

## POLICY Document for Xeomin (incobotulinumtoxinA)

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, and overall clinically appropriate use. This document provides specific information to both sections of the overall policy.

### Section 1: Preferred Product

- Policy information specific to preferred medications

### Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

## Section 1: Preferred Product

### EXCEPTIONS CRITERIA BOTULINUM TOXINS

#### I. PREFERRED PRODUCTS: BOTOX, DYSPORT

This policy informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

#### II. PLAN DESIGN SUMMARY

This program applies to the botulinum toxins products specified in this policy. Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a non-preferred product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

**Table. Botulinum Toxins**

	Product(s)
Preferred	<ul style="list-style-type: none"> <li>• <b>Botox</b> (onabotulinumtoxinA)</li> <li>• <b>Dysport</b> (abobotulinumtoxinA)</li> </ul>
Non-preferred	<ul style="list-style-type: none"> <li>• <b>Myobloc</b> (rimabotulinumtoxinB)</li> <li>• <b>Xeomin</b> (incobotulinumtoxinA)</li> </ul>

### **III. EXCEPTION CRITERIA**

Coverage for a non-preferred product is provided when ANY of the following criteria is met:

- A. Member is currently receiving treatment with the non-preferred product through health insurance, excluding when the non-preferred product is obtained as samples or via manufacturer's patient assistance programs.
- B. Member has had an inadequate response or an intolerable adverse event to both preferred products.
- C. Member is requesting Xeomin for the treatment of blepharospasm and has had an inadequate response or an intolerable adverse event to Botox.

## **Section 2: Clinical Criteria**

### **XEOMIN (incobotulinumtoxinA)**

#### **I. INDICATIONS**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### **A. FDA-Approved Indications**

1. Cervical dystonia in adults in both botulinum toxin-naïve and previously treated patients
2. Blepharospasm in adults who were previously treated with onabotulinumtoxinA (Botox)
3. Upper limb spasticity in adults

All other indications are considered experimental/investigational and are not a covered benefit.

#### **II. EXCLUSIONS**

Coverage will not be provided for cosmetic use.

#### **III. CRITERIA FOR INITIAL APPROVAL**

##### **A. Cervical dystonia**

Authorization of 12 months may be granted for treatment of cervical dystonia (eg, torticollis).

##### **B. Blepharospasm**

Authorization of 12 months may be granted for treatment of blepharospasm when the member has received a prior treatment with onabotulinumtoxinA.

##### **C. Upper limb spasticity**

Authorization of 12 months may be granted for treatment of upper limb spasticity.

## **IV. CONTINUATION OF THERAPY**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

### **REFERENCES:**

#### **SECTION 1**

1. Botox [package insert]. Irvine, CA: Allergan, Inc.; April 2017.
2. Dysport [package insert]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; December 2016.
3. Myobloc [package insert]. City, ST: Solstice Neurosciences, Inc.; May 2010.
4. Xeomin [package insert]. Frankfurt, Germany: Merz Pharmaceuticals GmbH; December 2015.

#### **SECTION 2**

1. Xeomin [package insert]. Dessau-Rosslau, Germany: Merz Pharmaceuticals, LLC.; December 2015