**Section:** Prescription Drugs  
**Effective Date:** January 1, 2013  
**Subsection:** CNS  
**Original Policy Date:** December 7, 2011  
**Subject:** Botox  
**Page:** 1 of 6  

**Last Review Status/Date:** December 6, 2012

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**BOTOX**

**Description**

Botox (onabotulinum toxin A)

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**Background**

Botulinum toxin (abbreviated either as BTX or BoNT) is a protein neurotoxin produced by the bacterium *Clostridium botulinum*. The botulinum toxins are characterized as 7 separate neurotoxins (labeled as types A, B, C [C1, C2], D, E, F, and G), which are antigenically and serologically distinct but structurally similar.

The neuromuscular blockade is achieved through prevention of docking/fusion of neurosecretory with the nerve synapse plasma membrane and release of neurotransmitters.

The various botulinum toxins have approved cosmetic and non-aesthetic uses. They possess individual potencies, and care is required to assure proper use and avoid medication errors. Recent changes to the established drug names by the FDA were intended to reinforce these differences and prevent medication errors. (1-2)

OnabotulinumtoxinA [BoNT-A (BOTOX®)] was initially approved in 1989 by the US Food and Drug Administration (FDA) for the treatment of strabismus, blepharospasm, and hemifacial spasm in patients aged younger than 12 years. Subsequently, additional indications have been approved for non-aesthetic uses.

OnabotulinumtoxinA is also used for a variety of non-labeled indications for which there is an evidence base and clinical recommendation. (3-11)
Regulatory Status

FDA-approved indication: Botox is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for: (12)

- Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer)
- Treatment of upper limb spasticity in adult patients
- Treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain
- Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients
- Treatment of blepharospasm associated with dystonia in patients ≥12 years of age
- Treatment of strabismus in patients ≥12 years of age

Important limitations: (12)

- Safety and effectiveness of Botox have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month).
- Safety and effectiveness of Botox have not been established for the treatment of upper limb spasticity in pediatric patients, and for the treatment of lower limb spasticity in adult and pediatric patients.
- Safety and effectiveness of Botox for hyperhidrosis in body areas other than axillary have not been established.
- Botulinum toxins are not interchangeable.

Related policies

Dysport, Myobloc, Xeomin

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.
Botox may be considered **medically necessary** for treatment of the conditions indicated below. Botox may be considered **investigational** for all other indications.

**Prior – Approval Requirements**

**Age** 12 years of age or greater except where otherwise indicated below

**Diagnoses**

Patient must have **ONE** of the following:

1. Achalasia
2. Blepharospasm associated with dystonia
3. Cervical dystonia
4. Chronic anal fissures
5. Dysphagia
6. Facial Nerve (VII) disorders
7. Hemifacial spasms
8. Hereditary spastic paraplegia
9. Hyperhidrosis
10. Neuromyelitis optica
11. Orofacial dyskinesia
12. Other dystonia (writer’s cramp, focal task specific dystonia, laryngeal)
13. Overactive, neurogenic bladder dysfunction (18 years of age or older)

**AND ONE** of the following:

a. Inadequate response to an anticholinergic
b. Intolerant of an anticholinergic

14. Prophylaxis of chronic migraine headaches* (18 years of age or older)
15. Spasmodic torticollis (clonic twisting of the head)
16. Spastic hemiplegia
17. Spasticity (upper and lower limbs) due to multiple causes [i.e. cerebral palsy, stroke, multiple sclerosis and post-traumatic brain and spinal cord injury] (no age restriction)
18. Sphincter of Oddi dysfunction
19. Strabismus associated with dystonia
20. Upper limb spasticity (18 years of age or older)

*chronic migraine headache defined as having ≥15 days per month with headache lasting 4 hours a day or longer
Prior – Approval Renewal Requirements

Same as above

Policy Guidelines

Pre – PA Allowance

None

Prior – Approval Limits

Duration 1 year

Prior – Approval Renewal Limits

Same as above

Rationale

Summary

Botulinum toxin (abbreviated either as BTX or BoNT) is a protein neurotoxin produced by the bacterium Clostridium botulinum. The botulinum toxins are characterized as 7 separate neurotoxins (labeled as types A, B, C [C1, C2], D, E, F, and G), which are antigenically and serologically distinct but structurally similar.

The various botulinum toxins have approved cosmetic and non-aesthetic uses. They possess individual potencies, and care is required to assure proper use and avoid medication errors. Recent changes to the established drug names by the FDA were intended to reinforce these differences and prevent medication errors. (1-2)

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Botox while maintaining optimal therapeutic outcomes.

References


Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
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<tr>
<td>August 2009</td>
<td>On August 3, 2009, the FDA announced it was changing the generic names for both Botox and Myobloc to avoid medication errors. <strong>Botox’s new generic name is onabotulinumtoxinA</strong>, after previously being known as botulinum toxin type A. <strong>Myobloc’s new generic name is rimabotulinumtoxinB</strong>, after previously being called botulinum toxin type B.</td>
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<td>July 2010</td>
<td>Updated ICD-9 codes, addition of ICD-10 codes, separation of criteria for Botox and Myobloc, and addition of the recently FDA approved diagnosis of spasticity in flexor muscles of the elbow, wrist and fingers for Botox.</td>
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</table>
BOTOX (onabotulinumtoxinA) for injection is indicated for the treatment of upper limb spasticity in adult patients, to decrease the severity of increased muscle tone in elbow flexors (biceps), wrist flexors (flexor carpi radialis and flexor carpi ulnaris) and finger flexors (flexor digitorum profundus and flexor digitorum sublimis). The efficacy and safety of BOTOX for the treatment of upper limb spasticity were evaluated in three randomized, multi-center, double-blind, placebo-controlled studies. Safety and effectiveness of BOTOX have not been established for the treatment of upper limb spasticity in pediatric patients, and for the treatment of lower limb spasticity in adult and pediatric patients.

October 2010
Updated criteria to mirror newly approved FDA indication for chronic migraine in adults.

September 2011
Updated criteria to mirror newly approved FDA indication for urinary incontinence in people with neurologic conditions such as spinal cord injury and multiple sclerosis who have overactivity of the bladder. Removal of ICD 9 and 10 codes due to lack of specificity. Additional compendial indications for botulinum toxin type A including spasticity (upper and lower limbs) due to multiple causes (i.e. cerebral palsy, stroke, multiple sclerosis and post-traumatic brain and spinal cord injury) in both adults and children, treatment of achalasia in patients who are considered poor candidates for endoscopic dilation or surgery, chronic anal fissure, sphincter of Oddi dysfunction, dysphagia and hyperhidrosis.

December 2012
Annual Review-no change in policy statement. Reference and editorial updates.

Keywords

This policy was approved by the FEP® Pharmacy and Therapeutics Committee on December 6, 2012 and is effective January 1, 2013.

Signature on File

James A. Ferrendelli, M.D.