UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Botulinum Toxins – Xeomin Utilization Management Medical Policy
- Xeomin® (incobotulinumtoxinA injection – Merz)

REVIEW DATE: 09/23/2026

OVERVIEW

Xeomin (incobotulinumtoxinA), an acetylcholine release inhibitor and neuromuscular-blocking agent, is indicated for the following uses:[1]

- **Blepharospasm** in adults.
- **Cervical dystonia** in adults.
- **Sialorrhea**, **chronic**, in patients ≥ 2 years of age.
- **Upper limb spasticity**, in patients ≥ 2 years of age.

Dosing Information

Potency units are specific to each botulinum toxin product and are not interchangeable with, or directly convertible to, the units of another botulinum toxin product.[1]

Safety

Botulinum toxin products carry a Boxed Warning regarding the risk of distant spread of toxin effect.[1] Postmarketing reports suggest symptoms consistent with botulinum toxin effects may occur beyond the injection site and may include asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. Serious cases, including life-threatening swallowing and breathing difficulties, have been reported.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Xeomin. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Requests for doses outside the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below.

Medical benefit coverage is not recommended for cosmetic use.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Xeomin is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Blepharospasm.** Approve for 1 year if the patient is ≥ 18 years of age.
   Note: This includes blepharospasm associated with dystonia, benign essential blepharospasm, seventh (VII) nerve disorders.

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Dosing. Approve up to a maximum dose of 100 units (50 units per eye), administered not more frequently than once every 12 weeks.

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2. Cervical Dystonia. Approve for 1 year if the patient is ≥ 18 years of age.
Note: Cervical dystonia is also known as spasmodic torticollis.

Dosing. Approve up to a maximum dose of 240 units (not to exceed 120 units for initial dose), administered not more frequently than once every 12 weeks.

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3. Sialorrhea, Chronic. Approve for 1 year if the patient is ≥ 2 years of age.

Dosing. Approve ONE of the following regimens (A or B):
- **A)** Patient is ≥ 18 years of age: Approve up to a maximum dose of 100 units (50 units per side), administered not more frequently than once every 16 weeks; OR
- **B)** Patient is < 18 years of age: Approve up to a maximum dose of 75 units (37.5 units per side), administered not more frequently than once every 16 weeks.

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4. Spasticity, Upper Limb(s). Approve for 1 year if the patient is ≥ 2 years of age.

Dosing. Approve ONE of the following regimens (A or B):
- **A)** Patient is ≥ 18 years of age: Approve up to a maximum dose of 400 units, administered not more frequently than once every 12 weeks; OR
- **B)** Patient is < 18 years of age: Approve if patient meets ONE of the following:
  - i. If treating one upper limb, approve up to a maximum dose of 8 units/kg (not to exceed 200 units), administered not more than once every 12 weeks.
  - ii. If treating both upper limbs, approve up to a maximum dose of 16 units/kg (not to exceed 400 units), administered not more frequently than once every 12 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Xeomin is not recommended in the following situations:

1. **Cosmetic Use**. Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical medical benefit.
   Note: Examples of cosmetic uses include facial rhytids, frown lines, glabellar wrinkling, horizontal neck rhytids, mid and lower face and neck rejuvenation, platysma bands, or rejuvenation of the periorbital region.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Xeomin® injection [prescribing information]. Raleigh, NC and Franksville, WI: Merz; June 2026.

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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/02/2024
Annual Revision	No criteria changes.	09/17/2025
Selected Revision	**Cervical Dystonia**: The dosing was updated from a maximum of 120 units to 240 units (not to exceed 120 units for initial dose).	10/01/2025
Update	**07/02/2026**: Overview updated for expanded indication to not exclude spasticity caused by cerebral palsy.	--
Annual Revision	**Spasticity, Upper Limb(s)**: The dosing for pediatric upper-limb spasticity was clarified for treatment of one versus both upper limbs.	09/23/2026

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