Policy and Procedure	
PHARMACY POLICY AND CRITERIA ORPTCNEU029.0826	**NEUROMUSCULAR DRUGS** **BOTULINUM TOXIN** See FDA Indications section for medications covered by policy
Effective Date: 10/1/2026	**Review/Revised Date**: 05/19, 08/19, 12/19, 03/20, 05/20, 07/20, 09/20, 11/20, 01/21, 05/21, 07/21, 07/22, 07/23, 12/23, 07/24, 01/24, 06/25, 06/26, 07/26 (JLS)
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Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:
Commercial
Medicaid

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA) approved and selected medically accepted indications not otherwise excluded from the benefit, as outlined below.

Medicaid/Oregon Health Plan (OHP) Members

Oregon: Services requested for OHP members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List. Coverage for Medicaid is limited to a condition that has been designated a covered line-item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services when all applicable indication-specific criteria below are met. The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit provides comprehensive and preventive health care services for children and adolescents up to their 21st birthday who are enrolled in Medicaid. Management of unfunded conditions falls under this benefit when they impact the ability to grow, develop or participate in school and the applicable indication-specific criteria below are met.

REQUIRED MEDICAL INFORMATION:

PHARMACY POLICY AND CRITERIA ORPTCNEU029	NEUROMUSCULAR DRUGS BOTULINUM TOXIN See FDA Indications section for medications covered by policy

Use of botulinum toxin therapy may be considered medically necessary for the conditions outlined below. Please refer to the "Billing Guidelines Appendix" for medically necessary diagnosis code groupings and billing requirements

1. OnabotulinumtoxinA (Botox®) may be considered medically necessary for the following indications:
    a. Chronic migraine headaches in adults
    b. Upper and lower limb spasticity in patients at least two years of age
    c. Cervical dystonia in adults
    d. Strabismus and blepharospasm associated with dystonia in patients at least 12 years of age
    e. Axillary or palmar hyperhidrosis in adults
    f. Overactive bladder in adults
    g. Urinary incontinence in patients at least five years of age
    h. Excessive salivation due to advanced Parkinson's disease
    i. Hemifacial spasm
    j. Chronic anal fissure in adults
    k. Spastic dysphonia/laryngeal dystonia in adults
    l. Achalasia
    m. Oromandibular dystonia in adults
    n. Focal hand dystonia in adults
2. AbobotulinumtoxinA (Dysport®) may covered for the following indications:
    a. Spasticity in patients two years of age and older
    b. Cervical dystonia in adults
    c. Blepharospasm in adults
3. IncobotulinumtoxinA (Xeomin®) may covered for the following indications:
    a. Chronic sialorrhea in patients two years and older
    b. Upper limb spasticity in patients at least two years of age
    c. Cervical dystonia in adults
    d. Blepharospasm in adults
4. RimabotulinumtoxinB (Myobloc®) may covered for the following indications:
    a. Cervical dystonia in adults
    b. Chronic sialorrhea in adult patients
5. DaxibotulinumtoxinA-lanm (Daxxify®) may be covered for the following indications:
    a. Cervical dystonia in adults

EXCLUSION CRITERIA:

Botulinum toxin is considered **cosmetic and is not covered** for the treatment of glabellar lines and/or fine wrinkles on the face, or platysma bands associated with platysma muscle activity.

- PrabotulinumtoxinA (Jeuveau®) will **not be covered** as it is only FDA approved for the treatment of glabellar lines and/or fine wrinkles on the face.

COVERAGE DURATION:
Initial authorization and reauthorization will be approved for one year

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Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:
Botulinum toxin injections are used to treat various focal muscle spastic disorders and excessive muscle contractions such as dystonias, spasms, twitches, etc. These drugs produce a presynaptic neuromuscular blockade by preventing the release of acetylcholine from the nerve endings. The resulting chemical denervation of muscle produces local paresis or paralysis and allows individual muscles to be weakened selectively. Botulinum toxins have the advantage of being potent neuromuscular blocking agents with good selectivity and duration of action.

Botulinum toxins types A and B are neurotoxins produced by *Clostridium Botulinum*. Botulinum Toxin Type A and Botulinum Toxin Type B have many similarities and as experience has been gained, medical consensus has gradually developed that the two toxins have similar, but not identical, properties. Each botulinum toxin product is pharmacologically and clinically distinct, and therefore, not interchangeable with any other botulinum toxin product. As a result, approved indications for the toxins differ.

The rationale for treatment is to create temporary paralysis of sufficient depth and duration that the injected muscles become slightly atrophied and stretched. The antagonist muscle shortens simultaneously taking up the slack created by agonist

paralysis. After several weeks enervation to the injected muscle returns. The safety and efficacy of long-term use of botulinum toxin is unknown.

