

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 indication.

FDA-approved Indications

Botox (onabotulinumtoxinA) is indicated for the treatment of:

- Overactive bladder
- Urinary incontinence due to detrusor overactivity
- Chronic migraine prophylaxis
- Upper and lower limb spasticity in patients 2 years of age and older
- Cervical dystonia
- Primary axillary hyperhidrosis
- Blepharospasm
- Strabismus

Approved Off-label Compendial Uses

- Excessive salivation
- Achalasia
- Hemifacial spasm
- Anal fissure
- Spasmodic dysphonia
- Oromandibular dystonia

Coverage Guidelines

The individual must meet the following criteria for select indications:

Overactive bladder

The individual must meet **BOTH** 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

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

- Condition is due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis, spina bifida); AND
- Had an inadequate response or intolerance to an anticholinergic medication; AND
- Does not have urinary tract infection or urinary retention.

Chronic migraine prophylaxis

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

- 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; AND
- For initial authorization, the individual is experiencing at least 15 headache days per month that last 4 hours a day or longer; OR
- For reauthorization, the individual must show therapeutic benefit with use defined as a 50% reduction in frequency of headache days per month.

Upper/lower limb spasticity

For reauthorization, the individual must show therapeutic benefit with 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; AND
- Condition is refractory to at least one topical agent.

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.¹

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 limb spasticity

Approve up to a maximum dose of 6 units per kilogram body weight (not to exceed 200 units), administered not more frequently than once every 12 weeks.

Pediatric lower limb spasticity

Approve up to a maximum dose of 8 units per kilogram body weight (not to exceed 300 units), 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 150 units, administered not more frequently than once every 3 months.

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® for injection [prescribing information]. Madison, NJ: Allergan; February 2021.
2. Bhidayasiri R, Truong DD. Expanding use of botulinum toxin. *J Neurol Sci*. 2005;235(1-2):1-9.
3. American Headache Society. The American Headache Society position statement on integrating new migraine treatments into clinical practice. *Headache*. 2019;59:1-18.
4. Vaezi MF, Pandolfino JF, Vela MF. ACG clinical guideline: diagnosis and management of achalasia. *Am J Gastroenterol*. 2013;108(8):1238-1249. Available at: <http://gi.org/guideline/diagnosis-and-management-of-achalasia/>. Accessed on May 27, 2020.
5. Wald A, Bharucha AE, Cosman BC, et al. ACG clinical guideline: management of benign anorectal disorders. *Am J Gastroenterol*. 2014;109(8):1141-57. Available at: <http://gi.org/guideline/management-of-benign-anorectal-disorders/>. Accessed on May 27, 2020.
6. Stachler RJ, Francis DO, Schwartz SR, et al. Clinical practice guideline: hoarseness (dysphonia). *Otolaryngology – Head and Neck Surgery*. 2018;Supplement:1-42. Available at: <https://journals.sagepub.com/doi/pdf/10.1177/0194599817751030>. Accessed on May 27, 2020.
7. Cheng CM, Chen JS, Patel RP. Unlabeled uses of botulinum toxins: A review, part 1. *Am J Health Syst Pharm*. 2006;63(2): 145–152.
8. Kao LY, Chao AN. Subtenon injection of botulinum toxin for treatment of traumatic sixth nerve palsy. *J Pediatr Ophthalmol Strabismus*. 2003;40(1):27-30.
9. Hung HL, Kao LY, Sun MH. Botulinum toxin treatment for acute traumatic complete sixth nerve palsy. *Eye*. 2005;19(3):337-341.
10. Lakraj AA, Moghimi N, Jabbari B. Sialorrhea: anatomy, pathophysiology and treatment with emphasis on the role of botulinum toxin. *Toxins*. 2013;5:1010-1031.
11. Simpson DM, Hallett M, Ashman EJ, 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;86:1818-1826. Available at: <http://www.neurology.org/content/86/19/1818.full>. Accessed on May 27, 2020.
12. OnabotulinumtoxinA (Botox®). Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Updated; May 16, 2021; Accessed June 2, 2021.
13. Vashishta R, Nguyen SA, White DR, Gillespie MB. Botulinum toxin for the treatment of sialorrhea: a meta-analysis. *Otolaryngol Head Neck Surg*. 2013;148(2):191-196.