UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Botulinum Toxins – Myobloc Utilization Management Medical Policy
- Myobloc® (rimabotulinumtoxinB injection – Solstice)

REVIEW DATE: 09/23/2026

OVERVIEW

Myobloc (rimabotulinumtoxinB), an acetylcholine release inhibitor and neuromuscular-blocking agent, is indicated for the following uses:[1]

- **Cervical dystonia,** to reduce the severity of abnormal head position and neck pain associated with cervical dystonia in adults.
- **Sialorrhea, chronic** in adults.

Other Uses with Supportive Evidence

Spasticity, Upper Limb: In the 2016 American Academy of Neurology guidelines (reaffirmed 2022), Myobloc is supported for use in adult upper limb spasticity (Level B; probably effective).[2] Of note, evidence is insufficient for Myobloc in the setting of lower limb spasticity (Level U). Botulinum toxin type B was shown to be effective in reducing spasticity in a randomized, double-blind, placebo-controlled study (n = 24) in hemiparetic patients with disabling elbow flexor overactivity after stroke or traumatic brain injury.[3] In one small, randomized, double-blind, placebo-controlled study in patients with upper-limb post-stroke spasticity (n = 15), Myobloc reduced spasticity at 2 weeks but was not statistically significant at other follow-up visits.[4]

Dosing Information

Potency units are specific to each botulinum toxin product and are not interchangeable with, or directly convertible to, the units of another botulinum toxin product.[1]

Definitive dosing has not been established for off-label uses of botulinum toxins, including Myobloc. In two placebo-controlled trials evaluating Myobloc for **upper limb spasticity**, total doses administered to the single affected arm ranged from 10,000 to 15,000 units.[3,4]

Safety

Botulinum toxin products carry a Boxed Warning regarding the risk of distant spread of toxin effect.[1] Postmarketing reports suggest symptoms consistent with botulinum toxin effects may occur beyond the injection site and may include asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. Serious cases, including life-threatening swallowing and breathing difficulties, have been reported.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Myobloc. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Requests for doses outside the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the dosing interval is provided in months, 1 month is equal to 30 days.

Medical benefit coverage is not recommended for cosmetic use.

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Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Myobloc is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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1. **Cervical Dystonia**. Approve for 1 year if the patient is ≥ 18 years of age.
   Note: Cervical dystonia is also known as spasmodic torticollis.

   Dosing. Approve up to a maximum dose of 10,000 units (not to exceed 5,000 units for initial dose), administered not more frequently than once every 12 weeks.

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2. **Sialorrhea, Chronic.** Approve for 1 year if the patient is ≥ 18 years of age.

   Dosing. Approve up to a maximum dose of 3,500 units (1,750 units per side), administered not more frequently than once every 12 weeks.

Other Uses with Supportive Evidence

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3. **Spasticity, Upper Limb.** Approve for 1 year if the patient is ≥ 18 years of age.

   Dosing. Approve up to a maximum dose of 15,000 units, administered not more frequently than once every 12 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Myobloc is not recommended in the following situations:

1. **Cosmetic Use.** Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical medical benefit.
   Note: Examples of cosmetic uses include facial rhytids, frown lines, glabellar wrinkling, horizontal neck rhytids, mid and lower face and neck rejuvenation, platysma bands, or rejuvenation of the periorbital region.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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REFERENCES

1. Myobloc® injection [prescribing information]. San Francisco, CA: Solstice Neurosciences; August 2025.
2. 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;86:1818-1826.
3. Gracies JM, Bayle N, Goldberg S, et al. Botulinum toxin type B in the spastic arm: a randomized, double-blind, placebo-controlled, preliminary study. *Arch Phys Med Rehabil.* 2014;95:1303-1311.
4. Brashear A, McAfee AL, Kuhn ER, et al. Botulinum toxin type B in upper-limb poststroke spasticity: a double-blind, placebo-controlled trial. *Arch Phys Med Rehabil*. 2004;85(5):705-709.
5. Walker TJ, Dayan SH. Comparison and overview of currently available neurotoxins. *Clin Aesthet Dermatol*. 2014;7(21):31-39.
6. Botox® injection [prescribing information]. Madison, NJ: Allergan; November 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	**Cervical Dystonia**: The following Note was added: Cervical dystonia is also known as spasmodic torticollis.	09/25/2024
Annual Revision	No criteria changes.	09/17/2025
Annual Revision	**Cervical Dystonia**: The maximum dosing limitation was updated from 5,000 to 10,000 units with clarification of not to exceed 5,000 units for initial dose. **Spasticity, Upper Limb**: The maximum dosing limitation was updated from 20,000 every 3 months to 15,000 units every 12 weeks.	09/23/2026

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