Pharmacy Prior Authorization
Botulinum Toxins – Clinical Guideline

**Botox** (onabotulinumtoxinA)  **Myobloc** (rimabotulinumtoxinB)
**Dysport** (abobotulinumtoxinA)  **Xeomin** (incobotulinumtoxinA)

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

- **Migraine Prophylaxis (Botox):**
  - Prevention of chronic migraine
    - Fifteen or more 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, for at least two months (60 days):
    - Beta-blocker: propranolol, metoprolol, timolol, atenolol, nadolol
    - Anticonvulsant: valproic acid or divalproex, topiramate
    - Antidepressants: amitriptyline, venlafaxine, duloxetine
  - Member is at least 18 years of age
  - 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, multiple sclerosis, spinal cord injury, cerebral palsy
  - Member had previous trial and failure with baclofen
  - Trial of physical therapy and/or occupational therapy
    - Botox and Dysport: Member is at least 2 years of age
  - Xeomin:
    - Upper limb spasticity, excluding spasticity caused by cerebral palsy: Member is at least 2 years of age
    - All other limb spasticity, member is at least 18 years of age

- **Focal Spasticity or Equinus Gait due to Cerebral Palsy (Botox, Dysport):**
  - Member is 2 years of age or older

- **Severe primary axillary hyperhidrosis - excessive underarm sweating (Botox, Dysport):**
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- 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
  - 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)
- Member is at least 18 years of age

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 or intolerance with two formulary urinary anticholinergics
  - For example, oxybutynin, trosplum, tolterodine, solifenacin
- Member is at least 5 years of age

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 or intolerance with two formulary urinary anticholinergics
  - For example, oxybutynin, trosplum, tolterodine, solifenacin
- Member is at least 18 years of age

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
- Member is at least 18 years of age
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• **Chronic anal fissures (Botox):**
  o Trial and failure of nitroglycerin ointment 0.4% (Rectiv) AND either bulk fiber supplements, stool softeners, or sitz baths for at least two months
  o Endoscopy has been completed to rule out Crohn’s disease
  o Member is at least 18 years of age

• **Chronic sialorrhea - excessive drooling (Botox, Myobloc, Xeomin):**
  o Trial and failure of anticholinergic such as glycopyrrolate (pediatric use ages 3-16 years) or benztropine (adults)
  o Botox: Member is at least 21 months of age
  o Xeomin: Member is at least 2 years of age
  o Myobloc: Member is at least 18 years of age

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

• **Botox for cervical dystonia (spasmodic torticollis):**
  o Member at least 16 years of age

• **Dysport, Myobloc, Xeomin for cervical dystonia:**
  o Member is at least 18 years of age

• **Botox for blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders:**
  o Member is at least 12 years of age

• **Xeomin for blepharospasm:**
  o Member is at least 18 years of age and previously treated with onabotulinumtoxinA (Botox)

• **Dysport for blepharospasm:**
  o Member is at least 18 years of age and previously treated with onabotulinumtoxinA (Botox) and incobotulinumtoxinA (Xeomin)

• **Botox for strabismus:**
  o Member is at least 12 years of age

• **Botox for hemifacial spasm:**
  o Member is at least 18 years of age

Last Update: 11/2020, 09/2021, 8/2022,
Effective: 10.1.2022
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Initial Approval:

• 6 months - Treatment is given every 12 weeks

Renewal Approval:

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

Additional Information:

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


Smith C, Pariser D. Primary focal hyperhidrosis; Waltham, MA. UpToDate. October 2021; [https://www.uptodate.com/contents/primary-focal-hyperhidrosis?search=Severe%20primary%20axillary%20hyperhidrosis%20&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2#H197353549](https://www.uptodate.com/contents/primary-focal-hyperhidrosis?search=Severe%20primary%20axillary%20hyperhidrosis%20&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2#H197353549).
Drug Information

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