

**Regence BlueCross BlueShield of Oregon · Regence BlueShield  
Regence BlueCross BlueShield of Utah · Regence BlueShield of Idaho  
Independent licensees of the Blue Cross and Blue Shield Association**

**Medication Policy Manual**

**Policy No:** dru048

**Topic:** Myobloc<sup>®</sup>, botulinum toxin type B

**Date of Origin:** December 14, 2001

**Revised/Effective Date:** April 7, 2009

**Next Review Date:** March 2010

**IMPORTANT REMINDER**

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

**Description**

Botulinum toxin is a neurotoxin that is injected into a muscle to cause temporary paralysis of that muscle.

## **Policy/Criteria**

**I.** Most contracts require prior authorization approval of botulinum toxin type B (BTX-B) prior to coverage. BTX-B may be considered medically necessary in patients with functional impairment originating from spasticity or dystonia (involuntary sustained muscle contraction) resulting from one of the following conditions:

**A.** A confirmed diagnosis of cervical dystonia or spasmodic torticollis with documentation of involuntary contractions of the neck muscles resulting in twisting and repetitive movements, and/or abnormal postures.

**OR**

**B.** Excessive saliva (sialorrhea) associated with Parkinson's disease.

**II.** Administration, Quantity Limitations, and Authorization Period

**A.** Regence does not consider BTX-B to be a self-administered medication.

**B.** When prior authorization is approved, BTX-B may be authorized in quantities up to four injection treatments within a 12 month period.

**C.** Authorization shall be reviewed at least every 12 months to confirm that current medical necessity criteria are met and that the medication is effective.

**III.** BTX-B is considered investigational for all other conditions, including, but not limited to:

**A.** Axillary hyperhidrosis <sup>[9, 15]</sup>

**B.** Carpal tunnel syndrome <sup>[11]</sup>

**C.** Cerebral palsy <sup>[18]</sup>

**D.** Palmar hyperhidrosis <sup>[8]</sup>

**E.** Refractory detrusor overactivity <sup>[10, 13]</sup>

**F.** Spasmodic dystonia <sup>[14]</sup>

**G.** Spastic movement disorders in children <sup>[17]</sup>

## H. Upper limb spasticity following stroke <sup>[16]</sup>

### Position Statement

- Botulinum toxin type B (BTX-B) is used in the treatment of cervical dystonia or spasmodic torticollis to reduce the severity and pain associated with abnormal neck position.
- Botulinum toxins (BTX-A and BTX-B) are also being investigated in many different conditions where muscle tension is thought to play a role. The quality of evidence from the majority of these studies is poor.
- FDA labeling indicates that units of BTX-B cannot be compared to or converted into units of any other botulinum toxin. <sup>[7]</sup> Therefore, the efficacy, dosing and safety of BTX-B cannot be based on extrapolation from other studies using other botulinum toxin serotypes.
- Use of botulinum toxin (all serotypes) for treatment of wrinkles or other cosmetic conditions is considered not medically necessary.

### *Clinical Efficacy*

- Results from three clinical studies support the efficacy of BTX-B in reducing neck pain and the severity of the abnormal head position associated with cervical dystonia or spasmodic torticollis in patients previously responsive to BTX-A <sup>[1, 3]</sup> or those patients who no longer respond to BTX-A. <sup>[4]</sup>
  - \* Cervical dystonia (or spasmodic torticollis) is characterized by involuntary contractions of the neck muscles resulting in twisting and repetitive movements, and/or abnormal postures. <sup>[19]</sup>
- Anatomically guided injections of BTX-B into the parotid and submandibular glands appear to effectively improve sialorrhea without causing dysphagia in patients with Parkinson's disease. <sup>[6]</sup>

### *Use of botulinum toxic type B in other conditions*

- There are four pilot studies of 20 subjects each that investigate BTX-B for use in palmer hyperhidrosis <sup>[8]</sup>, axillary hyperhidrosis <sup>[9]</sup>, refractory detrusor overactivity <sup>[10]</sup>, and carpal tunnel syndrome <sup>[11]</sup>. The evidence from these trials is of poor quality. Larger, well-designed trials are necessary to confirm the results.
- Additional pilot studies, case reports and observational studies have suggested potential benefit of BTX-B in the treatment of spasmodic dystonia <sup>[14]</sup>, axillary hyperhidrosis <sup>[15]</sup>, upper limb spasticity following stroke <sup>[16]</sup>, spastic movement disorders in children <sup>[17]</sup> and arm dystonia in children with cerebral palsy <sup>[18]</sup>. The evidence from these trials is of poor quality. Larger, well-designed clinical trials are needed to assess safety and efficacy of BTX-B in these conditions.

### *Safety*

- The most commonly reported adverse events observed in clinical trials of BTX-B include dry mouth, dysphagia, dyspepsia, and injection site pain. <sup>[7]</sup>
- Most trials of BTX-B did not use a placebo comparator. As a result, adverse events observed in clinical trials may not truly be related to treatment with BTX-B.
- Upon review of post-marketing information, the FDA has noted reports of systemic adverse reactions suggestive of botulism following the use of botulinum toxins type A and B. Outcomes include respiratory compromise, hospitalization and death and are most commonly observed in children treated for cerebral palsy-associated limb spasticity.
- The safety, efficacy and dosage of botulinum toxins have not been established for any condition in children less than 12 years of age.

### **References**

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5. Baumann L et al. "A double-blinded, randomized, placebo-controlled pilot study of the safety and efficacy of Myobloc<sup>®</sup> (botulinum toxin type B)-purified neurotoxin complex for the treatment of crow's feet: a double-blinded, placebo-controlled trial." *Dermatol Surg* 2003;29(5):508-15.
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Cross References
Botulinum Toxin, BlueCross BlueShield Association Medical Policy, 5.01.05; 6/2007.
Treatment of Hyperhidrosis, BlueCross BlueShield Association Medical Policy, 8.01.19; 2/2006.
Botox <sup>®</sup> , botulinum toxin type A injection dru006
Cosmetic and Reconstructive Surgery, Surgery Section; Medical Policy No. 12.

Codes	Number	Description
HCPCS	J0587	Botulinum toxin type B, per 100 units