Department:	Pharmacy Management	**Original Approval:**	12/11/2024
Policy No:	PM191	**Last Approval:**	10/17/2025
Policy Title:	IncobotulinumtoxinA (Xeomin) Clinical Coverage Criteria		
Approved By:	UM Criteria Subcommittee		
Applicable Line(s) of Business:	☒ **Washington Apple Health (Medicaid)** ☐ **Behavioral Health Services Only** ☒ **Apple Health Expansion** ☒ **Medicare Advantage/Special Needs Plan** ☒ **Medicare Advantage Only** ☒ **Cascade Select**		

Required Clinical Documentation for Review

Documentation required to determine medical necessity for IncobotulinumtoxinA (Xeomin):

1. History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service
2. Diagnosis
3. Labs/Diagnostics
4. Dosing and duration requested
5. Initial/Extended approval
6. Medical records from the last 6 months showing the patient's problems, history, prior treatments, response to treatment, imaging and laboratory studies, details of the skilled needs, details of any specific needs related to risk/trauma/cultural etc., assessment and plan
7. Prescribed by or in consultation with a specialist, when indicated.

Background

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.

For Medicare: This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in

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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.

Indications/Criteria

Medicaid and Individual & Family (Cascade Select) Members	***Continue to criteria for approval below.*** ***Preferred Products: Botox, Daxxify, Dysport, Xeomin*** ***Non-Preferred Products: Myobloc***
Medicare Members	***Step-utilization of Part D drugs not required.*** ***Preferred Products: Botox, Daxxify, Dysport, Xeomin*** ***Non-Preferred Products: Myobloc***

Medicaid/Cascade Select 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.

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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 120 units, administered not more frequently than once every 12 weeks.

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.

Medicare Criteria

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.

   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 if the patient is ≥ 18 years of age.

   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.**

Criteria. 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.**

Criteria. Approve for 1 year if the patient is ≥ 2 years of age.

Dosing. Approve one of the following regimens (A or B):

C) Patient is ≥ 18 years of age: Approve up to a maximum dose of 400 units, administered not more frequently than once every 12 weeks.

D) 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, platsymal 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.

Special Considerations

None.

Limitations/Exclusions

Please see link to member coverage documents below:

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Line of Business	Link to Member Coverage Documents
Medicare Advantage Plans (Including D-SNP)	https://medicare.chpw.org/ Select the appropriate plan from the "Plans" drop down on the top navigation bar.
Apple Health	https://www.chpw.org/for-members/benefits-and-coverage-imc/
Cascade Select	https://chnwhealthinsurance.chpw.org/member-center/plan-benefits/

Citations & References

CFR	42 CFR § 438.210	
WAC	WAC 284-43-2050	
RCW		
LOB & Contract Citation	☒ **WAHIMC** ☐ **BHSO** ☐ **Wraparound** ☐ **SMAC** ☐ **HH**	IMC Section 11.3: Medical Necessity Determination
	☒ **AHE**	AHE Section 11.3: Medical Necessity Determination
	☒ **MA/DSNP**	P&P supports all LOB requirements
	☒ **CS**	P&P supports all LOB requirements
Other Requirements		
NCQA Elements		
References	1. Xeomin® injection [prescribing information]. Raleigh, NC and Franksville, WI: Merz; August 2021. 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 10/1/2019). Accessed on December 10, 2024. 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 10/1/2023). Accessed on December 10, 2024. 4. Centers for Medicare and Medicaid Services, Noridian Healthcare Solutions, LLC. Local Coverage Determination: Botulinum Toxin Types	

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	A and B Policy (L35170) (Original effective date 10/1/2015; revision effective date 10/1/2019). Accessed on December 10, 2024. 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 10/1/2023). Accessed on December 10, 2024.

Revision History

Revision Date	Revision Description	Revision Made By
12/09/2024	New policy.	Alan Gabot, PharmD
12/11/2024	Approval	UM Criteria Subcommittee
10/07/2025	Annual review. Added the "Conditions Not Recommended for Approval" section, where the section currently consists of Cosmetic Use and circumstances not listed in the criteria.	Alan Gabot, PharmD
10/17/2025	Approval	UM Criteria Subcommittee

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