Mass General Brigham
Health Plan

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

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications**		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
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	**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	**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	**ALL** of the following: 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: a. **TWO** anticholinergic medications (e.g., oxybutynin, tolterodine) b. **ONE** anticholinergic medication and **ONE** β-3 adrenergic receptor agonist (mirabegron) 4. Dose is appropriate for stated indication

Neurogenic Bladder Dysfunction/Neurogenic Detrusor Overactivity (adults)	**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)	**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)	**ALL** of the following: 1. Diagnosis of **ONE** of the following: a. Severe primary axillary hyperhidrosis i. Member is ≥ 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	**ALL** of the following: 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: 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 ≤ 100 units no more frequently than every six months

Anal stenosis, chronic constipation, encopresis	**ALL** of the following: 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 ≤ 100 units no more frequently than every three months
Sialorrhea	**ALL** of the following: 1. Diagnosis of sialorrhea 2. Inadequate response or adverse reaction to TWO or contraindication to ALL of the following: 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: a. Myobloc b. Xeomin
Migraine prophylaxis, concomitant therapy with a CGRP inhibitor	**ALL** of the following: 1. Individual drug PA criteria must be met first where applicable 2. Diagnosis of migraine prophylaxis 3. Partial, but incomplete, response to Botox®
Migraine prophylaxis, dosing every 10 weeks	**ALL** of the following: 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
Myofascial pain syndrome	**ALL** of the following: 1. Diagnosis of myofascial pain syndrome 2. Inadequate response or adverse reaction to TWO or contraindication to ALL of the following agents: 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)
Myofascial pelvic pain syndrome	**ALL** of the following: 1. Diagnosis of myofascial pelvic pain syndrome

	2. Inadequate response, adverse reaction to TWO or contraindication to ALL of the following agents: 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	**ALL** of the following: 1. Diagnosis of Raynaud's Phenomenon 2. Inadequate response or adverse reaction to THREE or contraindication to ALL of the following: a. Calcium channel blocker (amlodipine or nifedipine) b. fluoxetine c. losartan d. PDE type 5 inhibitor e. Topical nitrate 3. Requested dose is ≤ 200 units/90 day

Dysport® (abobotulinumtoxinA)	
Cervical dystonia/spasmodic torticollis, Upper Limb Spasticity, Lower Limb Spasticity	**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)
Off-Label Indications	
Achalasia/esophageal dysphagia	**ALL** of the following: 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: 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 ≤ 250 units no more frequently than every six months
See Appendix for High Dose Requests	

Myobloc® (rimabotulinumtoxinB)

Cervical dystonia (spasmodic torticollis)	**ALL** of the following: 1. Diagnosis of cervical dystonia/spasmodic torticollis 2. Dose is appropriate for stated indication
Sialorrhea (salivary hypersecretion)	**ALL** of the following: 1. Diagnosis of sialorrhea 2. Physician attestation of inadequate response or 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	**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	**ALL** of the following: 1. Diagnosis of sialorrhea 2. Physician attestation of inadequate response or 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	

Off Label Indications for ALL agents	
Anal Fissures	**ALL** of the following: 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: a. topical nifedipine product b. topical nitroglycerin

Gastroparesis	**ALL** of the following: 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

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.
5. Bajwa ZH. Botulinum toxin pharmacology. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2010 [cited 2010 Dec 09]. Available from: http://www.utdol.com/utd/index.do.
6. Micromedex® Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc.; Updated periodically [cited 2021 Dec 17]. Available from: http://www.thomsonhc.com/.
7. Naumann M, So Y, Argoff CE, Childers MK, Dykstra DD, Gronseth GS, et al. Assessment: Botulinum neurotoxin in the treatment of autonomic disorders and pain. Neurology. 2008;70:1707-14.
8. Zalvan C, Bentianov B, Gonzalez-Yanes O, Blitzer A. Noncosmetic uses of botulinum toxin. Dermatol Clin. 2004;22:187-95.
9. Bleday R. Anal fissures: Medical Management. In: Weiser M, Friedman LS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Nov [cited 2021 Dec 17]. Available from: http://www.utdol.com/utd/index.do.
10. Brin MF, Lew MF, Adler CH, Comella SA, Factor SA, Jakovic J, et al. Safety and efficacy of NeuroBloc (botulinum toxin type B) in type A-resistant cervical dystonia. Neurology. 1999; 53: 1431-38.
11. Deik A, Comella C. Etiology, clinical features, and diagnostic evaluation of dystonia. In: Hurtig HI (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Nov [cited 2021 Dec 17]. Available from: http://www.utdol.com/utd/index.do.
12. Dressler D. Routine use of Xeomin in patients previously treated with Botox: long term results. European Journal of Neurology. 2009;16(2):2-5.
13. Mohammadi B, Balouch SA, Dengler R, Kollewe K. Long-term treatment of spasticity with botulinum toxin type A: an analysis of 1221 treatment in 137 patients. Neurological Research.2010;32(3):309-13.
14. Berman B, Seeberger L, Kumar R. Long-term Safety, Efficacy, Dosing, and Development of Resistance with Botulinum Toxin Type B in Cervical Dystonia. Movement Disorders. 2005; 20(2):233-37.
15. Factor SA, Molho ES, Evans S, Fuestel PJ. Efficacy and Safety of Repeated Doses of Botulinum Toxin Type B in Type A resistant and Responsive Cervical Dystonia. Movement Disorders. 2005;20(9):1152-60.
16. Heinen F, Desloovere K, Schroeder AS, Berweck S, Borggraefe I, Capenhout A, et al. The updated European Consensus 2009 on the use of Botulinum toxin for children with cerebral palsy.2010; 14:45-66.

