

Botulinum Toxins

Goal(s):

- Approve use of botulinum toxins for conditions funded under the Oregon Health Plan (OHP) and supported by evidence of benefit.
- Require positive response to therapy for continued use to manage chronic migraine headaches or overactive bladder.
- Allow case-by-case review for members covered under the EPSDT program.

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
- Searchable site for Oregon FFS Drug Class listed at 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 muscle over-activity (“overactive bladder”) or hyperhidrosis?	Yes: Go to Renewal Criteria	No: Go to #2
2. What diagnosis is being treated?	Record ICD10 code	
3. Is botulinum toxin treatment for any of the following? a. Upper or lower limb spasticity (G24.02, G24.1, G35, G36.0, I69.03- I69.06 and categories G71, and G80-G83) b. Strabismus due to a neurological disorder (H50.89) c. Blepharospasm (G24.5) d. Spasmodic torticollis (G24.3) e. Torsion dystonia (G24.9) f. Achalasia (K22.0)	Yes: Approve for up to 12 months	No: Go to #4
4. Is botulinum toxin treatment for chronic migraine, with ≥15 headache days per month, of which ≥8 days are with migraine?	Yes: Go to #5 Baseline headaches per month: _____	No: Go to #8
5. Is the botulinum toxin administered by, or in consultation with, a neurologist or headache specialist?	Yes: Go to #6	No: Pass to RPh. Deny; medical appropriateness.

Approval Criteria

<p>6. Has the patient had an adequate trial (2-6 months) without response, or has contraindications, to at least 3 of the following OHP preferred drugs (in the same or different drug classes)?</p> <ul style="list-style-type: none"> • Propranolol immediate-release, metoprolol, or atenolol • Topiramate, valproic acid, or divalproex sodium • Amitriptyline, nortriptyline, or venlafaxine • Candesartan or telmisartan 	<p>Yes: Go to #7</p>	<p>No: Pass to RPh. Deny; medical appropriateness. Recommend trial of preferred alternatives at www.orpdl.org/drugs/</p>
<p>7. Do chart notes indicate headaches are due to medication overuse?</p>	<p>Yes: Pass to RPh. Deny; medical appropriateness.</p>	<p>No: Approve no more than 2 injections given ≥ 3 months apart within a 12 month time period.</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 detrusor muscle over-activity (“overactive bladder”)?</p>	<p>Yes: Go to #9</p>	<p>No: Go to #10</p>
<p>9. Has the patient had an inadequate response to, or is intolerant to at least two urinary incontinence antimuscarinic or beta-3 adrenergic therapies, such as those listed below?</p> <ol style="list-style-type: none"> a. Fesoterodine (OHP preferred) b. Oxybutynin (OHP preferred) c. Solifenacin (OHP preferred) d. Darifenacin e. Flavoxate f. Mirabegron g. Tolterodine h. Trospium i. Vibegron 	<p>Yes:</p> <ul style="list-style-type: none"> • Baseline urine frequency/day: _____. • Baseline urine incontinence episodes/day: _____. <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>No: Pass to RPh. Deny; medical appropriateness.</p>

Approval Criteria

<p>10. Is botulinum toxin treatment for use in patient with chronic anal fissure documented to have lasted longer than 6 weeks?</p>	<p>Yes: Approve one-time dose for 6 months (may be injected into multiple sites on same day)</p>	<p>No: Go to #11</p>
<p>11. Is botulinum toxin treatment of primary axillary hyperhidrosis?</p> <p>Note: secondary axillary hyperhidrosis related to comorbid conditions and non-axillary hyperhidrosis are not FDA-approved.</p>	<p>Yes: If not eligible for EPSDT review: Pass to RPh. Go to #16</p> <p>If eligible for EPSDT review: Go to #12</p>	<p>No: Pass to RPh. Go to #16</p>
<p>12. Is the requested product prescribed by, or in consultation with, a neurologist or dermatologist?</p>	<p>Yes: Go to #13</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>13. Is there documentation that the diagnosis detrimentally impacts at least one of the following?</p> <ol style="list-style-type: none"> disability or health impairment (e.g., complications, comorbidities, etc) age-appropriate growth or development independence in self-care or activities of daily living ability to live and work in the setting of the patient's choice 	<p>Yes: Go to #14</p>	<p>No: Pass to RPh; Deny; medical necessity</p>
<p>14. Is there documentation of severe symptoms which interfere with daily activities more than once per week as indicated by one of the following:</p> <ul style="list-style-type: none"> Hyperhidrosis Disease Severity Scale (HDSS) ≥ 3 Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax) ≥ 3 Axillary Sweating Daily Diary – item 2 (sweating severity) ≥ 4 on a 0-10 point scale <p>Note: these same assessments should be evaluated for continuation of treatment.</p>	<p>Yes: Go to #15</p>	<p>No: Pass to RPh. Deny; medical necessity.</p>
<p>15. Is there documentation indicating lack of adequate treatment with non-pharmacologic management (e.g., trigger identification and avoidance, clothing modification, use of topical antiperspirants)?</p>	<p>Yes: Approve no more than 2 injections given ≥ 8 weeks apart within a 12-month time period.</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>

