

STANDARD MEDICARE PART B MANAGEMENT

Botulinum Toxins

BOTOX (onabotulinumtoxinA)
DYSPORT (abobotulinumtoxinA)
XEOMIN (incobotulinumtoxinA)
MYOBLOC (rimabotulinumtoxinB)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses 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. FDA-Approved Indications

- i. Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- ii. Treatment of urinary incontinence due to detrusor muscle overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- iii. Prophylaxis of headaches in adult patients with chronic migraine (≥ 15 days per month with a headache lasting 4 hours a day or longer)
- iv. Treatment of spasticity in patients 2 years of age and older
- v. Treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain
- vi. Treatment of severe primary axillary hyperhidrosis that is inadequately managed by topical agents in adult patients
- vii. Treatment of blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients ≥ 12 years of age
- viii. Treatment of strabismus in patients ≥ 12 years of age

2. Compendial Uses

- i. Achalasia
- ii. Auriculotemporal syndrome
- iii. Backache
- iv. Benign prostatic hyperplasia
- v. Cervicogenic headache
- vi. Chronic anal fissures
- vii. Congenital esotropia
- viii. Detrusor and sphincter dyssynergia

- ix. Difficulty speaking after total laryngectomy
- x. Disorder of esophagus
- xi. Epicondylitis
- xii. Essential tremor disorder
- xiii. Excessive salivation secondary to advanced Parkinson's disease
- xiv. Excessive salivation secondary to a disorder of the nervous system
- xv. Excessive tear production
- xvi. Fibromyalgia
- xvii. Gilles de la Tourette's syndrome
- xviii. Granuloma of vocal cords which is refractory to conventional surgical and medical therapies
- xix. Hemifacial spasm
- xx. Isolated oromandibular dystonia
- xxi. Larynx closure as adjunct to surgical procedure
- xxii. Myofascial pain syndrome
- xxiii. Oculomotor nerve injury
- xxiv. Organic voice tremor
- xxv. Palmar hyperhidrosis
- xxvi. Pelvic floor dyssynergia
- xxvii. Pharyngoesophageal segment spasm following total laryngectomy
- xxviii. Refractory idiopathic trigeminal neuralgia
- xxix. Spastic dysphonia
- xxx. Stuttering
- xxxi. Tardive dyskinesia
- xxxii. Temporomandibular joint disorder
- xxxiii. Tension-type headache
- xxxiv. Thoracic outlet syndrome
- xxxv. Whiplash injury to neck

B. DYSPORT

1. FDA-Approved Indications

- i. Treatment of adults with cervical dystonia
- ii. Treatment of spasticity in patients 2 years of age and older

2. Compendial Uses

- i. Achalasia in patients who are surgical candidates
- ii. Blepharospasm
- iii. Hemifacial spasm

C. XEOMIN

FDA-Approved Indications

- 1. Treatment of chronic sialorrhea in adult patients
- 2. Treatment of upper limb spasticity in adult patients
- 3. Treatment of upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy
- 4. Treatment of adults with cervical dystonia
- 5. Treatment of adults with blepharospasm

D. MYOBLOC

1. FDA-Approved Indication

- i. Treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia

ii. Treatment of chronic sialorrhea in adults

2. Compendial Uses

- i. Axillary hyperhidrosis
- ii. Bladder muscle dysfunction leading to overactive bladder
- iii. Bladder spasticity secondary to a spinal cord injury
- iv. Blepharospasm
- v. Hemifacial spasm
- vi. Palmar hyperhidrosis
- vii. Spastic dysphonia
- viii. Upper limb spasticity

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. CRITERIA FOR INITIAL APPROVAL

A. BOTOX

1. **Overactive bladder with urinary incontinence**

Authorization of 12 months may be granted for the treatment of overactive bladder with urinary incontinence.

2. **Urinary incontinence 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).

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.

4. **Limb spasticity**

Authorization of 12 months may be granted for the treatment of limb spasticity including hands and feet either as a primary diagnosis or as a symptom of a condition causing limb spasticity.

