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

This policy replaces Medical Policy 209: Drug: Botulinum Toxin Types A and B

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.

The criteria outlined below is adapted from the Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD) criteria – LCD35172

CRITERIA:
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… 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.”
1. Documentation that the patient has been unresponsive to conventional methods of treatments such as medication, physical therapy and other appropriate methods used to control and/or treat spastic conditions.
   - An exception to this general rule is that for certain treatments including focal dystonia, hemifacial spasm, orofacial dyskinesia, blepharospasm, severe writer's cramp, laryngeal spasm, or dysphonia, Botulinum toxin can be an initial mode of therapy, and in these circumstances it is not necessary to show that other methods of treatment have been tried and proven unsuccessful.

2. For certain spastic conditions (e.g., cerebral palsy, stroke, head trauma, spinal cord injuries and multiple sclerosis), coverage will be limited to those conditions listed in the Covered ICD-10-CM section of the LCD.

3. Botulinum toxin can be used to reduce spasticity or excessive muscular contractions to relieve pain, to assist in posturing and walking, to allow better range of motion, to permit better physical therapy, and to reduce severe spasm in order to provide adequate perineal and palmar hygiene.

4. Botulinum toxin has indications for overactive bladder and severe primary axillary hyperhidrosis.

5. Due to the rarity of severe organic writer's cramp, Medicare would not expect to see the treatment of this condition billed frequently.

6. There may be patients who require Electromyography (EMG) in order to determine the proper injection site(s). The electromyography procedure codes specified in the HCPCS section of this policy may be covered if the physician has difficulty in determining the proper injection site(s). It should be noted that needle electromyographic procedures include the interpretation of electrical waveforms measured by equipment that produces both visible and audible components of electrical signals recorded from the muscle(s) studied by the needle electrode. Electromyography equipment must be capable of showing both visual and auditory components of the electrical activity produced by and recorded from within muscle tissue by the needle electrode for myopathy or neuropathy diagnosis. For purposes of botulinum injection guidance, the EMG tools that have audible output alone are sufficient.

7. For the appropriate initial and total doses of Botulinum toxins please consult the FDA, manufacturers’ recommendations or the AHFS.

8. Coverage of treatments provided may be continued unless any two treatments in a row, utilizing an appropriate or maximum dose of a Botulinum toxin, fail to produce a satisfactory clinical response. In such situations it may be appropriate
to use an alternative Botulinum toxin once in order to determine if a more satisfactory response can be obtained. Providers must also document the results of and response to these injections.

9. Requests may be considered for redetermination (formerly appeal) for continued treatment during a treatment period or for resumption at a later date if satisfactory results have not been obtained and compelling clinical evidence of medical necessity for continued treatment is presented.

10. Medicare will allow payment for one injection per site regardless of the number of injections made into the site. A site is defined as including muscles of a single contiguous body part, such as a single limb, single eyelid, side of the face, side of the neck, both vocal cords, etc.

11. For treatment of achalasia and cardiospasm, Botulinum toxin should be used only after one or more of these conditions have been met and documented:
   - The patient has failed conventional therapy.
   - The patient is at high risk of complications from pneumatic dilation or surgical myotomy.
   - The patient who refuses surgical myotomy or balloon dilation, in reference to a less invasive risky procedure.
   - A prior myotomy or dilatation has failed.
   - A prior dilatation caused an esophageal perforation.
   - The patient has an epiphrenic diverticulum or hiatal hernia, both of which increase the risk of dilatation induced perforation.

12. Botulinum Toxin is covered for prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer).

13. It is also covered for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

14. Treatment of skin wrinkles ICD-10 CM code L11.8, L57.2, L57.4, L66.4, L87.1, L90.3, L90.4, L92.2, L94.8, L98.5, L98.6 using Botulinum toxin is cosmetic and is not covered by Medicare.

15. Acceptance of Botulinum Toxin has not been established for the following conditions (USP DI 2006):
   - Deviations over 50 prism diopters
   - Restrictive strabismus
Botulinum Toxin – Medicare Part B

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

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

• Chronic paralytic strabismus except to reduce antagonist contracture in conjunction with surgical repair
• Duane’s syndrome with lateral rectus muscle weakness
• Recurrent temporomandibular joint (TMJ) disorder

16. Anal spasm, irritable colon, biliary dyskinesia, or any treatment of spastic conditions not listed as covered in this policy are considered to be cosmetic, investigational, or not safe and effective.

17. The use of Botulinum toxin to treat muscle tension is considered not proven effective.

18. Due to the short life of Botulinum toxin, Medicare will reimburse the unused portion of these drugs only when vials are not split between patients. Use modifier JW to code for drug wastage on a separate line of the claim form. The documentation must show in the patient's medical record the exact dosage of the drug given, exact amount and reason for unavoidable wastage, and the exact amount of the discarded portion of the drug.

