

## SPECIALTY GUIDELINE MANAGEMENT

### BOTOX (onabotulinumtoxinA)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### A. FDA-Approved Indications

1. Overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication
2. Urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication
3. Prophylaxis of headaches in adult patients with chronic migraine ( $\geq 15$  days per month with headache lasting 4 hours a day or longer)
4. Treatment of upper limb spasticity in adult patients
5. Treatment of lower limb spasticity in adult patients
6. Cervical dystonia in adults, to reduce the severity of abnormal head position and neck pain associated with cervical dystonia
7. Severe primary axillary hyperhidrosis that is inadequately managed with topical agents
8. Strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above

##### B. Compendial Uses

1. Achalasia
2. Chronic anal fissures
3. Essential tremor
4. Excessive salivation secondary to advanced Parkinson's disease
5. Hemifacial spasm
6. Spasmodic dysphonia (laryngeal dystonia)

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. EXCLUSIONS

Coverage will not be provided for cosmetic use.

##### III. CRITERIA FOR INITIAL APPROVAL

##### A. **Blepharospasm**

Authorization of 12 months may be granted for treatment of blepharospasm.

##### B. **Cervical dystonia**

Authorization of 12 months may be granted for treatment of cervical dystonia (e.g., torticollis)

**C. Chronic migraine prophylaxis**

Authorization of 6 months (two injection cycles) may be granted for treatment of chronic migraine prophylaxis when all of the following criteria are met:

1. Member experiences headaches  $\geq$  15 days per month
2. Member completed adequate trial ( $\geq$  8 weeks) of at least one of the following oral migraine preventative therapies:
  - a. Divalproex sodium (Depakote, Depakote ER)
  - b. Topiramate (Topamax)
  - c. Gabapentin (Neurontin)
  - d. Amitriptyline (Elavil)
  - e. Venlafaxine (Effexor)
  - f. Atenolol/Metoprolol/Propranolol/Timolol/Nadolol
  - g. Nimodipine/Verapamil
  - h. Naproxen/other NSAID
  - i. Other oral migraine prophylactic therapy considered to be appropriate by the requesting clinician

**D. Overactive bladder with urinary incontinence**

Authorization of 12 months may be granted for treatment of overactive bladder with urinary incontinence when either of the following criteria is met:

1. The member has had an inadequate response to an anticholinergic medication
2. The member has experienced intolerance to an anticholinergic medication

**E. Primary axillary hyperhidrosis**

Authorization of 12 months may be granted for treatment of primary axillary hyperhidrosis.

**F. Strabismus**

Authorization of 12 months may be granted for treatment of strabismus.

**G. Upper limb spasticity**

Authorization of 12 months may be granted for treatment of upper limb spasticity.

**H. Lower limb spasticity**

Authorization of 12 months may be granted for treatment of lower limb spasticity.

**I. Urinary incontinence associated with a neurologic condition (eg, spinal cord injury, multiple sclerosis)**

Authorization of 12 months may be granted for treatment of urinary incontinence associated with a neurologic condition (eg, spinal cord injury, multiple sclerosis) when either of the following criteria is met:

1. The member has had an inadequate response to an anticholinergic medication
2. The member has experienced intolerance to an anticholinergic medication

**J. Achalasia**

Authorization of 12 months may be granted for treatment of achalasia.

**K. Chronic anal fissures**

Authorization of 12 months may be granted for treatment of chronic anal fissures.

**L. Essential tremor**

Authorization of 12 months may be granted for treatment of essential tremor.

**M. Excessive salivation due to advanced Parkinson's disease**

Authorization of 12 months may be granted for treatment of excessive salivation due to advanced Parkinson's disease.

**N. Hemifacial spasm**

Authorization of 12 months may be granted for treatment of hemifacial spasm.

**O. Spasmodic dysphonia (laryngeal dystonia)**

Authorization of 12 months may be granted for treatment of spasmodic dysphonia (laryngeal dystonia).

**IV. CONTINUATION OF THERAPY**

- A. All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria for all approvable conditions other than chronic migraine prophylaxis.
- B. Authorization of 12 months may be granted for treatment of chronic migraine prophylaxis when the member has achieved or maintained a 50% reduction in monthly headache frequency since starting therapy with Botox.

**V. APPENDIX**

**Preventative Therapies for Migraine**

- A. Antiepileptic drugs
  - Divalproex sodium
  - Topiramate
  - Gabapentin
- B. Antidepressants
  - Amitriptyline
  - Venlafaxine
- C. Beta-blockers
  - Atenolol
  - Metoprolol
  - Propranolol
  - Nadolol
  - Timolol
- D. Calcium channel blockers
  - Nimodipine
  - Verapamil
- E. Nonsteroidal anti-inflammatory drugs
  - Naproxen

**VI. REFERENCES**

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