every 12 weeks

**ICD-10:**

K22.0

**Blepharospasm**

**Covered Doses:**

Up to 200 units per treatment session given intramuscularly no sooner than every 12 weeks

**ICD-10:**

G24.5

**Hand Tremor**

**Covered Doses:**

Up to 100 units per treatment session given intramuscularly no sooner than every 12 weeks

**ICD-10:**

R25.1

**Hemifacial Spasm or Cranial Nerve Disorder VII**

onabotulinumtoxinA (Botox)

**Covered Doses:**

Up to 100 units per treatment session given intramuscularly no sooner than every 12 weeks

**ICD-10:**

G51.2, G51.3, G51.31, G51.32, G51.33, G51.39, G51.4, G51.8, G51.9

**Pediatric Cerebral Palsy**

**Covered Doses:**

Up to 300 units per treatment session given intramuscularly no sooner than every 12 weeks

**ICD-10:**

G80, G80.0, G80.1, G80.2, G80.8, G80.9

**Spasmodic Dysphonia / Laryngeal Spasm**

**Covered Doses:**

Up to 25 units per treatment session given intramuscularly no sooner than every 12 weeks

**ICD-10:**

J38.5, R49.0

**Strabismus**

**Covered Doses:**

Up to 25 units per muscle per treatment session given intramuscularly no sooner than every 12 weeks

**ICD-10:**

H49.8, H49.88, H49.881, H49.882, H49.883, H49.889, H49.9, H50.00, H50.2, H50.21, H50.22, H50.60, H50.69, H50.8, H50.89, H50.9

**Additional Information**

Migraines: AAN 2012 Level A and B Recommended Preventive Anti-Migraine Agents by Drug Class			
Antiepileptic Drugs	Beta Blockers	Antidepressants	Other
<b>Level A</b>	<b>Level A</b>	<b>Level A</b>	<b>Level A</b>
<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)
<b>Level B</b>	<b>Level B</b>	<b>Level B</b>	<b>Level B</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^</li> <li>zolmitriptan^</li> </ul>

**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

- 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

1. Ailani J, Burch RC, Robbins MS; Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. *Headache*. 2021;61(7):1021-1039. doi: [10.1111/head.14153](https://doi.org/10.1111/head.14153).
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4. Charles AC, Digre KB, Goadsby PJ, Robbins MS, Hershey A; American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. *Headache*. 2024 Apr;64(4):333-341. doi: [10.1111/head.14692](https://doi.org/10.1111/head.14692).
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6. Micromedex DrugDex [online drug compendium]. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>.
7. Sacco S, Ashina M, Diener HC, et al. Setting higher standards for migraine prevention: A position statement of the International Headache Society. *Cephalalgia*. 2025 Feb;45(2):3331024251320608. doi: [10.1177/03331024251320608](https://doi.org/10.1177/03331024251320608).
8. 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. *Neurology*. 2012 Apr 24;78(17):1337-45. doi: [10.1212/WNL.0b013e3182535d20](https://doi.org/10.1212/WNL.0b013e3182535d20). [Guideline reaffirmed October 18, 2025].
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10. Vaezi MF, Pandolfino JE, Yadlapati RH, Greer KB, Kavitt RT. ACG Clinical Guidelines: Diagnosis and Management of Achalasia. *Am J Gastroenterol*. 2020 Sep;115(9):1393-1411.
11. 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.

## Review History

Date of Last Annual Review: 2Q2026

Changes from previous policy version:

- Removed coverage for Anismus/Puborectalis syndrome and Piriformis Syndrome (Rationale: not supported by labeling or in compendia)

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