**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

The individual must meet the following criteria for select indications:

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

- Had an inadequate response or intolerance to an anticholinergic medication; **AND**
- 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 overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis, spina bifida); **AND**
- Had an inadequate response or intolerance to an anticholinergic medication; **AND**
- Does not have urinary tract infection or urinary retention.
**Chronic migraine prophylaxis**
The individual must meet all of the following criteria for initial approval:
- Had an inadequate response to at least 2 agents used for the prevention of chronic migraine (e.g., antidepressants, beta-blockers, anticonvulsant, or triptans); AND
- Botox is being used for prophylaxis of migraine headaches; AND
- For initial authorization, the individual is experiencing at least 15 headache days per month that last 4 hours a day or longer; OR
- 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 all of the following criteria for approval:
- Has been evaluated for potential causes of secondary hyperhidrosis to avoid symptomatic treatment of hyperhidrosis; AND
- 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**

**Urinary incontinence due to detrusor overactivity**
Approve up to a maximum dose of 200 units, administered not more frequently than once every 12 weeks.

**Overactive bladder**
Approve up to a maximum dose of 100 units, administered not more frequently than once every 12 weeks.

**Chronic migraine headache prophylaxis**
Approve up to a maximum dose of 155 units, administered not more frequently than once every 12 weeks.
**Adult upper/lower limb spasticity**
Approve up to a maximum dose of 400 units divided among selected muscles, administered not more frequently than once every 12 weeks. Administer no more than 50 units per site.

**Pediatric upper limb spasticity**
Approve up to a maximum dose of 6 units per kilogram body weight (not to exceed 200 units), administered not more frequently than once every 12 weeks.

**Pediatric lower limb spasticity**
Approve up to a maximum dose of 8 units per kilogram body weight (not to exceed 300 units), administered not more frequently than once every 12 weeks.

**Cervical dystonia**
Approve up to a maximum dose of 300 units, divided among affected muscles, administered not more frequently than once every 3 months.

**Primary axillary hyperhidrosis**
Approve up to a maximum dose of 50 units per axilla, administered not more frequently than once every 3 months.

**Blepharospasm**
Approve up to a maximum dose of 200 units, administered not more frequently than once every 3 months. Maximum dose of 5 units per site.

**Strabismus**
Approve up to a maximum dose of 25 units in any one muscle, administered not more frequently than once every 3 months.

**Excessive salivation**
Approve up to a maximum dose of 100 units (50 units per side), administered not more frequently than once every 16 weeks.

**Hemifacial spasm**
Approve up to a maximum dose of 25 units divided among affected areas, administered not more frequently than once every 3 months.

**Achalasia**
Approve up to a maximum dose of 100 units into the lower esophageal sphincter, administered not more frequently than once every 3 months.

**Chronic anal fissure**
Approve up to a maximum dose of 150 units, administered not more frequently than once every 3 months.
Spasmodic dysphonia (Laryngeal dystonia)
Approve up to a maximum dose of 25 units, administered not more frequently than once every 3 months.

Oromandibular dystonia
Approve up to a maximum dose of 400 units, administered not more frequently than once every 3 months.

References