Mass General Brigham
Health Plan

Botulinum Toxins:
Botox (onabotulinumtoxinA)
Myobloc (rimabotulinumtoxinB)
Daxxify (daxibotulinumtoxinA)
Dysport (abobotulinumtoxinA)
Xeomin (incobotulinumtoxinA)
Effective 01/01/2026

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Botox (onabotulinumtoxinA), Daxxify (daxibotulinumtoxinA-lanm), Dysport (abobotulinumtoxinA), Myobloc (rimabotulinumtoxinB) and Xeomin (incobotulinumtoxinA) are neurotoxins which inhibit the release of acetylcholine causing muscle denervation.

Preferred Agents	Non-Preferred Agents
Dysport	Botox (onabotulinumtoxinA)
Xeomin	Daxxify
	Myobloc

Non-cosmetic FDA-approved indications:

- Botox:
  - Treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication
  - Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication
  - Treatment of neurogenic detrusor overactivity in pediatric patients 5 years of age and older who have an inadequate response to or are intolerant of an anticholinergic medication
  - Prophylaxis of headaches in adult patients with chronic migraine (≥ 15 migraines per month with headache lasting 4 hours a day or longer)
  - Treatment of spasticity in patients 2 years of age and older
  - Treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain

    - Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients
    - Treatment of blepharospasm associated with dystonia in patients 12 years of age and older
    - Treatment of strabismus in patients 12 years of age and older
- Daxxify:
    - Treatment of cervical dystonia in adult patients
- Dysport:
    - Treatment of cervical dystonia in adults
    - Treatment of spasticity in patients 2 years of age and older
- Myobloc:
    - Treatment of cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia in adults
    - Treatment of chronic sialorrhea in adults
- Xeomin:
    - Treatment or improvement of chronic sialorrhea in patients 2 years of age and older
    - Treatment or improvement of upper limb spasticity in adults
    - Treatment or improvement of upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy
    - Treatment or improvement of cervical dystonia in adults
    - Treatment or improvement of blepharospasm in adults

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted when the following diagnosis-specific criteria is met:

Botox® (onabotulinumtoxinA)	
Achalasia	1. Member must have documented diagnosis of achalasia 2. Requests may be approved for up to 100 units every 3 months.
Chronic anal fissure	1. Diagnosis of chronic anal fissure 2. Member has tried and failed conservative therapy options (nitroglycerin ointment or nifedipine ointment) 3. 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. Diagnosis of chronic migraine 2. 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 3. The member is ≥ 18 years of age 4. The member has been experiencing at least 15 migraine headaches per month with a duration of at least 4 hours a day or longer 5. The member has had an inadequate response to a trial of at least TWO (2) different prophylactic migraine medications each with different mechanisms of action (a total of 2 required trials) that have each been tried for at least 60 days in duration within the past 3 years. Both 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 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 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 of chronic pain or pelvic floor spasms in women 2. Requests may be approved for up to 300 units every 3 months.
Lower limb spasticity	1. Diagnosis of lower limb spasticity 2. Member is 2 years of age or older 3. Member has had an inadequate response, adverse reaction, or contraindication to Dysport
Upper limb spasticity	1. Diagnosis of upper limb spasticity 2. Member is 2 years of age or older 3. Member meets ONE of the following: a. Member meets BOTH of the following: i. Member has upper limb spasticity due to cerebral palsy ii. Member has had an inadequate response, adverse reaction, or contraindication to Dysport b. Member meets BOTH of the following: i. Member has upper limb spasticity that is not due to cerebral palsy ii. Member has had an inadequate response, adverse reaction, or contraindication to one of the following: Dysport or Xeomin
Overactive bladder	1. Member is 18 years of age or older 2. Member has a diagnosis of overactive bladder or urinary incontinence 3. Documentation of ONE of the following: • Failed trial of two (2) long-acting urinary antispasmodics • 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 18 years of or older 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. Diagnosis of primary focal hyperhidrosis (axillary or palmar) 2. Member is 18 years of age or older 3. Treatment is provided by a dermatologist 4. A letter of medical necessity from treating dermatologist 5. Member has tried and failed at least a 60-day trial of a topical 20% aluminum chloride agent or oral glycopyrrolate 6. 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. Diagnosis of seventh cranial nerve disorder (e.g., hemifacial spasm, oromandibular dystonia, orofacial dyskinesia) 2. Member is 12 years of age or older 3. Requests may be approved for up to 100 units every 3 months.
Spasmodic dysphonia, laryngeal dysphonia (laryngeal spasm) or laryngeal dystonia	1. Member must have documented diagnosis of spasmodic dysphonia, laryngeal dysphonia (laryngeal spasm), or laryngeal dystonia 2. Requests may be approved for up to 100 units every 3 months
Cervical dystonia (spasmodic torticollis)	1. Diagnosis of cervical dystonia (spasmodic torticollis) 2. Member is 18 years of age or older 3. Member has had an inadequate response, adverse reaction, or contraindication to ONE of the following: a. Dysport b. Xeomin 4. Requests may be approved for up to 400 units every 3 months
Blepharospasm	1. Diagnosis of blepharospasm 2. Member meets ONE of the following: a. Member is 12-17 years of age b. Member meets BOTH of the following: i. Member is 18 years of age or older ii. Member has had an inadequate response, adverse reaction, or contraindication to Xeomin 3. Requests may be approved for up to 200 units every 30 days.
Strabismus	1. Diagnosis of strabismus 2. Member is 12 years of age or older 3. Requests may be approved for up to 200 units every 30 days
For all criteria: Member has NOT received Dysport, Myobloc, Daxxify or Xeomin injection within the past 4 months	

