Xeomin

Description

Xeomin (incobotulinumtoxinA)

Background
Xeomin (incobotulinumtoxinA) is an acetylcholine release inhibitor indicated for upper limb spasticity, cervical dystonia and blepharospasm. Xeomin 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. Xeomin differs from the other available botulinum toxins as it is free from complexing proteins, or bacterial proteins other than the active toxin. The theoretical advantage of a more pure product is that with high doses there is reduced sensitization and antibody formation. The three formulations of Botulinum toxin A (Botox, Dysport, and Xeomin) are each purified using different methods and are not interchangeable. Xeomin is the only botulinum toxin that does not require refrigeration prior to reconstitution (1).

Regulatory Status
FDA-approved indication: Xeomin is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the treatment of: (1)
1. Upper limb spasticity
2. Cervical dystonia
3. Blepharospasm in adults previously treated with onabotulinumtoxinA (Botox).

Xeomin has a boxed warning regarding the distant spread of toxin effect. The effects of Xeomin and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. 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 death. 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, Myobloc

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

Xeomin may be considered medically necessary for patients 18 years of age and older for the treatment of cervical dystonia, blepharospasm, or upper limb spasticity.

Xeomin 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. Blepharospasm
3. Upper limb spasticity

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

Duration 12 months

Rationale

Summary

Xeomin (incobotulinumtoxinA) is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for upper limb spasticity, cervical dystonia and blepharospasm. Xeomin differs from the other available botulinum toxins as it is free from complexing proteins, or bacterial proteins other than the active toxin. Xeomin 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 approval is required to ensure the safe, clinically appropriate and cost effective use of Xeomin while maintaining optimal therapeutic outcomes.

References


Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2012</td>
<td>Annual review and update.</td>
</tr>
<tr>
<td>September 2014</td>
<td>Annual review and reference update.</td>
</tr>
<tr>
<td>September 2015</td>
<td>Annual review and reference update.</td>
</tr>
<tr>
<td>January 2016</td>
<td>Addition of new indication of upper limb spasticity Policy change from 5.12.04 to 5.75.04</td>
</tr>
<tr>
<td>March 2016</td>
<td>Annual review</td>
</tr>
<tr>
<td>December 2016</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td>September 2017</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td><strong>Section:</strong></td>
<td>Prescription Drugs</td>
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<tr>
<td>-------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td><strong>Subsection:</strong></td>
<td>Neuromuscular Drugs</td>
</tr>
<tr>
<td><strong>Subject:</strong></td>
<td>Xeomin</td>
</tr>
</tbody>
</table>

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 15, 2017 and is effective on October 1, 2017.