Botulinum Toxins
BOTOX® (onabotulinumtoxinA)
DYSPORT™ (abobotulinumtoxinA)
MYOBLOC® (rimabotulinumtoxinB)
XEOMIN® (incobotulinumtoxinA)

Descriptive Narrative

Botulinum toxins are neurotoxins produced by the bacterium Clostridium botulinum. Botulinum toxins are used to treat various disorders of focal muscle spasm and excessive muscle contractions. When injected intramuscularly, the toxin blocks acetylcholine release at the neuromuscular junction. Advantage can be taken of this neuromuscular blockade to alleviate overactive neural activity in target organs (e.g., muscle or sweat glands) for therapeutic effect.

There are seven different botulinum neurotoxin serotypes referred to as A, B, C-1, D, E, F, and G.

Two different strains of C. botulinum produce the three commercial botulinum toxin biologics approved by the FDA: onabotulinumtoxinA (formerly botulinum toxin type A) (BOTOX®) and abobotulinumtoxinA (DYSPORT™) are produced by the Hall strain, and rimabotulinumtoxinB (formerly botulinum toxin type B) (MYOBLOC®) is produced by the Bean strain.

It is important to understand that BOTOX®, DYSPORT™, and MYOBLOC® are unique products that are not interchangeable. They are chemically, pharmacologically, and clinically distinct. Studies have shown that onabotulinum A (BOTOX®) and incobotulinumA (XEOMIN®) are equipotent. Please note that each product’s FDA-approved package insert states: “Units of biological activity cannot be converted into units of any other botulinum toxin or any other toxin assessed with any other specific assay method”, though the clinical evidence suggests that BOTOX® and XEOMIN® have similar biologic activity.
Criteria - OnabotulinumtoxinA (Botox®)

Iowa Medicaid covers OnabotulinumtoxinA (Botox®) injections when the following indications are met:

1. An appropriate medical diagnosis, such as:
   a. Focal dystonias.
   b. Blepharospasm, characterized by intermittent or sustained closure of the eyelids caused by involuntary contractions of the orbicularis oculi muscle.
   c. Individuals with cervical dystonia (spasmodic torticollis) of moderate or greater severity when the following criteria are met:
      1) Alternative causes of the member’s symptoms have been considered and ruled out, including chronic neuroleptic treatment, contractures, or other neuromuscular disorders; **AND**
      2) There is sustained head torsion and/or tilt with limited range of motion in the neck; **AND**
      3) There are clonic and/or tonic involuntary contractions of multiple neck muscles (e.g., sternocleidomastoid, splenius, trapezius, and/or posterior cervical muscles.
   d. Adductor spasmodic dysphonia/laryngeal dystonia.
   e. Jaw closing oromandibular dystonia causing persistent pain, interference with nutritional intake or significant speech impairment.
   f. Meige’s Syndrome/cranial dystonia.
   g. Spastic Conditions:
      1) Cerebral palsy.
      2) Cerebrovascular accident.
      3) Localized adductor muscle spasticity in multiple sclerosis.
      4) Spinal cord injury.
      5) Traumatic brain injury.
   h. Hemifacial spasms causing persistent pain or vision impairment.
   i. Strabismus disorders.
   j. Primary esophageal achalasia in patients who are considered poor surgical risks and patients who have a history of perforation.
   k. Chronic anal fissure in patients who have failed conservative treatment.
   l. Treatment of primary or secondary axillary or palmar hyperhidrosis when the condition is refractory to conventional medical treatment involving topical and pharmacotherapy. Must have documentation that the condition significantly interferes with ADLs and the condition is causing chronic skin irritations.
   m. Intracranial lesion or CVA induced voiding difficulty.
   n. Treatment of urinary incontinence due to detrusor over activity or well documented overactive bladder in adults who have an inadequate response to or are intolerant of anticholinergic medication.
   o. Prophylaxis of chronic migraines when there is failure, contraindication, or intolerance to at least two different migraine prophylaxis medications (e.g., beta blockers, calcium channel blockers, tricyclic antidepressants or anticonvulsant medications).
### Criteria - RimabotulinumtoxinB (Myobloc®)

Iowa Medicaid covers RimabotulinumtoxinB (Myobloc®) when the following indications are met:

1. Individuals with cervical dystonia (spasmodic torticollis) of moderate or greater severity when the following criteria are met:
   a. Alternative causes of the member’s symptoms have been considered and ruled out, including chronic neuroleptic treatment, contractures; or other neuromuscular disorders; **AND**
   b. There is sustained head torsion and/or tilt with limited range of motion in the neck; **AND**
   c. There are clonic and/or tonic involuntary contractions of multiple neck muscles (e.g., sternocleidomastoid, splenius, trapezius and/or posterior cervical muscles.
2. Ptyalism/sialorrhea (excessive secretion of saliva, drooling) that is socially debilitating and refractory to pharmacotherapy (including anticholinergics).
3. Intractable, disabling focal primary hyperhidrosis, when **ALL** of the following are met:
   a. Member is unresponsive or unable to tolerate pharmacotherapy prescribed for excessive sweating (e.g., anticholinergics, beta-blockers, or benzodiazepines) if sweating is episodic; **AND**
   b. Significant disruption of professional and/or social life has occurred because of excessive sweating; **AND**
   c. Topical aluminum chloride or other extra-strength antiperspirants are ineffective or result in a severe rash.

