



Xeomin® (incobotulinumtoxinA)

When requesting Xeomin® (incobotulinumtoxinA), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines for the covered indications.

FDA-approved Indications

Xeomin (incobotulinumtoxinA) is indicated for the treatment of:

- Cervical dystonia in adults.
- Blepharospasm in adults.
- Chronic sialorrhea in patients 2 years of age and older.
- Upper limb spasticity in patients 2 years of age and older.

Coverage Guidelines

The individual must be 18 years of age or older for approval of the following indications:

- Cervical dystonia.
- Blepharospasm.

The individual must be 2 years of age or older for approval of the following indications:

- Chronic sialorrhea.
- Upper limb spasticity.

Approval duration: 12 months

Dosing Recommendations

Blepharospasm

Approve up to a maximum dose of 100 units (50 units per eye), administered not more frequently than once every 12 weeks.

Cervical Dystonia

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

Adult Upper Limb Spasticity

Approve up to a maximum dose of 400 units, administered not more frequently than once every 12 weeks.

Pediatric Upper Limb Spasticity

Approve up to 8 units/kg for unilateral upper limb injections (maximum 200 units) or 16 units/kg for bilateral upper limb injections (maximum 400 units), administered not more frequently than once every 12 weeks.

Adult Chronic Sialorrhea

Approve up to a maximum dose of 100 units (50 units per side), administered not more frequently than once every 16 weeks.

Pediatric Chronic Sialorrhea

Approve up to a maximum dose of 75 units (37.5 units per side), administered not more frequently than once every 16 weeks.

References

1. Xeomin® (incobotulinumtoxinA) [prescribing information]. Raleigh, NC: Merz Pharmaceuticals, LLC: April 2021.
2. IncobotulinumtoxinA (Xeomin®). Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. [Updated; April 26, 2021; Accessed June 3, 2021].
3. Simpson, D et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. Report of the Guideline Development Subcommittee of the American Academy of Neurology. *American Academy of Neurology* (2016) 86: 1818-1826.
4. 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.
5. Barnes M, Schnitzler A, Medeiros L, et al. Efficacy and safety of NT 201 for upper limb spasticity of various etiologies – a randomized parallel-group study. *Acta Neurol Scand*. 2010;122(4):295-302.