Mass General Brigham
Health Plan

Botox® (onabotulinumtoxinA)
Myobloc® (rimabotulinumtoxinB)
Dysport® (abobotulinumtoxinA)
Xeomin® (incobotulinumtoxinA)
Effective 10/01/2022

Plan	☐ MassHealth UPPL ☒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.

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.' 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 <u>Initial requests</u> will be approved for up to 200 units every 3 months for 2 treatments only. <u>Recertification requests</u> may be approved for every 3-month dosing for the requested duration up to a 12-month period when documentation of ALL the following criteria are met, and documentation is provided: 1. Positive clinical response (i.e., decrease in frequency and/or severity of migraines) via physician assessment is submitted
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, 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 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)
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.

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 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) **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
4. 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)

References

1. Botox (onabotulinumtoxinA) [prescribing information]. Madison, NJ: Allergan USA; October 2019.
2. Brisinda, G., Maria, G., Bentivoglio, A.R., Cassetta, E., Gui, D., Albanese, A. (1999). "A comparison of injections of botulinum toxin and topical nitroglycerin ointment for the treatment of chronic anal fissure." New England Journal of Medicine, 341(2):65-69.

3. Jost WH, Friedman A, Michel O, et al. SIAXI: Placebo-controlled, randomized, double-blind study of incobotulinumtoxinA for sialorrhea. Neurology 2019; 92:e1982
4. Bekkers S, Delsing CP, Kok SE, et al. Randomized controlled trial comparing botulinum vs surgery for drooling in neurodisabilities. Neurology 2019; 92:e1195
5. Vaezi MF, Pandolfino JE, Vela MF. ACG clinical guideline: diagnosis and management of achalasia. *Am J Gastroenterol*. 2013;108(8):1238-1249.[PubMed 23877351]
6. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology 2016; 86:1818
7. Reddihough D, Erasmus CE, Johnson H, McKellar GM, Jongerius PH; Cerebral Palsy Institute. Botulinum toxin assessment, intervention and aftercare for paediatric and adult drooling: international consensus statement. *Eur J Neurol*. 2010;17(suppl 2):109-121.[PubMed 20633182]
8. Nelson RL, Thomas K, Morgan J, Jones A. Non surgical therapy for anal fissure. *Cochrane Database Syst Rev*. 2012;2:CD003431.[PubMed 22336789]
9. Dysport (abobotulinumtoxinA) [prescribing information]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc; September 2019.
   Tercica Ghei, M., Maraj, B.H., Miller, R., Nathan, S., O'Sullivan, C., Fowler, C.J., Shan, P.J.R., Malone-Lee, J. (2005). "Effects of botulinum toxin B on refractory detrusor overactivity: a randomized, double-blind, placebo controlled, crossover trial." The Journal of Urology, 174:1873-1877.
10. Myobloc (RimabotulinumtoxinB) [prescribing information]. South San Francisco, CA: Solstice Neurosciences; Updated September 2019.
11. Xeomin (IncobotulinumtoxinA) [prescribing information] Raleigh, NC: Merz Pharmaceuticals; May 2019.

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.”. Effective 10/01/2022
09/21/2022 – Reviewed at Sept P&T; Separated Comm/Exch vs MH policy; no clinical updates.