

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Botulinum Toxin – Xeomin Utilization Management Medical Policy

- Xeomin® (incobotulinumtoxinA injection – Merz)

REVIEW DATE: 10/02/2024

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 adults.
 - In pediatric patients ≥ 2 years of age, excluding spasticity caused by cerebral palsy.

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. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. 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 conditions.

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.

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

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 120 units, 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.
- 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.

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.
- B) Patient is < 18 years of age: 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 Uses.** 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 rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platysmal 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; July 2024.

HISTORY

| Type of Revision | Summary of Changes | Review Date |
|-----------------------|---|-------------|
| Early Annual Revision | <p>Blepharospasm: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. The following note was added to the indication: “This includes blepharospasm associated with dystonia, benign essential blepharospasm, seventh (VII) nerve disorders.”</p> <p>Cervical Dystonia: An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place.</p> <p>Sialorrhea, Chronic: An age requirement of ≥ 2 years was added. Previously there was not an age requirement in place.</p> <p>Spasticity, Upper Limb: An age requirement of ≥ 2 years was added. Previously there was not an age requirement in place.</p> | 10/11/2023 |
| Annual Revision | No criteria changes. | 10/02/2024 |