

## botulinum toxins

### Medicare Part B Drug Policy

- Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).
- Medicare Benefit Policy Manual - Pub. 100-02, Chapter 15, Section 50, describes national policy regarding Medicare guidelines for coverage of drugs and biologicals.
- Blue Shield of California (BSC) follows Medicare statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and policy articles for determining coverage for Part B drug requests when applicable.
- BSC Medicare Part B Drug Policies will be used when coverage criteria are not fully established or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs.

### 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, incobotulinumtoxinA, 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 or Cardiospasm
- Anal Fissures
- 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)
- Hyperhidrosis
- Laryngeal spasm/Spasmodic dysphonia
- Migraine
- Overactive bladder (OAB)/Urinary Incontinence due to detrusor overactivity associated with a neurologic condition
- Pediatric (infantile) cerebral palsy
- Sialorrhea (Drooling)
- Spasticity
- Strabismus (Esotropia and/or Exotropia)

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Any request for a condition not listed in policy must meet the definition of a medically accepted indication. Section 1861(t)(2)(B) of the Act defines "medically-accepted indication," as any use of a prescription drug or biological product which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included (or approved for inclusion) in one or more of the CMS approved compendia.

### **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.

### **Coverage Criteria**

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

#### **Achalasia or Cardiospasm**

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

Requirements listed within the Local Coverage Determination (LCD) L35170: Botulinum Toxin Types A and B Policy

#### **Covered Doses:**

Botox®: 100 units per treatment

Dysport®: 250 units per treatment

Xeomin®: Up to 100 units per treatment

#### **Coverage Period:**

Authorization on an episodic basis, per treatment basis

#### **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, 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:**

K60.0, K60.1

#### **Blepharospasm associated with dystonia, including benign essential blepharospasm**

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

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Requirements listed within the Local Coverage Determination (LCD) L35170: Botulinum Toxin Types A and B Policy

**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 50 units per eye or 100 units per treatment session every 12 weeks

**Coverage Period:**

One treatment every 12 weeks for 4 treatments.

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

**ICD-10:**

G24.5

**Cervical dystonia/Spasmodic torticollis**

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

Requirements listed within the Local Coverage Determination (LCD) L35170: Botulinum Toxin Types A and B Policy

**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: yearly (if patient had clinical benefit)

**ICD-10:**

G24.3

**Cranial nerve disorder VII or hemifacial spasm**

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

Requirements listed within the Local Coverage Determination (LCD) L35170: Botulinum Toxin Types A and B Policy

**Covered Doses:**

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

**Coverage Period:**

One treatment every 12 weeks for 4 treatments.

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

**ICD-10:**

G51.2, G51.31-G51.33, G51.4, G51.8

G51.31-G51.33 (Group 2 codes) must be paired with a Group 3 Code (i.e., one primary diagnosis and one secondary diagnosis). Please refer to billing and coding article (A57185) for complete list of covered ICD-10 codes.

**Focal limb dystonia of the upper extremity (Organic writer's cramp)****Meets medical necessity if all the following are met:**

Requirements listed within the Local Coverage Determination (LCD) L35170: Botulinum Toxin Types A and B Policy

**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, anticholinergics)
  - 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: yearly (if patient had clinical benefit)

**ICD-10:**

L74.510, L74.511, L74.512, L74.513, L74.519, L74.52

**Laryngeal spasm/Spasmodic dysphonia**

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

Requirements listed within the Local Coverage Determination (LCD) L35170: Botulinum Toxin Types A and B Policy

**Covered Doses:**

Botox® up to 30 units per treatment

**Coverage Period:**

Authorization on an episodic basis, per treatment basis

**ICD-10:**

J38.5

**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. ONE of the following (a or b):
  - 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 attestation accepted
  - b. Patient has a contraindication to all AAN-supported Level A or B migraine prophylactic agents

**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

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

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

1. ONE of the following (a or b):
  - a. Diagnosis of overactive bladder (OAB)
  - b. Diagnosis of incontinence due to detrusor overactivity (urge incontinence), either idiopathic or neurogenic (e.g., spinal cord injury, multiple sclerosis)
2. ONE of the following (a or b):
  - a. Patient had inadequate response or intolerance to ONE anticholinergic drug
  - b. Patient has a contraindication to all anticholinergics

**Covered Doses:**

Botox®: Up to 200 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, N49.8

**Pediatric (infantile) cerebral palsy**

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

Requirements listed within the Local Coverage Determination (LCD) L35170: Botulinum Toxin Types A and B Policy

**Covered Doses:**

Botox® up to 200 units per treatment

Dysport®: up to 1000 units per treatment

**Coverage Period:**

Authorization on an episodic basis, per treatment basis

**ICD-10:**

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

**Sialorrhea (Drooling)**

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

Requirements listed within the Local Coverage Determination (LCD) L35170: Botulinum Toxin Types A and B Policy

**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: yearly (if patient had clinical benefit)

**ICD-10:**

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K11.7

### **Spasticity**

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

Requirements listed within the Local Coverage Determination (LCD) L35170: Botulinum Toxin Types A and B Policy

#### **Covered Doses:**

Botox<sup>®</sup>: Up to 400 units per treatment

Dysport<sup>®</sup>:

- 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<sup>®</sup>: 10,000-15,000 units per treatment

Xeomin<sup>®</sup>: Upper limb spasticity up to 400 units

#### **Coverage Period:**

Up to 4 treatments per year (12 weeks apart)

Reauthorization: yearly (if patient had clinical benefit).

