| Market Applicability | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | X |

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# Botulinum Toxin

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization | Migraine indication: **Initial** 6 month approval, then ongoing treatment 1 year<br><br>All other indications: 1 year |

******Washington Medicaid – See State Specific Mandate below for diagnoses of migraine headache and tension-type headache***

| Medications |
|---|
| Botox (onabotulinumtoxinA) |
| Dysport (abobotulinumtoxinA) |
| Myobloc (rimabotulinumtoxinB) |
| Xeomin (incobotulinumtoxinA) |

## APPROVAL CRITERIA

Requests for botulinum toxin may be approved if the following criteria are met:

I. Individual has one of the following diagnoses:
   A. Disorders listed below if associated with spasticity or dystonia:
      1. Blepharospasm; **OR**
      2. Cerebral palsy; **OR**
      3. Facial nerve (VII) dystonia; **OR**
      4. Hemifacial Spasm; **OR**
      5. Hereditary spastic paraparesis; **OR**
      6. Idiopathic torsion dystonia; **OR**
      7. Lower limb spasticity; **OR**
      8. Multiple sclerosis; **OR**
      9. Neuromyelitis optica; **OR**
      10. Organic writer's cramp; **OR**
      11. Orofacial/oromandibulardystonias, including jaw closure dystonia and Meige's syndrome; **OR**
      12. Schilder's disease; **OR**
      13. Spasmodic dysphonia or laryngeal dystonia (a disorder of speech due to

| Market Applicability | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | X |

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abnormal control of the laryngeal muscles present only during the specific task of speaking); **OR**

14. Spastic hemiplegia; **OR**
15. Spasticity related to stroke, spinal cord injury, or traumatic brain injury; **OR**
16. Dystonia-associated strabismus; **OR**
17. Symptomatic torsion dystonia; **OR**
18. Other forms of upper motor neuron spasticity; **OR**
19. Upper limb spasticity; **OR**

B. Achalasia; **OR**
C. Anal fissures; **OR**
D. Significant drooling in individuals who are unable to tolerate scopolamine; **OR**
E. Idiopathic overactive bladder in adults who are unresponsive to or intolerant of a trial of anticholinergic therapy; **OR**
F. Neurogenic overactive bladder (also referred to as detrusor overactivity or detrusor sphincter dyssynergia) that is inadequately controlled with anticholinergic therapy; **OR**
G. Hirschsprung disease and associated functional obstruction caused by the inability of the internal anal sphincter to relax after prior surgical treatment;

**OR**

II. Individual has a diagnosis of cervical dystonia (spasmodic torticollis) of moderate or greater severity; **AND**
III. Individual is requesting initial treatment; **AND**
IV. Individual has a history of recurrent clonic or tonic involuntary contractions of one or more of the following muscles: sternocleidomastoid, splenius, trapezius and/or posterior cervical muscles; **AND**
V. Abnormal posturing, with limited range of motion in the neck, or sustained head tilt; **AND**
VI. The duration of the condition is greater than 6 months;

**OR**

VII. Individual has a diagnosis of cervical dystonia (spasmodic torticollis) of moderate or greater severity; **AND**
VIII. Individual is requesting subsequent injections; **AND**
IX. Response initial treatment documented in the medical records;

**OR**

X. Individual has a diagnosis of chronic migraine headaches; **AND**
XI. Individual is requesting initial treatment; **AND**
XII. Individual has 15 (fifteen)or more headache-days per month for more than 2 months, which, on at least 8 days per month, has features of a migraine headache (ICHD-3); **AND**

| Market Applicability | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | X |

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XIII. Individual has had a trial of and inadequate response or intolerance to two agents for migraine prophylaxis (at least one agent in any two of the following classes) or has a contraindication to all of the following medications (AAN/AHA 2012/2015, Level A and B evidence; ICSI 2013, high quality evidence):
   A. One of the following antidepressants: amitriptyline, venlafaxine; **OR**
   B. One of the following beta blockers: Metoprolol, propranolol, timolol (oral), nadolol, atenolol, nebivolol; **OR**
   C. The following calcium channel blocker: verapamil; **OR**
   D. One of the following antiepileptic agents: valproate sodium, divalproex sodium, topiramate, gabapentin;

