Botox® (onabotulinumtoxinA)
Myobloc® (rimabotulinumtoxinB)
Dysport® (abobotulinumtoxinA)
Xeomin® (incobotulinumtoxinA)
Effective 02/01/2023

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ 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)	
All indications except bladder dysfunction, migraine prophylaxis, hyperhidrosis	Prescriber provides documentation of **ALL** of the following: 1. **ONE** of the following diagnoses: 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)
Migraine Prophylaxis	Prescriber provides documentation of **ALL** of the following: 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 ≥ 15 days per month 4. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following *(e.g., concurrent diagnosis of depression, asthma, COPD, peripheral vascular disease, Raynaud's, baseline hypotension or bradycardia, and pheochromocytoma):* 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: a. amitriptyline, nortriptyline or protriptyline b. topiramate c. valproic acid d. venlafaxine 6. Dose is appropriate for stated indication *(See Appendix for 10-week dosing)*
Overactive bladder	Prescriber provides documentation of **ALL** of the following: 1. Diagnosis of overactive bladder 2. Prescriber is a urologist or consult notes from a urologist are provided 3. **ONE** of the following:

	a. Paid claims or physician attestation of inadequate response or adverse reaction to **TWO** anticholinergic medications (e.g., oxybutynin, tolterodine) b. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** anticholinergic medication and **ONE** β-3 adrenergic receptor agonist (mirabegron) c. Contraindication to **ALL** anticholinergic medications and β-3 adrenergic receptor agonists 4. Dose is appropriate for stated indication
Neurogenic Bladder Dysfunction/Neurogenic Detrusor Overactivity (adults)	Prescriber provides documentation of **ALL** of the following: 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: 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)	Prescriber provides documentation of **ALL** of the following: 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: 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)	Prescriber provides documentation of **ALL** of the following: 1. Diagnosis of **ONE** of the following: a. Severe primary axillary hyperhidrosis 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

Dysport® (abobotulinumtoxinA)	
Cervical dystonia/spasmodic torticollis, Upper Limb Spasticity, Lower Limb Spasticity	Prescriber provides documentation of **ALL** of the following: 1. **ONE** of the following diagnoses: 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)
See Appendix for High Dose Requests	

Myobloc® (rimabotulinumtoxinB)	
Cervical dystonia (spasmodic torticollis)	Prescriber provides documentation of **ALL** of the following: 1. Diagnosis of cervical dystonia/spasmodic torticollis 2. Dose is appropriate for stated indication
Sialorrhea (salivary hypersecretion)	Prescriber provides documentation of **ALL** of the following: 1. Diagnosis of sialorrhea 2. Physician attestation of inadequate response, adverse reaction to **TWO** or contraindication to **ALL** of the following agents: 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	

Xeomin® (incobotulinumtoxinA)	
All indications except Sialorrhea	Prescriber provides documentation of **ALL** of the following: 1. **ONE** of the following diagnoses: 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	Prescriber provides documentation of **ALL** of the following: 1. Diagnosis of sialorrhea 2. Physician attestation of inadequate response, adverse reaction to **TWO** or contraindication to **ALL** of the following agents: 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	

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. 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

Additional Off-label Uses of Botulinum Toxin Products
Listed below are approval criteria for common off-label requests.

Achalasia/esophageal dysphagia
Requests for Botox® or Dysport® for the treatment of achalasia, esophageal dysphagia may be considered for approval on a case-by-case basis if **ALL** of the following criteria have been met:

1. Prescriber is a gastroenterologist or surgeon or consult notes from a gastroenterologist or surgeon are provided
2. Documentation that member has failed a surgical option (e.g., pneumatic dilation, laparoscopic Heller myotomy with a partial fundoplication and peroral endoscopic myotomy [POEM]) or that member is not a surgical candidate or is unwilling to undergo these procedures.
3. Initial dose requested is up to 100 units of Botox® or 250 units Dysport® no more frequently than every six months

Anal stenosis, chronic constipation, encopresis
Requests for Botox® for the treatment of anal stenosis, chronic constipation, encopresis may be considered for approval on a case-by-case basis if **ALL** of the following criteria have been met:

1. Prescriber is a gastroenterologist or surgeon or consult notes from a gastroenterologist or surgeon are provided
2. Documentation that member has failed to respond to at least two laxatives
3. Documentation that member has failed to respond to dietary changes (e.g., increased intake of fluids and fiber) and/or behavior modification (e.g., biofeedback training, toilet training)
4. Initial dose requested is up to 100 units of Botox® no more frequently than every three months

Anal Fissures
Requests for botulinum toxin products for the treatment of anal fissures may be considered for approval on a case-by-case basis if **ALL** of the following criteria have been met:

1. Prescriber is a gastroenterologist or surgeon or consult notes from a gastroenterologist or surgeon are provided
2. Paid claims or documentation that member has had an inadequate response, adverse reaction or contraindication to topical nitroglycerin or topical nifedipine product

Gastroparesis
Requests for botulinum toxin products in **refractory** gastroparesis may be considered for approval on a case-by-case basis if **ALL** of the following criteria have been met:

1. Prescriber is a gastroenterologist or consult notes from a gastroenterologist are provided
2. Paid claims or documentation that member has had an inadequate response, adverse reaction or contraindication to metoclopramide
3. Paid claims or documentation that member has had an inadequate response, adverse reaction or contraindication to antiemetics

Raynaud's Phenomenon
Requests for Botox® in Raynaud's phenomenon may be approved if **ALL** of the following criteria have been met:

1. Diagnosis of Raynaud's Phenomenon
2. Physician attestation of inadequate response, adverse reaction to **THREE** or contraindication to **ALL** of the following agents:
    a. Calcium channel blocker (amlodipine or nifedipine)
    b. PDE type 5 inhibitor
    c. Topical nitrate
    d. Losartan
    e. Fluoxetine
3. Dosing does not exceed a total of 200 units per 90 days

Sialorrhea
If member meets criteria below, requests can be approved:

1. Diagnosis of sialorrhea
2. Physician attestation of inadequate response, adverse reaction to **TWO** or contraindication to **ALL** of the following agents:
    a. scopolamine
    b. glycopyrrolate
    c. atropine
    d. hyoscyamine
    e. TCA agent (e.g. amitriptyline, nortriptyline, etc.)
3. Dosing is appropriate (40 to 100 units every 3 to 6 months)
4. Physician attestation of inadequate response, adverse reaction, or contraindication to **BOTH** of the following agents:
    a. Myobloc
    b. Xeomin

<u>Concomitant CGRP Inhibitor and Botox Therapy</u>

If the provider documents a partial, but incomplete, response to Botox® therapy and wishes to add a CGRP inhibitor to supplement, this may be approved for 3 months.
Resubmission should document response to therapy and improvement of headache days per month and can be recertified for up to 6 months.

10-Week Botox Dosing for Migraine Prophylaxis
Every 10-week dosing may be approved if the member has had an initial positive response to therapy and is still experiencing a "wearing-off" of efficacy after a dose increase to 195 units.

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

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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.

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