CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Arkansas PASSE

DRUG NAME	Xeomin (incobotulinumtoxinA)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Xeomin is a neurotoxin produced from Clostridium botulinum serotype A. Xeomin works through the inhibition of acetylcholine release from peripheral nerve endings, causing neuromuscular blockage and muscle paralysis. Blepharospasm is the abnormal contraction of eyelids. Xeomin is indicated for the treatment or improvement of blepharospasm in adults.
Cervical dystonia (also known as spasmodic torticollis) involves the involuntary contractions of the neck that cause abnormal movements and postures of the neck and head. Xeomin is indicated for the treatment or improvement of cervical dystonia in adults.
Chronic sialorrhea, or excessive drooling, is a common symptom for patients with Parkinson's Disease or other neurological or cognitive impairments. Xeomin is indicated for the treatment or improvement of chronic sialorrhea in patients 2 years of age and older.
Xeomin is also indicated for the treatment or improvement of upper limb spasticity in adults and in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy.

Xeomin (incobotulinumtoxinA) will be considered for coverage when the following criteria are met:

Blepharospasm

For **initial** authorization:
1. Member is at least 18 years of age; 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/Quantity limit:** Not to exceed 50 units per eye (100 units per treatment session) every 12 weeks.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes show improved signs and symptoms (e.g., lessening of involuntary contraction).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Cervical Dystonia

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist or other specialist experienced with treating cervical dystonia; AND
3. Member has a documented diagnosis of moderate to severe cervical dystonia with dystonic symptoms

localized to the head, neck, shoulder areas.
4. **Dosage allowed/Quantity limit:** Up to 300 units every 12 weeks, divided among affected muscles.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show improved severity, disability, or pain compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Chronic Sialorrhea

For **initial** authorization:
1. Member is at least 2 years of age; 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/Quantity limit:** 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 all the above requirements are met, the medication will be approved for 16 weeks.

For **reauthorization**:
1. Chart notes have been provided that show the member has improvement of signs and symptoms of disease.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Spasticity (upper limb)

For **initial** authorization:

1. Member is at least 2 years of age; AND
2. Medication is prescribed by or in consultation with a neurologist or other specialist experienced with treating spasticity (e.g., PM&R); 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/Quantity limit:** (adult and pediatric) Maximum of 400 units per treatment session, every 12 weeks.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes show improved signs and symptoms (e.g., decrease in severity of increased muscle tone).

If all the above requirements are met, 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.
08/10/2021	Transferred to new template. Allowing additional specialists for cervical dystonia and spasticity indications.
03/04/2022	Allowing higher dose for cervical dystonia.
11/14/2023	Cervical dystonia: removed "Symptoms affect quality of life and daily functions." Updated references and clarified renewal criteria.

References:

1. Xeomin [package insert]. Raleigh, NC: Merz Pharmaceuticals, LLC; 2023.
2. 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.
3. Chen R, et al. Botulinum toxin for Post-stroke Limb Spasticity. Ischemic Stroke Therapeutics. 2016; 203-207.
4. Cameron MH, et al. Botulinum toxin for symptomatic therapy in multiple sclerosis. Curr Neurol Neurosci Rep. 2014 Aug;14(8):463.
5. Bavikatte G, Sit PL, Hassoon A. Management of Drooling of Saliva. *BJMP*. 2012;5(1):a507. [https://www.bjmp.org/content/management-drooling-saliva]
6. 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]
7. 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
8. 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
9. 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
10. 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
11. 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.
12. 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
13. Dashtipour K, Mari Z, Jankovic J, Adler CH, Schwartz M, Brin MF. Minimal clinically important change in patients with cervical dystonia: Results from the CD PROBE study. J Neurol Sci. 2019;405:116413. doi:10.1016/j.jns.2019.07.031
14. Dressler D, Adib Saberi F, Rosales RL. Botulinum toxin therapy of dystonia. J Neural Transm (Vienna). 2021;128(4):531-537. doi:10.1007/s00702-020-02266-z
15. Rodrigues FB, Duarte GS, Marques RE, et al. Botulinum toxin type A therapy for cervical dystonia. Cochrane Database Syst Rev. 2020;11(11):CD003633. Published 2020 Nov 12. doi:10.1002/14651858.CD003633.pub4

Effective date: 04/01/2024
Revised date: 11/14/2023