

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

The recommended initial dose is 50 units (25 units per eye). The total dose should not exceed 100 units per treatment session (50 units per eye), administered no more frequently than every 12 weeks.

Cervical Dystonia

The recommended dose is 120 units per treatment session, administered no more frequently than every 12 weeks.

Adult Upper Limb Spasticity

The recommended total dose is up to 400 units, administered no sooner than every 12 weeks.

Pediatric Upper Limb Spasticity

The recommended total dose is 8 units/kg (maximum 200 units) per single upper limb or 16 units/kg (maximum 400 units) in both upper limbs, administered no sooner than every 12 weeks.

Adult Chronic Sialorrhea

The recommended total dose is 100 units per treatment session consisting of 30 units per parotid gland and 20 units per submandibular gland, administered no sooner than every 16 weeks.

Pediatric Chronic Sialorrhea

The recommended dose is based on body weight administered in a 3:2 dose ratio into the parotid and submandibular glands, respectively, administered no sooner than every 16 weeks.

References

1. Xeomin® (incobotulinumtoxinA) [prescribing information]. Raleigh, NC: Merz Pharmaceuticals, LLC: September 2023.
2. IncobotulinumtoxinA (Xeomin®). Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. [Updated; April 11, 2024; Accessed April 22, 2024].
3. IncobotulinumtoxinA (Xeomin®). Micromedex. Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> Accessed on April 22, 2024.
4. 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.
5. 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.
6. 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.