

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

Reference number(s)
5218-A

- 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.

Coverage Criteria

Overactive bladder

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Authorization of 12 months may be granted for treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in an adult who has an inadequate response to or is intolerant of an anticholinergic medication.

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 anticholinergic treatment.

Chronic Migraine

Authorization of 6 months may be granted for the prophylaxis of headaches in an adult patient with chronic migraine (15 or more days per month with headache lasting 4 hours a day or longer).

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 when all of the following criteria are met:

- Severe is defined for this purpose as level 3 (sweating barely tolerable/frequently interferes with daily activity) or level 4 (sweating intolerable/always interferes with daily activities) on the Hyperhidrosis Disease Severity Scale (HDSS).
- Member is inadequately managed with topical agents.

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 the lower esophageal sphincter in the management of achalasia.

Anal fissure, chronic

Authorization of 12 months may be granted for treatment of chronic anal fissure.

Auriculotemporal syndrome

Authorization of 12 months may be granted for treatment of auriculotemporal syndrome (also known as Frey syndrome).

Backache

Authorization of 6 months may be granted for treatment of chronic lower back pain.

Benign prostatic hyperplasia

Authorization of 12 months may be granted for treatment of benign prostatic hyperplasia.

Cervicogenic headache

Authorization of 12 months may be granted for treatment of cervicogenic headache (also known as whiplash headache).

Detrusor and sphincter dyssynergia

Authorization of 12 months may be granted for treatment of detrusor sphincter dyssynergia (DSD).

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.

Disorder of esophagus

Authorization of 12 months may be granted for treatment of esophageal motility disorder.

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Sialorrhea

Authorization of 12 months may be granted for treatment of sialorrhea (excessive salivation) in a member with a neurologic disorder.

Epicondylitis

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

Essential tremor

Authorization of 12 months may be granted for treatment of essential hand tremor.

Excessive tear production

Authorization of 12 months may be granted for treatment of excessive tear production.

Fibromyalgia

Authorization of 12 months may be granted for treatment of fibromyalgia.

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.

Granuloma of vocal cords

Authorization of 12 months may be granted for treatment of vocal fold granulomas that were refractory to conventional surgical and medical therapies.

Hemifacial spasm

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

Idiopathic trigeminal neuralgia

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

Infantile esotropia

Authorization of 12 months may be granted for treatment of infants with esotropia.

Injury to oculomotor nerve

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

Isolated oromandibular dystonia

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

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.

Pelvic floor dyssynergia

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

Spasm of pharyngoesophageal segment

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

Spastic dysphonia

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

Stuttering

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

Tardive dyskinesia

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

Temporomandibular joint disorder

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

Tension headache

Authorization of 6 months may be granted for treatment of tension headache when any of the following criteria are met:

- Member failed trials of at least 3 preventive pharmacologic migraine therapies (e.g., beta-blockers, anticonvulsants, antidepressants) with or without concomitant behavioral and physical therapies, after titration to maximal tolerated doses or have medical contraindications to common therapies or who cannot tolerate common preventative therapies.
- Member experiences chronic daily headaches more than 15 days per month or recurrent headaches at least twice per month causing disability lasting 3 or more days per month.
- Standard abortive medication is required more than twice per week, or is contraindicated, ineffective or not tolerated.

Thoracic outlet syndrome

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

Whiplash injury to neck

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

Dosage and Administration

Chemodenervation treatment has a variable lasting beneficial effect from 12 to 16 weeks, following which the procedure may need to be repeated. It is appropriate to inject the lowest clinically effective dose at the

greatest feasible interval that results in the desired clinical result. Services performed for excessive frequency are not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers, and the reason for additional services is not justified by documentation.

References

1. Chemodenervation LCD (L33458) Version R24. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed July 25, 2024.
2. Billing and Coding: Chemodenervation (A56646) Version R10. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed July 25, 2024.
3. Botox [package insert]. Madison, NJ: Allergan USA Inc; November 2023.
4. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado. Available at <http://www.micromedexsolutions.com>. Accessed July 25, 2024.