onabotulinumtoxinA (Botox)

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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

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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.

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

Achalasia
Meets medical necessity if all the following are met:

Covered Doses:
Up to 100 units per treatment session given intramuscularly

Coverage Period:
One treatment session

ICD-10:
K22.0

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

Blepharospasm
Meets medical necessity if all the following are met:

Covered Doses:
Up to 200 units per treatment session given intramuscularly

Coverage Period:
One treatment session

ICD-10:
G24.5

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

Hand Tremor

Meets medical necessity if all the following are met:

Covered Doses:
Up to 100 units per treatment session given intramuscularly

Coverage Period:
One treatment session

ICD-10:
R25.1

Hemifacial Spasm or Cranial Nerve Disorder VII

Meets medical necessity if all the following are met:

1. Member is being treated by a neurologist or ophthalmologist

Covered Doses:
Up to 100 units per treatment session given intramuscularly

Coverage Period:
One treatment session

ICD-10:
G51.0, G51.1, G51.2, G51.3, G51.31, G51.32, G51.33, G51.39, G51.4, G51.8, G51.9

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:
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

Pediatric Cerebral Palsy
Meets medical necessity if all the following are met:

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

Coverage Period: Yearly, based on continued response to therapy

ICD-10:

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

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

Spasmodic Dysphonia/ Laryngeal Spasm

Meets medical necessity if all the following are met:

Covered Doses:

Up to 25 units per treatment session given intramuscularly

Coverage Period:

One treatment session

ICD-10:

J38.5, R49.0

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

Strabismus
Meets medical necessity if all the following are met:

Covered Doses:
Up to 25 units per muscle per treatment session given intramuscularly

Coverage Period:
One treatment session

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
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

- 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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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:

- Hemifacial Spasm or Cranial Nerve Disorder VII: Updated ICD-10 codes

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