Botox® (onabotulinumtoxinA)

Medicare Advantage

Applicable States: Illinois, Wisconsin, Minnesota, New York, Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont

Applicable LCD/LCA: L33646, A52848

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:

- Blepharospasm
- Cervical dystonia
- Hyperhidrosis, severe primary axillary
- Migrine headache prophylaxis
- Neurogenic detrusor overactivity (NDO) in pediatric patients
- Overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency
- Urinary Incontinence due to detrusor overactivity associated with a neurologic condition
- Upper and lower limb spasticity in patients 2 years of age and older
- Strabismus

Approved Off-label Compendial Uses

- Achalasia
- Anal fissure, chronic
- Spasticity, other than limb (e.g. spasticity secondary to spastic hemiplegia, hemiparesis, hemifacial spasm)
- Spasmodic dysphonia (Laryngeal dystonia)
- Oromandibular dystonia
- Essential tremor
- Dystonia, Focal Upper Limb
- Hyperhidrosis, Gustatory
- Hyperhidrosis, Primary Palmar, Plantar, and Facial
- Sialorrhea

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).

Migraine headache prophylaxis
The individual must meet the following criteria for approval:
- Is 18 years of age or older;
- For initial authorization, the individual is experiencing at least 15 migraine headache days per month that last 4 hours per day or longer;
- For reauthorization, the individual has had significant clinical benefit (e.g., reduction in overall number of migraine days per month or a reduction in number of severe migraine days per month).

Headache prophylaxis in patients with chronic daily headache
The individual must meet the following criteria for approval:
- The individual is experiencing at least 15 headache days per month that last 4 hours per day or longer for a period of at least 3 months;
- Has significant disability due to the headaches;
- Has tried and been refractory to at least one standard and usual conventional therapy;
- For reauthorization, the individual has demonstrated a significant decrease in the number and frequency of headaches and an improvement in function.

Upper/lower limb spasticity
The individual must meet the following criteria for approval:
- Is 2 years of age or older.

Primary axillary 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;
- Secondary causes of hyperhidrosis have been excluded;
- Has tried at least one topical prescription agent for axillary hyperhidrosis for at least 4 weeks and experienced inadequate efficacy or significant intolerance.

Note: Examples of topical agents include Xerac AC (aluminum chloride 6.25% topical solution), Drysol (aluminum chloride 20% topical solution), Qbrexza (glycopyrronium cloth 2.4% for topical use), Sofdra (glycopyrronium 12.45% topical gel).

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;
- Secondary causes of hyperhidrosis have been excluded;
- Has tried at least one topical agent for the treatment of hyperhidrosis for at least 4 weeks and experienced inadequate efficacy or significant intolerance.
  Note: Examples of topical agents include aluminum chloride antiperspirants.

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)
- Laryngeal dystonia (Spasmodic dysphonia)
- Oromandibular dystonia (Orofacial dystonia)
- Gustatory hyperhidrosis

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)

Approve the following indications:
- Dystonia, focal upper limb (e.g., focal hand dystonia)
- Achalasia (Esophageal achalasia or Achalasia cardia)
- Chronic anal fissure
- Sialorrhea
- Spasticity other than the limb (e.g. spasticity secondary to spastic hemiplegia, hemiparesis, hemifacial spasm)

Approval duration:
Initial and reauthorization: 12 months

Dosing Recommendations

Adult detrusor overactivity associated with a neurologic condition

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

Pediatric neurogenic overactivity (NDO)
The recommended dose is a maximum of 200 units. The re-treatment should be administered no more frequently than every 12 weeks.

Overactive bladder
The recommended total dose is 100 units up to a maximum of 200 units. The re-treatment should be administered no more frequently than every 12 weeks.

Chronic migraine and headache prophylaxis
The recommended dose is 155 units. The re-treatment should be administered 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 maximum dose per treatment is 8 units/kg (not to exceed 300 units). The re-treatment should be administered no more frequently than every 12 weeks.

When treating both lower limbs or the upper and lower limbs in combination, the total dose should not exceed the lower of 10 units/kg body weight or 340 units, in a 3-month interval.

Cervical dystonia
The recommended dose is 198 units to 300 units, divided among affected muscles. The re-treatment should be administered no more frequently than every 3 months.

Dystonia, Focal Upper Limb
The recommended dose in adults up to a maximum of 400 units. The recommended dose in pediatrics is 10 units/kg (not to exceed 340 units). The re-treatment should be 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. The re-treatment should be no more frequently than every 3 months.

Blepharospasm
The recommended maximum dose is 200 units. The re-treatment should be administered no more frequently than every 3 months.

Strabismus
The recommended maximum dose is 25 units in any one muscle. The re-treatment should be administered no more frequently than every 3 months.

Sialorrhea
The maximum recommended dose for adults is 100 units (50 units per side) and for pediatric patients is 75 units (37.5 units per side). The re-treatment should be administered no more frequently than every 3 months.

Hemifacial spasm
The recommended dose is 12 units to 15 units, divided among affected areas, up to a maximum dose of 25 units. The re-treatment should be administered no more frequently than every 3 months.

Spasticity, other than limb (e.g., spasticity secondary to spastic hemiplegia, hemiparesis, hemifacial spasm)
The recommended dose in adults is a maximum of 400 units and pediatrics is a max of 10 units/kg (not to exceed 340 units). The re-treatment should be administered no more frequently than every 3 months.

Achalasia
The recommended dose is 80 to 100 units in lower esophageal sphincter. The re-treatment should be administered no more frequently than every 3 months.

Anal fissure
The recommended dose is 5 units to 100 units. The re-treatment should be administered no more frequently than every 3 months.

Laryngeal dystonia (Spasmodic dysphonia)
The recommended dose is up to a maximum dose of 400 units. The re-treatment should be administered no more frequently than every 3 months.

Oromandibular dystonia
The recommended dose is 10 units to 40 units per muscle or a maximum of 400 units. The re-treatment should be administered no more frequently than every 3 months.

Essential tremor

The recommended dose is up to 400 units. The re-treatment should be administered no more frequently than every 3 months.

References

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