Effective Date **2/15/2023**
Next Review Date… **2/15/2024**
Coverage Policy Number **IP0509**

RimabotulinumtoxinB

Table of Contents

Related Coverage Resources

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. 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

This policy supports medical necessity review for rimabotulinumtoxinB (Myobloc®).

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

Initial Approval Criteria

RimabotulinumtoxinB (Myobloc) is considered medically necessary for the treatment of Cervical Dystonia (including spasmodic torticollis) when the individual meets ALL of the following criteria:

1. Documentation of BOTH of the following:
    a. Involuntary, simultaneous activation of agonist and antagonist muscles of the neck and shoulder (for example, sternocleidomastoid, splenius, levator scapulae, trapezius, semispinalis, scalene)
    b. Sustained head torsion and/or tilt with limited range of motion in the neck

2. Medication is prescribed by, or in consultation with, a board certified pain management specialist, a neurologist or a physical medicine and rehabilitation physician

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.

RimabotulinumtoxinB (Myobloc) is considered medically necessary for the treatment of Chronic Sialorrhea when the medication is prescribed by, or in consultation with, an endocrinologist, a neurologist or an otolaryngologist.

Dosing. The recommended dose for Chronic Sialorrhea is up to a maximum dose of 3,500 units (1,750 units per side), administered not more frequently than once every 12 weeks

---

RimabotulinumtoxinB (Myobloc) is considered medically necessary for the treatment of Limb Spasticity when the individual meets ALL of the following criteria:

1. 18 years of age or older
2. Documentation of significant decrease of function or Activities of Daily Living (for example, walking, washing, eating)
3. Medication is prescribed by, or in consultation with, a board certified pain management specialist, a neurologist or a physical medicine and rehabilitation physician

Dosing. The recommended dose for Limb Spasticity is 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.

Continuation of Therapy

Continuation of Myobloc is considered medically necessary when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial authorization is up to four (4) treatments in a 12 month period (one [1] treatment every 90 days).

If the initial approval criteria (listed above) are met AND clinical improvement with previous rimabotulinumtoxinB therapy is documented but duration of benefit is less than 90 days/treatment, then up to six treatments in a 12 month period (one treatment per 60 days) may be considered on a case-by-case basis.

Reauthorization approval duration: up to 12 months

Conditions Not Covered

Cosmetic use is considered not medically necessary.

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. Bruxism
2. Chronic low back pain

3. Gastroparesis
4. Headache, including Cervicogenic headache
5. Chronic daily headache
6. Migraine
7. Menstrual headache (for example, 90% of attacks generally occur between two days before menses and the last day of menses)
8. Tension-type headache
9. Hemorrhoid pain
10. Lateral epicondylitis
11. Nausea and vomiting, post sleeve gastrectomy
12. Myofascial pain
13. Hyperhidrosis
14. Spastic pelvic floor syndrome
15. Sphincter of Oddi dysfunction
16. Temporomandibular joint (TMJ) syndrome
17. Tics
18. Trigeminal Neuralgia
19. Voiding dysfunction associated with benign prostatic hyperplasia

Coding Information

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.

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

HCPCS Codes	Description
J0587	Injection, rimabotulinumtoxinB, 100 units

Background

OVERVIEW
Myobloc (rimabotulinumtoxinB) is indicated for the following uses:[1]

- **Cervical Dystonia** in adults.
- **Sialorrhea, chronic** in adults.

Other Uses with Supportive Evidence
Botulinum toxins, including Myobloc, have been studied in a variety of indications outside of FDA-approved uses. Literature is available to support use of Myobloc in the following condition:

- **Limb Spasticity:** Botulinum toxin type B was shown to be effective in a randomized, double-blind, placebo-controlled study (n = 24) in hemiparetic patients with disabling elbow flexor overactivity after stroke or traumatic brain injury.[2] 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.[3]

Dosing Considerations
The recommended initial dosage of Myobloc for cervical dystonia patients with a prior history of tolerating botulinum toxin injections is 2,500 Units to 5,000 Units divided among affected muscles. Patients without a prior history of tolerating botulinum toxin injections should receive a lower initial dosage. Subsequent dosing should be determined by the patient's individual response. The duration of effect in patients responding to Myobloc treatment for cervical dystonia has been observed in studies to be between 12 and 16 weeks at doses of 5,000 Units or 10,000 Units.[1]

The recommended dosage of Myobloc for chronic sialorrhea is 1,500 Units to 3,500 Units, divided among the parotid and submandibular glands. Patient response to treatment should be considered when determining subsequent Myobloc dosage. The typical duration of effect of each treatment is up to 3 months; however, the effect may vary in individual patients. The frequency of Myobloc repeat treatments should be determined by clinical response but should generally be no more frequent than every 12 weeks.[1]

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 (onabotulinumtoxinA) units.[4] For off-label indications addressed in this policy, specific dosing guidance is not available. In these cases, 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.[5]

Myobloc is a clear and colorless to light-yellow solution available as: 2,500 Units/0.5 mL in a single-dose vial, 5,000 Units/mL in a single-dose vial, and 10,000 Units/2 mL (5,000 Units/mL) in a single-dose vial.[1]

References

1. Myobloc® injection [prescribing information]. San Francisco, CA: Solstice Neurosciences; September 2020.
2. 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.
3. 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.
4. Walker TJ, Dayan SH. Comparison and overview of currently available neurotoxins. *Clin Aesthet Dermatol*. 2014;7(21):31-39.
5. Botox® injection [prescribing information]. Madison, NJ: Allergan; July 2021.