

Horizon BCBSNJ
Uniform Medical Policy Manual

Section	Treatment
Policy Number	059
Effective Date	01/01/1993
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Review Date	12/04/2001
Category	

Subject:

Botulinum Toxin

Description:

Botulinum is a family of toxins produced by the anaerobic organism *Clostridia botulinum*. There are seven distinct serotypes designated as type A, B, C-1, D, E, F, and G. Botulinum toxin is a powerful neuroparalytic agent that paralyzes muscles. When minute quantities are injected into spastic muscles, local denervation and muscle weakness occur thereby causing remission of symptoms.

Botulinum toxin type A (marketed as **Botox** by Allergan) was the first serotype to be approved by the US FDA for use in specific disorders of the eye, facial, and neck muscles in 1991.

Botulinum toxin type B (marketed as **Myobloc** by Elan Pharmaceuticals) was approved by the US FDA on December 8, 2000 for use in cervical dystonia.

Policy:

- I. Botulinum toxin treatments must be ordered and monitored by the treating physician who is experienced in the use of such neurolytic agents.
- II. A. **Botulinum toxin type A (Botox)** treatments are medically appropriate for any of the following FDA-approved indications:
 1. blepharospasm
 2. hemifacial spasm
 3. strabismus
 4. cervical dystonia (spasmodic torticollis)
- B. **Botulinum toxin type A (Botox)** treatments are also medically appropriate for the following off-label uses:
 1. limb dystonia
 2. intrasphincteric injection for achalasia
 3. oromandibular dystonia (orofacial dyskinesia or Meige syndrome, jaw-closing dystonia)
 4. focal and segmental limb dystonias (writer's cramp, typist's cramp, musician's cramp)
 5. spasmodic dysphonia or laryngeal dystonia (adductor type)
 6. cerebral palsy and dynamic limb contracture in ambulatory children (by improving gait, and by improving ankle dorsiflexion to permit strengthening and growth of muscles and to delay or prevent surgery with its associated health risks.)
 7. chronic upper or lower limb spasticity (e.g., associated with stroke, head trauma, spinal cord

injuries, multiple sclerosis) - by reducing pain from muscle spasm, improving limb posture and range of passive movement, allowing more comfortable limb positioning, improving ease of passive stretch, and producing functional benefits especially in ambulatory patients.

8. severe focal hyperhidrosis unresponsive to any local or systemic drug therapy which would otherwise be treated with invasive surgical procedure.
9. chronic anal fissure

C. **Botulinum toxin type A (Botox)** treatments for any other reason are either considered *investigational* (e.g., anal spasm, irritable colon, biliary dyskinesia, fibromyalgia, focal myofascial pain disorders, headache) or *cosmetic* (e.g., reduction of glabellar frown lines, elimination of hyperkinetic facial lines or wrinkles).

A. **Botulinum toxin type B (Myobloc)** treatment is medically appropriate for cervical dystonia.
[INFORMATIONAL NOTE: This is the only FDA-approved indication.]

B. **Botulinum toxin type B (Myobloc)** treatment for any other reason is considered *investigational*

IV. Although EMG (electromyography) guidance is generally not necessary, there may be patients who require it (e.g., after initial treatment failure) in order to determine the proper injection site(s).

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