FDA APPROVED INDICATIONS:

Botox® (onabotulinumtoxinA):

- Bladder Dysfunction in adults - – overactive bladder and detrusor overactivity associated with a neurologic condition
- Chronic Migraine in adults
    - Limitations of Use: Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in seven placebo-controlled studies.
- Spasticity in patients two years of age and older
    - Limitations of Use: has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture.
- Cervical dystonia in adults
- Primary axillary hyperhidrosis in adults that is inadequately managed with topical agents
    - Limitations of use:
        - Safety and effectiveness for hyperhidrosis in other body areas have not been established. Weakness of hand muscles and blepharoptosis may occur in patients who receive treatment for palmar hyperhidrosis and facial hyperhidrosis, respectively. Patients should be evaluated for potential causes of secondary hyperhidrosis (e.g., hyperthyroidism) to avoid symptomatic treatment of hyperhidrosis without the diagnosis and/or treatment of the underlying disease
        - Safety and effectiveness have not been established for treatment of axillary hyperhidrosis in pediatric patients under age 18
- Blepharospasm and strabismus associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and older.
- Pediatric Detrusor Overactivity associated with a neurologic condition
- Temporary improvement in the appearance of moderate to severe platysma bands associated with platysma muscle activity in adult patients.

Dysport® (abebotulinumtoxinA)

- Glabellar Lines
- Cervical dystonia in adults
- Spasticity in patients two years of age and older

Myobloc® (rimabotulinumtoxinB)
- Cervical dystonia in adults
- Chronic sialorrhea in adults

Xeomin® (incobotulinumtoxinA)
- Chronic sialorrhea in patients two years and older
- Glabellar Lines
- Cervical dystonia in adult patients
- Upper limb spasticity in adult patients
- Upper limb spasticity in pediatric patients two to 17 years of age, excluding spasticity caused by cerebral palsy
- Blepharospasm in adult patients

Jeuveau® (prabotulinumtoxinA-xvfs)
- Glabellar Lines

Daxxify® (DaxibotulinumtoxinA-lanm)
- Moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adults
- Cervical dystonia in adults

POSITION STATEMENT:
Coverage of botulinum toxin therapies is limited to medically accepted indications for the specific products. Medically accepted refers to FDA approved or generally recognized as efficacious by certain drug compendia references (e.g., Micromedex). As outlined below, claims for botulinum toxin therapy will be adjudicated if submitted with appropriate uses (ICD-10 codes).

The Medicaid Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit was introduced in 1967 as a part of the Social Security Act Amendments. The goal of the EPSDT benefit is to ensure that children under the age of 21 who are enrolled in Medicaid receive appropriate preventative, dental, mental health, and developmental specialty services. The EPSDT standard requires states to cover all medically necessary and medically appropriate treatment for children and adolescents on Medicaid, including medications, regardless of what services states provide to adults. Under EPSDT, the Prioritized List is a guidance tool for assessment of coverage. Medically appropriate and medically necessary services are defined in Oregon Administrative Rule (OAR) 410-120-000.

Table 1. Billing Guidelines and Coding

The following CPT/HCPCS Codes may be considered medically necessary when billed with instructions listed in Appendix A

CODES*	
CPT/HCPCS	**Description**
31513	Laryngoscopy, indirect; with vocal cord injection
31570	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic
31571	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic; with operating microscope or telescope
31573	Laryngoscopy, flexible; with therapeutic injection(s) (e.g., chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral
43192	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance
43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance
46505	Chemodenervation of internal anal sphincter
52287	Cystourethroscopy, with injection(s) for chemodenervation of the bladder
64611	Chemodenervation of parotid and submandibular salivary glands, bilateral
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (e.g., for blepharospasm, hemifacial spasm)
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (e.g., for chronic migraine)
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (e.g., for cervical dystonia, spasmodic torticollis)
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (e.g., for spasmodic dysphonia), includes guidance by needle electromyography, when performed
64642	Chemodenervation of one extremity; 1-4 muscle(s)
64643	Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (List separately in addition to code for primary procedure)
64644	Chemodenervation of one extremity; 5 or more muscles
64645	Chemodenervation of one extremity; each additional extremity, 5 or more muscles (List separately in addition to code for primary procedure)
64646	Chemodenervation of trunk muscle(s); 1-5 muscle(s)
64647	Chemodenervation of trunk muscle(s); 6 or more muscles
64650	Chemodenervation of eccrine glands; both axillae
64653	Chemodenervation of eccrine glands; other area(s) (eg, scalp, face, neck), per day
67345	Chemodenervation of extraocular muscle
95873	Electrical stimulation for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)

