

Botox® (onabotulinumtoxinA)
Dysport® (abobotulinumtoxinA)
Myobloc® (rimabotulinumtoxinB)
Xeomin® (incobotulinumtoxinA)
Effective 07/31/2023

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	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.

Indication	Botox®	Dysport®	Myobloc®	Xeomin®
Blepharospasm	✓	-	-	✓
Cervical Dystonia	✓	✓	✓	✓
Lower Limb Spasticity	✓	✓	-	-
Migraine Prophylaxis	✓	-	-	-
Neurogenic detrusor overactivity	✓			
Overactive bladder	✓	-	-	-
Sialorrhea	-	-	✓	✓
Strabismus	✓	-	-	-
Severe axillary hyperhidrosis	✓	-	-	-
Upper Limb Spasticity	✓	✓	-	✓
Urinary incontinence associated with neurologic conditions	✓	-	-	-

Coverage Guidelines

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

Botox® (onabotulinumtoxinA)

<p>All indications EXCEPT bladder dysfunction, migraine prophylaxis, hyperhidrosis</p>	<p>ALL of the following:</p> <ol style="list-style-type: none"> 1. ONE of the following diagnoses: <ol style="list-style-type: none"> a. Strabismus and blepharospasms associated with dystonia (including essential blepharospasm, cranial nerve VII disorders/hemifacial spasm) b. Focal dystonias (including cervical dystonia/spasmodic torticollis in members > 16 years of age; spasmodic dysphonia, oromandibular dystonia) c. Limb spasticity (due to cerebral palsy, multiple sclerosis, or other demyelinating CNS diseases, spinal cord injury) d. Focal spasticity related to cerebral vascular accident (including hemorrhagic stroke, anoxia, and traumatic brain injury) 2. Dose is appropriate for stated indication (prescriber must provide child's weight)
<p>Migraine Prophylaxis</p>	<p>ALL of the following:</p> <ol style="list-style-type: none"> 1. Diagnosis of migraine prophylaxis 2. Prescriber is a neurologist, pain medicine/anesthesiology physician or physical medicine/rehabilitation physician or consult notes from one are provided 3. Documentation of headache frequency \geq 15 days per month 4. Physician attestation of inadequate response or adverse reaction to ONE or contraindication to ALL of the following (<i>e.g., concurrent diagnosis of depression, asthma, COPD, peripheral vascular disease, Raynaud's, baseline hypotension or bradycardia, and pheochromocytoma</i>): <ol style="list-style-type: none"> a. atenolol b. metoprolol c. nadolol d. propranolol e. timolol 5. Physician attestation of inadequate response or adverse reaction to TWO or contraindication to ALL of the following: <ol style="list-style-type: none"> a. amitriptyline, nortriptyline or protriptyline b. topiramate c. valproic acid d. venlafaxine 6. Dose is appropriate for stated indication (<i>See Appendix for 10-week dosing</i>)
<p>Overactive bladder</p>	<p>ALL of the following:</p> <ol style="list-style-type: none"> 1. Diagnosis of overactive bladder 2. Prescriber is a urologist or consult notes from a urologist are provided 3. Paid claims or physician attestation of inadequate response or adverse reaction to ONE or contraindication to BOTH of the following classes: <ol style="list-style-type: none"> a. TWO anticholinergic medications (<i>e.g., oxybutynin, tolterodine</i>) b. ONE anticholinergic medication and ONE β-3 adrenergic receptor agonist (<i>mirabegron</i>)



