Drug Coverage Policy

Effective Date.....7/15/2025
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** 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).

Dosing Information
Definitive dosing has not been established for off-label uses of botulinum toxins, including Myobloc. Recommendations for maximum dosing and frequency for Myobloc are based on a suggested relative conversion of 50:1 between Myobloc and Botox units.[3] For **Spasticity, Upper Limb**, dosing is based on the Botox prescribing information, which states that in a 3-month interval, adults should not exceed a total dose of 400 units.[4]

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Policy Statement
Prior Authorization is recommended for prescription benefit coverage of Myobloc. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Myobloc as well as the monitoring required for adverse events and long-term efficacy, approval requires Myobloc to be prescribed by a physician who has consulted with or who specializes in the condition.

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

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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.

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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(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.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

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 Uses.** 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

<u>Spasticity, Upper Limb(s)</u>
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

References

1. Myobloc® injection [prescribing information]. San Francisco, CA: Solstice Neurosciences; December 2023.
2. Simpson DM, Hallett M, Ashman EJ, et al. Practice guidelines 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. Walker TJ, Dayan SH. Comparison, and overview of currently available neurotoxins. *Clin Aesthet Dermatol*. 2014;7(21):31-39.
4. Botox® injection [prescribing information]. Madison, NJ: Allergan; November 2023.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**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.	7/15/2025

	Updated dosing for use of Myobloc to treat *cervical dystonia* **from** "**Dosing.** 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". **Chronic Sialorrhea** **Updated** criteria to screen for age only. **Limb Spasticity** **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	

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