



## Pharmacy Prior Authorization Botulinum Toxins – Clinical Guideline

**Botox** (onabotulinumtoxinA)  
**Dysport** (abobotulinumtoxinA)

**Myobloc** (rimabotulinumtoxinB)  
**Xeomin** (incobotulinumtoxinA)

**Prior Authorization Guidelines for All Indications:** Botox, Myobloc, Dysport, Xeomin must be prescribed by an appropriate specialist based on indication and meet the following criteria:

- **Migraine Prophylaxis (*Botox*):**
  - Prevention of chronic migraine (at least 15 days per month with headaches lasting 4 hours a day or longer)
  - Member had inadequate response to or intolerable side effects with at least two medications from two classes of migraine headache prophylaxis medication for at least two months (60 days):
    - Beta-blocker: propranolol, metoprolol, timolol, atenolol, nadolol
    - Anticonvulsant: valproic acid or divalproex, topiramate
    - Antidepressants: amitriptyline, nortriptyline, venlafaxine, duloxetine
  - Age restriction: must be at least 18 years old
  - Medication will not be used concurrently with calcitonin gene-related peptide (CGRP) receptor antagonists
- **Chronic Limb Spasticity (*Botox, Xeomin, Dysport*):**
  - Spasticity may be due to an injury to the brain or spinal cord, or along with a neurological disorder (for example, stroke, traumatic brain injury (TBI), multiple sclerosis (MS), spinal cord injury (SCI), cerebral palsy (CP))
  - Failure of baclofen and at least one other formulary muscle relaxant such as dantrolene.
  - Trial of physical and/or occupational therapy
  - Age restriction (Botox and Dysport): must be at least 2 years old
  - Age restriction (Xeomin): must be at least 18 years old
- **Severe primary axillary hyperhidrosis (excessive underarm sweating) (*Botox, Dysport*):**
  - There is focal, visible, excessive sweating for at least 6 months without apparent cause and two of the following:
    - Interferes with daily activities
    - Bilateral and relatively symmetric

## Pharmacy Prior Authorization Botulinum Toxins – Clinical Guideline

- Onset before 25 years of age
  - Focal sweating stops during sleep
  - Family history of idiopathic hyperhidrosis
  - At least one episode per week
  - Failure of topical aluminum chloride (hexahydrate)
  - Age restriction: must be at least 18 years old
- **Neurogenic bladder (*Botox*):**
  - Diagnosis of urinary incontinence due to detrusor overactivity associated with neurologic condition
  - Trial of behavioral therapy (for example, bladder training, bladder control strategies, pelvic floor muscle training, fluid management) for at least 8-12 weeks
  - Trial and failure of two formulary urinary anticholinergics (for example, oxybutynin, trospium, tolterodine)
  - Age restriction: must be at least 18 years old
- **Overactive bladder (*Botox*):**
  - Trial of behavioral therapy (bladder training, bladder control strategies, pelvic floor muscle training, fluid management) for at least 8-12 weeks
  - Trial and failure of two formulary urinary anticholinergics (for example, oxybutynin, trospium, tolterodine)
  - Age restriction: must be at least 18 years old
- **Esophageal Achalasia (*Botox*):**
  - Member meets ONE of the following:
    - Member remains symptomatic despite surgical myotomy or pneumatic dilation
    - Member is at high surgical risk or unwilling to undergo surgical myotomy or pneumatic dilation
  - Age restriction: must be at least 18 years old
- **Chronic anal fissures (*Botox*):**
  - Trial and failure of nitroglycerin ointment 0.4% (Rectiv) AND either bulk fiber supplements, stool softeners, or sitz baths for at least two months
  - Endoscopy to rule out Crohn’s disease has been completed
  - Age restriction: must be at least 18 years old
- **Chronic sialorrhea (excessive drooling) (*Botox, Myobloc, or Xeomin*):**
  - Trial and failure of anticholinergic such as glycopyrrolate (pediatric use 3-16) or benztropine (adults)



## Pharmacy Prior Authorization Botulinum Toxins – Clinical Guideline

- Age restriction (Botox): must be at least 21 months old
- Age restriction (Xeomin, Myobloc): must be at least 18 years old
- **Focal spasticity or Equinus gait due to Cerebral Palsy (*Botox or Dysport*):**
  - Member will be enrolled in or is currently being managed with physical and/or occupational therapy
  - Age restriction: 2-18 years of age

**Botulinum toxins may also be approved if medically necessary for treatment of the following indications which have limited treatment options:**

- *Botox* for cervical dystonia (also called spasmodic torticollis) in member at least 16 years old
- *Dysport, Myobloc, Xeomin* for cervical dystonia: member is at least 18 years old
- *Botox* for blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders: member is at least 12 years old
- *Xeomin* for blepharospasm : member is at least 18 years old and previously treated with onabotulinumtoxinA (*Botox*)
- *Dysport* for blepharospasm: member is at least 18 years old and previously treated with onabotulinumtoxinA (*Botox*) and incobotulinumtoxinA (*Xeomin*)
- *Botox* for strabismus in member is at least 12 years old
- *Botox* for hemifacial spasm: member is at least 18 years old

### **Initial Approval:**

- 6 months
- Treatment should be given every 12 weeks

### **Renewal:**

- 1 year
- Treatment should be given once every 12 weeks
- *Botox*:
  - Should not exceed a cumulative dose of 400 units every 90 days for adults
  - Should not exceed the lower of 10 units per kg or 340 units every 90 days for pediatric patients



## Pharmacy Prior Authorization Botulinum Toxins – Clinical Guideline

### **Additional Information:**

**Note:** If members do not respond to a course of treatment (usually lasts for 12 weeks), treatment should be discontinued.