	4. Dose is appropriate for stated indication
Neurogenic Bladder Dysfunction/Neurogenic Detrusor Overactivity (adults)	<p>ALL of the following:</p> <ol style="list-style-type: none"> 1. Diagnosis of neurogenic bladder dysfunction 2. Prescriber is a urologist or consult notes from a urologist are provided 3. Paid claims or physician attestation of inadequate response or adverse reaction to ONE of the following or contraindication to ALL of the following classes: <ol style="list-style-type: none"> a. TWO anticholinergic medications (e.g. oxybutynin, tolterodine) b. ONE anticholinergic medication and ONE alpha blocker (e.g. prazosin, terazosin) c. ONE anticholinergic medication and ONE cholinergic agent (e.g. bethanechol) 4. Dose is appropriate for stated indication
Neurogenic Bladder Dysfunction/Neurogenic Detrusor Overactivity (pediatrics)	<p>ALL of the following:</p> <ol style="list-style-type: none"> 1. Diagnosis of neurogenic bladder dysfunction 2. Prescriber is a urologist or consult notes from a urologist are provided 3. Paid claims or physician attestation of inadequate response or adverse reaction to ONE of the following or contraindication to BOTH of the following classes: <ol style="list-style-type: none"> a. ONE anticholinergic medication (e.g. oxybutynin, solifenacin) b. ONE β-3 adrenergic receptor agonist (mirabegron) 4. Dose is appropriate for stated indication (not more frequently than every 12 weeks)
Primary focal hyperhidrosis (Axillary, Palmar, or Plantar)	<p>ALL of the following:</p> <ol style="list-style-type: none"> 1. Diagnosis of ONE of the following: <ol style="list-style-type: none"> a. Severe primary axillary hyperhidrosis <ol style="list-style-type: none"> i. Member is \geq 18 years of age OR 12 to <18 years of age b. Severe palmar hyperhidrosis c. Severe plantar hyperhidrosis 2. Prescriber is a dermatologist or neurologist or consult notes from a dermatologist or neurologist are provided 3. Physician attestation of inadequate response, adverse reaction or contraindication to aluminum chloride solution 4. Dose is appropriate for stated indication
Off-Label Indications	
Achalasia/esophageal dysphagia	<p>ALL of the following:</p> <ol style="list-style-type: none"> 1. Diagnosis of achalasia/esophageal dysphagia 2. Prescriber is a gastroenterologist or surgeon or consult notes from a gastroenterologist or surgeon are provided 3. ONE of the following: <ol style="list-style-type: none"> a. The member has failed a surgical option (e.g., pneumatic dilation, laparoscopic Heller myotomy with a partial fundoplication and peroral endoscopic myotomy [POEM]) b. The member is not a surgical candidate or is unwilling to undergo these procedures. 4. Initial requested dose is \leq 100 units no more frequently than every six months



<p>Anal stenosis, chronic constipation, encopresis</p>	<p>ALL of the following:</p> <ol style="list-style-type: none"> 1. Diagnosis of anal stenosis, chronic constipation, encopresis 2. Prescriber is a gastroenterologist or surgeon or consult notes from a gastroenterologist or surgeon are provided 3. Inadequate response or adverse reaction to TWO or contraindication to ALL laxatives 4. Inadequate response to dietary changes (e.g., increased intake of fluids and fiber) and/or behavior modification (e.g., biofeedback training, toilet training) 5. Initial requested dose is \leq 100 units no more frequently than every three months
<p>Sialorrhea</p>	<p>ALL of the following:</p> <ol style="list-style-type: none"> 1. Diagnosis of sialorrhea 2. Inadequate response or adverse reaction to TWO or contraindication to ALL of the following: <ol style="list-style-type: none"> a. atropine b. glycopyrrolate c. hyoscyamine d. scopolamine e. tricyclic antidepressant (e.g., amitriptyline, nortriptyline, etc.) 3. Appropriate dosing (40 to 100 units every 3 to 6 months) 4. Inadequate response, adverse reaction, or contraindication to BOTH of the following agents: <ol style="list-style-type: none"> a. Myobloc b. Xeomin
<p>Migraine prophylaxis, concomitant therapy with a CGRP inhibitor</p>	<p>ALL of the following:</p> <ol style="list-style-type: none"> 1. Individual drug PA criteria must be met first where applicable 2. Diagnosis of migraine prophylaxis 3. Partial, but incomplete, response to Botox®
<p>Migraine prophylaxis, dosing every 10 weeks</p>	<p>ALL of the following:</p> <ol style="list-style-type: none"> 1. Individual drug PA criteria must be met first where applicable 2. Diagnosis of migraine prophylaxis 3. Member received initial positive response to therapy 4. Member is still experiencing a “wearing-off” of efficacy after a dose increase to 195 units
<p>Myofascial pain syndrome</p>	<p>ALL of the following:</p> <ol style="list-style-type: none"> 1. Diagnosis of myofascial pain syndrome 2. Inadequate response or adverse reaction to TWO or contraindication to ALL of the following agents: <ol style="list-style-type: none"> a. cyclobenzaprine b. gabapentin or pregabalin c. local anesthetic (e.g., lidocaine patch) d. SNRI (e.g., duloxetine) e. TCA agent (e.g., amitriptyline) 3. Appropriate dosing (up to a total dose of 200 units)
<p>Myofascial pelvic pain syndrome</p>	<p>ALL of the following:</p> <ol style="list-style-type: none"> 1. Diagnosis of myofascial pelvic pain syndrome



