



## Prior Authorization Update: Botulinum Toxins

### Background:

The Oregon Health Authority (OHA) Health Evidence Review Commission (HERC) recommended amending Guideline Note 42, Chemodenervation for Chronic Migraine, of the Prioritized List of Health Services at the August 2018 meeting.<sup>1</sup> The following recommended changes will go into effect on October 1, 2018:

- Removal of calcium channel blockers from the recommended classes of pharmacological prophylaxis therapies<sup>1</sup>
- Addition of criteria which requires that the patient's condition has been appropriately managed for medication overuse<sup>1</sup>

With these changes, the updated Guideline Note will read as follows:

### GUIDELINE NOTE 42, CHEMODENERVATION FOR CHRONIC MIGRAINE

#### *Line 409*

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:

- A) have chronic migraine defined as headaches on at least 15 days per month of which at least 8 days are with migraine
- B) has not responded to or have contraindications to at least three prior pharmacological prophylaxis therapies (beta-blocker, anticonvulsant, or tricyclic antidepressant)
- C) their condition has been appropriately managed for medication overuse
- D) treatment is administered in consultation with a neurologist or headache specialist.

Treatment is limited to two injections 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.

### Purpose of the Prior Authorization Update:

The purpose of this prior authorization (PA) update is to align the botulinum toxins PA criteria with the updated Guideline Note.

### Recommendations:

- Update PA criteria to reflect current guidelines in the OHA Prioritized List of Health Services as outlined in **Appendix 1**.

### References:

1. Health Evidence Review Commission's Value-based Benefits Subcommittee Meeting Materials. Oregon Health Authority. August 9, 2018. <https://www.oregon.gov/oha/HPA/CSI-HERC/MeetingDocuments/VBBS%20Meeting%20Materials%208-9-2018.pdf>. Accessed August 21, 2018.

## Botulinum Toxins

**Goal(s):**

- Approve botulinum toxins for funded OHP conditions supported by evidence of benefit.
- 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 (billed as a physician administered or pharmacy claim) without associated dystonia or neurological disease diagnosis in last 12 months.

**Covered Alternatives:**

- Current PMPDP preferred drug list per OAR 410-121-0030 at [www.orpdl.org](http://www.orpdl.org)
- Searchable site for Oregon FFS Drug Class listed at [www.orpdl.org/drugs/](http://www.orpdl.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 (e.g., overactive bladder)?	<b>Yes:</b> Go to <b>Renewal Criteria</b>	<b>No:</b> Go to #2
2. What diagnosis is being treated?	Record ICD10 code	

## Approval Criteria

<p>3. Is botulinum toxin treatment for any of the following?</p> <ol style="list-style-type: none"> <li>Upper or lower limb spasticity (G24.02, G24.1, G35, G36.0, I69.03- I69.06 and categories G71, and G80-G83);</li> <li>Strabismus due to a neurological disorder (H50.89);</li> <li>Blepharospasm (G24.5);</li> <li>Spasmodic torticollis (G24.3);</li> <li>Torsion dystonia (G24.9); or</li> <li>Achalasia (K22.0).</li> </ol>	<p><b>Yes:</b> Approve for up to 12 months</p>	<p><b>No:</b> Go to #4</p>
<p>4. Is botulinum toxin treatment for 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 #8</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; medical appropriateness.</p>
<p>6. Has the patient had an inadequate response, or has contraindications, to at least 3 pharmacological prophylaxis therapies?</p> <ul style="list-style-type: none"> <li>Beta-blockers</li> <li>Tricyclic antidepressants</li> <li>Anticonvulsants</li> </ul>	<p><b>Yes:</b> Go to #7</p> <p>Baseline headaches/month: _____.</p>	<p><b>No:</b> Pass to RPh. Deny; medical appropriateness. Recommend trial of preferred alternatives at <a href="http://www.orpd.org/drugs/">www.orpd.org/drugs/</a></p>
<p>7. Do chart notes indicate headaches are due to medication overuse?</p>	<p><b>Yes:</b> Pass to RPh. Deny; medical appropriateness.</p>	<p><b>No:</b> Approve no more than 2 injections 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>8. Is botulinum toxin treatment for idiopathic or neurogenic detrusor over-activity (ICD10-CM N32.81)?</p>	<p><b>Yes:</b> Go to #9</p>	<p><b>No:</b> Pass to RPh. Go to #10</p>