5. **Cervical dystonia**

Authorization of 12 months may be granted for the treatment of adults with cervical dystonia (e.g., torticollis) when there is abnormal placement of the head with limited range of motion in the neck.

6. **Primary axillary hyperhidrosis**

Authorization of 12 months may be granted for the treatment of primary axillary hyperhidrosis.

7. **Blepharospasm**

Authorization of 12 months may be granted for the treatment of blepharospasm, including blepharospasm associated with dystonia and benign essential blepharospasm.

8. **Strabismus**

Authorization of 12 months may be granted for the treatment of strabismus.

- 9. Achalasia**
Authorization of 12 months may be granted for the treatment of achalasia.
- 10. Auriculotemporal syndrome**
Authorization of 12 months may be granted for the treatment of auriculotemporal syndrome.
- 11. Backache**
Authorization of 6 months may be granted for the treatment of chronic lower back pain.
- 12. Benign prostatic hyperplasia**
Authorization of 12 months may be granted for the treatment of benign prostatic hyperplasia.
- 13. Cervicogenic headache**
Authorization of 12 months may be granted for the treatment of cervicogenic headache.
- 14. Chronic anal fissures**
Authorization of 12 months may be granted for the treatment chronic anal fissures.
- 15. Congenital esotropia**
Authorization of 12 months may be granted for the treatment of congenital esotropia.
- 16. Detrusor and sphincter dyssynergia**
Authorization of 12 months may be granted for the treatment of detrusor and sphincter dyssynergia.
- 17. Difficulty speaking after total laryngectomy**
Authorization of 12 months may be granted for the treatment of difficulty speaking following a total laryngectomy.
- 18. Disorder of esophagus**
Authorization of 12 months may be granted for the treatment of disorder of the esophagus.
- 19. Epicondylitis**
Authorization of 12 months may be granted for the treatment of epicondylitis.
- 20. Essential tremor**
Authorization of 12 months may be granted for the treatment of disorder of essential tremor.
- 21. Excessive salivation secondary to a disorder of the nervous system or advanced Parkinson's disease**
Authorization of 12 months may be granted for the treatment of excessive salivation secondary to a disorder of the nervous system or advanced Parkinson's disease.
- 22. Excessive tear production**
Authorization of 12 months may be granted for the treatment of excessive tear production.
- 23. Fibromyalgia**
Authorization of 12 months may be granted for the treatment of fibromyalgia.
- 24. Gilles de la Tourette's syndrome**
Authorization of 12 months may be granted for the treatment of Gilles de la Tourette's syndrome.

25. Granuloma of vocal cords

Authorization of 12 months may be granted for the treatment of granuloma of the vocal cords that is refractory to conventional surgical and medical therapies.

26. Hemifacial spasm

Authorization of 12 months may be granted for the treatment of hemifacial spasm.

27. Idiopathic trigeminal neuralgia

Authorization of 12 months may be granted for the treatment of refractory idiopathic trigeminal neuralgia.

28. Isolated oromandibular dystonia

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

29. Larynx closure as adjunct to surgical procedure

Authorization of 12 months may be granted for the treatment of larynx closure as adjunct to surgical procedure.

30. Myofascial pain syndrome

Authorization of 12 months may be granted for the treatment of myofascial pain syndrome.

31. Oculomotor nerve injury

Authorization of 12 months may be granted for the treatment of oculomotor nerve injury.

32. Organic voice tremor

Authorization of 12 months may be granted for the treatment of organic voice tremor.

33. Palmar hyperhidrosis

Authorization of 12 months may be granted for the treatment of palmar hyperhidrosis.

34. Pelvic floor dyssynergia

Authorization of 12 months may be granted for the treatment of pelvic floor dyssynergia.

35. Pharyngoesophageal segment spasm following total laryngectomy

Authorization of 12 months may be granted for the treatment of pharyngoesophageal segment spasm following total laryngectomy.

