Market Applicability/Effective Date

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**Botulinum Toxin**  
DRUG.00006

**Override(s)**  
Approval Duration

Prior Authorization  
Migraine indication: **Initial** 6 month approval, then ongoing treatment 1 year

All other indications: 1 year

**Medications**  
Quantity Limit

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<tbody>
<tr>
<td>Botox (onabotulinumtoxinA)</td>
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<tr>
<td>Dysport (abobotulinumtoxinA)</td>
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<tr>
<td>Myobloc (rimabotulinumtoxinB)</td>
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<tr>
<td>Xeomin (incobotulinumtoxinA)</td>
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**APPROVAL CRITERIA**

I. The use of botulinum toxin may be approved for treatment of:
   A. Strabismus
   B. Achalasia
   C. 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. Cerebral palsy
   C. Facial nerve (VII) dystonia
   D. Hereditary spastic paraparesis
   E. Hemifacial Spasm
   F. Idiopathic torsion dystonia
   G. Multiple sclerosis
   H. Neuromyelitis optica
   I. Organic writer’s cramp
   J. Orofacial dyskinesia (that is, jaw closure dystonia)
   K. Schilder’s disease

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

WEB-PEC-0435-16
L. 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)

M. Spastic hemiplegia

N. Spasticity related to stroke, spinal cord injury, or traumatic brain injury

O. Symptomatic torsion dystonia

P. Other forms of upper motor neuron spasticity

III. The use of botulinum toxin may be approved for the treatment of significant drooling in individuals who are unable to tolerate scopolamine

IV. The use of botulinum toxin may be approved 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

Subsequent injections of botulinum toxin for the treatment of cervical dystonia (spasmodic torticollis) of moderate or greater severity may be approved when:

A. There is a response to the initial treatment documented in the medical records; **AND**

B. The individual still meets the medical criteria above

V. The use of botulinum toxin may be approved as a treatment of neurogenic overactive bladder (also referred to as detrusor overactivity or detrusor sphincter dyssynergia) that is inadequately controlled with anticholinergic therapy

VI. The use of botulinum toxin may be approved as a treatment of idiopathic overactive bladder in adults who are unresponsive to or intolerant of a trial of anticholinergic therapy.

VII. The use of botulinum toxin may be approved for the treatment of functional obstruction caused by the inability of the internal anal sphincter to relax in individuals with Hirschsprung disease who have undergone prior surgical treatment.

VIII. Botulinum toxin **may be approved** in the treatment of primary hyperhidrosis only for those individuals who have failed a 6 month trial of any one or more types of
nonsurgical treatment (i.e., topical dermatologics such as aluminum chloride, tannic acid, glutaraldehyde, anticholinergics; systemic anticholinergics, tranquilizers or non-steroid anti-inflammatory drugs) and meet any ONE of the following criteria:
A. Presence of medical complications or skin maceration with secondary infection; OR
B. Significant functional impairment, as documented in the medical record.

IX. Botulinum toxin is **may be approved** in the treatment of secondary hyperhidrosis when the condition is related to surgical complications and BOTH of the following criteria are met:
   A. Presence of medical complications or skin maceration with secondary infection; **AND**
   B. Significant functional impairment, as documented in the medical record.

X. An initial 6-month trial of botulinum toxin for prevention of chronic migraine headaches may be approved when all of the following are met:
   A. Adult individual diagnosed with chronic migraine; **AND**
   B. Fifteen (15) or more headache-days per month with headache lasting four (4) hours per day or longer; **AND**
   C. First episode at least six (6) months ago; **AND**
   D. Symptoms persist despite trials of at least 1 agent in any 2 of the following classes of medications used to prevent migraines or reduce migraine frequency:
      i. Antidepressants (for example, amitriptyline, nortriptyline, doxepin)
      ii. Antihypertensives (for example, propranolol, timolol)
      iii. Antiepileptics (for example, valproate, topiramate, gabapentin)

XI. Continuing treatment with botulinum toxin injection for ongoing prevention of chronic migraine headaches may be approved for individuals who have previously met criteria above and completed an initial 6-month trial when:
   A. Migraine headache frequency was reduced by at least 7 days per month (when compared to pre-treatment average) by the end of the initial trial; **OR**
   B. Migraine headache duration was reduced by at least 100 total hours per month (when compared to the pre-treatment average) by the end of the initial trial

XII. Botulinum toxin is considered **cosmetic** as a treatment of skin wrinkles or other cosmetic indications and is **NOT** approvable.

XIII. Botulinum toxin is considered investigational and **may not be approved** for the treatment of any other conditions including, but not limited to, the following:

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A. For the treatment of headache other than chronic migraine meeting the criteria above, including but not limited to tension, episodic, migraine (14 days per month or less), or chronic daily headaches.

B. For the treatment of individuals with Hirschsprung disease when the above criteria are not met.

C. The use of botulinum toxin, whether the same or a different product, following failure of an initial trial for the treatment of an approvable condition (as listed above) is considered investigational and may not be approved. Note: when the initial product was stopped due to a product specific intolerance or allergic reaction (rather than clinical failure), this investigational and non-approvable statement does not apply.

D. Anismus (pelvic floor dysynergia)

E. Behcet’s syndrome

F. Benign Prostatic Hypertrophy

G. Brachial Plexus Palsy

H. Carpal tunnel syndrome

I. Chronic motor tic disorder

J. Disorders of the esophagus (except as listed above)

K. Epicondylitis

L. Fibromyalgia/fibromyositis

M. Gastroparesis

N. Low back pain

O. Myofascial pain syndrome

P. Neck pain not related to conditions mentioned above

Q. Nystagmus

R. Parkinson’s disease

S. Post-mastectomy reconstruction syndrome

T. Reynaud's syndrome

U. Sphincter of Oddi dysfunction

V. Stuttering

W. Tics associated with Tourette’s Syndrome

X. Tinnitus

Y. Tourette’s Syndrome

Z. Tremors

AA. Urinary and anal sphincter dysfunction (except as listed above)

BB. Vaginismus

CC. Whiplash related disorders

DD. Zygomatic Fractures
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### State Specific Mandates

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**Separated from commercial line of business due to the commercial adding a step therapy**

**Key References:**


DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2015; Updated periodically.