Medicare Advantage Medical Utilization Review Policy

Policy:	**Botulinum Toxin – Xeomin Utilization Management Medical Policy** • Xeomin® (incobotulinumtoxinA injection – Merz)
Date	02/28/2023
Applicable Lines of Business:	Medicare Advantage – Medical
Applicable States:	NGS, J6: Wisconsin, Minnesota, Illinois NGS, JK: New York, Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont

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.

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 References 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 Reference 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.

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.

RECOMMENDED AUTHORIZATION CRITERIA

FDA-Approved Indications

1. Blepharospasm.

Criteria. 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.

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

Criteria. Approve for 1 year.

Dosing. Approve up to a maximum dose of 120 units, administered not more frequently than once every 12 weeks.

3. Sialorrhea, Chronic.

Criteria. 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.

Criteria. 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 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 [bn]

5. Spasticity, other than Upper Limb (i.e., spasticity secondary to spastic hemiplegia,[2] hemiparesis).[2]
Note: For upper limb spasticity, refer to FDA-Approved Indication above.

Criteria. 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 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

Xeomin has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

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.

REFERENCES

1. Xeomin® injection [prescribing information]. Raleigh, NC and Franksville, WI: Merz; August 2021.
2. Centers for Medicare and Medicaid Services, National Government Services, Inc, Local Coverage Determination: Botulinum Toxins (LCD L33646) (Original effective date 10/1/2015; revision effective date 05/01/2021). Accessed on February 21, 2023.
3. Centers for Medicare and Medicaid Services, National Government Services, Inc, Local Coverage Article: Billing and Coding: Botulinum Toxins (A52848) (Original effective date 10/1/2015; revision effective date 1/5/2023). Accessed on February 21, 2023.

HISTORY

Type of Revision	Summary of Changes	Date
Policy created	New Medicare Advantage Medical Policy	07/11/2018
Policy revision	Statement added to dosing to allow for approval of doses that are below the recommended maximum daily dose for each indication.	n/a
Policy revision	Removed the following criterion: "For all approvable indications, failure of two definitive, consecutive, treatment sessions involving a muscle or group of muscles could preclude further coverage of the serotype/product used in the treatment for a period of one year after the second session. It may be reasonable, however, to attempt treatment with a different serotype." L33646 provides this verbiage and it has since been interpreted as optional criterion because of the 'could' language. Not required to issue approval or denial but can be used when considering an appeal.	n/a
Policy revision	Reviewed and revised original policy created 07/11/2018 in accordance with Local Coverage Determination L33646 and Botulinum Toxin - Xeomin Utilization Review Policy.	08/28/2019
Policy revision	Non-clinical update to policy to add the statement "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 References section	1/30/2020

	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 Reference 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."	
Policy revision	*Removed criteria requirements for chronic sialorrhea *Removed spastic conditions of smooth muscle from conditions not recommended for approval	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. **Added coverage for the following indications:** Hyperhidrosis, Primary Axillary, Palmar/Plantar, and Facial and Spasticity Other than Upper Limb **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.	08/17/2021
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 examples of cerebral palsy, stroke, brain injury, spinal cord injury, multiple sclerosis and hemifacial spasm. Added examples of spastic hemiplegia, hemiparesis.	02/28/2023