

When requesting Botox® (onabotulinumtoxinA), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved off-label compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indications

- Botox® (onabotulinumtoxinA) is indicated for the treatment of:
 - o Overactive bladder symptoms of urge urinary incontinence, urgency, and frequency, in adult individuals who have an inadequate response to or who are intolerant to an anticholinergic medication
 - o Urinary incontinence due to detrusor overactivity associated with a neurologic condition (such as spinal cord injury or multiple sclerosis) in adult individuals who have experienced an inadequate response to or are intolerant to an anticholinergic medication
 - o Headache prophylaxis in adult individuals having chronic migraines (defined as, ≥ 15 headache days per month with headaches lasting 4 hours a day or longer)
 - o Spasticity in adult individuals
 - o Cervical dystonia in adult individuals to reduce the severity of abnormal head position and neck pain
 - o Severe axillary hyperhidrosis that is inadequately managed by topical agents in adult individuals
 - o Blepharospasm associated with dystonia in individuals ≥ 12 years of age
 - o Strabismus in individuals ≥ 12 years of age

Approved Off-label Compendial uses

- Excessive salivation
- Achalasia
- Hemifacial spasm

Coverage Guidelines

For all approved indications, the individual meets all of the following criteria for approval:

- Does not have hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation
- Does not have an infection at the proposed injection site
- Does not have urinary tract infections or urinary retention if the product is administered via intradetrusor injection
- Twelve years of age or older

Overactive Bladder

- Had an inadequate response or intolerance to an anticholinergic medication

Urinary Incontinence

The individual must meet **all** of the following criteria for approval:

- Condition is due to detrusor overactivity associated with a neurologic condition (such as a spinal cord injury or multiple sclerosis)
- Had an inadequate response or intolerance to an anticholinergic medication

Chronic Migraine Headaches

The individual must meet **all** of the following criteria for approval:

- Is experiencing at least 15 headache days per month that lasts 4 hours a day or longer
- Is being used for prophylaxis of headache
- Had an inadequate response to at least 2 agents used for the prevention of chronic migraine (e.g., tryptans, antidepressants, beta-blockers)

Upper limb spasticity

- To decrease the severity of increased muscle tone in elbow flexors, wrist flexors, finger flexors, or thumb flexors

Lower limb spasticity

- To decrease the severity of increased muscle tone in ankle flexors or toe flexors

Cervical Dystonia/Hemifacial Spasm

Primary Axillary Hyperhidrosis

The individual must meet **all** of the following criteria for approval:

- Has been evaluated for potential causes of secondary hyperhidrosis to avoid symptomatic treatment of hyperhidrosis
- Not being treated for hyperhidrosis in body areas other than axillary
- Condition is refractory to topical agents

Blepharospasm/Strabismus

- Condition is associated with dystonia, including benign essential blepharospasm or cranial nerve VII disorders

Excessive Salivation

- Condition is associated with advanced Parkinson's disease

Achalasia

- Has a poor response to pneumatic dilatation or is not a surgical candidate

Approval duration: 12 months

Additional Information for Prescribers¹

Our prescribers are alerted to the following safety concerns as educational points/reminders:

- Potency units of Botox® (onabotulinumtoxinA) are not interchangeable with other preparations of botulinum toxin products.
- Spread of toxin effects, including swallowing and breathing difficulties, can lead to death.
- Concomitant neuromuscular disorder may exacerbate clinical effects of treatment.
- Use with caution in individuals with compromised respiratory function.
- Post-void residual urine volume should be monitored in individuals treated for overactive bladder or detrusor overactivity associated with a neurologic condition who do not catheterize routinely, particularly individuals with multiple sclerosis or diabetes mellitus.

References

1. Botox® prescribing information. Irvine, CA: Allergan, Inc.: April 2017. http://www.allergan.com/assets/pdf/botox_pi.pdf. Accessed April 23, 2017
2. Klasco RK (Ed): DRUGDEX® System. Thomson Micromedex, Greenwood Village, CO. Accessed February 28, 2017. <http://www.micromedexsolutions.com>
3. Schaefer SM, Gottschalk CH, Jabbari B. Treatment of chronic migraine with focus on botulinum neurotoxins. *Toxins*. 2015;7:2615-2628
4. Shamliyan TA, Kane RL, Taylor FR. Migraine in Adults: Preventive Pharmacologic Treatments. Agency for Healthcare Research and Quality; Rockville MD, 2013.
5. Vaezi MF, Pandolfino JE, Vela MF. ACG Clinical Guideline: Diagnosis and Management of Achalasia. *Am J Gastroenterology* 2013: 1238-1249. http://gi.org/wp-content/uploads/2013/07/ACG_Guideline_Achalasia_July_2013.pdf. Accessed April 24, 2017.

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