**Note:** Continuing treatment with botulinum toxin injection for ongoing prevention of chronic migraine headaches is considered medically necessary when:

- Migraine headache frequency was reduced by at least 7 days per month (when compared to pre-treatment average) by the end of the initial trial; OR
- Migraine headache duration was reduced by at least 100 total hours per month (when compared to the pre-treatment average) by the end of the initial trial

### **References:**

1. Botox® (onabotulinumtoxinA) [package insert]. Allergan, Inc, Madison, NJ; Revised July 2020. <https://media.allergan.com/actavis/actavis/media/allergan-pdf-documents/product-prescribing/20190620-BOTOX-100-and-200-Units-v3-0USPI1145-v2-0MG1145.pdf>. Accessed Aug 19, 2020.
2. Dysport® (abobotulinumtoxinA) [package insert]. Wrexham, UK: Ipsen Biopharm, Ltd.; Revised July 2020. [https://www.ipsen.com/websites/Ipsen\\_Online/wp-content/uploads/2020/07/10002305/DYS-US-004998\\_Dysport-PI-July-2020.pdf](https://www.ipsen.com/websites/Ipsen_Online/wp-content/uploads/2020/07/10002305/DYS-US-004998_Dysport-PI-July-2020.pdf). Accessed August 19, 2020.
3. Xeomin® (incobotulinumtoxinA) [package insert]. Merz Pharmaceuticals, LLC, Raleigh, NC; Revised May 2019. <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=ccdc3aae-6e2d-4cd0-a51c-8375bfee9458&type=display>. Accessed August 19, 2020.
4. Myobloc® (rimabotulinumtoxinB) [package insert]. South San Francisco, CA: Solstice Neurosciences, Inc.; Revised May 2010. [https://myobloc.com/files/MYOBLOC\\_PI.pdf](https://myobloc.com/files/MYOBLOC_PI.pdf). Accessed August 19, 2020.
5. Simpson DM, Hallet 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;86:1818-1826.
6. Yelnik AP, Simon O, Bensmail D, et al. Drug treatments for spasticity. *Annals Phys Rehab Med*. 2009;52(10):746-756.
7. Smith C, Pariser D. Primary Focal Hyperhidrosis. Waltham, MA. UpToDate. Last Modified January 2, 2020. <https://www.uptodate.com/contents/primary-focal-hyperhidrosis>. Accessed August 19, 2020.
8. Evers S, Afra J, Frese A, Goadsby PJ, et al. EFNS guideline on the drug treatment of migraine – revised report of an EFNS task force. *Eur J Neurol*. 2009;16: 968–981.
9. S.D. Silberstein, S. Holland, F. Freitag, et al. Evidence-based guideline update: Pharmacologic treatment for episodic migraine prevention in adults. *Neurology* 2012;78;1337-1345.
10. Estemalik E, Tepper S. Preventive treatment in migraine and the new US guidelines. *Neuropsychiatric Disease and Treat*. 2013;9:709–720.
11. Olsson JE, Behrin HC, Forssman B, et al. Metoprolol and propranolol in migraine prophylaxis: a double-blind multicenter study. *Acta Neurol Scand*. 1984;70(3):160-168.
12. Dodick DW, et al. PREEMPT Chronic Migraine Study Group. OnabotulinumtoxinA for treatment of chronic migraine: pooled results from the double-blind, randomized, placebo-controlled phases of the PREEMPT clinical program. *Headache*. 2010;50(6):921.
13. Mahajan ST. Use of Botulinum Toxin for Treatment of Non-neurogenic Lower Urinary Tract Conditions. Waltham, MA. UpToDate. Last Modified: February 5, 2020. <https://www.uptodate.com/contents/use-of-botulinum-toxin-for-treatment-of-non-neurogenic-lower-urinary-tract-conditions>. Accessed August 19, 2020.
14. Ates F, Vaezi MF. The pathogenesis and management of achalasia: current status and future directions. *Gut Liver*. 2015;9(4):449-463.
15. Vaezi MF, Pandolfino JE, Vela MF. ACG clinical guideline: Diagnosis and management of achalasia. *American Journal of Gastroenterology*. 2013; 108:1238-1249.

