Botox® (onabotulinumtoxinA)
Myobloc® (rimabotulinumtoxinB)
Dysport® (abobotulinumtoxinA)
Xeomin® (incobotulinumtoxinA)

Prior Authorization Criteria
Drug Protocol Management
MassHealth/Commercial/Exchange

Botox®, Myobloc®, Dysport® and Xeomin® are specialty products; dispensing is available from AllWays Health Partners’ preferred specialty pharmacy provider CVS/ Caremark.

How do I obtain a prior authorization for Botox®, Myobloc®, Dysport® or Xeomin®?
• Download a prior authorization fax form & send to (866) 249-6155.
• Contact the specialty pharmacy provider or CVS/Caremark at (866) 814-5506 for questions.

Criteria for coverage of Botox® (onabotulinumtoxinA):

<table>
<thead>
<tr>
<th>Condition</th>
<th>Criteria</th>
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<tbody>
<tr>
<td>Achalasia</td>
<td>1. Member must have documented diagnosis</td>
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<td>2. Requests may be approved for up to 100 units every 3 months.</td>
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<tr>
<td>Chronic anal fissure</td>
<td>1. Member has tried and failed conservative therapy options (nitroglycerin ointment or nifedipine ointment)</td>
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<td>2. Requests may be approved for up to 100 units every 3 months.</td>
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<tr>
<td>Chronic migraines</td>
<td>Note: All non-migraine related headaches (e.g., tension headache, cluster headache, etc.) are excluded from coverage.</td>
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<td>1. The prescriber is a neurologist or headache specialist, or the prescription is being written for the member in consultation with a neurologist or headache specialist AND</td>
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<td>2. The member is ≥ 18 years of age AND</td>
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<td></td>
<td>3. The member has been experiencing at least 15 migraine headaches per month with a duration of at least 4 hours a day or longer AND</td>
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<td>4. The member has had an inadequate response to a trial of at least THREE (3) different prophylactic migraine medications each with different mechanisms of action (a total of 3 required trials) that have each been tried for at least 60 days in duration within the past 3 years. All three trials must be from Level A or Level B categories within the American Academy of Neurology (see acceptable trials below). Note: triptans will not be considered as ‘prophylactic options.’</td>
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<td>Acceptable trials include:</td>
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<td>1. Antiepileptic agents: divalproex sodium, valproate</td>
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<td></td>
<td>2. Antiepileptic agents: topiramate</td>
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<td>3. Beta-blockers: metoprolol, propranolol, timolol, atenolol, or nadolol</td>
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<td>4. Antidepressants: amitriptyline</td>
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<td>5. Antidepressants: venlafaxine</td>
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<td>Initial requests will be approved for up to 200 units every 3 months for 2 treatments only.</td>
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</tbody>
</table>
Recertification requests may be approved for every 3-month dosing for the requested duration up to a 12-month period when documentation of improvement via physician assessment is submitted indicating evidence of effectiveness, including the following:
1. A decrease in the frequency of migraine headaches (i.e., the specific number of headaches per month) **AND**
2. A decrease in the severity of migraine headaches

| Chronic pain and pelvic floor spasms in women | 1. Member must have documented diagnosis  
2. Requests may be approved for up to 300 units every 3 months. |
|-----------------|----------------------------------|
| Limb spasticity - upper and lower | 1. Member has upper and/or lower limb spasticity due to one of the following: 
| | a. Brain injury, MS, spinal cord injury, stroke **OR** 
| | b. Cerebral Palsy in pediatric patients 2 years of age and older |

| Overactive bladder | 1. Member is at least 18 years of age **AND** 
2. Member has a diagnosis of overactive bladder or urinary incontinence **AND** 
3. Documentation of one of the following: 
| | • Failed trial of two (2) long-acting urinary antispasmodics **OR** 
| | • Clinical rationale for why anticholinergic agents are not appropriate 
4. Requests may be approved for up to 100 units every 3 months. |

| Urinary incontinence due to detrusor overactivity associated with a neurologic condition | 1. Member is at least 18 years of age **AND** 
2. Member has documented diagnosis of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis). 
3. Member has failed at least one anticholinergic agent (e.g. flavoxate, oxybutynin, tolterodine, trosplum, Detrol® LA, Enablex®, Toviaz®, Vesicare®) 
4. Requests may be approved for up to 200 units every 6 months. |

| Primary focal hyperhidrosis (Axillary or Palmar) | 1. Member is at least 18 years of age **AND** 
2. Treatment is provided by a dermatologist **AND** 
3. A letter of medical necessity from treating dermatologist **AND** 
4. Member has tried and failed at least a 60-day trial of a topical 20% aluminum chloride agent or oral glycopyrrolate 
5. Requests may be approved for up to 100 units every 3 months. |

| Seventh cranial nerve disorders (e.g., hemifacial spasm, oromandibular dystonia, orofacial dyskinesia | 1. Member is at least 12 years of age 
2. Requests may be approved for up to 100 units every 3 months. |

| Sialorrhea (salivary hypersecretion) | 1. Member has a diagnosis of Parkinson’s disease **AND** 
2. Member has tried and failed therapy with glycopyrrolate **OR** 
1. Member is pediatric patient with cerebral palsy **AND** 
2. Member has tried and failed therapy with glycopyrrolate. 
3. Requests may be approved for up to 100 units every 3 months (adults and peds) |

| Spasmodic dysphonia, laryngeal dysphonia (laryngeal spasm) or laryngeal dystonia | 1. Member must have documented diagnosis 
2. Requests may be approved for up to 100 units every 3 months |

| Cervical dystonia (spasmodic torticollis) | 1. Member is at least 16 years of age 
2. Requests may be approved for up to 400 units every 3 months |

| Strabismus or Blepharospasm | 1. Member is at least 12 years of age 
2. Requests may be approved for up to 200 units every 30 days. |
## Criteria for coverage of Dysport® (abobotulinumtoxinA)

