



## Prior Authorization Review: Botulinum Toxins

### Background:

Currently, there are 3 botulinum toxin type A products (abobotulinumtoxina [Dysport®]; incobulinumtoxina (Xeomin®); onabotulinumtoxina (Botox®; Botox® Cosmetic) and one botulinum toxin type B product (rimabotulinumtoxinb [Myobloc®]) available commercially in the U.S. Indications and off-label uses for each of these products are listed in Table 1.

Table 1. Indications and Off-label Uses for Botulinum Toxins:<sup>1</sup>

<p><b>Botulinum toxin type A:</b></p> <ul style="list-style-type: none"> <li>• abobotulinumtoxina (DYSPOORT): cervical dystonia; glabellar lines; upper limb spasticity (off-label: achalasia; acquired nystagmus; anal fissures; hand dystonia; sialorrhea (drooling); spasticity of cerebral palsy; tardive dyskinesia; others)</li> <li>• incobulinumtoxina (XEOMIN): blepharospasm; cervical dystonia; glabellar lines (off-label: achalasia; sialorrhea; others)</li> <li>• onabotulinumtoxina (BOTOX; BOTOX COSMETIC): axillary hyperhidrosis; cervical dystonia; chronic migraine; glabellar lines; lateral canthal lines; overactive bladder; strabismus and blepharospasm associated with dystonia; upper limb spasticity; urinary incontinence due to detrusor overactivity (off-label: achalasia; anal fissures; hand dystonia; Raynaud phenomenon; sialorrhea; spasticity of cerebral palsy; tardive dyskinesia; others)</li> </ul>
<p><b>Botulinum toxin type B:</b></p> <ul style="list-style-type: none"> <li>• rimabotulinumtoxinb (MYOBLOC): cervical dystonia (off-label: sialorrhea)</li> </ul>

The Health Evidence Review Commission (HERC) updated treatment guidelines within the Prioritized List of Health Services for use of chemodenervation for chronic migraine and for detrusor over-activity of the bladder.<sup>2</sup> Specifically, the notes address continuing funding only for positive response from chemodenervation for these conditions. The guideline changes are highlighted in *italics* below. The change will be in effect January 1, 2016.<sup>2</sup>

### GUIDELINE NOTE XXX, CHEMODENERVATION FOR CHRONIC MIGRAINE<sup>2</sup>

Line 414

Chemodenervation for treatment of chronic migraine (CPT 64615) is included on this line for prophylactic treatment of adults who meet all of the following criteria:

1. have chronic migraine defined as headaches on at least 15 days per month of which at least 8 days are with migraine
2. has not responded to or have contraindications to at least three prior pharmacological prophylaxis therapies (beta-blocker, calcium channel blocker, anticonvulsant or tricyclic antidepressant)
3. treatment is administered in consultation with a neurologist or headache specialist.

Treatment is limited to two treatments given 3 months apart. Additional treatment requires documented positive response to therapy. *Positive response to therapy is defined as a reduction of at least 7 headache days per month compared to baseline headache frequency.*

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## **GUIDELINE NOTE XXX, CHEMODENERVATION OF THE BLADDER<sup>2</sup>**

### *Line 331*

Chemodenervation of the bladder (CPT 52287) is included on this line only for treatment of idiopathic detrusor over-activity or neurogenic detrusor over-activity (ICD-9 596.5x/ICD-10-CM N32.81) in patients who have not responded to or been unable to tolerate at least two urinary incontinence antimuscarinic therapies (e.g. fesoterodine, oxybutynin, solifenacin, darifenacin, tolterodine, trospium). Treatment is limited to 90 days, with additional treatment only if the patient shows documented positive response. *Positive response to therapy is defined as a reduction of urinary frequency of 8 episodes per day or urinary incontinence of 2 episodes per day compared to baseline frequency.*

A clinical Prior Authorization (PA) for botulinum toxins was last approved by the Oregon Pharmacy & Therapeutics (P&T) Committee in September 2014 (see **Appendix 1**).

### **Recommendations:**

- Modify PA criteria to reflect updated Guideline Notes approved by the HERC.
- No further review or research needed at this time.