16. Review treating condition, age, and ICD-10 code. ICD-10 codes included in the tables below are denied. If ICD-10 code is not included in the tables below, medical literature with evidence for use in funded conditions must be submitted by the prescriber. RPh may approve for up to 12 months for funded conditions with evidence of benefit.

If not eligible for EPSDT review: Deny for the following conditions; not funded by the OHP

If eligible for EPSDT review, evaluate FDA-approved indications and disease severity. If the drug is FDA approved for the condition AND prescriber submits documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc.), RPh may approve for up to 12 months.

- Axillary hyperhidrosis (L74.510)
- 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)
- 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)
- Unspecified diseases of the salivary glands (sialorrhea) (K11.5-K11.9,R68.2)

Deny for medical appropriateness because evidence of benefit is insufficient

- Dysphagia (R130; R1310-R1319)
- Secondary and non-axillary focal hyperhidrosis (L74511-L7452)
- Other disorders of sweat glands (L301; L740-L744; L748-L749; R61)
- 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 dystonia (e.g., "Writer's cramp") (G248, G249)
- Hyperplasia of the prostate (N400-403; N4283)

Approval Criteria

- 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.

Renewal Criteria

1. Is this a request for renewal of a previously approved prior authorization for management of migraine headache?	Yes: Go to #2	No: Go to #3
2. Is there documentation of a reduction of ≥ 7 migraine headache days per month compared to baseline migraine headache frequency?	Yes: Approve no more than 2 injections given ≥ 3 months apart. Baseline:____ migraine headaches/month Current:____ migraine headaches/month	No: Pass to RPh. Deny; medical appropriateness
3. Is this a request for renewal of a previously approved prior authorization for management of detrusor muscle over-activity (“overactive bladder”)?	Yes: Go to #4	No: Go to #5
4. Is there a reduction of urinary frequency of ≥ 8 episodes per day or urinary incontinence of ≥ 2 episodes per day compared to baseline frequency?	Yes: Approve for up to 12 months <ul style="list-style-type: none"> Baseline:____ urine frequency/day Current:____ urine frequency/day -or- <ul style="list-style-type: none"> Baseline:____ urine incontinence episodes/day Current:____ urine incontinence episodes/day 	No: Pass to RPh. Deny; medical appropriateness
5. Is the request for renewal of a previously approved prior authorization for axillary hyperhidrosis?	Yes: Go to #6	No: Go to Approval Criteria

Renewal Criteria

6. Is there documentation of symptom improvement from baseline as assessed by the prescribing provider?

Note: the following are described as clinically relevant responses to therapy:

- Total score ≤ 2 on the Hyperhidrosis Disease Severity Scale (HDSS) or Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax)
- ≥ 4 point improvement on the Axillary Sweating Daily Diary – item 2 (sweating severity)

Yes: Approve for 12 months

No: Pass to RPh; Deny; medical appropriateness

P&T / DUR Review: 4/25 (SF/SS); 6/23 (KS),4/22 (AG); 5/19 (KS); 9/18; 5/18; 11/15; 9/14; 7/14

Implementation: 5/12/25; 7/1/23; 5/1/22; 11/1/2018; 7/1/18; 10/13/16; 1/1/16