Approval Criteria Department of Pharmacy Services

Generic Name: botulinum toxin type A

Brand Name: Botox®

Medication Class: Neurotoxin

FDA Approved Uses
- Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition in adults who have had an inadequate response to, or are intolerant to, an anticholinergic medication
- Prophylaxis of headaches in adult patients with chronic migraine (≥ 15 days per month with headache lasting > 4 hours each day)
- Upper limb spasticity in adults
- Cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain
- Blepharospasm and Strabismus associated with Dystonia, in patients ≥ 12 years of age.
- Severe axillary hyperhidrosis that is inadequately managed with topical products in adult patients

Criteria for use
- Clinical documentation of diagnoses indicated in FDA Approved Uses above.
- Prescribed by a dermatologist, neurologist, oto-laryngologist, ophthalmologist, or psychiatrist.
- Pt must be ≥ 12 years of age
- Must have at least one of the following conditions:
  - Cervical dystonia
  - Blepharospasm
  - Strabismus
  - Migraine Headaches (not including cluster, tension, or other types of headaches)
    - Must have more than 4 migraines per month
    - Tried and failed, or intolerant to, at least one NSAID AND ASA/APAP + caffeine & butalbital
    - Tried and failed at least two (2) triptans
    - Tried and failed, or are intolerant to, prophylactic preventive therapies (beta blockers, tricyclic antidepressants, calcium channel blockers, topiramate)
  - Urinary Incontinence
    - Due to neurologic condition such as spinal cord injury or multiple sclerosis
    - Tried and failed, or intolerance to, at least two (2) anticholinergic agents

Not Approved For
- Severe primary axillary hyperhidrosis
- Any condition not identified above
- Any patient less than 12 years of age

Required Medical Information
- Clinical documentation to support diagnosis and previous therapies
Contraindications
- Infection at the proposed injection site
- Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation
- Patients with overactive bladder or detrusor overactivity associated with a neurologic condition who have acute UTI
- Patients with urinary retention and in patients with post-void residual (PVR) urine volume > 200 ml who are not routinely performing clean intermittent self-catheterization

Dosing
- Cervical dystonia: 198 – 300 Units distributed among muscles
- Blepharospasm / strabismus: 1.25 – 2.5 Units
- Migraine: 300 Units distributed among trigger points

Authorization
- One year

Approved by P&T Committee: 5/14/2013

References


