Humana. CareSource™

PHARMACY POLICY STATEMENT
Kentucky 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— up to 600 Units per treatment
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 with diagnosis of blepharospasm, as indicated by **one** or more of the following:
   a) Benign essential blepharospasm;
   b) Blepharospasm associated with dystonia;
   c) Blepharospasm associated with facial nerve (cranial nerve VII) disorders such as Bell palsy; AND
2. Member does **not** have neuromuscular disease (e.g., myasthenia gravis).
3. **Dosage allowed:** The total initial dose of Xeomin in both eyes should not exceed 70 Units (35 Units/eye). The maximum dose per eye: 10 - 50 Units.

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 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 6 months.

CERVICAL DYSTONIA (SPASMODIC TORTICOLLIS)

For **initial** authorization:

1. Member has a pain or abnormal head position with documented turning of the head (torticollis), lateral tilt of the neck (laterocollis), flexion of the head (anterocollis), or extension of the head (retrocollis) causing adverse effect on daily functioning; AND
2. Member has tried and failed one oral medication such as trihexyphenidyl (Artane), clonazepam (Klonopin), or baclofen; AND
3. Member does **not** have any of the following:
   a) Fixed contractures causing decreased neck range of motion;

b) Neuromuscular disease (e.g., myasthenia gravis);
c) Prior surgical treatment.
4. **Dosage allowed:** 300 Units.

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 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 6 months.

CHRONIC SIALORRHEA

For **initial** authorization:
1. Member is 18 years of age or older; AND
2. Member has chronic sialorrhea resulting from Parkinson's disease, atypical parkinsonism, stroke, or traumatic brain injury, that was present for at least three months (chart notes required); AND
3. Member does **not** have any of the following:
   a) A history of aspiration pneumonia, amyotrophic lateral sclerosis, salivary gland or duct malformation, and gastroesophageal reflux disease;
   b) Bleeding disorders or is currently on anticoagulants;
   c) Pregnancy.
4. **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.

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 has confirmed diagnosis of post-stroke spasticity of the upper limb (at least six months post-stroke); AND
2. Chart notes submitted with documentation of abnormal muscle tone that is interfering with functional ability (or that is expected to affect joint contracture in future growth); AND
3. Medication is being requested to improve function or allow additional therapeutic modality to be employed.
4. **Dosage allowed:** Vary 5-100 Units given in divided doses among affected muscles.

If member meets all the requirements listed above, the medication will be approved for 3 months.

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.

CareSource considers Xeomin (incobotulinumtoxinA) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Glabellar Lines (considered cosmetic)
- Tension headache, cervicogenic headache
- Myofascial pain syndrome
- Tremors such as benign essential tremor, chronic motor tic disorder and tics associated with Tourette Syndrome
- Parkinson's disease

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.

References:

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