Drug Coverage Policy

Effective Date..... 11/15/2025
Coverage Policy Number IP0509
Policy Title..... Myobloc

Botulinum Toxins – Myobloc

- Myobloc® (rimabotulinumtoxinB injection – Solstice Neurosciences)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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(s): 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
Toxin distribution varies between the commercially available botulinum toxin products.[1] Labeling for the botulinum toxin products states there is a lack of interchangeability between the products for various reasons, including differences in the units of biological activity.[5]

Definitive dosing has not been established for off-label uses of botulinum toxins, including Myobloc. [5] For **Spasticity, Upper Limb**, the Botox prescribing information states that in a 3-month interval, an adult should not exceed a total dose of 400 units.[6]

Coverage Policy

Policy Statement
Prior Authorization is required for benefit coverage of Myobloc. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. 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.

Benefit coverage is not recommended for cosmetic use.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information.

Myobloc is considered medically necessary when the following criteria are met:

FDA-Approved Indications

1. **Cervical Dystonia**. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   Note: Cervical dystonia is also known as spasmodic torticollis.
   A) Patient is ≥ 18 years of age; AND
   B) Patient has a diagnosis of cervical dystonia **[documentation required]**; AND
   C) Patient has sustained head torsion and/ or tilt with limited range of motion in the neck **[documentation required]**; AND
   D) Prescribed by or in consultation with a pain medicine specialist, neurologist, or physical medicine and rehabilitation physician

   Dosing. Approve up to a maximum dose of 5,000 units, administered not more frequently than once every 12 weeks.

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

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

   Dosing. Approve up to a maximum dose of 20,000 units, administered not more frequently than once every 3 months.

Conditions Not Covered

Myobloc (rimabotulinumtoxinB) for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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 rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platysmal bands, or rejuvenation of the periorbital region.

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Cervical Dystonia

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)

HCPCS Codes	Description
J0587	Injection, rimabotulinumtoxinB, 100 units

Sialorrhea, Chronic

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
64611	Chemodenervation of parotid and submandibular salivary glands, bilateral

HCPCS Codes	Description
J0587	Injection, rimabotulinumtoxinB, 100 units

Spasticity, Upper Limb(s)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
64642	Chemodenervation of one extremity; 1-4 muscle(s)
64643	Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (List separately in addition to code for primary procedure)
64644	Chemodenervation of one extremity; 5 or more muscles
64645	Chemodenervation of one extremity; each additional extremity, 5 or more muscles (List separately in addition to code for primary procedure)
64646	Chemodenervation of trunk muscle(s); 1-5 muscle(s)
64647	Chemodenervation of trunk muscle(s); 6 or more muscles

HCPCS Codes	Description
J0587	Injection, rimabotulinumtoxinB, 100 units

***Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.**

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.

Revision Details

Summary of Changes	Review Date	Effective Date
Policy Title **Updated from** "RimabotulinumtoxinB" **to** "Botulinum Toxins – Myobloc." **<u>Cervical Dystonia</u>** **Updated** *cervical dystonia* criteria for approval to require a screen patient is at least 18 years of age, documentation for diagnosis, documentation of head torsion with limited range of motion, specialist requirement. **Updated** dosing for use of Myobloc to treat *cervical dystonia* **from** "**<u>Dosing.</u>** The recommended dose for Cervical Dystonia is up to a maximum dose of 10,000 units, administered not more frequently than once every 12 weeks" **to** "**Dosing.** Approve up to a maximum dose of 5,000 units, administered not more frequently than once every 12 weeks". **<u>Chronic Sialorrhea</u>** **Updated** criteria to screen for age only. **<u>Limb Spasticity</u>** **Updated** criteria to screen for age only. **Conditions Not Covered** **Updated** *conditions not covered* to only screen for cosmetic uses; no other uses listed to be excluded from coverage for *conditions not covered*. **Coding Information:** **Added CPT coding tables for the following codes**: 64616, 64611, 64642, 64643, 64644, 64645, 64646, 64647	5/22/2025	7/15/2025
Updated policy template	10/16/2025	11/15/2025

The policy effective date is in force until updated or retired.

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