Effective Date: 12/2009
Revised: 9/2013, 5/2016, 8/2016, 12/2019 Last Reviewed: 12/2019 Scope: Medicaid

BOTOX (onabotulinumtoxinA)

POLICY

I. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review (both initial requests and continuation of therapy requests):

A. Where drug will be obtained - through pharmacy benefit (filled at specialty pharmacy) or through medical benefit ('buy and bill')
B. CPT codes associated with Botox administration
C. Servicing provider name and NPI for Botox administration

II. CRITERIA FOR INITIAL APPROVAL

A. Blepharospasms

Authorization of 3 months may be granted for treatment of blepharospasms in patients who are 12 years of age or older.

B. Cervical Dystonia

Authorization of 3 months may be granted for treatment of cervical dystonia in patients who are 16 years of age or older when both of the following criteria are met:

1. Patient has a history of recurrent involuntary contraction of one or more muscles in the neck
2. Patient has sustained head tilt or has abnormal posturing with limited range of motion in the neck

C. Strabismus

Authorization of 3 months may be granted for treatment of strabismus in patients who are 12 years of age or older.

D. Upper and Lower Limb Spasticity

Authorization of 3 months may be granted for treatment of upper and/or lower limb spasticity when all the following criteria are met:

1. Limb spasticity is due to either of the following:
    a. Brain injury, MS, or spinal cord injury
    b. Cerebral palsy in patients 2 years of age and older
2. Patient's baseline score for tone and/or resistance of affected areas from a validated measuring tool (e.g., Ashworth Scale, Physician Global Assessment, Clinical Global Impression [CGI]) is assessed.

E. Chronic Migraine

Authorization of 6 months may be granted for treatment of chronic migraine in patients who are 18 years of age or older when all the following criteria are met:

1. Patient must have diagnosis of migraine headaches. **NOTE: All non-migraine related headaches (e.g., tension headache, cluster headache, etc.) are excluded from coverage.*
2. Botox is prescribed by, or in consultation with, a neurologist or headache specialist
3. Patient has been experiencing at least 15 migraine headaches per month with a duration of at least 4 hours a day or longer
4. Patient has had an inadequate response to a trial of at least one prophylactic migraine medication from each of the following three classes of drugs (a)-(c) for a total of 3 required trials, with each trial at least 60 days in duration, within the past 3 years:
    a. Antiepileptic agents (e.g., divalproex sodium, valproate, topiramate)
    b. Beta-blockers (e.g., metoprolol, propranolol, atenolol, nadolol)
    c. Antidepressants (e.g., amitriptyline, venlafaxine)

F. Severe Primary Axillary Hyperhidrosis

Authorization of 6 months may be granted for treatment of severe primary axillary hyperhidrosis when all of the following criteria are met:

1. Patient has had an inadequate response to topical agents
2. Patient meets either of the following criteria:
    a. Patient has a history of medical complications such as skin infections or significant functional impairments
    b. Hyperhidrosis has significantly impacted the patient's activities of daily living

G. Incontinence due to Detrusor Overactivity

Authorization of 3 months may be granted for treatment of incontinence due to detrusor overactivity when the patient has had an inadequate response to a 1 month or longer trial of two medications from either the antimuscarinic class (e.g., darifenacin, oxybutynin, solifenacin, tolterodine, trospium) or beta 3-adrenoceptor agonist class (i.e., mirabegron).

H. Overactive Bladder (OAB)

Authorization of 3 months may be granted for treatment of overactive bladder when both of the following criteria are met:

1. Patient has bothersome urinary symptoms, consisting of urgency, frequency, nocturia and/or urgency incontinence
2. Patient has had an inadequate response to a 1 month or longer trial of two medications from either the antimuscarinic class (e.g., darifenacin, oxybutynin, solifenacin, tolterodine, trospium) or beta 3-adrenoceptor agonist class (i.e., mirabegron).

III. CONTINUATION OF THERAPY

A. Blepharospasms

Authorization of 12 months may be granted for treatment of blepharospasms in patients who meet all initial authorization criteria, are tolerating treatment, and have experienced positive clinical response with Botox therapy as evidenced by improvement in severity and/or frequency of eyelid spasms.

B. Cervical Dystonia

Authorization of 12 months may be granted for treatment of cervical dystonia in patients who meet all initial authorization criteria, are tolerating treatment, and have experienced positive clinical response with Botox therapy as evidenced by both of the following:

1. Improvement in severity and frequency of pain
2. Improvement of abnormal head positioning

C. Strabismus

Authorization of 12 months may be granted for treatment of strabismus in patients who meet all initial authorization criteria, are tolerating treatment, and have experienced positive clinical response with Botox therapy as evidenced by an improvement in alignment of prism diopters compared to pre-treatment baseline.

D. Upper and Lower Limb Spasticity

Authorization of 12 months may be granted for treatment of upper and/or lower limb spasticity who meet all initial authorization criteria, are tolerating treatment, and have experienced positive clinical response with Botox therapy as evidenced by a decrease in tone and/or resistance of affected areas based on a validated measuring tool (e.g., Ashworth Scale, Physician Global Assessment, Clinical Global Impression [CGI]).

E. Chronic Migraine

Authorization of 12 months may be granted for treatment of chronic migraine in patients who meet all initial authorization criteria, are tolerating treatment, continue to utilize prophylactic intervention modalities (i.e., pharmacotherapy, behavioral therapy, physical therapy, etc.), and have experienced positive clinical response with Botox therapy as evidenced by both of the following:

1. Significant decrease in the number, frequency, and/or intensity of headaches
2. Improvement in function

F. Severe Primary Axillary Hyperhidrosis

Authorization of 12 months may be granted for treatment of severe primary axillary hyperhidrosis in patients who meet all initial authorization criteria, are tolerating treatment, and have experienced positive clinical response with Botox therapy as evidenced by both of the following:

1. Significant reduction in spontaneous axillary sweat production
2. Significant improvement in activities of daily living

G. Incontinence due to Detrusor Overactivity

Authorization of 12 months may be granted for treatment of incontinence due to detrusor overactivity in patients who meet all initial authorization criteria, are tolerating treatment, the post-void residual (PVR) is periodically assessed as medically appropriate, and have experienced positive clinical response with Botox therapy as evidenced by significant reduction in weekly frequency of urinary incontinence episodes.

H. Overactive Bladder (OAB)

Authorization of 12 months may be granted for treatment of overactive bladder in patients who meet all initial authorization criteria, are tolerating treatment, the post-void residual (PVR) is

periodically assessed as medically appropriate, and have experienced positive clinical response with Botox therapy as evidenced by reduction in weekly frequency of urinary incontinence episodes, urgency episodes, urge incontinence episodes and/or micturition frequency episodes.

IV. QUANTITY LIMIT

Botox has a quantity limit of 1 fill every 90 days.