

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 (≥ 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 an oral migraine preventative therapy such as:
 - 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

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. REFERENCES

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5. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults. Report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology*. 2012;78(17):1337-45.
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8. Pringsheim T, Davenport W, Mackie G, et al. Canadian Headache Society guideline for migraine prophylaxis. *Can J Neurol Sci*. 2012;39(2 Suppl 2):S1-59.
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10. Zesiewicz TA, Elble RJ, Louis ED et al. Evidence-based guideline update: Treatment of essential tremor: Report of the Quality Standards Subcommittee of the American Academy of Neurology: *Neurology* 2011; 77: 1752-1755.