Aetna Better Health®

Pharmacy Prior Authorization
Botulinum Toxins – Clinical Guideline

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

General Authorization Guidelines for All Indications:

- NOT prescribed for cosmetic purposes
- Prescribed by an appropriate specialist based on indication
- Prescribed within the FDA-approved dosing

Additional Criteria Based on Indication:

- **Chronic Limb Spasticity (*Botox, Xeomin, Dysport):***
  - Spasticity is due to hereditary spastic paraplegia, spastic hemiplegia due to stroke, traumatic brain (TBI) or spinal cord injury (SCI), or multiple sclerosis (MS) or other demyelinating diseases of the CNS
  - Failure of baclofen and at least one other formulary muscle relaxant such as tizanidine or dantrolene.
  - Trial of physical and/or occupational therapy
  - Abnormal muscle tone is either interfering with functional ability OR is expected to result in joint contracture
  - Age restriction (Botox and Xeomin): must be at least 18 years old
  - Age restriction (Dysport): 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 *(Botox)*:**
  - Score of 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS)
  - Patient has medical complications from hyperhidrosis (e.g., skin maceration with secondary skin infections)
  - Failure of a 2 month trial of topical aluminum chloride 20%
  - Age restriction: must be at least 18 years old
- **Migraine Prophylaxis *(Botox)*:**
  - Migraine frequency of 15 days or more in a 30-day period for at least 3 months with each headache lasting 4 hours or longer
  - Failure of (e.g., <50% reduction in migraine frequency after at least 2 months duration, or intolerance to) at least 2 medications commonly used for migraine prophylaxis:
    - Beta-blocker: propranolol
    - Anticonvulsant: valproic acid or divalproex, topiramate
    - Antidepressants: amitriptyline
  - Age restriction: must be at least 18 years old
- **Neurogenic bladder *(Botox)*:**
  - Trial of behavioral therapy (e.g., bladder training or pelvic floor exercises)
  - Failure of 2 urinary anticholinergics (e.g., oxybutynin, trospium, tolterodine). Note: Trospium and tolterodine may require step therapy.
  - Age restriction: must be at least 18 years old
- **Overactive bladder *(Botox)*:**
  - Trial of behavioral therapy (e.g., bladder training or pelvic floor exercises)
  - Trial and failure of 3 urinary anticholinergics (i.e., oxybutynin, trospium, tolterodine). Note: Trospium and tolterodine require step therapy with oxybutynin.
  - Age restriction: must be at least 18 years old
- **Achalasia *(Botox)*:**

- Patient meets ONE of the following:
  - Patient remains symptomatic despite surgical myotomy or pneumatic dilation.
  - Patient is not a candidate for surgical myotomy or pneumatic dilation or refuses procedure(s).
  - Patient presents with atypical achalasia symptoms and Botox is needed to help guide therapy and/or confirm diagnosis
- Malignancy at esophagogastric junction has been ruled out by endoscopic evaluation
- Age restriction: must be at least 18 years old

- **Chronic anal fissures *(Botox)*:**
  - Trial and failure of nitroglycerin ointment 0.4% (Rectiv) for at least 3 weeks AND either bulk fiber supplements, stool softeners, or sitz baths for at least 1 month
  - Crohn's disease has been ruled out
  - Age restriction: must be at least 18 years old
- **Sialorrhea *(Botox or Myobloc)*:**
  - Sialorrhea (excessive drooling) is associated with a neurological disorder (e.g., Parkinson's disease, amyotrophic lateral sclerosis, cerebral palsy
  - Failure of an anticholinergic (e.g., glycopyrrolate and benztropine)
  - Patient has medically significant complications due to sialorrhea (e.g, chronic skin maceration or uncontrolled infections)
  - Age restriction (Botox): must be at least 3 years old
  - Age restriction (Myobloc): must be at least 18 years old
- **Spasticity or equinus gait due to Cerebral Palsy *(Botox or Dysport)*:**
  - Patient will be enrolled in or is currently being managed with occupational therapy
  - Age restriction: pediatric patient (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 in patients at least 16 years old
  - *Dysport, Myobloc, Xeomin* for cervical dystonia in patients at least 18 years old
  - *Botox* for blepharospasm in patients at least 12 years old
  - *Xeomin* for blepharospasm in patients at least 18 years old who were previously treated with onabotulinumtoxinA (Botox)
  - *Botox* for strabismus in patients at least 12 years old and with deviations of < 50 prism diopters
  - *Botox* for hemifacial spasm in patients at least 18 years old

Initial Approval:

- 6 months
- Treatment is given no sooner than once every 12 weeks

Renewal:

- 1 year
- Treatment is given no sooner than once every 12 weeks
- Botox: Should not exceed a cumulative dose of 400 units every 90 days

References:

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