### Criteria - AbobotulinumtoxinA (Dysport™ Brand of Botulinum Toxin Type A)

Iowa Medicaid covers AbobotulinumtoxinA (Dysport™ Brand of Botulinum Toxin Type A) when the following indications are met:

1. Blepharospasm, characterized by intermittent or sustained closure of the eyelids caused by involuntary contractions of the orbicularis oculi muscle.
2. Cervical dystonia, (spasmodic torticollis) of moderate or greater severity when **ALL** of the following criteria are met:
   a. Alternative causes of the member’s symptoms have been considered and ruled out, including chronic neuroleptic treatment, contractures, or other neuromuscular disorders; **AND**
   b. There is sustained head torsion and/or tilt with limited range of motion in the neck; **AND**
c. There are clonic and/or tonic involuntary contractions of multiple neck muscles (e.g., sternocleidomastoid, splenius, trapezius and/or posterior cervical muscles).

d. Limb spasticity, including:
   1) Equinus varus deformity in children with cerebral palsy.
   2) Hereditary spastic paraplegia.
   3) Limb spasticity due to multiple sclerosis.
   4) Limb spasticity due to other demyelinating diseases of the central nervous system (including adductor spasticity and pain control in children undergoing adductor-lengthening surgery as well as children with upper extremity spasticity).
   5) Spastic hemiplegia, such as due to stroke or brain injury.

Criteria - IncobotulinumtoxinA (Xeomin®)

Iowa Medicaid covers IncobotulinumtoxinA (Xeomin®) for the following:

1. Treatment of adults with cervical dystonia (spasmodic torticollis) of moderate or greater severity when the following criteria are met:
   a. Alternative causes of the member’s symptoms have been considered and ruled out, including chronic neuroleptic treatment, contractures, or other neuromuscular disorders; AND
   b. There is sustained head torsion and/or tilt with limited range of motion in the neck; AND
   c. There are clonic and/or tonic involuntary contractions of multiple neck muscles (e.g. sternocleidomastoid, splenius, trapezius, and/or posterior cervical muscles).
   d. Adductor spasmodic dysphonia/laryngeal dystonia.
   e. Jaw closing oromandibular dystonia causing persistent pain, interference with nutritional intake or significant speech impairment.
   f. Meige’s syndrome/cranial dystonia.

2. Treatment of blepharospasm in adults previously treated with OnabotulinumtoxinA (Botox®).

Criteria – Non-Covered

Non-covered indications for the use of Botulinum Toxins due to being investigational, experimental, or unproven include:

2. TMJ or chronic orofacial pain.
3. Headache: tension, chronic daily headache.
4. Tics.
5. Voiding dysfunction associated with any of the following:
   a. BPH.
   b. Urge incontinence refractory to anticholinergic therapy.
6. Paralytic scoliosis.
7. Diabetic gastroparesis.
Botulinum toxin therapy is considered not medically necessary for the treatment of cosmetic conditions.

**Coding**

**HCPCS Code:**

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<thead>
<tr>
<th>Product</th>
<th>Code</th>
<th>Description</th>
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<tr>
<td>BOTOX®</td>
<td>J0585</td>
<td>Injection, onabotulinumtoxinA, 1 unit</td>
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<td>DYSPORT™</td>
<td>J0586</td>
<td>Injection, abobotulinumtoxinA, 5 units</td>
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<td>MYOBLOC®</td>
<td>J0587</td>
<td>Injection, rimabotulinumtoxinB, 100 units</td>
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<td>XEOMIN®</td>
<td>J0588</td>
<td>Injection, incobotulinumtoxinA, 1 unit</td>
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**NOTE:** List may not be complete. All PA requests subject to individual review.

**References**

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

**Criteria Change History**

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<thead>
<tr>
<th>Change Date</th>
<th>Changed By</th>
<th>Description of Change</th>
<th>Version</th>
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<tr>
<td>3/13/2018</td>
<td>Medical Director</td>
<td>Added narrative under Description regarding Botox® and Xeomin® being equipotent and having similar biologic activity.</td>
<td>9</td>
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<tr>
<td>5/1/2017</td>
<td>Policy</td>
<td>Formatting changes.</td>
<td>8</td>
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<tr>
<td>1/20/2017</td>
<td>CAC</td>
<td>Criterion #1n removed over activity “associated with a neurologic condition such as spinal cord injury, multiple sclerosis” and added “or well-documented overactive bladder”.</td>
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## Criteria Change History (continued)

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<tr>
<th>Change Date</th>
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<tr>
<td>1/15/2015</td>
<td>CAC</td>
<td>Removed criterion #1q as was duplicate of #1n. Under non-covered removed “wrinkles” and included in “cosmetic conditions”.</td>
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<tr>
<td>1/16/2015</td>
<td>CAC</td>
<td>Added paragraph in References.</td>
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<td>1/30/2014</td>
<td>Medical Director</td>
<td>HCPS codes added.</td>
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<tr>
<td>1/17/2014</td>
<td>CAC</td>
<td>Criterion #1”o” - remove &gt; 15 days per month with headache lasting four hours a day or longer.</td>
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<tr>
<td>2/18/2013</td>
<td>Medical Director</td>
<td>Clarification and addition of information on incobotulinumtoxinA.</td>
<td>2</td>
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<tr>
<td>11/2/2010</td>
<td>Medical Director</td>
<td>New FDA criteria.</td>
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