BlueCross BlueShield Federal Employee Program

MYOBLOC (rimabotulinumtoxin B)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

Cosmetic indications are excluded from coverage.

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.