PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Xeomin (incobotulinumtoxinA)
BILLING CODE	J0588
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office
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. It is the only botulinum toxin that does not require refrigeration before reconstitution.
Blepharospasm is the abnormal contraction of eyelids. Xeomin was approved as a first-line treatment for Blepharospasm by the FDA in 2019. In a Phase 3, randomized, double-blind, placebo-controlled, multi-center trial, Xeomin demonstrated a statistically significant improvement in baseline Jankovic Rating Scale (JRS) Severity subscores.
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 of adults with cervical dystonia in both botulinum toxin-naïve and previously treated patients.
Chronic sialorrhea, or excessive drooling, is a common symptom for patients with Parkinson's Disease or other neurological or cognitive impairments. Xeomin is the first neuromodulator approved to treat pediatric patients with chronic sialorrhea.
Xeomin was approved as treatment for upper limb spasticity by the FDA in 2020. The approval was based on the results of a randomized, multi-center, placebo-controlled trial showing improvement in muscle tone (Ashworth Scale Score) and a 7-point Investigator's Global Impression of Change Scale. Xeomin is also the first neuromodulator approved to treat pediatric upper limb spasticity.

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

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/Quantity limit:** 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 or other specialist experienced with treating cervical dystonia; 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/Quantity limit:** Up to 300 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/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 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.

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 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 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.
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.

References:

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Effective date: 07/01/2022
Revised date: 03/04/2022