	<ol style="list-style-type: none"> 2. Inadequate response, adverse reaction to TWO or contraindication to ALL of the following agents: <ol style="list-style-type: none"> a. gabapentin or pregabalin b. muscle relaxant (e.g., cyclobenzaprine) c. SNRI (e.g., duloxetine) d. TCA agent (e.g., amitriptyline) e. vaginal diazepam 3. Appropriate dosing (up to a total dose of 300 units)
Raynaud's Phenomenon	<p>ALL of the following:</p> <ol style="list-style-type: none"> 1. Diagnosis of Raynaud's Phenomenon 2. Inadequate response or adverse reaction to THREE or contraindication to ALL of the following: <ol style="list-style-type: none"> a. Calcium channel blocker (amlodipine or nifedipine) b. fluoxetine c. losartan d. PDE type 5 inhibitor e. Topical nitrate 3. Requested dose is \leq 200 units/90 day

<u>Dysport® (abobotulinumtoxinA)</u>	
Cervical dystonia/spasmodic torticollis, Upper Limb Spasticity, Lower Limb Spasticity	<p>ALL of the following:</p> <ol style="list-style-type: none"> 1. ONE of the following diagnoses: <ol style="list-style-type: none"> a. Cervical dystonia/spasmodic torticollis b. Upper limb spasticity c. Lower limb spasticity 2. Dose is appropriate for stated indication (prescriber must provide child's weight)
Off-Label Indications	
Achalasia/esophageal dysphagia	<p>ALL of the following:</p> <ol style="list-style-type: none"> 1. Diagnosis of achalasia/esophageal dysphagia 2. Prescriber is a gastroenterologist or surgeon or consult notes from a gastroenterologist or surgeon are provided 3. ONE of the following: <ol style="list-style-type: none"> a. The member has failed a surgical option (e.g., pneumatic dilation, laparoscopic Heller myotomy with a partial fundoplication and peroral endoscopic myotomy [POEM]) b. The member is not a surgical candidate or is unwilling to undergo these procedures. 4. Initial requested dose is \leq 250 units no more frequently than every six months <p style="text-align: center;">See Appendix for High Dose Requests</p>

<u>Myobloc® (rimabotulinumtoxinB)</u>
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Cervical dystonia (spasmodic torticollis)	ALL of the following: <ol style="list-style-type: none"> 1. Diagnosis of cervical dystonia/spasmodic torticollis 2. Dose is appropriate for stated indication
Sialorrhea (salivary hypersecretion)	ALL of the following: <ol style="list-style-type: none"> 1. Diagnosis of sialorrhea 2. Physician attestation of inadequate response or adverse reaction to TWO or contraindication to ALL of the following agents: <ol style="list-style-type: none"> a. scopolamine b. glycopyrrolate c. atropine d. hyoscyamine e. TCA agent (e.g., amitriptyline, nortriptyline, etc) 3. Dose is appropriate for stated indication
See Appendix for High Dose Requests	

<u>Xeomin® (incobotulinumtoxinA)</u>	
All indications except Sialorrhea	ALL of the following: <ol style="list-style-type: none"> 1. ONE of the following diagnoses: <ol style="list-style-type: none"> a. Cervical dystonia/spasmodic torticollis b. Upper limb spasticity c. Blepharospasm 2. Dose is appropriate for stated indication (prescriber must provide child's weight)
Sialorrhea	ALL of the following: <ol style="list-style-type: none"> 1. Diagnosis of sialorrhea 2. Physician attestation of inadequate response or adverse reaction to TWO or contraindication to ALL of the following agents: <ol style="list-style-type: none"> a. scopolamine b. glycopyrrolate c. atropine d. hyoscyamine e. Tricyclic antidepressant agent (e.g. amitriptyline, nortriptyline, etc) 3. Dose is appropriate for stated indication (prescriber must provide child's weight, which may be accepted over the phone)
See Appendix for High Dose Requests	

Off Label Indications for ALL agents	
Anal Fissures	ALL of the following: <ol style="list-style-type: none"> 1. Diagnosis of anal fissures 2. Prescriber is a gastroenterologist or surgeon or consult notes from a gastroenterologist or surgeon are provided 3. Inadequate response or adverse reaction to ONE or contraindication to BOTH of the following: <ol style="list-style-type: none"> a. topical nifedipine product b. topical nitroglycerin



Gastroparesis	ALL of the following: <ol style="list-style-type: none"> 1. Diagnosis of gastroparesis 2. Prescriber is a gastroenterologist or surgeon or consult notes from a gastroenterologist or surgeon are provided 3. Inadequate response, adverse reaction, or contraindication to metoclopramide 4. Inadequate response or adverse reaction to ONE or contraindication to ALL antiemetics
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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

Reauthorizations require physician attestation of a positive response to therapy.

