

# Jurisdiction Specific Medicare Part B

## Botox

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Botox	onabotulinumtoxinA

### 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.

- Overactive Bladder
- Detrusor Overactivity associated with a neurologic condition
- Chronic migraine
- Spasticity
- Cervical dystonia
- Hyperhidrosis
- Blepharospasm
- Strabismus
- Achalasia
- Anal fissure, chronic
- Auriculotemporal syndrome
- Backache
- Benign prostatic hyperplasia
- Cervicogenic headache

- Detrusor and sphincter dyssynergia
- Difficulty talking – total laryngectomy
- Disorder of esophagus
- Sialorrhea
- Epicondylitis
- Essential tremor
- Excessive tear production
- Fibromyalgia
- Gilles de la Tourette's syndrome
- Granuloma of vocal cords
- Hemifacial spasm
- Idiopathic trigeminal neuralgia, refractory
- Infantile esotropia
- Injury to oculomotor nerve (acute)
- Isolated oromandibular dystonia
- Larynx closure – adjunct to surgical procedure
- Neuropathic pain – spinal cord injury
- Organic voice tremor
- Pelvic floor dyssynergia
- Spasm of pharyngoesophageal segment – total laryngectomy
- Spastic dysphonia
- Stuttering
- Tardive dyskinesia
- Temporomandibular joint disorder
- Tension-type headache
- Thoracic outlet syndrome
- Whiplash injury to neck

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

## Exclusions

The following are exclusions to therapy:

- Treatment of wrinkles using Botulinum toxins is considered to be cosmetic and is not covered.

Reference number(s)
5204-A

- Payment will not be made for any spastic condition of smooth muscle, such as spastic colon and biliary dyskinesia.

## Coverage Criteria

### Overactive Bladder

Authorization of 12 months may be granted for treatment of overactive bladder in an adult who has been unresponsive to conventional treatment.

### Detrusor Overactivity Associated with a Neurologic Condition

Authorization of 12 months may be granted for treatment of over activity associated with a neurologic condition in a member 5 years of age and older with an inadequate response to an oral anticholinergic agent.

### Chronic Migraine

Authorization of 6 months may be granted for the prophylaxis of headaches in an adult with chronic migraine when all of the following criteria are met:

- Headache on 15 or more days per month, of which at least 8 headache days per month meet criteria for migraine without aura or respond to migraine-specific treatment.
- Member has significant disability due to the headaches.
- Member has been refractory to standard and usual conventional therapy.

### Spasticity

Authorization of 12 months may be granted for treatment of upper and lower limb spasticity in a member 2 years of age or older.

### Cervical Dystonia

Authorization of 12 months may be granted for treatment of cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia (spasmodic torticollis) in an adult.

### Hyperhidrosis

Authorization of 12 months may be granted for treatment of severe primary axillary hyperhidrosis (primary focal hyperhidrosis) in an adult when all of the following criteria are met:

- Member has focal, visible, severe sweating of at least six (6) months duration without apparent cause with at least two (2) of the following characteristics: bilateral and relatively symmetric, significant impairment in daily activities, age of onset less than 25 years, positive family history, and cessation of focal sweating during sleep.
- Member is inadequately managed with topical therapy.

## Blepharospasm

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

## Strabismus

Authorization of 12 months may be granted for treatment of strabismus in a member 12 years of age and older.

## Achalasia

Authorization of 12 months may be granted for treatment of achalasia when any of the following criteria are met:

- Member has not responded satisfactorily to conventional therapy.
- Member is at high risk of complication from pneumatic dilation or surgical myotomy.
- Member has had treatment failure with pneumatic dilation or surgical myotomy.
- Member had perforation from pneumatic dilation.
- Member has an epiphrenic diverticulum or hiatal hernia.
- Member has esophageal varices.

## Anal Fissure, Chronic

Authorization of 12 months may be granted for treatment of chronic anal fissure in adult who has not responded satisfactorily to conventional therapy.

## Auriculotemporal Syndrome

Authorization of 12 months may be granted for treatment of auriculotemporal syndrome (also known as Frey syndrome) in an adult that has been unresponsive to conventional methods of treatments.

## Backache

Authorization of 6 months may be granted for treatment of chronic lower back pain in an adult who has been unresponsive to conventional treatment.

## Benign Prostatic Hyperplasia

Authorization of 12 months may be granted for treatment of benign prostatic hyperplasia in an adult who has been unresponsive to conventional treatment.

## Cervicogenic Headache

Authorization of 12 months may be granted for treatment of cervicogenic headache (also known as whiplash headache) in an adult who has been unresponsive to conventional treatment.

## Detrusor and Sphincter Dyssynergia

Authorization of 12 months may be granted for treatment of detrusor sphincter dyssynergia (DSD) in an adult that has been unresponsive to conventional methods of treatments.

## Difficulty Talking – Total Laryngectomy

Authorization of 12 months may be granted for treatment of voice failure after tracheoesophageal puncture (TEP) and prosthesis placement after total laryngectomy in an adult who has been unresponsive to conventional methods of treatments.

