

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

Approved Off-label Compendial uses

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

Coverage Guidelines

For all approved indications, the individual meets all of the following criteria for approval. Select indications, below have additional requirements.

- 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.
- Twelve years of age or older

Overactive Bladder

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

- Had an inadequate response or intolerance to an anticholinergic medications
- 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 over activity associated with a neurologic condition (such as a spinal cord injury or multiple sclerosis)
- Had an inadequate response or intolerance to an anticholinergic medication
- Does not have urinary tract infection or urinary retention

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)
- In order to gain reauthorization the member must show therapeutic benefit defined as a 50% reduction in frequency of headache days per month.

Upper/lower limb spasticity

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

- To decrease the severity of increased muscle tone in finger (flexor digitorum profundus and flexor digitorum sublimis), thumb (adductor pollicis and flexor pollicis longus), wrist (flexor carpi radialis and flexor carpi ulnaris), elbow (biceps brachii), ankle (gastrocnemius, soleus and tibialis posterior), and toe flexors (flexor hallucis longus and flexor hallucis brevis).
- In order to gain reauthorization must be on therapy over three months and have objective documentation of therapeutic benefit in the medical chart.

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

Anal Fissure

- Failure of 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-** 200 units every 12 weeks.
- **Overactive bladder-** 100 units every 12 weeks
- **Chronic migraine-** 155 units every 12 weeks
- **Upper/lower limb spasticity-** every 12 weeks

Muscle (upper limb)	Recommended dose (total dose [# of sites])
biceps brachii	100-200 units [4]
flexor carpi radialis, flexor carpi ulnaris	12.5-50 units [1]
flexor digitorum profundus, flexor digitorum sublimis	30-50 units [1]
adductor pollicis, flexor pollicis longus	20 units [1]
Muscle (lower limb)	
gastrocnemius medial head, gastrocnemius lateral head, soleus, tibialis posterior	75 units [3]
flexor hallucis longus and flexor digitorum longus	50 units [2]

- **Cervical dystonia-** 200-300 units every 12 weeks
- **Primary axillary hyperhidrosis-** 50-60 units intradermally per axilla every 12 weeks
- **Blepharospasm-** 1.25 to 2.5 units every 12 weeks
- **Strabismus-** 1.25 to 5 units IM injected into 1 muscle access efficacy 7-14 days and subsequent doses may be increased 2 fold to a maximum 25 units/muscle
- **Sialorrhea-** 10 to 100 units every 12 weeks
- **Hemifacial spasm-** 12 to 15 units injected in divided doses of 2.5 to 5 units into affected areas

- **Achalasia**- 80 to 100 units every 12 weeks
- **Chronic Anal Fissure**- 5 to 20 units every 4 weeks
- **Spasmodic dysphonia (Laryngeal dystonia)**- 1.25-5 units IM every 12 weeks
- **Oromandibular dystonia**- 25-50 units IM into each masseter muscle; if satisfactory results are not obtained, 5-40 units may also be injected into the temporalis muscle.

References

1. Botox® (onabotulinumtoxinA) [prescribing information]. Irvine, CA: Allergan, Inc.: May 2018. Accessed June 14, 2018.
2. OnabotulinumtoxinA (Botox®). In: DRUGDEX® System Micromedex. Greenwood Village, CO: Thompson Reuters (Healthcare) Inc. [Updated; May 22, 2018; Accessed June 14, 2018],
4. OnabotulinumtoxinA (Botox®). In: AHFS Drug Information Online Electronic Medical Library. Bethesda, MD: American Society of Health-System Pharmacists. [Updated February 27, 2018; Accessed July 16, 2018].
5. 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.