Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

Botox (onabotulinumtoxinA)

GPI CODING:

74400020******

DESCRIPTION:

Botox® (onabotulinumtoxinA) is indicated for the treatment of cervical dystonia, severe primary axillary hyperhidrosis that is inadequately managed with topical agents, strabismus, blepharospasm associated with dystonia, upper limb spasticity, and prophylaxis of headaches in adults with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer).

APPROVAL DURATION:

Chronic Migraine
Initial approval: 6 months

All other indications
Approval duration: lifetime

CRITERIA FOR BOTOX

I. The use of botulinum toxin may be approved for treatment of:

A. Strabismus
B. Achalasia
C. Chronic anal fissures

II. The use of botulinum toxin may be approved for the treatment of the following disorders if associated with spasticity or dystonia:

A. Blepharospasm
B. Upper limb spasticity
C. Equinus foot, if related to cerebral palsy
D. Hereditary spastic paraplegia
E. Infantile cerebral palsy
F. Multiple sclerosis
G. Neuromyelitis optica
H. Schilder's disease
I. Spastic hemiplegia
J. Spasticity related to stroke or spinal cord injury
K. Idiopathic torsion dystonia
L. Organic writer's cramp
M. Orofacial dyskinesia (ie, jaw closure dystonia)
N. Spasmodic dysphonia or laryngeal dystonia (a disorder of speech due to abnormal control of the laryngeal muscles present only during the specific task of speaking)
O. Symptomatic torsion dystonia
P. Facial nerve (VII) dystonia

Q. Other forms of upper motor neuron spasticity

III. The use of botulinum toxin may be approved for the treatment of sialorrhea (drooling) associated with Parkinson's disease.

IV. The use of botulinum toxin is considered medically necessary in the initial treatment of cervical dystonia (spasmodic torticollis) of moderate or greater severity when all of the following criteria are met:

A. History of recurrent clonic and/or tonic involuntary contractions of one or more of the following muscles: sternocleidomastoid, splenius, trapezius and/or posterior cervical muscles; **AND**
B. Sustained head tilt and/or abnormal posturing with limited range of motion in the neck; **AND**
C. The duration of the condition is greater than 6 months.
D. Subsequent injections of botulinum toxin for the treatment of cervical dystonia (spasmodic torticollis) of moderate or greater severity are considered medically necessary when:
    i. There is a response to the initial treatment documented in the medical records; **AND**
    ii. The patient still meets the medically necessary criteria above.

V. The use of botulinum toxin is considered medically necessary as a treatment of incontinence related detrusor overreactivity and incontinence of neurogenic origin (ie, spinal cord injury, multiple sclerosis) that is inadequately controlled with anticholinergic therapy.

VI. The use of botulinum toxin is considered medically necessary for bladder detrusor sphincter dyssynergia of neurogenic origin.

VII. Treatment of hyperhidrosis with botulinum toxin may be approved for patients who meet the following criteria:

A. Diagnosis is incapacitating primary focal hyperhidrosis, defined as:
    i. Hyperhidrosis significantly interferes with the patient's ability to perform age-appropriate activities of daily living (ie, sweat soaks clothing to the extent that it is necessary to change clothes and/or shower more than once during the course of a normal day; sweat on the hands smudges written documents or interferes with the ability to grip items such as pens/pencils, eating utensils, hand tools) **OR**
    ii. The condition is causing persistent or chronic cutaneous conditions such as skin maceration, dermatitis, fungal infections, and secondary microbial conditions; **AND**
B. Patient has failed a 6 month trial of one or more nonsurgical treatments, as indicated below:
    i. Aluminum chloride
    ii. Gannic acid
    iii. Glutaraldehyde
    iv. Topical or systemic anticholinergics
    v. Tranquilizers
    vi. Non-steroidal anti-inflammatory drugs

VIII.The use of botulinum toxin may be approved for prophylaxis of chronic migraine headaches for patients who meet the following criteria:

A. Patient must have documented* chronic migraine characterized by the following:
    i. Headache on ≥15 days per month **AND**
    ii. Headache lasts ≥4 hours a day **AND**
    iii. Headaches for ≥3 months **AND**
B. Patient has been evaluated for medication overuse headache and treated as appropriate **AND**

C. Patient has completed adequate trials (≥8 weeks each) of at least 2 oral preventative agents from different pharmacological classes: antiepileptic drugs, antidepressants, beta blockers, calcium channel blockers, or angiotensin converting enzyme inhibitors/angiotensin receptor blockers **OR**
D. Patient has documented contraindications to all pharmacological classes not tried **OR**
E. Patient has not completed adequate trials of all pharmacological classes for other documented clinical reasons such as an adverse event, allergic reaction, intolerance, or significant drug interaction **AND**
F. For continuation of botulinum toxin therapy, the patient's documented* headache frequency must have decreased by at least 7 days per month or the headache duration must have decreased by at least 100 hours per month relative to pre-treatment.

**** Physicians requesting initial therapy or renewals are required to provide information from the headache diary or other evidence of the patient's headache frequency and duration.***

IX. Botulinum toxin may NOT be approved for the treatment of any other conditions including, but not limited to, the following:

A. Headache, except as noted for prophylaxis of chronic migraine
B. Anismus
C. Chronic motortic disorder
D. Fibromyalgia/fibromyositis
E. Gastroparesis
F. Low back pain/joint pain
G. Myofascial pain syndrome
H. Neck pain not related to conditions mentioned above
I. Parkinson's disease
J. Tics associated with Tourette's Syndrome
K. Tremors
L. Urinary and anal sphincter dysfunction
M. Stuttering
N. Carpal tunnel syndrome
O. Tinnitus