17. Schwerin A, Berweck S, Fietzek UM, Heinen F. Botulinum Toxin B Treatment in Children with Spastic Movement Disorders a Pilot Study. Pediatric Neurology. 2004;31(2):109-13.
18. American Gastroenterological Association. American Gastroenterological Association Medical Position Statement: Diagnosis and Care of Patients with Anal Fissures. Gastroenterology. 2003;124:233-34.
19. Abrams GM, Wakasa M. Chronic complications of spinal cord injury and disease. In: Aminoff MJ, Silveira MJ (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Nov [cited 2021 Dec 11]. Available from: http://www.utdol.com/utd/index.do.
20. Siddiqui NY, Reynolds WS. Use of botulinum toxin for treatment of lower urinary tract conditions: Indications and clinical evaluation. In: Brubaker L (Ed). UpToDate [database on the internet]. Waltham (MA): 2021 Nov [cited 2021 Dec 17]. Available from: http://www.utdol.com/utd/index.do.
21. Chen G, Liao L. Injections of Botulinum Toxin A into the detrusor to treat neurogenic detrusor overactivity secondary to spinal cord injury. Int Urol Nephrol. 2010 Nov. Epub 2010 Nov 26.
22. Masaoka T, Tack J. Gastroparesis: Current Concepts and Management. Gut and Liver.2009;3(3):166-73.
23. Galvez-Jimenez, N. Symptom-based management of amyotrophic lateral sclerosis. In: Shefner JM, Morrison RS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Nov [cited 2021 Dec 17]. Available from: http://www.utdol.com/utd/index.do.
24. Hockstein NG, Samadi DS, Gendron K, Handler SD. Sialorrhea: A management challenge. AmFamPhysician. 2004;69:2628-34.
25. Silberstein SD, Holland S, Freitag F, Dodick DW, Argoff C, Ashman E. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. Neurology. 2012;78:1337-45.
26. Garza I, Schwedt TJ. Chronic migraine. In: Swanson JW (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Dec 17]. Available from: http://www.utdol.com/utd/index.do.
27. Ko DT, Hebert PR, Coffey CS, Sedrakyan A, Curtis JP, Krumholz HM. β-Blocker Therapy and Symptoms of Depression, Fatigue, and Sexual Dysfunction. The Journal of the American Medical Association (JAMA). 2002 Jul 17; 288(3):351-357.
28. 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 May 10;86:1818-26.
29. Glaser DA, Pariser DM, Hebert AA, Landells I, Somogyi C, Weng E, et at. A prospective, nonrandomized, open-label study of the efficacy and safety of onabotulinumtoxinA in adolescents with primary axillary hyperhidrosis. Pediatr Dermmat. 2015 Sep-Oct;32(5):609-17.
30. Soloman BA, Hayman R. Botulinum toxin type A therapy for palmar and digital hyperhidrosis. JAmAcadDermatol. 2000;42(6):1026.
31. Simonetta Moreau M, Cauhepe C, Magues JP, Senard JM. A double-blind, randomized, comparative study of Dysport vs. Botox in primary palmar hyperhidrosis. Br J Dermatol. 2003;149(5):1041.
32. Baumann L, Slezinger A, Halem M, Vujevich J, Mallin K, Charles C, Martin LK, Black L, Bryde J. Double-blind, randomized, placebo-controlled pilot study of the safety and efficacy of Myobloc (botulinum toxin type B) for the treatment of palmar hyperhidrosis. Dermatol Surg. 2005 Mar;31(3):263-70.
33. Vadoud-Seyedi J. Treatment of plantar hyperhidrosis with botulinum toxin type A. Int J Dermatol. 2004 Dec;43(12):969-71.
34. Benohanian A. Treatment of recalcitrant plantar hyperhidrosis with type-A botulinum toxin injections and aluminum chloride in salicylic acid gel. Dermatol Online J. 2008;14(2):5. Epub 2008 Feb 28.
35. Smith CC, Pariser D. Primary focal hyperhidrosis. In: Dellavalle RP, Owen C (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Nov [cited 2021 Dec 17]. Available from: http://www.utdol.com/utd/index.do.

