Botox

Description

Botox (onabotulinum toxin A)

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 (1).

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).

Regulatory Status
FDA-approved indications: Botox is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for: (3)

1. Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication
2. Treatment of urinary incontinence due to detrusor over-activity 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.
3. Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer).
4. Treatment of upper or lower limb spasticity in adult patients.
5. Treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain.
6. Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients.
7. Treatment of blepharospasm associated with dystonia in patients ≥12 years of age.
8. Treatment of strabismus in patients ≥12 years of age.

Limitations of Use:
Safety and effectiveness of Botox have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) (3).

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 (3).

Safety and effectiveness of Botox have not been established for the treatment of hyperhidrosis in body areas other than axillary (4).

Botulinum toxins are not interchangeable. Total accumulated dose should not exceed 400 IU over a 3 month interval (3).

Some products have cosmetic indications which are excluded from coverage.

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

No age restriction

Diagnosis

Patient must have the following:

Spasticity (upper and lower limbs) due to multiple causes [i.e. cerebral palsy, stroke, multiple sclerosis and post-traumatic brain and spinal cord injury]

Age

12 years of age or older

Diagnoses

Patient must have ONE of the following:

1. Blepharospasm associated with dystonia
2. Strabismus

Age

18 years of age or older

Diagnoses

Patient must have ONE of the following:

1. Achalasia
2. Overactive bladder (OAB)
   **AND ONE** of the following:
   a. Inadequate response to an anticholinergic
   b. Intolerant of an anticholinergic
3. Incontinence associated with a neurologic condition (spinal cord injury, multiple sclerosis, etc)
   **AND ONE** of the following:
   a. Inadequate response to an anticholinergic
   b. Intolerant of an anticholinergic
4. Chronic anal fissures
5. Dystonia
   a. Cervical
   b. Writer’s cramp
   c. Focal task specific
   d. Laryngeal
6. Dysphagia
7. Facial Nerve (VII) disorders
8. Hemifacial spasms
9. Hereditary spastic paraplegia
10. Hyperhidrosis
11. Neuromyelitis optica
12. Orofacial dyskinesia
13. Prophylaxis of chronic migraine headaches
   a. Patient is experiencing ≥15 days per month with headache lasting 4 hours a day or longer
14. Spasmodic torticollis (clonic twisting of the head)
15. Spastic hemiplegia
16. Sphincter of Oddi dysfunction
17. Upper or lower limb spasticity

AND the following:
   1. NO dual therapy with other botulinum toxins

Prior – Approval Renewal Requirements

Age
No age restriction

Diagnosis
Patient must have the following:

Spasticity (upper and lower limbs) due to multiple causes [i.e. cerebral palsy, stroke, multiple sclerosis and post-traumatic brain and spinal cord injury]

Age
12 years of age or older

Diagnoses
Patient must have ONE of the following:

1. Blepharospasm associated with dystonia
2. Strabismus

Age
18 years of age or older
Diagnoses

Patient must have ONE of the following:

1. Achalasia
2. Overactive bladder (OAB)
3. Incontinence associated with a neurologic condition (spinal cord injury, multiple sclerosis, etc)
4. Chronic anal fissures
5. Dystonia
   a. Cervical
   b. Writer’s cramp
   c. Focal task specific
   d. Laryngeal
6. Dysphagia
7. Facial Nerve (VII) disorders
8. Hemifacial spasms
9. Hereditary spastic paraplegia
10. Hyperhidrosis
11. Neuromyelitis optica
12. Orofacial dyskinesia
13. Prophylaxis of chronic migraine headaches
   a. Response to therapy has shown the frequency has decreased to be <15 days per month
14. Spasmodic torticollis (clonic twisting of the head)
15. Spastic hemiplegia
16. Sphincter of Oddi dysfunction
17. Upper or lower limb spasticity

AND the following:
1. NO dual therapy with other botulinum toxins

Policy Guidelines
Pre – PA Allowance
None

Prior – Approval Limits
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 (3).

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
On August 3, 2009, the FDA announced it was changing the generic names for both Botox and Myobloc to avoid medication errors. Botox's new generic name is onabotulinumtoxinA, after previously being known as botulinum toxin type A. Myobloc's new generic name is rimabotulinumtoxinB, after previously being called botulinum toxin type B.

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.

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.

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

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.

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

May 2016 Addition of quantity limits 100 IU vial 4 vials per 90 days or 200 IU vial 2 vials per 90 days or any combination that does not exceed 400 IU per 90 days

June 2016 Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 24, 2016 and is effective on July 1, 2016.

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