### **References:**

1. Facts & Comparisons® eAnswers [internet database]. Indianapolis, IN: Wolters Kluwer, 2015 Clinical Drug Information LLC. Updated September 2015. Accessed October 12, 2015.
2. Value-based Benefits Subcommittee Meeting Archive; DRAFT minutes, October 1, 2015 meeting. Health Evidence Review Commission, Oregon Health Authority. Available at <http://www.oregon.gov/oha/herc/CommitteeMeetingMaterials/VbBS%20Minutes%2010-1-2015.pdf>. Accessed October 20, 2015.

## Botulinum Toxins

**Goal(s):**

- Approve botulinum toxins for funded OHP conditions supported by evidence of benefit (eg, dystonia or spasticity associated with certain neurological diseases).
- Require positive response to therapy for use in chronic migraine headaches or overactive bladder.

**Length of Authorization:**

- From 90 days to 12 months

**Requires PA:**

- Use of botulinum toxins without associated dystonia or neurological disease diagnosis in last 12 months.

**Covered Alternatives:**

- Preferred alternatives listed at [www.orpd.org/drugs/](http://www.orpd.org/drugs/)

Approval Criteria		
1. Is this a request for renewal of a previously approved prior authorization for management of migraine headache or detrusor over-activity (eg, overactive bladder)?	<b>Yes:</b> Go to Renewal Criteria	<b>No:</b> Go to #2
2. What diagnosis is being treated?	Record ICD10 code	

## Approval Criteria

<p>3. Does patient have diagnosis of neurological-induced dystonia or spasticity in which a botulinum toxin is a first-line treatment option? Examples:</p> <ul style="list-style-type: none"> <li>• Genetic torsion dystonia 333.6x;</li> <li>• Acquired torsion dystonia 333.7x;</li> <li>• Blepharospasm 333.81;</li> <li>• Spasmodic torticollis 333.83;</li> <li>• Other fragments of torsion dystonia 333.89;</li> <li>• Paralysis associated with CVD 438.2x-432.5x;</li> <li>• Multiple sclerosis 340.xx;</li> <li>• Neuromyelitis optica 341.0;</li> <li>• Spastic hemiplegia, other specified hemiplegia 342.xx;</li> <li>• Cerebral palsy 343.xx;</li> <li>• Quadriplegia and quadraparesis 344.0x;</li> <li>• Paraplegia 344.1;</li> <li>• Diplegia of upper limbs 344.2;</li> <li>• Monoplegia of lower limb 344.3x;</li> <li>• Monoplegia of upper limb 344.4x;</li> <li>• Unspecified monoplegia 344.5;</li> <li>• Other specified paralytic syndrome 344.89;</li> <li>• Muscular dystrophies 359.0x-359.2x; or</li> <li>• Strabismus in other neuromuscular disorders 378.73.</li> </ul>	<p><b>Yes:</b> Approve for up to 12 months</p>	<p><b>No:</b> Go to #4</p>
<p>4. Does patient have a diagnosis of chronic migraine with <math>\geq 15</math> headache days per month, of which <math>\geq 8</math> days are with migraine?</p>	<p><b>Yes:</b> Go to #5</p>	<p><b>No:</b> Go to #7</p>
<p>5. Is the botulinum toxin administered by, or in consultation with, a neurologist or headache specialist?</p>	<p><b>Yes:</b> Go to #6</p>	<p><b>No:</b> Pass to RPh. Deny for medical appropriateness.</p>

## Approval Criteria

<p>6. Has the patient had an inadequate response, or has contraindications, to <math>\geq 1</math> drugs from each of the following 3 drug classes?</p> <ul style="list-style-type: none"> <li>• Beta-blockers: (propranolol; metoprolol; atenolol; nadolol; or timolol)</li> <li>• Tricyclic antidepressants: (nortriptyline or amitriptyline)</li> <li>• Anticonvulsants: (divalproex sodium/valproic acid; carbamazepine; topiramate; or gabapentin)</li> <li>• Calcium channel blockers (diltiazem; verapamil; or nimodipine)</li> </ul>	<p><b>Yes:</b></p> <ul style="list-style-type: none"> <li>• Baseline headaches/month: _____.</li> </ul> <p>Approve no more than 2 treatments given <math>\geq 3</math> months apart.</p> <p>Additional treatment requires <u>documented</u> positive response to therapy from baseline (see Renewal Criteria).</p>	<p><b>No:</b> Pass to RPh. Deny for medical appropriateness and recommend trial of preferred alternatives at <a href="http://www.orpd.org/drugs/">www.orpd.org/drugs/</a></p>
<p>7. Does patient have a diagnosis idiopathic or neurogenic detrusor over-activity (eg, overactive bladder syndrome) (ICD10-CM N32.81)?</p>	<p><b>Yes:</b> Go to #8</p>	<p><b>No:</b> Pass to RPh and go to #9</p>
<p>8. Has the patient had an inadequate response to, or is intolerant of, <math>\geq 2</math> incontinence anti-muscarinic drugs (eg, fesoterodine, oxybutynin, solifenacin, darifenacin, tolterodine, or trospium)?</p>	<p><b>Yes:</b></p> <ul style="list-style-type: none"> <li>• Baseline urine frequency/day: _____.</li> <li>• Baseline urine incontinence episodes/day: _____.</li> </ul> <p>Approve for up to 90 days.</p> <p>Additional treatment requires <u>documented</u> positive response to therapy from baseline (see Renewal Criteria).</p>	<p><b>No:</b> Pass or RPh. Deny for medical appropriateness.</p>