19. Scheduling of more than one patient is encouraged to prevent wastage of Botulinum toxins. If a vial is split between two patients, the billing in these instances must be for the exact amount of Botulinum toxin used on each individual patient. Medicare would not expect to see billing for the full fee amount for Botulinum toxin on each beneficiary when the vial is split between two or more patients.
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
- Chronic Migraine
- Upper and lower limb spasticity in adults
- Upper limb spasticity in pediatric patients 2-17 years old
- Pediatric lower limb spasticity (2 to 17 years of age), excluding spasticity caused by cerebral palsy
- Cervical dystonia
- Primary axillary hyperhidrosis
  - 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

Dysport® (abobotulinumtoxinA)
- Glabellar Lines
- Cervical dystonia
- Spasticity in adults
- Lower limb spasticity in pediatric patients 2 years of age and older
- Upper limb spasticity in pediatric patients 2 years of age and older, excluding spasticity caused by cerebral palsy

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

Xeomin® (incobotulinumtoxinA)
- Chronic Sialorrhea in adult patients
- Glabellar Lines
- Cervical dystonia in adult patients
- Upper limb spasticity in adult patients
- Blepharospasm in adult patients

Jeuveau® (prabotulinumtoxinA-xvfs)
- Glabellar Lines

**POSITION STATEMENT:**
The safety and efficacy of long term use of Botox, Myobloc, Dysport or Xeomin is unknown.
# MEDICAL PRIOR AUTHORIZATION POLICY AND CRITERIA

**ORPTCNEU030**

## NEUROMUSCULAR DRUGS

**BOTULINUM TOXIN**

- **Botox®** (onabotulinumtoxinA)
- **Dysport®** (abobotulinumtoxinA)
- **Jeuveau®** (prabotulinumtoxinA-xvfs)
- **Myobloc®** (rimabotulinumtoxinB)
- **Xeomin®** (incobotulinumtoxinA)

## CPT/HCPCS CODES

**Medicare Part B Only**

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<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>31513</td>
<td>Laryngoscopy, indirect; with vocal cord injection</td>
</tr>
<tr>
<td>31570</td>
<td>Laryngoscopy, direct, with injection into vocal cord(s), therapeutic</td>
</tr>
<tr>
<td>43201</td>
<td>Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance</td>
</tr>
<tr>
<td>43236</td>
<td>Esophagastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance</td>
</tr>
<tr>
<td>46505</td>
<td>Chemodenervation of internal anal sphincter</td>
</tr>
<tr>
<td>52287</td>
<td>Cystourethroscopy, with injection(s) for chemodenervation of the bladder</td>
</tr>
<tr>
<td>64611</td>
<td>Chemodenervation of parotid and submandibular salivary glands, bilateral</td>
</tr>
<tr>
<td>64612</td>
<td>Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)</td>
</tr>
<tr>
<td>64615</td>
<td>Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)</td>
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<tr>
<td>64616</td>
<td>Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)</td>
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<td>64617</td>
<td>Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed</td>
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<td>64640</td>
<td>Destruction by neurolytic agent; other peripheral nerve or branch</td>
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<td>64642</td>
<td>Chemodenervation of one extremity; 1-4 muscle(s)</td>
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<td>64643</td>
<td>Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (List separately in addition to code for primary procedure)</td>
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<td>Chemodenervation of one extremity; 5 or more muscles</td>
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<tr>
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<td>Chemodenervation of one extremity; each additional extremity, 5 or more muscles (List separately in addition to code for primary procedure)</td>
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<td>Chemodenervation of trunk muscle(s); 1-5 muscle(s)</td>
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<td>64647</td>
<td>Chemodenervation of trunk muscle(s); 6 or more muscles</td>
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<td>Chemodenervation of eccrine glands; both axillae</td>
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<td>64653</td>
<td>Chemodenervation of eccrine glands; other area(s) (eg, scalp, face, neck), per day</td>
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<td>67345</td>
<td>Chemodenervation of extraocular muscle</td>
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<tr>
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<td>J0587</td>
<td>Injection, rimabotulinumtoxinB, 100 units</td>
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<tr>
<td>J0588</td>
<td>Injection, incobotulinumtoxinA, 1 unit</td>
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</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</tr>
<tr>
<td>64999</td>
<td>Unlisted procedure, nervous system</td>
</tr>
</tbody>
</table>

**REFERENCE/RESOURCES:**

2. Dysport package insert.
3. Xeomin package insert. Franksville, WI; Maerz Aesthetics; 2018 Sept.
5. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically.