

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME	Xeomin (incobotulinumtoxinA)
BILLING CODE	J0588
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see “Dosage Allowed”
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Xeomin (incobotulinumtoxinA) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

BLEPHAROSPASM

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Medication is prescribed by or in consultation with a neurologist or ophthalmologist; AND
3. Member has a diagnosis of blepharospasm, characterized by spasms inducing narrowing or closure of the eyelids.
4. **Dosage allowed:** Not to exceed 50 units per eye (100 units per treatment session) every 12 weeks.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes show improved signs and symptoms (e.g. lessening of involuntary contraction).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CERVICAL DYSTONIA (SPASMODIC TORTICOLLIS)

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of moderate to severe cervical dystonia as evidenced by involuntary contractions of neck muscles, leading to abnormal movements or postures; AND
4. Symptoms affect quality of life and daily functions.
5. **Dosage allowed:** Up to 120 units every 12 weeks, divided among affected muscles.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes show improved signs and symptoms (e.g. severity of abnormal head position, neck pain).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CHRONIC SIALORRHEA

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has diagnosis of chronic sialorrhea impacting quality of life for at least 3 months; AND
4. Member has tried and failed or has a contraindication to at least TWO anticholinergic drugs (e.g. scopolamine, benztropine, glycopyrrolate, amitriptyline); AND
5. **Dosage allowed:** The recommended total dose is 100 Units per treatment session consisting of 30 Units per parotid gland and 20 Units per submandibular gland. (May repeat after no fewer than 16 weeks).

If member meets all the requirements listed above, the medication will be approved for 16 weeks.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

SPASTICITY (upper limb only)

For **initial** authorization:

1. Member is 2 years of age or older; AND
2. Medication is prescribed by or in consultation with a neurologist; AND
3. Member has a documented diagnosis of UPPER limb spasticity that affects daily functioning and quality of life; AND
4. Spasticity is secondary to a neurologic condition such as stroke, or brain or spinal cord injury; AND
5. Member has tried or is unable to try a conservative treatment approach such as physical therapy or oral medication (e.g. baclofen, tizanidine).
6. **Dosage allowed:** (adult and pediatric) Maximum of 400 units per treatment session, every 12 weeks.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes show improved signs and symptoms (e.g. decrease in severity of increased muscle tone).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Xeomin (incobotulinumtoxinA) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
08/06/2018	New policy for Xeomin created. Age requirement removed for diagnoses of Cervical Dystonia and Upper Limb Spasticity. Criterion “no infection at proposed injection site” removed from Cervical Dystonia diagnosis; pain and abnormal head position requirements clarified and medications trial added. For Upper Limb Spasticity Ashworth scale requirement removed, post-stroke requirement and chart notes requirement of abnormal muscle tone documentation added.
04/05/2019	New indication of Chronic Sialorrhea added. Dose allowance increased for diagnosis of Cervical Dystonia. Trial of Botox removed form diagnosis of Blepharospasm.
06/09/2020	Edited criteria for Chronic Sialorrhea to more closely align with Myobloc – simplified exclusion criteria and added trial of anticholinergics. Changed qty limit at top of document.
08/24/2020	<u>Blepharospasm</u> : Extend re-auth duration to 12 mo, added specialist, re-phrased dose, revised diagnostic phrasing. Added reference. <u>Cervical dystonia</u> : Added age limit and specialist requirement. Re-worded the diagnosis requirement. Removed trial of oral medication. Removed exclusions. Corrected the dose. Extended re-auth duration. Updated references. <u>Spasticity</u> : Added age and specialist. Added trial of conventional treatment. Extended initial auth duration. Corrected the dose. Added references. Label recently expanded to include pediatrics.

References:

- Xeomin [package insert]. Greensboro, NC: Merz Pharmaceuticals, LLC; May 2019.
- Brashear A, Lew MF, Dykstra DD, et al, “Safety and Efficacy of NeuroBloc (Botulinum Toxin Type B) in Type A-Responsive Cervical Dystonia,” *Neurology*, 1999, 53(7):1439-46.
- Clinical Use of Botulinum Toxin,” *Arch Neurol*, 1991, 48(12):1294-8.
- Benecke R, Jost WH, Kanovsky P, et al, “A New Botulinum Toxin Type A Free of Complexing Proteins for Treatment of Dystonia,” *Neurology*, 2005, 64(11):1949-51.
- Borodic GE and Pearce LB, “New Concepts in Botulinum Toxin Therapy,” *Drug Saf*, 1994, 11(3):145-52. Jankovic J and Brin MF, “Therapeutic Uses of Botulinum Toxin,” *N Engl J Med*, 1991, 324(17):1186-94.
- Naumann M and Jankovic J, "Safety of Botulinum Toxin Type A: A Systematic Review and Meta-Analysis," *Curr Med Res Opin*, 2004, 20(7):981-90.
- Russman, BS, Tilton, A, Gormley ME. Jr. Cerebral palsy; a rational approach to a treatment protocol, and the role of botulinum toxin in treatment, *Muscle Nerve Suppl* 1997; 6:S181.
- Fishman LM, Anderson C, Rosner B. Botox and physical therapy in the treatment of Piriformis syndrome *Am J Phys Med Rehabil*. 2002 Dec;81(12):936-42.
- Assessment: botulinum neurotoxin for the treatment of movement disorders (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. <http://www.guideline.gov/content.aspx?id=12947>(March11, 2011).
- Assessment: botulinum neurotoxin for the treatment of spasticity (an evidence-based review). Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. <http://www.guideline.gov/content.aspx?id=12942>(March112011).
- Simpson DM, et al. Assessment: Botulinum neurotoxin for the treatment of movement disorders (an evidence-based review). Report of the Therapeutics and Technology Subcommittee of the American Academy of Neurology. *Neurology*. 2008;70(19):1699-706.
- Neumann M, et al. Assessment: Botulinum neurotoxin in the treatment of autonomic disorders and pain. Report of the Therapeutics and Technology Subcommittee of the American Academy of Neurology. *Neurology*. 2008; 70:1707-14.
- Keam SJ, Muir VJ, Deeks ED. Botulinum toxin A (Dysport): in dystonias and focal spasticity. *Drugs* 2011;71(8):1043-58.
- Ondo WG, Hunter C, Moore W. A double-blind placebo-controlled trial of botulinum toxin B for sialorrhea in Parkinson’s disease. *Neurology*. 2004;62(1):37-40.
- Simpson DM, 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. *Neurology*. 2016 May 10;86(19):1818-26.
- Teasell R, et al. Evidence to practice: botulinum toxin in the treatment of spasticity post stroke. *Top Stroke Rehabil*. 2012 Mar-Apr;19(2):115-21.
- Chen R, et al. Botulinum toxin for Post-stroke Limb Spasticity. *Ischemic Stroke Therapeutics*. 2016; 203-207.

18. Cameron MH, et al. Botulinum toxin for symptomatic therapy in multiple sclerosis. *Curr Neurol Neurosci Rep*. 2014 Aug;14(8):463.
19. Bavikatte G, Sit PL, Hassoon A. Management of Drooling of Saliva. *BJMP*. 2012;5(1):a507. [<https://www.bjmp.org/content/management-drooling-saliva>]
20. Pellegrini A, Lunetta C, et. al. Sialorrhea: How to manage a frequent complication of motor neuron disease. *EMJ Neurol*. 2015;3[1]:107-113. [<https://emj.emg-health.com/wp-content/uploads/sites/2/2018/02/Sialorrhoea-How-to-Manage-a-Frequent-Complication-of-Motor-Neuron-Disease.pdf>]
21. Jost WH, Friedman A, Michel O, et al. Long-term incobotulinumtoxinA treatment for chronic sialorrhea: Efficacy and safety over 64 weeks. *Parkinsonism & Related Disorders*. 2020;70:23-30. doi:10.1016/j.parkreldis.2019.11.024
22. Cervical Dystonia. NORD (National Organization for Rare Disorders). <https://rarediseases.org/rare-diseases/cervical-dystonia/>. Published July 19, 2019. Accessed July 17, 2020.
23. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. *Neurology*. 2016;86(19):1818-1826. doi:10.1212/wnl.0000000000002560
24. Dressler D, Altenmueller E, Bhidayasiri R, et al. Strategies for treatment of dystonia. *Journal of Neural Transmission*. 2015;123(3):251-258. doi:10.1007/s00702-015-1453-x
25. Defazio G, Hallett M, Jinnah HA, Berardelli A. Development and validation of a clinical guideline for diagnosing blepharospasm. *Neurology*. 2013;81(3):236-240. doi:10.1212/WNL.0b013e31829bdf6
26. Lindsay C, Kouzouna A, Simcox C, Pandyan AD. Pharmacological interventions other than botulinum toxin for spasticity after stroke. *Cochrane Database of Systematic Reviews* 2016, Issue 10. Art. No.: CD010362. DOI: 10.1002/14651858.CD010362.pub2.
27. FDA approves first pediatric indication for xeomin® (incobotulinumtoxinA) for the treatment of upper limb spasticity, excluding spasticity caused by cerebral palsy | Merz USA. Merz USA. Published August 19, 2020. Accessed August 24, 2020. <https://www.merzusa.com/news/fda-approves-first-pediatric-indication-for-xeomin/>.

Effective date: 10/20/2020

Revised date: 08/24/2020