Botox® (onabotulinumtoxinA)
Myobloc® (rimabotulinumtoxinB)
Dysport® (abobotulinumtoxinA)
Xeomin® (incobotulinumtoxinA)
Prior Authorization Criteria
Drug Protocol Management
MassHealth/Commercial/Exchange

Botox®, Myobloc®, Dysport® and Xeomin® are specialty products; dispensing is available from AllWays Health Partners' preferred specialty pharmacy provider CVS/ Caremark.

How do I obtain a prior authorization for Botox®, Myobloc®, Dysport® or Xeomin®?

- Download a prior authorization fax form & send to (866) 249-6155.
- Contact the specialty pharmacy provider or CVS/Caremark at (866) 814-5506 for questions.

Criteria for coverage of Botox® (onabotulinumtoxinA):

Condition	Criteria
Achalasia	1. Member must have documented diagnosis
Chronic anal fissure	1. Member has tried and failed conservative therapy options (nitroglycerin ointment or nifedipine ointment)
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 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
Chronic pain and pelvic floor spasms in women	1. Member must have documented diagnosis
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 or Urinary incontinence	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 for why anticholinergic agents are not appropriate
Primary axillary hyperhidrosis	1. Treatment is provided by a dermatologist **AND** 2. A letter of medical necessity from treating dermatologist **AND** 3. Member has tried and failed an adequate trial of topical therapy with a 20% aluminum chloride agent
Seventh cranial nerve disorders (e.g., hemifacial spasm, oromandibular dystonia, orofacial dyskinesia	1. Member is at least 12 years of age
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 pediatric patient with cerebral palsy **AND** 2. Member has tried and failed therapy with glycopyrrolate.
Spasmodic dysphonia, laryngeal dysphonia (laryngeal spasm) or laryngeal dystonia	1. Member must have documented diagnosis
Cervical dystonia (spasmodic torticollis)	1. Member is at least 16 years of age
Strabismus or Blepharospasm	1. Member is at least 12 years of age

Criteria for coverage of Dysport® (abobotulinumtoxinA)

Condition	Criteria
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)
Lower 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)
For all criteria: Member has not had a botulinum toxin injection within the past 4 months	

Criteria for coverage of Myobloc® (rimabotulinumtoxinB)

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

Criteria for coverage of Xeomin® (incobotulinumtoxinA)

Condition	Criteria
Blepharospasm	1. Member is at least 18 years old **AND** 2. Member has tried and failed or has developed a resistance to onabotulinumtoxinA (Botox)
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)
Chronic Sialorrhea	1. Member is at least 18 years of age **AND** 2. Member has a diagnosis of chronic sialorrhea in adult patients with neurological disorders (Parkinson's disease, amyotrophic lateral sclerosis (ALS), cerebral palsy (CP), or in patients who have had a stroke) **AND** 3. Member has tried and failed or has developed a resistance to onabotulinumtoxinA (Botox)
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)
For all criteria: **Member has not received a botulinum toxin injection within the past 4 months.**	

All other conditions 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

For all conditions, unless otherwise specified, AllWays Health Partners will continue to approve Botox, Dysport, Myobloc and Xeomin therapy when clinical documentation has been submitted by the provider indicating improvement in the member's condition while receiving one of these agents.

Approval Period

Initial Authorizations:

1. Migraines and hyperhidrosis: 6 months
2. All other diagnoses: 3 months

Reauthorizations:

1. All diagnoses: 12 months

Exclusions:

1. AllWays Health Partners will not cover Botox, Dysport, Myobloc or Xeomin for the following conditions:
    a. Facial rhytids
    b. Frown lines

c. Glabellar wrinkling
d. Horizontal neck rhytids
e. Hyperfunctional facial lines
f. Mid and lower face and neck rejuvenation
g. Platysmal bands
h. Rejuvenation of the periorbital region
i. Lateral canthal lines (Crow's feet)

2. Botox® Cosmetic
3. Dysport® 300 units (abobotulinumtoxinA) (glabellar lines)

References:

1. Botulinum Toxin Treatment for Hyperhidrosis. (2008). (Hayes accessed March 2009).
2. Botulinum Toxin Treatment for Spasticity Following Stroke. (2008). (Hayes accessed March 2009).
3. Botulinum Toxin Treatment for Spasticity Due to Cerebral Palsy. (2008). (Hayes accessed March 2009).
4. 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.
5. Dysport [package insert] (2009). 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.
6. Kolbasnik, J., Waterfall, W.E., Fachnie, B., Ying, C., Tougas, G. (1999). "Long-term efficacy of Botulinum toxin in classical achalasia: A prospective study." The American Journal of Gastroenterology, 94:3434-3439.
7. Myobloc [package insert] (2009). Solstice Simpson, D.M., Gracies, J.M., Graham, H.K., Miyasaki, J.M., Naumann, M., Russman, B., Simpson, L.L., So, Y. (2008). "Assessment: Botulinum neurotoxin for the treatment of spasticity (an evidence-based review): Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology." Neurology, 70:1691-1698
8. Xeomin [package insert] (2010). Merz Pharmaceuticals.

Review History:

Implemented: 12/1/05
Updated: 01/03/2011 (Exclusions section update w/ new Dysport product); 05/17/11 (Xeomin BART); 09/19/13 (Dysport 300 units glabellar lines product; 04/08/13 file & Botox crow's feet); 06/09/14 (Migraine trials to 3 based on specialist input); 11/20/17; 02/26/18 P&T; 7/5/18 (added diag of chronic sialorrhea to Xeomin)
Reviewed: 9/25/06; 9/24/07; 9/22/08; 9/21/09; 9/27/2010; 9/19/11; 09/24/12; 11/25/13; 11/24/14 P&T Mtg