Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCNEU030.0626	**NEUROMUSCULAR DRUGS** **BOTULINUM TOXIN** See FDA Approved Indications for Covered Drugs
Effective Date: 8/1/2026	**Review/Revised Date**: 05/19, 08/19, 11/19, 03/20, 04/20, 01/21, 07/22, 07/23, 12/23, 07/24, 01/25, 06/25, 02/26, 06/26 (JLS)
Original Effective Date: 09/19	**P&T Committee Meeting Date**: 06/19, 08/19, 10/19, 12/19, 02/20, 04/21, 08/21, 08/22, 08/23, 12/23, 10/24, 02/25, 08/25, 06/26 (cv)
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Medicare Part B

POLICY CRITERIA:

COVERED USES:
The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

Please refer to the "Billing Guidelines Appendix" for medically necessary diagnosis code groupings and billing requirements

Service	Medicare Guidelines
Botulinum Toxin Types A and B	Local Coverage Determination (LCD) criteria – L35172

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 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 Botox, Myobloc, Dysport or Xeomin is unknown.

FDA APPROVED INDICATIONS:

Botox® (onabotulinumtoxinA)

- Bladder Dysfunction in adults – over active 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 the 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 of age 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 Guidance from LCD: "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 Toxin Type A (Botox-onabotulinumtoxinA, Xeomin -incobotulinumtoxinA, Dysport-abotulinumtoxinA, and daxibotulinumtoxinA-lanm) are derived from a culture of Hall strain Clostridium Botulinum. Botulinum Toxin Type B (Myobloc – rimabotulinumtoxinB) is derived from the Bean strain of Clostridium Botulinum. Type B has the same action on neuromuscular conduction (blockade) as Type A.

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 two toxins differ. This A/B MAC has determined that the separate accepted indications for the four toxins will be combined into a single list of covered indications in this Local Coverage Determination (LCD) policy. However, it is the responsibility of providers to use each drug in accordance with the FDA approved indications unless there are valid and documented reasons stating why the unapproved/off label form is used. "Providers should consult the package insert of each neurotoxin to identify the FDA approved indications for each product."

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*	
31513	Laryngoscopy, indirect; with vocal cord injection

31570	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic
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 (eg, for blepharospasm, hemifacial spasm)
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed
64640	Destruction by neurolytic agent; other peripheral nerve or branch
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
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then **prior-authorization is required.**	
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. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Botulinum Toxin Types A and B (L35172). Revision Effective Date 2/22/2026. Available at https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35172&ver=72&bc=CAAAAAAAAAAA (accessed February 26, 2026)
2. Centers for Medicare & Medicaid Services. Billing and Coding: Botulinum Toxin Types A and B Policy (A57185). Revision Effective Date 2/22/2026. Available at https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=57185 (accessed February 26, 2026)

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
J0585 J0586 J0587	F64.0 F64.1 F64.8 F64.9
J0585	G43.001, G43.009, G43.011, G43.019, G43.101, G43.109, G43.111, G43.119, G43.401, G43.409, G43.411, G43.419,

Medication HCPCS	ICD-10 Diagnosis Codes
	G43.501, G43.509, G43.511, G43.519, G43.601, G43.609, G43.611, G43.619, G43.701, G43.709, G43.711, G43.719, G43.A0, G43.A1, G43.B0, G43.B1, G43.C0, G43.C1, G43.D0, G43.D1, G43.801, G43.809, G43.811, G43.819, G43.901, G43.909, G43.911, G43.919, G43.E01, G43.E09, G43.E11, G43.E19
J0585, J0586, J0588	G04.1, G11.4, G24.02, G24.09, G24.1, G24.2, G25.0, G25.1, G25.2, G25.61, G25.69, G25.89, G35.A, G35.B0, G35.B1, G35.B2, G35.C0, G35.C1, G35.C2, G35.D, G80.0, G80.1, G80.2, G80.3, G80.4, G80.8, G81.11, G81.12, G81.13, G81.14, G82.21, G82.22, G82.51, G82.52, G82.53, G82.54, G83.0, G83.11, G83.12, G83.13, G83.14, G83.21, G83.22, G83.23, G83.24, I69.031, I69.032, I69.033, I69.034, I69.041, I69.042, I69.043, I69.044, I69.051, I69.052, I69.053, I69.054, I69.131, I69.132, I69.133, I69.134, I69.141, I69.142, I69.143, I69.144, I69.151, I69.152, I69.153, I69.154, I69.231, I69.232, I69.233, I69.234, I69.241, I69.242, I69.243, I69.244, I69.251, I69.252, I69.253, I69.254, I69.331, I69.332, I69.333, I69.334, I69.341, I69.342, I69.343, I69.344, I69.351, I69.352, I69.353, I69.354, I69.831, I69.832, I69.833, I69.834, I69.841, I69.842, I69.843, I69.844, I69.851, I69.852, I69.853, I69.854, I69.931, I69.932, I69.933, I69.934, I69.941, I69.942, I69.943, I69.944, I69.951, I69.952, I69.953, I69.954
J0585, J0586, J0587, J0588, J0589	G24.02, G24.09, G24.1, G24.2, G24.3, G80.3, M43.6, M47.812, M47.892, M54.2, Q68.0
J0585	H49.01, H49.02, H49.03, H49.11, H49.12, H49.13, H49.21, H49.22, H49.23, H49.31, H49.32, H49.33, H49.41, H49.42, H49.43, H49.881, H49.882, H49.883, H49.9, H50.00, 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, H50.22, H50.30, H50.311, H50.312, H50.32, H50.331, H50.332, H50.34, H50.40, 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, H50.631, H50.632, H50.641, H50.642, H50.651, H50.652, H50.661, H50.662, H50.671, H50.672, H50.681, H50.682, H50.69, H50.811, H50.812, H50.89, H50.9, H51.0, H51.11, H51.12, H51.21, H51.22, H51.23, H51.8
J0585	L74.510, L74.511, L74.512, L74.513, L74.519, L74.52, L74.8, L74.9
J0584	N30.10, N30.11, R39.89

Medication HCPCS	ICD-10 Diagnosis Codes
J0585	N32.81, N39.41, N39.42, N39.43, N39.44, N39.45, N39.46, N39.490, N39.491, N39.492, N39.498
J0585	N31.1, N31.2, N31.8, N31.9
J0585	G51.2, G51.31, G51.32, G51.33, G51.4, G51.8
J0585	K60.0, K60.1, K60.2, K60.30, K60.311, K60.312, K60.313, K60.319, K60.321, K60.322, K60.323, K60.329, K60.40, K60.411, K60.412, K60.413, K60.419, K60.421, K60.422, K60.423, K60.429, K60.50, K60.511, K60.512, K60.513, K60.519, K60.521, K60.522, K60.523, K60.529
J0585	J38.01, J38.02, J38.5, R49.0, R49.8
J0585	K22.0
J0585	G24.8
J0585, J0588	G24.5
J0586, J0587, J0588	K11.7
J0585	G24.1, G24.2, G24.4, G24.8
J0585, J0588	H02.041, H02.042, H02.044, H02.045, H02.141, H02.142, H02.144, H02.145
J0585, J0586, J0588	G81.11, G81.12, G81.13, G81.14