



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: botulinum toxin type A and type B

Brand Name: Botox, Myobloc

Medication Class: neurotoxin

FDA Approved Uses: cervical dystonia, strabismus, blepharospasm
Severe primary axillary hyperhidrosis (SPAH)

Off-label Use: migraine headaches

Usual Dose: cervical dystonia- 198-300 U distributed among muscles
Blepharospasm- 1.25-2.5 U
SPAH- 50 U per axilla
Migraine –average 300U± distributed among trigger points

Duration of Therapy: Variable. Maximum treatment for SPAH is 1-2 treatments per year.
Migraine – approx. every 3-6 months indefinitely

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Prescribed by a dermatologist, gastroenterologist, neurologist, otolaryngologist, ophthalmologist, or psychiatrist
- Must be greater than 12 years of age
- Must have at least one of the following conditions:
 - Cervical dystonia, blepharospasm, strabismus, cranial nerve VII disorders such as hemifacial spasm, jaw-closing oromandibular dystonia
 - Idiopathic torsion dystonia, symptomatic torsion dystonia
 - Exotropia
 - Blepharospasm, other disorders of strabismus, unspecified disorders of binocular eye movements, disorders of eye movement
 - Spasmodic torticollis
 - Paralytic strabismus, mechanical strabismus
 - Hereditary spastic paraplegia
 - Multiple Sclerosis, other demyelinating diseases of the central nervous system
 - Anal spasm
 - Spastic hemiplegia
 - Laryngeal spasm
 - Schilders disease
 - Achalasia- Approval will be considered for patients who:
 - Have failed conventional therapy
 - Are at high risk of complications of pneumatic dilation or surgical myotomy
 - Have failed a prior myotomy or dilation



- Have had a previous dilation induced perforation
- Have an epiphrenic diverticulum or hiatal hernia, both of which increase the risk of dilation-induced perforation.
- Severe primary axillary hyperhidrosis (SPAH):
 - Severe PAH is defined as scores of 3 or 4 on the HDSS* and,
 - Cannot be managed by use of topical agents such as prescription antiperspirants.
- Migraine headaches, but not cluster, tension, or other types of headaches
 - Must have more than 4 migraines per month and/or migraines are more than once a month but are debilitating
 - Tried and failed or intolerant to at least one NSAID or ASA/APAP with caffeine & butalbital.
 - Tried and failed or intolerant to at least two triptans.
 - Tried and failed or intolerant to the usual prophylactic preventive therapies (beta blockers, tricyclic antidepressants, calcium channel blockers, topiramate, etc.)

*Hyperhidrosis Disease Severity Scale (HDSS)-

1= "underarm sweating never noticeable/never interferes with my daily activities"

2= "Underarm sweating tolerable/sometimes interferes with my daily activities"

3= "Underarm sweating barely tolerable/frequently interferes with my daily activities"

4= "Underarm sweating intolerable/always interferes with my daily activities"

Not Approved if:

- Pregnant patient
- Patient on aminoglycosides
- Patient has corneal exposure or corneal ulceration
- Patient has cluster headaches, tension headaches
- Patient has not tried the usually accepted migraine therapies
- Patient has urinary and sphincter dysfunction
- Patient has Bell's Palsy
- Patient has fibromyositis
- Patient has Touretes syndrome
- Patient has chronic motor tics
- Patient has myasthenia gravis
- Patient has myofacial pain syndrome
- Patient is using medication for cosmetic reasons

Contraindications: Pregnant patients, patients with corneal exposure, patients with retrobulbar hemorrhages sufficient to compromise retinal circulation, patients sensitive or allergic to other botulinum toxins.

Special Issues: Severe laryngeal and respiratory weakness has occurred. Care must be used when injecting botulinum toxin A, B into these areas.

P&T Approval: _____ Date: _____