**OR**

XIV. Individual has a diagnosis of chronic migraine headaches; **AND**

XV. Individual is requesting continued treatment; **AND**

XVI. Individual has completed an initial 6-month trial and the following criteria are met:
   A. Individual has a reduction in the overall number of migraine days or reduction in number of severe migraine days per month; **AND**
   B. Individual has obtained clinical benefit deemed significant by individual or prescriber;

**OR**

XVII. Individual has a diagnosis of primary hyperhidrosis; **AND**

XVIII. Individuals has failed a 6-month trial of any one or more types of nonsurgical treatment (for example: topical dermatologics such as aluminum chloride, tannic acid, glutaraldehyde or anticholinergics, systemic anticholinergics, tranquilizers or non-steroid anti-inflammatory drugs); **AND**

XIX. Individual has one of the following:
   A. Presence of medical complications or skin maceration with secondary infection; **OR**
   B. Significant functional impairment, as documented in the medical record;

**OR**

XX. Individual has a diagnosis of secondary hyperhidrosis; **AND**

XXI. Condition is related to surgical complications; **AND**
   A. Presence of medical complications or skin maceration with secondary infection; **AND**
   B. Significant functional impairment, as documented in the medical record.

Requests for botulinum toxin may not be approved for the following:

| Market Applicability | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | X |

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I. Individual is using for skin wrinkles or other cosmetic indications; **OR**

II. Individual has headache diagnosis other than chronic migraine (example, tension, episodic migraine [14 migraine days per month or less], or chronic daily headaches); **OR**

III. Individual has had a treatment failure of botulinum toxin for any condition listed above (exception would be due to product specific intolerance or allergic reaction); **OR**

IV. Individual has any diagnosis not listed as an approvable diagnosis, including, but not limited to, the following:

A. Anismus (pelvic floor dyssynergia)
B. Bechet's syndrome
C. Benign Prostatic Hypertrophy
D. Brachial Plexus Palsy
E. Carpal tunnel syndrome
F. Chronic motor tic disorder
G. Disorders of the esophagus (except as listed above)
H. Epicondylitis
I. Fibromyalgia/fibromyositis
J. Gastroparesis
K. Low back pain
L. Myofascial pain syndrome
M. Neck pain not related to conditions mentioned above
N. Nystagmus
O. Parkinson's disease
P. Post-mastectomy reconstruction syndrome
Q. Reynaud's syndrome
R. Sphincter of Oddi dysfunction
S. Stuttering
T. Tics associated with Tourette's Syndrome
U. Tinnitus
V. Tourette's Syndrome
W. Tremors
X. Urinary and anal sphincter dysfunction (except as listed above)
Y. Vaginismus
Z. Whiplash related disorders
AA. Zygomatic Fractures

| Market Applicability | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | X |

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| State Specific Mandates | | |
|---|---|---|
| State name<br>N/A | Date effective<br>N/A | Mandate details (including specific bill if applicable)<br>N/A |
| Washington | 1/1/18 | For treatment of chronic migraine (as defined by the International Headache Society defined as headaches on >= 15 days per month of which >= 8 days are with migraine), OnabotulinumtoxinA is covered when the following criteria are met:<br><br>1) Has not responded to at least three prior pharmacological prophylaxis therapies from two different classes of drugs AND<br><br>2) Condition is appropriately managed for medication overuse<br><br>OnabotulinumtoxinA injections **must be discontinued** when the condition:<br>1) Has shown inadequate response to treatment (defined as <50% reduction in headache days per month after two treatment cycles) OR<br><br>2) Has changed to episodic migraine (defined as <15 headache days per month) for three consecutive months.<br><br>Maximum of five treatment cycles. Additional treatment cycles may be considered at health plan discretion.<br><br>• Migraine indication (onabotulinum toxin A only): **Initial** 1 dose (up to 155 units) per 12 weeks; 1 dose (up to 155 units) per 12 week approval for continued therapy if criteria met until 5 doses have been received.<br><br>Treatment of chronic tension-type headache with OnabotulinumtoxinA is **not a covered benefit**. |

| Market Applicability | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **FL & FHK** | **FL MMA** | **FL LTC** | **GA** | **KS** | **KY** | **MD** | **NJ** | **NV** | **NY** | **TN** | **TX** | **WA** |
| **Applicable** | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | X |

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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.

CRX-ALL-0274-18