Policy:	**Botulinum Toxin – Xeomin Utilization Management Medical Policy** • Xeomin® (incobotulinumtoxinA injection – Merz)
Date:	06/23/2026
Applicable Lines of Business:	Medicare Advantage – Medical
Applicable States/Territories:	Noridian JE: California, American Samoa, Guam, Hawaii, Northern Mariana Islands, Nevada Noridian JF: Alaska, Idaho, Oregon, Washington, Arizona, Montana, North Dakota, South Dakota, Utah, Wyoming
Applicable NCDs, LCDs, and/or LCAs	L35172, A57186, L35170, A57185

SUMMARY OF EVIDENCE

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 to 17 years of age, excluding spasticity caused by cerebral palsy.

ANALYSIS OF EVIDENCE

The information provided in the summary of evidence is supported by labeled indications, CMS-approved compendia, published clinical literature, clinical practice guidelines, and/or applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs). Refer to the Sources of Information section of this policy for additional information.

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 indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. 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.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the Sources of Information section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Sources of Information section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

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Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

Indications with a ^ below are referenced in both the corresponding Standard Medical Utilization Management Internal Policy AND applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications may be internally developed and/or referenced in applicable NCDs, LCDs, and/or LCAs. For these indications, internally developed coverage criteria is denoted throughout the policy in the following manner: 1) IC-L (internal criteria supported by the labeled indication), 2) IC-COMP (internal criteria supported by CMS-approved compendia), 3) IC-ISGP (internal criteria intended to interpret or supplement general provisions outlined in applicable NCDs, LCDs, and/or LCAs), or 4) IC-EC (internal criteria intended to expand coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs). For these indications, coverage criteria that is NOT denoted with one of the above indicators is referenced in applicable NCDs, LCDs, and/or LCAs. Additional information supporting the rationale for determination of internal coverage criteria can be found via the Sources of Information section.

Indications with a @ below are referenced in the corresponding Standard Medical Utilization Management Internal Policy, but are NOT directly referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs). Coverage criteria for these indications is internally developed. These indications and their respective coverage criteria represent expanded coverage beyond the coverage outlined in applicable NCDs, LCDs, and/or LCAs.

Indications with a # below are supported and referenced in applicable National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and/or Local Coverage Articles (LCAs), but are NOT directly referenced in the corresponding Standard Medical Utilization Management Internal Policy. Coverage criteria for these indications is referenced in applicable NCDs, LCDs, and/or LCAs.

RECOMMENDED AUTHORIZATION CRITERIA

FDA-Approved Indications

1. Blepharospasm. ^

Note: This includes blepharospasm associated with dystonia, benign essential blepharospasm, seventh (VII) nerve disorders.

Criteria. Approve for 1 year if the patient is ≥ 18 years of age. IC-L

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. ^

Note: Cervical dystonia is also known as spasmodic torticollis.

Criteria. Approve for 1 year if the patient is ≥ 18 years of age. IC-L

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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. ^

Criteria. Approve for 1 year if the patient is ≥ 2 years of age. [IC-L]

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.

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4. Spasticity, Upper Limb(s). ^

Criteria. Approve for 1 year if the patient is ≥ 2 years of age. [IC-L]

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** 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 under the Medicare 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.

SOURCES OF INFORMATION

1. Xeomin® injection [prescribing information]. Raleigh, NC and Franksville, WI: Merz; July 2024.
2. Centers for Medicare and Medicaid Services, Noridian Healthcare Solutions, LLC. Local Coverage Determination: Botulinum Toxin Types A and B (L35172) (Original effective date 10/1/2015; revision effective date 2/22/2026). Accessed on June 23, 2026.
3. Centers for Medicare and Medicaid Services, Noridian Healthcare Solutions, LLC. Local Coverage Article: Billing and Coding: Botulinum Toxin Types A and B (A57186) (Original effective date 10/1/2019; revision effective date 4/9/26). Accessed on June 23, 2026.
4. Centers for Medicare and Medicaid Services, Noridian Healthcare Solutions, LLC. Local Coverage Determination: Botulinum Toxin Types A and B Policy (L35170) (Original effective date 10/1/2015; revision effective date 2/22/26). Accessed on June 23, 2026.

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5. Centers for Medicare and Medicaid Services, Noridian Healthcare Solutions, LLC. Local Coverage Article: Billing and Coding: Botulinum Toxin Types A and B Policy (A57185) (Original effective date 10/1/2019; revision effective date 4/9/26). Accessed on June 23, 2026.

HISTORY

Type of Revision	Summary of Changes	Date
Policy created	New Medicare Advantage Medical Policy	04/15/2020
Policy revision	"Cervical Dystonia" updated to "Cervical Dystonia (spasmodic torticollis)"	06/09/2020
Policy revision	**Sialorrhea, Chronic:** Dosing was updated to reflect pediatric maximum dose of 75 units (37.5 units per side).	01/22/2021
Policy 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 AND Spasticity, other than Upper Limb** – added these indications for coverage **Cosmetic Uses:** Examples were moved from the Condition Not Recommended for Approval into a Note. **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.	08/03/2021
Policy revision	**Hyperhidrosis, Primary Axillary, Palmar/Plantar, and Facial:** This Other Use with Supportive Evidence was removed from the policy. **Spasticity, other than Upper Limb:** Removed hemifacial spasm from examples.	02/28/2023
Policy revision	**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." **Cervical Dystonia:** An age requirement of ≥ 18 years was added. Previously there was not an age requirement in place. **Sialorrhea, Chronic:** An age requirement of ≥ 2 years was added. Previously there was not an age requirement in place. **Spasticity, Upper Limb**: An age requirement of ≥ 2 years was added. Previously there was not an age requirement in place. The following other uses with supportive evidence were removed from the policy: **Spasticity, other than Upper Limb**	11/09/2023
Policy review	No criteria changes. Review based on review of commercial policy annual review.	11/06/2024
Policy revision	No criteria changes. Formatting and notation updates.	06/18/2025
Policy review	No criteria changes, based on review of commercial policy	10/01/2025
Policy revision	**Cervical Dystonia**: The dosing was updated from a maximum of 120 units to 240 units (not to exceed 120 units for initial dose).	10/10/2025
Policy review	No criteria changes, review of LCD/LCA surveillance	10/23/2025
Policy review	No criteria changes, CMS surveillance review	02/04/2026, effective 02/22/2026
Policy review	No criteria changes, CMS surveillance review	04/02/2026
Policy review	No criteria changes, CMS surveillance review	06/23/2026

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