Limitations

1. Initial Authorizations will be granted for 3 months for the first course of therapy.
2. Reauthorizations will be granted for 12 months.
3. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).
4. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name formulation is preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at www.mass.gov/druglist.
5. **Exclusions:**
 - a. The Plan 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)

Appendix

High Dose of Botulinum Toxin Products

	Adults: Requests for adults beyond the FDA-approved dose can be approved up to the following doses:	Pediatrics: Requests for members less than 18 years of age (or less than 60 kg) can be approved up to the following doses:
	Maximum Approvable Dose	Maximum Approvable Dose



Botox® (onabotulinumtoxinA)	Up to 840 units	Up to 25 units/kg or a max total dose of up to 600 units (this would be multiple administration sites; please follow max dose per treatment session in respective area per PI)
Dysport® (abobotulinumtoxinA)	Up to 1,500 units	Up to 25 units/kg or a max total dose of up to 1,000 units
Myobloc® (rimabotulinumtoxinB)	Up to 25,000 units	Up to 400 units/kg or a max total dose of 10,000 units
Xeomin® (incobotulinumtoxinA)	Up to 840 units	Requests for dosing outside of FDA-approved use in pediatric patients will be evaluated on a case-by-case basis

References

1. Botox® [package insert]. Irvine (CA): Allergan, Inc; 2021 Jul.
2. Dysport® [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; 2020 Jul.
3. Myobloc® [package insert]. South San Francisco (CA): Solstice Neuroscience, Inc; 2021 Mar.
4. Xeomin® [package insert]. Raleigh (NC): Merz Pharmaceuticals, LLC; 2021 Aug.
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Review History

12/01/2005 – Implemented
09/25/2006 – Reviewed
09/24/2007 – Reviewed
09/22/2008 – Reviewed
09/21/2009 – Reviewed
09/27/2010 – Reviewed
01/03/2011 – Exclusions section updated with new Dysport product
05/17/2011 – Xeomin BART
09/19/2011 – Reviewed
09/24/2012 – Reviewed
09/19/2013 – Dysport 300 units glabellar lines product
04/08/2013 – Botox exclusion: crow’s feet
11/25/2013 – Reviewed
06/09/2014 – Added migraine trials to 3 based on specialist input
11/24/2014 – Reviewed
11/20/2017 – Updated
02/26/2018 – Updated
07/05/2018 – Added diagnosis of chronic sialorrhea to Xeomin
11/26/2018 – Updated
09/18/2019 – Added restriction of using concurrent CGRP with Botox for migraine and new indication of sialorrhea for Myobloc
11/20/2019 – Added new indications for upper limb spasticity in pediatrics and increased max dose for this indication from 1000 units to 1500 units
05/20/2020 – Reviewed and Updated May P&T Mtg; updated reauthorization for chronic migraines to decrease in frequency and/or severity of migraines. Effective 8/1/20.
07/20/2022 – Reviewed and Updated for July P&T; removed the following statement “The member is not concurrently using a calcitonin-gene receptor antagonist (CGRP), including, but not limited to Ajovy, Aimovig, Emgality.”
09/21/2022 – Separated Comm/Exch vs MH policy; no clinical updates. Effective 10/1/2022
1/11/2023 – Reviewed and updated for Jan P&T. Matched MH UPPL criteria for all drugs. Added Appendix sections. Clarified approval durations. Updated references. Effective 2/1/23.
04/12/23 – Reviewed and updated for Apr P&T. Diagnosis of primary axillary hyperhidrosis age criteria update. Added specific criteria points to Concomitant CGRP and Botox therapy and 10-week botox dosing for migraine prophylaxis. Effective 6/5/23.
07/12/23 – Reviewed and updated for P&T. Off-label criteria were added for Botox for myofascial pain syndrome and for myofascial pelvic pain syndrome. Brand preferred and mandatory generic language was added under Limitations. Brand preferred and mandatory generic language was added under Limitations. Effective 7/31/23