Dysport® (abobotulinumtoxinA)

Cervical dystonia (spasmodic torticollis)	1. Diagnosis of cervical dystonia (spasmodic torticollis) 2. Member is 18 years of age or older 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. Diagnosis of spasticity 2. Member is 2 years of age or older Requests may 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 received Myobloc, Botox, Daxxify or Xeomin injection within the past 4 months	

Myobloc® (rimabotulinumtoxinB)	
Cervical dystonia (spasmodic torticollis)	1. Diagnosis of cervical dystonia (spasmodic torticollis) 2. Member is 18 years of age or older 3. Member has had an inadequate response, adverse reaction, or contraindication to one of the following: Dysport or Xeomin 4. Initial approvals for members previously untreated with botulinum toxin may be approved for up to 2500 units 5. Reauthorization requests may be approved for up to 10,000 units every **16** weeks
Sialorrhea (salivary hypersecretion)	1. Diagnosis of chronic sialorrhea 2. Member is 18 years of age or older 3. Member has had an inadequate response, adverse reaction, or contraindication to Xeomin 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 received Dysport, Xeomin, Botox or Daxxify injection within the past 4 months	

Xeomin® (incobotulinumtoxinA)	
Blepharospasm	1. Diagnosis of blepharospasm 2. Member is 18 years of age or older 3. Requests may be approved for up to 100 units every 3 months.
Sialorrhea	1. Diagnosis of chronic sialorrhea 2. Member is 2 years of age or older 3. Requests may be approved for up to 100 units every **16** weeks
Cervical dystonia (spasmodic torticollis)	1. Diagnosis of cervical dystonia (spasmodic torticollis) 2. Member is 18 years of age or older 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. Diagnosis of upper limb spasticity 2. Member is 18 years of age or older 3. Requests may be approved for up to 400 units every 3 months

For all criteria: Member has NOT received Botox, Dysport, Daxxify or Myobloc injection within the past 4 months.	

