Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCNEU030.1024	**NEUROMUSCULAR DRUGS** **BOTULINUM TOXIN** See FDA Approved Indications for Covered Drugs
Effective Date: 1/1/2025	**Review/Revised Date**: 05/19, 08/19, 11/19, 03/20, 04/20, 01/21, 07/22, 07/23, 12/23, 07/24 (JCN)
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
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.

Service	Medicare Guidelines
Botulinum Toxin	Local Coverage Determination (LCD) criteria – LCD35172

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.

PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCNEU030	NEUROMUSCULAR DRUGS BOTULINUM TOXIN See FDA Approved Indications for Covered Drugs

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 two 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

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.”

BILLING GUIDELINES

See the associated local coverage article (LCA) for additional billing and coding guidance:

Billing and Coding: Botulinum Toxin Types A and B (A57186)

CPT/HCPCS CODES

Medicare Part B Only	
Prior Authorization Required	
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

REFERENCE/RESOURCES:

1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Botulinum Toxin Types A and B (L35172). Available at https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35172&ver=68&keyword=botulinum%20toxin&keywordType=starts&areaId=all&docType=NCD,MCD,F,P&contractOption=all&sortBy=relevance&bc=1 (accessed July 5, 2024)
2. Centers for Medicare & Medicaid Services. Billing and Coding: Botulinum Toxin Types A and B Policy (A57185). Available at https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=57185 (accessed July 5, 2024)