BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.75.004

Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Neuromuscular Drugs	**Original Policy Date:**	September 24, 2010
Subject:	Xeomin	**Page:**	1 of 5

Last Review Date: December 12, 2025

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 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

6. Temporary improvement in the appearance of moderate to severe glabellar lines with corrugator and/or procerus muscle activity 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).

Cosmetic indications are excluded from coverage.

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** if the conditions indicated below are met.

Xeomin may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age No age restriction

Diagnosis

Patient must have the following:

1. Upper limb spasticity

AND the following:

1. **NO** dual therapy with other botulinum toxins
2. Pediatric patients **only:** spasticity is not caused by cerebral palsy

Age 2 years of age or older

Diagnosis

Patient must have the following:

1. Chronic sialorrhea (excessive salivation)

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

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 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]. Raileigh, NC: Merz Pharmaceuticals, LLC; July 2024.

Policy History

Date	Action
December 2012	Annual review and update.
September 2014	Annual review and reference update.
September 2015	Annual review and reference update.
January 2016	Addition of new indication of upper limb spasticity Policy change from 5.12.04 to 5.75.04
March 2016	Annual review
December 2016	Annual editorial review Addition of no dual therapy with other botulinum toxins to criteria
September 2017	Annual editorial review
July 2018	Addition of sialorrhea indication
September 2018	Annual review and reference update
September 2019	Annual review and reference update
September 2020	Annual editorial review and reference update. Revised upper limb spasticity to no age requirement to match Botox
January 2021	Updated age requirement for chronic sialorrhea to include patients 2 years of age and older. Clarified upper limb spasticity to exclude spasticity caused by cerebral palsy in pediatric patients and added the word chronic to sialorrhea diagnosis per FEP
March 2021	Annual editorial review
December 2022	Annual review and reference update. Changed policy number to 5.75.004
December 2023	Annual review and reference update

June 2024	Annual review
December 2024	Annual review and reference update
December 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.