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

Please refer to billing and coding article (A57185) under section titled 'ICD-10-CM Codes that support medical necessity' for complete list of covered diagnosis codes

- G83.0\*; G83.11\*; G83.12\*; G83.13\*; G83.14\*; N31.0\*; N31.1\*; N31.9\* in Group 1 requires a second code from Group 2 in order to be payable.
- ALL Group 2 ICD-10-CM codes require a second code from Group 3 in order to be payable and are used only when there is spasticity of central nervous system origin (must be used in pairs, i.e., one primary diagnosis and one secondary diagnosis)

### **Strabismus (Estropia and/or Exotropia)**

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

Requirements listed within the Local Coverage Determination (LCD) L35170: Botulinum Toxin Types A and B Policy

#### **Covered Doses:**

Botox<sup>®</sup> Initial dose up to 5 units per muscle injected

#### **Coverage Period:**

Authorization on an episodic basis, per treatment basis

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

H49.88x, H49.9, H50.00, H50.21-H50.22, H50.69, H50.89

### **Additional Information**

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## **Summary of Evidence**

The contents of this policy were created after examining the following resources:

1. The prescribing information for Botox, Dysport, Myobloc, and Xeomin
2. CMS approved compendium in accordance with the accepted compendia ratings listed:
  - a. Micromedex DrugDex - Class I, Class IIa, of Class IIb
  - b. American Hospital Formulary Service-Drug Information (AHFS-DI) - supportive narrative text
  - c. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium - Category 1 or 2A
  - d. Lexi-Drugs – “Use: Off-Label” and rated as “Evidence Level A”
  - e. Clinical Pharmacology - supportive narrative text
3. Local Coverage Determination (LCD) L35170: Botulinum Toxin Types A and B Policy

## **Explanation of Rationale:**

- Support for FDA-approved indications can be found in the manufacturer’s prescribing information.
- Support for Local Coverage Determination (LCD) covered indications can be found in LCD L35170.
- American Society of Colon and Rectal Surgeons and American College of Gastroenterology guidelines on the management of anal fissures consider botulinum toxin A injection an option for the treatment of anal fissures resistant to first-line therapies.
- The American Headache Society (AHS) and American Academy of Neurology (AAN) support use of evidence-based preventive treatments in patients with severe, disabling, or frequent migraine attacks, as well as those who cannot tolerate or are nonresponsive to acute treatment.

## **References**

1. CMS Benefit Policy Manual. Chapter 15; § 50 Drugs and Biologicals
2. Medicare Coverage Database. Available at <https://www.cms.gov/Medicare-Coverage-Database/search.aspx>
3. Social Security Act (Title XVIII) Standard References, Sections: 1862(a)(1)(A) Medically Reasonable & Necessary; 1862(a)(1)(D) Investigational or Experimental; 1833(e) Incomplete Claim; 1861(t) (1) Drugs and Biologicals
4. 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.
5. AHFS®. Available by subscription at <http://www.lexi.com>
6. Botox® (onabotulinumtoxinA) [Prescribing information]. Madison, NJ: Allergan; 7/2021.
7. DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
8. Dysport® (abobotulinumtoxinA) [Prescribing information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc.; 7/2020.
9. Dysport prescribing information [United Kingdom]. Ipsen Pharmaceuticals. Available at: <http://emc.medicines.org.uk/document.aspx?documentId=870>
10. 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.



11. Myobloc® (rimabotulinumtoxinB) [Prescribing information]. Rockville, MD: Solstice Neurosciences, Inc.; 3/2021.
12. Xeomin® (incobotulinumtoxinA) [Prescribing information]. Raleigh, NC: Merz Pharmaceuticals, LLC.; 8/2021.
13. 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>
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15. Stewart DB Sr, Gaertner W, Glasgow S, Migaly J, Feingold D, Steele SR. Clinical practice guideline for the management of anal fissures. *Dis Colon Rectum*. 2017;60(1):7-14.
16. Wald A, Bharucha AE, Limketkai B, et al. ACG clinical guidelines: management of benign anorectal disorders. *Am J Gastroenterol*. 2021;116(10):1987-2008.
17. 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: 4Q2024

Changes from previous policy version:

- New Part B policy

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

The company complies with applicable state laws and federal civil rights laws and does not discriminate, exclude people, or treat them differently on the basis of race, color, national origin, ethnic group identification, medical condition, genetic information, ancestry, religion, sex, marital status, gender, gender identity, sexual orientation, age, mental disability, or physical disability. La compañía cumple con las leyes de derechos civiles federales y estatales aplicables, y no discrimina, ni excluye ni trata de manera diferente a las personas por su raza, color, país de origen, identificación con determinado grupo étnico, condición médica, información genética, ascendencia, religión, sexo, estado civil, género, identidad de género, orientación sexual, edad, ni discapacidad física ni mental. 本公司遵守適用的州法律和聯邦民權法律，並且不會以種族、膚色、原國籍、族群認同、醫療狀況、遺傳資訊、血統、宗教、性別、婚姻狀況、性別認同、性取向、年齡、精神殘疾或身體殘疾而進行歧視、排斥或區別對待他人。