VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 06/30/2021

OVERVIEW

Xeomin (incobotulinumtoxinA) 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.[1]

Other Uses with Supportive Evidence

Botulinum toxins, including Xeomin, have been studied in a variety of indications outside of FDA-approved uses. Literature is available to support use of Xeomin in the following conditions:
- **Hyperhidrosis, Primary Axillary, Palmar/Plantar, and Facial:** American Academy of Neurology (AAN) guidelines state that botulinum toxins are probably safe and effective and should be considered for palmar hyperhidrosis (plantar and facial hyperhidrosis are not addressed in the AAN guideline).[2] Overall, topical antiperspirants (e.g., aluminum chloride) are the recommended first-line therapy for the treatment of primary axillary hyperhidrosis and focal hyperhidrosis.[3-6] In the setting of primary axillary hyperhidrosis, Qbrexza® (glycopyrronium cloth 2.4% for topical use), a topical anticholinergic, may also be used first-line.[7] Studies have demonstrated efficacy of Xeomin in palmar/plantar, cranial, and axillary hyperhidrosis.[8-10]
- **Spasticity, Other Than Upper Limb (i.e., spasticity or hypertonia due to cerebral palsy, stroke, brain injury, spinal cord injury, multiple sclerosis, hemifacial spasm):** Per the AAN, Xeomin is established effective in upper limb spasticity (Level A), and botulinum toxin (formulation not specified) may be considered in hemifacial spasm (Level C).[11,12] Oral medications have a long history in spasticity treatment (e.g., baclofen, benzodiazepines, phenytoin, or gabapentin) yet they have dose-limiting side effects and limited diffusion across the blood brain barrier.[13] In a prospective, randomized study in patients (n = 192) with upper limb spasticity due to stroke, brain injury, multiple sclerosis, or cerebral palsy, the majority of patients treated with Xeomin had improvement in functional disability and in muscle tone.[14] In a Phase III randomized study in patients (n = 148) with post-stroke upper limb spasticity, Xeomin was significantly more effective than placebo at Week 4 and at Week 12.[15] In addition, the efficacy of Xeomin in the treatment of hemispasticity, arm spasticity, generalized spasticity, paraspasticity, leg spasticity, and hemifacial spasm was demonstrated in patients (n = 95) previously treated with Botox for at least 1 year under stable conditions and crossed over in a blinded fashion to Xeomin for 3 years.[8]

Dosing Considerations

Definitive dosing has not been established for off-label uses of botulinum toxins, including Xeomin. Recommendations for maximum dosing and frequency for Xeomin are based on a suggested relative conversion of 1:1 between Xeomin and Botox units.[16] Specific dosing considerations by indication are noted below. For other indications addressed in this policy, specific dosing guidance is not available. In these cases, dosing is based on the Botox prescribing information, which states that in a 3-month interval,

adults should not exceed a total dose of 400 units, and pediatric patients should not exceed a total dose of the lesser of 10 units/kg or 340 units in a 3-month interval.[17]

- **Hyperhidrosis, Primary Axillary, Palmar/Plantar, and Facial**: Botox is indicated for axillary hyperhidrosis at a dose of 50 units per axilla.[17] For other forms of hyperhidrosis, definitive dosing has not been established.

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 1 year in duration. In cases where the dosing interval is provided in months, 1 month is equal to 30 days.

Medical benefit coverage is not recommended for cosmetic conditions.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

FDA-Approved Indications

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1. Blepharospasm. Approve for 1 year.

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.
Note: Cervical dystonia is also known as spasmodic or cervical 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.

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.** Approve for 1 year.
   Note: For other forms of spasticity that do not fit this condition of approval, refer to Other Uses with Supportive Evidence, Spasticity.

   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.

Other Uses with Supportive Evidence

5. **Hyperhidrosis, Primary Axillary, Palmar/Plantar, and Facial.** Approve for 1 year if the patient has tried at least one topical agent.
   Note: Examples of topical agents include topical aluminum chloride or Qbrexa (glycopyrronium cloth 2.4% for topical use).

   Dosing. Approve one of the following regimens (A or B):
   A) Primary axillary hyperhidrosis: Approve a maximum dose of 50 units per axilla, administered not more frequently than once every 3 months.
   B) Palmar/plantar or facial hyperhidrosis: Approve one of the following regimens (i or ii):
      i. Patient is ≥ 18 years of age: Approve up to a maximum dose of 400 units, administered not more frequently than once every 3 months.
      ii. Patient is < 18 years of age: Approve up to a maximum dose of 10 units/kg (not to exceed 340 units), administered not more frequently than once every 3 months.

6. **Spasticity, other than Upper Limb (i.e., spasticity or hypertonia due to cerebral palsy, stroke, brain injury, spinal cord injury, multiple sclerosis, hemifacial spasm).** Approve for 1 year.
   Note: For upper limb spasticity, refer to FDA-Approved Indication above.

   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 3 months.
   B) Patient is < 18 years of age: Approve up to a maximum dose of 10 units/kg (not to exceed 340 units), administered not more frequently than once every 3 months.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Xeomin is not recommended in the following situations:

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

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

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13. Pathak MS, Nguyen HT, Graham HK, et al. Management of spasticity in adults: practical application of botulinum toxin. *Eur J Neurol*. 2006;13 Suppl 1:42-50.
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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Cervical Dystonia (spasmodic torticollis):** The phrase "spasmodic torticollis" was added.	06/03/2020
Selected Revision	**Dosing:** Dosing for Sialorrhea, Chronic was updated to reflect pediatric maximum dose of 75 units (37.5 units per side).	01/20/2021
Annual Revision	**Cervical Dystonia:** The phrase "spasmodic torticollis" was removed from the approval condition. A Note was added that cervical dystonia is also known as spasmodic or cervical torticollis. **Hyperhidrosis, Primary Axillary, Palmar/Plantar, and Facial:** Examples of topical agents were moved from criteria into a Note. **Cosmetic Uses:** Examples were moved from the Condition Not Recommended for Approval into a Note. **Fibromyalgia:** The Condition Not Recommended for Approval was removed from the policy. **Dosing:** For Spasticity, Upper Limb in a patient < 18 years of age, dosing was updated such that the maximum dose is the lesser of 16 units/kg or 400 units, administered not more frequently than once every 12 weeks. In the following Other Uses with Supportive Evidence, the dosing was updated such that the maximum dose for patients < 18 years of age is the lesser of 10 units/kg or 340 units in 3 months (adult maximum dosing remains unchanged at 400 units in 3 months): Hyperhidrosis, Palmar/Plantar and Facial; and Spasticity, other than Upper Limb.	06/30/2021