

Botox® (onabotulinumtoxinA)

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 for the covered indications.

FDA-approved Indications

Botox (onabotulinumtoxinA) is indicated for the treatment of:

- Overactive bladder
- Urinary incontinence due to detrusor overactivity
- Chronic migraine prophylaxis
- Adult upper and lower limb spasticity
- Pediatric upper limb spasticity
- Cervical dystonia
- Primary axillary hyperhidrosis
- Blepharospasm
- Strabismus

Approved Off-label Compendial Uses

- Excessive salivation
- Achalasia
- Hemifacial spasm
- Anal fissure
- Spasmodic dysphonia
- Oromandibular dystonia
- Pediatric lower limb spasticity

Coverage Guidelines

The individual must meet the following criteria for select indications:

Overactive bladder

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

- Had an inadequate response or intolerance to an anticholinergic medication; AND
- Does not have urinary tract infection or urinary retention.

Urinary incontinence due to detrusor overactivity

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; AND
- Does not have urinary tract infection or urinary retention.

Chronic migraine headache prophylaxis

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

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

For reauthorization, the individual must show therapeutic benefit defined as a 50% reduction in frequency of headache days per month.

Upper/lower limb spasticity

For reauthorization, the individual must show therapeutic benefit from Botox use (e.g. reduction of muscle stiffness).

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;
- Is not being treated for hyperhidrosis in body areas other than axillary; AND
- Condition is refractory to at least one topical agent.

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

The individual had a poor response to pneumatic dilatation or is not a surgical candidate.

Anal fissure

The individual failed conservative therapy (e.g. sitz baths, topical anesthetics, and increased dietary fiber).

Approval duration:

- Initial authorization: Migraine 6 months, all other indications 12 months
- Reauthorization: 12 months

Dosing Recommendations

Urinary incontinence due to detrusor overactivity

Approve up to a maximum dose of 200 units, administered not more frequently than once every 12 weeks.

Overactive bladder

Approve up to a maximum dose of 100 units, administered not more frequently than once every 12 weeks.

Chronic migraine headache prophylaxis

Approve up to a maximum dose of 155 units, administered not more frequently than once every 12 weeks.

Adult upper/lower limb spasticity

Approve up to a maximum dose of 400 units divided among selected muscles, administered not more frequently than once every 12 weeks. Administer no more than 50 units per site.

Pediatric upper/lower limb spasticity

Approve up to a maximum dose of 6 units per kilogram body weight or 200 units, whichever is lower, divided among selected muscles administered not more frequently than once every 12 weeks.

Cervical dystonia

Approve up to a maximum dose of 300 units, divided among affected muscles, administered not more frequently than once every 3 months.

Primary axillary hyperhidrosis

Approve up to a maximum dose of 50 units per axilla, administered not more frequently than once every 3 months.

Blepharospasm

Approve up to a maximum dose of 200 units, administered not more frequently than once every 3 months. Maximum dose of 5 units per site.

Strabismus

Approve up to a maximum dose of 25 units in any one muscle, administered not more frequently than once every 3 months.

Excessive salivation

Approve up to a maximum dose of 100 units (50 units per side), administered not more frequently than once every 16 weeks.

Hemifacial spasm

Approve up to a maximum dose of 25 units divided among affected areas, administered not more frequently than once every 3 months.

Achalasia

Approve up to a maximum dose of 100 units into the lower esophageal sphincter, administered not more frequently than once every 3 months.

Chronic anal fissure

Approve up to a maximum dose of 25 units, administered not more frequently than once every 4 weeks.

Spasmodic dysphonia (Laryngeal dystonia)

Approve up to a maximum dose of 25 units, administered not more frequently than once every 3 months.

Oromandibular dystonia

Approve up to a maximum dose of 400 units, administered not more frequently than once every 3 months.

References

1. Botox® (onabotulinumtoxinA) [prescribing information]. Irvine, CA: Allergan, Inc.: June 2019. Accessed July 1, 2019.
2. OnabotulinumtoxinA (Botox®). In: DRUGDEX® System Micromedex. Greenwood Village, CO: Thompson Reuters (Healthcare) Inc. [Updated; June 21, 2019; Accessed July 1, 2019].
3. Simpson, DN, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical, dystonia, adult spasticity, and headache. Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016; 86(19):1818-1826.
4. Schwabe, AL. Botulinum Toxin in the Treatment of Pediatric Upper Limb spasticity. *Seminars in Plastic Surgery*. 2016 Feb; 30(1): 24-28.
5. Guyot, P, et al. Botulinum Toxins Type A (Bont-A) in the Management of Lower Limb Spasticity in Children: A Systematic Literature Review and Bayesian Network Meta-analysis. *Journal of Child Neurology*. Feb. 25, 2019; 34(7): 371-381.
6. Koman LA, Mooney JF, Smith BP, et al: Botulinum toxin type A neuromuscular blockade in the treatment of lower extremity spasticity in cerebral palsy: a randomized, double-blind, placebo-controlled trial. BOTOX Study Group. *J Pediatr Orthop* 2000; 20(1):108-115.