## Pharmacy Prior Authorization Botulinum Toxins – Clinical Guideline

16. Wald A, Bharucha AE, Cosman BC, Whitehead WE. ACG clinical guideline: management of benign anorectal disorders. *Am J Gastroenterol*. 2014;109:1141-1157.
17. Bleday R. Anal Fissure: Medical Management. Waltham, MA. UpToDate. Last Modified February 24, 2020. <https://www.uptodate.com/contents/anal-fissure-medical-management>. Accessed August 19, 2020.
18. Reddihough D, Erasmus CE, Johnson H, McKellar GMW, Jongerius PH. Botulinum toxin assessment, intervention and aftercare for pediatric and adult drooling: international consensus statement. *Eur J Neurol*. 2010;17(Suppl 2):109-121.
19. Jongerius PH, van den Hoogen FJA, van Limbeek J, Gabreels FJ, van Hulst K, Rotteveel JJ. Effect of Botulinum Toxin in the Treatment of Drooling: A Controlled Clinical Trial. *Pediatrics*. 2004; 114(3): 620 -627.
20. Reddihough D, Erasmus CE, Johnson H, McKellar GMW, Jongerius PH. Botulinum toxin assessment, intervention and aftercare for pediatric and adult drooling: international consensus statement. *Eur J Neurol*. 2010;17(Suppl 2):109-121.
21. Walshe M, Smith M, Pennington L. Interventions for drooling in children with cerebral palsy. *Cochrane DB Syst Rev*. 2012, Issue 11. Art. No.: CD008624. DOI: 10.1002/14651858.CD008624.pub3.
22. Jongerius PH, van den Hoogen FJA, van Limbeek J, Gabreels FJ, van Hulst K, Rotteveel JJ. Effect of Botulinum Toxin in the Treatment of Drooling: A Controlled Clinical Trial. *Pediatrics*. 2004; 114(3): 620 -627.
23. Costa J, et al. Botulinum toxin type A therapy for blepharospasm (Review). *COCHRANE DB SYST REV*. 2004, Issue 2. Art.No.: CD004900. DOI: 10.1002/14651858.CD004900.pub2.
24. Patterson MC. Management and prognosis of cerebral palsy. UpToDate. <http://www.uptodate.com>. Updated April 8, 2016. Accessed August 19, 2020.
25. Pavone V, Testa G, Restivo DA, et al. Botulinum toxin treatment for limb spasticity in childhood cerebral palsy. *Front Pharmacol*. 2016;7:29.
26. Koman LA, Brashear A, Rosenfeld S, et al: Botulinum toxin type a neuromuscular blockade in the treatment of equinus foot deformity in cerebral palsy: a multicenter, open-label clinical trial. *Pediatrics* 2001; 108(5):1062-1071.
27. AbobotulinumtoxinA for equinus foot deformity in cerebral palsy: a randomized controlled trial. 2016;137(2): e20152830.
28. Delgado MR, Hirtz D, Aisen M, et al. Practice parameter: pharmacologic treatment of spasticity in children and adolescents with cerebral palsy (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. *Neuro*. 2010;74(4):336.
29. Hoare BJ, Wallen MA, Imms C, Villanueva E, Rawicki HB, Carey L. Botulinum toxin A as an adjunct to treatment in the management of the upper limb in children with spastic cerebral palsy (update). *Cochrane Database Syst Rev*. 2010;(1): CD003469. doi: 10.1002/14651858.CD003469.pub4.
30. Fehlings D, Rang M, Glazier J, et al: An evaluation of botulinum-A toxin injections to improve upper extremity function in children with hemiplegic cerebral palsy. *The Journal of Pediatrics*. 2000; 137:331-337.
31. Gold Standard. (2016, Jan 26). Botox. Tampa, Florida, USA. Retrieved August 16, 2017, from <http://www.clinicalpharmacology-ip.com/Forms/Monograph/monograph.aspx?cpnum=1219&sec=monindi&t=0>
32. Gormley, EA, Lightner, DJ, Burgio, KL, et al. Diagnosis and Treatment of Overactive Bladder (non-Neurogenic) in Adults:AUA/SUFU guideline. *The Journal of Urology*, 2012; 188 (6), 2455-2463.
33. Abrams, GM, Wakasa, M. Chronic Complications of Spinal Cord Injury and Disease. Waltham, MA. UpToDate. Last Modified December 6, 2018. <https://www.uptodate.com/contents/chronic-complications-of-spinal-cord-injury-and-disease>. Accessed August 19, 2020.
34. Egevad. G. Petkova, Y, Villholm, O. Sialorrhea in Patients with Parkinson’s Disease: Safety and Administration of Botulinum Neurotoxin. *Journal of Parkinson’s Disease*. 2014 :4 (3): 321-326.
35. American Academy of Neurology. <https://www.aan.com/Guidelines/home/GetGuidelineContent/377>. Accessed August 2, 2018.



## **Pharmacy Prior Authorization Botulinum Toxins – Clinical Guideline**

36. National Institute of Neurological Disorders and Stroke. Spasticity information page. <https://www.ninds.nih.gov/Disorders/All-Disorders/Spasticity-Information-Page>. Accessed August 19, 2020.