PHARMACY PRIOR AUTHORIZATION
Clinical Guideline – Botulinum Toxin
Botox® (botulinum toxin type A) and Myobloc® (rimabotulinumtoxin type B)

Indications:
Botox:
• For the treatment of
  o Blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above
  o Cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia
  o Facial wrinkles
  o Severe primary axillary hyperhidrosis (excessive sweating) that is inadequately managed with topical agents
  o Strabismus
  o Urinary incontinence due to detrusor overactivity associated with a neurologic condition
  o Spasticity
  o Migraine prophylaxis in adult patients with chronic migraine

Myobloc:
• For the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia

Authorization Guidelines:
For Patients who meet all of the following:
• Cervical dystonia Blepharospasm, Strabismus, Spasmotic dysphonia, Chronic management of focal spasticity in pediatric patients (2-18 years of age) with cerebral palsy with concurrent equinus gait (tiptoeing), Urinary incontinence and Migraine prophylaxis: medical records documenting diagnosis

• Severe primary axillary hyperhidrosis
  ➢ Medical records documenting diagnosis, exclusion of secondary causes of hyperhidrosis, and medical complications such as skin maceration with secondary skin infections
  ➢ Trial and failure of two consecutive months of topical aluminum chloride 20%

Initial Approval:
• 1 treatment every 3 months;
• Cerebral Palsy: 6 months Supporting medical records documenting diagnosis

Renewal:
• 3 months; Cerebral Palsy: 1 year
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Clinical Practice Guideline

- Medical records supporting response to therapy and Review of Rx history

Additional Information:

Note: FDA issued an early communication in 2008 about an ongoing safety review regarding Botox and Botox Cosmetic. FDA has received reports of systemic adverse reactions including respiratory compromise and death following the use of botulinum toxins types A and B for both FDA-approved and unapproved uses. The most serious cases had outcomes that included hospitalization and death, and occurred mostly in children treated for cerebral palsy-associated limb spasticity. The pediatric botulism cases occurred in patients less than 16 years old, with reported symptoms ranging from dysphagia to respiratory insufficiency requiring gastric feeding tubes and ventilatory support. Serious outcomes included hospitalization and death. The most commonly reported use of botulinum toxin among these cases was treatment of limb muscle spasticity associated with cerebral palsy. For Botox, doses ranged from 6.25 to 32 Units/kilogram (U/kg) in these cases. For Myobloc, reported doses were from 388 to 625 U/kg. The FDA will communicate to the public its conclusions, resulting recommendations, and any regulatory actions after the review of the data are completed.

References: