

Jurisdiction Specific Medicare Part B Myobloc

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
Myobloc	rimabotulinumtoxinB

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.

- Cervical dystonia
- Chronic sialorrhea
- Hyperhidrosis
- Incontinence – Spinal cord injury
- Overactive bladder
- Spastic dysphonia
- 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.

Exclusions

The following are exclusions to therapy:

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

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

Coverage Criteria

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.

Chronic Sialorrhea

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

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.

Incontinence – Spinal cord injury

Authorization of 12 months may be granted for treatment of bladder spasticity in a spinal cord injury in an adult with an inadequate response to an oral anticholinergic agent.

Overactive bladder

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

Spastic dysphonia

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

Upper limb spasticity

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

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 R16. Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed August 15, 2024.
2. Billing and Coding: Botulinum Toxins (A56472) Version R8. Available at: Available at: <https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>. Accessed August 15, 2024.
3. Myobloc [package insert]. Rockville, MD: Solstice Neurosciences, LLC.; March 2021.
4. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado. Available at <http://www.micromedexsolutions.com>. Accessed August 15, 2024.