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, 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
  - Failure of baclofen and at least one other formulary muscle relaxant such as dantrolene
  - 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 will be enrolled in, or is currently being managed with physical therapy and/or occupational therapy

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- Member is 2 years of age to 18 years of age

- **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)
  - 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, trospium, 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, trospium, 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

- **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 has been completed to rule out Crohn's disease
  - Member is at least 18 years of age

- **Chronic sialorrhea - excessive drooling *(Botox, Myobloc, Xeomin)*:**
  - Trial and failure of anticholinergic such as glycopyrrolate (pediatric use ages 3-16 years) or benztropine (adults)
  - Botox: Member is at least 21 months of age
  - Xeomin: Member is at least 2 years of age
  - 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):
  - Member at least 16 years of age
- Dysport, Myobloc, Xeomin for cervical dystonia:
  - Member is at least 18 years of age
- Botox for blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders:
  - Member is at least 12 years of age
- Xeomin for blepharospasm:
  - Member is at least 18 years of age and previously treated with onabotulinumtoxinA (Botox)
- Dysport for blepharospasm:
  - Member is at least 18 years of age and previously treated with onabotulinumtoxinA (Botox) and incobotulinumtoxinA (Xeomin)
- Botox for strabismus:
  - Member is at least 12 years of age
- Botox for hemifacial spasm:

- Member is at least 18 years of age

Initial Approval:

- 6 months - Treatment is given every 12 weeks

Renewal Approval:

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

Additional Information:

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