Botox® (onabotulinumtoxinA)  
Myobloc® (rimabotulinumtoxinB)  
Dysport® (abobotulinumtoxinA)  
Xeomin® (incobotulinumtoxinA)  
Effective February 1, 2020

<table>
<thead>
<tr>
<th>Plan</th>
<th>Program Type</th>
</tr>
</thead>
</table>
| ☑ MassHealth  
☒ Commercial/Exchange | ☑ ☑ Prior Authorization  
☐ Quantity Limit  
☐ Step Therapy |

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Specialty Limitations</th>
</tr>
</thead>
</table>
| ☑ Pharmacy Benefit  
☐ Medical Benefit (NLX) | These medications have been designated specialty and must be filled at a contracted specialty pharmacy. |

<table>
<thead>
<tr>
<th>Contact Information</th>
<th>Specialty Medications</th>
</tr>
</thead>
</table>
| All Plans | Phone: 866-814-5506  
Fax: 866-249-6155 |

<table>
<thead>
<tr>
<th>Plan</th>
<th>Specialty Medications</th>
</tr>
</thead>
</table>
| ☑ MassHealth  
☒ Commercial/Exchange | Non-Specialty Medications |
| ☑ Commercial  
☐ Exchange | Phone: 866-255-7569  
Fax: 888-836-0730 |
| ☑ Commercial  
☐ Exchange | Phone: 855-245-2134  
Fax: 855-582-2022 |

<table>
<thead>
<tr>
<th>Plan</th>
<th>Medical Specialty Medications (NLX)</th>
</tr>
</thead>
</table>
| ☑ All Plans | Phone: 844-345-2803  
Fax: 844-851-0882 |

| Exceptions | N/A |

**Overview**
Botox, Dysport, Myobloc and Xeomin are neurotoxins which inhibit the release of acetylcholine causing muscle denervation.

**Coverage Guidelines**
Approval will be granted if the member meets all the medication and condition specific criteria.

### Botox® (onabotulinumtoxinA)

**Achalasia**
1. Member must have documented diagnosis  
2. Requests may be approved for up to 100 units every 3 months.

**Chronic anal fissure**
1. Member has tried and failed conservative therapy options (nitroglycerin ointment or nifedipine ointment)  
2. Requests may be approved for up to 100 units every 3 months

**Chronic migraines**
Note: All non-migraine related headaches (e.g., tension headache, cluster headache, etc.) are excluded from coverage.
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**  
2. The member is ≥ 18 years of age **AND**  
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**
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.’

5. The member is not concurrently using a calcitonin-gene receptor antagonist (CGRP), including, but not limited to Ajovy, Aimovig, Emgality.

Acceptable trials include:
1. Antiepileptic agents: divalproex sodium, valproate
2. Antiepileptic agents: topiramate
3. Beta-blockers: metoprolol, propranolol, timolol, atenolol, or nadolol
4. Antidepressants: amitriptyline
5. Antidepressants: venlafaxine

Initial requests will be approved for up to 200 units every 3 months for 2 treatments only.
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 AND
3. The member is not concurrently using a calcitonin-gene receptor antagonist (CGRP), including, but not limited to, Ajovy, Aimovig, Emgality.

| 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 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, trospium, Deterol 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 |
<table>
<thead>
<tr>
<th>Disorder</th>
<th>Criteria</th>
</tr>
</thead>
</table>
| Seventh cranial nerve disorders (e.g., hemifacial spasm, oromandibular dystonia, orofacial dyskinesia) | 4. Member has tried and failed at least a 60-day trial of a topical 20% aluminum chloride agent or oral glycopyrrlate  
5. Requests may be approved for up to 100 units every 3 months |
| Sialorrhea (salivary hypersecretion)                                     | 1. Member is at least 12 years of age  
2. Requests may be approved for up to 100 units every 3 months. |
| Spasmodic dysphonia, laryngeal dysphonia (laryngeal spasm) or laryngeal dystonia | 1. Member has a diagnosis of Parkinson’s disease AND  
2. Member has tried and failed therapy with glycopyrrolate OR  
1. Member is a 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) |
| 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. |
| Dysport® (abobotulinumtoxinA)                                           | 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 1000 units  
4. Reauthorization requests may be approved for up to 1000 units every 3 months. |
| Lower and upper 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 1500 units every 3 months if being treated for both upper and lower limb spasticity  
4. Requests for adults will be approved for up to 1500 units every 3 months* |

*NOTE: The maximum recommended total dose (upper and lower limbs 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

| Myobloc® (rimabotulinumtoxinB)                                         | 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 members previously untreated with botulinum toxin may be approved for up to 2500 units
4. Reauthorization requests may be approved for up to 10,000 units every 16 weeks

**Sialorrhea (salivary hypersecretion)**

1. Member is at least 18 years of age
2. Member is diagnosed with chronic sialorrhea
3. Member has tried and failed treatment with or has developed resistance to onabotulinumtoxinA (Botox) **AND**
4. Member has tried and failed therapy with glycopyrrolate.
5. Requests may be approved for up to a maximum of 3500 units every 3 months

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

**Xeomin® (incobotulinumtoxinA)**

**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 has 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) **AND** rimabotulinumtoxinB (Myobloc)
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**

Require documentation of clinical benefit including any diagnosis specific improvements listed in the criteria.

**Limitations**

1. Initial Authorizations:
   a. Migraines and hyperhidrosis: 6 months (2 doses)
   b. All other diagnoses: 3 months (1 dose)
2. Reauthorizations are issued for 12 months
3. Quantity limits are applicable as noted in the criteria

399 Revolution Drive, Suite 810, Somerville, MA 02145 | allwayshealthpartners.org
4. Exclusions:
   a. AllWays Health Partners will not cover Botox, Dysport, Myobloc or Xeomin for the following conditions: facial rhytids, frown lines, glabellar wrinkling, horizontal neck rhytids, hyperfunctional facial lines, mid and lower face and neck rejuvenation, platysmal bands, rejuvenation of the periorbital region, lateral canthal lines (crow’s feet)
   b. Botox® Cosmetic
   c. Dysport® 300 units (abobotulinumtoxinA) (glabellar lines)

References
15. Xeomin (IncobotulinumtoxinA) [prescribing information] Raleigh, NC: Merz Pharmaceuticals; May 2019.

**Review History**

12/01/05 – Implemented
09/25/06 – Reviewed
09/24/07 – Reviewed
09/22/08 – Reviewed
09/21/09 – Reviewed
09/27/10 – Reviewed
01/03/11 – Exclusions section updated with new Dysport product
05/17/11 – Xeomin BART
09/19/11 – Reviewed
09/24/12 – Reviewed
09/19/13 – Dysport 300 units glabellar lines product
04/08/13 – Botox exclusion: crow’s feet
11/25/13 – Reviewed
06/09/14 – Added migraine trials to 3 based on specialist input
11/24/14 – Reviewed
11/20/17 – Updated
02/26/18 – Updated
07/05/18 – Added diagnosis of chronic sialorrhea to Xeomin
11/26/18 – Updated
09/18/19 – Added restriction of using concurrent CGRP with Botox for migraine and new indication of sialorrhea for Myobloc
11/20/19 – Added new indications for upper limb spasticity in pediatrics and increased max dose for this indication from 1000 units to 1500 units

**Disclaimer**

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.