

JURISDICTION SPECIFIC MEDICARE PART B

BOTULINUM TOXINS **BOTOX (onabotulinumtoxinA)** **DYSPORE (abobotulinumtoxinA)** **MYOBLOC (rimabotulinumtoxinB)** **XEOMIN (incobotulinumtoxinA)**

POLICY

I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- A. Botox
 1. Overactive bladder
 2. Detrusor overactivity associated with a neurological condition
 3. Chronic migraine
 4. Spasticity
 5. Cervical dystonia
 6. Primary axillary hyperhidrosis
 7. Blepharospasm and strabismus
 8. Esophageal achalasia
 9. Chronic anal fissure
 10. Essential hand tremor
 11. Focal limb dystonia
 12. Hemifacial spasm
 13. Isolated oromandibular dystonia
 14. Laryngeal dystonia
 15. Simple motor tics
 16. Vocal tics
- B. Dysport
 1. Cervical dystonia
 2. Spasticity
 3. Blepharospasm
 4. Hemifacial spasm
 5. Isolated oromandibular dystonia
- C. Myobloc
 1. Cervical dystonia
 2. Chronic sialorrhea
- D. Xeomin
 1. Chronic sialorrhea
 2. Upper limb spasticity
 3. Cervical dystonia
 4. Blepharospasm

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| Reference number(s) |
| 4499-A |

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. EXCLUSIONS

Coverage will not be provided for cosmetic use.

III. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

- A. Medical record must support the use of the selected ICD-10-CM code(s). Submitted CPT/HCPCS code must describe the service performed
- B. Documentation of unsuccessful, inadequate response, or not a candidate for conventional methods of treatment and/or other appropriate methods used to control condition as applicable (a statement outlining relevant medical history is acceptable)
- C. Results of pertinent tests/procedures
- D. Type of botulinum toxin used, strength of toxin, dosage and frequency of injections
- E. Support of the clinical effectiveness of the injections
- F. Support for the medical necessity of localization procedures if performed
- G. Site(s) injected

IV. CRITERIA FOR APPROVAL

A. BOTOX

1. Overactive bladder with urinary incontinence

Authorization of 12 months may be granted for the treatment of overactive bladder with symptoms of incontinence, urgency, and frequency in adults who have had an inadequate response to or are intolerant of an anticholinergic medication.

2. Detrusor overactivity associated with a neurologic condition

Authorization of 12 months may be granted for the treatment of urinary incontinence associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in member 5 years of age or older who have had an inadequate response to or are intolerant of an anticholinergic medication.

3. Chronic migraine prophylaxis

Authorization of 6 months (two injection cycles) may be granted for the treatment of chronic migraine headache when the member has migraine headaches at least 15 days per month and headaches last 4 hours a day or longer.

4. Spasticity

Authorization of 12 months may be granted for the treatment of spasticity in members 2 years of age and older.

5. Cervical dystonia

Authorization of 12 months may be granted for the treatment of adults with cervical dystonia.

6. Primary axillary hyperhidrosis

Authorization of 12 months may be granted for the treatment of primary axillary hyperhidrosis that is inadequately managed with topical agents.

7. Blepharospasm and strabismus

Authorization of 12 months may be granted for the treatment of strabismus and blepharospasm associated with dystonia, including essential blepharospasm or VII nerve disorders in members 12 years of age and older.

8. Esophageal achalasia

Authorization of 12 months may be granted for the treatment of esophageal achalasia in adults who are considered poor surgical candidates for pneumatic dilation or surgical myotomy.

9. Chronic anal fissures

Authorization of 12 months may be granted for the treatment chronic anal fissures in members with inadequate response to conservative or pharmacologic treatment.

10. Essential hand tremor

Authorization of 12 months may be granted for the treatment of disorder of essential tremor when the following conditions are met:

- a. The member has a high amplitude tremor that disrupts activities of daily living
- b. The member experienced an inadequate response to oral pharmacotherapy such as propranolol and primidone.

11. Focal limb dystonia

Authorization of 12 months may be granted for the treatment of focal limb dystonia.

12. Hemifacial spasm

Authorization of 12 months may be granted for the treatment of hemifacial spasm (cranial nerve VII disorder) in adults.

13. Isolated oromandibular dystonia

Authorization of 12 months may be granted for the treatment of isolated oromandibular dystonia in adults.

14. Laryngeal dystonia

Authorization of 12 months may be granted for the treatment of adductor type laryngeal dystonia (adductor-type spastic dysphonia).

15. Simple motor tics

Authorization of 12 months may be granted for the treatment of bothersome simple motor tics in adolescents and adults when the benefits of treatment outweigh the risks.

16. Vocal tics

Authorization of 12 months may be granted for the treatment of severely disabling or aggressive vocal tics in older adolescents and adults when the benefits of treatment outweigh the risks.

B. DYSPORT

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1. Cervical dystonia

Authorization of 12 months may be granted for the treatment of adults with cervical dystonia.

2. Spasticity

Authorization of 12 months may be granted for the treatment of spasticity in members 2 years of age and older.

3. Blepharospasm

Authorization of 12 months may be granted for the treatment of blepharospasm in adults.

4. Hemifacial spasm

Authorization of 12 months may be granted for hemifacial spasm (cranial nerve VII disorder) in adults.

5. Isolated oromandibular dystonia

Authorization of 12 months may be granted for the treatment of isolated oromandibular dystonia in adults.

C. MYOBLOC

1. Cervical dystonia

Authorization of 12 months may be granted for the treatment of cervical dystonia in adults.

2. Chronic sialorrhea

Authorization of 12 months may be granted for the treatment of chronic sialorrhea in adults.

D. XEOMIN

1. Chronic sialorrhea

Authorization of 12 months may be granted for the treatment of chronic sialorrhea in members 2 years of age and older.

2. Upper limb spasticity in adults

Authorization of 12 months may be granted for the treatment of upper limb spasticity in adults.

3. Upper limb spasticity in pediatric members

Authorization of 12 months may be granted for the treatment of upper limb spasticity in pediatric members 2 to 17 years of age, excluding spasticity caused by cerebral palsy.

4. Cervical dystonia

Authorization of 12 months may be granted for the treatment of adults with cervical dystonia.

5. Blepharospasm

Authorization of 12 months may be granted for the treatment of blepharospasm in adults.

V. DOSAGE AND ADMINISTRATION

The lowest effective dose and longest dosing interval that produces the desired clinical effect should be used.

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VI. REFERENCES

1. Botulinum Toxins LCD (L38809) Original Version. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed February 5, 2021.
2. Billing and coding: Botulinum toxins (A58423) Original Version. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed February 5, 2021.
3. Botox [package insert]. Irvine, CA: Allergan, Inc.; July 2020.
4. Dysport [package insert]. Wrexham, UK: Ipsen Biopharm, Ltd.; July 2020.
5. Xeomin [package insert]. Dessau-Rosslau, Germany: Merz Pharmaceuticals, LLC. August 2020.
6. Myobloc [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; August 2019.