



Prior Authorization Approval Criteria

botulinum toxins types A and B

Generic name:	Botulinum toxins type A and B
Brand names:	Botox (type A); Myobloc (type B)
Medication class:	Neurotoxin
FDA-approved uses:	Cervical dystonia, strabismus, blepharospasm, severe primary axillary hyperhidrosis (SPAH)
Usual dose:	Cervical dystonia: 198-300 U distributed among muscles Blepharospasm: 1.25-2.5 U SPAH: 50 U per axilla
Duration of therapy:	Variable. Maximum treatment for SPAH is 1-2 treatments per year.

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

- Prescribed by a neurologist, otolaryngologist, ophthalmologist, or physiatrist
- 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
 - Schilder's disease
 - Severe primary axillary hyperhidrosis (SPAH):
 - SPAH is defined as scores of 3 or 4 on the HDSS*, and
 - Cannot be managed by use of topical agents such as prescription antiperspirants.

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"

Contraindications:

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

Not approved if:

- Pregnant patient
- Patient on aminoglycosides
- Patient has corneal exposure or corneal ulceration
- Patient has headaches including migraines, cluster headaches, tension headaches
- Patient has urinary and sphincter dysfunction
- Patient has Bell's palsy
- Patient has fibromyositis
- Patient has Tourette's syndrome
- Patient has chronic motor tics
- Patient has myasthenia gravis
- Patient has myofacial pain syndrome
- Patient is using medication for cosmetic reasons

Special issues:

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

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 11/15/04