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

Overactive bladder
The individual must meet the following criteria for approval:

- Had an inadequate response or intolerance to an anticholinergic medication;
- Does not have a urinary tract infection;
- Does not have urinary retention with the exception of individuals who are routinely performing clean intermittent self-catheterization.

Urinary incontinence
The individual must meet the following criteria for approval:

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

- Does not have urinary retention with the exception of individuals who are routinely performing clean intermittent self-catheterization.

Chronic migraine prophylaxis
The individual must meet the following criteria for approval:
- Botox is being used for prophylaxis of migraine headaches;
- Had an inadequate response to at least 2 agents used for the prevention of chronic migraine (e.g., antidepressants, beta-blockers, anticonvulsant, or triptans);
- 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 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 the following criteria for approval:
- Has been evaluated for potential causes of secondary hyperhidrosis to avoid symptomatic treatment of hyperhidrosis;
- 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

Adult detrusor overactivity associated with a neurologic condition
The recommened total dose is 200 units, administered not more frequently than once every 12 weeks.

Pediatric detrusor overactivity associated with a neurologic condition
Patients weigh greater than or equal to 34 kg: the recommended total dose is 200 units, administered not more frequently than once every 12 weeks.

Patients weigh less than 34 kg: the recommended total dose is 6 units/kg, administered not more frequently than once every 12 weeks.

Overactive bladder
The recommended total dose is 100 units, administered not more frequently than once every 12 weeks.

Chronic migraine headache prophylaxis
The recommended total dose is 155 units, administered not more frequently than once every 12 weeks.

Adult upper/lower limb spasticity
The recommended total dose is up to 400 units divided among affected muscles, administered not more frequently than once every 12 weeks.

Pediatric upper limb spasticity
The recommended total dose is 3 units/kg to 6 units/kg (maximum 200 units) divided among affected muscles, administered not more frequently than once every 12 weeks.

Pediatric lower limb spasticity
The recommended total dose is 4 units/kg to 8 units/kg (maximum 300 units) divided among affected muscles, administered not more frequently than once every 12 weeks.

Cervical dystonia
The recommended dose is 198 units to 300 units, divided among affected muscles, administered not more frequently than once every 3 months.

Primary axillary hyperhidrosis
The recommended dose is 50 units per axilla, administered not more frequently than once every 3 months.

Blepharospasm
The recommended dose is 1.25 units-2.5 units into each of 3 sites per affected eye, administered not more frequently than once every 3 months.

Strabismus
The recommended maximum dose is 25 units in any one muscle, administered not more frequently than once every 3 months.

Excessive salivation
The recommended maximum dose is 100 units (50 units per side), administered not more frequently than once 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 not more frequently than once every 3 months.

Achalasia
The recommended maximum dose is 100 units into the lower esophageal sphincter, administered not more frequently than once every 3 months.

Chronic anal fissure
The recommended maximum dose is 150 units, administered not more frequently than once 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 25 units, administered not more frequently than once every 3 months.

Oromandibular dystonia
The recommended maximum dose is 400 units, administered not more frequently than once every 3 months.

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