95874	Needle electromyography for guidance in conjunction with chemodenervation (List separately in addition to code for primary procedure)
J0585	Injection, onabotulinumtoxina, 1 unit
J0586	Injection, abobotulinumtoxina, 5 units
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a, 1 unit
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit
J3590	Injection, prabotulinumtoxin a
S2340	Chemodenervation of abductor muscle(s) of vocal cord
S2341	Chemodenervation of adductor muscle(s) of vocal cord
31599	Unlisted procedure, larynx
43499	Unlisted procedure, esophagus
64999	Unlisted procedure, nervous system

*Coding Notes:
• The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
• All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be denied as not covered. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, prior authorization is recommended.
• See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.
• HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCE/RESOURCES:

1. Botox. Package insert. Allergan Pharmaceuticals; 2023 .
2. Dysport. Package insert. Galderma Laboratories, L.P; 2024.
3. Xeomin. Package insert. Merz Aesthetics; 2024.
4. Myobloc. Package insert. Solstice Neurosciences; 2024.
5. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically.

Appendix A. Billing Guidelines

Non-covered Diagnosis Codes
Glabellar lines (ICD-10 L98.8) is excluded from coverage.

Medical Necessary Diagnosis Codes
Botulinum toxin therapy may be considered medically necessary when billed with diagnosis code listed below. If a diagnosis code not listed below is billed, then the claim is considered not medically necessary.

Medication HCPCS	ICD-10 Diagnosis Codes	Age Restrictions
J0585 J0586 J0587	F64.0 F64.1 F64.8 F64.9	N/A
J0585	G43.70 G43.701 G43.709 G43.71 G43.711 G43.719	Adults only
J0585 J0586	M62.838	At least two years of age
J0585 J0586 J0587 J0588 J0589	G24.3	Adults only
J0585	L74.510 L74.512	Adults only
J0585	N32.81	Adults only
J0585	R39.81 R32 N39.3 N39.41 N39.42 N39.43 N39.44 N39.45 N39.46 N39.490 N39.491 N39.492 N39.498	At least five years of age

Medication HCPCS	ICD-10 Diagnosis Codes	Age Restrictions
J0585	K11.7 G20.A1 G20.A2 G20.B1 G20.B2 G20.C G21.0 G21.1 G21.11 G21.19 G21.2 G21.3 G21.4 G21.8 G21.9	N/A
J0585	G51.31 G51.32 G51.33 G51.39	N/A
J0585	K60.1	Adults only
J0585	J38.3 J38.5	Adults only
J0585	K22.0	N/A
J0585	G24.4	Adults only
J0585	G24.8 G24.9	Adults only
J0586 J0588	G24.5	Adults only
J0588	K11.7	At least two years of age
J0587	K11.7	Adults only
J0585	H49.00 H49.01 H49.02 H49.03 H49.10 H49.11 H49.12 H49.13 H49.20 H49.21 H49.22 H49.23 H49.30 H49.31	At least 12 years of age

Medication HCPCS	ICD-10 Diagnosis Codes	Age Restrictions
	H49.32 H49.33 H49.40 H49.41 H49.42 H49.43 H49.811 H49.812 H49.813 H49.819 H49.88 H49.881 H49.882 H49.883 H49.889 H49.9 H50.00 H50.01 H50.011 H50.012 H50.021 H50.022 H50.031 H50.032 H50.041 H50.042 H50.05 H50.06 H50.07 H50.08 H50.10 H50.111 H50.112 H50.121 H50.122 H50.131 H50.132 H50.141 H50.142 H50.15 H50.16 H50.17 H50.18 H50.21	

Medication HCPCS	ICD-10 Diagnosis Codes	Age Restrictions
	H50.22 H50.30 H50.31 H50.311 H50.312 H50.32 H50.33 H50.331 H50.332 H50.34 H50.40 H50.41 H50.411 H50.412 H50.42 H50.43 H50.50 H50.51 H50.52 H50.53 H50.54 H50.55 H50.60 H50.611 H50.612 H50.621 H50.622 H50.629 H50.631 H50.632 H50.639 H50.641 H50.642 H50.649 H50.651 H50.652 H50.659 H50.661 H50.662 H50.669 H50.671 H50.672 H50.679 H50.681	

Medication HCPCS	ICD-10 Diagnosis Codes	Age Restrictions
	H50.682 H50.689 H50.69 H50.81 H50.811 H50.812 H50.89 H50.9 G24.5	