## Approval Criteria

9. Has the patient had an inadequate response to, or is intolerant of,  $\geq 2$  incontinence anti-muscarinic drugs (e.g., fesoterodine, oxybutynin, solifenacin, darifenacin, tolterodine, or trospium)?

### Yes:

- Baseline urine frequency/day: \_\_\_\_\_.
- Baseline urine incontinence episodes/day: \_\_\_\_\_.

Approve for up to 90 days.

Additional treatment requires documented positive response to therapy from baseline (see Renewal Criteria).

**No:** Pass to RPh. Deny; medical appropriateness.

10. 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**

Axillary hyperhidrosis and palmar hyperhidrosis (ICD-10 L74.52, R61)  
Neurologic conditions with none or minimally effective treatment or treatment not necessary (G244; G2589; G2581; G2589; G259);  
Facial nerve disorders (G510-G519);  
Spastic dysphonia (J387);  
Anal fissure (K602);  
Disorders of sweat glands (e.g., focal hyperhidrosis) (L301; L740-L759; R61);  
Other disorders of cervical region (M436; M4802; M530; M531; M5382; M5402; M5412; M542; M6788);  
Acute and chronic disorders of the spine without neurologic impairment (M546; M545; M4327; M4328; M532X7; M532X8; M533; M438X9; M539; M5408; M545; M5430; M5414-M5417; M5489; M549);  
Disorders of soft tissue (M5410; M609; M790-M792; M797);  
Headaches (G44209; G44009; G44019; G44029; G44039; G44049; G44059; G44099; G44209; G44219; G44221; G44229; G44309; G44319; G44329; G4441; G4451-G4453; G4459; G4481-G4489; G441; R51);  
Gastroparesis (K3184)  
Lateral epicondylitis (tennis elbow) (M7710-M7712)

**Deny for medical appropriateness because evidence of benefit is insufficient**

Dysphagia (R130; R1310-R1319);  
Other extrapyramidal disease and abnormal movement disorders (G10; G230-GG238; G2401; G244; G250-G26);  
Other disorders of binocular eye movements (e.g., esotropia, exotropia, mechanical strabismus, etc.) (H4900-H518);  
Tics (F950-F952; F959);  
Laryngeal spasm (J385);  
Spinal stenosis in cervical region or brachial neuritis or radiculitis NOS (M4802; M5412-M5413);  
Spasm of muscle in absence of neurological diagnoses (M6240-M62838);  
Contracture of tendon (sheath) in absence of neurological diagnoses (M6240; M62838);  
Amyotrophic sclerosis (G1221);  
Clinically significant spinal deformity or disorders of spine with neurological impairment (M4800; M4804; M4806; M4808; M5414-M5417);  
Essential tremor (G25.0)  
Hemifacial spasm (G513)  
Occupational dystonias (e.g., “Writer’s cramp”) (G248, G249)  
Hyperplasia of the prostate (N400-403; N4283)  
Conditions of the back and spine for the treatment of conditions on lines 346 and 527, including cervical, thoracic, lumbar and sacral conditions. See Guideline Note 37.

<b>Renewal Criteria</b>		
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 $\geq 7$ headache days per month compared to baseline headache frequency?	<b>Yes:</b> Approve no more than 2 injections given $\geq 3$ months apart.  Baseline: _____ headaches/month Current: _____ headaches/month	<b>No:</b> Pass to RPh. Deny; 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; medical appropriateness

P&T / DUR Review: 9/18 (JP); 5/18; 11/15; 9/14; 7/14  
 Implementation: TBD; 7/1/18; 10/13/16; 1/1/16