BlueCross BlueShield Federal Employee Program

XEOMIN
(incobotulinum toxin A)

RATIONALE FOR INCLUSION IN PA PROGRAM

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 purer product is with higher 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 indications: Xeomin is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the treatment of: (1)

1. Chronic sialorrhea in patients 2 years of age and older
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 of Xeomin in pediatric patients for uses other than chronic sialorrhea and upper limb spasticity not caused by cerebral palsy have not been established (1).

Summary

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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 of Xeomin in pediatric patients for uses other than chronic sialorrhea and upper limb spasticity have not been established (1).

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

References

1. Xeomin [package insert]. Raleigh, NC: Merz Pharmaceuticals, LLC; July 2024.