Drug Coverage Policy

Effective Date..... 11/15/2025
Coverage Policy Number IP0639
Policy Title..... Xeomin

Botulinum Toxin – Xeomin

- Xeomin® (incobotulinumtoxinA injection – Merz)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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

Coverage Policy

Policy Statement
Prior Authorization is required for 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.

Benefit coverage is not recommended for cosmetic use.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information.

Xeomin is considered medically necessary when ONE of the following criteria are met:

FDA-Approved Indications

1. **Blepharospasm.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   Note: This includes blepharospasm associated with dystonia, benign essential blepharospasm, seventh (VII) nerve disorders.
   A) Patient is ≥ 18 years of age; AND
   B) Patient has intermittent or sustained closure of the eyelids caused by involuntary contractions of the orbicularis oculi muscle **[documentation required]**; AND
   C) Prescribed by or in consultation with a neurologist or ophthalmologist

   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 meets ALL of the following (A, B, C, and D):
   Note: Cervical dystonia is also known as spasmodic torticollis.
   A) Patient is ≥ 18 years of age; AND
   B) Patient has a diagnosis of cervical dystonia **[documentation required]**; AND
   C) Patient has sustained head torsion and/ or tilt with limited range of motion in the neck **[documentation required]**; AND
   D) Prescribed by or in consultation with a pain medicine specialist, neurologist, or physical medicine and rehabilitation physician

   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.

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 Covered

Xeomin (incobotulinumtoxinA) for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as newly published data are available):

1. **Cosmetic Use.** 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.

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Blepharospasm

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)

HCPCS Codes	Description
J0588	Injection, IncobotulinumtoxinA, 1 unit

Cervical Dystonia

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)

HCPCS Codes	Description
J0588	Injection, IncobotulinumtoxinA, 1 unit

Sialorrhea, Chronic

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
64611	Chemodenervation of parotid and submandibular salivary glands, bilateral

HCPCS Codes	Description
J0588	Injection, IncobotulinumtoxinA, 1 unit

Spasticity, Upper Limb(s)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
64642	Chemodenervation of one extremity; 1-4 muscle(s)
64643	Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (List separately in addition to code for primary procedure)
64644	Chemodenervation of one extremity; 5 or more muscles
64645	Chemodenervation of one extremity; each additional extremity, 5 or more muscles (List separately in addition to code for primary procedure)
64646	Chemodenervation of trunk muscle(s); 1-5 muscle(s)
64647	Chemodenervation of trunk muscle(s); 6 or more muscles

HCPCS Codes	Description
J0588	Injection, IncobotulinumtoxinA, 1 unit

References

1. Xeomin® injection [prescribing information]. Raleigh, NC and Franksville, WI: Merz; July 2024.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy.	7/15/2025
Annual Revision	**Updated** policy template. **Cervical Dystonia**: The dosing was updated from a maximum of 120 units to 240 units (not to exceed 120 units for initial dose).	11/15/2025

The policy effective date is in force until updated or retired.