## Approval Criteria

9. RPh only: Medical literature with evidence for use in funded conditions must be submitted and determined to be appropriate for use before approval is granted.

### **Deny for the following conditions; not funded by the OHP**

Neurologic conditions with none or minimally effective treatment or treatment not necessary (333.82; 333.84; 333.94-333.99);  
Facial nerve disorders (351.xx);  
Spastic dysphonia (478.79);  
Anal fissure (565.0);  
Disorders of sweat glands (eg, focal hyperhidrosis) (705.xx);  
Other disorders of cervical region (723.xx, EXCEPT 723.4);  
Disorders of sweat glands (705.0-705.1; 705.21-705.9; 780.8);  
Acute and chronic disorders of the spine without neurologic impairment (724.1; 724.2; 724.4-724.6; 727.70-724.9);  
Disorders of soft tissue (729.0-729.2);  
Headaches (307.81; 339.xx; 784.0);  
Gastroparesis (536.3)

### **Deny for medical appropriateness for the following conditions; evidence of benefit is insufficient**

Dysphagia (787.2x);  
Other extrapyramidal disease and abnormal movement disorders (333.xx, EXCEPT 333.6x; 333.7x; 333.81; 333.83; 333.89);  
Other disorders of binocular eye movements (eg, esotropia, exotropia, mechanical strabismus, etc.) (378 EXCEPT 378.73);  
Tics (307.2x);  
Laryngeal spasm (478.75);  
Spinal stenosis in cervical region or brachial neuritis or radiculitis NOS (723.0 and 723.4);  
Spasm of muscle in absence of neurological diagnoses (728.85);  
Contracture of tendon (sheath) in absence of neurological diagnoses (727.81);  
Amyotrophic sclerosis (335.20);  
Clinically significant spinal deformity or disorders of spine with neurological impairment (724.00-724.09; 724.4);  
Hyperplasia of prostate (600.xx)

Renewal Criteria		
1. Is this a request for renewal of a previously approved prior authorization for management of migraine headache?	<b>Yes:</b> Go to #2	<b>No:</b> Go to #3
2. Is there documentation of a reduction of >7 headache days per month compared to baseline headache frequency?	<b>Yes:</b> Approve for up to 12 months  Baseline: ____ headaches/month Current: ____ headaches/month	<b>No:</b> Pass to RPh. Deny for medical appropriateness
3. Is this a request for renewal of a previously approved prior authorization for management of idiopathic or neurogenic detrusor over-activity?	<b>Yes:</b> Go to #4	<b>No:</b> Go to Approval Criteria
4. Is there a reduction of urinary frequency of $\geq 8$ episodes per day or urinary incontinence of $\geq 2$ episodes per day compared to baseline frequency?	<b>Yes:</b> Approve for up to 12 months  <ul style="list-style-type: none"> <li>• Baseline: ____ urine frequency/day</li> <li>• Current: ____ urine frequency/day</li> </ul> -or- <ul style="list-style-type: none"> <li>• Baseline: ____ urine incontinence episodes/day</li> <li>• Current: ____ urine incontinence episodes/day</li> </ul>	<b>No:</b> Pass to RPh. Deny for medical appropriateness

P&T / DUR Review: 11/15 (AG); 9/14 (KK); 7/14 (KK)  
 Implementation : TBD