36. Weinberg T, Solish N, Murray C. Botulinum neurotoxin treatment of palmar and plantar hyperhidrosis. Dermatol Clin. 2014 Oct;32(4):505-15.
37. Fass R. Approach to the evaluation of dysphagia in adults. In: Feldman M (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Nov [cited 2021 Dec 17]. Available from: http://www.utdol.com/utd/index.do.
38. Spechler SJ. Overview of the treatment of achalasia. In: Talley NJ (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Nov [cited 2021 Dec 17]. Available from: http://www.utdol.com/utd/index.do.
39. Pasricha PJ, Ahuja NK. Pneumatic dilation and botulinum toxin injection for achalasia. In: Talley NJ (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Nov [cited 2021 Dec 17]. Available from: http://www.utdol.com/utd/index.do.
40. Vaezi MF, Pandolfino JE, Vela MF. ACG clinical guideline: diagnosis and management of achalasia. Am J Gastroenterol. 2013;108(8):1238.
41. Zaninotto G, Bennett C, Boeckxstaens G, Costantini M, Ferguson MK, Pandolfino JE, et al. The 2018 ISDE achalasia guidelines. Dis Esophagus. 2018;31(9):1-29.
42. Kahrilas PJ, Bredenoord AJ, Carlson DA, Pandolfino JE. Advances in the management of esophageal motility disorders. Clin Gastroenterol Hepatol. 2018;16(11):1692.
43. Khashab MA, Vela MF, Thosani N, Agrawal D, Buxbaum JL, Abba Fehmi SM, et al. ASGE guideline on the management of achalasia. Gastrointest Endosc. 2020 Feb;91(2):213-227.
44. Sood MR. Chronic functional constipation and fecal incontinence in infants, children and adolescents: Treatment. In: Li BU (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Nov [cited 2021 Dec 17]. Available from: http://www.utdol.com/utd/index.do.
45. Friedmacher F, Puri P. Comparison of posterior internal anal sphincter myectomy and intrasphincteric botulinum toxin injection for treatment of internal anal sphincter achalasia: a meta-analysis. Pediatr Surg Int. 2012 Aug;28(8):765-71.
46. Wigley FM. Treatment of Raynaud phenomenon: Initial Treatment. In: Axford JS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Dec 17]. Available from: http://www.utdol.com/utd/index.do.
47. Wigley FM. Treatment of Raynaud phenomenon: Refractory or progressive ischemia. In: Axford JS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Dec 17]. Available from: http://www.utdol.com/utd/index.do.
48. Vashishta R, Nguyen S, White DR, Gillespie MB. Botulinum toxin for the treatment of sialorrhea: A meta-analysis. Otolaryngology-Head and Neck Surgery; 148(2):191-196.
49. Ruiz-Roca JA, Pons-Fuster E, Lopez-Jornet P. Effectiveness of the botulinum toxin for treating sialorrhea in patients with Parkinson's disease: A systematic review. J Clin Med. 2019;8(317):1-12.
50. Armanious M, Khalil N, Lu Y, Jimenez-Sanders R. Erenumab and OnabotulinumtoxinA Combination Therapy for the Prevention of Intractable Chronic Migraine without Aura: A Retrospective Analysis. J Pain Palliat Care Pharmacother. 2021 Mar;35(1):1-6. doi: 10.1080/15360288.2020.1829249. Epub 2020 Oct 30. PMID: 33125303.
51. Pellesi, L., Do, T.P., Ashina, H., Ashina, M. and Burstein, R. (2020), Dual Therapy With Anti-CGRP Monoclonal Antibodies and Botulinum Toxin for Migraine Prevention: Is There a Rationale?. Headache: The Journal of Head and Face Pain, 60: 1056-1065. https://doi.org/10.1111/head.13843
52. Bendtsen L, Sacco S, Ashina M, Mitsikostas D, Ahmed F, et al. Guideline on the use of onabotulinumtoxinA in chronic migraine: a consensus statement from the European Headache Federation. J Headache Pain. 2018 Sep;19(91). doi: 10.1186/s10194-018-0921-8.
53. Masters-Israilov A, Robbins MS. OnabotulinumtoxinA Wear-off Phenomenon in the Treatment of Chronic Migraine. Headache. 2019 Nov;59(10):1753-1761. doi:10.1111/head.13638. Epub 2019 Sep 16. PMID: 31524289.

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 07/31/2023