Aetna Better Health®

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 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, venlafaxine
    - 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

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- 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 Approval:

- 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:

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

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