

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 with symptoms of urge urinary incontinence, urgency, and frequency
- Urinary Incontinence due to detrusor overactivity associated with a neurologic condition
- 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
- Chronic anal fissure
- Spasmodic dysphonia (Laryngeal dystonia)
- Oromandibular dystonia
- Essential tremor
- Dystonia, Focal Upper Limb
- Hyperhidrosis, Gustatory
- Hyperhidrosis, Primary Palmar, Plantar, and Facial

Coverage Guidelines

Overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency

The individual must meet the following criteria for approval:

- Is 18 years of age or older;
- Has tried at least one other pharmacologic therapy (e.g., beta-3 agonist, anticholinergic medication)

Urinary incontinence due to detrusor overactivity associated with a neurologic condition

The individual must meet the following criteria for approval:

- Is 5 years of age or older;
- Had tried at least one other pharmacologic therapy (e.g., beta-3 agonist, anticholinergic medication)

Chronic migraine prophylaxis

The individual must meet the following criteria for approval:

- Is 18 years of age or older;
- Botox is being used for prophylaxis of migraine headaches;
- Botox is prescribed by or after consultation with a neurologist or headache specialist;
- For initial authorization, the individual is experiencing at least 15 headache days per month that last 4 hours a day or longer;
- For reauthorization, the individual must show therapeutic benefit with use defined as a reduction in overall number of migraine days per month or a reduction in number of severe migraine days per month.

Upper/lower limb spasticity

- Is 2 years of age or older;
- For reauthorization, the individual must show therapeutic benefit with Botox use (e.g., reduction of muscle stiffness).

Primary axillary hyperhidrosis and Primary palmar/plantar/facial hyperhidrosis

The individual must meet the following criteria for approval:

- Is 18 years of age or older;
- Hyperhidrosis is significantly interfering with the ability to perform age-appropriate activities of daily living;
- Has been evaluated for potential causes of secondary hyperhidrosis to avoid symptomatic treatment of hyperhidrosis;
- Condition is refractory to at least one topical agent for at least 4 weeks.
Note: Examples of topical agents include Xerac AC (aluminum chloride 6.25% topical solution), Drysol (aluminum chloride 20% topical solution), Obrexza (glycopyrronium cloth 2.4% for topical use), Sofdra (glycopyrronium 12.45% topical gel).

Essential tremor

- Is 18 years of age or older;
- Has tried at least one other pharmacologic therapy for the treatment of tremors (e.g., primidone, atenolol, sotalol, propranolol, alprazolam, gabapentin, or topiramate).

The individual must be 18 years of age or older for approval of the following indications:

- Cervical dystonia (Spasmodic torticollis)
- Hemifacial spasm

- Excessive salivation
- Spasmodic dysphonia (Laryngeal dystonia)
- Oromandibular dystonia
- Dystonia, focal upper limb (e.g., focal hand dystonia)
- Gustatory hyperhidrosis
- Achalasia (Esophageal achalasia or Achalasia cardia)
- Chronic anal fissure

The individual must be 12 years of age or older for approval of the following indications:

- Blepharospasm (e.g., blepharospasm associated with dystonia, benign essential blepharospasm, seventh [VII] nerve disorders)
- Strabismus (e.g., esotropia, exotropia, hypertropia, hypotropia)

Approval duration:

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

Reauthorization: 12 months

Dosing Recommendations

Adult detrusor overactivity associated with a neurologic condition

The recommended dose is 200 units per treatment. The re-treatment should be administered no more frequently than every 12 weeks.

Pediatric detrusor overactivity associated with a neurologic condition

Patients weigh greater than or equal to 34 kg: the recommended dose is 200 units per treatment.

Patients weigh less than 34 kg: the recommended dose is 6 units/kg.

The re-treatment should be administered no more frequently than every 12 weeks.

Overactive bladder

The recommended total dose is 100 units. The re-treatment should be administered no more frequently than every 12 weeks.

Chronic migraine headache prophylaxis

The recommended dose is 155 units. The recommended re-treatment is no more frequently than every 12 weeks.

Adult upper/lower limb spasticity

The recommended total dose is 400 units divided among affected muscles.

The re-treatment should be administered no more frequently than every 12 weeks.

Pediatric upper limb spasticity

The recommended dose is 3 units/kg to 6 units/kg divided among affected muscles. The total dose per treatment should not exceed 6 units/kg or 200 units, whichever is lower.

The re-treatment should be administered no more frequently than every 12 weeks.

Pediatric lower limb spasticity

The recommended dose is 4 units/kg to 8 units/kg divided among affected muscles. The total dose per treatment session should not exceed 9 units/kg or 300 units, whichever is lower. The re-treatment should be administered no more frequently than every 12 weeks.

Cervical dystonia

The recommended dose is 198 units to 300 units, divided among affected muscles, administered no more frequently than every 3 months.

Dystonia, Focal Upper Limb

The recommended dose is a maximum of 400 units, administered no more frequently than every 3 months.

Primary axillary hyperhidrosis

The recommended dose is 50 units per axilla. The re-treatment should be administered no more frequently than every 3 months.

Hyperhidrosis, Palmar/Plantar/Facial and Gustatory

The recommended dose is a maximum dose of 400 units, administered no more frequently than every 3 months.

Blepharospasm

The recommended initial dose is 1.25 units-2.5 units. The cumulative dose of Botox in a 30-day period should not exceed 200 units. The retreatment should be administered no more frequently than every 3 months.

Strabismus

The recommended maximum dose is 25 units in any one muscle. The subsequent injections should not be administered until the effects of the previous dose have dissipated as evidenced by substantial function in the injected and adjacent muscles.

Excessive salivation

The recommended dose is 15 units to 125 units in each parotid gland. 100 units (50 units per side), administered no more frequently than every 16 weeks.

Hemifacial spasm

The recommended dose is 12 units to 15 units, divided among affected areas, up to a maximum dose of 25 units, administered no more frequently than every 3 months.

Achalasia

The recommended dose is 80 to 100 units in lower esophageal sphincter, administered no more frequently than every 3 months.

Chronic anal fissure

The recommended dose is 5 units to 15 units up to a maximum of 100 units, administered no more frequently than every 3 months.

Spasmodic dysphonia (Laryngeal dystonia)

The recommended dose 1.25 units to 5 units into affected muscles, up to a maximum dose of 400 units, administered no more frequently than every 3 months.

Oromandibular dystonia

The recommended dose is 10 units to 40 units per muscle, administered no more frequently than every 3 months.

Essential tremor

The recommended dose is 50 units to 100 units, administered no more frequently than every 3 months.

References

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