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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 120 Units per treatment

LIST OF DIAGNOSES CONSIDERED NOT Click Here
MEDICALLY NECESSARY

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 failed treatment with Botox; AND
- 3. Member does **not** have neuromuscular disease (e.g., myasthenia gravis).
- 4. **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 <u>reauthorization</u>:

- 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:

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- a) Fixed contractures causing decreased neck range of motion;
- b) Neuromuscular disease (e.g., myasthenia gravis);
- c) Prior surgical treatment.
- 4. Dosage allowed: 120 Units.

If member meets all the requirements listed above, the medication will be approved for 6 months. For <u>reauthorization</u>:

- 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.

SPASTICITY (Upper Limb Only)

For *initial authorization:*

- 1. Member has confirmed diagnosis of post-stroke spasticity of the upper limb (at least six months poststroke); 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 <u>reauthorization</u>:

- 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
- Sialorrhea due to Parkinson's disease

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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.

References:

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