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 three medications from two classes of migraine headache prophylaxis medication for at least three months (90 days):
    - Beta-blocker: propranolol, metoprolol, timolol, atenolol, nadolol
    - Anticonvulsant: valproic acid or divalproex, topiramate
    - Antidepressants: amitriptyline, venlaxafine
    - Angiotensin-converting enzyme inhibitors (ACE-Is)/angiotensin II receptor blockers (ARBs): lisinopril, candesartan, losartan, valsartan
    - Calcium channel blockers: diltiazem, nifedipine, nimodipine, verapamil
  - 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): Lower limb spasticity: must be at least 18 years old
  - Age restriction (Botox): Upper limb spasticity: must be at least 2 years old
  - Age restriction (Dysport and Xeomin): Upper limb spasticity: must be at least 18 years old
  - Age restriction (Dysport): Lower limb spasticity: must be at least 2 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
- 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)
- 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 8 units/kg or 300 units every 90 days for pediatric patients

### Additional Information:

Last Update: 11/2019
Effective: 4/2020
**Aetna Better Health**

Pharmacy Prior Authorization

Botulinum Toxins – Clinical Guideline

**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:**


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