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

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**Dosing Recommendations**

**Adult detrusor overactivity associated with a neurologic condition**
The recommended 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.

References