Xeomin

Description

Xeomin (incobotulinumtoxinA)

Background
Xeomin (incobotulinumtoxinA) is an acetylcholine release inhibitor indicated for chronic sialorrhea, 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. Chronic sialorrhea in adults
2. Upper limb spasticity in adults
3. Upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy
4. Cervical dystonia in adults
5. Blepharospasm in adults
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 the treatment of cervical dystonia, blepharospasm, sialorrhea, or upper limb spasticity and if the conditions indicated below are met.

Xeomin may be considered investigational for all other indications.

Prior-Approval Requirements

Age  No age restriction

Diagnoses
Patient must have the following:
1. Upper limb spasticity

AND the following:
1. NO dual therapy with other botulinum toxins

Age  18 years of age or older
Diagnoses
Patient must have **ONE** of the following:
1. Cervical dystonia (spasmodic torticollis)
2. Blepharospasm
3. 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**
Xeomin (incobotulinumtoxinA) is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for chronic sialorrhea, 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

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<td>December 2012</td>
<td>Annual review and update.</td>
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<td>September 2014</td>
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<td>September 2015</td>
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<tr>
<td>January 2016</td>
<td>Addition of new indication of upper limb spasticity</td>
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<td>Policy change from 5.12.04 to 5.75.04</td>
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<td>Addition of no dual therapy with other botulinum toxins to criteria</td>
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<td>Addition of sialorrhea indication</td>
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<tr>
<td>September 2020</td>
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<td>Revised upper limb spasticity to no age requirement to match Botox</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 11, 2020 and is effective on October 1, 2020.