Daxxify® (daxibotulinumtoxinA)	
Cervical dystonia (spasmodic torticollis)	1. Diagnosis of cervical dystonia (spasmodic torticollis) 2. Member 18 years of age or older 3. Member has had an inadequate response, adverse reaction, or contraindication to one of the following: Dysport or Xeomin 4. Initial approvals for members previously untreated with botulinum toxin may be approved for up to 250 units for **12 weeks** 5. Reauthorization requests may be approved for up to 250 units every **12** weeks
For all criteria: Member has NOT received Botox, Dysport, Myobloc or Xeomin 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 the following:

1. Initial neurotoxin prerequisite trial requirements for the requested diagnosis are met
2. Documentation of clinical benefit including any diagnosis specific improvements listed in the criteria.

Limitations

1. Initial Authorizations:
    a. Migraines, urinary incontinence, 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, Daxxify, 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. Bekkers S, Delsing CP, Kok SE, et al. Randomized controlled trial comparing botulinum vs surgery for drooling in neurodisabilities. Neurology 2019; 92:e1195
2. Botox (onabotulinumtoxinA) [prescribing information]. North Chicago, IL: Abbvie Inc.; November 2023.
3. 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.
4. Daxxify (daxibotulinumtoxinA) [prescribing information]. Newark, CA: Revance Therapeutics Inc; November 2023.
5. Dysport (abobotulinumtoxinA) [prescribing information]. Cambridge, MA: Ipsen Biopharmaceuticals, Inc; September 2023.

6. Jost WH, Friedman A, Michel O, et al. SIAXI: Placebo-controlled, randomized, double-blind study of incobotulinumtoxinA for sialorrhea. Neurology 2019; 92:e1982
7. Myobloc (RimabotulinumtoxinB) [prescribing information]. Rockville, MD: Solstice Neurosciences, LLC; March 2021.
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. 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]
10. 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
11. Vaezi MF, Pandolfino JE, Vela MF. ACG clinical guideline: diagnosis and management of achalasia. *Am J Gastroenterol*. 2013;108(8):1238-1249.[PubMed 23877351]
    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.
12. Xeomin (IncobotulinumtoxinA) [prescribing information]. Raleigh, NC: Merz Pharmaceuticals; July 2024.

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.
06/14/2023 – Reviewed and updated for Jun P&T; Botox will be preferred product. Xeomin, Dysport, Myobloc will be non-preferred. Criteria updated for non-preferred products to review prior use of Botox. Effective 9/1/23
10/11/2023 – Reviewed and Updated for Oct P&T; updated reauthorization duration of approval for urinary incontinence to 6 months based on FDA dosing. Updated Member has not had a botulinum toxin injection within the past 4 months to be drug specific. Effective 1/1/24
04/10/2024 – Reviewed and Updated for April P&T; Added Daxxify as non-preferred agent. Effective 5/1/2024
10/09/2024 – Reviewed and updated for October P&T. Updated preferred product strategy; effective 1/1/2025, Dysport and Xeomin will be preferred agents. Updated Botox criteria for chronic migraine, decreasing the number of previous trials with a prophylactic medication from three to two. Updated Botox approval criteria to require trial and failure with Dysport or Xeomin for the diagnosis of upper limb spasticity and Dysport for lower limb spasticity. Removed criteria for sialorrhea from Botox approval criteria. Updated Botox criteria for cervical dystonia, increasing the age requirement from 16 to 18 years of age to match FDA-approved indication, and require trial and failure with either Xeomin or Dysport. Updated Botox criteria for blepharospasm to require that either the member is 12-17 years of age or the member is 18 years of age or older and has had a trial and failure with either Xeomin or Dysport. Updated Dysport and Xeomin criteria to remove step through requirements with other neurotoxins. Updated Myobloc criteria to require step through with Xeomin for sialorrhea and Xeomin or Dysport for cervical dystonia. Throughout policy removed language stating that member must step through Botox. Updated reauthorization criteria to require that member continues to meet initial criteria, with exception of chronic migraine. Effective 1/1/2025.
11/13/2024 – Reviewed and updated for November P&T. Removed note that Daxxify is a specialty drug. Effective 1/1/2025.
10/08/2025 – Reviewed and updated for October P&T. Updated policy to reflect that it no longer applies to the medical benefit. Effective 01/01/2026.