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 indication: 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** for patients 18 years of age and older for the treatment of cervical dystonia or sialorrhea.

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
Section: Prescription Drugs  Effective Date: October 1, 2019
Subsection: Neuromuscular Drugs  Original Policy Date: October 27, 2001
Subject: Myobloc  Page: 3 of 4

Prior - Approval Limits
Duration  12 months

Prior – Approval *Renewal Limits*
Duration  12 months

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

Policy History
<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 2005</td>
<td>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.</td>
</tr>
<tr>
<td>August 2009</td>
<td>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.</td>
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<tr>
<td>December 2012</td>
<td>Annual review-no change in policy statement. Reference and editorial updates.</td>
</tr>
<tr>
<td>September 2014</td>
<td>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</td>
</tr>
</tbody>
</table>
### Section: Prescription Drugs  
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### Subsection: Neuromuscular Drugs  
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<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>September 2015</td>
<td>Annual editorial review.</td>
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</tbody>
</table>
| 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 |

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.