## Disorder of Esophagus

Authorization of 12 months may be granted for treatment of esophageal motility disorder in an adult who has been unresponsive to conventional treatment.

## Sialorrhea

Authorization of 12 months may be granted for treatment of chronic sialorrhea in a member 2 years of age and older who has failed to respond to a reasonable trial of traditional therapies (e.g., anticholinergics and speech therapy) or who have a contraindication to or cannot tolerate anticholinergic therapy.

## Epicondylitis

Authorization of 12 months may be granted for treatment of lateral humeral epicondylitis (tennis elbow) for an adult who did not respond to conventional treatment.

## Essential Tremor

Authorization of 12 months may be granted for treatment of essential hand tremor in an adult who has been unresponsive to conventional treatment.

## Excessive Tear Production

Authorization of 12 months may be granted for treatment of excessive tear production in an adult that has been unresponsive to conventional methods of treatments.

## Fibromyalgia

Authorization of 12 months may be granted for treatment of fibromyalgia in an adult.

## Gilles de la Tourette's Syndrome

Authorization of 12 months may be granted for treatment of tics and associated premonitory symptoms in a member with Tourette syndrome in an adult.

## Granuloma of Vocal Cords

Authorization of 12 months may be granted for treatment of vocal fold granulomas in an adult who was refractory to conventional surgical and medical therapies.

## Hemifacial Spasm

Authorization of 12 months may be granted for treatment of hemifacial spasm in an adult.

## Idiopathic Trigeminal Neuralgia

Authorization of 12 months may be granted for treatment of refractory idiopathic trigeminal neuralgia in an adult that has been unresponsive to conventional methods of treatments.

## Infantile Esotropia

Authorization of 12 months may be granted for treatment of an infant with esotropia who has been unresponsive to conventional methods of treatments.

## Injury to Oculomotor Nerve

Authorization of 12 months may be granted for treatment of acute injury to oculomotor nerve in an adult.

## Isolated Oromandibular Dystonia

Authorization of 12 months may be granted for treatment of isolated oromandibular dystonia in an adult.

## Larynx Closure as Adjunct to Surgical Procedure

Authorization of 12 months may be granted for treatment of a member requiring larynx closure as adjunctive therapy to surgical procedures of the larynx.

## Neuropathic pain – spinal cord injury

Authorization of 12 months may be granted for treatment of spinal cord injury-associated neuropathic pain in an adult.

## Organic Voice Tremor

Authorization of 12 months may be granted for treatment of organic voice tremor in an adult who has been unresponsive to conventional methods of treatments.

## Pelvic Floor Dyssynergia

Authorization of 12 months may be granted for treatment of pelvic floor dyssynergia in an adult who has been unresponsive to conventional methods of treatments.

## Spasm of Pharyngoesophageal Segment – Total laryngectomy

Authorization of 12 months may be granted for treatment of pharyngoesophageal segment spasm following total laryngectomy in an adult who has been unresponsive to conventional methods of treatments.

## Spastic Dysphonia

Authorization of 12 months may be granted for treatment of adductor spasmodic dysphonia (e.g., laryngeal dystonia) in an adult.

## Stuttering

Authorization of 12 months may be granted for treatment of stuttering in an adult.

## Tardive Dyskinesia

Authorization of 12 months may be granted for treatment of symptoms of tardive dyskinesias associated with long-term neuroleptic use in an adult.

## Temporomandibular Joint Disorder

Authorization of 12 months may be granted for treatment of temporomandibular joint disorders in an adult.

## Tension Headache

Authorization of 6 months may be granted for treatment of chronic tension-type headache in an adult when all of the following criteria are met:

- Headache disorder occurs greater than 15 days a month (in many cases daily with a duration of four or more hours - for a period of at least 3 months).
- Member has significant disability due to the headaches.
- Member has been refractory to standard and usual conventional therapy.

## Thoracic Outlet Syndrome

Authorization of 12 months may be granted for treatment of symptoms associated with thoracic outlet syndrome in an adult.

## Whiplash Injury to Neck

Authorization of 12 months may be granted for treatment of chronic whiplash-associated neck pain in an adult.

## Continuation of Therapy

- Failure of two definitive, consecutive, treatment sessions involving a muscle or group of muscles could preclude further coverage of the serotype used in the treatment for a period of one year after the second session. It may be reasonable, however, to attempt treatment with a different serotype.
- Authorization of 12 months may be granted for treatment of chronic tension-type headache or chronic migraine when the member demonstrates a significant decrease in the number and frequency of headaches and an improvement in function upon receiving Botulinum toxin.

## Dosage and Administration

It is generally not considered medically necessary to give Botulinum toxin injections for spastic or excess muscular contraction conditions more frequently than every 90 days.

## References

1. Botulinum Toxins (L33949) Version R18. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed July 23, 2024.
2. Billing and Coding: Botulinum Toxins (A56472) Version R11. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed July 23, 2024.
3. Botox [package insert]. Madison, NJ: Allergan USA Inc; November 2024.
4. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado. Available at <http://www.micromedexsolutions.com>. Accessed July 23, 2024.