36. Spastic dysphonia

Authorization of 12 months may be granted for the treatment of spastic dysphonia.

37. Stuttering

Authorization of 12 months may be granted for the treatment of stuttering.

38. Tardive dyskinesia

Authorization of 12 months may be granted for the treatment of tardive dyskinesia.

39. Temporomandibular joint disorder

Authorization of 12 months may be granted for the treatment of temporomandibular joint disorder.

40. Tension-type headache

Authorization of 12 months may be granted for the treatment of tension-type headache.

41. Thoracic outlet syndrome

Authorization for 12 months may be granted for the treatment of thoracic outlet syndrome.

42. Whiplash to the neck

Authorization for 12 months may be granted for the treatment of whiplash to the neck.

B. DYSPORT**1. Cervical dystonia**

Authorization for 12 months may be granted for the treatment of adults with cervical dystonia (e.g., torticollis) when there is abnormal placement of the head with limited range of motion in the neck.

2. Limb spasticity

Authorization for 12 months may be granted for the treatment of upper or lower limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity.

3. Achalasia

Authorization for 12 months may be granted for the treatment of achalasia.

4. Blepharospasm

Authorization for 12 months may be granted for the treatment of blepharospasm, including blepharospasm associated with dystonia and benign essential blepharospasm.

5. Hemifacial spasm

Authorization for 12 months may be granted for hemifacial spasm.

C. XEOMIN**1. Blepharospasm**

Authorization for 12 months may be granted for the treatment of blepharospasm, including blepharospasm associated with dystonia and benign essential blepharospasm.

2. Cervical dystonia

Authorization for 12 months may be granted for the treatment of adults with cervical dystonia (e.g., torticollis) when there is abnormal placement of the head with limited range of motion in the neck.

3. Upper limb spasticity

Authorization for 12 months may be granted for the treatment of upper limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity.

4. Excessive salivation

Authorization for 12 months may be granted for the treatment of excessive salivation (chronic sialorrhea).

D. MYOBLOC**1. Cervical dystonia**

Authorization for 12 months may be granted for the treatment of adults with cervical dystonia (e.g., torticollis) when there is limited range of motion in the neck.

2. Axillary hyperhidrosis

Authorization of 12 months may be granted for the treatment of primary axillary hyperhidrosis.

3. Overactive bladder with urinary incontinence

Authorization of 12 months may be granted for the treatment of overactive bladder with urinary incontinence.

4. Bladder spasticity secondary to a spinal cord injury

Authorization of 12 months may be granted for the treatment of bladder spasticity secondary to a spinal cord injury.

5. Blepharospasm

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

6. Excessive salivation

Authorization of 12 months may be granted for the treatment of excessive salivation (chronic sialorrhea).

7. Hemifacial spasm

Authorization of 12 months may be granted for hemifacial spasm.

8. Palmar hyperhidrosis

Authorization of 12 months may be granted for the treatment of palmar hyperhidrosis.

9. Spastic dysphonia

Authorization of 12 months may be granted for the treatment of spastic dysphonia.

10. Upper limb spasticity

Authorization of 12 months may be granted for the treatment of upper limb spasticity either as a primary diagnosis or as a symptom of a condition causing limb spasticity.

III. CONTINUATION OF THERAPY

Authorization of 24 months may be granted for all members (including new members) who are continuing with botulinum toxin therapy when the following criteria are met:

1. The member is currently receiving therapy with the requested botulinum toxin drug.
2. The botulinum toxin drug requested is for a diagnosis or condition enumerated in Section II.
3. The botulinum toxin drug requested has been effective for treating the diagnosis or condition.

IV. REFERENCES

1. Botox [package insert]. Irvine, CA: Allergan, Inc.; July 2020.
2. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado. Available at <http://www.micromedexsolutions.com>. Accessed July 28, 2020.
3. AHFS Drug Information. Available at <http://online.lexi.com/lco>. Accessed July 28, 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.