Pharmacy Prior Authorization
Botulinum Toxins – Clinical Guideline

**Prior Authorization Guidelines for All Indications:**
- Botox, Myobloc, Dysport, Xeomin must be prescribed by an appropriate specialist based on indication and meet following criteria:
  - **Migraine Prophylaxis (Botox):**
    - Prevention of chronic migraine (more than 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 two months (60 days):
      - Beta-blocker: propranolol, metoprolol, timolol, atenolol, nadolol
      - Anticonvulsant: valproic acid or divalproex, topiramate
      - Antidepressants: amitriptyline, venlafaxine
    - Age restriction: must be at least 18 years old
  - **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(axillae, palms and soles) (Botox):**
    - Member has medical complications from hyperhidrosis (e.g., skin maceration with secondary skin infections)
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• Neurogenic bladder (Botox):
  o Trial of behavioral therapy (e.g., bladder training or pelvic floor exercises)
  o Trial and failure of two formulary urinary anticholinergics (e.g., oxybutynin, trospium, tolterodine).
  o Age restriction: must be at least 18 years old

• Overactive bladder (Botox):
  o Trial of behavioral therapy (e.g., bladder training or pelvic floor exercises)
  o Trial and failure of 3 formulary urinary anticholinergics (e.g., oxybutynin, trospium, tolterodine).
  o 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 not a candidate for surgical myotomy or pneumatic dilation or refuses procedure(s).
  ▪ Member presents with atypical achalasia symptoms and Botox is needed to help guide therapy and/or confirm diagnosis
  o Malignancy at esophagogastric junction has been ruled out by endoscopic evaluation
  o Age restriction: must be at least 18 years old

• 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 one month
  o Age restriction: must be at least 18 years old
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- **Sialorrhea (excessive secretion of saliva, drooling) (Botox or Myobloc):**
  - Trial and failure of anticholinergic such as glycopyrrolate and benztropine
  - Member has significant complications due to sialorrhea such as chronic skin maceration or infections
  - Age restriction (Botox): must be at least 21 months old
  - Age restriction (Myobloc): must be at least 18 years old

- **Spasticity or equinus gait due to Cerebral Palsy (Botox or Dysport):**
  - Member will be enrolled in or is currently being managed with 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 in member is at least 16 years old
- Dysport, Myobloc, Xeomin for cervical dystonia: member is at least 18 years old
- Botox for blepharospasm: member is at least 12 years old
- Xeomin for blepharospasm: member is at least 18 years old who were previously treated with onabotulinumtoxinA (Botox)
- Botox for strabismus in member is at least 12 years old and with deviations of < 50 prism diopters
- 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

Last Update: 11/2017
Effective: 2/1/2018
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- Botox: Should not exceed a cumulative dose of 400 units every 90 days

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

References:

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