CareSource

PHARMACY POLICY STATEMENT
Marketplace

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 2 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 one anticholinergic drug (e.g. scopolamine, benztropine, glycopyrrolate, amitriptyline).
5. **Dosage allowed:** May repeat no sooner than every 16 weeks;
   Adult:

Gland(s)	Units Per Side	Total
Parotid gland(s)	30 Units	60 Units
Submandibular gland(s)	20 Units	40 Units
Both Glands	50 Units	**100 Units**

   Pediatric:

Body weight	Parotid gland, each side		Submandibular gland, each side		Total dose, both glands, both sides
	Dose per gland	Volume per injection	Dose per gland	Volume per injection	
12 kg or more to less than 15 kg	6 Units	0.24 mL	4 Units	0.16 mL	20 Units
15 kg or more to less than 19 kg	9 Units	0.36 mL	6 Units	0.24 mL	30 Units
19 kg or more to less than 23 kg	12 Units	0.48 mL	8 Units	0.32 mL	40 Units
23 kg or more to less than 27 kg	15 Units	0.6 mL	10 Unts	0.4 mL	50 Units
27 kg or more to less than 30 kg	18 Units	0.72 mL	12 Units	0.48 mL	60 Units
30 kg or more	22.5 Units	0.9 mL	15 Units	0.6 mL	75 Units

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 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.

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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	Blepharospasm: Extend re-auth duration to 12 mo, added specialist, re-phrased dose, revised diagnostic phrasing. Added reference. Cervical dystonia: 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. Spasticity: Added age and specialist. Added trial of conventional treatment. Extended initial auth duration. Corrected the dose. Added references. Label recently expanded to include pediatrics.
12/31/2020	Updated the age limit and dosing for chronic sialorrhea to include pediatric patients, per recent label change. Added a couple references. Changed from try 2 anticholinergics to try 1 anticholinergic.

References:

1. Xeomin [package insert]. Raleigh, NC: Merz Pharmaceuticals, LLC; 2020.
2. 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.

3. 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.
4. Chen R, et al. Botulinum toxin for Post-stroke Limb Spasticity. Ischemic Stroke Therapeutics. 2016; 203-207.
5. Cameron MH, et al. Botulinum toxin for symptomatic therapy in multiple sclerosis. Curr Neurol Neurosci Rep. 2014 Aug;14(8):463.
6. Bavikatte G, Sit PL, Hassoon A. Management of Drooling of Saliva. *BJMP*. 2012;5(1):a507. [https://www.bjmp.org/content/management-drooling-saliva]
7. 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]
8. 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
9. Cervical Dystonia. NORD (National Organization for Rare Disorders). https://rarediseases.org/rare-diseases/cervical-dystonia/. Published July 19, 2019. Accessed July 17, 2020.
10. 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
11. 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
12. 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.0b013e31829bfdf6
13. 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.
14. 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/.
15. Seppi K, Chaudhuri KR, Coelho M, et al. Update on treatments for nonmotor symptoms of Parkinson's disease—an evidence-based medicine review. *Movement Disorders*. 2019;34(2):180-198. doi:10.1002/mds.27602
16. Glader L. Sialorrhea in Cerebral Palsy. AACPDM. https://www.aacpdm.org/publications/care-pathways/sialorrhea. Published June 4, 2018. Accessed January 4, 2021.

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