**Pharmacy Pre-Authorization Criteria**

| **Drug(s)** | Botox Medications  
|             | Botox (onaBotulinum toxin type A)  
|             | Dysport (abobotulinumtoxin A)  
|             | Myobloc (botulinum toxin type B)  
|             | Xeomin (incobotulinumtoxin A)  |
| **Policy #** | 21100  
|             | Botox, J-0585  
|             | Dysport, J-0586  
|             | Myobloc, J-0587  
|             | Xeomin, J-0588  |
| **Indications** | FDA-Approved Indications  
|             | 1. Blepharospasm or strabismus associated with dystonia  
|             | 2. Cervical dystonia (Torticollis); defined as a condition in which the neck muscles contract involuntarily, causing the head to twist or turn to one side  
|             | 3. Primary axillary hyperhidrosis after a trial with at least one topical agent  
|             | 4. Upper limb spasticity in adults  
|             | 5. Prophylaxis of headaches in adults with chronic migraine (≥ 15 days per month with headache lasting ≥ 4 hours a day or longer).  
|             | 6. Urinary incontinence due to detrusor overactivity  
|             | 7. Overactive Bladder  
|             | 8. Reduction of increased muscle stiffness in the ankles and toes of adult patients with lower limb spasticity.  

Botulinum toxin type A may be considered medically necessary in patients with functional impairment originating from spasticity or dystonia (involuntary sustained muscle contraction) resulting from one of the following (off-label) conditions:

- Idiopathic Torsion Dystonia  
- Symptomatic Torsion Dystonia  
- Orofacial dyskinesia (i.e. jaw closure dystonia)  
- Organic Writer’s Cramp  
- Persistent Nerve VI Palsy (*duration of 1 month or longer)  
- Torsion dystonia (fragments of)  
- Hereditary Spastic Paraplegia  
- Multiple Sclerosis  
- Neuromyelitis Optica  
- Schilder’s Disease  
- Central demyelinating of corpus callosum  
- Demyelinating disease of CNS-unspeicified  
- Spastic Hemiplegia-- Spasticity related to stroke, or spinal cord injury
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<tr>
<th>Indication</th>
<th>Criteria</th>
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<tr>
<td>Infantile Cerebral Palsy</td>
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<tr>
<td>Other Facial Nerve Disorders</td>
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<td>Laryngeal adductor spastic dysphonia</td>
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<td>Spasmodic Dysphonia</td>
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<td>Individual consideration for the use of Botulinum Toxin Type A may be given to patients with the following conditions and who have failed to respond to generally accepted treatments:</td>
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<td>Anal Fissures</td>
<td>Patients will be assessed for trial and/or failure with other therapeutic alternatives, such as nitroglycerin ointment.</td>
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<td>Achalasia/Cardiospasm</td>
<td>in patients who have not responded to dilation therapy or who are considered poor surgical candidates.</td>
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<td>Migraine headaches</td>
<td>Botox will be considered medically necessary for members meeting ALL of the following criteria in A, B, C, and D:</td>
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<td>A: The member has a persistent history of recurring debilitating headaches.</td>
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<td>B: A neurologist or a physician who is qualified to treat headache (ie a headache or migraine specialist) has thoroughly evaluated the member and has established a diagnosis of migraine headaches</td>
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<td>C: Chronic migraine are experienced at least 15 days per month with headache lasting 4 hours a day or longer</td>
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<td>D: Adequate trials of prophylactic therapy from at least THREE (3) different therapy classes were either not effective or not tolerated. (Anticonvulsants, Beta Blockers, Calcium Channel Blockers, Tricyclics, SSRIs)</td>
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<td>Overactive Bladder</td>
<td>Botox will be considered medically necessary for members who have had an intolerance to, or treatment failure of, two (2) adequate trials of anticholinergic medications and have not had an active urinary tract infection prior to treatment</td>
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<td>Detrusor Sphincter Dysnergia</td>
<td>Botox will be considered medically necessary for members who have had an intolerance to, or treatment failure of, an adequate trial of an anticholinergic medication and no active urinary tract infection prior to treatment</td>
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<td>Axillary Hyperhidrosis</td>
<td>Botox will be considered medically necessary for members who have had an intolerance to, or treatment failure of, an adequate trial of topical prescription strength aluminum chloride (i.e. Drysol) and/or other extra strength antiperspirants</td>
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<td>All other Indications above</td>
<td>Botox will be considered medically necessary if medication is being used on-label</td>
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**Drug(s)**

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<th>Botox Medications</th>
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**Limitations**

If the above criteria are met, initial authorization is limited to TWO (2) Botox treatments in a 6 month period or one treatment every 12 weeks (subject to eligibility), for all Indications other than Hyperhidrosis. For Hyperhidrosis, initial authorization and reauthorization (when granted) shall be limited to 100 Units (50 Units per axilla) per 6 month period. (Maximum 2 treatments (200 Units) per year).

Botulinum toxin type A is considered investigational for other indications, including but not limited to:

- Chronic Motor Tic disorder
- Tics associated with Tourette’s syndrome
- Tension Headaches
- Tremors such as essential (benign) tremor
- Skin Wrinkles or other cosmetic indications
- Low Back Pain
- Piriformis Syndrome (entrapment of the sciatic nerve by the piriformis muscle)

**References**

1. Botox® [package insert]. Irvine, CA; Allergan Pharmaceuticals
5. Dysport full prescribing information, Ipsen Biopharmaceuticals Inc, Basking Ridge, NJ
6. Myobloc full prescribing information. Solstice Neurosciences, Inc., South San Francisco, CA

**P&T Review History**

9/04, 6/05, 12/06, 6/07, 6/08, 9/09, 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 2/16, 2/17, 1/18

**Revision Record**

12/10, 9/11, 11/12, 5/13, 3/16, 5/16, 2/17