

## Specialty Pharmacy Program

### Botulinum Toxin Type A and B

#### DESCRIPTION

Botox<sup>®</sup> (onabotulinumtoxinA) is indicated for the treatment of cervical dystonia, severe primary axillary hyperhidrosis that is inadequately managed with topical agents, strabismus, blepharospasm associated with dystonia, and upper limb spasticity.

Dysport<sup>®</sup> (abobotulinumtoxinA) is indicated for the treatment of cervical dystonia.

Xeomin<sup>®</sup> (incobotulinumtoxinA) is indicated for the treatment of cervical dystonia and for the treatment of blepharospasm in patients previously treated with Botox.

Myobloc<sup>®</sup> (rimabotulinumtoxinB) is indicated for the treatment of cervical dystonia.

#### APPROVAL DURATION

Approval duration: lifetime

#### APPROVAL CRITERIA

- I. The use of botulinum toxin may be approved for treatment of:
  - A. Strabismus
  - B. Achalasia
  - C. Chronic anal fissures
  
- II. The use of botulinum toxin may be approved for the treatment of the following disorders if associated with spasticity or dystonia:
  - A. Blepharospasm
  - B. Upper limb spasticity
  - C. Equinus foot, if related to cerebral palsy
  - D. Hereditary spastic paraplegia
  - E. Infantile cerebral palsy
  - F. Multiple sclerosis
  - G. Neuromyelitis optica
  - H. Schilder's disease
  - I. Spastic hemiplegia
  - J. Spasticity related to stroke, or spinal cord injury
  - K. Idiopathic torsion dystonia
  - L. Organic writer's cramp
  - M. Orofacial dyskinesia (i.e., jaw closure dystonia)
  - N. Spasmodic dysphonia or laryngeal dystonia (a disorder of speech due to abnormal control of the laryngeal muscles present only during the specific task of speaking)
  - O. Symptomatic torsion dystonia
  - P. Facial nerve (VII) dystonia
  - Q. Other forms of upper motor neuron spasticity
  
- III. The use of botulinum toxin may be approved for the treatment of significant drooling in patients who are unable to tolerate scopolamine or in whom it has been ineffective.

- IV. The use of botulinum toxin is considered medically necessary in the initial treatment of cervical dystonia (spasmodic torticollis) of moderate or greater severity when all of the following criteria are met:
  - A. History of recurrent clonic and/or tonic involuntary contractions of one or more of the following muscles: sternocleidomastoid, splenius, trapezius and/or posterior cervical muscles; AND
  - B. Sustained head tilt and/or abnormal posturing with limited range of motion in the neck; AND
  - C. The duration of the condition is greater than 6 months.
  - D. Subsequent injections of botulinum toxin for the treatment of cervical dystonia (spasmodic torticollis) of moderate or greater severity are considered medically necessary when:
    - 1. There is a response to the initial treatment documented in the medical records; AND
    - 2. The patient still meets the medically necessary criteria above.
  
- V. The use of botulinum toxin is considered medically necessary as a treatment of incontinence related detrusor overreactivity and incontinence of neurogenic origin (i.e., spinal cord injury, multiple sclerosis) that is inadequately controlled with anticholinergic therapy.
  
- VI. The use of botulinum toxin is considered medically necessary for bladder detrusor sphincter dyssynergia of neurogenic origin.
  
- VII. Treatment of hyperhidrosis with botulinum toxin may be approved for patients who meet the following criteria:
  - 1. Diagnosis is incapacitating primary focal hyperhidrosis, defined as:
    - 1. Hyperhidrosis significantly interferes with the patient's ability to perform age-appropriate activities of daily living (i.e., sweat soaks clothing to the extent that it is necessary to change clothes and/or shower more than once during the course of a normal day; sweat on the hands smudges written documents or interferes with the ability to grip items such as pens/pencils, eating utensils, hand tools.)" OR
    - 2. The condition is causing persistent or chronic cutaneous conditions such as skin maceration, dermatitis, fungal infections, and secondary microbial conditions; AND
  - 2. Patient has failed a 6 month trial of one or more nonsurgical treatments, as indicated below:
    - 1. Aluminum chloride
    - 2. Gannic acid
    - 3. Glutaraldehyde
    - 4. Topical or systemic anticholinergics
    - 5. Tranquilizers
    - 6. Non-steroidal anti-inflammatory drugs
  
- VIII. Botulinum toxin is considered cosmetic as a treatment of skin wrinkles or other cosmetic indications and is NOT approvable.
  
- IX. Botulinum toxin may NOT be approved for the treatment of any other conditions including, but not limited to, the following:
  - A. Headache, including but not limited to tension, migraine or chronic daily headaches
  - B. Anismus
  - C. Chronic motortic disorder
  - D. Fibromyalgia/fibromyositis
  - E. Gastroparesis
  - F. Low back pain
  - G. Myofascial pain syndrome
  - H. Neck pain not related to conditions mentioned above
  - I. Parkinson's disease
  - J. Tics associated with Tourette's Syndrome
  - K. Tourette's Syndrome
  - L. Tremors
  - M. Urinary and anal sphincter dysfunction
  - N. Stuttering

- O. Carpal tunnel syndrome
- P. Tinnitus