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</table>
| Cervical dystonia (spasmodic torticollis)        | 1. Member is at least 18 years of age **AND**  
2. Member has tried and failed treatment with or has developed resistance to onabotulinumtoxinA (Botox)  
3. Initial requests may be approved for up to 500 units  
4. Reauthorization requests may be approved for up to 1000 units every 3 months. |
| Lower limb spasticity in pediatrics or spasticity in adults | 1. Member is at least 2 years of age **AND**  
2. Member has tried and failed treatment with or has developed resistance to onabotulinumtoxinA (Botox)  
3. Requests for members aged 2-17 may be approved for up to 1000 units every 3 months.  
4. Requests for adults will be approved for up to 1500 units. |

**NOTE:**  
*The maximum recommended total dose (upper and lower combined) should not exceed 1500 units every 3 months*

For all criteria: Member has not had a botulinum toxin injection within the past 4 months

## Criteria for coverage of Myobloc® (rimabotulinumtoxinB)

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| Cervical dystonia (spasmodic torticollis)        | 1. Member is at least 18 years of age **AND**  
2. Member has tried and failed treatment with or has developed resistance to onabotulinumtoxinA (Botox)  
3. Initial approvals for treatment naïve members may be approved for up to 2500 units  
4. Reauthorization requests may be approved for up to 10,000 units every 16 weeks |

For all criteria: Member has not had a botulinum toxin injection within the past 4 months

## Criteria for coverage of Xeomin® (incobotulinumtoxinA)

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| Blepharospasm                                    | 1. Member is at least 18 years old **AND**  
2. Member has tried and failed or has developed a resistance to onabotulinumtoxinA (Botox)  
3. Requests may be approved for up to 100 units every 3 months. |
| Sialorrhea                                       | 1. Member is at least 18 years old **AND**  
2. Member as tried and failed treatment with or has developed resistance to onabotulinumtoxinA (Botox)  
3. Requests may be approved for up to 100 units every 16 weeks |
| Cervical dystonia (spasmodic torticollis)        | 1. Member is at least 18 years old **AND**  
2. Member has tried and failed or has developed a resistance to onabotulinumtoxinA (Botox)  
3. Initial requests may be approved for up to 200 units every 3 months.  
4. Reauthorizations may be approved for up to 400 units every 3 months. |
| Upper limb spasticity                            | 1. Member is at least 18 years of age **AND**  
2. Member has tried and failed or has developed a resistance to onabotulinumtoxinA (Botox) |
3. Requests may be approved for up to 400 units every 3 months

For all criteria: Member has not received a botulinum toxin injection within the past 4 months.

All other conditions AND doses exceeding the limits set within the criteria will be reviewed on a case by case basis. Risk-benefit assessment should precede any decision for use in unlabeled indications as well as establishing that the patient is unresponsive to conventional treatment options.

**Continuation of Therapy**
For all conditions, unless otherwise specified, AllWays Health Partners will continue to approve Botox, Dysport, Myobloc and Xeomin therapy when clinical documentation has been submitted by the provider indicating improvement in the member’s condition while receiving one of these agents.

**Approval Period**

**Initial Authorizations:**
1. Migraines and hyperhidrosis: 6 months
2. All other diagnoses: 3 months

**Reauthorizations:**
1. All diagnoses: May be approved for up to 12 months when documentation of clinical benefit is submitted.

**Exclusions:**
1. AllWays Health Partners will not cover Botox, Dysport, Myobloc or Xeomin for the following conditions:
   a. Facial rhytids
   b. Frown lines
   c. Glabellar wrinkling
   d. Horizontal neck rhytids
   e. Hyperfunctional facial lines
   f. Mid and lower face and neck rejuvenation
   g. Platysmal bands
   h. Rejuvenation of the periorbital region
   i. Lateral canthal lines (Crow’s feet)
2. Botox® Cosmetic
3. Dysport® 300 units (abobotulinumtoxinA) (glabellar lines)

**References:**


14. Xeomin (incobotulinumtoxinA) [prescribing information] Raleigh, NC: Merz Pharmaceuticals; December 2015.

**Review History:**
Implemented: 12/1/05
Updated: 01/03/2011 (Exclusions section update w/ new Dysport product); 05/17/11 (Xeomin BART); 09/19/13 (Dysport 300 units glabellar lines product; 04/08/13 file & Botox crow’s feet); 06/09/14 (Migraine trials to 3 based on specialist input); 11/20/17; 02/26/18 P&T; 7/5/18 (added diag of chronic sialorrhea to Xeomin); 11/26/18
Reviewed: 9/25/06; 9/24/07; 9/22/08; 9/21/09; 9/27/2010; 9/19/11; 09/24/12; 11/25/13; 11/24/14 P&T Mtg