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5.75.003

Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Neuromuscular Drugs	**Original Policy Date:**	October 27, 2001
Subject:	Myobloc	**Page:**	1 of 4

Last Review Date: December 8, 2023

Myobloc

Description

Myobloc (rimabotulinumtoxin B)

Background
Rimabotulinumtoxin is a protein neurotoxin produced by the bacterium *Clostridium botulinum.* Myobloc acts as a neuromuscular blocking agent that works by preventing the release of neurotransmitters. This produces a paralyzing effect of the surrounding area of injection (1).

Regulatory Status
FDA-approved indications: Myobloc is indicated for: (1)

1. the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia
2. the treatment of chronic sialorrhea in adults

Myobloc has a boxed warning regarding the distant spread of toxin effect. The effects of Myobloc and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties that can be life threatening and there have been reports of deaths. The risk of symptoms is probably greatest in patients who have underlying conditions that would predispose them to these symptoms (1).

Safety and effectiveness have not been established in patients under the age of 18 years of age (1).

Related policies
Botox, Dysport, Xeomin

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Myobloc may be considered **medically necessary** if the conditions indicated below are met.

Myobloc may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Cervical dystonia (spasmodic torticollis)
2. Excessive salivation (sialorrhea)

AND the following:

1. **NO** dual therapy with other botulinum toxins

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Rimabotulinumtoxin is a protein neurotoxin produced by the bacterium *Clostridium botulinum.* Myobloc has a boxed warning regarding the distant spread of toxin effect after injection. Safety and effectiveness have not been established in patients under the age of 18 years of age (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Myobloc while maintaining optimal therapeutic outcomes.

References

1. Myobloc [prescribing Information]. Louisville, KY: Solstice Neurosciences, LLC; March 2021.

Policy History

Date	Action
July 2005	Use of botulinum toxin for treatment of intractable migraine headache is recognized as clinically appropriate therapy. MCMC (the external physician review organization) has approved 100% of these requests for the time period of October 2002 to June 2003.
August 2009	On August 3, 2009, the FDA announced it was changing the generic names for both Botox and Myobloc to avoid medication errors. Botox's new generic name is onabotulinumtoxinA, after previously being known as botulinum toxin type A. Myobloc's new generic name is rimabotulinumtoxinB, after previously being called botulinum toxin type B.
December 2012	Annual review-no change in policy statement. Reference and editorial updates.

September 2014	Annual editorial review and reference update. Change age to 18 and remove criteria for migraine headache. This diagnosis is not FDA approved for this botulinum toxin
September 2015	Annual editorial review.
December 2016	Annual editorial review Addition of no dual therapy with other botulinum toxins to criteria Policy number change from 5.12.03 to 5.75.03
September 2017	Annual review
September 2018	Annual review
September 2019	Annual review. Addition of sialorrhea indication
September 2020	Annual review
June 2021	Annual review
June 2022	Annual review and reference update
June 2023	Annual review. Changed policy number to 5.75.003
December 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.