

Reference number(s)
5240-A

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.

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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.

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.

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 anticholinergic treatment.

Overactive bladder

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.

Spastic dysphonia

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

Upper limb spasticity

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

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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 August 15, 2024.
2. Billing and Coding: Chemodenervation (A56646) Version R8. 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. DRUGDEX® System (electronic version). Truven Health Analytics, Greenwood Village, Colorado. Available at <http://www.micromedexsolutions.com>. Accessed August 15, 2024.