

# Specialty Guideline Management

## 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	rimabotulinumtoxin B

### 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.

#### FDA-approved Indications

- Treatment of cervical dystonia in adults to reduce the severity of abnormal head position and neck pain associated with cervical dystonia
- Treatment of chronic sialorrhea in adults

#### Compendial Uses

- Primary axillary and palmar hyperhidrosis
- Upper limb spasticity

All other indications are considered experimental/investigational and not medically necessary.

### Prescriber Specialties

The medication must be prescribed by or in consultation with a provider specialized in treating the member's condition.

Reference number(s)
2249-A

## Exclusions

Coverage will not be provided for cosmetic use.

## Coverage Criteria

### Cervical dystonia

Authorization of 12 months may be granted for treatment of adults with cervical dystonia (e.g., torticollis) when all of the following are met:

- Member is 18 years of age or older
- Member has abnormal placement of the head with limited range of motion in the neck

### Chronic Sialorrhea (excessive salivation)

Authorization of 12 months may be granted for treatment of chronic sialorrhea (excessive salivation) when all of the following are met:

- Member is 18 years of age or older
- Member is refractory to pharmacotherapy (e.g., anticholinergics)

### Primary axillary and palmar hyperhidrosis

Authorization of 12 months may be granted for treatment of primary axillary or palmar hyperhidrosis when all of the following criteria are met:

- Significant disruption of professional and/or social life has occurred because of excessive sweating; and
- Topical aluminum chloride or other extra-strength antiperspirants are ineffective or result in a severe rash.

### Upper limb spasticity

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

## Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria and be experiencing benefit from therapy.

## References

Reference number(s)
2249-A

1. Myobloc [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; March 2021.
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3. AHFS Drug Information. <http://online.lexi.com/lco>. Accessed August 14, 2024.
4. Lexi-Drugs. Hudson, OH: Lexicomp, 2019. <http://online.lexi.com/>. Accessed August 14, 2024.
5. Simpson DM, Hallett M, Ashman EJ et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology* 2016; 86 (19) 1818-1826.
6. Lakraj AA, Moghimi N, Jabbari B. Sialorrhea: Anatomy, Pathophysiology and Treatment with Emphasis on the Role of Botulinum Toxins. *Toxins* 2013, 5, 1010-1031
7. Glader L, Delsing C, Hughes A et al. Sialorrhea in cerebral palsy. *American Academy for Cerebral Palsy and Developmental Medicine Care Pathways*. <https://www.aacpdm.org/publications/care-pathways/sialorrhea>. Accessed August 14, 2024.
8. Garuti G, Rao F, Ribuffo V et al. Sialorrhea in patients with ALS: current treatment options. *Degener Neurol Neuromuscul Dis*. 2019; 9: 19–26.